Research Protection Program (RPP)
Policies and Procedures

Office of Research Compliance
Institutional Review Board

Table of Contents

Table of Contents

Table of Contents

Section 1

Organizational Commitment to the Research Protection Program (RPP)

RPP Policy 1.01	1.01 The Institution and Its Commitment to the Research Protection Program (RPP)	Updated 2023 Sept. 28

1. Purpose

To describe the Institution and its commitment to the Research Protection Program (RPP).

2. Policy

The Institution is committed to the Human Participant RPP through the establishment and funding of an Institutional Review Board (IRB) operating in full compliance with the Department of Health and Human Services (HHS) regulations at 45 CFR §46 and all common rule agencies.

2.1 Composition of Institution

The Institution is comprised of the University of Arkansas at Little Rock (UA Little Rock) which includes the Bowen Law School and the Clinton School of Public Service.

2.2 Institutional Commitment

The Institution is committed to ensuring the existence and evolution of premier educational programs and high-quality research that is conducted with integrity, is consistent with ethical standards, and is respectful of all individuals and groups (RPP Policies 1.04 *Vision, Mission, and Values Statement for the RPP*, and 2.01 *IRB Membership Requirements and Responsibilities*).

2.3 IRB Authorization

The IRB has been authorized by the Institutional Official (IO) to review and approve all human participant research conducted by the faculty, students, staff, or other Institutional representatives, regardless of where the research is conducted, unless the IRB accepts the review and approval of another duly constituted accredited IRB.

2.4 Local Institution Authorization

The IRB has been authorized by the IO to provide review services for local institutions. This service will be in accordance with all policies and procedures by which the IRB acts at UA Little Rock.

2.5 FDA-Regulated Research

UA Little Rock generally does not conduct Food and Drug Administration (FDA)-regulated research.

A. If UA Little Rock *does* conduct FDA-regulated research, the UA Little Rock IRB will not review the research. UA Little Rock will utilize the University of Arkansas for Medical Sciences (UAMS) IRB for any FDA-regulated research conducted on the UA Little Rock campus or by UA Little Rock researchers.

See Appendix B for Revision History

RPP Policy 1.02	1.02 Federalwide Assurance	Updated 2023 Sept. 28

1. Purpose

To describe the agreement with the HHS Office for Human Research Protections (OHRP) through the Federalwide Assurance (FWA).

2. Policy

It is the IRB's policy that this Institution will file and maintain an agreement with OHRP through a FWA. This Institution has declared that all institutional components listed under the UA Little Rock FWA (#00002205) must comply with this assurance.

2.1 Governance

The FWA commits UA Little Rock to applying HHS regulations to human participant research as required by 45 CFR §46. The UA Little Rock IRB may apply equivalent policies and procedures for research not covered by regulations.

2.2 Principles

The Institution has determined that all of its activities related to human participant research, regardless of funding source, will be guided by the ethical principles found in the *Belmont Report*.

2.3 IRB Establishment

The Institution has designated establishment and registration of one IRB with provisions for sufficient meeting space and staff to support the IRB's review and recordkeeping duties (RPP Policies 1.05 *IRB Charter, Appointments, and Administrative Structure* and 2.02 *IRB Meetings and Member Responsibilities*).

2.4 IRB Membership

The Institution will maintain a list of IRB members identified by name, earned degree, representative capacity, indications of experience, any employee relationship between the member and the Institution, and will maintain a current curriculum vita for each IRB member. Changes in IRB memberships will be documented and maintained by the IRB Administrator as per 45 CFR §46.108(a)(2) and 45 CFR §46.115(a)(5).

2.5 IRB Process

The Institution has established RPP written policies and procedures as required under HHS regulations 45 CFR §46.103.

A. The IRB will conduct initial and continuing review of research (at intervals appropriate to the degree of risk and/or review type, but not less than once per year) as applicable. The investigator and the Institution will be provided written notification of the findings and actions taken by the IRB (RPP Policies 3.02 *Ethical Principles Governing Research Under the Jurisdiction of the IRB*, 3.03 *Initial Application Submission*, 3.04 *Criteria for IRB Approval of Research*, 3.05 *IRB Review*, and 10.01 *Continuing Review*).

B. The IRB will determine which projects require review more often than annually (RPP Policy 3.10 *Assessing the Need for Interim Continuing Review, Monitoring and Verification from Sources Other than the Investigator*) and which projects require verification from sources other than the investigators that no material changes have occurred since the previous IRB review.

C. The IRB will ensure that proposed changes in approved research protocols are reported promptly and are not initiated without IRB review and approval, except when necessary, to eliminate immediate risk to the participant (RPP Policy 11.01 *Request for Modification*).

D. The IRB will have the authority to observe, or have a third party observe, the consent process and the research.

E. The IRB Administrator shall ensure prompt reporting to the IRB. The IRB Administrator and the IRB Chair will ensure prompt reporting to appropriate institutional officials, and as required any applicable federal regulatory officials (OHRP, National Science Foundation, and other department or agency heads) (RPP Policy 12.03 *Reporting Incidents to OHRP or Department and Agency Heads*).

See Appendix B for Revision History

RPP Policy 1.03	1.03 Mission and Objectives Statement of UA Little Rock	Updated 2023 Sept. 28

1. Purpose

To describe the mission and objectives statements for UA Little Rock.

2. Policy

UA Little Rock has developed a comprehensive mission statement and objectives.

2.1 Mission

UA Little Rock's mission is to develop the intellect of students; to discover and disseminate knowledge; to serve and strengthen society by enhancing awareness in scientific, technical, and cultural arenas; and to promote humane sensitivities and understanding of interdependence. Within this broad mission are the responsibilities to use quality instruction to instill in students a lifelong desire to learn; to use knowledge in ways that will contribute to society; and to apply the resources and research skills of the University community to the service of the city, state, nation, and world in ways that will benefit humanity (adopted by the UA Little Rock Faculty Senate, 1988).

2.2 Objectives

The University, through its various programs, works toward six mission objectives:

A. **Excellence in Instruction**: The University has a responsibility to provide excellence in instruction to ensure high-quality education for its students. This responsibility includes developing faculty teaching skills, awareness of the ways students learn, assessment of student learning outcomes, and enhancement of resources to support effective instruction.

B. **Scholarly Inquiry**: The University has a responsibility to use scholarly inquiry to advance the discovery, preservation, and dissemination of knowledge. This responsibility includes the creation of a university environment that supports diverse research activities by faculty, staff, and students.

C. **Service to Society**: The University has a responsibility to serve society through the application of knowledge and research skills. This responsibility includes applying the

University's resources to local, state, national, and international needs in order to improve the human condition.

D. **Community of Learning**: The University has a responsibility to provide a community of learning through creation of an academic environment that stimulates students, faculty, and staff to become lifelong learners. This environment should heighten the intellectual, cultural, and humane sensitivities of students, faculty, and staff.

E. **Accessibility**: The University has a responsibility to serve the needs of a heterogeneous student population and to make its resources accessible to the general public and to local, state, national, and international groups. This responsibility includes creating opportunities for access to the University's academic and other resources.

F. **Responsiveness**: The University has a responsibility to remain responsive to a changing environment and society. This responsibility includes a continuous assessment of the University's strengths and weaknesses in planning for and meeting internal and external needs. It also includes developing the faculty's, staff's, and students' desires and capacities in order to create an academic community that is open to change and ready to meet the demands of a dynamic environment and student body (adopted by the UA Little Rock Faculty Senate, 1988).

See Appendix B for Revision History

RPP Policy 1.04	1.04 Vision, Mission, and Values Statement for the RPP	Updated 2023 Sept. 28

1. Purpose

To describe the vision, mission, and values statement for the Research Protection Program (RPP).

2. Policy

The RPP has developed a comprehensive vision, mission, and values statement.

2.1 Vision

The RPP for UA Little Rock, also referred to as the "Institution" and affiliates, will be an RPP where:

A. Investigators will conduct research with the highest thought, technical skill, and care;

B. Investigators will adhere to high standards of research ethics; comply with all applicable federal, state, and local laws and regulations; and always consider the rights and welfare of research participants; and

C. IRB members and staff will keep abreast of the latest developments in the ethics and regulations of human participant research and will perform thorough and consistent review of research proposals.

2.2 Mission

The RPP's mission is to constantly improve and respond to new ethical and regulatory challenges in order to ensure the protection of human participants who choose to participate in research conducted by investigators at the Institution and affiliates.

2.3 Values

A. Faculty, staff, students, and others who serve as investigators will emphasize the conduct of quality research that is carried out with scientific integrity and in an ethical manner.

B. Investigators will respect all individuals and groups served by UA Little Rock.

See Appendix B for Revision History

RPP Policy 1.05	1.05 IRB Charter, Appointments, and Administrative Structure	Updated 2023 Sept. 28

1. Purpose

To describe the Institutional Review Board (IRB) charter, appointments, and administrative structure.

2. Policy

It is the IRB's policy that the structure and composition of the IRB be in full accordance with US Department of Health and Human Services (HHS) policies at 45 CFR §46.

2.1 IRB Charter

The UA Little Rock IRB is a duly constituted IRB with an established membership in full accordance with the requirements of HHS regulations 45 CFR §46.107.

A. It is the only IRB of record for all faculty, staff and students of UA Little Rock.

2.2 Institutional Official

The Chancellor is the Institutional Official (IO) in accordance with the provisions of the FWA (#00002205). The IO appoints the Chair of the IRB and all IRB members.

2.3 Institutional Official Designate

The IO may appoint an individual who will serve as the designate for the administrative supervision of the Office of Research Compliance (ORC).

2.4 IRB Administrator

The IRB Administrator reports to the Vice Provost for Research and Dean of the Graduate School. The IRB Administrator has a continuous appointment. The IRB Administrator is primarily involved in the development of RPP policies and procedures, revision of IRB forms, compliance issues, conflict resolution, completion of required federal forms, scheduling, attending, and providing minutes for IRB meetings, and continuing education of both IRB members and investigators.

2.5 Office of Research Compliance (ORC)

The ORC serves as the administrative office for the IRB. Its staff is hired and operated under the direction of the Vice Provost for Research and Dean of the Graduate School

2.6 IRB Chair

The IRB Chair is nominated by the IRB and appointed by the IO. The IRB Chair may be chosen from existing members of the IRB. The Chair should be a UA Little Rock tenured faculty member. The IRB Chair works closely with the IRB Administrator. The IRB Chair is primarily involved in conducting IRB meetings; reviewing protocols; reviewing adverse events (AE) and serious problems; facilitating continuing education for IRB members and investigators; updating and promoting development of policies, procedures and IRB forms; and serving as a resource for investigators and the IRB regarding issues related to University and Federal policies. The IRB Chair reports to the IO. The IRB Chair receives a course release each semester and the salary of one summer course during the summer months during the course of tenure.

See Appendix B for Revision History

RPP Policy 1.06	1.06 Authority Granted by UA Little Rock to the IRB Operating in the RPP	Updated 2024 Feb. 01

1. Purpose

To describe the authority granted by UA Little Rock to the Institutional Review Board (IRB) operating in the Research Protection Program (RPP).

2. Policy

It is the IRB's policy that the Institution provide sufficient resources and decisional autonomy for the IRB to carry out its duties independently of the Institution in full accordance with US Department of Health and Human Services (HHS) policies at 45 CFR §46.

2.1 Authorization

UA Little Rock through its Chief Executive Officer, the Chancellor, authorizes the IRB to independently review and approve all human participant research conducted or supported by the faculty, students, staff, or other representatives of UA Little Rock when such research is part of their institutional responsibilities, regardless of where the research is conducted, unless the IRB accepts the review and approval of another duly accredited constituted IRB with a FWA for research conducted at other study sites.

2.2 IRB Research Approval

The IRB will review and approve all human participant research before it can be conducted by anyone on the premises of UA Little Rock property or facilities.

2.3 IRB Authority

The IRB will exercise its authority in full accordance with HHS regulations 45 CFR §46 and UA Little Rock RPP Policies and Procedures. This authority includes review and approval of *exempt* research under 45 CFR §46.101(b); research that qualifies for *expedited review* under 45 CFR §46.110; and research that requires review by the *Full Board*. The IRB has the empowerment, flexibility, and discretion to raise the standards of protection above those afforded to research participants in 45 CFR §46 as it deems appropriate and necessary in particular cases, although it may not lower the protections below those afforded by 45 CFR §46.

2.4 Human Participant Research at UA Little Rock

The Institution will apply 45 CFR §46, including Subparts A, B, C, and D, to all human participant research, regardless of funding, with the exceptions noted in RPP Policy 7.03 *Research Involving Prisoners* for Subpart C.

Subpart B is intended to apply to all human participant research, including that performed in the social and behavioral sciences, as noted in RPP Policy 7.02 *Research Involving Pregnant Women, Human Fetuses, and Neonates*. UA Little Rock does not conduct research involving investigational test articles.

In the event that a FDA regulated study is presented to the UA Little Rock IRB, the UA Little Rock PI and their advisor (if the PI is a student) will seek to work with a UAMS collaborator who will serve on the study. After the UAMS collaborator is added the standard UAMS IRB Reliance Agreement will be completed. UA Little Rock will rely on the UAMS IRB's determinations and will remain responsible for other aspects of human research protections as described in the individual reliance agreement.

2.5 Appropriate IRB Review

Per HHS regulations 45 CFR §46.112, UA Little Rock acknowledges that research that has been approved by the IRB may be subject to further appropriate review by the Institutional Official (IO) or IO designate. However, no official (including the IO) may approve research if it has not been approved by the IRB. In addition, any attempt to improperly influence the IRB from within or outside the Institution is strictly prohibited. IRB members are to report any attempts to unduly influence their decisions from within or outside the Institution to the IRB Chair, or the Vice Provost for Research, or the IO, or IO designate. The individual receiving the report will investigate the allegations, and if true, will take any needed corrective action.

2.6 Disapproval of Research

IRB approval of research can be overturned by the IO or IO designate. The reason(s) for administrative disapproval of research by the IO or IO designate shall be provided in writing to the IRB. The IRB, which will act in this case as a communication conduit, will notify the Principal Investigator (PI) of any disapproval in writing and provide the reason(s) for the disapproval. The PI may appeal the disapproval through the IRB by submitting a written appeal, which the IRB will communicate to the IO or IO designate.

See Appendix B for Revision History

Section 2

Membership and Standard Operating Procedures

RPP Policy 2.01	2.01 IRB Membership Requirements and Responsibilities	Updated 2023 Nov. 8

1. Purpose

To describe Institutional Review Board (IRB) membership requirements and responsibilities.

2. Policy

It is UA Little Rock's policy that the IRB will include an appropriately diverse mixture of backgrounds and experiences in accordance with the HHS regulations under 45 CFR §46.107.

2.1 IRB Members

The IRB will have at least 10 members. Members will include at least 1 representative from each academic college on campus, the Ottenheimer Library, the Bowen Law School, the Clinton School, and one representative who is unaffiliated with UA Little Rock. Members serve renewable terms, the dates of which are staggered among members to provide continuity. Initial and renewal terms range from 1 to 5 years.

A. IRB members may be granted an extended leave due to medical, personal, or professional reasons and may then return to complete their terms.

2.2 Diverse Membership

Members will represent varying academic disciplines and have the necessary credentials to provide appropriate review of submitted protocols. The IRB will represent the diversity of the community in order to provide guidance on varying perspectives and sensitivities. The IRB will be sufficiently qualified through experience, expertise, and diversity (including race, gender, cultural backgrounds, and community attitudes) to provide appropriate review of research with a primary focus on protection of human participants.

2.3 Unaffiliated Membership

The IRB will include at least 1 member who is not affiliated with the Institution. The unaffiliated member must not:

A. have any professional relationship with the Institution as an employee, consultant, volunteer faculty, or student and

B. be a family member (first and second degree relative) of someone who has a professional relationship with the Institution.

2.4 Scientific and Non-Scientific Members

The IRB will include at least 1 member whose primary concerns are in scientific areas and at least 1 member whose primary concerns are in non-scientific areas.

2.5 IRB Membership Appointment

The Institutional Official (IO) appoints all IRB members; however, the IRB may make recommendations on whom to appoint. The IO will issue a letter of appointment to the candidate indicating the expected length of service.

A. The Chair/Director of the unit to which the member belongs will also receive a letter from the IO. It will:

(1) Acknowledge the importance of the service being rendered;

(2) State the length of service; and

(3) Request that the IRB member be available for full board meetings.

(a) Toward that end, the standard meeting time will be identified and the IO will request that the new member not have schedule conflicts--including teaching and other assignments--during the scheduled time of the IRB meetings.

(i) This protection of availability is to be implemented as soon as possible, preferably within 1 semester of appointment to the IRB.

2.6 Ex-Officio Members

The Office of Research Compliance staff and the Vice Provost of Research and Dean of the Graduate School are ex-officio, non-voting members of the IRB.

2.7 Legal Counsel

The IRB will have access to the University's General Counsel to offer legal counsel to the Board.

2.8 Ad hoc Members

In situations where a vulnerable population (children, prisoners, or persons with mental or physical impairment) is involved in research under IRB review and the Board does not already have a member with appropriate background and experience working with said population, the Board will include an ad hoc expert to serve in that capacity. This individual must have a close working

knowledge, understanding, and appreciation of the needs of said vulnerable population.

2.9 Ad hoc Prisoner Representative

In situations where a prisoner is involved in research under IRB review and the Board does not already have a member with appropriate background and experience to serve in the capacity of prisoner representative, the Board will include an ad hoc prisoner representative to serve in that capacity. This individual must have a close working knowledge, understanding, and appreciation of the prison conditions in the facility where the research will be conducted.

2.10 IRB Members with Conflict of Interest

Where IRB members have conflicts of interest (as defined by RPP Policy 2.05 *IRB Conflict of Interest Management*) pertaining to the research to be reviewed, members must excuse themselves from the meeting room before the final review discussion and vote, except when requested by the IRB to be present to provide information. IRB members with conflicts of interest must not participate in any type of reviews associated with said project.

2.11 Expert Consultants

When review of a proposal requires expertise that is not available on the Board, the IRB will request assistance from an expert consultant. These individuals will have access to all documents submitted to the IRB relevant to the specific project under review and may participate in the deliberations and make recommendations on the project but will not vote (see RPP Policy 2.03 *IRB Consultants*).

2.12 IRB Member Responsibilities

IRB members are expected to be fully engaged in the RPP and will be involved by carrying out the following responsibilities:

A. Be an active member of the IRB and:

- **(1)** Keep certification valid at the level decided by the Board (currently Responsible Conduct in Research Social and Behavioral modules and Human Research Group II CITI training)
- **(2)** Sign up to serve as a reviewer
- **(3)** Be available when on duty to fulfill responsibilities as a reviewer
- **(4)** Notify the IRB Administrator when unable to fulfill obligations to:
  - **(a)** Attend Full Board meetings

(b) Serve as a reviewer for a new protocol

(c) Review a revision of a previously assigned protocol or

(d) Respond to requests for revision in a timely manner.

B. Serve as a reviewer for new protocols and:

(1) Complete reviews in a timely manner:

(a) Responding to co-reviewers within 5 business days of protocol being assigned, and

(b) Adhering to 10-working-days turnaround time.

C. Serve as a reviewer for requests for continuing review.

D. Serve as a reviewer for internal unanticipated problems involving risk to the participant or others.

E. Serve as a reviewer for external AEs or serious problems.

F. Serve as a reviewer for modifications in protocol and/or consent documents.

G. Serve as a reviewer for incidents of noncompliance.

H. Engage in continuing education.

2.13 IRB Interim Members

A. Interim members are appointed by the IO, based on the recommendation of the IRB.

B. An interim member has all the rights, roles, and responsibilities of an IRB member.

2.14 IRB Membership Information

The IRB Administrator will maintain a list of the current IRB membership and track any changes.

The membership list must contain the following information:

A. Name

B. Earned degrees

C. Affiliated or non-affiliated status

D. Status as a scientific or non-scientific member

E. Specific scientific qualifications (such as board certifications and licenses) and other relevant experience sufficient to describe each member's chief anticipated contribution to the IRB deliberations

F. Representative capacities of each IRB member, which IRB member is a prisoner representative, and which IRB members are knowledgeable about or experienced with

working with children, pregnant women, decisionally impaired individuals, and other vulnerable populations locally involved in research.

G. Role on the IRB (Chair, etc.)

H. Voting status

I. Relationship (e.g. employment) between the individual IRB member and the organization.

2.15 IRB Membership Roster

The IRB roster is public information. The names of the IRB members who review specific protocols will not be released for reasons of confidentiality.

See Appendix B for Revision History

RPP Policy 2.02	2.02 IRB Meetings and Member Responsibilities	Updated 2023 Nov. 8

1. Purpose

To describe the structure of Institutional Review Board (IRB) meetings and member responsibilities.

2. Policy

It is the IRB's policy that the structure of the IRB meetings and responsibilities of IRB members are clearly defined.

2.1 IRB Meeting Dates

IRB meeting dates are determined at the beginning of the academic year and posted on the website. Board members will be notified when the list is posted.

2.2 Meeting Notices

Before the scheduled IRB meeting, the IRB staff will notify each member officially reminding each of the date, time, and location of the IRB meeting. At that time IRB members can update their availability.

2.3 Application Deadlines

Materials will be available approximately 5 business days before the IRB meeting, IRB applications and supporting materials for review will be available to IRB members on the IRB-designated secure electronic system.

2.4 Protocol Distribution

For reviews by a convened IRB, all IRB members are provided with the full protocol containing all the relevant information needed to determine whether the proposed research fulfilled the criteria for approval.

A. A primary and secondary reviewer will be assigned to a protocol being brought before the full board. The review team will perform an in-depth review of all pertinent documentation available. All other IRB members will review the provided material so they can discuss the materials at the convened meeting.

B. Approximately 72 hours before the meeting, the review team will post questions and concerns to the Full Board via IRB-designated secure electronic system.

2.5 IRB Quorum

A quorum will be established in accordance with federal requirements. If a quorum is not met or is lost, any official actions will be postponed and the meeting will be re-convened as soon as possible (see RPP Policy 2.11 *IRB Quorum and Voting Requirements*).

2.6 IRB Members Voting on Policies

Members will review and vote on IRB policies as required (see RPP Policy 2.13 *Policy Review and Approval*). At the discretion of the Chair, members may vote on policy changes via the IRB-designated secure electronic system.

2.7 Invited IRB Guests

Persons may be invited to attend IRB meetings as guests under the following conditions:

A. Guest attendance is at the discretion of the Board

B. Guests may be asked to leave at any time

C. Guests will be asked to state the purpose of their visits and

D. If the request is granted, the guests will be required to sign a confidentiality statement and may be requested to leave the room during any discussion as necessary. Visitors may not vote.

2.8 Other Guests

Attendance at an IRB meeting by individuals, who are not Principal Investigators (PIs), is at the discretion of the board.

A. If the request is granted, the guests will be required to sign a confidentiality statement and may be requested to leave the room during any discussion as necessary. Visitors may not vote.

2.9 IRB Members Reviews of Protocols

IRB members will serve as primary or secondary reviewers. A primary and secondary reviewer will be assigned to all initial reviews, tabled protocols, changes in protocol, and continuing reviews.

See Appendix B for Revision History

RPP Policy 2.03	2.03 IRB Consultants	Updated 2023 Nov. 8

1. Purpose

To describe the identification, appointment, and role of Institutional Review Board (IRB) consultants.

2. Policy

It is the IRB's policy that services of expert consultants will be obtained as needed.

2.1 Determination of Consultant Need

Either before or during review of a protocol, the assigned reviewers may request the input of an expert. The IRB Chair or the IRB board will determine the need for an appointment of an expert consultant, either a scientist or a non-scientist, in accordance with the provisions of 45 CFR §46.107(e). Depending upon the nature and magnitude of the problem or concern, the IRB may seek more than one consultant.

2.2 Consultant Selection

Consultants may be selected from within the Institution or from outside the Institution based upon the required expertise.

2.3 Confidentiality

Consultants will sign a Confidentiality Agreement prior to reviewing or receiving detailed information regarding the protocol in question.

2.4 Discussion by Consultants

Consultants generally participate in the IRB's discussion of the protocol and may be asked to provide a written review which becomes part of the minutes.

2.5 Voting by Consultants

Consultants who attend an IRB meeting cannot vote and are excused upon conclusion of discussion of the protocol in question.

2.6 Consultant Conflict of Interest

Potential consultants will be queried by the IRB Chair or IRB Administrator before any services are rendered as to whether they have any potential conflicts of interest with the relevant investigators or funding agencies. If they do, they will be excused and another consultant found.

2.7 Vulnerable Participants

When the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, the IRB Chair or IRB Administrator will ensure that one or more individuals who are knowledgeable about or experienced in working with such participants will be present at the meeting.

See Appendix B for Revision History

RPP Policy 2.04	2.04 Orientation and Initial Training for New IRB Members	Updated 2023 Nov. 8

1. Purpose

To describe the orientation and initial training for new Institutional Review Board (IRB) members and the staff of the Office of Research Compliance (ORC).

2. Policy

It is the IRB's policy to provide new IRB members with an orientation and initial training that includes the information necessary to facilitate the performance of assigned responsibilities.

2.1 Orientation

All new IRB members will receive an orientation that includes general information about the IRB and the review process.

2.2 Web-Based Training

All IRB members and staff are required to complete the web-based program Collaborative Institutional Training Initiative (CITI) Human Research Group 2 and the Responsible Conduct in Research Social and Behavioral courses. IRB members are required to complete the social science/behavioral research training track. These are accessible through www.citiprogram.org.

A. A passing score of 100 % is required for the Human Research course. The Responsible Conduct of Research course requires a passing score of 80%.

B. CITI certification is valid for 3 years for both courses.

2.3 Tertiary Reviews

New members must serve as tertiary reviewers on 10 IRB protocols before they can serve as a secondary reviewer then primary reviewer. New members are encouraged to provide their analysis of the protocol to the primary reviewer within 5 working days of being assigned a protocol(s). The primary reviewer will provide the new member with feedback on the analysis. Feedback will also be provided to the IRB Chair on the timeliness and quality of responses offered by the new member.

See Appendix B for Revision History

RPP Policy 2.05	2.05 IRB Member Conflict of Interest Management	Updated 2023 Nov. 8

1. Purpose

To describe the identification and management of Institutional Review Board (IRB) member conflict of interest (COI).

2. Definitions

2.1 Immediate Family Member

Parent(s) or spouse of a parent, spouse, partner, biological or adopted child, or anyone who may be claimed as a dependent under the Internal Revenue Code, grandchild or grandparent by blood, marriage, or adoption of the IRB member.

3. Policy

It is the IRB's policy to identify and appropriately manage all IRB members' potential conflicts of interest. However, all IRB members themselves should be sensitive to potential conflicts of interest and act appropriately.

3.1 Notification of COI

Preferably upon receipt of IRB meeting materials, all IRB members must notify the IRB Chair or the IRB Administrator of a COI in advance of the upcoming meeting or upon assignment as a reviewer. If IRB members are uncertain if a potential COI exists, they are encouraged to consult with the IRB Administrator.

3.2 Declaration of COI

Prior to the beginning of each meeting, IRB members will be asked to declare, but are not required to describe, any COI that is related to the protocols under review.

3.3 Participation by Members with COI

Any individual with a COI can be a member of the IRB; however, the member cannot participate in the review and approval process for any protocol in which the member has a COI. In cases where the assigned initial reviewer has a COI, the IRB protocol is reassigned to another reviewer. When the member has a COI, the member may be present only to provide information if requested by the IRB. The member must be excused during the voting phases of the review and may not participate in the vote. The excused member is not counted toward a quorum when the vote on the protocol in question is taken. Minutes must reflect whether or not these requirements have been met.

3.4 Identification of COI

A COI exists when the IRB member (or an immediate family member):

A. Serves as a Principal Investigator (PI) or Supervising Investigator and is, accordingly, listed on the IRB application or has served as a scientific advisor to the PI

B. Is an advisor (e.g., thesis/dissertation committee chair) or a direct supervisor of a trainee's (e.g., graduate or undergraduate student) research

C. Has identified themselves as having a conflict of interest for other reasons such as having a close personal or professional association with the submitting investigator

D. Has received payments or anticipates receiving such payment during the next 12 months. Payments include salary, consulting fees, royalty, licensing payments from intellectual property, or honoraria and/or gifts from the commercial company sponsoring the research or their representative(s) or from a company with a financial interest in the product or service being tested over the past 12 months

E. Has equity interest in the commercial company sponsoring the research or in the product or service being tested or more than 5% of the business entity (when aggregated for the investigator and the investigator's immediate family member), determined by reference to publicly listed prices (excluding mutual funds)

F. Has any equity interest in the commercial company sponsoring the research when the value cannot be determined by reference to publicly listed prices (e.g., start-up companies) or other reasonable measures of fair market value

G. Holds a paid or unpaid position as director, officer, partner, trustee, or any other significant position (e.g., scientific advisory board/consultant) in the company sponsoring the research or in a company with a financial interest in the product or service being tested

H. Holds patent rights or royalties from such rights, the value of which may be affected by the outcome of the research, including royalties under any royalty-sharing agreements involving UA Little Rock

I. Has a financial interest in a company that has a marketed product or is in the process of developing a new product

that is, or will be, in direct market competition with the product in the protocol under IRB review

J. Has a personal relationship or a conflict with any investigator(s) listed on the IRB application that would potentially cause the IRB member to be perceived as less than objective in their review; or

K. Has an ownership interest or compensation related to the research, the value of which may be affected by the outcome of the research.

3.5 Records of COI

The IRB meeting minutes will record the name of the IRB member with the COI and indicate that the member was recused and did not vote.

See Appendix B for Revision History

RPP Policy 2.06	2.06 Continuing Education Requirements for IRB Members	Updated 2023 Nov. 8

1. Purpose

To describe the Institutional Review Board's (IRB) program of continuing education for its members.

2. Policy

It is the IRB's policy to provide IRB members with ongoing continuing education concerning new regulations, updated HHS Office of Human Research Protections (OHRP) guidance documents, Association for the Accreditation of Human Research Protection Programs accreditation standards, issues in the field of research ethics, OHRP compliance citations, and other areas of interest that are related to human participant protection.

2.1 Re-Certification

When re-certification is required, IRB members must complete the continuing education modules available through the CITI training program. They must attain a score of 100% for the Human Research Group II course and 80% for the Responsibility Conduct od Research course to be considered certified by UA Little Rock standards.

2.2 Website and IRB Secure Electronic System

IRB members are encouraged to access the UA Little Rock-IRB website and the IRB-designated secure electronic system, which maintains links to OHRP and other sites of interest to IRB members.

A. The IRB-designated secure electronic system contains current conference materials and other educational materials.

2.3 Educational Materials

IRB members will be provided educational items at Board meetings. These items may be current journal articles addressing issues of human participant research, new or updated guidance issued by OHRP, or other items of interest.

2.4 Other Available Materials

Newly published books on research ethics and protection of human participants are available in the Office of Research Compliance (ORC) for IRB members.

2.5 National Conferences

The IRB Chair will attend the national conferences on human research participant protections on a regular basis for the purpose of continued education. This educational experience is supported through the ORC budget.

2.6 Other Regional and National Conferences

IRB members are offered the opportunity, on a rotating basis, to attend regional and national conferences on human participant protections. This educational experience is supported through the ORC budget

2.7 Advanced Training and Certifications

The IRB Chair and IRB members are expected to pursue the appropriate advanced Collaborative Institutional Training Initiative (CITI) training in Human Research Protection and Responsible Conduct of Research.

See Appendix B for Revision History

RPP Policy 2.07	2.07 Evaluation of IRB Members	Updated 2023 Nov. 8

1. Purpose

To describe evaluation of the performance of Institutional Review Board (IRB) members.

2. Policy

It is the IRB's policy to carry out evaluations of IRB members and provide feedback as necessary to individual IRB members.

2.1 Performance Assessment

Performance is assessed based upon meeting attendance records, thoroughness of reviews, participation in IRB discussions, and service on subcommittees.

2.2 Extended Leave

IRB members may be granted an extended leave due to medical, personal, or professional reasons and may then return to complete their terms.

2.3 Performance Resolution

If an IRB member's performance is judged to be deficient, the IRB Chair will discuss IRB concerns with the member and seek a satisfactory resolution.

2.4 Termination

Members who do not adequately fulfill their responsibilities may be asked to step down from IRB membership by the Institutional Official (IO) at the IO's instigation or at the recommendation of the IRB chair.

2.5 Notification of Termination

If an IRB member's appointment is terminated, the IO (or IO designate) will notify the member in writing. The IO (or IO designate) at the IO's discretion may notify the IRB member's supervisor or other administrative officials of this decision.

2.6 Acknowledgement of Service

By the end of the calendar year the IRB Chair will write letters which attest to the quality and value of the member's service on the IRB.

2.7 Evaluation of IRB Chair

The Chair may be evaluated on an annual basis by the IO, which will include feedback from the IRB members.

2.8 Responsibility Distribution

The IRB Administrator, IRB Chair, and IO (or IO designate) may meet periodically to evaluate distribution of responsibilities within the Research Protection Program (RPP) in order to maximize effectiveness.

See Appendix B for Revision History

RPP Policy 2.08	2.08 IRB Member Confidentiality	Updated 2022 May 15

1. Purpose

To describe the requirements for Institutional Review Board (IRB) members to maintain the confidentiality of protocol reviews.

2. Policy

It is the IRB's policy to maintain strict confidentiality of all reviews and other actions.

2.1 Confidentiality

All IRB members will keep confidential all protocols and other information pertaining to research reviewed by the IRB, which is unavailable to non-IRB members.

2.2 Secured Materials

All IRB review material is stored in the IRB-designated secure electronic system or disposed of in a manner that preserves confidentiality. Additional files are also saved in secure folders and access is maintained by UA Little Rock Information Services. IRB material should not be left unsecured in the IRB meeting room. Materials should only be left in the room at the end of the meeting for proper filing or shredding by IRB staff.

2.3 Discussion with Consultants of Non-Proprietary Information

Protocols *without* proprietary information or confidentiality restrictions may be discussed with expert internal or external consultants. Confidentiality should be safeguarded by assigned consultants.

2.4 Discussion with Consultants of Proprietary Information

In the case of protocols *with* proprietary information or confidentiality restriction that requires consultation with an internal or external consultant, approval will be made by the IRB Chair. Confidentiality should be safeguarded by assigned consultants.

2.5 Confidentiality Agreements

All IRB members, the IRB Administrator, Vice Provost of Research, and internal or external consultants will have a signed IRB Confidentiality Agreement on file in the ORC.

See Appendix B for Revision History

RPP Policy 2.09	2.09 IRB Reviewer Assignment	Updated 2024 Feb. 1

1. Purpose

To describe Institutional Review Board (IRB) reviewer assignment for full board meetings; protocol reviews, or continuing reviews; and requests for modification reviews.

2. Policy

It is the IRB's policy to assign reviewers who have knowledge of IRB procedures and research and knowledge of the issues in the area under review. Correspondence regarding reviews is conducted through the IRB-designated secure electronic system.

2.1 Review Assignments

The IRB Administrator, based on the duty roster, will assign reviewers (primary, secondary, and tertiary when appropriate) for protocol reviews, continuing reviews, and requests for modification reviews.

A. The primary reviewer is responsible for summarizing issues raised by the assigned reviewers and for forwarding these to the IRB Administrator.

(1) If the contact among reviewers has not been initiated within 5 calendar days after the protocol has been assigned, the IRB Administrator and IRB Chair must be contacted by the reviewer who has been attempting to make contact.

(a) The IRB Administrator and IRB Chair may reassign the protocol to a new member or the IRB Chair may step in to replace the non-responding reviewer.

B. The summary will be forwarded to the IRB Administrator through the IRB-designated secure electronic system with a copy to the reviewers.

C. The summary will include:

(1) Concerns raised by reviewers and, if appropriate, recommendations for change

(2) Disposition of the Request for Review:

(a) Approval as is

(b) Revise and resubmit for re-review or

(c) Refer to full board for review.

D. Subsequent revisions, corrections, and any changes to the protocol currently under review will be forwarded by the IRB Administrator to the initial reviewers for re-evaluation.

E. Responsibility for a protocol is retained by the primary reviewer until final disposition.

F. If one of the reviewers is not available, the IRB Chair may:

(1) Step-in to serve as a second reviewer or

(2) Select another IRB member to serve if the primary reviewer is not available.

2.2 Documentation for Reviewers

Each IRB reviewer receives the following documentation as applicable:

A. Complete protocol application form

B. Proposed consent/parental permission/assent form(s)

C. Recruitment materials/participant information

D. Data collection instruments (including all surveys and questionnaires)

E. For continuing reviews IRB members review all of the above. If the initial protocol required a full review, the continuing review requires a full board review.

F. For protocol modifications members receive the complete history of the project along with the modification form and requested documents.

If IRB reviewers require additional information to complete the review, they may contact the IRB Administrator to make the request of the investigator.

2.3 Reviewer Presentation and Recommendation

The reviewers assigned to a protocol being brought to the Full Board for review must prepare to present it and propose recommendations.

A. After the IRB Board has convened, if the full board deems it appropriate the reviewers who presented the protocol will continue as reviewers for the protocol for its post-board revision(s). Thereafter, the protocol is the responsibility of the primary reviewer.

(1) Only a member who attended the full board meeting in which the protocol was presented may serve as a secondary reviewer. The IRB Chair or a designee will serve as a secondary reviewer.

2.4 Questions of COI

A Principal Investigator (PI) who is concerned about a conflict of interest (COI) on the part of any IRB member related to his/her protocol is encouraged to contact the IRB Chair.

A. The Chair and IRB Administrator will meet with the PI to hear the concerns.

(1) Appropriate documentation will be maintained to reflect this process.

B. If the Chair and the IRB Administrator feels there is a COI, the protocol will be reassigned to other reviewers.

C. If the IRB Chair or members have a concern about a COI or an appearance of a COI, they should recuse themselves from reviewing the protocol in question.

See Appendix B for Revision History

RPP Policy 2.10	2.10 Written Reviews by IRB Members and Development of the IRB Review Letter	Updated 2024 Feb. 1

1. Purpose

To describe the procedures for submission of written reviews by Institutional Review Board (IRB) members and the development of the IRB review letter.

2. Policy

It is the IRB's policy for IRB reviewers to submit written comments regarding the IRB application, the detailed protocol, the consent/assent documents, and other pertinent issues.

2.1 Full Board Reviews

Reviews for Full Board meetings are submitted orally during the IRB meeting.

A. The IRB review letter, issued following a full board meeting, which reflects the decisions of the board, is developed by the IRB Administrator.

B. The IRB Administrator will summarize the concerns raised by the presenting reviewers as well as any additional ones raised by the IRB Board.

C. The IRB review letter should be forwarded to the Principal Investigator (PI) within 3 business days of the meeting.

2.2 Electronic Submissions

All other reviews of protocols are submitted separately through the IRB-designated electronically secure system to the IRB Administrator.

A. The review should be submitted to the IRB Administrator in accordance with the expected decision date.

B. The review should be copied to all reviewers.

2.3 Submission Deficiencies

The review forwarded to the IRB Administrator should address significant deficiencies and/or major points for clarification. The protocol and supporting documentation should be referenced as necessary.

2.4 Contact with PIs

Reviewers are discouraged from initiating contact with PIs. If such a request is made by the PI, the request should be directed to the IRB Chair.

2.5 Review Letter

The review letter sent to the PI must include:

A. Mandated changes and

B. Reiteration that no research may commence until the PI has received a letter granting such permission.

2.6 Approval Letter

Approval letters must include:

A. A statement that any changes to the protocol require a Request for Modification

B. A statement about reporting Adverse Events (AEs) and

C. Time frame of expiration of approval.

See Appendix B for Revision History

RPP Policy 2.11	2.11 IRB Quorum and Voting Requirements	Updated 2022 May 15

1. Purpose

To describe Institutional Review Board (IRB) quorum and voting requirements.

2. Policy

It is the IRB's policy to conduct Full Board meetings in compliance with HHS regulations 45 CFR §46.108(b).

2.1 Full Board Quorum

A Full Board cannot vote in the absence of a quorum. A duly constituted quorum must include:

A. A simple majority of the voting membership and

B. At least 1 member whose primary concerns and interests are in a non-scientific area; 1 IRB member may fulfill both criteria of non-scientist and non-affiliate (see RPP Policy 2.01 *IRB Membership Requirements and Responsibilities*) at the same meeting. The minutes must reflect in what capacity each member is serving for that meeting.

2.2 Prisoner Representative

When the IRB reviews any protocols, amendments, unanticipated problems involving risk to the participants or others, AEs, or compliance problems related to research involving prisoners, an individual prisoner representative (external consultant or IRB member) must be present in accordance with 45 CFR §46.304(b) (see RPP Policy 2.01 IRB *Membership Requirements and Responsibilities*).

2.3 Convened Meetings

The IRB Administrator has the responsibility to monitor the members present at convened meetings and determine that meetings are convened appropriately and remain so for the duration of the meeting.

2.4 Abstention Votes

IRB members who abstain from voting (recorded as an "abstention") are included in the quorum.

2.5 IRB Members with Conflict of Interest (COI)

Any IRB member who has a COI will be recused in accordance with US Department of Health and Human Services (HHS) regulations 45 CFR §46.107(e). IRB members with a COI are prohibited from participating in the discussion or from voting and will only provide information upon request of the IRB (see RPP Policy 2.05 *IRB Member Conflict of Interest Management*).

2.6 Meetings Below Quorum

If attendance at a convened Full Board meeting falls below a quorum, the meeting may be adjourned and will be reconvened at the earliest possible time.

2.7 Motions

A simple majority of the IRB members, which constitutes a quorum, is necessary for a motion to pass.

A. Members may be present in person, on audio or video conference, or on the web with video exchange during the discussion and vote of the motion.

B. If a member must leave the meeting *temporarily* before the vote is taken, the vote can be delayed.

C. Voting by absentee ballot is not permitted.

D. If a motion fails to pass by a simple majority vote, other motions will be entertained.

(1) If no further motions are made, the protocol or issue under discussion will automatically be deemed to have been "tabled" and will be referred, as needed, to an IRB subcommittee for further study.

2.8 Voting

At the discretion of the IRB Chair, voting may be by written ballot, electronic ballot, a show of hands, or voice vote. The official minutes will record the number of votes to approve, disapprove, table, or abstain without individual voting-member identification.

2.9 Minority Opinions

Whenever a difference of opinions arises during an IRB meeting, the minority opinion will be included in the minutes of the meeting.

See Appendix B for Revision History

RPP Policy 2.12	2.12 IRB Minutes	Updated 2022 May 15

1. Purpose

To describe the requirements for the minutes of Institutional Review Board (IRB) meetings.

2. Policy

It is the IRB's policy to maintain minutes of IRB meetings in accordance with HHS regulations 45 CFR §46.115(a)(2).

2.1 IRB Minutes

The IRB minutes will include core minutes and detailed review letters to investigators, which are cited as addenda in the core minutes and thus are an official component of the minutes.

A. The core IRB minutes will identify the IRB members, IRB alternates who are serving to replace IRB primary members, IRB alternates who are non-voting, consultants, administrative staff, and any guests in attendance at the meeting.

2.2 Conflict of Interest (COI) in Minutes

The core IRB minutes will include the names of IRB members who have a COI and are recused (absent) from the discussion and the vote and will provide a notation indicating that a COI was the reason for the absence.

2.3 Absent IRB Members

The core IRB minutes will include the names of IRB members who do not have a COI but are absent from the room at the time of the vote.

2.4 Recording of Votes

The core IRB minutes will include only the vote counts for all board actions (e.g., for, against, and abstentions).

2.5 Discussion Summary

The core IRB minutes should include, if relevant, a written summary of the discussion and resolution of controversial issues. A controversial issue is clarified for the purposes of this policy as one that generated a contentious discussion among members of the IRB over a human participant protection issue. Examples include, but are not limited to:

A. Concerns over the acceptability of the risk-benefit relationship of the research

B. Concerns over additional protections for a vulnerable participant population and whether the protocol meets the requirements of US Department of Health and Human Services (HHS) regulations 45 CFR §46 Subpart C or D

C. Concerns over investigator's qualifications or

D. Concerns related to noncompliance.

2.6 Record for Continuing Review

The core IRB minutes will include a determination of when continuing review is required more often than annually, as required by HHS regulations 45 CFR §46.109(e).

A. This determination will be based upon factors such as:

(1) Risk level of the research

(2) Inclusion of a vulnerable participant population and

(3) History of Principal Investigator (PI) noncompliance.

2.7 Duration of Approvals

The core IRB minutes will include the duration of IRB approval accorded to a protocol.

2.8 Identification of Populations

The core IRB minutes will include specific comments relevant to the inclusion of certain (e.g., vulnerable) populations as applicable to the research.

3. Risks or Alternative Procedures

Core minutes may also include justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the HHS-approved sample consent document.

3.1 Project Verification

The core IRB minutes will include an IRB determination of which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review. This determination will be based on a history of noncompliance as well as other factors as the IRB deems appropriate.

3.2 New Business

In addition to the review of pending applications, core meeting minutes may include information regarding expedited, exemptions, and continuing approvals; modifications; and any other business appropriate for IRB meetings.

3.3 IRB Minutes Addenda

The IRB minutes addenda (detailed review letters to investigators) may include any of the following:

A. The basis for requiring changes in or disapproving research

B. Any IRB required modifications of the initial IRB protocol, consent/assent documents, requested clarifications, or request for additional information

C. IRB required modifications of amendments to the IRB application and consent/assent documents

D. IRB required actions in response to reports of unanticipated problems involving risk to the participant or others

E. Documentation of compliance with the requirements of HHS regulations 45 CFR §46(B)(C)(D), as applicable (This may include documentation of determinations required by the regulations and the protocol-specific findings justifying those determinations)

F. Documentation of compliance with HHS regulations 45 CFR §46.111(b), which require additional protections for vulnerable participants such as persons who are decision-impaired, persons who are economically or socially disadvantaged, and patients who are terminally ill

G. Documentation of IRB determinations involving waiver or alteration of informed consent, in accordance with HHS regulations 45 CFR §46.116(d), including protocol-specific findings justifying those determinations. (see RPP Policy 6.05 *Waiver or Alternation of Consent Process or Documentation*)

H. Documentation of IRB determinations involving a waiver of the requirement for obtaining a signed consent form in accordance with HHS regulations 45 CFR §46.117(c)(1)(2).

3.4 Copies of Minutes

The Institutional Official (IO) (or IO designate) and all IRB members have access to complete copies of IRB minutes.

3.5 Dissemination of Minutes

The complete IRB minutes will be provided to HHS Office for Human Research Protections (OHRP), auditing groups, and the courts in accordance with all applicable federal, state, and institutional requirements when requested.

See Appendix B for Revision History

RPP Policy 2.13	2.13 RPP Policy Review and Approval	Updated 2023 Sept. 28

1. Purpose

To describe the review and approval process for Research Protection Program (RPP) policies.

2. Policy

It is the IRB's policy to continually, and at least annually, assess the adequacy of existent policies and the need for new policies as the field of research ethics and human participant protection evolves. Each RPP that has been approved and included in the most current group of policies and procedures will be reviewed regularly.

2.1 Policy Review and Approval

Proposed RPP policies which significantly impact the IRB review system, investigators, and the Institution will be reviewed first by the IRB Chair in consultation with the IRB Administrator. Next, they will be reviewed and approved by the IRB Board and the IRB Chair. The IO will provide final approval.

2.2 Internal Administrative Procedures

RPP internal administrative procedures will be shared with the IRB for their information but do not require formal approval.

2.3 Draft Policy Review

When a draft policy is scheduled for review at the IRB meeting, all members of the IRB will be given a copy of the draft policy approximately one week in advance of the meeting.

2.4 Policy Review Meetings

All IRB members will be invited to attend the meeting at which the policy will be reviewed.

2.5 IRB Member Votes on Policy Changes

In the case of policy changes, all IRB members have the right to cast their votes (for, against, or abstain) either in person at the IRB meeting or via email within the designated electronically secure system.

2.6 Member Positions on Policies

IRB members may provide arguments in support of their votes or, if absent, request that another IRB member present the absent member's position to the Board.

2.7 Electronic Voting

In instances where approval of a policy is necessary before the next regularly scheduled meeting, voting procedure by an electronic system alone will be allowed for consideration of a policy.

2.8 Majority Approval or Disapproval

In order for a policy to be approved or disapproved, a majority of the entire IRB membership must vote in favor, either in person or by email within the designated electronically secure system, for the motion to carry.

2.9 Failed Motions

If the motion to approve a policy fails to pass, the draft policy may be referred to the IRB Chair or an IRB subcommittee for further discussion and revision before re-consideration.

See Appendix B for Revision History

RPP Policy 2.14	2.14 IRB Records	Updated 2024 Feb. 1

1. Purpose

To describe the maintenance and composition of Institutional Review Board (IRB) records.

2. Policy

It is the IRB's policy that records will be maintained in full accordance with U.S. Department of Health and Human Services (HHS) regulations 45 CFR §46.

2.1 Documentation of IRB Activities

Under HHS regulations 45 CFR §46.115, the IRB will maintain documentation of all IRB activities.

2.2 Document Retention

Where appropriate, the Office of Research Compliance (ORC) will maintain all records, reports, and other required documents as specified by federal regulations and UA Little Rock policies on record retention. The following documentation will be maintained for a minimum of 3 years:

A. Copies of all research protocols reviewed

B. Scientific evaluations, if any, which accompany the protocols

C. Progress reports submitted by research investigators

D. Reports of injuries to participants

E. Reports of unanticipated problems involving risk to participants including Adverse Events (AE) reports and documentation of IRB review of these reports

F. Minutes of IRB meetings

G. Records of continuing review activities

H. Copies of all correspondence between the IRB, ORC, and Principal Investigator (PI)

I. List of IRB members

J. Sample consent documents and

K. Written policies and procedures for the IRB as required under 45 CFR § 46.115(6).

2.3 IRB Protocol Files

The IRB protocol files will include:

A. Initial and revised protocols that may include the original protocol form, consent/assent forms, recruitment materials, flyers/scripts, site letters, and any other required materials, Collaborative Institutional Training Initiative (CITI) reports

B. Federal grant applications (as appropriate)

C. All decision letters

D. Initial IRB receipt letter to the PI

E. Further review letters

F. PI response to the IRB further review letter

G. All correspondence to and from PIs/Advisors, IRB Reviewers

H. All interim progress reports, if requested or required

I. Final IRB approval letter

J. All requests for changes and the correspondence pertaining to the request, including:

(1) Copies of the modified protocol and/or

(2) Copies of the modified IRB approved consent form.

K. All Continuing Reviews and the correspondence pertaining to the request, including copies of the consent documents approved in conjunction with continuing review

L. IRB records must document any determinations required by the regulations and protocol-specific findings supporting those determinations including:

(1) Waiver or alternation of the consent process

(2) Research involving pregnant women, fetuses and neonates

(3) Research involving prisoners

(4) Research involving children.

M. All interim progress reports, if requested or required

N. Reports of unanticipated problems (internal AEs, internal fatal AEs, external AEs, and unanticipated problems involving risk to the participant or others) and the correspondence pertaining to the reports, including copies of supporting documentation and consent documents

O. Incidents of noncompliance, including documentation of investigation correspondence, and reports to IOs and HHS Office of Human Research Protections (OHRP), where appropriate and:

P. Results from correspondence regarding the findings.

2.4 Length of Retention

The complete file is maintained for 3 years after the original termination date.

2.5 Secure Database

The IRB maintains a secure database. The database is under constant revision to add information necessary to more efficiently provide service to the IRB and investigators. Current database will contain:

A. IRB protocol number

B. Title of protocol

C. Review category (for review, determination, continuation, modification)

D. Date protocol was received, expected decision date by reviewers, date of approval, continuing review, date of approved protocol change, and date by which additional information is needed

E. Status of the study (approved, disapproved, pending review, tabled, closed, withdrawn, and preliminary review)

F. PI's name, affiliation

G. Faculty advisor's name, affiliation and

H. Types of participants (UA Little Rock students and specific class of protected or vulnerable population.

See Appendix B for Revision History

Section 3

Initial IRB Review of Protocols

RPP Policy 3.01	3.01 Activities Requiring IRB Review and Determination	Updated 2022 May 15

1. Purpose

To describe investigational activities requiring IRB review and determination.

2. Definitions

2.1 Research

According to HHS regulations 45 CFR §46.102(d), "Any systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

2.2 *The Belmont Report*

Provides further clarification of "research" as follows: "…the term 'research' designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships)."

2.3 FDA Research

According to FDA regulations, "Any experiment that involves a test article and one or more human participants and that either is subject to requirements for prior submission to the FDA under Section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the FDA under these Sections of the act, but the results of which are intended to be submitted later to, or held for inspection by the FDA as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding non-clinical laboratory studies. An activity is an experiment (21 CFR §312), when: It involves any use of a drug, other than the use of a marketed (approved) drug device in the course of medical practice:

2.4 Generalizable Research

Important in this definition are the words "designed to contribute to generalizable knowledge." A study must be systematic and designed to contribute to generalizable or transferable knowledge in order to be considered research that must meet the requirements of the human participant regulations. Although publication is often viewed as evidence of research status, it is not the only criterion. "Systematic investigations" often result in published studies, yet they do not qualify as research because they were not designed to contribute to generalizable knowledge. In general, activities that contribute to generalizable knowledge are those that attempt to make comparisons or draw conclusions from the gathered data; attempt to identify generalizable principles of historical or social development; seek underlying principles or laws of nature that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes; create general explanations about all that has happened in the past; or predict the future.

2.5 Generalizable Knowledge

Generalizable knowledge is not limited to quantitative studies designed to produce generalizations. Qualitative studies may also contribute to generalizable knowledge through the use of focus groups, case studies, ethnographies, interviews, or other means to identify general themes that the reader can choose to transfer to another situation.

2.6 Human Subject (Participant)

According to HHS regulations 45 CFR §46.102(e), "A living individual about whom an investigator (whether professional or student) conducting research: (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

A. In this set of policies, the word "participant" is substituted for the word "subject."

B. Human subject as defined by FDA regulations is an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. In the case of a medical device, a human subject/participant also means a human on whose specimen an investigational device is used.

2.7 Human Participant Research

An activity that either meets the HHS definition of research and involves human participants, as defined by HHS regulations, or meets the FDA definition of research and involves human participants, as defined by FDA regulations.

2.8 Identifiable Biospecimen

Identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

2.9 Intervention

Physical procedures by which data are gathered (e.g., drawing blood) and manipulations of the participant or the participant's environment that are performed for research purposes.

2.10 Interaction

Communication or interpersonal contact between investigator and participant.

2.11 Engagement in Research

In general, the Institution is considered engaged in non-exempt human participants research when the involvement of UA Little Rock's faculty, staff, or students in a project includes any of the following (based on OHRP Guidance on Engagement of Institutions in Human Subjects Research found at http://www.hhs.gov/ohrp/policy/engage08.html:

A. The receipt of an award through a grant, contract, or cooperative agreement for non-exempt human participant research (i.e., awardee institutions), even where all activities involving human participants are carried out by employees or agents of another institution.

B. Intervention for research purposes with any human participants of the research by performing invasive or noninvasive procedures. Examples of invasive or noninvasive procedures include drawing blood; collecting buccal mucosa cells using a cotton swab; administering individual or group counseling or psychotherapy; administering drugs or other treatments; surgically implanting medical devices; utilizing physical sensors; and utilizing other measurement procedures.

C. Intervention for research purposes with any human participant of the research by manipulating the environment. Examples of manipulating the environment include controlling environmental light, sound, or

temperature; presenting sensory stimuli; and orchestrating environmental events or social interactions.

D. Interaction for research purposes with any human participant of the research. Examples of interacting include engaging in protocol dictated communication or interpersonal contact; asking someone to provide a specimen by voiding or spitting into a specimen container; and conducting research interviews or administering questionnaires.

E. Obtaining the informed consent/assent of human participants for the research.

F. Obtaining for research purposes identifiable private information or identifiable biological specimens from any source for the research. It is important to note that, in general, those who obtain identifiable private information or identifiable specimens for non-exempt human participants research are considered engaged in the research, even if the Institution's faculty, staff, or students do not directly interact or intervene with human participants. In general, obtaining identifiable private information or identifiable specimens includes, but is not limited to:

(a) observing or recording private behavior;

(b) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; and

(c) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.

G. In general, OHRP considers private information or specimens to be individually identifiable as defined in 45 CFR §46.102(e)(5-6) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

2.12 Private Information

Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., academic record information or a medical record).

2.13 Identifiable Private Information

Information where the identity of the participant is or may readily be ascertained by the investigator or associated with the information (e.g., "the only male teacher in school" is readily ascertainable.)

2.14 Systematic Investigation

An activity that involves a prospective research plan that incorporates data collection, either quantitative or qualitative, and data analysis in order to answer a research question.

2.15 General Conclusions

Investigations designed to develop or contribute to *generalizable knowledge* are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

3. Policy

3.1 IRB Approval

IRB approval is required for all research involving human participants, as defined above, which is conducted by faculty, students, staff, or others under the jurisdiction of the IRB (i.e. research performed on the premises of UA Little Rock and research involving human participants conducted elsewhere by investigators as part of their institutional responsibilities, unless the investigation is conducted under a cooperative research agreement.)

A. In reviewing research involving human participants, the IRB will apply HHS 45CFR §46 in accordance with RPP Policy 1.02 Federal Wide Assurance.

B. The IRB classifies research as social science/ behavioral or biomedical.

3.2 Classification of Human Participant Research

The following examples are examples only and are not exhaustive of all human research. They may be conducted at one location or as multi-center projects.

A. Social Science and Behavioral Research

(1) Social science and behavioral research include all research performed with intent to develop generalizable knowledge about behaviors, attitudes, and interactions among and between individuals, groups, and cultures. Generally, this category of research has no intent of producing a diagnostic, preventive, or therapeutic benefit to the participant

who is not seeking nor expecting a health benefit from the research. There may, or may not, be any prospect of direct participant benefit associated with this category of research.

(2) Types of research involving human participants that may fall under the social science and behavioral research category include, but are not limited to:

(a) Qualitative social science research,

(b) Ethnographic research,

(c) Oral History research,

(d) Observational research,

(e) Survey research,

(f) Education research,

(g) Criminal justice research,

(h) Student research, or

(i) Other – at various times, other disciplines might perform research falling under the jurisdiction of the IRB. For example, an engineering protocol might research how individuals respond to certain engineering techniques.

B. Biomedical Research

(1) Biomedical research at UA Little Rock generally, but not exclusively, refers to clinical/patient-oriented investigations, biomedical engineering research, and exercise science and nutrition studies research. Such protocols will be reviewed by the standing IRB, and if need be, a special panel will be convened.

C. Epidemiological Research

Epidemiological research targets specific health outcomes, interventions, or disease states and attempts to reach conclusions about cost-effectiveness, efficacy, efficiency, interventions, or delivery of services to affected populations. Some epidemiological research is conducted through surveillance, monitoring, and reporting programs — such as those employed by the Centers for Disease Control and Prevention (CDC) — whereas other epidemiological research may employ retrospective review of medical, public health, and/or other records. Because epidemiological research often involves aggregate examination of data, it may not be research involving human subjects. When this is the case, the PI should

submit the research to the IRB to determine whether it is research involving human subjects. For additional information regarding epidemiological research, refer to RPP 5.02 Epidemiological Research Guidelines.

D. Repository Research, Tissue Banking, and Databases

Research utilizing stored data or materials (cells, tissues, fluids, and body parts) from individually identifiable living persons qualifies as Human Research and requires IRB review. When data or materials are stored in a bank or repository for use in future research, the IRB should review a protocol detailing the repository's policies and procedures for obtaining, storing, and sharing its resources, for verifying informed consent provisions, and for protecting participants' privacy and maintaining the confidentiality of data. The IRB may then determine the parameters under which the repository may share its data or materials with or without IRB review of individual research protocols. For additional information concerning research using data and specimens, refer to RPP 9.02 Limited or Public Data Sets, RPP 9.03 Medical Records, and RPP 9.04 Review of Protected Health Information in Preparation for Research.

E. Pilot Studies

Pilot studies involving human participants are considered Human Research and require IRB review and approval before conduct of the research commences.

3.3 Examples of Non-Research Activities which Require IRB Review

A. Quality Improvement (Program evaluation, needs assessment)

(1) In general, quality improvement projects are not considered human participants research unless there is a clear intent to use the data derived from the project to contribute to generalizable knowledge.

(a) However, depending on the project it may require an IRB determination as to whether it is considered human participant research (HPR). Factors that may influence this are: target population, nature of questions being asked, privacy issues etc., Respondent's perception of coercion may also be a risk factor.

(2) Change in scope, purpose or any significant element of a project may also change a project's status from *not* Human Participants Research (NHPR) to HPR and therefore require IRB review.

(3) If a quality improvement project is completed (i.e., all the data are collected, analyzed, and conclusions have been drawn) and the decision is made to publish or present the data, it is research.

B. Student Projects or Classroom Demonstrations

(1) Student projects are considered research when there is a clear intent to contribute to generalizable knowledge. However, a student project that is conducted *within the confines of the classroom only* is not considered research. In this case, the student's supervisor and/or department are responsible to exert appropriate oversight of the project.

(2) Student research involving a vulnerable population or a special class of participants is never exempt from review and requires IRB approval.

3.4 Examples of Non-Research Activities

A. Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focuses directly on the specific individuals about whom the information is collected.

B. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in disease, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

C. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

D. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

3.5 Determination of When an Activity Constitutes Human Participant Research

A. Any individual who is unsure whether or not a proposed activity constitutes "research involving human participants" must submit a Request for Protocol Review.

(1) If the research meets the FDA definition of research and involves human participants as defined by federal regulations, the project will be assigned to UAMS IRB for review.

3.6 Type of Review

The type of IRB review required depends upon the nature of the proposal (e.g., determination, full board, expedited or exempt. All proposals fitting the category of exempt or expedited are reviewed by a minimum of 2 IRB Board members.

A. The OHRP Human Subject Regulations Decision Charts: 2018 Requirements covering the various categories (https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html) are available to reviewers and used as appropriate. The designated list of research falling into the expedited categories (63 FR 60364-60367, November 9, 1998 see https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html) are available to reviewers and are also used. A review team cannot disapprove the research. Disapproval of research requires a review of the full convened board in keeping with 45 CFR §46.108(b).

B. Any proposals which require a review by the full convened board [45 CFR §46.108(b)] and proposals about which reviewers have concerns will be referred to the full board.

C. A *continuing review* is a review of a project that has been previously approved by the IRB. The continuing review follows the same process as the original protocol. Protocols which required review by a full convened board will be reviewed by the full convened board. Approval of a continuing review will extend the original expiration date.

D. A modification of a protocol is a review of a protocol with an approval period that has not yet expired, to which the PI is now requesting changes. The review of the modification follows the same process as that of the original protocol. The modification does not extend the approval date.

3.7 Post-hoc Approval

There is absolutely no post-hoc approval of a research project or approval of data collected under any conditions in which there was not prior IRB approval of the project.

3.8 Sponsored Research

The University agrees to follow the research protocol, applicable state and federal law, and UA Little Rock's ethical standards.

See Appendix B for Revision History

RPP Policy 3.02	3.02 Ethical Principles Governing Research Under the Jurisdiction of the IRB	Updated 2024 March 18

1. Purpose

To describe the ethical principles which govern research under the jurisdiction of the IRB.

2. Policy

It is the IRB's policy that all research which is reviewed and approved by the Board and conducted under its jurisdiction will conform to the following guidance documents: 1) The Nuremberg Code and 2) The *Belmont Report*. HHS regulations (45 CFR §46) reflect the basic ethical principles for the conduct of human participant research found in these documents.

All researchers, participating personnel, and IRB members are charged with upholding the ethical principles contained in the aforementioned guidance documents as they apply to the research project in question. The IRB protocol and consent document review form and the process of IRB review are designed to help IRB members and investigators ensure that research reflects the highest ethical standards (RPP Policy #3.04 Criteria for IRB Approval of Research).

2.1 The Nuremberg Code

The Nuremberg Code contains 10 basic principles, which are presented in abbreviated form below:

A. The voluntary consent of the human participant is absolutely essential. Researchers must ensure that they obtain voluntary consent from all participants.

B. The research should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of research.

C. Research should be so designed and based on the results of animal or computational models and knowledge of the natural history of the disease or other problem under study to ensure that the anticipated results justify the performance of the research.

D. The research should be so conducted as to avoid all unnecessary physical and mental suffering and injury to the participant or others.

E. No research should be conducted if death or disabling injury is an expected result.

F. The degree of risk should never exceed the humanitarian importance of the problem to be solved by the research.

G. Proper preparations should be made and adequate facilities provided to protect the participant against even remote possibilities of injury, disability, or death.

H. The research should be conducted only by persons who are scientifically qualified to conduct the research.

I. During the course of the research, the human participant should be allowed to voluntarily withdraw at any time.

J. During the course of the research, those in charge must be prepared to terminate research at any stage if it is likely to result in injury, disability, or death to the participant.

2.2 The *Belmont Report*

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research released the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. The three basic ethical principles described in the *Belmont Report* are:

A. Respect for Persons

(1) The ethical principal of respect for persons has two components: acceptance of individual autonomy and protection of those with diminished autonomy. Autonomous individuals demonstrate the ability to make informed choices and act on those choices. These choices must be acknowledged and accepted by others as a demonstration of respect, as long as those choices are not harmful to others. Conversely, some individuals may be incapable of making informed choices and require special protection. The principle of respect for persons in the research context is demonstrated through the process of informed consent, including the process of assent and proxy consent for potential participants requiring special protections.

B. Beneficence

(1) The principle of beneficence is defined in two ways: (1) do no harm, and (2) maximize the potential benefits and minimize all potential harms (e.g., risks) related to research participation. While there is an imperative that no harm comes to the participant, it should be recognized that there is potential for harm due to unknown factors associated with the research. To minimize this risk, the potential benefits to the

participant and society must be determined and maximized.

C. Justice

(1) The principle of justice implies a sense of "fairness." Justice occurs when the burdens and benefits are equally carried by all. To achieve justice in the research context, recruitment of potential participants must occur without discrimination, bias, or undue influence in order to distribute the burdens and benefits of research equitably for individuals' and society's good. Inequities must be justified.

See Appendix B for Revision History

RPP Policy 3.03	3.03 Initial Application Submission	Updated 2022 May 15

1. Purpose

To describe IRB deadlines, submission materials, and pre-review process.

2. IRB Deadlines

Application forms and submission deadlines can be obtained through the UA Little Rock website. Applications are reviewed in the order in which they are received.

2.1 Protocol Submissions

Protocols may be submitted on a continuing basis.

2.2 Protocol Review

Protocols that are determined to require Full Board review will be discussed at the next scheduled meeting, as long as that meeting is no fewer than 10 business days away (dates are published annually and listed on the UA Little Rock website).

A. Incomplete submissions will result in delay of IRB review.

3. Materials to Include in the IRB Submission of Initial Applications

The following (as applicable) must be submitted to the IRB in the order listed below:

3.1 Request for Determination

A. In instances where the PI is unsure as to whether the research constitutes HPR, the PI must submit the IRB Request for Review form and request a determination.

(1) While the review form is the same for all IRB reviews, a Request for Determination does not require any additional support material such as CITI, consent forms, etc.

(2) However, should the project be determined to meet criteria for HPR, the additional documentation will be required.

(3) This will delay the review process and timeline.

3.2 Request for Review

A. UA Little Rock uses one general initial review form. The application must include sufficient detail to facilitate IRB

review. This application form can be obtained from the UA Little Rock website.

3.3 Informed Consent and Assent Form(s)

A. The consent and assent forms must be appropriate for the proposed study population (e.g., adult, proxy, parental, youth, and child). Examples can be obtained from the UA Little Rock website.

3.4 Participant Recruitment Material(s)

A. Copies of all advertisements, letters, transcripts of broadcast materials and other recruitment material will be required by the IRB for review and approval where applicable.

B. Only student research requires copies of letters requesting permission and letters granting approval to collect data at a specific site.

3.5 Description of Performance Site for All Non-Institutional Sites

A. Performance sites are defined as:

(1) sites where Institutional investigators or staff interact with participants, collect data, or solicit consent; or

(2) sites over which the IRB has responsibility. Performance sites do not include other sites that have an IRB participating in a multi-center study.

B. All performance sites must be identified and described (i.e., why the site is included in the study).

3.6 Other Relevant Materials

A. All surveys, assessment tools, screen shots of websites, and other relevant materials must be submitted for IRB review.

B. A copy of the detailed protocol and a copy of the complete grant narrative (excluding form pages, budget, bio sketches, etc.) must be available upon request.

4. IRB Pre-Review

4.1 Receipt of Applications

As new applications are received by the IRB office:

A. The protocol will be officially registered in the IRB database and assigned an IRB protocol number.

B. The PI will be sent an email verifying receipt of the protocol and will be provided with an IRB protocol number.

(1) This protocol number will be the identifier of the protocol for the life of the study.

4.2 Application Screening

All applications submitted for IRB review are screened by the IRB staff to determine if:

A. All required documents have been submitted and are complete; and

B. All personnel listed on the application (PI, supervising investigator, and other participating personnel) are currently CITI certified (required training in the protection of human participants - see RPP Policy 3.09 Required Training in the Protection of Human Participants)

4.3 Need for Additional Information

The PI will be contacted by email or phone to correct errors, provide missing documents, or provide additional information if needed.

See Appendix B for Revision History

RPP Policy 3.04	3.04 Criteria for IRB Approval of Research	Updated 2022 May 15

1. **Purpose**

   To describe the criteria required for IRB approval of human participant research.

2. **Policy**

   It is the IRB's policy that all requests for review will undergo rigorous scrutiny that will allow a determination that the protocol meets:

   1) the criteria specified in HHS regulations 45 CFR §46.111 and

   2) IRB RPP Policies and Procedures.

5 CFR §46.111 criteria are listed as follows and are the reference guide for all IRB review.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to participants are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

(2) Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of participants is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

(7) When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

(b) When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

3. Criteria for IRB Approval

3.1 Purpose of the Study

The IRB may determine if the background and literature citations support the stated purpose of the study (see RPP Policy 3.06 *Scientific and Scholarly Merit Review of Proposals*) relative to the risks to participants.

3.2 Characteristics of the Participant Population

A. The IRB will examine the characteristics of the proposed participant sample to determine whether:

(1) The eligibility criteria are appropriate with respect to the nature and goals of the research, and

(2) The selection of participants is equitable without any form of discrimination or bias. Any proposed exclusion of persons on the basis of age, gender, reproductive status, race/ethnicity, or any other stated factor must be justified scientifically by the investigator. In particular, the following may be examined:

(a) Accrual

The IRB must be assured that the minimum number of participants consented to this study is sufficient for the purpose of this study and that sufficient justification is provided relative to participants' risks.

(b) Gender

The IRB must be assured that the proposed distribution is suitable for the purpose of the study and appropriate justification for the inclusion or exclusion based on gender is

provided. Furthermore, women of childbearing potential and pregnant women should not be excluded from participation in research unless sufficient justification is provided.

(c) Age range of participants

The IRB must be assured that the proposed age range is suitable for the purpose of the study and appropriate justification for the inclusion or exclusion of particular age groups (such as children or the elderly) is provided.

(d) Race and ethnicity

The IRB must be assured that the proposed distribution of participants by race/ethnicity is suitable for the purpose of the study and appropriate justification for the inclusion or exclusion of particular persons or groups is provided.

(e) Vulnerable participants

The IRB will determine if the research is approvable for inclusion of vulnerable populations under HHS regulations 45 CFR §46, Subpart B (pregnant women [RPP 7.02 *Research Involving Pregnant Women, Human Fetuses, and Neonates*]), Subpart C (prisoners [RPP Policy 7.03 *Research Involving Prisoners*]), and Subpart D (children [RPP Policy 7.04 *Research Involving Children*]). In addition, the IRB will determine if special protections are required for persons who are decisionally impaired (RPP Policy 7.05 *Research Involving Participants who are Decisionally Impaired*) as well as other potentially vulnerable populations.

(f) Inclusion/exclusion criteria

The IRB will determine if the inclusion and exclusion criteria are appropriate for the purpose of this study and if the stated exclusion criteria minimize risk to potential participants.

3.3 Methods and Procedures

A. The IRB must determine if the interventions and follow-up procedures are appropriate for the stated purpose of the research. Interventions and procedures considered "standard of care" must be identified clearly.

B. The IRB accepts the need for certain types of behavioral and social science studies to employ strategies that include either deception and/or the withholding of information. Employment of such strategies must, however, be justified. (See RPP 5.05 *Use of Deception in Research*)

3.4 Data Storage and Confidentiality

A. The length of time required to store data is 3 years past the end of the study.

B. Special guidelines for storage of data are a function of the sensitivity of the material and are the responsibility of the PI.

C. The IRB will review the methods to be used to protect confidentiality and will ensure that appropriate protections are in place in consideration of the nature of the research, the vulnerability of the participant population, and the risk associated with a breach of confidentiality.

(1) If research data with participant identifiers will be made available to persons other than the listed investigators, sponsor, or federal agency, the IRB will review the justification for sharing this data and determine acceptability in accordance with all applicable regulations, including the Family Educational Rights and Privacy Act (FERPA) and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (RPP Policies 9.01 *Definition and Description of Protected Health Information Identifiers* and 9.03 *Medical Records*).

(2) If the research involves the collection of sensitive information where a breach of confidentiality would constitute a serious risk, the IRB will consider the need for a Confidentiality Certificate (RPP Policy 3.11 *Certificate of Confidentiality*). The IRB may also waive documentation of informed consent in accordance with HHS 45 CFR §46.117(c).

3.5 Risk - Benefit Assessment

The IRB will review the research design in order to be assured that the potential risks to the participants are minimized and the potential benefits maximized by utilization of procedures consistent with sound research design which does not unnecessarily expose participants to risk (see RPP Policy 3.06 Scientific and Scholarly Merit Review of Proposals).

A. Potential Risks

(1) Both immediate and latent (delayed) risks of any procedure involving human participants will be reviewed by the IRB to ensure that risks to participants are identified and minimized. The estimated probability, severity, average duration, and reversibility of any potential harm will be considered according to available empirical data. Furthermore, since certain populations of vulnerable participants may be at greater risk than others, the IRB will take into consideration the potential risk characterization of the participants and ensure that appropriate additional protections are in place as needed.

B. Risk Classification

(1) Risk is classified as: 1) minimal, 2) greater than minimal, or 3) significant. The IRB will review carefully the risk classification of the research, as it will determine the need for interim review requirements.

(2) Minimal risk is defined as the probability (of occurrence) and magnitude (seriousness) of harm or discomfort (e.g., physical, psychological, social) associated with the research are *not greater than those ordinarily encountered in daily life* (of healthy persons in the general population) or during the performance of routine physical or psychological examinations or tests.

(3) A uniform standard of minimal risk based upon the daily life of a normal, average, healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests he/she would be expected to encounter will normally be used for research involving adults. However, under certain circumstances, application of the minimal risk classification will be based upon a consideration of the risks inherent in each

participant's life, thereby resulting in a relative standard of minimal risk *which is more stringent*. Factors such as age, repetitive procedures, and vulnerability will be considered in determining if a study qualifies as minimal risk.

(4) When research involves children, a uniform standard of minimal risk also will be employed, which is based upon *the daily life of a normal, average, healthy child living in a safe environment* or the performance of routine psychological and medical examinations he/she would be expected to encounter as part of a standard well-child examination.

C. Minimization of risk (data and safety monitoring)

(1) The IRB will review data and safety monitoring that must fit the design, nature, and risk profile of the research. In some cases, the nature of the research may require a safety and monitoring plan (see RPP Policy 3.10 *Assessing the Need for Interim Continuing Review, Monitoring and Verification for Sources Other than the Investigator*). Such a plan is meant to assure that the research project has appropriate oversight. The oversight ensures the safety of the participants and the integrity of the data. The IRB will determine whether or not a research project requires review more often than annually (RPP Policy 3.10 *Assessing the Need for Interim Continuing Review, Monitoring and Verification for Sources Other than the Investigator*) and will establish appropriate reporting and/or monitoring procedures that may include observation of the consent process, observation of on-going research, or review of research records (see RPP Policy 7.01 *Additional Protections for Vulnerable Populations*).

In order to approve research in which the IRB considers provisions for monitoring data to ensure the safety of participants to be appropriate, the IRB will determine that the research plan makes adequate provisions. The following items will be addressed, where appropriate, during the IRB review.

(a) What safety information will be collected, including serious

(b) adverse events?

(c) How the safety information will be collected (e.g., with case report

(d) forms, at study visits, by telephone calls with participants).

(e) The frequency of data collection, including when safety data

(f) collection starts.

(g) The frequency of periodicity of review of cumulative safety data.

(h) The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor, including the frequency of reporting.

(i) For studies that do not have or are not required to have a data monitoring committee and are blinded, have multiple sites, enter vulnerable populations, or employ high-risk interventions, the IRB needs to carefully review the data and safety monitoring plan and determine whether a data monitoring committee is needed.

(j) If not using a data monitoring committee, and if applicable, statistical tests for analyzing the safety data to determine whether harm is occurring.

(k) Provisions for the oversight of safety data (e.g., by a data monitoring committee).

(l) Conditions that trigger an immediate suspension of the research, if applicable.

(2) The IRB also will determine whether a research project requires verification from sources other than the investigators that no material changes have occurred since the previous IRB review (RPP Policy 3.10 *Assessing the Need for Interim Continuing Review, Monitoring and Verification for Sources Other than the Investigator*).

D. Potential Benefits

(1) The IRB will review the anticipated benefits to both the participant and to society. In addition, the IRB will consider whether the benefits are maximized to the greatest extent possible through proper protocol

design. Financial or other forms of compensation are not considered a benefit to be derived from research participation. Although the participant may consider financial compensation an incentive, this fact will not be used in the risk-benefit analysis.

E. Risk-Benefit

The IRB will examine the relationship of the risks to the benefits identified in the application. The following is a series of principles, which the IRB will take into consideration:

(1) In research involving the study of the efficacy and safety of a therapeutic or diagnostic method, where there is the potential for participants to receive a direct health benefit (e.g., clinical research), the risk-benefit relationship of the research must be at least as favorable to the participant as that presented by alternate standard therapies available to the participant in the non-research context.

(2) In research involving a combination of a standard therapy (used solely for the benefit of the participant and not part of the research protocol) with specified research procedures, the anticipated benefits of the therapy must not be used to justify exposing participants to the risks associated with the research procedures. Conversely, only the risks associated with the research procedures should be used in determining acceptability of the risk-benefit relationship.

(3) In research that has no likelihood or intent of producing a diagnostic, preventative, or therapeutic benefit to the participant (e.g., behavioral research and non-clinical biomedical research), the potential risk to the participant must be outweighed or balanced by the potential benefit to society.

F. Alternatives to Participation

(1) The IRB will review the alternatives outside of the research context that are available and may be of reasonable benefit to the participant.

3.6 Participant Financial Obligations

The IRB may review the financial obligations of the participant relative to participating in the study. The IRB application should clearly identify who will be financially responsible for research-related interventions or procedures as well as other potential costs of participation (e.g., travel, child care, food).

3.7 Compensation for Participation

The IRB will review the amount of compensation (monetary as well as other forms) for participation in order to ensure that it is not coercive and is fair (see RPP Policy 3.15 *Compensation for Research Participants*).

3.8 Conflict of Interest

A. The IRB will review any potential COI on the PI's part (see RPP Policy 3.07 *Conflict of Interest Review by the IRB*). This review will be based upon the Board's charge to ensure protection of the rights and welfare of human participants. This charge includes authority to:

(1) Ensure disclosure in the consent document of any conflict of interest of the investigator which are judged by the IRB to be material to the participant's decision whether or not to participate in research;

(2) Ensure there is an appropriate plan for monitoring of the research which may involve observation of the consent process, auditing of records, and reporting of interim research results to the IRB; and

(3) Require informed consent be obtained by a qualified individual other than the PI.

3.9 Participant Identification and Recruitment

A. The IRB may review the method of prospective participant identification and recruitment in order to be assured it is ethically and legally acceptable (see RPP Policy 3.16 *Recruitment of Participants Through Advertisements*). Advertisements (e.g., newspaper ads, fliers, radio ads) used to recruit participants are considered an extension of the recruitment and informed consent processes and, therefore, must be reviewed by the IRB.

B. Informed consent and assent

(1) Consent

A procedure to ensure that a participant knows the risks and costs involved in the proposed research project.

(2) Assent

A child's active agreement to participate in research after appropriate consent has been obtained (see RPP Policies 7.01 *Additional Protections for Vulnerable Populations*, 6.01 *Development of the Informed Consent or Assent Record*, and 6.04 *Re-Consent/Assent of Research Participants*).

C. The IRB will review both the consent form and the process of informed consent as described in the IRB application to ensure that consent will be sought only under appropriate circumstances, which allow the prospective participant to engage in thoughtful decision making. Specifically, the IRB will determine the following:

(1) The process of consent/assent is appropriate in considering the nature of the research, risks to the participants, and characteristics of the participant population (see RPP Policy 6.03 *Alternative Methods of the Consent Process*).

(2) All required consent/assent document(s) utilize appropriate IRB-approved templates, which can be found on the UA Little Rock IRB website. The IRB templates ensure that:

(a) The informed consent/assent form(s) contain the informed consent elements required by HHS regulations (see RPP Policies 6.01 *Development of the Informed Consent or Assent Record* and 6.02 *Required Elements for Informed Consent*).

(b) The assent form(s) contain the IRB-required elements of assent (see RPP Policies 6.02 *Required Elements for Informed* Consent and 6.04 *Re-Consent/Assent of Research Participants*).

(c) The documentation of informed consent conforms to RPP 6.01 *Development of the Informed Consent*.

3.10 Investigator Qualifications

The IRB (see RPP Policy 3.08 *Qualification and Responsibilities of Research Personnel*) will review the PI's qualifications and must be assured that:

A. The investigator has the appropriate qualifications and licensure (when appropriate) to carry out the procedures involving human participants with an acceptable degree of risk.

B. The investigator has adequate facilities and equipment to conduct the research with an acceptable degree of risk.

C. For student projects, a faculty member must be listed as the secondary investigator/advisor.

3.11 Scientific and Scholarly Merit and Resource Review

A. The IRB must ensure that the research has undergone substantive scientific and scholarly merit and resource review (see RPP Policy 3.06 *Scientific and Scholarly Merit Review of Proposals*).

3.12 Letters of Agreement

For all student-led research, prior to final approval by the IRB, letters of endorsement or agreement must be submitted from all performance sites, which include acknowledgement of any specifications regarding each study site's participation and what access, services, facilities, or personnel each will provide for the research project.

A. If UA Little Rock is the lead site for a multi-institutional protocol, and either data are collected and analyzed at UA Little Rock or AEs or serious problems tracked at UA Little Rock, then a copy of the approval from the IRB of all reporting sites must be provided. If additional sites are added after approval of this application, then letters of IRB approval must be submitted as they become available.

B. Letters of agreement must be received from study sites not associated with UA Little Rock (such as schools, nursing homes, and prisons), stating that the site administrator is aware of the study and will allow the UA Little Rock PI and study personnel to utilize their site to conduct the study.

4. Additional Administrative Review

A. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by UA Little Rock officials. Those officials cannot, however, approve any research project unless it is first approved by the IRB. When a study is considered controversial, the IRB Chair will forward a copy of the protocol to the IO (or IO designate) and the PI will be so notified.

See Appendix B for Revision History

RPP Policy 3.05	3.05 IRB Review	Updated 2022 May 15

1. Purpose

To describe the IRB's review categories.

2. Policy

It is the IRB's policy that initial review of research must be conducted in accordance with HHS regulations 45 CFR §46. The IRB is the final determinant of the type of review that a protocol requires.

2.1 Decisions after a Review

A. After a review takes place, the investigator will be notified of the IRB's decision concerning the proposal. Reviewed proposals will be assigned to one of three categories:

(1) Approved

(a) The proposal is approved and released. The investigator may begin the study.

(2) Further Action Required

(a) The investigator will be notified in writing as to the nature of the required modifications and/or clarifications. As soon as the investigator complies in writing with all requirements to the satisfaction of the reviewers, an approval letter will be issued, and the investigator may begin the study.

(3) Referred to Full Board Review

(a) When the IRB Chair or the reviewers have a serious concern and have determined the proposal should be reviewed by the Full Board.

2.2 Actions after Full Board Review

A. After the IRB meeting, the investigator will be notified in writing of the IRB's decision concerning the protocol.

(1) In accordance with the IRB's decision, the IRB letter will specifically detail items requiring clarification, modification, or justification.

(2) The PI will be requested to respond to IRB concerns.

(3) The IRB minutes should reflect the IRB determination.

B. Protocols reviewed by the Full Board will be assigned to one of six categories:

(1) **Approval and full release**: No modifications or clarifications are required, and the investigator may begin the study.

(2) **Further Action Required**: This category is restricted to modifications/clarifications.

(a) The investigator will be notified in writing as to the nature of the required modifications and/or clarifications. These are to be reflected in a revised and resubmitted IRB protocol.

(b) When the investigator complies with all requirements as determined by the IRB Chair or designate, a release will be issued, and the investigator may begin the study.

(3) **Further action required with Full Board re-review of specific modifications/clarifications**. This category is restricted to modifications/clarifications which are considered substantive in nature.

(a) The investigator will be notified in writing as to the nature of the required modifications and/or clarifications. These are to be reflected in a revised and resubmitted IRB protocol.

(b) When the investigator complies with all requirements as determined by the Full Board at a convened meeting, a release will be issued, and the investigator may begin the study.

(4) **Tabled**. This category is restricted to applications where the IRB requires a significant amount of additional information and/or has a serious concern.

(a) The investigator will be notified in writing of the IRB's decision concerning the protocol. The IRB Chair or a member of the Board may be assigned to discuss the protocol with the investigator.

(b) When the investigator submits the required materials for re-review, the tabled protocol will be reviewed at the next IRB meeting in adherence with published submission deadlines for full board meetings. Whenever possible, the IRB reviewers who performed the initial

review will be assigned to re-review the protocol. When that is not possible, the IRB reviewers are encouraged to consult, as necessary, with the previous reviewer in order to resolve any problems or concerns that may still exist.

(5) **Decline to complete the review**. This category is restricted to applications that are significantly deficient in information, content, or clarity so that an adequate review of the protocol cannot take place.

(a) The application will be returned to the PI with instructions to review and revise the application in consideration of application instructions and guidelines and to resubmit the application to the IRB when ready.

(6) **Disapproved**. This category is restricted to applications that have very serious design flaws or where participants will be placed at undue risk.

(a) The investigator has the right to appeal to the IRB.

(b) An appeal must be done in writing.

(c) When appropriate, the IRB will seek consultation from nationally recognized experts in the field, other IRBs, OHRP, or the National Science Foundation Office of the Inspector General. Every attempt will be made to resolve the identified problem(s). The IRB, however, retains final authority over whether or not a proposal can be approved.

See Appendix B for Revision History

RPP Policy 3.06	3.06 Scientific and Scholarly Merit Review of Proposals	Updated 2022 May 15

1. Purpose

To describe the requirements for scientific and scholarly merit review of all research proposals submitted to the IRB for review.

2. Policy

It is the IRB's policy that all research proposals must undergo a substantive scientific or scholarly merit and resource review per HHS regulations 45 CFR §46.111(a)(1)(i), 45 CFR §46.111 (a)(2), and 45 CFR §46.115(a)(1).

2.1 Scientific and Scholarly Merit Requirements

The IRB, utilizing member expertise and/or consultants, will evaluate the scientific and scholarly validity of a proposed study. The IRB has broad-based disciplinary expertise, which allows a judgment to be made that the proposed research meets the criteria below in consideration of the need to satisfy scientific and scholarly merit requirements. The IRB will determine whether the risk/benefit ratio is acceptable.

A. The research uses procedures consistent with sound research design.

B. The research design will allow the proposed research question to be answered.

C. The knowledge to be gained from the research is sufficiently important from the research or training perspective

2.2 Consultants

When the IRB does not have sufficient expertise, the Board will utilize a consultant (RPP Policy 2.03 *IRB Consultants*).

See Appendix B for Revision History

RPP Policy 3.07	3.07 Conflict of Interest Review by the IRB	Updated 2022 May 15

1. Purpose

To describe the IRB review process for determining a PI conflict of interest (COI).

2. Policy

It is the IRB's policy that the PI, the responsible party for the research, declare all perceived significant financial or other conflicts of interest.

2.1 Conflict of Interest Form

All researchers are required to disclose any possible conflicts of interest or commitment in accordance with the UA Little Rock Conflict of Interest Policy – 309.6.

When submitting a protocol for research for which the researchers have a possible conflict of interest researchers must confirm that they have fulfilled the requirements of the University policy. If a conflict is disclosed, the IRB will not approve a protocol until the investigator has a conflict management plan approved by the appropriate university officials, and that is reviewed and determined by the IRB to be appropriate for avoiding conflicts of interest in the research process.

2.2 IRB Protections.

The Full Board will review the potential COI and management plan in terms of the Board's obligation to ensure protection of the rights and welfare of human participants. Possible additional protections include:

A. Ensure disclosure in the consent document of any financial interests of the investigator that are judged by the IRB to be material to the participant's decision whether or not to participate in research;

B. Ensure there is an appropriate plan for monitoring of the research, which may involve observation of the consent process, auditing of records, and interim reporting of research results to the IRB; and

C. Require informed consent be obtained by a qualified individual other than the PI.

See Appendix B for Revision History

RPP Policy 3.08	3.08 Qualification and Responsibilities of Research Personnel	Updated 2022 May 15

1. Purpose

To describe the qualifications and responsibilities of personnel involved in the conduct of human participant research.

2. Policy

It is the IRB's policy that all personnel involved in the conduct of human participant research must possess the appropriate experience, skill, and licensure.

2.1 Human Participant Training

All personnel listed on the IRB application are required to complete the appropriate Human Participants Protection training through the CITI program Group I (see RPP Policy 3.09 *Required Training in the Protection of Human Participants*). The IRB will not approve new protocols or changes or re-approve existing protocols until *all* listed personnel in the IRB application have been trained.

2.2 Research Personnel Classifications

The following are the classifications of research personnel:

A. Principal Investigator (PI)

This individual assumes *overall* responsibility for the study design and for the development and submission of the protocol to the IRB, for the obtaining of informed consent/assent from prospective participants on behalf of *all* authorized personnel listed on the application, for the conduct of the research, and for the publication of the findings that ensue from data collection.

(1) Only 1 individual may be listed as a PI for a study.

(2) Students may serve as the PI and, therefore, may be listed on the protocol as the PI. However, a faculty member-advisor must supervise the project and be listed on the protocol as a Faculty Advisor.

(3) Even if a student is listed as the PI, oversight and responsibility for the project rests upon the faculty advisor.

B. Faculty Advisor & Other Key Personnel

(1) These individuals assume *shared* responsibility for the project design and contribute substantively to the development and submission of the protocol to the IRB, to the obtainment of informed consent/assent from prospective participants, to the conduct of the research, and to the publication of the findings that ensue from data collection.

(2) If the PI is a student, the Faculty Advisor must co-sign the protocol before it will be accepted by the IRB for review.

C. Participating Personnel

These individuals are faculty or undergraduate or graduate students who have a limited or no role in project design. Project personnel may interact with participants, analyze data, or obtain consent. This could include but not limited to, individuals such as research assistants or co-investigators. Regardless of their specific duties on the project, participating personnel must have sufficient knowledge about the protocol and study design to effectively perform their respective project roles.

(1) Participating personnel must have the appropriate CITI training.

D. Limited Research Worker

(1) These individuals are required to take CITI training and must meet *all* the criteria listed below to qualify for such status:

(a) Have no responsibilities in project design,

(b) Are *not* enrolled as a student at UA Little Rock, and

(c) Are *not* UA Little Rock faculty.

(2) Further, these individuals must meet at least one of the following conditions:

(a) Have limited independent decision-making responsibilities in study implementation and data collection, or

(b) Have no role in data collection but may have access to multiple participants' identity and confidential data.

See Appendix B for Revision History

RPP Policy 3.09	3.09 Required Training in the Protection of Human Participants	Updated 2022 May 15

1. Purpose

To describe training requirements for all personnel involved in conducting human participant research.

2. Policy

It is the IRB's policy that all personnel involved in the conduct of human participant research must receive training in the protection of human participants.

2.1 Collaborative IRB Training Initiative (CITI)

Training in the protection of human participants is primarily accomplished through completion of this web-based training program.

A. Personnel to be Certified

Research personnel who are considered to be engaged in the research process per RPP 3.01 *Activities Requiring IRB Review and Determination* must complete training associated with the conduct of human participants research. They should also be listed on the IRB application. Research personnel are classified as follows:

(1) PIs

(2) Co-Investigator

(3) Faculty Advisors (if any) and Key Personnel

(4) Participating Personnel

(5) Limited Research Workers

(6) Community partner

Community research partners are typically from non-academic settings such as community agencies, health care delivery organizations, public health departments, or schools.

B. Training Tracks

(1) Basic Course Group I: Social and Behavioral Research Investigators and Key Personnel

(a) to be completed by PIs, faculty advisors, and key and participating personnel at UA Little

Rock who will conduct any type of human participant research.

(2) Responsible Conduct of Research (RCR)

(a) to be completed by all who are listed on protocols. (see University Policy 603.5 – *Responsible Conduct of Research (RCR) Training*). These individuals should choose the RCR area most closely related to their discipline.

(3) Limited Research Worker: Basic Course - Group I CITI training.

(a) In certain circumstances such as in community based participatory research, training through the CITI program may not be as effective and appropriate to ensure knowledge of human research participant protections. Any investigator proposing the use of training other than the CITI program for non-UA Little Rock personnel must have approval from the IRB.

C. Student Research

(1) All students conducting human participant research or having any responsibility for project design or data collection must take the Basic Group 1 CITI course and RCR.

D. External Investigators or Subcontract Recipients

(1) The IRB will accept certificates of training from other institutions when research personnel include external investigators or subcontract recipients who have been trained elsewhere and are under the legal jurisdiction of that institution with respect to compliance with federal regulations. A copy of any certification must be provided to the IRB.

E. New research Personnel added to IRB-Approved Research

(1) All new research personnel must complete Basic Group 1 CITI applicable training and RCR prior to the conduct of any associated human participants research activity.

F. IRB Approval of Research

(1) All research personnel must be CITI trained/certified prior to IRB approval of initial research applications, requests for continuing review, or modifications.

(2) Current project personnel whose prior certification may have lapsed must renew certification prior to IRB approval or any new requests for continuing review. If any listed personnel member's training will expire within 30 days, approval will not be granted for initial research, continuing review, or modification applications.

G. Access to the CITI Training Program

(1) A link to the CITI training system is available through the UA Little Rock IRB website. Following registration, the individuals will be able to immediately access the system.

H. CITI-Test Data Confidentiality

(1) Individual test scores are confidential and are not shared or disclosed outside the UA System.

I. Minimum Passing Score Required for Certification

(1) The IRB requires a passing score of 100% overall to receive CITI Curriculum Group: Human Research reports.

(2) The IRB requires a passing score of 80% on the RCR.

J. CITI Certification Renewal

(1) Certification by CITI course is valid for 3 years from the original date of completion. Certification must be renewed at that time in order for the individual to be listed as an authorized study personnel in new IRB applications or requests for continuing review. Certification renewal is available through the CITI Refresher Course.

(2) To renew certification:

(a) UA Little Rock faculty, students, and staff must complete the appropriate track in the Refresher Course in CITI.

(b) The IRB requires an overall passing score of 100% for a renewal of CITI certification.

(c) RCR courses do not have a refresher course. The course available in your discipline will have to be retaken.

2.2 Other Training Requirements

A. All research personnel listed on the IRB application are expected to read the *Belmont Report*, which is posted on the OHRP website (www.hhs.gov/ohrp/).

B. All research personnel listed on the IRB application are to be familiar with UA Little Rock's IRB policies, accessible on the UA Little Rock website.

C. All research personnel listed on the IRB application are expected to be reasonably familiar with the requirement of HHS regulations 45 CFR §46, which can be accessed on the OHRP website (www.hhs.gov/ohrp/)

See Appendix B for Revision History

RPP Policy 3.10	3.10	Assessing the Need for Interim Continuing Review, Monitoring, and Verification for Sources Other than the Investigator	Updated 2022 May 15

1. Purpose

To describe the criteria that the IRB will use at both initial and continuing review in determining the need for: 1) more frequent IRB review, 2) increased monitoring, and 3) verification from sources other than the investigator that no material changes have occurred since previous IRB review.

2. Policy

It is the IRB's policy that that all research will be assessed at both initial and continuing review in accordance with the requirements set forth by HHS regulations 45 CFR §46.103(b)(4).

2.1 Increased Monitoring and/or Interim Continuing Review

A. Unless specifically waived by the IRB, research that meets any of the following criteria will require review more often:

(1) Significant risk to research participants (e.g., death, permanent or long- lasting disability or morbidity, severe toxicity) without the possibility of direct benefit to the participants;

(2) The involvement of especially vulnerable populations likely to be subject to coercion (e.g., institutionalized psychiatric patients, incarcerated minors); or

(3) A history of non-compliance on the part of the PI or the faculty advisor.

B. The following factors will determine which studies require review more frequently:

(1) The probability, magnitude or change of anticipated risks to participants;

(2) The likely medical condition of the proposed participants;

(3) The overall qualifications of the PI and other members of the research team;

(4) The specific experience of the PI and other members of the research team in conducting similar research;

(5) The nature and frequency of AEs observed in similar research at this and other institutions;

(6) The novelty of the research making unanticipated AEs and/or serious problems more likely; and/or

(7) Any other factors that the IRB deems relevant.

C. When the IRB determines the need for increased monitoring, the PI, and when appropriate the Faculty Advisor, will be notified of these requirements in writing, and this oversight may be accomplished by either:

(1) Submission of interim reports by the PI, or

(2) Auditing of investigator records.

D. If the IRB determines the need for more frequent continuing review, the PI will be notified in writing, and the IRB approval period will be set accordingly.

E. Based on the criteria factors 2.1(A and B), and/or RPP 3.04 *Criteria for IRB Approval of Research* the IRB will determine whether the research will be reviewed more often.

2.2 Verification from Sources Other than the Investigator

A. The following circumstances may require verification from sources other than the investigator that no material changes have occurred since the previous IRB review:

(1) History of noncompliance.

(2) Recurrent delays in submitting modifications.

(3) High number of IRB approval expirations

(4) Failure to respond to IRB review letters or other correspondence in a timely manner.

B. When the IRB determines that verification from sources other than the investigator is necessary, the IRB Chair along with designated IRB member(s) will perform the necessary verification by conducting an audit.

See Appendix B for Revision History

RPP Policy 3.11	3.11 Certificate of Confidentiality	Updated 2022 May 15

1. Purpose

To describe the process for applying for a Certificate of Confidentiality (CoC) from the NIH.

2. Policy

It is the IRB's policy that a Certificate of Confidentiality may be required for certain research proposals where the potential of disclosure of sensitive, personally identifiable information creates significant risk of harm or damage to the participant.

2.1 Purpose of the Certificate of Confidentiality

A. Certificates are issued by the NIH for the purpose of protecting identifiable research information from compelled disclosure. The certificate allows the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

B. Federal funding of the research is not a prerequisite.

C. A Certificate does not prevent voluntary disclosures such as limited disclosure to protect the participant or others from serious harm, as in cases of child abuse.

D. A research protocol cannot rely on a Certificate to withhold data if the participant consents in writing to the disclosure.

2.2 Applicable Research

A. The project must be categorized as research (see RPP Policy 3.01 *Activities Requiring IRB Review and Determination*) for a definition of research.

B. The research must be IRB-approved.

C. The information collected must be "sensitive" (e.g., disclosure will involve significant harm or damage to the participant).

(1) Per NIH Policy, identifiable sensitive information means information about an individual that is gathered or used during the course of biomedical, behavioral, clinical, or other research where the following may occur:

(a) An individual is identified; or

(b) For which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

D. Personally identifiable information is collected during the research.

E. The investigator and/or the IRB determine that a Certificate is necessary to minimize risk to participants.

F. Certificates are issued for single, well-defined research projects rather than groups or classes of projects. Occasionally, a Certificate can be issued for cooperative multi-site projects. A coordinating center or "lead" institution can apply on behalf of all institutions involved in the protocol. The lead institution must ensure that all participating institutions conform to the application assurances and inform participants appropriately about the Certificate, its protections, and circumstances in which voluntary disclosures would be made.

2.3 Sensitive Research Categories include:

A. Information relating to sexual attitudes, preferences, or practices;

B. Information relating to the use of alcohol, drugs, or other addictive substances;

C. Information pertaining to illegal conduct;

D. Information that, if released, could damage a participant's financial standing, employability, or reputation within the community;

E. Information that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination;

F. Information pertaining to an individual's psychological well-being or mental health; or

G. Genetic information.

2.4 Application Process

A. If the research is funded by the NIH, then the research data or information is automatically protected by a CoC from NIH if the researcher is conducting research in which identifiable, sensitive information is collected or used.

(1) A CoC may be issued for research that:

(a) Meets the definition of human participants research, including exempt research in which subjects can be identified;

(b) Is collecting or using human biospecimens that are identifiable or that have a risk of being identifiable;

(c) Involves the generation of individual level human genomic data;

(d) Involves any other information that might identify a person.

(2) For research funded by CDC, FDA, HRSA, and SAMHSA, the researcher will need to work through these agencies to determine the mechanism to apply for a CoC.

(3) For HHS agencies other than those noted in Section A and B above, the researcher can apply for a CoC through the NIH using the NIH online application system. The NIH may issue a CoC for specific health-related projects using sensitive identifiable information.

B. If the research is funded by a non-HHS agency or a non-federally funded agency, NIH may grant a CoC for research projects that are:

(1) Collecting or using identifiable, sensitive information

(2) On a topic that is within the HHS health related research mission

(3) Storing the research information collected or used in the US

(4) And for research that:

(a) Meets the definition of human participants research, including exempt research in which subjects can be identified;

(b) Is collecting or using human biospecimens that are identifiable or that have a risk of being identifiable;

(c) Involves the generation of individual level human genomic data;

(d) Involves any other information that might identify a person.

C. For non-NIH funded research, in addition to the completed application, the PI will be required to provide documentation of IRB approval and a copy of the informed consent form(s) as it would read if a Certificate of Confidentiality is obtained (e.g., explains the Certificate, its protections and the circumstances in which voluntary disclosures might be made).

D. Both the PI and the IO are required to sign the Certificate application.

E. Additional information and detailed instructions may be found on the National Institutes of Health website at: https://humansubjects.nih.gov/coc/index

2.5 After CoC Approval

A. Investigators must provide final approval of the Certificate of Confidentiality to the IRB.

B. If the Certificate applies to UA Little Rock only, no additional documentation is required after final submission to the UA Little Rock IRB.

C. If the Certificate applies to multiple sites and UA Little Rock is the lead institution, the IRB staff will maintain accurate records to include but not limited to:

(1) List of all participating sites agreeing to uphold the Certificate of Confidentiality

(2) All approved consent documents from each participating site

(3) All executed authorization agreements

See Appendix B for Revision History

RPP Policy 3.12	3.12 IRB Approval of Multi-Site or Cooperative Research	Updated 2022 May 15

1. Purpose

To describe the conditions under which the IRB will review and accept or approve multi-site cooperative research. The applicable circumstances are:

1.1 UA Little Rock serves as the Reviewing IRB for research conducted at external sites either through multi-site or cooperative research with an affiliate of UA Little Rock or the individual(s) acting independently.

1.2 UA Little Rock serves as the Relying IRB when UA Little Rock is engaged in multi-site or cooperative research. (See RPP 3.01 *Activities Requiring IRB Review and Determination* for details regarding engagement of UA Little Rock.)

2. Definitions

2.1 IRB of record

The IRB that conducts the initial review and maintains oversight. Other terms used to describe the IRB of record are Reviewing IRB, single Institutional Review Board or the sIRB (per the NIH).

2.2 Institutional Authorization Agreement (IAA)

Also called the reliance agreement, which documents respective authorities, roles, responsibilities and communication between the organizations included in the agreement.

2.3 Multi-site Research

A study that uses the same protocol or research plan to conduct human subjects research at more than one site.

2.4 Cooperative Research

Research that involves more than one institution.

2.5 Reviewing IRB

The IRB that conducts the initial review and maintains continuing oversight. Other terms used to describe the reviewing IRB are the Single Institutional Review Board or the sIRB (per the NIH) or the IRB-of record.

2.6 Relying IRB

The IRB that accepts the initial review and continuing oversight, as applicable, of the Reviewing IRB

3. Policy

It is the IRB's policy that, in recognition of the importance of cooperative, multi-site research and the potential for duplication of effort, the IRB may agree to enter into a joint review arrangement and to either serve as the Reviewing or Relying IRB for funded and/or nonfunded non-exempt cooperative or multi-site research in accordance with HHS regulations 45 CFR §46.114 or the National Institutes of Health policy "Use of a Single Institutional Review Board for Multi-Site Research" (NOT-OD-16-094). A written agreement must be executed to identify the IRB of record when conducting non-exempt multi-site or cooperative research.

3.1 Authority

Decision-making authority related to entering into an agreement as either the Reviewing or Relying IRB is held by the [IRB] Institutional Official, or designee.

3.2 Conditions for serving as the Reviewing IRB

For non-exempt research (i.e., research reviewed using the Expedited or Full Board review method), UA Little Rock may act as the Reviewing IRB for a non- UA Little Rock research site or individual engaged in human participants research if the following conditions are met:

A. A protocol is submitted with this request or there is a prior MOU between the institutions

B. The Relying Institution or external investigator must agree to comply with all UA Little Rock Research Protection Program Policies and Procedures.

C. Either an authorization agreement, written agreement or individual investigator agreement must be fully executed between UA Little Rock and the non-UA Little Rock institution or non-UA Little Rock investigator.

D. The non-UA Little Rock site is located in the United States.

3.3 Conditions for Serving as the Relying IRB

For non-exempt research (i.e., research reviewed using the Expedited or Full Board review method), the following conditions must be met for UA Little Rock to cede review to another institution and act as the Relying IRB:

A. A formal request by the UA Little Rock investigator must be submitted.

B. A UA Little Rock faculty, staff, and/or student is engaged in the multi-site or cooperative human participants research.

C. The non-UA Little Rock Institution (i.e., Reviewing IRB) has accepted full responsibility to protect the rights and welfare

of all participants enrolled within its institution, in accordance with Health and Human Services regulations at 45 CFR §46, and any other applicable regulatory requirements.

D. The non-UA Little Rock institution has a current Federal Wide Assurance (FWA) approved by the Office of Human Research Protections (OHRP).

E. The UA Little Rock IRB has received a copy of the protocol, consent/assent document(s), and the non-UA Little Rock IRB approval notification.

F. An authorization or written agreement is fully executed between UA Little Rock and the non-UA Little Rock institution.

G. If the Reviewing IRB is non-accredited, the Reviewing IRB must provide an assurance that it will conduct its review consistent with the applicable ethical standards and regulations, as detailed within the authorization or written agreement.

3.4 Written Agreements

A. For federally funded, supported, or regulated research studies:

(1) If a non-UA Little Rock site has its own FWA, an IAA or other written agreement is required between UA Little Rock and the other site.

(2) If a non-UA Little Rock site is the primary awardee or engages in federally funded or supported research activities, the site must have its own, current FWA.

(3) If UA Little Rock is the prime awardee of the federal grant or coordinating center for the research study, then the institution must ensure that all of its sub-awardees engaged in such research operate under an appropriate FWA for the protection of human participants.

(4) If a collaborating investigator is not acting as an employee of an FWA-holding institution, the collaborating investigator engaged in research activities will be required to enter into an individual investigator agreement (IIA).

B. For non-federally funded research studies:

(1) If a non-UA Little Rock site has its own FWA, an IAA or other written agreement is required between UA Little Rock and the other site.

(2) If a non-UA Little Rock site does not have an FWA, or the collaborating investigator is not acting as an employee of an FWA-holding institution, the UA Little Rock study team must obtain a letter from the appropriate official from that organization documenting that the organization is award of and supports their employees' engagement in human participants research.

3.5 Conditions for when sIRB requirements may not be appropriate

A. The research involves an awardee or performance site outside of the United States.

B. The research requires more than single IRB review by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

C. The [Federal] department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

3.6 Exempt Research

In the case of exempt human participants research, regardless of funding source, the UA Little Rock IRB may act as the Reviewing IRB for a non-UA Little Rock research site or cede review of a project to another institution's IRB.

3.7 IRB Review

A. The UA Little Rock IRB Chair, along with IRB member(s), will review the submission and are authorized to accept external IRB approval.

See Appendix B for Revision History

RPP Policy 3.13	3.13 Research Records Retention and Security	Updated 2022 May 15

1. Purpose

To describe the requirements for retention and security of research records.

2. Policy

It is the IRB's policy that the research record maintained by the IRB and PI must:

- Contain an accurate and complete account of the conduct of the study;
- Be maintained and stored securely; and
- Be retained for the required amount of time following completion of the research in accordance with HHS regulations 45 CFR §46.115(b), and sponsor requirements as applicable or as specified by the IRB.

2.1 Research Records Kept by the IRB

The research record must include, but is not limited to:

A. Initial proposal:

(1) Complete Request for Review protocols

(2) Grant (if applicable and appropriate)

(3) Consent and assent forms (if applicable and appropriate)

(4) Case report forms (if applicable)

B. Requests for change to the protocol and/or consent (and when appropriate, assent) forms

C. Requests for continuing review and corresponding documents

D. Reports of AEs and unanticipated problems involving risk to the participant or others

E. Single participant protocol deviation and retrospective protocol by the violation reports

F. Issues of noncompliance

G. IRB-PI correspondence

H. If a protocol is cancelled without participant enrollment, IRB records and support documents are retained for at least 3 years after cancellation.

2.2 Research Records Kept by the PI

A. The PI also will maintain copies of sponsor contracts and correspondence (if applicable) and participant files that should contain:

(1) Signed consent documents,

(2) Laboratory results, and

(3) Other applicable information.

B. The PI (and faculty advisor when appropriate) must retain all elements listed above for a period, in accordance with HHS, which is currently a minimum of 3 years beyond the life of the study.

C. If the investigator resigns from UA Little Rock before the end of the designated period, the department of record must maintain the research records unless otherwise specified. The investigator, however, may have a copy of the research records in accordance with applicable UA Little Rock records policies.

D. For student research, the faculty advisor must retain a copy of the research records, as defined above.

2.3 Security of Research Records

A. All research records and databases must be maintained and stored securely, in a manner that protects participants' privacy and confidentiality by preventing unauthorized access (e.g., locked file cabinets and offices; fax machines placed away from high traffic areas and use of study participant identifiers known only to research staff).

B. Storage must comply with UA Little Rock policies and procedures pertaining to information security.

C. Records must be accessible for inspection and copying by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner.

See Appendix B for Revision History

RPP Policy 3.14	3.14 Appeals of IRB Reviews and Decisions	Updated 2022 May 15

1. Purpose

To describe the procedure a PI may take to express disagreement with IRB decisions.

2. Policy

It is the IRB's policy that PIs have the right to disagree with IRB decisions and seek resolution.

2.1 IRB Decision and Appeals

Results of an IRB review will be conveyed to the PI by the IRB Administrator through written correspondence. Individual IRB members should not discuss the results of the IRB review with the PI unless requested to do so by the IRB Chair or the Full Board.

A. If a PI disagrees with the IRB's written decision, the PI is encouraged to contact the IRB Administrator and/or IRB Chair and provide a written response detailing justification for the disagreement.

B. If the disagreement is related to a substantive human protection issue and the protocol was reviewed by the IRB, the protocol will be referred back to the IRB.

C. An appeal of a disapproval of research project must be reviewed at a full board meeting.

D. If the disagreement does not represent a substantive human protection issue, the IRB Chair will seek a resolution.

E. If resolution of the disagreement requires direct interaction with the PI, the PI may be invited to attend a portion of the IRB meeting to address IRB concerns

F. While the IO may provide input and make recommendations to the investigator and IRB for expeditious resolution of the matter, final determinations for approval/disapproval remain under the purview of the IRB. Because the IO is responsible for policies and procedures followed by the IRB, the IO may review IRB decisions to ensure that the decision-making process is appropriate. If the IO has concerns regarding the process that the IRB has followed in making a decision, the IO may

request that the IRB reconsider the decision. However, the IO cannot overrule an IRB decision.

2.2 Conflict of Interest

Any PI who believes there is a conflict of interest on the part of any IRB member relative to his/her protocol is encouraged to contact the IRB Chair and/or the Institutional Official (IO). All necessary steps will be taken to address the issue in a timely manner.

2.3 IRB of record

The IRB at UA Little Rock is the only IRB of record for all UA Little Rock faculty, staff and students. No other IRB may serve in lieu of the IRB at UA Little Rock, unless a memorandum of understanding (MOU) or reliance agreement has been extended by the IRB at UA Little Rock to the other IRB.

See Appendix B for Revision History

RPP Policy 3.15	3.15 Compensation for Research Participants	Updated 2022 May 15

1. Purpose

To describe any form of compensation for research participants.

2. Policy

It is the IRB's policy that compensation for research participants may be acceptable if:

- The possibility of coercion or undue influence is minimized, and
- The compensation is considered a recruitment incentive, not a benefit, in accordance with HHS regulations 45 CFR §46.116.

The type of participant payments and/or incentives may include, but are not limited to, extra credit, cash, gift cards, items (e.g., books, pens, t-shirts), etc. The type and amount of payment and/or incentive is considered on a case-by-case basis in relation to the participant population, reimbursement for out-of-pocket expenses, payment for time and burdens, and recruitment incentives.

2.1 Requirements

A. Compensation for participation is not an obligation of the researcher toward the participant. Compensation may be offered but is not required.

B. Generally, participation in research should not require financial sacrifice but should be revenue-neutral for participants.

C. Compensation should not be used as a "benefit" to offset risks (either quantitative or qualitative) associated with the research.

D. Generally, compensation should be based upon the premise that participation in research requires time and effort from the participant. Compensation, when offered, should be based on a reasonable consideration of the duration of time spent in preparation for, participation in, and recovery from research interventions in addition to the effort expended during the research activities.

(1) Interventions are understood to include such elements as procedures performed, visits to a clinic or research setting, phone interviews, or surveys

completed. If appropriate, such compensation should include all parties involved. For example, if a family member is required to be present to drive a research participant home after a procedure, that person's time can be compensated.

E. In order to minimize the risk that cumulative compensation for prolonged participation could create, the compensation plan should be described clearly in the consent form, including the portion of compensation that will be received at each study milestone, as well as the total amount to be paid. Justification for the specific compensation plan needs to be provided and comply with the enumerated principles.

(1) Credit for payment is to accrue as the study progresses and not be contingent only upon the participant completing the study. Any amount paid as a bonus for completion should be reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.

F. The UA Little Rock IRB does not allow payment in exchange for referrals of prospective participants (finder's fees), nor does it allow payments to the organization or research staff designed to accelerate recruitment that were tied to the rate or timing of enrollment (bonus payment).

2.2 Use of Lottery

A. Due to the concerns relating to fairness and the potential for coercion and undue influence, the IRB will review carefully the use of a lottery or raffle as a mechanism for participant compensation. The IRB will consider such plans for participant compensation on a case-by-case basis with appropriate justification provided by the PI.

B. Under certain conditions, a lottery or raffle can be used as a recruitment incentive. In these cases, lotteries/raffles are not participant compensation as such. The justification for the use of a lottery or raffle as a recruitment incentive is required to be provided by the PI.

C. If a lottery or drawing is used, the following items must be described in the protocol and informed consent document(s):

(1) Description of the odds of "winning". The odds of winning as stated to the participant must remain at least as good as what the researcher promised. For example, the researcher plans to recruit 25 participants and tells the participants that the odds of

winning are 1in 25. Thirty participants are recruited. The researcher now must offer two incentives so that the odds remain at least 1 in 25. The odds can improve, but they cannot become worse.

(2) Description of when and how the winners are notified.

(3) Description of the prize.

(4) Description of who is conducting the drawing and how the drawing is being completed to ensure an unbiased process is followed.

2.3 Other Inducements

A. Providing students extra class credit for participation in research may be included in a class syllabus. At that time the exact nature or scope of the tasks must be outlined and the matching compensation detailed.

(1) The amount of extra credit should be reasonable and is to be left to the discretion of the course instructor.

(2) Instructors should make reasonable efforts to avoid offering excessive or inappropriate financial or other inducements for research participation when such inducements are likely to coerce participation.

(3) All students should have equal opportunity to earn the extra credit offered for research. This may include offering assignments that are comparable in time and effort to participation in the research project.

(4) The nature of the tasks and the exact compensation must be included in the protocol for review.

(5) Confidentiality issues associated with receipt of the extra credit must be addressed and resolved in the research protocol and consent form.

B. Performance-based payment incentives may be partially dependent on the participant's performance in the study. For example, the payment total may accrue based on how many responses were correct in a memory recall game or a math assessment.

(1) When using performance-based payment incentives a base payment amount must be provided to all participants and described within the protocol and consent form.

(2) A range of possible payment totals must also be described within the protocol and consent form unless otherwise approved.

(3) Performance-based payment totals may differ between participants.

See Appendix B for Revision History

RPP Policy 3.16	3.16 Recruitment of Participants Through Advertisements	Updated 2022 May 15

1. Purpose

To describe the IRB requirements for recruitment of participants through advertisements.

2. Policy

It is the IRB's policy that, as a function of perceived risk to participants, all participant recruitment strategies, including printed newspaper advertisements, bulletins, flyers, multimedia, Internet and social media, radio, and television, will be reviewed and approved before they can be used to recruit potential participants.

2.1 Design of Advertisements

A. Advertisements should be limited to information a potential participant may need to determine if they are interested and eligible to participate in a study.

B. Advertisements should include the following:

(1) Purpose of the research;

(2) Eligibility criteria (in shortened form);

(3) Location of the research, contact person, and phone number for further information;

(4) Listing of realistic benefits to the participant;

(5) Time or other commitments required from the participant;

(6) If applicable incentives or compensation, which are intended to motivate participation, should be described, e.g. direct payment, lottery;

(7) A statement indicating that the project has been reviewed and approved by the IRB at UA Little Rock.

C. The following are *not* permitted to be included in advertisements:

(1) Statement or implication of a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol;

(2) Claims, either explicitly or implicitly, that the research procedures are safe or effective for the purposes under investigation; or

(3) Any exculpatory language.

D. Advertisements should use appropriate reading level, formatting, font size and bolding in order to ensure the prospective participants are not misled by having their attention inappropriately drawn to a particular section of the advertisement. If a website or social media is to be used to advertise for a research study, the website address or social media account must be identified to the IRB.

E. Copies of all advertisements, including radio and television scripts, must be submitted to the IRB for review and approval.

2.2 IRB review

The IRB review will include:

A. The information contained in the advertisements.

B. The mode of its communication.

(1) If social media tools are used to target specific participant characteristics (e.g. demographics, religion, keywords) they must be described

(2) If social media ads are used explain what happens when a potential participant clicks the ad, including identifying new websites when the ad link opens

C. The final test copy of printed advertisements.

D. The final audio/video taped advertisements.

The IRB ensures that advertisements do not emphasize the payment or the amount to be paid by such means as unduly large or bold type. A final copy of the recruiting advertisement must be sent to the IRB upon final printing or publication.

See Appendix B for Revision History

Section 4

Quality Improvement Assessment of the Institutional Review and Procedures

RPP Policy 4.01	4.01 Quality Improvement Assessment Program	Updated 2022 May 15

1. Purpose

To describe the Quality Improvement Assessment Program.

2. Policy

It is the IRB's policy that the Quality Improvement Assessment Program will be conducted to measure, improve, and maintain the effectiveness, quality, and compliance of research activities conducted by UA Little Rock, faculty, staff, and students.

2.1 Quality Improvement Assessment Program

A. The IRB Quality Improvement Assessment Program has been developed to reflect the vision, purpose, and mission of the Institution and the RPP.

B. The Quality Improvement Assessment Program is designed to be proactive, non-punitive, and focused on education of Board members, investigators, staff, and students about ethical and regulatory responsibilities in the conduct of human participant research. The focus of the program will encompass the IRB review system, IRB documentation, and policies and procedures.

2.2 Quality Improvement Assessment Program Objectives

A. Periodically the IRB Chair will meet with the IO (or IO designate) to review questions, concerns, and suggestions emanating from investigators with the purpose of assessing and improving the RPP. Additionally, Quality Improvement Assessment Program Objectives will be to:

(1) Evaluate the IRB protocol review process.

(2) Identify the educational and training needs of the research community and determine the best methods for meeting those needs through:

(a) Individualized training to meet the specialized needs of specific PIs and their research personnel, and

(b) General education programs designed for the UA Little Rock research community.

2.3 Study Selection Criteria

A. The criteria for selecting the studies to be assessed must reflect the full range of the research reviewed by the IRB. The criteria include specific categories of research, including:

(1) Research with a student PI;

(2) Research with a faculty PI;

(3) Federal grant funded research;

(4) Research involving vulnerable populations (e.g., pregnant women, children, individuals who are decisionally impaired, and prisoners);

B. Selected studies must be currently IRB-approved

C. Some studies may be selected for assessment based on recommendations by the IRB Administrator, Chair, or IRB members. The recommendations may be based on:

(1) Issues related to non-compliance;

(2) Problems with continuing review, informed consent, or other IRB review;

(3) Monitoring reports issued by outside agencies (sponsors, OHRP, or others) that revealed problems areas; or

(4) Other non-specified issues.

2.4 Review of IRB Records

Once a research protocol has been chosen for Quality Improvement Assessment, the ORC staff will carefully review the entire IRB file in advance. Specifically, the following questions must be addressed:

A. Does the IRB file contain all the records required by HHS 45 CFR §46.115 in sufficient detail to demonstrate compliance and performance of a substantive review(s)? The file must contain:

(1) IRB application (original version and IRB-approved version);

(2) Detailed protocol (if applicable);

(3) Informed consent/assent documents (if applicable);

(4) Participant recruitment advertisements (e.g., newspapers, radio, television, posters, and letters) (if applicable);

(5) AE or unanticipated problem(s) reports (if applicable);

(6) Requests for Continuing Review (if applicable);

(7) Requests for Change in the Protocol and/or Consent/Assent (if applicable);

(8) Noncompliance Investigations (if applicable);

(9) Previous Quality Improvement Assessment records (if applicable); and

(10) All correspondence between the IRB and the PI (if applicable).

B. Are the IRB minutes pertaining to the protocol(s) in question sufficiently detailed per HHS 45 CFR §46.115(a)(2), if applicable?

(1) For example, the IRB meeting attendance is recorded; the vote on the protocol is recorded (number for, against, and abstaining); and nonparticipation of IRB members with a conflict of interest is documented. The basis for the Board's action(s) is recorded, where appropriate. Additional protections for vulnerable participants are documented in accordance with HHS 45 CFR §46 (C) and (D). There is a reasonable detailed summary of the IRB's discussion of any controversial issues and their resolution.

C. Is the consent document approved by the IRB in compliance with HHS 45 CFR? §46.116?

D. Were the IRB's initial review and subsequent reviews (e.g., amendments and AEs) and the IRB office's handling of the review timely and efficient?

E. Did the IRB review capture the majority of changes needed in the protocol, especially any related to risk or informed consent?

F. Was continuing review substantive? Was the continuing review conducted within the IRB approval period per HHS 45 CFR §46.109(e)?

G. Were AEs or other unanticipated problems involving risk to the participant or others promptly reported to the IRB and, if required, the OHRP per the requirements of HHS 45 CFR §46.108(a)(4)?

H. Was termination of approval or suspension of research as a result of serious or continuing noncompliance promptly reported to the investigator, appropriate institutional officials, and if applicable to the granting agency or department head or OHRP per 45 CFR §46.108(a)(4)?

2.5 Quality Improvement Assessment Report and Follow-Up

A. After the Quality Improvement Assessment is complete and all findings are analyzed and reviewed by the board, a written report will be developed. Each report will refer to the findings of the preceding report as appropriate.

B. Future Actions

The written report will be used as a planning document for changes and resources.

See Appendix B for Revision History

Section 5

General Requirements and Guidelines

RPP Policy 5.01	5.01 Students and Post Docs as Researchers	Updated 2022 May 15

1. Purpose

To describe requirements for research conducted by students and post docs.

2. Policy

It is the IRB's policy that research conducted by students and postdocs will adhere to the regulations set forth in HHS 45 CFR §46 and the ethical standards contained in the *Belmont Report* and will comply with all the policies and procedures of the UA Little Rock IRB. For the purpose of this policy students include both the undergraduate and graduate levels.

3. Research Responsibility

All student and post doc research is the responsibility of the supervising faculty. It is the responsibility of faculty advisors to assist students and post docs in preparing review materials for the IRB and to ensure that the research is conducted in accordance with UA Little Rock's agreement with the federal government and with applicable UA Little Rock policy.

4. Students and post docs as researchers in projects that require IRB approval:

4.1 Independent Research

Any research conducted by students or post docs which uses human beings as participants and which is a systematic investigation designed to develop or contribute to generalizable knowledge must be reviewed and approved by the IRB. This includes, but is not limited to, all independent undergraduate research projects and honors theses, masters' theses and dissertations that involve human participants research.

A. Approval must be obtained before recruitment of participants or data collection commences.

4.2 External Data Collection

When data is to be collected outside of the UA Little Rock community, student researchers and post docs must obtain a letter from the appropriate authority (i.e., owner, manager, supervisor, website administrator etc.) granting them permission to collect data.

A. The letter of permission to collect data at the site must be attached to the protocol.

B. In the event that no appropriate authority can be identified, the student is to consult the instructor.

4.3 Prisoner Participants

Research with participants who are prisoners must be submitted for Full Board review (See RPP 7.*01 Research Involving Prisoners*).

4.4 Vulnerable Populations

Research with participants who are members of a vulnerable population may require submission for Full Board review (See RPP 7.01 *Additional Protections for Vulnerable Populations*).

4.5 Project Dissemination Off-Campus

Students and post docs with projects that may be disseminated off campus, on the web or publicly shared must submit a protocol to IRB for review.

4.6 Ethics Training

Student researchers, post docs, co-investigator(s), and faculty advisor are required to complete research ethics education (Group 1 CITI and RCR) and submit certificates of completion with the application.

5. Students and post docs as researchers in projects that may not require IRB approval

5.1 Educational Data Analyses

Class projects involving secondary data analyses that are assigned and conducted as educational exercises may not require IRB approval.

5.2 Educational Research Methods

Students and post docs engaged in activities in courses with the limited objective of teaching research methods and skills may not need IRB approval.

5.3 CITI Training Exemption

Students and post docs participating in classroom projects that do not require IRB review are not required to complete CITI training.

A. However, colleges, departments, and instructors are encouraged to require all students enrolled in Research Methods classes (or research method-type) to complete CITI training.

5.4 Educational Project Presentations

Projects that were developed for educational purposes may be presented on campus, physically or online (as long as the platform is restricted to the UA Little Rock faculty, students, and post docs) with the following statement prominently displayed: *The project is not defined as research per federal guidelines because it was conducted to meet the educational requirements of (insert class title here) under the supervision of (insert name of instructor.) It was not reviewed by the UA Little Rock IRB.*

5.5 Project Dissemination Off-Campus

Projects that were developed for educational purposes, without IRB approval, may not be disseminated off-campus, in any medium.

5.6 Non-Research Projects

Class projects or practica that involve direct interaction (e.g., in person, via mail, email, web surveys, or telephone) but where the purpose is training or an educational exercise or professional development and do not meet the criteria for research and may not require IRB approval. Such projects should not put the participants at more than minimal risk, and the data must be recorded so that it maintains the participant's confidentiality (e.g. with no names, social security numbers, or any other codes that can be linked to a list of names).

A. Neither approval nor determination of human research status is required, but may be requested, if instructor or students or post docs are unsure or if documentation is required by gatekeepers (e.g., schools, businesses) for access to participants.

B. Class instructors are responsible for providing the necessary training in protecting the privacy of individuals and confidentiality of any resulting information, along with training in the relevant professional ethics.

(1) The instructor should provide information about the assignment for the students or post docs to distribute to people who participate in these class projects. The information should list the instructor as the appropriate contact person should questions arise.

6. Class Instructor Responsibility when IRB Approval is Not Necessary

6.1 General

A. Class instructors are responsible for discussing the guidelines and ethics for the protection of research participants with their students and post docs and incorporating these into their methodology. Particular emphasis should be placed on:

(1) Developing an awareness of the types of risk participants may be exposed to in various types of research projects, i.e., psychological, social, physical, economic, and legal;

(2) Obtaining voluntary informed consent to participate in a way that honestly informs participants of the purpose and potential risks and benefits of the research;

(3) Protecting privacy and confidentiality of the participants.

See Appendix B for Revision History

RPP Policy 5.02	5.02 Epidemiological Research Guidelines	Updated 2022 May 15

1. Purpose

To describe the guidelines required when conducting epidemiological research.

2. Policy

It is the IRB's policy that all epidemiological research will be performed in accordance with the regulations set forth in HHS 45 CFR §46.

2.1 Introduction

A. Epidemiological research is defined as the collection and analysis of the patterns, causes and effects of health and disease conditions in defined populations.

B. Some epidemiological research requires access to many sources of Protected Health Information (e.g., medical records, databases, disease registries, and hospital discharge records). As a result, the greatest risk associated with this research is breach of confidentiality and privacy. While the HIPAA Privacy Rule is not intended to obstruct epidemiological research, the investigator must understand and follow specific rules in order to meet the HIPAA Privacy Rule regulations as well as minimize the risks.

2.2 Development of the Protocol

A. During the development of an epidemiological research protocol, the investigator must consider several questions and be prepared to justify the responses in the IRB protocol submitted for review. Consideration of these questions will aid the investigator in meeting the requirements of the HIPAA Privacy Rule, HHS regulations 45 CFR §46, and all applicable IRB requirements:

(1) What is the purpose of the research and what data is required to achieve the purpose of the research?

(2) Will retrospective (already existing) or prospective (collected in the future) data be used in the study?

(3) Where will the data come from (e.g., medical record review, databases, registries, or clinical interaction with participants)?

(4) Will the research involve banking of data for future use or for purposes that are not integral to the current research?

(5) Does, or will, the collected data contain Protected Health Information or other information that can be directly, or indirectly, linked to a participant? If yes, why will the link to a participant be required, and how long will the identifiers be retained?

(6) Does the investigator have ethical access to the data (e.g., through a treatment relationship with potential participants or through control of an extant database)?

(7) Does the research have the potential to collect data on the participant (e.g., proband--the family member through whom a family's medical history comes to light) and other related individuals (e.g., family members) identified by the participant or through other means (e.g., surveys and questionnaires)?

(8) Do data security measures conform to current state of the art practices?

2.3 Protected Health Information

A. Identifiers

The HIPAA Privacy Rule states that only the *minimum Protected Health Information necessary to achieve the research objective* can be used. Where it has been determined that participant identifiers are crucial to the research, the investigator must list the identifiers to be used and provide justification for their use (see RPP Policy 9.01 *Definition and Description of Protected Health Information Identifiers* for a list of the identifiers.)

B. Limited Data Set

(1) In cases where the investigator provides justification for a need to maintain participant links to the data, the use of a Limited Data Set should be considered (see RPP Policy 9.02 *Limited or Public Data Sets* for further information.)

(2) The investigator who is using the Limited Data Set *cannot* maintain the linked code. At UA Little Rock, the ORC will normally maintain such codes. To obtain a Limited Data Set, the investigator must complete a UA Little Rock Data Use Agreement (DUA). This will identify the investigator as the recipient of the Limited Data Set, how the data may be used and

disclosed by the investigator, and assurances that the data will be protected.

(3) During consideration of the application, the IRB will determine if the use of the Limited Data Set meets the HIPAA and HHS requirements for waiver of informed consent.

C. De-Identified Data Set

(1) If the data has been de-identified, the IRB will consider one of two review options:

(a) The IRB may determine that this qualifies for exemption under Health and Human Services regulations at 45 CFR §46.101(b).

(b) The research is not considered human participant research; therefore, it is not subject to Health and Human Services regulations at 45 CFR §46.

2.4 Informed Consent

A. Informed consent must be obtained from the participants, unless the IRB approves a waiver or alteration.

2.5 Waiver or Alterations of Informed Consent

A. While protection of patient privacy and confidentiality is the primary goal of HIPAA regulations, it is understood that situations may arise where obtaining informed consent may be impractical (e.g., research conducted on existing databases or repositories where no contact information is available). In these cases, HIPAA and HHS regulations have provided for IRB waiver or alteration of informed consent, if approved by the Full Board.

B. The following criteria must be met:

(1) The use or disclosure of Protected Health Information involves no more than minimal risk;

(2) An adequate plan to protect participant identifiers from improper use and disclosure must be presented to the IRB (e.g., data is coded or linked and the codes are stored separately);

(3) An adequate plan to destroy participant identifiers at the earliest opportunity must be presented to the IRB (unless there is a health research justification for retaining the identifiers or required by law); and

(4) Using the "reasonable person standard," the alteration of the waiver of informed consent will not

adversely affect the rights and welfare of the individuals.

C. The research cannot practicably be conducted without the waiver or alteration of informed consent and without provided justification.

D. The research cannot be conducted without access to and use of the Protected Health Information. The objectives and validity of the study must provide justification for the use of specific Protected Health Information.

E. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

2.6 Participant Recruitment

A. All participant recruitment activities must be approved by the IRB).

B. IRB approval of the recruitment plan is particularly important in situations where the investigator requests that a participant identify family members (or other applicable individuals) that might qualify for the study. It is important to note that the investigator has ethical access only to the enrolled participant, not those individuals identified by the participant. The investigator, or specialist, may not directly contact the family members (or others) without permission of those individuals.

C. The IRB recommends where possible the following recruitment plan be utilized:

(1) The participant may be asked if they have family members that might qualify for the study. Rather than request the names and contact information, the investigator should ask the participant to speak with family members about the project. The participant may be provided an IRB-approved informational brochure or letter to give to the family member. The brochure/letter should provide information on who to contact for further information. Contact would be initiated by individuals expressing an interest in the study.

2.7 Research Involving the Development of a Database

There are two separate activities to consider in the development of a database. Each is considered a separate research activity under the HIPAA regulations and will require IRB-approved informed consent (authorization), unless the IRB grants a waiver or alteration to the informed consent requirement:

A. Creation of a Research Database or Repository

The use or disclosure of Protected Health Information for creating a research database or repository.

(1) During consideration of an IRB application to create a research database or repository, the IRB must consider:

(a) Will the database maintain Protected Health Information? If yes, what is the investigator's justification?

(b) Will informed consent (authorization) be required, or does the database meet the qualifications for waiver or alteration of informed consent? In most cases, if the database involves collection of data through direct intervention or interaction with the participant, the IRB will require informed consent.

(c) Has the investigator provided sufficient assurance that the Protected Health Information in the database will not be used or disclosed for future research without IRB approval prior to use?

B. Future Research Using a Database

The use or disclosure of Protected Health Information in the database for a future research purpose.

(1) Creation of a database for the purposes of research *does not* mean the database can be used for any future research without specific IRB approval of the proposed study. Therefore, use of a database for research not specifically approved by the IRB requires submission of an application and approval by the IRB prior to use for future research. At that time, informed consent requirements will be based on the Protected Health Information present in the database, prior informed consent of the subject to authorize the placement of Protected Health Information in the database, the purpose of the research, and prior IRB waiver or alteration of informed consent.

See Appendix B for Revision History

RPP Policy 5.03	5.03 Exercise Protocol Guidelines	Updated 2022 May 15

1. Purpose

To describe the guidelines required when conducting studies that include exercise.

2. Policy

It is the IRB's policy that all exercise studies will be conducted in accordance with HHS regulations 45 CFR §46.

2.1 Introduction

A. While investigators and IRB members agree that exercise testing does involve risk, there is very little data about the actual level or incidence of the risk and whether those risks can be fully prevented by any level of protection procedures. Bright-line rules regarding appropriate screening procedures and required safeguards for all exercise-related research are impossible to identify. As such, protocols involving exercise testing are assessed individually to determine appropriate requirements on a case-by-case basis, taking into consideration study participants, procedures, and possible risks.

B. Minimum expectations for exercise-related research are described below; however, the IRB may request additional requirements.

3. Health Screening

A. In general, risks of participation in exercise testing are caused by the presence of known or unknown cardiovascular, pulmonary, or metabolic diseases. As such, investigators conducting research involving exercise testing must conduct screening procedures to identify the presence, signs, symptoms, and/or risk factors of such diseases in potential participants.

B. Participants who screen positively for the presence, signs, symptoms, and/or risk factors of cardiovascular, pulmonary, or metabolic diseases will be considered and referred to as higher risk participants, and appropriate safeguards must be conducted to avoid occurrence of adverse events and other risks.

C. Screening procedures must include the following, at a minimum, for all participants:

(1) a questionnaire designed to discover the participants health history and identify known symptoms and risk factors for cardiovascular, pulmonary, or metabolic disease

(2) pulse measurement to assist in determining whether or not an unknown symptom or risk factor exists

(3) at least one blood pressure measurement to assist in determining whether or not an unknown symptom or risk factor exists

D. The IRB application should include the following information regarding screening:

(1) list of proposed screening procedures

(2) justification if the screening process does not include the above minimum procedures

(3) whether participants will be enrolled if the screening process determines them to be higher risk

(4) if the study is designed to test higher-risk participants, an assessment of risk factors or diseases which make the population higher risk

4. Safeguards During Exercise Intervention

A. It is the responsibility of the investigator to propose an appropriate plan for safeguarding participants during the exercise intervention, given the proposed procedures and subject population. Some research involving higher risk participants may require that the study team have access to physician supervision or other medical expertise during exercise intervention. In those situations, utilization of a local emergency response team (e.g., 911) may be appropriate, while other studies may necessitate a specified physician to be present onsite.

5. Information for IRB Protocol

A. In order for the IRB to assess whether the proposed plan is appropriate, the investigator should include the following information in the IRB protocol:

(1) whether higher risk participants will be enrolled and, if so, an assessment of the risk

(2) whether the investigators conducting the exercise intervention have been trained in CPR or other first aid, and, if so, the training received

(3) access to medical emergency equipment, if any, during the exercise intervention

(4) assessment of the local emergency response units and whether use of these units during an adverse event is appropriate

6. Identifying minimal risk vs greater than minimal risk research

A. Unless additional concerns are raised, the IRB may utilize the following guidance when determining whether exercise-related research should be considered minimal risk or greater than minimal risk. When making this determination, the IRB should consider the characteristics of potential participants and the intensity of the proposed exercise intervention. For example, walking the length of a standard hallway would be considered minimal risk for most healthy participants, but may be greater than minimal risk for elderly participants or those recovering from knee surgery.

B. Minimal risk means that the probability or magnitude of harm or discomfort anticipated in the research is not greater in and of itself than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (as defined by 45 CFR §46.102(j)).

C. The following research should be considered minimal risk:

(1) sub-maximal exercise (as defined in the protocol) testing in healthy, asymptomatic participants, (not higher risk).

(2) research involving maximal and sub-maximal exercise (as defined in the protocol) testing in athletes.

(3) research involving muscle stimulation; however, the IRB will need to make this determination on a case- by-case basis, considering the specific muscle group(s) to be stimulated and the method used to stimulate.

D. The following research should be considered greater than minimal risk:

(1) maximal exercise testing in non-athletes.

(2) research that is intended to cause fatigue, exhaustion, or muscle soreness beyond that which would normally be experienced by the proposed participants.

See Appendix B for Revision History

RPP Policy 5.04	5.04 Research Conducted in Foreign Countries	Updated 2024 May 23

1. Purpose

To describe the guidelines for research conducted in foreign countries.

1.1 Role of PI

A. The Principal Investigator (PI) is a faculty member, staff, student, or other representative of the UA Little Rock, and the research is conducted at the international site by the PI.

B. The PI is a faculty member, staff, student, or other representative of UA Little Rock and the research is conducted under the direction of the PI by external investigators unaffiliated with the Institution.

2. Policy

It is the IRB's policy that all research in foreign countries will be conducted in accordance with HHS regulations 45 CFR §46. The IRB will review all human participants research being conducted in foreign countries regardless of the foreign institution's IRB or Ethics Committee approval system.

2.1 Non-Federally Funded Research

A. Non-federally funded research that is conducted in a foreign country is subject to all of the IRB requirements, except that IRB requirements can be waived in consideration of the culture and local customs of the country in which the research is conducted. Investigators who seek a waiver of *any* IRB requirements must provide appropriate justification to the IRB.

(1) Any justifications for waivers of IRB requirements based on claims of local practices or customs will be independently verified with the foreign institution and/or appropriate governmental agency, or consultant when applicable.

2.2 Federally Funded Research

A. Federally funded research which is conducted in a foreign country is subject to all of the IRB requirements with exceptions granted in accordance with the federal (model) policy and OHRP guidance.

B. According to the model policy for the protection of human participants and OHRP requirements, when federally funded

research takes place in foreign countries, a FWA must be filed by the institution in that country. However, procedures normally followed in the foreign countries to protect human participants may differ from those set forth in the model policy. In these circumstances, a department or agency head must determine that the procedures prescribed by the foreign institution afford protections that are at least equivalent to those provided in the model policy. If the procedures meet these criteria, a department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in the model policy.

2.3 IRB Requirements

A. The PI must ascertain and uphold local laws and customs as long as they do not contradict other sections of this policy (RPP 5.04). This is documented in the approved protocol.

B. Researchers should also be aware that local definition for a minor or of what constitutes a sensitive topic may differ.

C. If the PI is not fluent with the foreign country's language, any documents employed in the course of the research must be translated into English and back to the foreign language by an expert third party who is fluent in both languages (English and the foreign language).

D. The PI assumes overall responsibility for the safe and proper conduct of the research in full compliance with all applicable U.S. regulations, country specific laws/regulations, local IRB requirements, and UA Little Rock RPP Policies.

E. The PI must adhere to UA Little Rock export control policies and describe how data will be transported back to the United States (if applicable).

F. The PI must complete the relevant CITI module: "Additional Modules of Interest: International Studies."

2.4 Research Involving Collaboration with an International Institution

The international institution must provide assurance to the IRB that all of its activities related to human participant research, regardless of funding source, will be guided by the ethical principles in one of the following documents:

A. The *Declaration of Helsinki* (as adopted in 1996 or 2000, or most current version);

B. The *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Participants of Research of the*

U.S. National Commission for the Protection of Human Participants of Biomedical and Behavioral Research;

C. Other appropriate international ethical standards recognized by federal departments and agencies that have adopted the US Federal Policy for the Protection of Human Participants. A copy of these standards must be provided by the institution.

D. In addition, the IRB requires all the documents submitted to the foreign site, and confirmation of IRB approval (or equivalent) from the foreign site, a copy of the protocol, and a copy of the informed consent document.

(1) If there is no local IRB authorized to review protocols, UA Little Rock IRB will serve as the IRB of record.

2.5 Non-exempt Research

When non-exempt research is conducted at an international site by UA Little Rock's faculty, staff, students, or other representative of UA Little Rock, the following apply:

A. Review and approval of the research will be required by both the (1) UA Little Rock IRB, and (2) any local IRB at the international site which has review and oversight jurisdiction over the research, where applicable.

B. Protections of human participants at the international site must be at least equivalent to 45 CFR §46 Subparts B and D as applicable.

C. International research involving prisoners may only be permitted if the following can be documented:

(1) There must be clear and overwhelming evidence that the research meets all criteria for IRB approval of research (see RPP Policy 3.04 *Criteria for IRB Approval of Research*),

(2) There must be clear and overwhelming evidence that the research meets the criteria for IRB approval of research under Subpart C within 45 CFR §46 (See RPP Policy 7.03 *Research Involving Prisoners*).

(3) Institutional Official approval.

2.6 Additional IRB review elements

The IRB will consider the following items when reviewing international research.

A. The qualifications of the PI and research personnel to conduct research in the specific country.

B. The consent process and consent documents are appropriate for the languages of the participant and communication with the participant population.

C. Arrangements are made to communicate with the participants throughout the research.

D. Verification that the PI has in place a process handling:

(1) Modifications to the research

The IRB and investigators should consider as many contingencies as possible when research is reviewed and approved.

E. Complaints, noncompliance, protocol deviations, and unanticipated problems involving risk to participants or others.

F. Post-approval monitoring of the research.

G. IRB mechanisms for communicating with the PI and research personnel when they are conducting the research in other countries.

3. Verification of International Research Standards

The DHHS Office for Human Research Protection (OHRP) maintains the International Compilation of Human Research Protections. The Compilation lists the law, regulations, and guidelines for over 50 foreign countries.

This Compilation is maintained in electronic format, with direct web links to each country's regulatory organizations, laws, and other resources that establish local standards. OHRP provides this Compilation to assist researchers and IRBs in verifying that research studies are complying with local laws and customs.

The Compilation can be accessed on the OHRP website: http://www.hhs.gov/ohrp/international/index.html.

3.1 If legal information is not available via the OHRP Compilation, additional resources will be sought, for example from general counsel or a consultant when applicable.

See Appendix B for Revision History

RPP Policy 5.05	5.05 Use of Deception in Research	Updated 2022 May 15

1. Purpose

To describe requirements for research that includes deception or incomplete disclosure of information.

2. Definitions

2.1 Authorized Deception

To inform participants prior to the study that a study will not be described accurately or that some procedures will be deceptive, provides them an opportunity to decide whether or not to participate on these terms.

2.2 Deception

To intentionally provide misleading or false information.

NOTE: Examples of studies that involve deception might include having Participants complete a quiz and are falsely told that they did poorly, regardless of their performance, or having participants who don't know they are in a research study are observed to see how they behave when they find valuables (e.g., wallet, laptop) unattended in a public location.

2.3 Incomplete Disclosure

To withhold information about the true purpose or nature of the research.

NOTE: Examples of studies that involve incomplete disclosure might include having participants take a quiz for research but they are not told the research question involves how background noise affects their ability to concentrate, or having participants complete a survey to evaluate customer service when the true purpose of the study is to correlate psychological responses with patient care satisfaction.

3. Policy

The use of deception or incomplete disclosure of information in research with human participants may be allowed when it follows these general guidelines:

3.1 Use of deception and incomplete disclosure is usually only acceptable for studies that are minimal risk.

3.2 The use of deception/incomplete disclosure should have no adverse effects on the well-being of participants.

3.3 The IRB must be supplied with sufficient information to determine that the value of the research outweighs the risk of waiving some aspects of the requirement for full disclosure in the informed consent process. (See RPP 6.05 *Waiver of Informed Consent and Waiver of Documentation of Consent*)

3.4 There is no reasonable alternative to scientifically and effectively addressing the research question without the use of deception/incomplete disclosure.

3.5 Participants are not deceived about any aspect of the study that would alter their willingness to participate.

3.6 As soon as it is appropriate, debriefing should be accomplished and the deception/incomplete disclosure explained to participants.

3.7 When appropriate, participants should be informed prospectively of the use of deception/incomplete disclosure and consent to its use.

3.8 During debriefing inform participants of their right to withdraw their data, if they wish, and how that will be accomplished.

4. IRB Review and IRB Application Requirements

Research involving authorized deception may not require a waiver or alternation of consent elements. Research involving deception or incomplete disclosure of information must meet all criteria for IRB approval (See RPP Policy 3.04 *Criteria for IRB Approval of Research*) and all criteria for approval of a waiver of consent or alteration of consent elements (See RPP Policy 6.05 *Waiver or Alteration of Consent*).

4.1 Studies that use deception and/or the withholding of information as part of their experimental design must meet all the requirements of 45 CFR §46.116(f), described below, and include a post-study debriefing, unless an exception is granted by the IRB.

4.2 In the event that a study includes the use of deception, the investigator must:

A. Provide a justification for the deception (i.e., why the study could not be conducted without deception);

B. Describe the manner of deception (e.g., the participants are not informed of the true intent of the study) and/or how the deception will take place (e.g., a confederate will simulate an accident);

C. Note whether the deception results in any increased risk to participants (e.g., confederates engage in a staged altercation which could result in emotional upset);

D. Describe how any additional risks would be minimized (where appropriate);

E. Describe the method for debriefing. Debriefing should occur as soon as possible after the participants complete the research related activities. Address what steps the PI will take to make sure the participants have an accurate understanding of the deception or incomplete disclosure as well as the reasons for using this methodology;

F. If no debriefing is planned, provide justification.

5. Consent, Authorized Deception, Consent Documentation and Debriefing

Research involving deception or incomplete disclosure of information, by design, does not include all elements of the consent process or removes the consent process altogether. In order to ensure the basic principle of respect for persons found in the *Belmont Report* guidance for the ethical conduct of research using deception or incomplete disclosure research will or may as necessary, include the following, as applicable:

5.1 Authorized Deception

Research using this process *must* inform participants during the consent process that the study will not be described accurately or that some procedures will be deceptive.

5.2 Consent and Debriefing Documentation

Research using authorized deception or incomplete disclosure of information must document consent and debriefing using either a signature, e-signature, or other form of documentation recording that the consent process occurred if the research qualifies as exempt research unless the research qualifies for waiver of consent documentation (See RPP Policy 6.05 *Waiver or Alteration of Consent*).

5.3 Debriefing Process and IRB application requirements

Research using deception or incomplete disclosure must include a debriefing process at the end of the study, when appropriate. Debriefing may be inappropriate if debriefing regarding the deception may cause more harm than the deception itself. The following considerations must be included and described in the appropriate IRB application:

A. Participants should be debriefed as early as feasible. If an immediate debriefing may compromise study results, debriefing information can be sent when the study is completed via mail, email or by phone, or participants can be given a URL where they can get debriefing information and a date upon which it will be available.

B. When appropriate, the research may include an option for participants to withdraw their data from the study after they learn the true nature of the research, if it is of a particularly sensitive nature (e.g., the withheld aim of the study is that the researcher is measuring participants' racism).

C. If the research will not include a debriefing process, justification for not including this process must be described in the IRB application.

5.4 Participant Debriefing Information

If a debriefing process is appropriate for the research, the process may include the following information, as appropriate and serve the following purposes:

A. inform participants of the true goals of the research study,

B. remove any effects of false information they were given,

C. educate participants about the research process, why deception is sometimes necessary, how false beliefs can sometimes persevere, and

D. reiteration of the societal/scientific benefit of research

See Appendix B for Revision History

Section 6

Informed Consent

RPP Policy 6.01	6.01 Development of the Informed Consent or Assent Record	Updated 2022 May 15

1. Purpose

To describe development of the informed consent or assent document (hereinafter referred to as the "consent document(s)" in this policy). This includes the initial and on-going process of informed consent.

2. Policy

It is the IRB's policy that informed consent and assent records will be developed in accordance with regulations at HHS 45 CFR §46.116

2.1 Informed Consent

The prospective participant has sufficient knowledge and comprehension of the elements of informed consent (see RPP Policy 6.02 *Required Elements for Informed Consent*) prior to enrollment and during participation in research. This is accomplished through the initial and on-going process of informed consent.

2.2 IRB Responsibility

A. The IRB will require that information given to participants as part of informed consent is in accordance with HHS regulations 45 CFR §46.116.

B. The IRB may require that information, in addition to that required by regulations, be given to participants when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of participants in accordance with HHS 45 CFR §46.109(b). The IRB has authority to observe or have a third party observe the consent process and/or the conducting of research [45 CFR §46.109(g)]. Guidelines through the use of a template are available to assist all investigators in meeting requirements of federal regulations and IRB Policies (available through the UA Little Rock Research Compliance website).

2.3 Investigator Responsibilities

A. The investigator has a legal and ethical obligation to ensure that the prospective research participant has sufficient knowledge and comprehension of the elements of informed consent, meaning that the prospective research participant must be able to make an informed decision whether or not to participate in research. Obtaining informed consent

should be seen as a communication process of explanation and not as an act of signing a form. As part of the process of obtaining informed consent, PIs must ensure that each element of consent is explained carefully and simply to the prospective participant. Ultimately, the investigator bears full responsibility for obtaining valid informed consent from the participant.

B. Investigators should provide an opportunity, before the study begins, for participants to ask any questions they may have and have them answered.

C. Investigators should also be sensitive to participants' privacy during the consent process, as they discuss the study and answer questions.

D. Investigators should be sensitive to the participant's, interpreter's, or translator's needs when participants do not speak English as a first language or are hearing impaired.

E. A key information section which is concise and focused is required for all consent forms longer than 4 pages. A key information section may be required if the project is complex or involves numerous research procedures.

2.4 Identification of Type of Consent and Assent

A. Adult Consent

Utilized when enrolling competent adults (in Arkansas defined as individuals 18 years of age or older and individuals under 18 years of age who are legally emancipated or who are otherwise able to consent to the procedures involved in the research).

B. Proxy, Legally Authorized Representative, or Durable Power of Attorney Consent

Utilized when enrolling adults with decisional impairment. In addition to proxy, legally authorized representative, or durable power of attorney consent, assent of the adult who is decisionally impaired is also required.

C. Screening Consent

Used to obtain participant consent to allow study-related screening tests for potential enrollment in a study. Full study consent will follow.

D. Addendum Consent

Commonly used to obtain additional consent from participants for auxiliary studies (e.g., tissue banking). Also, may be used to inform currently enrolled participants of new information pertaining to the research.

E. Parent or Legal Guardian Consent

Utilized when enrolling children (in Arkansas defined as individuals under 18 years of age, except those who are legally emancipated or who are otherwise able to consent to the procedures involved in the research) in a research study. In addition to parent or legal guardian consent the following are required:

(1) *Adult Assent*: To be used when enrolling adults who are decisionally impaired

(2) *Youth Assent*: To be used for children aged 13 through 17 years.

(3) *Child Assent*: To be used for children aged 6 through 12 years.

F. Parent Notification

Can be utilized when documentation of parental consent either is not a requirement for approval or can be waived (ex. some research conducted in the classroom where all students are completing educational activities but have the option to opt out of the research, non-exempt research projects where documentation of parental consent can be waived, etc.). In order to utilize the parent notification process for non-exempt research, the research must meet all criteria for IRB approval (See RPP Policy 3.04 *Criteria for IRB Approval of Research*) and all criteria for approval of a waiver of parental consent or alteration of parental consent elements (See RPP Policy 6.05 *Waiver or Alteration of Consent*).

G. Screening Consent

Used to obtain participant consent to allow study-related screening tests for potential enrollment in a study. Full study consent will follow.

2.5 Identification of Study Personnel

A. PIs, Co-PIs and faculty advisors, if any, listed in the IRB application, must be identified in the informed consent document in accordance with HHS regulations 45 CFR §46.111(a)(4) and §46.116(a)(7).

B. A contact phone number and/or email for the PI and co-Investigator must be provided. If the PI is a student, an official phone number and/or email address of the supervising faculty must be included in the consent process.

(1) The IRB recommends that PIs do not include home or personal cell telephone numbers.

2.6 Parental, Legal Guardian, Proxy, Legally Authorized Representative, and Durable Power of Attorney Consent Documents

A. These consent records should reflect that it is the minor, or other vulnerable participant, who is the participant in the study. The individual giving consent (parent or legally authorized representative) is providing permission to allow the participant to participate in the study.

2.7 Adult, Youth, and Child Assent Documents

Assent documents should reflect the age, maturity and cognitive ability of the decisionally impaired adults, youth, and children that will be the research participants. (See RPP Policies 7.04 *Research Involving Children* and 7.05 *Research Involving Participants who are Decisionally Impaired*.)

2.8 Readability

A. The consent and assent information must be written or presented in language that it is readily understood by the least educated of the participants to be involved. Generally, the level of language of the adult consent should be around an eighth-grade standard. Youth and child assent should be provided in an age-appropriate style.

B. Medical and scientific terms should be avoided where possible. If PIs use medical jargon, the lay terms should be used first and then the medical term included in parentheses.

C. Appropriate units of measurement for the procedure should be used.

2.9 Exculpatory Language

The consent document or record must not contain any exculpatory language through which the participant or the participant's representative is made to waive, or appear to waive, any of the participant's legal rights. Additionally, the consent document or record must not release, or appear to release, the research investigator, the sponsor, UA Little Rock, or its agents from liability for negligence.

See Appendix B for Revision History

RPP Policy 6.02	6.02 Required Elements for Informed Consent	Updated 2022 May 15

1. Purpose

To describe the required elements for the informed consent process and its documentation.

2. Policy

It is the IRB's policy that the IRB will ensure that informed consent is documented in accordance with and to the extent required by HHS 45 CFR §46.116, and §46.117 unless consent and/or documentation is waived by the IRB.

2.1 Informed Consent Documents

The consent documents must be:

A. Appropriate to the research and participant population being studied;

B. Approved by the IRB and include the elements of informed consent required by HHS 45 CFR §46.116 and 117;

C. Signed by the participant or the participant's legally authorized representative [HHS 45 CFR §46.117(a)], unless the IRB has waived the requirement for signed informed consent; and

D. When the informed consent document is signed, a copy must be provided to the participant or legally authorized representative [HHS 45 CFR §46.117(a)].

2.2 Required Elements for Informed Consent Documents

The following are the required elements that must be present in all consent documents:

A. Informed consent will include the following elements:

(1) A statement that the study involves research [HHS 45 CFR §46.116(b)(1)];

(2) An explanation of the purposes of the research [HHS 45 CFR §46.116(b)(1)];

(3) The expected duration of the participant's participation in the research [45 CFR §46.116(b)(1)];

(4) A description of the procedures to be followed [HHS 45 CFR §46.116(b)(1)];

(5) Identification of any procedures which are experimental [HHS 45 CFR §46.116(b)(1)];

(6) A description of any reasonably foreseeable risks or discomforts to the participants [HHS 45 CFR §46.116(b)(2)];

(a) The agreement, written or oral, entered into by the participant, may not include language through which the participant is made to waive, or to appear to waive, any legal rights, or to release, or appear to release the investigator, the sponsor, UA Little Rock, or its agents from liability for negligence.

(7) A description of any benefits to the participant or to others which may reasonably be expected from the research [HHS 45 CFR §46.116(b)(3)];

(8) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant [HHS 45 CFR §46.116(b)(4)];

(9) A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained [HHS 45 CFR §46.116(b)(5)];

(a) Confidentiality, as defined in the 1993 Office for Protection in the Research Risks IRB Guidebook, "pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission."

(10) For research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs; whether any medical treatments are available if injury occurs; and, if so, what they consist of, or where further information can be obtained [HHS 45 CFR §46.116(b)(6)];

(11) Information regarding who to contact for answers to pertinent questions about the research [HHS 45 CFR §46.116(b)(7)].

(12) Information regarding who to contact in the event of a research-related injury to the participant [HHS 45 CFR §46.116(a)(7)];

(13) Information regarding whom to contact regarding participants' rights; for example, "Sometimes study participants have questions or concerns about their rights. If you have such questions, you should call Office of Research Compliance at the following phone number, email address etc.," [HHS 45 CFR §46.116(b)(7)]; and

(14) A statement that participation is voluntary and that refusal to participate involves no penalty or loss of benefits to which the participant is otherwise entitled. That the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. For example, "You are free to decide not to participate in this study. You can also withdraw at any time without harming your relationship with the researchers or the University of Arkansas at Little Rock or other agent." [HHS 45 CFR §46.116(b)(8)].

(15) One of the following statements when research involves the collection of identifiable private information or identifiable biospecimens:

(a) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimen and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative, if this might be a possibility;

OR

(b) A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

B. If appropriate to the research, indicate whether the informed consent process provides the following 9 additional elements of information [HHS45 CFR §46.116(c)]:

(1) A statement that the particular treatment or procedure may involve risks to the participant (or to

the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable.

(2) Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's or the legally authorized representative's consent.

(3) Any additional costs to the participants that may result from participation in the research.

(4) The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant (i.e., safety issues).

(5) A statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided to the participant.

(6) The approximate number of participants involved in the in the research at the institution and nationally.

(7) A statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit.

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions; and

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

(10) Checkboxes specifically denoting consent for optional or variable procedures.

C. The IRB may require additional information to that required by HHS 45 CFR §46 be provided to participants when, in its judgment, the information would meaningfully add to the protection of the rights and welfare of participants (HHS 45 CFR §109 (b)). Such information may be:

(1) Why the participant was selected;

(2) Where research will take place; or

(3) The age of participants (participants under 18-years-old require parental informed consent in Arkansas, except those who are legally emancipated or who are otherwise able to consent to the procedures involved in the research).

(4) If the project requires and/or is subject to a Certificate of Confidentiality (CoC), the participant must be informed about the Certificate and any limitations of the Certificate included when the Certificate cannot be used to refuse to disclose information.

(5) The IRB may require the consent process be monitored or observed when individuals with decisional impairments are involved.

(6) The IRB may require waiting periods prior to consenting.

(7) The IRB may require an advocate or ombudsman oversee the consent process for individuals with decisional impairments

(8) The IRB may require procedural changes or additional protections for individuals with decisional impairments.

(9) When individuals with decisional impairments are potential research participants, the IRB may require the investigator to use techniques that would confirm that individuals did understand the consent process.

2.3 Documentation of Consent Process

The consent process must be appropriately documented in accordance with HHS regulations 45 CFR §46.117. Subject to any waiver or alteration as referenced above, the informed consent of the participant must be gained by one of the following methods:

A. A written consent document that contains the required elements of informed consent. This form may be read to the participant or the participant's legally authorized representative. The researcher must give either the participant or the representative adequate opportunity to read it before it is signed and dated; or

B. A short, written consent document stating that the required elements of informed consent have been presented orally to the participant or the participant's legally authorized representative. This method requires a witness to the consent process and an IRB approved written summary of what is to be said to the participant or the representative.

The short form itself must be signed and dated by the participant or the representative. The witness must sign both the short form and a copy of the summary, and the person actually obtaining consent must sign a copy of the summary. A copy of the summary must be given to the participant or the representative, in addition to a copy of the short form.

C. A request to waive the use of a signed and dated consent form may only be approved by IRB if:

(1) The only record linking the participant and the research is the consent document and the principal risk is the potential harm resulting from a breach of confidentiality. Participants must be asked whether they want documentation linking them with the research, and the participant's wishes will govern; or

(2) The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

2.4 Screening, Recruiting or Determining Eligibility

The IRB may approve non-exempt research where consent need not be obtained for the purpose of screening, recruiting, or to determine participant eligibility where the investigator must collect identifiable private information or identifiable biospecimens. Either of the following criteria must be met for this exception to apply:

A. Information will be obtained through oral or written communication with the participant or legally authorized representative; or

B. Private identifiable information or identifiable biospecimens are accessed through [archival] records or stored biospecimens.

2.5 Observation of the Consent Process

A. The IRB has authority to observe or have a third party observe the consent process and/or the conduct of research [HSS 45 CFR §109 (g)]. The IRB may choose to observe the consent process where it determines that such observation will contribute meaningfully to the reduction of risk to the research participant. For example, the IRB may observe in situations with vulnerable populations where such observation of the consent might minimize coercion or undue influence or in situations involving non-compliance with the consent process.

B. If the IRB decides that the consent process should be observed, the investigator will be notified before such observation.

See Appendix B for Revision History

RPP Policy 6.03	6.03 Alternative Methods of the Consent Process	Updated 2022 May 15

1. Purpose

To describe the guidelines governing consent not obtained in person.

2. Policy

It is the IRB's policy that consent not obtained in person will be gained in accordance with HHS regulations 45 CFR §46.

2.1 Introduction

Whenever possible, consent should be obtained in person by an authorized investigator. However, the IRB recognizes that an alternative informed consent process may, at times, be necessary. Therefore, under extenuating circumstances, the IRB may approve an alternative informed consent process.

A. IRB approval of an alternative consent process for research requires a waiver of the requirement for written documentation of consent. In lieu of written consent documentation, consent will be acquired via another medium.

B. The consent process needs to include all required elements of the consent disclosure (see RPP Policy 6.02 *Required Elements for Informed Consent*), unless the IRB approves a waiver or alteration of the consent process.

2.2 IRB Requirements for Use of an Alternative Consent Process

A. The IRB will review the proposed method of consent based upon:

(1) The nature of the study,

(2) The risk level, and

(3) Participant population needs.

B. The proposed method of consent must be fully explained and justified in the IRB protocol.

2.3 Re-consent for Significant or Minor Changes or Disclosure of Additional Risks

The following describes IRB requirements for re-consent for significant changes or disclosure of significant additional risks and

re-consent for minor changes or disclosure of additional minor risks:

A. With appropriate scientific rationale and justification, the IRB may approve an alternative consent procedure to allow the participant to be notified of changes or new risks.

B. The IRB may determine what procedure and documentation are required to ensure the maximum protection to the participant.

C. Each element of the consent document, which has been changed, must be explained to the participant, and the participant's comprehension should be assessed as necessary. For example, an investigator may ask the participant to provide a summary of the new information. The participant must be given the opportunity to ask questions.

(1) In the case of significant changes or risks it may be necessary to extend the process over several days and include other individuals such as the participant's family members. The participant must be instructed in the signing of the consent form and must return the original signed document to the investigator by mail or electronically. Participants must be re-consented in the presence of the investigator when they return to research site for follow-up.

(2) In the case of minor changes or risks the participant must be instructed in the signing of the consent form and must return the original signed document to the investigator by mail or electronically.

D. In all cases, the alternative process of consent must be documented in the research record by indicating the reason for the alternative method used, date, time, and personnel involved in obtaining and documenting consent.

See Appendix B for Revision History

RPP Policy 6.04	6.04 Re-Consent/Assent of Research Participants	Updated 2022 May 15

1. Purpose

To describe the process of re-consent/assent of research participants.

2. Policy

It is the IRB's policy that the process of re-consent/assent of research participants will be conducted in accordance with HHS regulations 45 CFR §46.

2.1 Consent Duration

The initial consent process agreement with the participant at enrollment remains in effect for the duration of the participant's participation in the study or until the IRB approves a change in the consent process, which requires re-consent/assent of participants.

2.2 Continued Participation

Informed consent/assent, however, is an ongoing process, not simply the document signed by the participant during enrollment in the research. In order to validate the voluntary nature of participation in research and exhibit respect for the individual, PIs must provide participants with any new information that may affect their willingness to continue to participate in the research. HHS regulations 45 CFR §46.116(b) (5), therefore, require investigators to inform participants of any important new information that is germane to the participant's willingness to continue participating in the study.

2.3 Continuing Review

During the continuing review process, previously approved consent forms must be submitted for review.

A. The IRB does not require re-consent of previously enrolled participants, unless the IRB approves a request for change during the continuing review process or identifies new information which requires re-consent of the participants.

2.4 Changes in Information

Commonly, minor information (e.g., changes in personnel or administrative changes in the consent document) is provided to participants through verbal exchanges between the investigator and participant without undergoing a formal re-consent

procedure. Minor information is unlikely to affect a participant's willingness to continue participation in a study.

A. Significant new information which requires re-consent/assent of participants must be acquired through use of an IRB-approved, revised consent process. Significant new information may include:

(1) Changes in the duration of the study, or

(2) Major changes in the methods of the study.

See Appendix B for Revision History

RPP Policy 6.05	6.05 Waiver or Alteration of Consent Process or Documentation	Updated 2022 May 15

1. Purpose

To describe the situations in which the IRB may waive or alter the informed consent process and/or waive consent documentation.

2. Policy

It is the IRB's policy that all requests for waiver or alteration of the informed consent process or consent documentation must undergo appropriate IRB review, and when waivers or alterations are granted, they are given based on HHS regulations 45 CFR §46.111(a) (4) and (5), 45 CFR §46.116(a) to (f), 45 CFR §46.117(a) to (c).

2.1 Waiver or Alteration of Consent Process

A. The IRB may waive the requirement for informed consent per HHS 45 CFR §46.116(f), or allow an alteration of some or all of the elements of informed consent found at 45 CFR §46.116(a-c) only if it finds that each of the following 4 elements (or 5 elements if using identifiable private information or identifiable biospecimens) are met. This is different from waiving the requirement of documentation of informed consent. To waive or alter the requirement for informed consent or an element of informed consent, the following criteria must be met, as applicable:

(1) The research involves no more than minimal risk to participants;

(2) The waiver or alteration will not adversely affect the rights and welfare of the participants;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the participants will be provided with additional pertinent information after participation (HHS 45 CFR §46.116(d)).

(5) If the research involves using identifiable private information or identifiable biospecimens, the research could not be carried out without using such information or biospecimens in an identifiable format.

2.2 Waiver of Documentation of Informed Consent Document

A. The IRB may waive the requirement that the participant or the participant's representative sign a written consent document (45 CFR §46.117 (c)) if it finds:

(1) That the signed consent is the only link that could result in potential harm to the participant if a breach of confidentiality occurred; OR

(2) That the research presents no more than the minimal risk of harm to participants and involves no procedure for which written consent is normally required outside of the research context (e.g., part of a routine, classroom exercise where the data would have been collected in any case.); OR

(3) If the participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to participants and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

B. When the IRB considers waiving the requirement to obtain documentation of the consent process, the IRB shall review a description of the information that will be provided to participants.

C. In cases in which the documentation requirement is waived, the IRB may require the investigator to offer participants a written statement regarding the research.

2.3 Waiver or Alteration of Consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials

To waive or alter the requirement for informed consent or an element of informed consent, the following criteria must be met, as applicable.

A. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate or otherwise examine:

(1) Public benefit or service programs

(2) Procedures for obtaining benefits or services under those programs.

(3) Possible changes in or alternatives to those programs or procedures.

(4) Possible changes in methods or levels of payment for benefits or services under those programs

B. The research cannot practicably be carried out without the waiver or alteration.

See Appendix B for Revision History

Section 7

Vulnerable Populations and Special Classes of Participants

RPP Policy 7.01	7.01 Additional Protections for Vulnerable Populations	Updated 2022 May 15

1. Purpose

To describe additional protections for vulnerable populations.

2. Definition

2.1 Vulnerable population

An individual or group of individuals with limited autonomy (e.g., lacks independence in decision making for a variety of reasons) or is otherwise at increased risk compared to non-vulnerable individuals. Within any population of vulnerable participants, individuals will have different levels of vulnerability based on the level of capacity, circumstance, or condition affecting independent decision-making.

3. Policy

It is the IRB's policy that the vulnerability of a potential participant population will be evaluated to ensure that appropriate protections are in place for any participant who may be vulnerable in accordance with HHS regulations 45 CFR §46.111(a).

HHS regulations 45 CFR §46 provide special protections for pregnant women (Subpart B), prisoners (Subpart C) and children (Subpart D). HHS Regulations 45 CFR §46 do not, however, include *specific* requirements for the protection of other vulnerable participant populations including but not limited to persons with diminished functional capacity, those who are, terminally ill, or economically or educationally disadvantaged.

In these situations, the IRB, in consultation with the investigator, will determine the appropriate means to protect the rights and welfare of the individuals.

3.1 Categories of Vulnerable Populations

Vulnerable populations may be categorized according to the following groups:

A. Federally identified vulnerable populations:

(1) Prisoners (see RPP Policy 7.03 *Research Involving Prisoners*)

(2) Children (see RPP Policy 7.04 *Research Involving Children*)

(3) Pregnant women (see RPP Policy 7.02 *Research Involving Pregnant Women, Human Fetuses, and Neonates*)

(4) Fetuses and neonates (see RPP Policy 7.02 *Research Involving Pregnant Women, Human Fetuses, and Neonates*)

(5) Diminished functional capacity (see RPP Policy 7.05 *Research Involving Participants with Diminished Functional Capacity*)

B. Examples of other types of vulnerable populations, not federally identified:

(1) Comatose

(2) Terminally ill

(3) Economically disadvantaged

(4) Educationally disadvantaged

(5) Socially disadvantaged

(6) Employees and students (see RPP Policy 7.06 *Research Involving Employees and/or Students*)

(7) Others, as determined by the IRB and investigator

3.2 Factors that May Influence Vulnerability

A. The nature of the research. The risks of the research.

B. An increased probability of risk occurrence in the proposed population.

C. Degree of autonomy, or limited autonomy, present in the proposed population.

D. The clinical status of the proposed population.

E. The educational status of the proposed population.

F. The economic status of the proposed population.

G. The presence of a support system (e.g., family and friends) for the proposed population.

H. Cultural or social factors associated with the proposed population.

3.3 Additional Protections for Vulnerable Populations

A. Upon determining the vulnerability of an individual or population, the IRB and investigator will provide special protections against risk. These additional protections will include those specified by RPP policies for research involving pregnant women, prisoners, children, or participants with diminished functional capacity.

B. Other additional protections, as deemed necessary by the IRB, may also include:

(1) The use of an extended consent process,

(2) The use of a consent monitor,

(3) Appointment of a participant advocate,

(4) Involvement of the participant's family and/or friends,

(5) Limits placed on risk,

(6) Exclusion from participating in the research,

(7) Increased safeguards to protect privacy and confidentiality,

(8) Increased monitoring of the research by the IRB or other mechanisms,

(9) More lenient withdrawal criteria, and

(10) Longer study follow-up.

See Appendix B for Revision History

RPP Policy 7.02	7.02 Research Involving Pregnant Women, Human Fetuses, and Neonates	Updated 2022 May 15

1. Purpose

To describe the IRB requirements for research involving pregnant women, fetuses, and neonates.

2. Definitions

2.1 Pregnancy

Period from confirmation of implantation of a fertilized egg within the uterus until the fetus has been delivered. Implantation is confirmed through a presumptive sign of pregnancy (e.g., missed periods or a positive pregnancy test). While confirmation may be in error, investigators must presume that a living fetus was present until evidence is presented to the contrary.

2.2 Fetus

The product of conception from implantation until delivery.

2.3 Viable neonate

A neonate, after delivery that can survive to the point of independently maintaining heartbeat and respiration. A viable neonate is covered by HHS regulations 45 CFR §46(A and D.)

2.4 Nonviable neonate

A neonate after delivery that, although living, is not viable.

3. Policy

UA Little Rock RPP policies provide for additional protections for pregnant women, fetuses, and neonates involved in research.

Irrespective of funding, all research focusing, involving, or that might involve secondary risk to pregnant women, human fetuses and neonates (as defined in HHS regulations 45 CFR §46(B)) must satisfy the additional protections described in HHS 45 CFR §46(B).

3.1 IRB Review

All research involving, focusing, or that might involve secondary risk to pregnant women, human fetuses and neonates will be reviewed by the Full Board and comply with regulations 45 CFR §46(A).

3.2 Research involving pregnant women or fetuses

A. Pregnant women may be involved in research, irrespective of funding source, if all of the following conditions are met:

(1) Appropriate preclinical studies, including studies on pregnant animals and clinical studies involving non-pregnant women, have been conducted and provided data for assessing potential risks of pregnant women and fetuses.

(2) Any risk to the fetus is caused solely by interventions that offer direct benefit for the woman or fetus, or if there is no prospect of direct benefit, the risk to the fetus must not be greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

(3) Any risk to the pregnant woman or the fetus is the least possible to achieve the research objectives.

(4) No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

(5) Individuals engaged in research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

(6) Individuals engaged in research will have no part in determining the viability of a neonate.

(7) Consent of the pregnant woman alone is required for research which:

(a) Offers direct benefit to the pregnant woman only, or

(b) Will not directly benefit the woman or fetus, but:

(i) There is no more than minimal risk to the fetus, and

(ii) The purpose of the research is to develop important knowledge, and the data cannot be obtained by any other means.

(8) Consent of the pregnant woman and father is required if the research offers direct benefit to only the fetus. However, the father's consent is not required if he is unavailable, has diminished functional capacity/ability, or is temporarily incapacitated or if the pregnancy resulted from rape or incest.

(9) The consent must fully disclose the reasonable foreseeable impact of the research on the fetus (e.g., risk).

(10) Assent and parental permission for pregnant children's participation in research must be obtained in accordance with HHS regulations 45 CFR §46(D) (see RPP Policy 7.04 *Research Involving Children*).

(11) Consent of the pregnant woman alone is required for research which:

(a) Offers direct benefit to the pregnant woman only, or

(b) Offers direct benefit to the woman and fetus, or

(c) Will not directly benefit the woman or fetus but provides no more than minimal risk to the fetus.

3.3 Research involving placenta and dead fetus(es) or fetal material

A. Research involving the placenta, dead fetus, or fetal material after delivery may occur if all federal, state, or local laws and regulations are met. If any information associated with the material used in the research can be linked in any way to a living person, HHS regulations view the living person as a research participant, and the research is subject to the regulations discussed in this policy.

B. It is the PI's responsibility to document to the IRB that local and or state laws do not contradict federal guidelines.

(1) If State law on this matter contradicts federal regulations, University Counsel must be consulted.

3.4 Research not otherwise approvable

A. The HHS Secretary may conduct or fund research that the IRB does not feel meets the above policy if the following conditions are met:

(1) The IRB finds that the research, which will be funded by HHS, presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, provided the Secretary has determined through consultation with a panel of experts that the research does, in fact, meet the requirements of 45 CFR §46.204; OR

(2) The HHS Secretary has determined that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health and welfare of pregnant women or fetuses or neonates; is conducted in accord with sound ethical principles; and informed consent will be obtained.

B. Note: For non-HHS funded research involving pregnant women, fetuses, or neonates, the UA Little Rock IRB will convene an equivalent panel of experts to advise the IRB.

3.5 Non-pregnant participants who become pregnant during research

A. If a participant becomes pregnant while actively participating in a research protocol and this contingency was not addressed *a priori*, the investigator must:

(1) Determine if it is in the best interest of the pregnant participant to continue participating in the study or terminate participation in the study by completing the report on unanticipated problems or AEs involving risks to research participants or others, as described in RPP Policy 12.01 *Unanticipated Problems Involving Risk and Adverse Events*.

(a) If it is in the best interest of the pregnant participant to remain in the study, adequate justification must be provided to receive IRB approval for the participant to continue. If it is not in the best interest of the participant to continue, the participant's participation must be terminated.

(2) Submit the study for re-review by the Full Board, as soon as possible, in consideration of this policy.

3.6 Documentation of IRB findings under HHS Subpart B

A. The IRB will fully document compliance with HHS Subpart B in the minutes of the IRB meeting by documenting the required determinations and protocol– specific findings justifying those determinations.

See Appendix B for Revision History

RPP Policy 7.03	7.03 Research Involving Prisoners	Updated 2022 May 15

1. Purpose

To describe the procedure for research involving prisoners.

2. Definitions

2.1 Prisoner

According to HHS regulations, any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute; individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution; and individuals detained pending arraignment, trial, or sentencing.

2.2 Minimal risk in prisoner research

According to HHS regulations, "The probability and magnitude of *physical* or *psychological harm* that is normally encountered in the daily lives or in the routine medical, dental, or psychological examination of *healthy persons*."

3. Policy

It is the IRB's policy that the IRB will adhere to HHS regulations 45 CFR §46(C) which provides for additional protections for prisoners involved in social/behavioral and biomedical research. These special protections include individuals who are prisoners at the time of enrollment in the study as well as participants who become incarcerated after enrollment in a study. The IRB will apply HHS Subpart C to all research involving prisoners regardless of funding, except for those described under "Special Circumstances" below. All research, with no exception, involving prisoners, will be brought to Full Board Review.

3.1 Permitted Research Involving Prisoners

A. Social/behavioral and biomedical research may involve prisoners as participants only if:

(1) The IRB has reviewed, approved, and determined that the research falls under one of the categories listed:

(a) Study of the possible causes, effects, and processes of incarceration and of criminal behavior, provided that the study presents no

more than minimal risk, and no more than inconvenience to the participants;

(b) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;

For the remaining two categories, it should be noted that final approval, as indicated below, rests with the Secretary of HSS with OHRP acting on behalf of the Secretary. Following IRB approval, the entire research proposal (including the IRB- approved protocol, any relevant HSS grant application or proposal, consent documents, any IRB application forms, and any other information requested or required by the IRB for initial review) will be submitted to OHRP. OHRP will consult with appropriate experts, including experts in penology, medicine, and ethics, and publish notice, in the Federal Register, of intent to approve such research. HSS through ORHP, will issue its approval in writing to the IRB

(c) Research on conditions particularly affecting prisoners as a class (for example, research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults)

(d) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the proposal is reviewed by OHRP (as discussed above.)

For research which is not funded by HHS, neither certification to OHRP nor expert review for Categories 3 and 4 is required. The IRB will only approve research, which fits one or more of the designated categories. In addition, the IRB will, at its discretion, convene an equivalent expert review body to review studies classified as 3 or 4.

3.2 Expedited Review of Research Involving Prisoners

HSS regulations allow expedited review; however, OHRP recommends that the convened IRB review all research involving prisoners. Therefore, the IRB will normally not use expedited review for protocols, changes, or continuing review of research involving prisoners.

A. If the expedited review process is used for minor modifications to research, one of the two procedures described in 3.2 C(2) below may be used based on the type of modification.

B. Modifications involving more than a minor change are reviewed by the convened IRB.

(1) The same procedure used for initial review must be used including the responsibility of the prisoner representative to review the modification and to participate in the meeting (as described in Section 3.4).

C. Continuing Review

(1) The same procedure used for initial review must be used for continuing review including the responsibility of the prisoner representative to review the continuing review materials and participate in the meeting (as described in Section 3.4).

(a) If no participants have enrolled, the research may receive continuing review using the expedited procedure under expedited category 8 (see RPP 3.01 *Activities Requiring IRB Review and Determination*).

(2) Research involving interaction with prisoners may be reviewed by the expedited procedure if a determination is made that the research involves no greater than minimal risk for the prison population being studied.

(a) The prisoner representative must concur with the determination that the research involves no greater than minimal risk.

(b) The prisoner representative must review the research as a reviewer, designated by the chair or consultant. This may be as one of the original review team or as an addition, as appropriate.

(c) Review of modifications and continuing review must use the same procedures for initial

review using the expedited procedure including the responsibility of the prisoner representative.

(3) Research that does not involve interaction with prisoners (e.g., existing data, record review) may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied.

(a) Review by a prisoner representative is not required.

(b) The prisoner representative may review the research as a reviewer or consultant if designated by the IRB Chair.

(c) Review of modifications and continuing review must use the same procedures as initial review.

D. When a participant is incarcerated temporarily while enrolled in a study.

(1) If the temporary incarceration has no effect on the study, keep the participant enrolled.

(2) If the temporary incarceration has an effect on the study, handle according to the guidance in section 3.2 A-C.

3.3 Exempt Review of Research Involving Prisoners

HSS regulations do not allow exemption of research involving prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners (see 45 CFR §46.104(b)(2)).

3.4 IRB Membership Requirements for review of research involving prisoners

In addition to federal requirements regarding any research involving human participants, the IRB will satisfy the following additional requirements when the research involves prisoners, regardless of funding source:

A. The majority of the members of the IRB will not have an association with the prison(s) involved in the study.

B. At least one member of the IRB present at the IRB meeting and involved in the review will be a prisoner representative. The prisoner representative will have a close working knowledge, understanding, and appreciation of prison conditions from the perspective of the prisoner.

(1) The prisoner representative must be a voting member of the IRB. The prisoner representative may be listed as an alternative member who becomes a voting member when needed.

(2) The prisoner representative must review research involving prisoners, focusing on the requirements in Subpart C or equivalent protections. The prisoner representative will receive all review materials pertaining to the research (as will the rest of the committee).

(3) The prisoner representative must be present at a convened meeting when the research involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved.

(a) The prisoner representative may attend the meeting by phone, video-conference, or webinar, as long as the representative is able to participate in the meeting as if they were present in person at the meeting.

(4) The prisoner representative must present a review either orally or in writing at the convened meeting of the IRB when the research involving prisoners is reviewed.

C. The IRB Administrator will maintain an IRB roster of all members including their expertise to ensure a prisoner representative is available for research involving prisoners as required by HSS regulations at 45 CFR §46.103(b)(3). The IRB Administrator will be aware of the impact of roster changes on quorum requirements under HHS regulations at 45 CFR §46.108(b). The IRB is aware that the special composition requirement for research involving prisoners involves not only the initial review of the protocol, but also continuing review, protocol/consent amendments, review of reports of unanticipated problems involving risks to participants, and all other IRB matters pertaining to the protocol.

3.5 Special Circumstances

A. When a previously enrolled participant becomes a prisoner

When a previously enrolled research participant becomes a prisoner and the relevant research was *not* reviewed and approved by the IRB in accordance with the requirements of HHS regulations 45 CFR §46(C), the PI must report the situation to the IRB immediately.

(1) Upon notification that a previously enrolled research participant has become a prisoner and that the PI wishes to have the prisoner continue to participate in the research, the IRB will promptly re-review the protocol in accordance with the requirements of HHS Subpart C (as applicable).

(2) All research activities and interventions for the now incarcerated prisoner- participant must stop until the protocol is reviewed under the HHS requirements of Subpart C, except where the PI can justify that it is in the best interest of the participant to remain in the HSS-funded research study while incarcerated. The IRB Chair may determine that the participant may continue to participate until all the requirements of HHS Subpart C are satisfied.

B. When a potential participant is an adolescent detained in a juvenile detention facility

If a potential participant is an adolescent detained in a juvenile detention facility, the individual is both a child and a prisoner. In such a case, HHS regulations 45 CFR §46(C) (prisoners involved in research) and 45 CFR §46(D) (children involved in research) apply and must be satisfied.

C. When the proposed participant population may have high risk of incarceration during the course of the study.

Predetermination of a participant population's potential for incarceration carries additional risks of violating the rights of justice and respect for persons. The definitions of minimal risk and the risk/benefit analysis may not truly be applicable to the participant population. However, the IRB may choose to review the proposal under HHS regulations 45 CFR §46(C).

3.6 Additional Criteria to Assess Research Involving Prisoners (aka IRB Findings)

The IRB will follow all pertinent federal regulations pertaining to human participant research as well as make seven additional findings (see below) for research involving prisoners regardless of funding source:

A. The research represents one of the categories permissible under HHS regulations pertaining to research involving prisoners.

B. Any possible benefits to the prisoners through their participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, are not of such a magnitude that their ability to weigh the risks of the research against the value of such advantages in the limited-choice environment of the prison is impaired.

C. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.

D. Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the PI provides to the IRB justification in writing for following some other procedures, control participants will be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.

E. The information is presented in language which is understandable to the participant population.

F. Adequate assurance exists that parole boards will not take into account a prisoner's participation in research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.

G. If the IRB finds that there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of an individual prisoner's sentence and ensuring that participants are informed of this fact.

3.7 Documentation of Additional Criteria (aka IRB Findings)

Per federal regulations, the IRB will prepare and maintain adequate documentation of IRB activities. For the purposes of HHS Subpart C, the IRB activities include adding the specific criteria (findings) required under HHS regulations along with protocol-specific findings justifying those determinations. Documentation can occur in the meeting minutes and/or in the official approval letter. OHRP accepts documentation of protocol-specific information justifying each IRB finding required under HHS 45 CFR §46.305(a) to be one way of adequately documenting the IRB activities required under Subpart C. The IRB will follow the aforementioned OHRP guidance.

3.8 Research Funded by HHS Involving Prisoners

A. The IRB is responsible for providing certification to OHRP that the IRB has made the seven findings applicable to HHS-funded research involving prisoners. The IRB will send OHRP a certification letter to this effect which includes:

(1) The name and address of the Institution;

(2) Identification of the research protocol and the relevant HHS grant application or proposal;

(3) A copy of all paperwork necessary for IRB initial review (IRB-approved protocol, relevant HHS grant application or proposal, IRB application, consent(s), etc.);

(4) Verification of the presence of a prisoner representative during consideration of the study;

(5) Verification of the seven required findings (listed above); and

(6) Determination that the research meets one of the above categories of research permissible by federal regulations.

B. Prisoner research certification letters should be mailed to the OHRP Prisoner Research Contact person in the Office of Human Research Protections at the Department of Health and Human Services.

See Appendix B for Revision History

RPP Policy 7.04	7.04 Research Involving Children	Updated 2022 May 15

1. Purpose

To describe the procedures for research involving children.

2. Definitions

2.1 Children

Persons who have not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted.

A. In Arkansas, individuals under the age of 18-years with the exceptions noted below are considered to be "children," as defined by HHS regulations, because they have not attained the legal age to consent to treatments or procedures involved in some research, and the additional protections of HHS Subpart D are required.

(1) The exceptions to this rule are the following individuals who are able to consent to treatments or procedures involved in the research, so that they do not meet the HHS definition of "children," and the additional protections of HHS Subpart D are not required:

(a) Emancipated minors, or

(b) Individuals of any age where the research procedures are limited to:

(i) Use of contraceptives,

(ii) Treatment for venereal disease, or

(iii) Treatment for drug abuse.

2.2 Age of majority

According to HHS and Arkansas Statute §9-25-101, "all persons under 18-years of age are declared to be minors, but, if any person marries under the age of 18-years, his or her minority ends." If the potential participant is Native American living on federal tribal lands, regardless of the state, federal law has set the age of majority at age 18. The IRB Chair, in consultation with the IRB Administrator, will determine which individuals meet the HHS definition of "children" in the cases where the research is

conducted outside of Arkansas or under Native American jurisdiction.

2.3 Emancipated Minor

A legal status conferred upon persons who have not yet attained the age of legal competency, as defined by Arkansas State law, but who are entitled to treatment as if they had.

A. Minors do not meet the HHS definition of "children," when such individuals are under 18- but at least 16-years of age and who are legally emancipated (Arkansas Statute §9-26-104).

B. Emancipated Minor

A person under 18-years of age who resides apart from his or her parents; is not under the care, custody, control, or supervision of his or her parents; who receives no financial support or services from his or her parents; and is responsible for securing his or her own support.

2.4 Parent

A child's biological or adoptive parent.

2.5 Guardian

An individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care. The IRB Chair, in consultation with the IRB Administrator, will decide which individuals meet the HHS definition of "Guardian."

2.6 Legally Authorized Representative

A legally authorized representative (LAR) is defined as "an individual, a judicial or other body, authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures involved in the research" (45 CFR §46.102(i)). For a more detailed definition of LAR and who can provide consent, see RPP 7.03 Research Involving Participants With Diminished Functional Capacity/Ability.

2.7 Commensurate

The requirement that children and/or their guardians are familiar with procedures that are reasonably similar in nature and risk proportionally to those the child has experienced, or is expected to experience, and not restricted to specific situations the child has experienced or will likely experience in the future.

2.8 Consent/Permission

The agreement of parent(s) or guardian(s) to the participation of his/her (their) child or ward in research.

2.9 Assent

A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

2.10 Dissent

A child's decision to decline participation in research.

2.11 Disorder or Condition

A specific (or set of specific) physical, psychological, neuro developmental, or social characteristic(s) that an established body of scientific evidence or clinical knowledge has shown to negatively affect children's health and wellbeing or to increase their risk of developing health problems in the future.

2.12 Minimal Risk

The risks that normal, average, healthy children encounter while living in safe environments or as the risks associated with routine physical or psychological examinations or tests. The determination of minimal risk should take into account that:

A. Children face differing risks at different ages;

B. Risks associated with repetitive tests may increase;

C. Special/unique characteristics may make a certain population more vulnerable than average children (e.g., hemophilia); and

D. The risks associated with routine examinations or tests are equivalent to a routine well-child examination.

2.13 Minor Increase Over Minimal Risk

The determination whether the research procedures or interventions present a minor increase over minimal risk. The IRB will consider the following 5 criteria in determining inherent risk:

A. Magnitude,

B. Probability,

C. Duration,

D. Cumulative characteristics, and

E. Irreversibility of risk to the child.

2.14 Vital Importance

The extent to which the research is:

A. Essential for the scientific understanding or evaluation of procedures to alleviate the disorder or condition, and

B. Perceived as essential by practitioners and family stakeholders for the understanding or amelioration of the child's disorder.

3. Policy

It is the IRB's policy that the IRB will review all research proposals involving participation of children in accordance with HHS regulations 45 CFR §46(D) and applicable state laws. The IRB will classify the research in accordance with HHS Subpart D and document how and why the proposal meets the requirements.

3.1 Categories of Research

A. HHS regulations specify that the IRB may only approve research involving children if it falls under one or more of the following 4 categories:

(1) Research not involving greater than minimal risk (e.g. most educational studies, studies in which behavior is not manipulated) (HHS 45 CFR §46.404)

(a) The potential risks must be outweighed or balanced by the potential benefits to the participants and/or society.

(b) Adequate provisions must be made for soliciting assent of the children and permission of the parent(s) or guardian(s).

(2) Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual participants (HHS 45 CFR §46.405)

(a) The risk is justified by the anticipated benefit to the participants.

(b) The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parent(s) or guardian(s).

(3) Research involving greater than minimal risk and no prospect of direct benefit to individual participants but likely to yield generalizable knowledge about the participant's disorder or condition (HHS 45 CFR §46.406).

(a) The risk represents a minor increase over minimal risk.

(b) The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their

actual or expected medical, dental, psychological, social, or educational situations.

(c) The intervention or procedure is likely to yield generalized knowledge about the participant's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition.

(d) Adequate provisions are made for soliciting assent of the children and permission of their parent(s) or guardian(s).

(4) Research, not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (HHS 45 CFR §46.407).

(a) If the research is HHS funded, the IRB will submit research meeting category #4 to HHS for approval.

(b) If the research is not HHS-funded, the IRB will, at the board's discretion, convene an equivalent expert review panel.

3.2 Process of Consent/Assent

A. Children cannot legally give consent on their own behalves. The consent/permission of one or both parent(s) or legal guardian(s) is, therefore, required before they can participate in any research projects, unless waived by the IRB under the provisions of HHS regulations 45 CFR §46.116(f), 45 CFR §46.408(c).

B. The IRB will make a determination whether permission of one or both parents is required for research approvable under HHS regulations 45 CFR §46.404 or §46.405. The IRB's determination of whether permissions should be obtained from one or both parents will be documented in the reviewers' comments and in the meeting minutes for those protocols reviewed by the full convened board.

(1) If the research involves activities that are *no more than minimal risk*, consent of only one parent must be obtained.

(2) If the research involves *greater than minimal risk but presents the prospect of direct benefit* to individual participants, consent of only one parent may be obtained.

(3) If the research involves *greater than minimal risk and no prospect of direct benefit* to individual participants, consent of both parents must be obtained, unless one parent is deceased, unknown, incompetent, or not reasonably available. Consent of both parents is not required, however, when only one parent has the legal responsibility for the care and custody of the child.

C. Consent of an Emancipated Minor

Minors may, with IRB approval, legally consent on their own behalf when they do not meet the HHS definition of "child." In Arkansas, if participants under the age of 18 are legally declared emancipated, they may consent to participate in research because they no longer meet the HHS definition of a child; therefore, HHS Subpart D does not apply.

D. Assent of Children

(1) In addition to obtaining parental/legal guardian consent (permission), the investigator must also solicit assent of minor participants age 6-years or older, unless the participant displays intellectual or emotional development below that of the average 6-year-old child, or the IRB has deemed otherwise.

(2) Obtaining assent shows respect for a child's developing autonomy. In most circumstances (non-therapeutic research), children's deliberate objection should be regarded as a veto to their involvement in the research.

E. Dissent of Children

(1) Dissent from participation or withdrawal from research is always to be honored, unless the protocol affords access to a therapeutic intervention that is not otherwise available. In that case, parental consent for therapeutic intervention may override a child's dissent. If so, the child should be informed of the parental override. This information must be provided to the child prior to the intervention procedure.

F. Waiver of Assent

With prior IRB approval, child assent may be waived by parents or guardians for interventions that hold the prospect of direct benefit to the child in accordance with HHS 45 CFR §46.408(a). Assent may also be waived by the IRB under 45 CFR §46.116(d).

G. Situations Where Minors Are Not Children

Under the following circumstances, minors are not considered "children" and can consent for themselves:

(1) If the research only involves a treatment for which a minor's consent is permissible under applicable law (e.g., use of contraceptives, treatment for venereal disease or substance use).

(2) If participants under the age of 18 are legally declared emancipated, they may consent to participate in research.

H. Waiver of Parental Consent

(1) Situations may be encountered where, with appropriate scientific rationale and justification, the IRB may approve a waiver of the requirements for parental consent as described in Subpart D of HHS 45 CFR §46.

(a) If the IRB determines that a research protocol is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (example, neglected or abused children), it may waive the consent requirements noted in RPP Policy 6.01 Development of the Informed Consent or Assent Record, provided an appropriate mechanism for protecting the children who will participate as participants in the research is substituted and provided that the waiver is not inconsistent with federal, state, or local law.

(i) The choice of an appropriate mechanism will depend upon the nature and purpose of the activities described in the protocol; the risk and anticipated benefit to the research participants; and their age, maturity, status, and condition.

(2) With IRB approval, the following conditions *may* qualify for a waiver of parental consent:

(a) If the research involves a treatment for which a minor's consent is permissible under applicable law (e.g., use of contraceptives, treatment for venereal disease or substance use).

(b) If participants under the age of 18 are legally declared emancipated, they may consent to participate in research.

(c) If the study involves administration of a sensitive survey that deals with a minor's personal/private behavior such as substance use, sexual activity, or criminal activity, providing all of the following conditions are met as prescribed by HHS 45 CFR §46.116(f) and the IRB determines that:

(i) The research involves no more than minimal risk;

(ii) The lower end of the participants' age range is no less than 13-years;

(iii) The nature of the survey is such that it is unlikely that adolescents who are experiencing emerging maturity and developing autonomy would be prepared to discuss participation in a research project with their parents that involves what the adolescents considers to be their personal and private behavior;

(iv) The research could not practicably be carried out without a waiver of parental consent (e.g., inadequate sample size);

(v) The value of the data to be derived from the research is significant, and the waiver in the judgment of the IRB will not adversely affect parental rights using the "prudent or careful parent standard"; or

(vi) The policy of the involved school or organization does not require parental consent for the research project.

(3) Waiver of Parental Consent must be approved by the Full Board.

I. Wards

HHS regulations 45 CFR §46.408 set specific requirements for children who have been declared wards of the state or any other agency, institution, or entity.

(1) Wards can participate in research approved under

(2) HHS regulations §46.406 or § 46.407 if:

(a) The research is related to their status as a ward, or

(b) The research is conducted in schools, camps, hospitals, institutions, or similar settings where the majority of children involved in research are not wards.

(3) The IRB will require appointment of an advocate for each child who is a ward.

(a) The advocate serves in addition to any other individual acting on behalf of the child as a guardian or in the absence of the parent(s).

(b) The advocate may represent more than one child.

(c) The advocate must have the background and experience to act in the best interest of the child for the duration of the child's participation in research.

(d) The advocate must not be associated in any way with the research, the investigator(s), or the guardian organization. The federal regulations do not specifically exclude IRB members from serving as a child advocate if the other conditions are met.

J. Re-consent of participants reaching the age of majority

(1) All minor participants actively participating in an IRB-approved study must be consented using the adult IRB-approved informed consent document *at the first visit after reaching the legal age of majority*. If the minor participated in a study that is completed, except for data analysis, re-consent is not required.

(2) The now adult participant has the right to refuse to continue participation in the study. This is to be respected. Undue pressure or coercion to continue may not be applied. While new data may not be collected on participants refusing participation, existing prior data collected under the assent/proxy consent process can be used.

(3) If, upon reaching the age of majority, the now adult participant is found to have diminished functional capacity/ability the participant remains vulnerable and the proxy/parental consent remains in effect.

This must be documented in the study records, and the IRB must be notified.

3.3 Consent and Assent Documents

A. General Considerations for Writing an Assent Form or Narrative

(1) Assent serves to provide information to the child and to allow the child to dissent. With these purposes in mind, the following points should be considered when writing the "Child Assent Form" or the "Youth Assent Form."

(a) In deciding whether to seek assent, the PI should consider the minor's age as an important criterion, but cognitive and educational level also needs to be considered.

(b) In seeking assent, PIs should not take undue advantage of children's developmental limitations related to their voluntariness (acquiescence to authority figures and any lack of ability to express their rights).

(c) When a researcher is uncertain as to whether assent should be sought from the child or adolescent, the IRB may consult appropriate experts.

B. Participant is less than 6 years old:

(1) If the participant is under the age of 6-years, only a "Parental/Guardian Consent Form" is required. The Parental/Guardian Consent Form should include relevant elements of informed consent, as outlined previously, and be written in a proxy consent style that indicates it is the parent or legal representative who is consenting to allow the minor to participate in the study. The standard statements must be modified for the Parental Consent form (e.g., all references to "you" must be changed to "your child").

(a) Child agreement should be obtained as appropriate.

C. Participant is 6-12 years old

(1) If the participant is 6- through 12-years of age, a child assent form or narrative using simple language written at the appropriate cognitive and educational level of the youngest prospective participant in the 6- through 12-year-old range is required.

(2) The assent form or narrative must contain the following elements employing language suitable for the *cognitive and educational level of the child*:

(a) Title and purpose of the study;

(b) Explanation of procedures (what the child is being asked to do);

(c) Freedom to withdraw;

(d) Basis for participant selection ;

(e) Opportunity to ask questions;

(f) Potential risks/discomforts;

(g) Potential benefits;

(h) Statement concerning consultation with parents;

(i) Confidentiality statement.

D. Participant is 13-17 years old

(1) Youth Assent Form

If the participant is 13- to 17-years of age, a "Youth Assent Form" is required. The youth assent process is based on the child assent process and form but should be revised to meet the cognitive and educational level of an average youth.

(a) The youth assent form must contain simple language written at the appropriate cognitive and educational level of the youngest prospective participant in the youth age range. The Youth Assent form must contain all of the required elements of consent (see RPP Policy 6.02 Required Elements for Informed Consent) except instructions about emergency care and the rights of research participants, and should follow the general format of the adult consent form.

3.4 Documentation of IRB findings under HHS Subpart D

A. The IRB will fully document compliance with HHS Subpart D in the minutes if there is a review of the protocol by the full convened board.

B. For protocols that do not require review by the full convened board the documentation will occur in the reviewers' comments.

See Appendix B for Revision History

RPP Policy 7.05	7.05 Research Involving Participants with Diminished Functional Capacity/Ability	Updated 2022 May 15

1. Purpose

To describe additional protections for with diminished functional capacity/ability.

2. Definitions

2.1 Assent

A positive indication of willingness to participate in a research study.

2.2 Participants with Diminished Functional Capacity/Ability

A person who lacks the ability to reason, exhibit sound judgment, and provide voluntary consent to participate in research. The impairment may fluctuate (e.g., mental disorders), deteriorate with time (e.g., Alzheimer's), result from health conditions (e.g., coma or other infirmity) or be a more permanent or long-term condition.

2.3 Health care

Any care, treatment, service or procedure to maintain, diagnose, treat or otherwise affect an individual's physical or mental condition.

2.4 Legally Authorized Representative or Guardian as defined by 45 CFR §46.102

A legally authorized representation (LAR) is defined as "an individual, a judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the participants' participation in the procedures involved in the research 45 CFR §46.102(c)."

2.5 Capacity to Consent:

The ability to provide legally effective consent to enroll in a research study.

3. Policy

It is the IRB's policy that research involving participants with diminished functional capacity/ability and who cannot provide voluntary informed consent must include appropriate additional protections in accordance with HHS regulations 45 CFR §46.111(b).

3.1 Appointment and authority of the LAR

A. Research involving Health Care

The following individuals may provide consent for research involving Health Care on behalf of individuals with diminished functional capacity/ability or who have not reached the age of majority under Arkansas law:

(1) Any parent, whether an adult or a minor, for his or her minor child (Child as used here includes biological or adopted children.).

(2) Any guardian, conservator, or custodian, for his or her ward or other charge under disability pursuant to a court order.

(3) A minor who is married, emancipated or incarcerated for him/herself.

(4) A person designated in writing by an adult individual as having authority to make health care decisions for the individual, such as a health care proxy, health care agent, durable power of attorney for healthcare or surrogate decision maker.

(5) In the absence of an alternate decision maker designated by the individual, a person designated as a surrogate decision maker by the individual's designated physician in the individual's medical record.

B. The following persons may serve as a LAR for research that does not involve health care on behalf of individuals with diminished functional capacity/ability or who have not reached the age of majority in Arkansas:

(1) Any parent, whether an adult or a minor, for his or her minor child (Child as used here includes biological or adopted children.).

(2) Any guardian, conservator, or custodian, for his or her ward or other charge under disability.

(3) A minor who is married, emancipated or incarcerated for him/herself.

(4) A person designated in writing by an adult individual as having authority to make decisions for the individual, such as a power of attorney.

(5) A person designated in writing by an adult individual as having authority to make health care decisions for the individual, such as a health care proxy, health

care agent, durable power of attorney for healthcare or surrogate decision maker.

(6) In the absence of an alternate decision maker designated by the individual, a person designated as a surrogate decision maker by the individual's designated physician in the individual's medical record.

(7) In cases where the proxy is unclear, the IRB Chair in consultation with the IRB Administrator, will decide which individuals meet the HHS definition of "legally authorized representative."

C. If prospective participants lack the ability/capacity to consent, they can only be enrolled in research if:

(1) LAR provides consent on their behalf, or,

(2) A waiver of consent is approved by the IRB.

D. The LAR should normally use "substituted judgement" where possible as opposed to "best interests". It is important for LARs to consider what would be participants' position given a choice whether or not to participate in the research when they were not cognitively impaired.

E. Appropriate documentation should be obtained and maintained by the investigator in the research files (e.g. Signed Durable Power of Attorney forms.)

3.2 Elements of Acceptable Research

A. Research that is expected to include persons with diminished functional capacity/ability must address how determinations will be made as to whether a participant has decision making capacity to consent both before and during the research and how those participants will be protected.

B. Research with people who have diminished functional capacity/ability must fall in to one of two categories:

(1) The proposed research is minimal risk. The investigator must demonstrate to the IRB that there is a compelling reason to include cognitively impaired individuals as participants. Individuals with diminished functional ability/capacity must not be participants in research simply because they are readily available.

OR

(2) The research presents a potential of direct benefit to the participant. Individuals with diminished functional capacity/ability may not be participants in research

that is greater than minimal risk, unless that research has a potential to directly benefit the participant and the potential benefits outweigh the potential risks.

C. Investigator responsibilities when proposing research involving persons with diminished functional capacity include:

(1) Provide a plan to assess the capacity to consent before and during the research. The plan should indicate an individual with relevant expertise will evaluate prospective participants' capacity to consent and make an objective determination regarding each participant's capacity to consent. Any additional methods used to assist with these evaluations, such as conducting interviews, screening tests, or formal assessment instruments, should also be described, noting that cognitive tests and competence assessment instruments alone cannot provide the basis of the evaluator's determination, and should at most supplement or support the evaluator's judgment.

(2) If capacity to consent is likely to be found lacking, provisions to obtain the permission of an appropriate LAR should be made.

(3) If feasible, researchers should try to support or enhance prospective participants' ability to consent. Methods such as designing a multi-step consent process (capacity assessment, presentation of information, obtaining consent to each step separated by a certain period of time) or enhanced presentation of consent information using materials other than a written consent form may be appropriate.

(4) For participants incapable of providing consent, but capable of communicating a preference regarding participation, the PI should make reasonable efforts to provide information about the research and ensure that the participant is willing to join the study.

(5) Describe in the submission any additional safeguards that are in place to protect the rights and welfare of participants with diminished functional capacity/ability.

D. IRB responsibilities when reviewing and approving research involving persons with diminished functional capacity/ability include:

(1) The IRB may only approve research involving persons with diminished functional capacity/ability when the following conditions are met:

(a) The research cannot reasonably be conducted without these participants' participation.

(b) The proposed research has all necessary safeguards in place to protect the rights and welfare of participants with diminished functional capacity/ability.

(c) The informed consent process and document are appropriate for these participants, and include provisions for assessing potential participants' ability to provide their own consent and for seeking consent from an LAR, as appropriate.

(2) The IRB should consider whether to require investigators to solicit prospective participants' assent, keeping in mind that the dissent of a participant should always be respected.

(3) Assessing whether participants' functional capacity/ability may fluctuate during research participation, and if so, whether appropriate measures are in place to ensure participants' rights, safety, and welfare are protected throughout participation.

(4) The IRB should consider the following elements when reviewing research involving people with diminished functional capacity/ability:

(a) Whether the population targeted for recruitment represents the population with the least degree of impairment to functional abilities compatible with the study's aims.

(b) The possibility the participants may be unusually sensitive to the possible risks of the research.

(c) The results of any previous research involving the experimental intervention in animals or humans with unimpaired functional abilities.

(d) Whether the proposed method of assessing capacity/ability to consent is appropriate to the research (the assessment methodology should increase in rigor as the degree of risk and the extent of impairment to participants' functional capacity/ability increase).

(e) Whether assent from participants should be sought and, if so, the proposed method for doing so is appropriate.

(f) Whether knowledge likely to be gained through the study will improve the understanding of the condition, disease or behavior affecting the participant population.

(g) Compensation for participation is appropriate and is being provided to the appropriate person (i.e. monetary payments should be given to the participant or to an individual who regularly manages the participant's finances, if participants do not manage their own expenses.

3.3 Assent/Dissent, LAR Consent and Forms

A. In the case of prospective participants with diminished functional capacity/ability, when it has been determined that consent is required and the participant does not possess the ability/capacity to consent, the participant's Legally Authorized Representative must provide written proxy consent.

(1) The *Proxy Consent Form* must include all required elements of the informed consent and be written in the proxy consent style that indicates that the LAR is providing permission to allow the participant with diminished functional capacity/ability to participate in the study.

B. The *Adult Assent Form* is based on the adult consent form but should be written in simple language aimed at the appropriate cognitive level of the participants with diminished functional capacity/ability to be enrolled in the study. The Adult Assent Form must contain all required elements of consent.

3.4 Application of Laws

A. IRB and/or investigators must apply state and local laws that reach beyond Federal laws relevant to research involving humans as participants. Examples of such laws are reporting of child abuse and educational privacy laws. University counsel is available for advice in all cases as needed and requested. UA Little Rock's IRB Administrator, IRB Chair, and members of the IRB have access at all times to university legal counsel for assistance in applying laws to research involving human participants.

See Appendix B for Revision History

RPP Policy 7.06	7.06 Research Involving Employees and/or Students	Updated 2022 May 15

1. Purpose

To describe additional requirements for research that involves UA Little Rock employees and/or students.

2. Policy

It is the IRB's policy that recruitment of employees and/or students in the laboratory, office, or class of an investigator is generally discouraged, particularly in research involving more than minimal risk to the participant. This participant population is considered potentially vulnerable because of the subordinate position to the investigator and the potential for coercion or undue pressure. However, research conducted with UA Little Rock employees or students must follow the same guidelines as research with any other participants.

2.1 Students as Research Participants

A. The Parental Informed Consent form that covers studies with no more than minimal risk may be used by departments with research participation requirements when participants are children (defined in Arkansas as individuals under 18 years of age, except those who are legally emancipated or who are otherwise able to consent to the procedures involved in the research).

B. If course requirements or extra credit options involve research participation, alternative activities must be available to students so they do not feel coerced into research participation.

(1) Alternative activities should not be graded. If the research participant receives the credit for participating regardless of the quality of the participation, the alternative should be assessed on a similar participated/did not participate differentiation.

(2) The alternative activity should be equivalent in time, energy, and effort to the research activity.

C. The student's UA Little Rock identification number ("T number"), social security number, telephone number, or initials are not acceptable as identification codes for tracking confidential data.

(1) The IRB recommends a coding system that adequately protects confidentiality.

D. It is preferable that the course instructor not know who participated in the research until after the last date for a grade appeal for the semester of data collection has passed.

2.2 Requirements

A. If an investigator wishes to recruit participants from within the laboratory, office, or class, the IRB Request for Review form must clearly address:

(1) The nature of the professional relationship between the investigator and the prospective participants.

(2) Justification of the need to recruit participants from the investigator's laboratory, office, or class. This justification must be particularly strong for any study which involves greater than minimal risk procedures.

(3) A description of the method of participant recruitment and how situational coercion will be minimized to the greatest extent possible. The investigator should consider:

(a) The use of a general posting and not engage in one-on-one solicitation;

(b) The use of an individual to obtain consent who does *not* have any supervisory or instructional role relative to the prospective participant.

(4) Use of any approved department participant pool protocols.

(5) Appropriateness of the proposed informed consent process. The process should involve providing participants with all relevant information about the study, including a description of possible risks and benefits, in clear and simple language and in a manner appropriate to the research. When appropriate, the consent process shall also make clear that neither a decision whether or not to participate or to continue in the study, nor their individual study results (e.g. survey responses) will have any bearing on the participants' academic or employment or on any future relationship with the institution.

2.3 IRB Review

A. The IRB will carefully examine the proposed inclusion of this participant population and must ensure that special protections for this population are in place to minimize the potential for coercion or undue influence.

See Appendix B for Revision History

Section 8

Funding Agencies

RPP Policy 8.01	8.01 Certification of Review to Funding Agencies	Updated 2022 May 15

1. Purpose

To describe the process of certification of review to funding agencies.

2. Policy

It is the IRB's policy that certification of review will be sent to funding agencies in full accordance with HHS regulations 45 CFR §46 and all other applicable funding agency/sponsor regulations and/or policy.

2.1 Grant Application Covered by one IRB Protocol

A. When an investigator either submits a grant application involving human participants to ORSP or receives notification, for example from the NIH of a fundable score, the investigator must identify the IRB protocol number that covers the human participants activities described in the grant application.

B. If the title on the IRB protocol on file does *not* match the title of the project listed on the grant application, the investigator should submit to the IRB a "Request for Modification" with either of the following:

(1) Addition of a second title (noted on the grant application) to the IRB protocol, or

(2) Substitution of the new title.

C. Regardless of which option is selected by the investigator, data collection may not begin until the matter has been resolved with the IRB.

D. It is acceptable for consent document(s) to have a lay title rather than a scientific title. However, this should be documented for the record in the IRB application.

2.2 Grant Application Covered by Two or More IRB Protocols

A. In a situation where the human participant activities portion of a grant application is covered by two or more IRB protocol numbers, ORSP and the IRB will not require matching titles. However, the submission must specifically identify the IRB protocol which covers each section of the grant application.

2.3 Commercially-Sponsored Contracts

A. When research is commercially sponsored, it is preferable that titles match between all documents (i.e., contract, protocol, consent document(s), and IRB application). The sponsor's protocol number may be included in the protocol title. However, the IRB discourages inclusion of sponsor's names in protocol titles.

See Appendix B for Revision History

Section 9

Data Sets, Protected Health Information, and Internet-Based Research

RPP Policy 9.01	9.01 Definition and Description of Protected Health Information Identifiers	Updated 2022 May 15

1. Purpose

To define and describe Protected Health Information identifiers.

2. Policy

It is the IRB's policy that the use of Protected Health Information will be in full accordance with HHS regulations 45 CFR §46 and other applicable federal, state, and local laws.

2.1 HIPAA Privacy Rule

The HIPAA Privacy Rule was issued in 2002, with a compliance date of April 14, 2003. The purpose of this rule is to provide additional protections of the privacy rights of participants involved in research. The HIPAA Privacy Rule contains requirements designed to ensure that the Protected Health Information of research participants is appropriately used and/or disclosed during the conduct of research. UA Little Rock Student Health Services is a "covered entity" and, therefore, complies with HIPAA.

2.2 Protected Health Information

Protected Health Information is defined as any *individually identifiable health information* whether oral or recorded in any medium that:

A. Is used or disclosed during the course of any research project whereas the individually identifiable health information was obtained from a covered entity

B. Is created or received by a covered entity

C. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past,

D. present, or future payment for the provision of health care to an individual.

Only the minimum Protected Health Information necessary to achieve the research objectives can be used.

2.3 Individually Identifiable Protected Health Information

The individually identifiable Protected Health Information list contains 18 identifiers. If *any* of the 18 identifiers are associated with the health information, then the information is considered

"protected." De-identification of Protected Health Information requires either:

A. Removal of all 18 identifiers, OR

B. Documentation by an expert statistician of how he/she determined that the risk of participant identification using a subset of identifiers present is very small.

C. The 18 identifiers are:

(1) Names;

(2) Postal address information: street address, city, county, precinct, ZIP code (except specified combinations);

(3) All elements of dates (except year) related to an individual (e.g. birth, admission, discharge). For participants over 89 years of age, all elements of dates (including year) must be removed;

(4) Telephone numbers;

(5) Fax numbers;

(6) Electronic mail addresses;

(7) Social security numbers;

(8) Medical record numbers;

(9) Health plan beneficiary numbers;

(10) Account numbers;

(11) Certificate/license numbers;

(12) Vehicle identifiers and serial numbers, including license plate numbers;

(13) Device identifiers and serial numbers;

(14) Web universal resource locators (URL);

(15) Internet protocol address numbers;

(16) Biometric identifiers, including finger and voice prints;

(17) Full-face photographic images (and any comparable images); and

(18) Any other unique identifying number, characteristic, or code.

See Appendix B for Revision History

RPP Policy 9.02	9.02 Limited or Public Data Sets	Updated 2022 May 15

1. Purpose

To describe the use of Limited Data Sets or Public Data Sets.

2. Definitions

2.1 Limited Data Set

Limited data sets are data sets stripped of certain direct identifiers that are specified in the Privacy Rule. These data sets may be used or disclosed only for public health, research, or health care operations purposes. Because limited data sets contain certain identifiers, they are not de-identified information under the Privacy Rule

2.2 Public Data Set

Public use data files are data files prepared by investigators or data suppliers with the intent of making them available for public use. The data available to the public are not individually identified nor maintained in a readily identifiable form.

3. Policy

It is the IRB's policy that the use of Limited Data Sets or Public Data Sets will be in full accordance with HHS regulations 45 CFR §46.

3.1 Limited Data Sets

A. A researcher with IRB approval and a DUA between the researcher and the covered entity can use and disclose Protected Health Information that contains a Limited Data Set without a HIPAA authorization or a waiver of consent granted by the IRB.

B. Limited Data Sets have all the direct identifiers of the individual or relatives, employers, or household members of the individual removed, except for a few, such as the following:

(1) A unique identifying number, characteristic, or code (e.g., a registry or study number);

(2) Elements of dates (e.g., birth)

(3) Town, city, state, and ZIP code.

C. One of the advantages associated with the use of a Limited Data Set is that it is not subject to the HIPAA requirements

of accounting for disclosure of Protected Health Information. Additionally, the Limited Data Set also allows the maintenance of a linked code, which permits re-identification of an individual in the future should the need arise. However, the investigator who is using the Limited Data Set cannot maintain the linked code. It must be maintained by a third party that is not involved in any way with the research or supervised by the researchers.

3.2 Public Data Sets

A. UA Little Rock IRB has established a list of publicly available data sets that are published on the UA Little Rock IRB webpage.

B. PIs may submit additional names to the list, by contacting the IRB Administrator.

C. When the data from these data sets are employed in research they do not require IRB review, as long as:

(1) The data sets appear on the UA Little Rock Inventory of Public Data Sets which is posted on the UA Little Rock IRB webpage; and

(2) None of the limitations listed under 2.3 D apply.

D. IRB review is required when:

(1) Investigators seek to merge or enhance data sets.

(2) If the investigator seeks to obtain additional data from the database owner.

(3) If submitting a proposal to obtain the use of a dataset is required.

(4) If a DUA is involved.

(5) Using restricted datasets.

See Appendix B for Revision History

RPP Policy 9.03	9.03 Medical Records	Updated 2022 May 15

1. Purpose

To describe the research use of medical records which contain Protected Health Information.

2. Definitions

2.1 Designated Record Set

The medical and billing records about individuals and records used to make decisions about individuals.

2.2 Authorized Investigators

Any faculty member, student, or staff member who is working with a person, having ethical/legal access to Protected Health Information materials in a non-research context, and who will assume responsibility for maintaining confidentiality safeguards and is approved per project.

2.3 Existing Medical Records

Medical records existing at the time of initial submission of the IRB application (e.g., date of the PI signature on the IRB application) and not when the IRB grants final approval and release of the study.

2.4 Non-Authorized Investigators

Person(s) who do not fall within the definition of an authorized investigator.

3. Policy

It is the IRB's policy to use and disclose Protected Health Information (PHI) in accordance with HIPAA requirements and HHS regulations 45 CFR §46.

3.1 Access to Medical Records

A. PHI may not be used or disclosed without an IRB approved informed consent form and HIPAA Authorization Form signed by the individual to whom the PHI pertains, or a waiver of the requirements for consent and HIPAA authorization has been approved by the IRB.

B. Only authorized investigators listed by name in the IRB application will have access to confidential records to be

used for research purposes where participant identifiers are present and

(1) The authorized investigator requesting access to PHI has received permission from the patient to allow, in accordance with an IRB-approved protocol or registry to: a) contact the patient directly for purposes of recruitment; b) access and use of PHI for research purposes; or c) include the PHI in a registry.

(a) The permission may be in writing, or if oral, permission is obtained and documented.

(b) Obtaining patient permission includes the following elements of disclosure:

(i) The PHI will be used for research purposes under an IRB approved protocol.

(ii) Allowing access to the PHI is voluntary.

(iii) The participant may revoke the authorization at any time.

(iv) Identify who will be accessing the patient's records.

(v) Provide a description of the condition or characteristics which are being screened.

(vi) Provide an expiration date or expiration event (e.g. "end of the research study", "none.")

C. Non-authorized investigators will have access to confidential records to be used for research purposes with IRB and covered entity approval *only* when the following conditions are met:

(1) Approval is obtained to use the records from the covered entity (e.g., medical records department); OR

(2) The investigator has obtained informed consent/HIPAA authorization from the participant; OR

(3) *All* Protected Health Information has been de-identified in accordance with HIPAA requirements.

D. In all cases, the non-authorized investigator must have received CITI training, especially in regard to confidentiality and privacy.

See Appendix B for Revision History

RPP Policy 9.04	9.04 Review of Protected Health Information in Preparation for Research	Updated 2022 May 15

1. Purpose

To describe the process of review of Protected Health Information in preparation for research.

2. Policy

It is the IRB's policy that the review of Protected Health Information in preparation for research will be conducted in full accordance with HHS regulations 45 CFR §46.

2.1 Investigator Review of Medical Records

HIPAA permits an investigator to review medical records containing Protected Health Information in preparation for a research project without obtaining an authorization or a waiver of consent from the IRB.

A. The investigator must file the appropriate request for access with the pertinent institution (e.g., UA Little Rock Student Health Center, local hospital or clinic). If the Protected Health Information is not contained within the medical record, the request should be filed with the IRB.

B. The investigator must certify:

(1) The review of Protected Health Information will be conducted solely to determine the feasibility of a research project or for similar purposes in preparation for research;

(2) The Protected Health Information may not be recorded, copied, or removed from the records repository in the course of review; and

(3) The Protected Health Information that is accessed is solely for research purposes.

(4) The PI certifies that no PHI will be removed from the covered entity during the review.

C. If an investigator intends to record any Protected Health Information for the express purpose of contacting prospective research participants, the appropriate IRB application and associated informed consent documents must be submitted and approved by the IRB *prior* to the review of the medical records.

2.2 Research Involving the Use of PHI

A. IRB applications will be processed and reviewed in accordance with RPP Policy 3.05 *IRB Review*.

B. Research involving PHI is not exempt if the investigator records the data in such a manner that participants can be identified either directly or through any of the 18 HIPAA identifiers linked to the participant. If participant identifiers must be temporarily maintained in order to permit the investigator to identify additional records for inclusion in the study, informed consent/authorization is required unless the IRB may grant a waiver of informed consent and waiver of Authorization in accordance with the following specific requirements of HIPAA and 45 CFR §46.116(f):

(1) Only the minimum amount of participant identifier data is recorded. Whenever possible, data should be recorded without PHI.

(2) The use or disclosure of Protected Health Information or data which is not Protected Health Information involves no more than minimal risk.

(3) The alteration or waiver of informed consent will not adversely affect the rights and welfare of the participants.

(4) The research cannot practicably be carried out without the alteration or waiver.

(5) There must be an adequate plan to protect participant identifiers from improper use and disclosure.

(6) There must be an adequate plan to destroy the identifiers associated with Protected Health Information at the earliest opportunity, unless there is a health or research justification for retaining the identifiers or retention is required by law.

(7) Whenever appropriate, the participants will be provided with additional pertinent information after participation.

(8) If identifiers are recorded for the purpose of selecting a prospective participant population and the investigator intends to subsequently solicit informed consent to participate in a prospective study, specific guidelines must be followed regarding initial contact with potential participants. Contact with potential participants should originate with an individual who has the appropriate professional relationship with the

potential participant (e.g., primary care physician, counselor, teacher, etc.). If an investigator does not have such a relationship, they should obtain assistance from someone who does. Once the appropriate professional has originated the contact, negotiation for informed consent can begin as with any other research protocol.

C. The PI must file a request for access with the pertinent institution

2.3 Participant Recruitment

A. The participant recruitment methods must be disclosed in the appropriate IRB applications.

B. Only individuals with permitted access, those who have an IRB-approved research protocol and require access to records containing PHI, are permitted to contact prospective participants directly for the purposes of recruitment providing the IRB has approved the contact method.

C. Only the person(s) who has permitted access may contact prospective participants on behalf of the investigator providing the IRB has approved the contact method (e.g., personal conversation, telephone, or letter).

D. All subject recruitment methods must be in compliance with RPP Policy 3.16 *Recruitment of Participants Through Advertisements*.

See Appendix B for Revision History

RPP Policy 9.05	9.05 Use of the Internet for Research Data Collection	Updated 2022 May 15

1. Purpose

To describe research involving the Internet for data collection and recruitment.

2. Definitions

2.1 Active Data Collection

Data collection through direct interaction or intervention with a participant via direct email, web surveys, or other electronic instruments. Active internet data collection typically involves the use of online surveys or questionnaires, and/or the experimental manipulation of an online environment as a stimulus to collect reactions or responses from participants.

2.2 Active Electronic Recruitment

Recruitment which involves tools such as email or other electronic solicitations (such as instant messaging or text messaging) to contact potential research participants).

2.3 Passive Data Collection

Data collection which involves observation without active intervention with or involvement of participants, and possibly without their knowledge (e.g. collecting data from Twitter feeds, Facebook profiles, blogs, online chat rooms/forums, etc.). Data mining, sorting through data to identify patterns and establish relationships, is a term that does not necessarily pertain only to internet research; however, research involving the observation and reporting of online behavior is sometimes called data mining.

2.4 Passive Electronic Recruitment

Recruitment which involves advertisements which are electronic versions of printed media advertisements. Some examples include advertisements on a website or a pop-up window ad which occurs when a potential participant visits a particular web site.

2.5 Publicly Available Information Online

Information considered available to the public through the internet includes:

A. Sites which have no restrictions on access to the information. These sites are ones in which the individual or social media/network site has not placed any restrictions on access to the information about themselves online (i.e., public Twitter feeds, publicly available profiles, blogs/chat rooms/forums that do not require an account to access, etc.).

B. Sites containing information that, by law, is considered public. In most cases, information from these sites will be available without restriction, although access to the information may require payment of a fee. Many federal, state, and local government sites are included in this category, i.e., property tax records, birth and death records, real estate transactions, certain court records, voter registration and voting history records, etc.

C. News, entertainment, classified, and other information-based sites where information is posted for the purpose of sharing with the public.

D. Open access data repositories, where information has been legally obtained (with IRB approval, if necessary) and is made available with minimal or no restriction.

E. Records as state agency reports, property tax assessments, marriage licenses, real estate transactions, voter registration, etc. are now searchable online. Internet tools and sites have made access to such public documents easier, but the essential nature of the data is still public. Publicly available documents include those that are:

(1) Available at no charge to anybody with a computer;

(2) Available to anybody willing to pay the requisite fee.

2.6 Restricted Access Information

Information with restricted access. In this case an individual has restricted access, in any way, to the data, or the social media/network/site has restrictive provisions in its terms of service. These restrictions establish an expectation of privacy.

3. Policy

The IRB must review all research activities, including participant recruitment, involving the use of the internet with the same considerations and standards for approval of research (45 CFR §46.111), for informed consent, and voluntary participation as all other research activities under the jurisdiction of the UA Little Rock IRB.

3.1 Types of Data Collection and Security

A. Active Data Collection

The internet is a non-secured medium, as data in transit is vulnerable. A potential source of risk is harm resulting from breach of confidentiality and is accentuated if the research involves data that places participants at risk of criminal or civil liability or could damage their financial standing, employability, insurability, or reputation.

The following applies to research that involves active internet data collection:

(1) An internet consent document should include all the elements of a regular signed consent, as appropriate. Investigators should consider requesting a Waiver of Documentation of Consent if they will not be able to obtain print or electronic signatures for online consent procedures. In these cases the consent line should include a statement to the effect of, "By completing the survey, you are agreeing to participate in the research." Web-based surveys should allow for a click button to agree or not agree. Online consent may not be appropriate for studies involving highly sensitive information.

(2) The investigator must describe the technology chosen for implementation of the research and justify that the plan is based upon the sensitivity of the research. For online platforms, investigators should ensure the platform is appropriate for collecting and storing research data. Such documentation should be provided to the IRB in the submission.

(3) An alternative means for completing a survey may be offered where appropriate (such as printing the survey and mailing it in).

(4) Survey instruments should be designed in a way that allows participants to skip questions or provide a response such as "I choose not to answer." If participants will not be allowed to skip questions, a justification should be provided in the submission.

(5) If the survey platform allows, at the end of a survey there should be one button to submit the data and another button to discard the data. The purpose of these buttons is to ensure that a participant may withdraw at any time and to help them understand that if they wish to withdraw, even after completing the survey, their data can be discarded prior to

transmission to the investigator. An alternative is to include instructions in the consent form that the participant can close the browser.

B. Passive Data Collection

(1) Research involving Publicly Available Information Online

If the individual or social media/network site has not placed any restrictions on access to the information about themselves online (i.e., public Twitter feeds, publicly available profiles, blogs/chat rooms/forums that do not require an account to access, etc.), investigators planning to collect this data:

(a) Must submit the research protocol to the UA Little Rock IRB to obtain a formal determination. This protocol should describe all sources and accessibility of the data to be obtained for the research. While it is possible that this research may be considered Not Human Participant Research, investigators should not make their own determinations in these cases, as this is an emerging field.

(b) Generally all data on an individual should be de-identified and only presented in aggregate including identifiers such as photos, usernames, and combinations that could readily identify an individual.

(i) In cases where the research requires that individuals be identified, investigators should include a justification in the protocol submitted to the IRB so that the IRB can make a decision on the impact to the participants.

(ii) Investigators should avoid any effort to discern the individuals' identity, and avoid accidental revelation of their identity.

(2) Research Involving Restricted Access Information/Observation of Online Communities

(a) If an individual has restricted access to the data in any way or if the social media/network site has restrictive provisions in its terms of service, an expectation of privacy has been

established and the investigator must seek IRB approval before conducting the research. Examples of such restrictions include:

(i) When the investigator has to request or seek access from the individual or from the group that the individual belongs to.

(ii) When the investigator has to belong to, be invited to, or invite others to a particular "interest" or "friend" group.

(iii) When the investigator seeks access when "role playing" or recruits individuals who have the restricted access.

(b) When the research involves the passive observation of online behavior that is restricted, the UA Little Rock IRB will make every effort to ensure the protection of human participants who participate in online communities (such as cancer support groups, etc.) and do not intend or agree (in advance) for their online discussions to be used for research purposes. The following practices should be followed:

(i) Recognize that access to a support groups' conversation online does not give the investigator an automatic right to conduct research on that conversation. Technology alone (access) cannot be used as a legitimate justification for use of the information as if it were intended to be public if the users perceive their interactions are private. Investigators should consider whether their research would be conducted the same way if they were observing the same interactions in-person.

(ii) Recognize that permissions should be obtained from the list/group/community manager, and an announcement should be made to the list/group/community that an observation is taking place for research purposes, (after IRB approval and PRIOR to collecting ANY research data). If permission will NOT be

obtained, a justification should be provided in the submission. It is not acceptable to use the justification that knowledge of the investigator's presence will affect the behavior because most online groups allow persons to join and not participate.

(iii) Obtain informed consent unless a waiver of consent is approved by the UA Little Rock IRB.

(iv) Informed consent/permissions will not be waived by the IRB due to concerns that permissions would not be granted by the community. However, it may be appropriate for the investigator to request a waiver of signed/documented informed consent.

1. Procedures must be in place to verify that research participants are adults, unless the study is specifically approved to enroll children.

2. If the community disclosed to the members that the online forum or discussion group may be part of a research project, the IRB may still require additional permissions and/or informed consent (depending on the sensitivity of the research/discussion, clarity of such prior disclosure, and confidentiality of participants).

3.2 Informed Consent for Internet-Based Research

A. Surveys

(1) Active Consent

Internet-based surveys could include "I agree" or "I do not agree" buttons with which participants would indicate their active choice of whether or not they consent to participate. In some cases, it may be appropriate to provide participants with informed consent information, and inform them that submitting the completed survey implies their consent.

(2) Documentation of Consent

If the UA Little Rock IRB determines that documented consent is required, the investigator may email the consent form to participants who may then type their name and the date into the spaces provided on the consent form, and return it to the investigator via email.

B. Confidentiality

Investigators conducting web-based research should be careful not to make guarantees of confidentiality or anonymity, as the security of online transmissions may not be guaranteed.

C. High-Risk Studies

Online consent may not be suitable for high-risk studies where the research involves data that:

(1) places participants at risk of criminal or civil liability, or

(2) could damage their financial standing, employability, insurability, reputation, or

(3) could be stigmatizing.

3.3 Data Collection and Security

All data must be protected as it moves along the communication pathways (e.g., from the participant to the server, from the server to the investigator). Additionally, all databases storing identifiable information or data must be protected regardless of the source creating the data (e.g., encryption of the database, de-identifying the data).

A. Data Collection, Transmission, and Storage

(1) The IRB must review and approve the method and procedures for data collection and security.

(2) Investigators must provide information regarding the transmission and storage of the data.

(3) When an investigator chooses to have a separate server for data collection or storage, the IRB must review and approve its administration.

(4) The level of security should be appropriate to the risk. Research involving sensitive topics may require additional protections such as certified digital signatures for informed consent, encryption of data transmission, or technical separation of identifiers and data.

3.4 Participant Recruitment Using the Internet

A. The UA Little Rock IRB must review and approve all recruitment materials posted on the internet, e.g. through a website, a banner advertisement, an email solicitation or direct message.

B. Computer- and internet-based procedures for advertising and recruiting potential study participants (e.g., internet advertising, e-mail solicitation, banner ads, text messages, instant messages) must follow the IRB guidelines for recruitment (See RPP Policy 3.16 *Recruitment of Participants Through Advertisements*).

C. Active recruitment methods require documentation of the source of the list of participant contact information and documented permission of the list owner if private or restricted.

(1) Recipients of electronic invitations to research (depending upon the nature of the research) may need to be informed of how their electronic address was obtained and any permission obtained prior to the contact.

(2) If the research involves a sensitive topic or issues of confidentiality, the use of an email address or other electronic address may be denied by the IRB due to risks to privacy and confidentiality.

3.5 Additional Considerations for Internet Research Involving Children/Minors

A. Investigators working with children online are subject to the Children's Online Privacy Protection Act (COPPA) in addition to human participant regulations. In addition, investigators must not collect personal information from a minor without verifiable parental consent or a waiver thereof. As appropriate, technology may be used to help screen out minors, such as software that checks for Internet Monitoring software or Adult Check systems.

See Appendix B or Revision History

Section 10

Continuing Review

RPP Policy 10.01	10.01 Continuing Review	Updated 2022 May 15

1. Purpose

To describe the IRB's process for conducting continuing review.

2. Policy

It is the IRB's policy that continuing review will generally be conducted in accordance with HHS regulations 45 CFR §46.109(e) and (f)(1) as applicable.

2.1 Continuing Review

The approval period for all protocols is one year. Protocols must be renewed employing a "Request for Continuation" form.

A. In order for a study to continue without interruption, the IRB must re-review and approve the protocol *prior* to the IRB approval expiration date.

(1) If an investigator does not provide continuing review information to the IRB, or the IRB has not approved the protocol by the expiration date, the investigator must stop all research activities, including recruitment, enrollment, interventions, interactions, and collection of private identifiable data, and stop all interventions and interactions on current participants,

(2) If the IRB finds an overriding safety concern or ethical issue that pertains to the best interests of participants, the IRB may allow the research activity to continue.

B. Continuing Review must occur until:

(1) Enrollment of new participants is permanently closed; and

(2) All participants have completed all research-related interventions.

(3) The research only remains active for long-term follow-up of participants.

2.2 Risk Level

A. All human participant studies are subject to continuing review based on the level of risk as assessed by the IRB.

(1) Projects that were initially reviewed by the full board may continue to receive full board review. The type of review will be determined at the time of renewal.

2.3 Continuing Review Submission Requirements

A. It is the PI's responsibility to submit the IRB Request for Continuation, which must include copies of all consent and assent forms being currently used and any changes in consent and assent forms for the future in sufficient time to allow the IRB to complete a substantive and meaningful review of the research and to provide the PI with a timely, written response prior to the expiration date.

(1) Generally, sufficient time for a substantial and meaningful review requires at least 45 calendar days.

B. If the designated IRB reviewers determine that a project requires review more often, the investigator will be so notified at the time of initial review and/or at the time of continuing review. Factors which determine the frequency of continuing review are described in RPP Policy 3.10 *Assessing the Need for Interim Continuing Review, Monitoring and Verification for Sources Other than the Investigator*.

2.4 Pre-Screen

A. The IRB Administrator is responsible for pre-screening of all protocols undergoing continuing review. At any time, the IRB Administrator may seek guidance from the IRB Chair during the pre-review process.

(1) The protocol file is pulled and IRB number, title(s) and study personnel list are checked for accuracy, and training for personnel is verified.

(2) The current Request for Continuation will be compared with the initial application and any previous requests for continuing review as well as other documents found in the IRB file.

(3) The primary and secondary reviewers are provided with the complete application.

(4) The copy of the most recent consent and/or assent documents will be reviewed.

(a) The consent and/or assent documents will be closely checked to determine if any changes have been made to the document without an accompanying Request for Modification form.

B. Discrepancies or omissions in the Request for Continuation will result in an email to the PI and/or study coordinator requesting clarification and/or correction to appropriate forms.

(1) If the problems in the application are of such magnitude that IRB review is not possible, the full application and supporting documents will be sent back to the PI for revision and resubmission.

C. In situations of suspected non-compliance, the PI will be notified. A complete review of the IRB study file will be performed by the IRB Administrator and the IRB Chair to determine what further action should be taken in accordance with RPP Policy 12.02 *Non-Compliance*.

D. For Full Board continuing reviews, copies of all correspondence (emails or letters) resulting from the pre-review process will be forwarded to all IRB members.

2.5 Full Board Review Procedure

A. If the research initially required Full Board approval, the Request for Continuation must also be approved by the Full Board, unless the project qualifies for expedited review at the time of continuing review under categories 8(b) or 9 of the approved Expedited category list at 45 §46.110. The IRB retains the authority to determine whether continuing review is required in the future.

Required Full Board reviews are distinct from instances where the IRB *chose* to bring the protocol to Full Board.

B. Requests for Continuing Review are scheduled for Full Board consideration at the monthly IRB meeting. Each attending member will receive and review, in advance, all requests for continuing review and associated consent/assent documents to be considered at the meeting and a complete copy of the protocol file.

C. The primary reviewer will present to the Full Board the results of their review, and any remaining concerns will be discussed by the members who are also expected to have reviewed the application and the consent/assent documents. Each protocol will be voted on separately in accordance with IRB policy (see RPP Policy 2.11 *IRB Quorum and Voting Requirements*).

D. The IRB will determine the need for increased monitoring or whether more frequent continuing review is required in accordance with RPP Policy 3.10 *Assessing the Need for Interim Continuing Review, Monitoring and Verification for Sources Other than the Investigator*.

E. Approval periods cannot exceed one year from the date of the initial continuing approval letter.

2.6 IRB Actions

A. Re-approval

No modifications or clarifications are required. All of the criteria for IRB approval previously outlined in HHS regulations 45 CFR §46.111 are satisfied.

(1) The investigator will be notified of the re-approval in writing and is authorized to continue the study.

B. Revisions Required

Clarification(s) or information concerning the protocol is necessary for completion of the record.

(1) The investigator will be notified of the requested changes in writing and asked to make the necessary modifications and return the materials before approval can be granted.

(2) Failure to respond to the IRB continuing review clarification letter within *30 calendar days* may result in revocation of approval of the study. In such a case, all research-related activities must immediately cease.

(a) If in such cases the IRB determines it is in the best interests of the participants the IRB may allow the research activity to continue.

C. Referred for further review by the Full Board

This action is taken when the IRB has identified significant concerns related to participant safety and/or conduct of the study.

(1) All research-related activities must immediately cease, unless an exception is granted by the IRB in consideration of a written request.

(2) The IRB must receive a satisfactory response from the PI regarding any necessary modifications and/or clarifications of the protocol and/or consent document(s) within *30 calendar days*.

(a) Failure to respond to the IRB continuing review letter within the designated time period may result in termination of the study.

D. Refusal to Complete Review

This category is restricted to applications which are deficient and preclude the IRB from performing a substantive and meaningful review.

(1) The investigator will be notified in writing to revise the request n in accordance with IRB requirements. During the remaining IRB approval period, the investigator is authorized to continue the research.

(2) If the PI fails to respond within the remaining IRB approval period, the protocol will be classified as "approval expired."

(a) If IRB approval expires, all research-related activities must immediately cease, unless an exception is granted by the IRB in consideration of a written request.

E. Disapproved

The IRB will "Disapprove" a protocol where there is a serious concern regarding participant safety and/or compliance. The protocol will be suspended or possibly terminated, and a report submitted to OHRP in accordance with RPP Policy 12.03 *Reporting Incidents to OHRP or Department and Agency Heads*.

(1) No new participants can be enrolled. All research-related activities must cease and the Full Board will make a determination if currently enrolled participants may continue participation in the study. The Research Integrity Officer (RIO) will be notified.

2.7 IRB Reapproval Notification

A. Upon IRB reapproval of a research project, the PI will be sent a letter of re- approval. The letter will provide a summary of investigator responsibilities and also will remind investigators that changes in research activity may not be initiated without IRB review and approval.

B. The reapproved consent/assent forms should be kept on file as master copies.

C. Initial and amended informed consent documents signed by the participant remain in effect for the duration of participation in the study.

(1) Previously enrolled participants are *not* required to be reconsented following continuing review, *unless* the IRB approves a change during the continuing review process which requires re-consent of

participants (e.g., participant notification of new risks or changes in protocol).

2.8 IRB Approval Termination

A. If a PI fails to submit the IRB Request for Continuation or respond to the IRB review letter in sufficient time, the protocol will be classified as "IRB approval terminated."

2.9 Ten-Year Protocol Requirements

A. All non-exempt research that reaches a 10-year approval period, with plans of future participant enrollment and data collection, will be required to submit a new project form. This will ensure that the research remains approved under current federal and institutional policies. Investigators will need to submit a new project for review and approval prior to the expiration date. If the new project cannot be approved prior to the 10-year expiration date, investigators must submit a continuing review form to keep the existing project open. These projects can be reapproved for a 90-day period to allow time for approval of the new project. The next update required date cannot be extended without continuing review approval by the expiration date, as applicable.

B. Projects that reach a 10-year approval period with only plans of identifiable data analysis may be permitted to submit additional continuing review forms to maintain IRB approval.

See Appendix B for Revision History

RPP Policy 10.02	10.02 Suspension and Termination	Updated 2022 May 15

1. Purpose

To describe the conditions under which suspension and termination apply and the process thereof.

2. Definitions

2.1 Suspension of Approval

A. Suspension of IRB approval is a directive of the IRB or the IRB Chair to either temporarily or permanently stop some, or all, previously approved research activities due to safety or noncompliance concerns. Suspended protocols remain open and require continuing review.

2.2 Termination of Approval

A. Termination of IRB approval is a directive of the IRB to stop permanently all activities in one or more previously approved research protocols because the research can no longer be conducted safely or the PI has not conducted the research in full compliance with the applicable federal regulations and RPP policies.

B. Terminated protocols are considered closed, and no longer require continuing review.

2.3 Institution Directed Termination of IRB Approval

A. The Institutional Official (IO) can issue a directive in writing that IRB approval of research be terminated.

3. Policy

It is the IRB's policy that suspension or termination of IRB approval of research will generally be conducted in accordance with HHS regulations 45 CFR §46.113. The IRB has the authority to suspend or terminate IRB approval of research that: is not being conducted in accordance with IRB requirements or has been associated with unexpected serious harm to participants and to implement institutional directed suspension or termination of IRB approval of research.

4. Procedures for Suspension or Termination of IRB Approval

4.1 Procedures for Suspension of IRB Approval

A. The IRB Chair in consultation with the IRB Administrator may suspend research to ensure protection of the rights and welfare of participants.

B. Suspension directives made by the IRB Chair must be reviewed at a meeting of the IRB. The IRB will be convened as soon as possible and may decide to suspend or terminate the research.

C. The IRB shall take appropriate action(s) as necessary to protect the right and welfare of currently enrolled participants in accordance with Section 4.4 of this policy.

D. Any suspension of IRB approval will include a written statement of the reasons for the IRB's action and will be reported promptly to the investigator and IO.

E. The PI must:

(1) report to the IRB any adverse events or outcomes associated with the suspension.

(2) notify research participants currently in the study of suspension of IRB approval of research activities. Participants should be advised of any follow-up necessary for safety reasons. The IRB reserves the right to contact participants regarding suspension of IRB approval when the PI is unable or if the IRB deems it is necessary, or inappropriate for the PI to do so.

F. The IRB shall give the PI an opportunity to appeal the suspension in writing or in a meeting if so requested. Appeals will follow the process outlined in RPP Policy 12.02 *Non-Compliance*, Section 4.6(E).

G. The IRB has the final authority to act on any appeals, and the decision of the IRB cannot be overturned.

H. The convened IRB must approve the release of a study suspension.

4.2 Procedures for Termination of IRB Approval

A. The convened IRB may terminate IRB approval of research if such action is warranted in accordance with Section 3 of this policy.

B. The convened IRB will:

(1) take appropriate action(s) as necessary to protect the rights and welfare of currently enrolled participants in accordance with Section 4.4 of this policy.

(2) afford the PI due process.

(3) include a written statement of the reasons for the IRB's action and promptly notify the PI.

(4) promptly notify the IO of the termination of IRB approval of research

(5) notify other officials at the Institution, as appropriate, of the termination of IRB approval of the research.

C. The PI must:

(1) report to the IRB any adverse events or outcomes associated with the termination;

(2) notify research participants of termination of IRB approval of research. Participants must be advised of any follow-up necessary for safety reasons (i.e., arrange for appropriate medical care off study). No individual, however, can be compelled to participate in follow-up;

D. The IRB reserves the right to contact participants regarding termination of IRB approval when the PI is unable or if the IRB deems it is necessary, or inappropriate for the PI to do so.

E. The IRB shall give the PI an opportunity to appeal the termination in writing or in a meeting if so requested. Appeals will follow the process outlined in RPP Policy 12.02 *Non-Compliance*, Section 4.6(E).

F. The IRB has the final authority to act on any appeals and the decision of the IRB cannot be overturned.

4.3 Procedures for Institution Directed Termination of IRB Approval

A. The IO may terminate IRB approval of any, or all of a PI's research protocols in consultation with the IRB Chair, and/or appropriate administrative officials within the organization.

B. Notification

(1) The IO shall notify the PI, and other institutional officials as appropriate, in writing that the research has been terminated and the reasons(s) for such action.

(2) The IRB Chair shall provide notification of termination to the IRB.

(3) The PI must report to the IRB any adverse events or outcomes associated with the termination.

(4) The PI must notify research participants of the institution directed termination of the research. Participants must be advised of any follow-up

necessary for safety reasons. No individual, however, can be compelled to participate in follow-up.

(5) The IRB reserves the right to contact participants regarding termination of IRB approval when the PI is unable or if the IRB deems it is necessary, or inappropriate for the PI to do so.

C. Appeal

(1) The PI may file a written appeal with the IO within 10 business days of receipt of the institution directed termination.

(2) The IO has full authority to act on the appeal and may convene an ad hoc committee to make a recommendation regarding appropriate action.

(3) The PI will be afforded due process and is entitled to meet with the IO and/or the ad hoc committee. The PI may bring legal counsel who will be restricted to observation only. If the PI wishes to bring legal counsel, the PI shall give at least 2 business days advance written notice in order to ensure UA Little Rock General Counsel can be notified and present on behalf of the Institution.

(4) The decision of the IO with regard to appeal of an institution directed termination is final.

4.4 Actions to Protect Participants

A. One or more of the following actions, as appropriate, will be taken in order to protect the rights and welfare of participants when research is suspended or terminated. In some cases, actions may require participant approval.

(1) Arrange for appropriate medical care off study.

(2) Transfer the participants to another investigator

(3) Continue the research under independent monitoring.

(4) Inform current participants of the suspension or termination.

(5) Inform former participants of the suspension or termination.

(6) Require amendment of the protocol.

(7) Require implementation of a corrective action plan.

(8) Require or permit follow-up of participants for safety reasons.

(9) Suspend or terminate the PI's protocol.

(10) Suspend or terminate some or all of the PI's protocols where similar participant safety risks have been identified or may be reasonably expected.

(11) Suspend or terminate other investigators' protocols where similar participant safety risks have been identified or may be reasonably expected.

(12) Other actions as necessary.

5. Reporting Suspensions and Terminations to OHRP, Department or Agency Heads

All applicable incidents will be promptly reported to OHRP and relevant Department or Agency heads per RPP Policy 12.03 *Reporting Incidents to OHRP or Department and Agency Heads*.

See Appendix B for Revision History

Section 11

Amendments to Approved Protocols

RPP Policy 11.01	11.01 Request for Modification	Updated 2022 May 15

1. Purpose

To describe the process for requesting modification to an approved protocol.

2. Definitions

The following definitions of changes include, but are not limited to, the examples listed.

2.1 Informational Changes

A. have no potential impact on the risks for research participants, and/or

B. clarify or provide only editorial updates to the protocol, informed consent form, or supporting documents.

C. Examples include:

(1) Changes in researcher contact information

(2) Deletion of study personnel

(3) Correction of typographical errors

(4) Minor administrative changes in the protocol by the sponsor

(5) Revision of wording that does not change content or meaning, but adds to the understandability/clarity of information provided to the participant

(6) Addition of study sites

2.2 Minor Changes

A. Minor changes may impact the research participant, but do not significantly affect the risks to the participant.

B. Examples include:

(1) Addition of study personnel

(2) Addition of investigative or performance site(s) involving no major changes to the protocol and/or the informed consent document. (See Section 2.3 of this policy for a description of major changes.)

(3) Addition/deletion of questionnaires or questionnaire items which are consistent with those previously approved and do not change the consent process.

(4) Deletion of interventions

(5) Addition/deletion of study procedures which are consistent with those previously approved.

(6) Minor change in eligibility requirements. For example, increasing the age range in an adult population between the ages of 19-65 years by 5 to 10 years.

(7) Change in follow-up schedules

(8) Revisions to the consent form which are not substantive in nature.

(9) Additional communication to participants that do not present a significant concern such as adding a follow-up contact.

(10) Decrease in compensation

(11) Increase in compensation that will not affect the voluntary nature of the project based on the population and potential increase in coercion.

2.3 Major Changes

Major changes are classified as minimal risk revisions or major risk revisions.

A. Minimal risk revision means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

B. Major risk revisions involve more than minimal risks to research participants. These changes reflect a major-risk change in the direction of the study that may substantially change the purpose or goals of the study.

C. Examples include:

(1) Addition of investigative or performance site(s) in conjunction with one of the major changes listed below or similar changes.

(2) Adding a substance which may be intended for participant ingestion, changing dosages, or frequency of administration

(3) Addition of a study phase. For example, the project includes pre- and post-phases and a three-month follow-up will be added.

(4) Changing the treatment

(5) Revising edibility requirements. For example, including a vulnerable population that is not consistent with those previously approved.

(6) Addition of study procedures that are not consistent with those previously approved. For example, moving from paper and pencil survey administration to online survey administration would generally be seen as a major change.

(7) Addition/deletion of questionnaires or questionnaire items which are not consistent with those previously approved. For example, a study asks about educational goals and motivation, but the researcher now wants to include data about impacts of sexual activity on education.

(8) Addition or increase in compensation that will affect the voluntary nature of the project based on the population and potential increase in coercion.

(9) Substantive revisions to the informed consent forms, which would likely incorporate changes 1-8 above.

3. Policy

It is the IRB's policy that review of all requests for modifications in approved protocols will be conducted in full accordance with HHS regulations 45 CFR §46.

3.1 Proposed revisions

A. Any proposed revision that substantively deviates from the original purpose and objectives of the project must be submitted as a new protocol.

B. Any proposed change in a protocol which affects the human participants must be reviewed and approved by the IRB prior to implementation, except when:

(1) An immediate change is necessary to eliminate a risk to the participants or

(2) Providing participants with:

(a) New information on AEs, or

(b) Research results considered essential to a participant's decision whether to continue participating.

3.2 Submission Requirements

A. Investigators must submit:

(1) IRB Request for Modification in Protocol form.

(2) Complete description of the changes requested.

(3) Revised consent/assent document(s) (as appropriate).

(a) The IRB files must contain a complete and accurate description of the research. Therefore, changes indicated in the Request for Modification in Protocol must be described clearly.

(b) Re-consent of current participants is dependent upon the nature of the change. Informational changes, such as revising the telephone number or correcting typographical errors, normally do not require re-consent.

(i) Minor changes may require re-consent of current participants depending on the nature of the change. The PI must provide a plan, as necessary, for notification of current participants. Re-consent of current participants is normally required for major changes, such as changing the treatment or revising eligibility requirements.

(ii) For significant changes, re-consent of current participants utilizing the revised IRB-approved consent document or addendum is required. A witness is required during the re-consent process. The revised consent document that will be used to consent new participants and to re-consent current participants must be submitted for review as part of the change request.

3.3 Change to Eliminate Immediate Risk Prior to IRB Approval

A. If a change is initiated without any IRB approval in order to eliminate immediate risks to the participants or to provide essential information to the participants, the IRB must be notified, and the Request for Modification filed, as soon as possible, but no later than 2 business days from the time the change was initiated.

B. The investigator is authorized to implement changes without IRB approval in order to eliminate apparent immediate risks to participants.

3.4 IRB Review

A. If the Request for Modification requires immediate implementation, the IRB Administrator will notify the IRB

Chair. The IRB Chair will determine if there is significant risk to the participant(s), which requires immediate implementation of the amendment. In the event that an immediate approval for the Request for Modification occurs, the IRB will be notified of the action at the next meeting. At that time, the IRB will review the Request for Modification and may:

(1) Formally approve the action taken by the IRB Chair; and/or

(2) Determine that additional information or modifications are necessary to decrease risk to the participants.

B. The criteria for reviewing and approving a modification are the same as those for the initial review (See RPP Policy 3.04 *Criteria for IRB Approval of Research*).

C. For Requests for Modification which did not require a review by the convened board, two or more IRB reviewers are provided all submitted materials for the review of modifications to research previously approved by the IRB. It is expected that the reviewers will perform an in-depth review of all pertinent documentation and make a decision about whether to approve the modification or refer it to the convened board.

D. When a modification is approved there is no extension of the original approval date.

E. When the original protocol required approval by the convened board the level of review is determined by whether the changes are minor or major.

(1) Minor Changes

For research initially required to be approved by the convened board, minor changes will undergo a pre-review conducted by the IRB Administrator. Once the IRB Administrator has determined that the change request is complete, the request will be submitted to the IRB Chair, who will serve as the designated reviewer under 45 CFR §46.110(b)(1)(ii). A second reviewer will also be assigned. The reviewers may request additional revisions prior to approval of the change. The designated reviewers have the authority to request that the revisions be reviewed by the convened IRB if the revisions affect the risk level of the research.

(2) Major Changes

For research initially approved by the convened board, major changes will undergo a pre-review conducted by the IRB Administrator. Once the IRB Administrator has determined that the change request is complete, the request will be submitted to the next scheduled convened IRB meeting. Two reviewers will be assigned the request and will perform an in-depth review of all pertinent documentation. All other IRB members will review all provided materials in enough depth to discuss the information at the convened meeting.

(3) The full committee will review the change request. The IRB may request additional revisions prior to approval of the change request. If the changes affect the original scope of the research, a new protocol may be requested. Depending on the nature of revisions, the IRB has the authority to disapprove the requested changes.

See Appendix B for Revision History

Section 12

Unanticipated Problems and Adverse Events

RPP Policy 12.01	12.01 Unanticipated Problems Involving Risk and Adverse Events	Updated 2022 May 15

1. Purpose

To describe the procedure to ensure prompt reporting to the IRB, appropriate IOs, sponsor, coordinating center, and the appropriate regulatory agencies of unanticipated problems involving risks to participants or others and adverse events as applicable.

2. Definition

2.1 An Unanticipated Problem Involving Risk to Participants or Others

Any event (incident, experience, or outcome) which meets all of the criteria specified below (unexpected, serious, and related or possibly related):

(1) It is unexpected in terms of nature, severity, or frequency considering:

(a) the nature of the research,

(b) the characteristics of the participant population, and

(c) the information contained in the protocol, protocol-related documents, and the informed consent form.

(2) It suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously know or recognized.

(3) It is related or possibly related to participation in the research or procedures involved in the research. This means there is a reasonable possibility based upon available information that the event may have been caused by procedures involved in the research

2.2 Adverse Events

Any untoward or unfavorable occurrence in a participant (e.g. physical or psychological, social, legal, or economic harm) temporally associated with participation in the research (whether or not related to participation in the research). This means that the adverse event (AE) may be expected or unexpected, and related or unrelated to participation in the research.

3. Policy

It is the IRB's policy to comply with HHS regulations 45 CFR §46.108(a)(4)(i) and to have policies and procedures that ensure reporting of any unanticipated problems involving risk to participants or others to the IRB, regulatory agencies, and IOs.

3.1 Examples of problems which must be reported to the IRB within 2 business days include, but are not limited to:

A. Any physical, psychological, social, legal, or economic harm experienced by a participant, which in the opinion of the PI is both unexpected and related to the research procedure;

(1) Harm is "unexpected" when its nature or severity are not accurately reflected in the consent document.

(2) Harm is "related to the research procedures" if, in the opinion of the PI, it is more likely than not:

(a) To be caused by the research procedures, or

(b) The event affects the rights and welfare of current participants.

B. Information that indicates a change to the risks or potential benefits of the research for example;

(1) An interim analysis or safety monitoring report indicates that the frequency or magnitude of harms or benefits might be different from those initially presented to the IRB.

(2) A paper is published from another study that shows that the risks or potential benefits of the research might be different from those initially presented to the IRB.

C. Adverse or other events that meet the criteria in 2.1.

D. External events that are determined to be unanticipated problems (i.e., by another IRB for a multicenter study).

E. Breach of confidentiality;

F. Change to the protocol taken without prior IRB review to eliminate an apparent immediate risk to a research participant;

G. Incarceration of a participant in a protocol not approved to enroll prisoners;

H. An event that requires reporting to the sponsor;

I. Sponsor-imposed suspension;

J. Complaint of a participant; or

K. Protocol deviation.

3.2 IRB review of reported problems.

A. In the case of a reported problem, the IRB Administrator advises the IRB Chair, and they review the problem reports and determine whether each is an unanticipated problem involving risks to participants or others. If the report is an unanticipated problem involving risks to participants or others, it is referred to the IRB for review.

(1) The IRB will also consider whether each report involves noncompliance. If so, the noncompliance policy is followed.

(2) The IRB may determine that an event has multiple classifications. For example, a protocol violation may be classified as both an unanticipated problem involving risks to participants or others and noncompliance.

(3) If the IRB determines that the report is neither an unanticipated problem involving risks to participants or others nor noncompliance, it is filed and no further action is taken. The IRB determination is documented in the minutes.

B. The IRB will take all actions necessary to protect human participants, including suspension or termination of the study (See RPP Policy 10.02 *Suspension and Termination*).

C. If referred for IRB review, reviewers are assigned to review the Adverse Event form. Members receive the following for in-depth review:

(1) The Adverse Event form and all submitted supporting materials,

(2) The current consent form, and

(3) All materials necessary to reach a determination

D. The IRB discusses and votes on whether the event or problem represents an unanticipated problem involving risks to participants or others as defined above. If the IRB determines that the event or problem represents an unanticipated problem involving risks to participants or others, a serious adverse event, or a protocol violation, RPP Policies 12.03 *Reporting Incidents to OHRP or Department and Agency Heads* and/or 12.02 *Noncompliance* will be followed.

E. The IRB may choose from the following actions on all reportable events or problems:

(1) No action,

(2) Modification of the research protocol,

(3) Modification of the information disclosed during the consent process,

(4) Additional information provided to past participants,

(5) Notification of current participants (required when such information may relate to participants' willingness to continue to take part in the research),

(6) Requirement that current participants re-consent to participation,

(7) Modification of the continuing review schedule,

(8) Monitoring of the research,

(9) Monitoring of the consent,

(10) Suspension of the research,

(11) Termination of the research,

(12) Requiring additional training for the PI/study team regarding human participants protections,

(13) Collection of additional information pending a final decision, and

(14) Referral to other organizational entities (e.g., legal counsel, risk management).

4. Reporting to Institutional Officials, OHRP, Department or Agency Heads, and Sponsors

A. All required reports will be submitted in accordance with RPP 12.03 *Reporting Incidents to OHRP or Department and Agency Heads*.

See Appendix B for Revision History

RPP Policy 12.02	12.02 Noncompliance	Updated 2022 May 15

1. Purpose

To: 1) define noncompliance, 2) describe categories of noncompliance, 3) describe procedures for reporting noncompliance to the IRB, 4) address IRB actions, and 5) outline procedures for reporting noncompliance to OHRP and Department or Agency heads.

2. Definitions

2.1 Noncompliance

The failure to comply with any HHS regulations, IRB requirements, and/or applicable local, state, or federal law. Noncompliance may be assessed as nonserious, serious, or continuing or a combination of these. Noncompliance may also constitute an unanticipated problem involving risks to participants or others as defined in RPP 12.01 *Unanticipated Problems Involving Risk and Adverse Events*.

2.2 Nonserious noncompliance

An incident that does not satisfy the definition of serious noncompliance in Section 2.4 of this policy.

2.3 Incident of noncompliance

A finding of noncompliance.

2.4 Serious noncompliance

Failure to comply with HHS regulations and/or IRB requirements, which in the judgment of the IRB, places human participants at elevated or unacceptable risk, decreases potential benefits to participants, jeopardizes the safety, welfare, or rights of research participants or others, compromises the integrity of the RPP, or compromises a research participant's ability to render informed consent.

2.5 Continuing noncompliance

A pattern of noncompliance that, in the judgment of the IRB, suggests a likelihood that instances of noncompliance will continue without intervention. "Continuing noncompliance" also includes failure to respond to a request to resolve an episode of noncompliance. "Continuing noncompliance" includes:

A. Multiple incidents of noncompliance in a 12-month period occurring in any one research protocol. The incidents of noncompliance may involve one specific issue or different issues.

B. Multiple incidents of serious or nonserious noncompliance in a 12-month period carried out by the same individual in multiple research protocols. The incidents of noncompliance may involve one specific issue or different issues.

Classification of noncompliance as "continuing" will depend upon the circumstances. The IRB reserves the right to judge noncompliance as continuing in circumstances that do not meet the above definition.

2.6 Allegation of noncompliance

An unproven assertion of noncompliance.

3. Policy

All members of the University community involved in human participant research are expected to comply with the ethical standards of professional conduct in accordance with federal and state regulations and UA Little Rock IRB policies governing the conduct of research involving human participants. Therefore, it is the IRB's policy that investigators and research staff must immediately report to the IRB Administrator, IRB Chair or any IRB member any allegations or incidents of noncompliance.

All allegations or incidents of noncompliance will be promptly investigated in order to ensure ongoing adequate protection of the rights and welfare of research participants. Confidentiality will be preserved and due process observed.

Serious or continuing noncompliance and suspensions or terminations of IRB approval will be promptly reported to OHRP and Department or Agency heads or other relevant parties when required by applicable regulations. (See RPP Policies 10.02 *Suspension and Termination* and 12.03 *Reporting Incidents to OHRP or Department and Agency Heads*).

4. Procedures for Reporting Allegations or Incidents of Noncompliance

4.1 Investigators and research staff must report all allegations or incidents of noncompliance *immediately* to the IRB Administrator, IRB Chair, or any IRB member.

4.2 The IRB Administrator will document receipt of an allegation of noncompliance in writing.

4.3 Whistleblowers will be offered all protections they are entitled to by Federal law under the Inspector General Act of 1978. UA Little Rock does not tolerate retaliation against individuals who come forward in good faith with allegations of noncompliance. Retaliation will be immediately reported to the IO.

4.4 Response to an Allegation of Noncompliance

A. The IRB Administrator, in consultation with the IRB Chair, will draft a letter informing the PI of the allegation and the immediate subsequent actions to be taken by the PI. These may include:

(1) Ceasing and desisting further recruitment of participants

(2) Ceasing and desisting from any research-related activities.

B. The letter will be delivered to the PI within 3 business days of receipt of the allegation.

(1) The letter will be sent to the official university email of the PI with a request for acknowledgment of receipt within 3 business days.

(2) If the acknowledgment of receipt is not received within 3 business days, the letter will be delivered through email a second time. See Section 4.4 D (2) for the process if no acknowledgement is received.

(3) The IRB Administrator will document the date and time of all transmissions of the letter and keep a copy of the email(s), letter, and acknowledgment (or lack thereof) including date and time stamps.

C. If deemed appropriate, the IRB Chair will engage in the following actions:

(1) Notify the IO.

(2) In consultation with the IO the following actions will be considered if appropriate:

(a) UA Little Rock IT Services will be notified in order to preserve any data.

(b) If the protocol in question receives funding of any sort, ORSP will be notified to suspend funds associated with said (and only said) protocol or grant.

(3) The IO will then determine who else needs to be advised of the allegation and whether any of the above listed steps will be implemented.

(4) If either of the above steps is implemented, the IRB will be apprised of the allegation and notified that these steps have been taken. This will be conveyed through the IRB's electronically secure system.

D. As soon as possible, but no later than 8 business days after the acknowledgment of receipt of the allegation letter, the IRB Chair and the IRB Administrator will evaluate the information collected from the person reporting an allegation of noncompliance and from the PI to determine whether it has merit.

(1) If the IRB Chair and IRB Administrator are unable to conduct the preliminary investigation independently, others may be requested to assist, or an audit team may be appointed.

(2) If the PI has not responded to any IRB Administrator and IRB communications, the IO will be consulted on how to proceed.

E. If the IRB Chair, in consultation with the IRB Administrator, determines that the allegation of noncompliance has no basis in fact, this determination is communicated to the PI, and other involved individuals as appropriate, and no other action is taken.

F. If the IRB Chair, in consultation with the IRB Administrator, determines that the allegation of noncompliance has merit, it is handled as an incident of noncompliance.

4.5 Procedure for Handling an Incident of Noncompliance that has Merit

A. If the allegation has been found to have merit, the IRB Chair will verbally notify the IO immediately. The IO will then determine who else needs to be advised of the allegation.

B. The IRB Chair, in consultation with the IRB Administrator, will appoint an audit team consisting of a minimum of 2 IRB members who have no conflict of interest with any of the parties involved in the allegation.

C. The PI will be advised in writing that an audit team has been appointed, who the team members are, and the PI will be instructed to offer all assistance to the auditors.

(1) A letter will be sent to the official university email of the PI with a request for acknowledgment of receipt within 3 business days.

(2) If the acknowledgment of receipt is not received within 3 business days the letter will be delivered through email a second time. See Selection 4.4 D (2) for the process if no acknowledgement is received.

(3) The IRB Administrator will document the date and time of all transmissions of the letter and will keep a copy of the email(s), letter, and acknowledgement (or lack thereof) including date and time stamps.

D. The audit team, in consultation with the IRB Chair and the IRB Administrator, will decide on the next steps in the investigation. These may include:

(1) Developing questions to be submitted to the PI

(a) The team will decide if answers are to be in writing or in a written record of a meeting.

(b) The time frame within which the response is due.

(2) Meeting with the PI.

(3) Reviewing any and all documents pertaining to the allegation.

E. When the audit team is ready to report on its findings, but no later than 21 business days from the date of appointment, the team will instruct the IRB Administrator to place the report on the IRB agenda no later than the next regularly scheduled meeting of the convened IRB as long as that meeting is no less than 5 business days from the receipt of the written report.

F. When the IRB convenes, the members will be provided with the following for in-depth review:

(1) The report of the unanticipated problem,

(2) The current consent form,

(3) The protocol application,

(4) Any other relevant information.

G. All efforts should be made to minimize the delay in reaching a decision.

4.6 IRB Audit Decisions:

A. The IRB may decide that further investigation is necessary to reach a decision.

B. The IRB may find that there is no issue of noncompliance and no further action is needed.

C. The IRB may determine the incident to be *neither serious nor continuing*:

(1) The IRB may consider the following actions on all incidents of noncompliance which is neither serious nor continuing:

(a) Take no further action,

(b) Require corrective actions.

(2) The PI will be informed of the decision by letter.

(a) The letter will be sent to the official University email of the PI with a request for acknowledgment of receipt within 3 business days.

(b) If the acknowledgment of the receipt is not received within 3 business days, the letter will be delivered through email a second time. See Section 4.4 D (2) for the process if no acknowledgement is received.

(c) The IRB Administrator will document the date and time for all transmissions of the letter and keep a copy of the email(s), letter, and acknowledgement (or lack thereof) including date and time stamps.

(3) If necessary, IT Services will be informed and will act accordingly.

(4) If necessary, ORSP will be informed and will act accordingly.

D. The IRB may determine the incident to *be serious or continuing*.

(1) The IRB considers the following actions on all incidents of serious or continuing noncompliance:

(a) Increased monitoring of the study,

(b) Requiring interim reports from the PI. If the PI is a student, then the reports are required from the advisor,

(c) Monitoring the consent process,

(d) Increased frequency of continuing review,

(e) Disclosure to the participants information, which may affect willingness to continue in the study,

(f) Provision of additional information to past participants,

(g) Require current participants to re-consent to participation,

(h) Required additional training of the PI and or/study personnel in the protection of human participants,

(i) Suspension of the study,

(j) Termination of the study, or

(k) Suspension of all PI's studies pending a full audit of said studies,

(l) Other actions as appropriate.

(2) The PI will receive a written determination from the IRB.

(a) The letter will be sent to the PI's official University email with a request for acknowledgment of receipt within 3 business days.

(b) If the acknowledgment of the receipt is not received within 3 business days, the letter will be delivered through email a second time. See Section 4.4 D (2) for the process if no acknowledgement is received.

(c) The IRB Administrator will document the date and time of all transmissions of the letter and keep a copy of the email(s), letter and acknowledgement (or lack thereof) including date and time stamps.

(3) The letter will inform the PI of:

(a) The IRB's determination,

(b) IRB actions regarding the current study and others not associated with the noncompliance,

(c) Any required reporting of all noncompliance found to be serious or continuing to OHRP and Federal Department or Agency Heads in accordance with RPP Policy 12.03 *Reporting Incidents to OHRP or Department and Agency Heads*,

(d) Recommendations to the Research Integrity Officer (RIO) that may include:

(i) A letter of reprimand be placed in the PI's personnel file and/or the file of other study personnel;

(ii) The suspension of PI's privilege to conduct research for a specific period of time or termination of the privilege;

(iii) Termination of PI's employment or the employment of specific study personnel, or

(iv) Referral of the case for further action or investigation to the RIO.

E. Faculty Appeals of IRB Determination of Noncompliance

(1) A PI is entitled to one appeal of the IRB decision.

(2) The PI must notify the IRB Administrator of the intent to appeal within 5 business days of the date of the delivery of the IRB decision letter.

(3) The PI may submit a written appeal and any information supporting that appeal within 10 business days of the date of the delivery of the IRB decision letter. The PI will submit the written appeal to the IRB, at irb@ualr.edu. All materials must be received by 5 p.m. on the 10th business day.

(4) The written appeal must clearly present:

(a) Which finding(s) of the convened IRB or IRB Chair are being disputed;

(b) All evidence supporting the PI's claim that the finding(s) should be overturned. No new evidence may be submitted during the appeals meeting; and

(c) All relevant reasoning supporting the PI's claim that the finding(s) and determination(s) should be overturned.

(5) The appeal will be reviewed no later than the next regularly scheduled meeting of the convened IRB as long as that meeting is no less than 5 business days from the receipt of the written appeal.

(6) The PI may also request to attend the convened IRB meeting. The PI will receive the date that has been set for the appeals meeting at least 5 business days in advance using the PI's official university email with a request for acknowledgement within 3 business days. If no acknowledgment is received within 3 business days, then the notification will be sent again

using the PI's official university email. The meeting will not exceed 2 hours.

(a) The PI may bring nonparticipating supporters or legal counsel who will be restricted to observation only. If the PI wishes to bring legal counsel, the PI shall give at least 3 business days advance written notice to irb@ualr.edu to ensure that UA Little Rock General Counsel can be notified and present on behalf of the Institution.

(b) During the meeting, the PI will present the argument for the appeal.

(c) The IRB is not required to deliberate or engage verbally with the PI during the meeting.

(d) At the conclusion of the meeting, the IRB Chair, in consultation with the convened IRB and the IRB Administrator, will convene a second meeting to make a decision on the appeal.

(e) This meeting will be held no less than 24 hours later and no more than 5 business days after the end of the meeting convened to hear the appeal.

F. Appeal Decision

(1) The convened IRB may accept the appeal, or deny the appeal.

(a) If the appeal is successful, the IRB will automatically review the corrective action plan.

(b) If the appeal is denied, the IRB decision is final and the original determination and corrective action plan stands.

(2) Once the decision has been made, the IRB Administrator will notify the PI of the decision regarding the appeal and the final decision on the allegation of noncompliance.

(3) The letter will advise the PI of the steps that the IRB will adopt as a result of the decision.

(a) The letter will be sent to the PI's official University email with a request for acknowledgment of receipt within 3 business days.

(b) If the acknowledgment of the receipt is not received within 3 business days, the letter will be delivered through email a second time. See Section 4.4 D (2) for the process if no acknowledgement is received.

(c) The IRB Administrator will document the date and time of all transmissions of the letter. The IRB Administrator will keep a copy of the email(s), letter and acknowledgement (or lack thereof) including date and time stamps.

G. Notifications of the noncompliance will not be sent to the cognizant Dean, Department Head, or other parties until the period for informing the IRB of the intent to appeal has passed without notice or until the appeal has been heard and a decision reached by the convened IRB, whichever occurs first.

4.7 Noncompliance in Student Research

A. The PI may be the student, but the faculty advisor will be the focus of the IRB investigation.

(1) All correspondence and communication will go to the faculty advisor and student PI.

(2) It is the faculty advisor's responsibility to inform the student of the IRB's communications and the information contained therein.

See Appendix B for Revision History

RPP Policy 12.03	12.03 Reporting Incidents to OHRP or Department and Agency Heads	Updated 2022 May 15

1. Purpose

To describe the procedure to ensure prompt reporting to Institutional Officials, OHRP, Department and Agency Heads, and Sponsors as applicable and within the appropriate time frame.

2. Definitions

2.1 An Unanticipated Problem Involving Risks to Participants or Others

Defined as an event that meets the criteria specified in RPP Policy 12.01 *Unanticipated Problems Involving Risk and Adverse Events*.

2.2 Serious Noncompliance

Defined as an incident that meets the criteria specified in RPP Policy 12.02 *Non-Compliance*.

2.3 Continuing Noncompliance

Defined as an incident that meets the criteria specified in RPP Policy 12.02 *Non-Compliance*.

2.4 Suspension or Termination of IRB Approval of Research

Are directives that meet the criteria specified in RPP Policy 10.02 *Suspension and Termination*.

2.5 Internal Study Hold

A mandatory directive by the IRB to the PI in writing to suspend further participant accrual on an IRB-approved protocol. Such directives may be issued when the IRB has a concern about an unresolved AE, serious problem reports, or other issues which impact participant safety.

2.6 External Study Hold

A mandatory directive by the sponsor or cooperative group to the PI in writing to suspend further participant accrual on an IRB-approved protocol.

3. Policy

It is the IRB's policy that the following incidents will be promptly reported to Institutional Officials, OHRP, Department or Agency heads (if applicable), and/or Federal or non-Federal Sponsors in accordance with HHS regulations 45 CFR §46.108(a)(4) or to other federal agencies when the research is overseen by those agencies:

3.1 Any unanticipated problem involving risk to the participant or others,

3.2 Any serious noncompliance,

3.3 Any continuing noncompliance, and

3.4 Any suspension or termination of IRB approval.

In general, reporting requirements to Institutional Officials, OHRP, Department or Agency heads (if applicable), and/or Federal or non-Federal Sponsors apply to all nonexempt human participants research that is:

3.5 Conducted or supported by HHS

3.6 Conducted or supported by any non-HHS federal department or agency that has adopted the Common Rule and is covered by an FWA

3.7 conducted as a multi-site research study consistent with and agreed upon between the applicable institutions or

3.8 conducted or supported by non-Federal Sponsors.

Reporting to OHRP of unanticipated problems involving risk to the participant or others, which occurs at institutions not under the jurisdiction of the IRB, is the responsibility of the external institution.

4. IRB Reports

The IRB Chair or designate is responsible for the prompt submission of all required written reports to OHRP and Department or Agency heads.

A. The IRB Chair or designate may notify the appropriate oversight body verbally in advance of a written report when the incident is particularly serious.

B. All required reports will be submitted no later than 30 business days from the time the convened IRB makes a final determination concerning the incident.

C. If the research is conducted or funded by any Federal Agency other than DHHS that is subject to the "Common Rule", the report is sent to OHRP and the head of the agency as applicable.

D. Reports to the IO and appropriate oversight body must include the following:

(1) Name of the institution conducting the research;

(2) Protocol number and the number of any applicable award(s);

(3) Name of the principal investigator on the protocol;

(4) Identification of the sponsor, if applicable;

(5) Title of the research project and/or grant proposal in which the problem occurred;

(6) Timeline and detailed description of the problem;

(7) Any applicable reports from IRB consultants; and

(8) Corrective action plan approved by the convened IRB.

4.2 Notification of Reporting

(1) Copies of the required report and any necessary supporting documents must be provided to:

(a) The individual(s) directly responsible for the noncompliance or adverse or unanticipated event;

(b) The PI;

(c) The IO;

(d) Any Federal sponsor; and

(e) Other appropriate individuals as determined by the IO, IRB, or RIO.

See Appendix B for Revision History

RPP Policy 12.04	12.04 Audits by Outside Agencies	Updated 2022 May 15

1. Purpose

To describe audits by outside agencies.

2. Policy

It is the IRB's policy that the IRB will cooperate with audits by outside agencies in full accordance with HHS regulations 45 CFR §46.

2.1 Audit of the IRB by the FDA, OHRP, Department of Defense, or NIH Cooperative Group

A. If ORC or the IRB is contacted by a representative from a federal agency or a NIH cooperative group for an audit of the IRB, the following actions must be taken:

(1) Ask for the reason for the visit, if this has not already been provided;

(2) Inquire what documents and information will be required during the investigation;

(3) Immediately contact the IRB Administrator and the IRB Chair;

(4) Send an email confirming the visit to the IRB Administrator, the IRB Chair, and the IO or IO designate.

B. When the auditor(s) arrives, ask to see the auditor's identification for name and agency affiliation. Additionally, if the investigation is being conducted by a federal agency, the auditor may provide a copy of the official correspondence detailing the reason for the visit.

C. During the visit, the IRB Administrator and IRB Chair should be available to the auditor. A written record of the study files that are reviewed must be kept.

D. During the closing interview, it is preferable that the IRB Chair and the IRB Administrator are present. If the IRB Chair and/or the IRB Administrator are not available, then an IRB member may join the interview. The IRB Administrator will note all issues identified by the investigation and the action proposed by the auditor(s) (if applicable).

(1) If the IRB Administrator is unable to attend the exit interview then the IRB member will provide a summary of the results of the interview and required actions resulting from the investigation. If necessary, all individuals involved in the investigation will meet with the IRB Chair and IRB Administrator for debriefing.

(2) Following the discussion described in 2.1 D(1) above the IRB Administrator will immediately send an email to the IRB Chair and the IO or IO designate providing a synopsis of the investigation and the preliminary results presented at the closing interview. Special emphasis will be placed on those areas where deficiencies were found that require attention.

E. The IRB Chair and the IRB Administrator will meet within 5 business days following the investigation to propose a corrective action plan to address deficiencies found during the investigation.

(1) The IRB will be notified of the investigation and action plan.

(2) The IRB may modify the plan as necessary.

F. The IRB Administrator will notify by email all PIs whose study files were examined during the investigation. Results from the audit that are pertinent to the specific study will be discussed. Following receipt of the official letter from the regulatory agency, the PI will also be notified of areas of concern related to the study.

G. The IRB will normally receive a report of the results of an audit. Where there are identified areas of concern or sanctions placed, the IRB Chair, IRB Administrator, and other appropriate UA Little Rock officials will respond to the agency.

2.2 OHRP For-Cause Investigation of Noncompliance and Not-For-Cause Compliance Oversight Evaluation

A. If the IO receives notification from OHRP that OHRP has initiated a for-cause investigation of noncompliance or a not-for-cause compliance oversight evaluation, the IO, together with the IRB Chair, IRB Administrator, and other appropriate IOs, will respond immediately and appropriately with an action plan to address the matter.

2.3 Audits of Investigator's Records by Outside Agencies

A. When a PI is contacted by a representative from any federal agency, sponsor, or other entity for an investigation or

audit of a research protocol, the IRB must be notified of the visit. If the visit is pre-planned, an email may be sent to the IRB Administrator. If it is a no-notice investigation or audit, the IRB Administrator should be notified as soon as possible. The following information must be provided to the IRB:

(1) The protocol # and title;

(2) The name of the governmental agency, sponsor, or other entity;

(3) Name of the investigator;

(4) The dates of the visit; and

(5) The type of visit:

(a) routine surveillance/monitoring visit,

(b) "for-cause" investigation, or

(c) other:_____.

B. Following the investigation or audit, the PI must notify the IRB of any compliance issues identified during the exit interview.

(1) If the investigation or audit revealed conditions or practices that are of significant departure from the federal regulations with potential for sanctions, the IRB Chair must be immediately notified.

(a) If the IRB Chair is not available, the IRB Administrator should be informed. This information will be relayed to other appropriate UA Little Rock officials as soon as possible and this RPP Policy 12.04 will be implemented as necessary.

C. A copy of the official letter detailing the results of the investigation must be provided to the IRB. If the investigation or audit revealed areas of concern, the PI must provide the IRB with a copy of the response with particular emphasis on the corrective action plan.

D. The convened IRB will be given all information and will determine what action is necessary, including reporting noncompliance to OHRP and FDA.

See Appendix B for Revision History

Appendix

A -- Abbreviation List

B -- Revision History

C -- Acknowledgements

A
RPP
Appendix

Abbreviations Used

Updated
2022
May
15

Abbrv.	Definition
AE	Adverse Events
CFR	Code of Federal Regulations
CITI	Collaborative Institutional Training Initiative
CoC	Certificate of Confidentiality
COI	Conflict of Interest
COPA	Children's Online Privacy Protection Act
DUA	Data Use Agreement
FDA	US Food and Drug Administration
FWA	Federalwide Assurance
HHS	US Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HPR	Human Participants Research
IO	Institutional Official (Chancellor)
IRB	Institutional Review Board
LAR	Legally Authorized Representative
MOU	Memorandum of Understanding
NIH	US National Institutes of Health
OHRP	HHS Office for Human Research Protections
ORC	Office of Research Compliance
ORSP	Office of Research and Sponsored Programs
PHI	Protected Health Information
PI	Principal Investigator
RCO	Research Compliance Officer
RIO	Research Integrity Officer

RPP	Research Protection Program
SACHRP	HHS Secretary's Advisory Committee on Human Research Protections
sIRB	Single IRB
SOP	Standard Operating Procedure
UAMS	University of Arkansas for Medical Sciences

B RPP Appendix	Revision History	Updated 2022 May 15

All policies and procedures, except those noted as new, existed in previous versions of this manual. Updates refer to changes made since the May 2018 version.

Table of Contents

Changes to All Policies

May 15, 2022

- RCO changed to IRB Administrator.
- RPP Policy Names were added to the Policy Number referenced.
- References to ORC Staff removed.
- He/she replaced with appropriate descriptor.
- All protocols receive a minimum of two reviewers.
- When students were mentioned, post docs were included.
- Updated language for persons with diminished functional capacity.
- Nouns referring to people changed to plural when possible.

Section 1

Policy 1.01

May 15, 2022

- § 2.1 The Clinton School of Public Service was added.

September 28, 2023

- Reviewed by IRB Chair, IRB Administrator, and Board with no changes

Policy 1.02

May 15, 2022

- § 2.4 has been revised to include the information that is required for the IRB roster. The IRB Roster no longer needs to be reported to OHRP. The roster will be maintained by the IRB Administrator.

September 28, 2023

- § 2.1 Reworded to reflect current FWA. IRB Board approved on September 7, 2023. Chancellor approved on September 28, 2023.

Policy 1.03

May 15, 2022

- No change.

September 28, 2023

- Reviewed by IRB Chair, IRB Administrator, and Board with no changes.

Policy 1.04

May 15, 2022

- No change.

September 28, 2023

- Reviewed by IRB Chair, IRB Administrator, and Board with no changes.

Policy 1.05

May 15, 2022

- § 2.4 was retitled and revised to reflect reorganization of the Office of Research Compliance.
- § 2.5 was updated to reflect that the Vice Provost for Research and Dean of the Graduate School is responsible for the Office of Research Compliance.
- § 2.6 was updated to reflect the reporting pathway of the IRB Chair.

September 28, 2023

- Reviewed by IRB Chair, IRB Administrator, and Board with no changes.

Policy 1.06

May 15, 2022

- § 2.4 has been revised to include the relevant RPP policies, RPP# 7.02 and 7.03.
- § 2.5 has been updated to reflect current administrative titles and the reporting path for improper attempts to influence the IRB.

February 1, 2024

- § 2.4 statement on FDA research was updated to reflect current practice.

Section 2

Policy 2.01

May 15, 2022

- § 2.1 - The Clinton School was added.
- § 2.2 - Additional descriptors added to IRB qualifications.
- § 2.6 - Ex-officio members, IRB Administrator and Vice Provost of Research and Dean of the Graduate School added
- § 2.10 - Changed to clarify when IRB members leave the meeting due to COI
- § 2.12 - Edited to identify CITI modules and to make training expectations more general.
- § 2.14 - Reporting of IRB membership changed to reflect current policy.
- § 2.15 - Clarification that names of reviewers are confidential.

November 8, 2023

- § 2.6 - IRB administrator language replaced with Office of Research Compliance staff.
- § 2.12 (A. 1) – Added the words Human Research to the language.
- § 2.12 (A. 2) – Added an a to the language.
- § 2.12 (A. 3) – Added an a to the language.
- Reviewed by IRB Chair, IRB Administrator, and Board with minor editing changes.

Policy 2.02

May 15, 2022

- § 2.2 was modified to remove type of notification and to reflect current practice of timing of notification.
- § 2.3 was modified to provide some flexibility in the timing of the availability of materials.
- § 2.4 was modified to add secondary reviewer and review team.
- § 2.5 was modified to reflect those official actions would take place at the reconvened meeting.
- § 2.9 was added to describe the current review process.

November 8, 2023

- Reviewed by IRB Chair, IRB Administrator, and Board with no changes.

Policy 2.03

May 15, 2022

- § 2.1 Section of 45 CFR §46.107 given correct subsection letter. Added the IRB Chair to the list of who determines the need for a consultant.
- § 2.3 Confidentiality section added.
- § 2.4 Added that any written review is part of the minutes.
- § 2.7 and 2.8 RCO changed to IRB Administrator.

November 8, 2023

- Reviewed by IRB Chair, IRB Administrator, and Board with no changes.

Policy 2.04

May 15, 2022

- § 2.1 Removed details of orientation.
- § 2.2 Names of modules and length of CITI certification added.
- § 2.3 New members serve as tertiary reviewers. ORC changed to IRB administrator.

November 8, 2023

- § 2.1 - Changes made to reflect that the review process is included in training.
- § 2.2 - Changes made to reflect accurate names of training programs.
- § 2.3 - Changes made to reflect more clearly the current review process.
- Reviewed by IRB Chair, IRB Administrator, and Board with minor editing changes.

Policy 2.05

May 15, 2022

- § 2.1 Removed types of reviews and replaced with "assignment as a reviewer."
- § 2.3 Absent was changed to "excuse."
- Footnote 1: The relationships of grandparent and adoption were added.
- § 2.4 C & D. The dollar amount was removed.
- § 2.4 E. Added "other reasonable measures of fair market value."

November 8, 2023

- § 3.3 - Changed to directly reflect what 46.107 (D) says about the presence of a member with a COI in a meeting.

- § 3.4 - C added to reflect current practice of COI with personal or professional relationships.
- Reviewed by IRB Chair, IRB Administrator, and Board with minor editing changes.

Policy 2.06

May 15, 2022

- § 2.8 Description of CITI training updated.

November 8, 2023

- § 2.1 Description of CITI Re-Certification updated.
- Reviewed by IRB Chair, IRB Administrator, and Board with minor editing changes.

Policy 2.07

May 15, 2022

- § 2.1 was deleted since it is covered in Section 2.7.
- § 2.7 was modified to reflect current practice and remove unnecessary detail.
- § 2.9 was deleted to reflect current administrative structure.

November 8, 2023

- Reviewed by IRB Chair, IRB Administrator, and Board with no changes.

Policy 2.08

May 15, 2022

- § 2.2 has been updated to reflect current storage practices.
- § 2.3 and 2.4 removed references to the ORC.
- § 2.5 Updated the titles of the UA Little Rock personnel.

Policy 2.09

May 15, 2022

- § 2.1 Tertiary reviewer added to reflect current practice.

- § 2.2 added to include the documentation provided to reviewers for all protocols.
- § 2.3 Provides a procedure for selecting a secondary reviewer if one is needed.
- § 2.4 Further defines the procedure to follow if there is an issue concerning COI.

February 1, 2024

- Section 2 Policy minor wording change.

Policy 2.10

May 15, 2022

- § 2.6 Approval letters no longer include C.

February 1, 2024

- Section 2.1 Order of events changed to reflect current practice.

Policy 2.11

May 15, 2022

- § 2.8 electronic ballot was added.

Policy 2.12

May 15, 2022

- § 2.1 Minutes to include detailed review letters cited as addenda.
- § 2.5 Contentious discussion added to definition of controverted issue.
- § 2.7 Timeframe of approval required.
- § 2.8 Comments about vulnerable populations as applicable to the research added.
- § 3.2 Minutes may cover relevant new business.
- § 3.4 Removed the term “files” as its use was ambiguous.

Policy 2.13

May 15, 2022

- § 2.1 was modified to replace RCO with IRB Administrator and to reflect the current method of policy approval.

September 28, 2023

- § 2 Policy & 2.1 Reworded to reflect regular review and to distinguish the process of approval for no change or minor changes and major changes. Approved by the IRB Board on September 7, 2023 and the Chancellor on September 28, 2023 with minor revisions.

Policy 2.14

May 15, 2022

- § 2 was modified to define the HHS abbreviation.
- § 2.2 added documentation described in L. Section J removed "HHS approved" from consent documents.
- § 2.3 (G) removed language about different protocol status classifications. Section I clarified that a copy of the consent form may be included. Section K was added to include documentation of issues covered by the regulations.

February 1, 2024

- Section 2.5 D & E Wording changed to reflect current terminology.

Section 3

Policy 3.01

May 15, 2022

- § 2.1 C Removed last section of quotation which could not be verified.
- § 2.1 F Updated definition of human participant.
- § 2.1 G. Added definition of engagement
- § 2.1 L Added medical record as an example.
- § 2.3 Added clarification of the role of the examples.
- § 2.3 C. Added section on Epidemiological Research.
- § 2.3 D. Added section on Repository Research, Tissue Banking, and Databases
- § 2.3 E. Added section on Pilot Studies.
- § 2.5 Added examples of Non-Research Activates.
- § 2.6 Updated how to get a human participant research determination.

- § 2.7 Edits and additions added to clarify the type of IRB review and the review process.
- § 2.9 A. Section on Sponsored Research added to cover the university commitment.

Policy 3.02

May 15, 2022

- § 2.1 A-J Edited to reflect more current language.

Policy 3.03

May 15, 2022

- § 3. Title of IRB review form added

Policy 3.04

May 15, 2022

- § 2 expanded to list the criteria for 45 CFR §46.111.
- § 3.2 A (2) clarified that it is the minimum number of participants.
- § 3.3 B & C Material removed that is now in RPP 5.05 Use of Deception in Research
- § 3.5 B (2) Clarified that in certain circumstances the relative standard of minimal risk is more stringent.
- § 3.5 C Information that might be required in a data safety monitoring plan is listed.
- § 3.5. E Added to address the evaluation of the risk-benefit ratio.
- § 3.8 A (1). clarified that any conflict of interest can be covered.
- § 3.8 A (3) Removed action that is inconsistent with revised RPP 3.07 Conflict of Interest Review by the IRB
- § 3.10 C Added that a faculty member must be the listed as a secondary investigator or advisor.

Policy 3.05

May 15, 2022

- § 2.2 B (6). Removed information about appeals that is covered elsewhere in the RPP

Policy 3.06

May 15, 2022

- § 2.1 This section was edited to make it more concise.

Policy 3.07

May 15, 2022

- §2. Other conflicts of interest added.
- § 2.1 Title changed to reflect content revisions. Content revised to reflect current university procedures.
- § 2.2,2.3,2.4 removed to reflect current university procedures.
- § 2.5 Clarified that any of the protections listed could be implemented.

Policy 3.08

May 15, 2022

- § 2.2 C. Further defined the role of research personnel.
- § 2.2 D Clarified the role of the limited research worker so that someone who has a role as translator for one person might not be required to have CITI training.

Policy 3.09

May 15, 2022

- § 2.1 A Further definition of research personnel was added.
- § 2.1 B. Titles for CITI training changed to most current. Redundancy eliminated. Added requirement for RCR training. Added option for other training for community based participatory research.
- § 2.1 C. Added clarification about the need for student researchers to take CITI and RCR.
- § 2.1 D. Changed ORC to RCR.
- § 2.1 E. Clarified training needed for new research personnel.
- § 2.1 F Clarified that training that is close to expiration must be renewed prior to approval of research.
- § 2.1 H Eliminated redundancy concerning the confidentiality of CITI test data.

- § 2.1 I Added the passing score needed for the RCR.
- § 2.1 J 2(c) Clarified what is needed for RCR renewal.
- § 2.2 Eliminated redundancy.

Policy 3.10

May 15, 2022

- § 1 Redefined the frequency of continuing review.
- § 2.1 C 2 No longer specify ORC as the auditor of investigator records.
- § 2.2 A 2& 3 Added to the list of circumstances requiring verification.

Policy 3.11

May 15, 2022

- § 2 removed redundant language about the function of the Certificate of Confidentiality (CoC).
- § 2.2 C. Added information about the definitions of the National Institutions of Health (NIH) policy on sensitive information.
- § 2.4 Modified the application process to cover research funded by NIH and non-NIH funded research.
- § 2.5 added to indicate steps after approval of the (CoC).

Policy 3.12

May 15, 2022

- § 1 added sections 1.1 and 1.2.
- § 2 clarified the types of joint review arrangements and referenced the National Institutes of Health policy.
- § 2.1 added to provide definitions.
- § 2.2 added to clarify authority.
- § 2.3 added conditions for serving as the reviewing IRB.
- § 2.4 added to provide conditions for serving as the relying IRB.
- § 2.5 added to clarify the documents needed for federally funded and non-federally funded research.
- § 2.6 added to list conditions for exceptions to the sIRB requirements.
- § 2.7 modified to clarify the process for exempt research.
- § 2.3 on authorization agreement removed because covered elsewhere.

Policy 3.13

May 15, 2022

- § 2.1 A 1. The word "complete" was added.

Policy 3.14

May 15, 2022

- § 2.1 was retitled to add Appeals. The appeal process is described.
- § 2.2 and 2.3 were removed because the information is now included in section 2.1.
- New § 2.2 covering conflict of interest was added.
- § 2.3 This information was given its own section and reliance agreement was added to the ways another IRB could serve as the IRB of record.

Policy 3.15

May 15, 2022

- § 2. Examples of participant incentives or compensation and criteria for evaluation of the compensation plan were added.
- § 2.1 Redundant information was eliminated. Clarification about finders' fees and recruitment bonus fees to recruitment staff was added. The section on payment to minors was removed.
- § 2.2 Requirements for the use of a lottery were added.
- § 2.3 A description of the requirements for performance-based incentives was added.

Policy 3.16

May 15, 2022

- § 2. Internet and social media were added to recruitment strategies.
- § 2.1 The list of what advertisements should include was expanded and clarified.
- § 2.1 B. Advertisements are defined as including more than print media.
- § 2.2 was added to identify the elements of IRB review.

Section 4

Policy 4.01

May 15, 2022

- § 2. Goals of the Quality Assessment Improvement Program were added.
- § 2.2 Changes reflect current practice and activities that are within the scope of IRB resources.
- § 2.3 Study selection criteria reflect both common types of protocols as well as those that may have special regulatory requirements.
- § 2.4. The phrase "if applicable" was added to several sections when needed. Question E was added about protocol review. Clarifying information was added to question H.
- § 2.5 A report to PIs was removed because the PIs files are not audited.

Section 5

Policy 5.01

May 15, 2022

- § 2. A definition of student level was included.
- § 3. Elaboration on the responsibility of the supervising faculty was added.
- § 4.1 The definition of independent projects now includes the general definition of research and examples of student projects that are covered.
- § 4.4 Protected class was changed to vulnerable populations.
- § 4.6 RCR was added to the training requirements.
- § 6. Title was eliminated due to redundancy.
- § 6.4 Protections for participants were added.

Policy 5.02

May 15, 2022

- § 2.2 Question 8 on data security added.
- § 2.7 B.1. Language added to clarify that IRB review of future use of a database for research is required. Informed consent requirements are listed.

Policy 5.03

May 15, 2022

- § 2.1, 2.2 removed and updated with a new section 2.1,
- New § 3-6.
- All new sections were adapted from the University of Indiana Human Subjects guidance on exercise protocols.

Policy 5.04

May 15, 2022

- § 1.1 was added to define the role of the PI.
- § 2. Clarification regarding the role of the UA Little Rock IRB in reviewing protocols was added
- § 2.1 A (1) about verifying local customs and practices was added.
- § 2.2 B HHS representation was changed to department or agency head. Clarified that the FWA must be filed by the foreign institution.
- § 2.3 A Added the requirement to document upholding local laws and customs in the protocol.
- § 2.3 D Added to define PI responsibility.
- § 2.4 D Clarified what the PI should submit to the UA Little Rock IRB.
- § 2.5 Added to clarify which institutions need to review, what is required for human participant protection, and requirements for research with prisoners.
- § 2.6 Added to provide additional issues the UA Little Rock IRB will address.
- § 3 Added to describe the process of verification of international research standards.

May 23, 2024

- § 2.4 changed the language to Research Involving Collaboration with an International Institution.

Policy 5.05

May 15, 2022

- New Policy - Adapted from the University of Nebraska Policy and University of Texas at Austin policy.

Section 6

Policy 6.01

May 15, 2022

- § 1. Clarification that informed consent is a process was added.
- § 2.2 B. ORSP changed to UA Little Rock Research Compliance.
- § 2.3 E. Added to describe the key elements section that might be required.
- § 2.3 B. Adult assent was added.
- § 2.3 E. Clarification that assent is also added was required.
- § 2.3 G. Added to define screening consent.
- § 2.5 B. Clarified that faculty PI information should be added.
- § 2.7 Added to clarify requirements for the assent documents.

Policy 6.02

May 15, 2022

- § 2 Clarified that consent and/or document could be waived. HHS Regulations numbers added or corrected as needed.
- § 2 A 13 Office of Research Compliance listed as contact for questions from participants.
- § 2 A 15 Added statements about the future use of identifiable information or identifiable biospecimens.
- § 2.3 Clarified the section applies unless there is an approved waiver or alternation of informed consent.
- § 2.4 Added to cover screening potential participants.
- § 2.5 A Clarified that the IRB can observe the consent and/or research process.

Policy 6.03

May 15, 2022

- § 2 Updated telephone consent to consent not obtained in person.
- § 2.1 Included alteration of consent process.
- § 2.3 added "minor" to the title.
- § 2.3 C Lists what happens when the consent document is changed.
- § 2.3 D Addresses the documentation of the alternative consent process.

Policy 6.04

May 15, 2022

- No change.

Policy 6.05

May 15, 2022

- § 2.1 A Clarified that there may be five elements of informed consent.
- § 2.1 A (5) Added fifth element of consent.
- § 2.2 Changed "signed" to "documentation" in title.
- § 2.2 3 Added to cover cultural groups for which signing forms is not the norm.

Section 7

Policy 7.01

May 15, 2022

- § 2 Added Subpart B,

Policy 7.02

May 15, 2022

- § 2.3 (8) Updated language for persons with diminished functional capacity.

Policy 7.03

May 15, 2022

- § 2.2 A (1) Added directions about when ORHP must approve research with prisoners.
- § 2.3 and 2.4 Added
- § 2.5 specified the duties of the IRB Administrator regarding the roster and the prisoner representative.
- § 2.6 (2) Added when a participant who becomes incarcerated can remain in the study.
- § 2.8 Added the location of IRB documentation.

- § 2.9 B Added more description of the contact in ORHP for prisoner research certification letters.

Policy 7.04

May 15, 2022

- § 2.1 F. Definition of legally authorized representative added based on the Policy 15.1 of the University of Arkansas Medical Sciences Institutional Review Board.
- § 2.1 H Permission added to label since the terms is often used.
- § 2.3 F Added when assent can be waived by the IRB.
- § 2.3 G Added to define when minors can give consent.
- § 2.3 H (1) Added reference to HHS regulations.
- § 2.3 J (3) Updated language for persons with diminished functional capacity
- § 2.4 A. Added the criteria of cognitive and educational level.
- § 2.4 A (c) Provided examples. of developmental limitations.
- § 2.4 C (1) Added cognitive level and repeated the 6- through 12-year-old level.
- § 2.4 C (2) Lists additional elements for the assent form and incorporates some that were in a now deleted section
- § 2.4 D. Includes a description of elements required for the youth assent form
- § 2.5 Clarified when the documentation occurs in the reviewers' comments.

Policy 7.05

May 15, 2022

- § 2.1 B Added additional information to about the length of an impairment.
- § 2.1 C Added a definition of health care.
- § 2.1 D. Added definition of legally authorized representative.
- § 2.1 E Added definition of capacity to consent.
- § 2.2 A & B Definition of who can be a legally authorized representative based on Policy 17.1 of the University of Arkansas Medical Sciences IRB.
- § 2.2 C Clarified when those who lack the ability/capacity to consent can participate in research.
- § 2.2 D. Describes how the legally authorized representative makes the consent decision.

- § 2.2 E. Describes the documentation that should be kept by the investigator.
- § 2.3 Modified to provide an expanded description of research issues to address when those with diminished functional capacity/ability are included.
- § 2.4 Retitled for clarification.
- § 2.5 ORC staff changed to IRB Administrator to reflect current administrative structure.

Policy 7.06

May 15, 2022

- § 2.1 B Adds clarification about the requirements for alternative activities.
- § 2.2 A Added name of IRB form.
- § 2.2 (4) (5). Added to what must be covered in the IRB application.

Section 8

Policy 8.01

May 15, 2022

- § 2 Added funding agency regulations and policies to the list.

Section 9

Policy 9.01

May 15, 2022

- § 2.2 Provides an expanded definition of protected health information.

Policy 9.02

May 15, 2022

- § 2.2 B. Added additional categories for those who must have identifiers removed.

Policy 9.03

May 15, 2022

- § 2.1 D. Clarified the definition of an authorized investigator.
- § 2.2 A Describes what authorization is needed for PHI.
- § 2.2 B Clarifies what is needed for investigator to have access to confidential records.

Policy 9.04

May 15, 2022

- § 2.1 C 4 Added to the list of what an investigator must certify.
- § 3 Added as a description of the requirements for research involving the use of PHI.
- § 4 Added to address participant recruitment.

Policy 9.05

May 15, 2022

- This policy replaces the former policy RPP 9.05 Internet and Publicly Available Information. Sections were adapted from policies at University of Virginia, University of California, and 2013 SACHRPP Guidance.

Section 10

Policy 10.01

May 15, 2022

- § 2.1 Added that the approval period for all protocols is one year.
- § 2.3 A Added inclusion of future consent forms to materials for continuing review.
- § 2. 5 A Added when a continuation of a project which required full board review can use expedited review.
- § 2.9 Added to cover what occurs when a project has been. approved for ten years.

Policy 10.02

May 15, 2022

- § 2. Added description of IRB authority.
- § 3.1 A Added safety and noncompliance as reasons for suspension.
- § 3.2 A. Added reasons for termination.
- § 3.3 Added definition of institution directed termination.
- § 4.1 B Added when the IRB would be convened.
- § 4.1 C through H added to clarify procedures for suspension.
- § 4.2 Added to address procedures for IRB termination of research.
- § 4.3 Added procedures for institution directed termination of approval.
- § 4.4 Added a list of actions to protect participants.
- § 5 Added information about reporting.

Section 11

Policy 11.01

May 15, 2022

- § 2.1 A list of definitions and examples of changes was added.
- § 2.2 A Clarified when a new protocol is required.
- § 2.3 A (3) (b) Clarifies when re-consent is required.
- § 2.5 A Updated the title of the current modification form.
- § 2.5 B Identifies the criteria for reviewing and approving a modification.
- § 2.5 C Clarifies the number and responsibilities of reviewers.
- § 2.5 D. Clarifies that the approval date is not extended for modifications.
- § 2.5 E Added to address level of review.

Section 12

Policy 12.01

May 15, 2022

- § 1 Added adverse events.
- § 2.1 A Reworded to clarify definition of unanticipated problem.
- § 2.1 B Added definition of adverse event.
- § 2.2 B Added social, legal or economic harm.
- § 2.2 B (1) Changed specificity to nature for clarification.
- § 2.3 D Added events described in § 2.1 to list of examples.
- § 2.3 E Added external events.
- § 2.3 A (2) Clarified that an event can have multiple classifications.

- § 2.3 A (3) Added documentation is kept in IRB minutes.
- § 2.3 C Added name of current report corm for adverse events.
- § 2.3 C (2) Added consent form.
- § 2.3 D Clarified that determinations of serious adverse events and protocol violations follow the policies listed.
- § 2.3 E (12) Added training to the list.
- § 3 Added to reference appropriate RPP policy.

Policy 12.02

May 15, 2022

- § 2. Specified who receives reports of noncompliance. Also clarified the others who receive reports.
- § 2.1 A Added to the definition of noncompliance and added the appropriate RPP.
- § 2. B Added a definition on nonserious noncompliance.
- § 2.3 D Clarified the definition of serious noncompliance.
- § 2.3 E Added that the definition of continuing does not limit IRB consideration of other circumstances.
- § 2.2 Title edited for clarification.
- § 2.2 A Specified who receives reports of noncompliance
- § 2.2 C Added statement about UA Little Rock.
- § 2.3 B Added details to the process of notification of the PI.
- § 2.3 D Added with the 8 business days start.
- § 2.3 F Added IRB Administrator for consultation.
- § 2.4 B Specified smallest size of audit team.
- § 2.4 C Added details to the process of notification of the PI and made it consistent with other notifications.
- § 2.4 D. (1) (a) Clarified a written record of a meeting is needed.
- § 2.4 E Changed when the report of the audit team may be placed on the IRB meeting agenda.
- § 2.4 F. Added item 4.
- § 2.5 C (2) Added details to the process of notification of the PI and made it consistent with other notifications
- § 2.5 D (1) Added that PIs who are students can also be required to submit reports to b. Added option l.
- § 2.5 D (2) Added details to the process of notification of the PI and made it consistent with other notifications
- § 2.5 E (2) Changed time given for notification of appeal.
- § 2.5 E (3) Changed time given for receipt appeal materials and added how to submit them.

- § 2.5 E (5) Added time frame for when appeal may be addressed by the convened board.
- § 2.5 E (6) Clarified the notification of a PI who wants to attend the appeal meeting.
- § 2.5 E (6)(1) Clarified who can attend the appeals meeting.
- § 2.5 E (6) (5) Changed time frame for meeting of the convened IRB to decide on the appeal.
- § 2.5 F (1) (b) Added corrective action.
- § 2.5 F (3) Added details to the process of notification of the PI and made it consistent with other notifications.
- § 2.5 G Clarified when others are notified about the IRB decision of the noncompliance.
- § 2.6 A (1) Added student PI.

Policy 12.03

May 15, 2022

- § 1 Added to the list of those who receive reports.
- § 2 Added to the list of those who receive reports. Added the type of research for which reports are required.
- § 2.1 A-D. Replaced definitions with reference to relevant RPP policies section
- § 2.2 A. Replaced ORHP with a more inclusive term.
- § 2.2 B Changed length of time to submit report.
- § 2.2 C Clarified report might be sent to other Federal Agencies.
- § 2,2 D. Provides a more detailed list of what to include in the report.
- § 2.3 Edited title to be more inclusive.
- § 2.3 A (5) Added who can decide others who might receive report.

Policy 12.04

May 15, 2022

- § 2.1 D Substitute IRB member for ORC staff to reflect current administrative structure.

C RPP Appendix	Acknowledgements	Updated 2022 May 15

The initial version of the UA Little Rock Institutional Review Board Research Protection Program Policies and Procedures Manual was based on the pre-2018 version of the University of Nebraska-Lincoln's (UNL) Human Research Protection Program (HRPP) Policies and Procedures. Much of this revised UA Little Rock IRB RPP Policies and Procedures Manual follows the UNL HRPP 2018 revision.

Some sections of the revised UA Little Rock IRB RPP Policies and Procedures Manual were based on:

- The University of Indiana Human Subjects Guidance on Exercise Protocols,
- The University of Texas at Austin Policy and Procedures,
- The University of Virginia Policy and Procedures,
- The University of California Los Angeles Guidance and Procedure, and
- The University of Arkansas Medical Sciences IRB Policies.