**Template Instructions for Adult Informed Consent**

**The first 4 pages of this document are instructions. Please read the instruction pages carefully and delete them before submitting your consent form.**

**Instructions to Researchers:**

1. When using the template complete the prompts in **red**. Before submitting to the IRB delete the instructions in red and any prompts in black that you did not use from the form you submit for review.

2. The consent form must include several elements (per federal regulations 45 CFR 46, part 46.116). Depending on the nature of the project (topic, population, methodology) the UA Little Rock IRB may require additional information that is not specifically listed in the regulations to ensure that participants are adequately informed.

3. All participation in research must be **voluntary**. Participants in your project must do so **willingly**. If your participants are children, you must first obtain parental consent to approach the children, before you solicit children’s assent. (See *Guidelines for Creating a Child Assent Form*.)

4. Researchers may create their own consent documents, or use the templates provided by the UA Little Rock IRB. All consent forms must contain the required information.

5. Information in the consent document must be organized to facilitate comprehension. Consent documents should be written in plain language, generally at the 8th-grade reading level. The reading level can be higher if the target population tends to have a higher literacy level than the general population or lower if the literacy level is lower. Tools such as the Flesch-Kincaid can help calculate reading level.

6. The consent form should also address the issue of age. If participants are under 18 parental consent is required. In studies with adults, it is necessary to verify that participants are 18 or older. A simple solution is to include a statement that the participant acknowledges that they are over the age of 18. This statement is often included as a check box with the consent statements at the end of the consent form.

7. Participants must have the opportunity to obtain a copy of the consent form. In studies in which the consent is delivered electronically, participants can be instructed to take a screenshot of the consent form.

8. If the study includes audio, video, or other forms of recording, the consent process must include a separate consent checkbox for these procedures.

9. Do **not** recycle informed consent documents across projects. Starting with a fresh template ensures that your information is accurate for your current project and includes all required elements.

10. If your project is complex, involves numerous research procedures, or involves vulnerable populations, or the consent form is more than 2 double-spaced pages in length, a key information section **must** be included. The key information section will help potential subjects understand why they might or might not want to participate in the study.

The IRB may also request that PIs include this section for funded research as well as other types of research. This section is labeled “Important Information about This Study” in the template.

The key information should include the following:

* 1. Identification of the project as a research study and that participation is voluntary
	2. Purpose of the research, duration of participation, and a description of research procedures
	3. Foreseeable risks or discomforts, if any
	4. Expected benefits to participants or others, if any
	5. Alternative procedures or treatments that might benefit the participant.

 (Note: This applies primarily to clinical research. It can apply in situations that offer extra credit for research with an alternative for getting extra credit without research participation)

11. Elements of Informed Consent as required by federal guidelines:

* 1. A statement that the study involves research and that explains the purpose of the study.
	2. A description of what you will be asking the participant to do and how much time they will spend participating in the study.
	3. If appropriate, an explanation if any of the procedures is novel in application (as when testing a new device or procedure).
	4. A description of the anticipated risk, harms, discomforts, and inconvenience.
	5. If the research involves more than minimal risk, what treatments may be offered to participants if they are harmed in the study?
	6. A description of possible benefits that may reasonably be expected to the participant, or society, from the study. There must be benefits of some type. Participants may experience the benefits directly or indirectly (the benefits may occur for others). All benefits should be stated as may or might.
	7. If appropriate, a disclosure of alternative procedures or treatments instead of those in the study.
	8. If appropriate, a description of any compensation for participating in the study, and the conditions thereof.
	9. A statement explaining how information will be kept secure, e.g., data kept separate from consent forms; password protection; who will see data. Student researchers must include the names of any faculty who may see the data.
	10. A statement that taking part in the study is voluntary, and there will be no penalty or loss of benefits for not participating (e.g., loss of services from the organization or a lower grade in the class).
	11. A statement that the individual can stop participating at any time.
	12. A statement that tells participants what will happen to their data if they decide to stop. Researchers may choose to use this data. However, participants must know in advance that this is what will happen.
	13. If appropriate, information that alerts participants to any consequences to them should they withdraw while dependent on some intervention to maintain normal function.
	14. Name, phone number, and email of the person(s) the participant may contact if they have any questions about the study or if there is a research-related injury or adverse event. The IRB recommends that researchers not use personal information.
	15. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens 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 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.
	16. The following statement about IRB approval, with IRB contact and PI contact information for questions: This study has been reviewed and approved by UA Little Rock's Institutional Review Board (IRB). The IRB has determined that this study meets the ethical obligations required by federal law and University policies.  If you have questions or concerns regarding this study please contact the Principal Investigator (provide university email and university phone number if available) or Advisor (If there is an advisor provide university email and phone number if available). If you have any questions regarding your rights as a research participant, please contact the Office of Research Compliance at 501-916-6209 or irb@ualr.edu.

12. Under certain conditions the IRB may authorize **a waiver of *signed* informed consent.** This means that participants must be provided with the required consent information, but do not **sign** the consent document. Waivers of signed consent are appropriate in these situations:

1. More than minimum risk: Where the signature on the consent document would be the only record linking the participant to the research and the principal risk of harm to the participant would be a breach of confidentiality. If the waiver is granted participants must be offered the option of signing the consent.
2. Minimum risk: Where the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context. Much of minimal risk research qualifies for a waiver of signed consent. Rather than signing a consent form, participants are asked to check a box indicating an agreement to participate at the end of the consent form.
3. Minimum risk: Where participants are members of a distinct cultural group or community in which signing forms is not the norm. In this case, an appropriate mechanism to document that informed consent was provided and obtained is required.

13. Additional Elements of Informed Consent that might be required for certain types of research:

1. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo fetus, if the participant is or may become pregnant) which are currently unforeseeable.
2. Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent
3. Any additional costs to the participant that may result from participation in the research.
4. The consequences of a participant’s decision to withdraw and procedures for orderly termination of participation by the participant
5. A statement that significant new findings developed during the course of the research that might influence the participant’s willingness to continue participation will be provided to the participant.
6. The approximate number of participants involved in the study.
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.
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a humane germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

***Do not forget to delete the first 4 pages.***

**Consent to Participate in Research**

**Title of Study**

**Introduction**

You are invited to participate in a research project. In this research, we are investigating/testing/evaluating \_\_\_\_\_\_\_\_\_\_\_\_\_\_. This study is being conducted by *Name of PI,* *all Co- PIs*, *Department at UA Little Rock, if PI is a student include:* The Faculty advisor is *Name, Department at UA Little Rock.* *If there are eligibility criteria for participants list them here.* This consent form will help you choose whether to participate in the study. Feel free to ask if anything is not clear in this consent form.

*See instruction 10 in the template instructions for information about when the “Important Information about this Study” section is required.*

**Important Information About This Study**

Things you should know:

* The purpose of the study is to [briefly describe the study’s purpose].
* To participate, you must be [briefly describe eligibility criteria]
* If you choose to participate, you will be asked to [do what, when, where, and how]. This will take [State total length of time. If there are multiple sessions give the number].
* Risks or discomforts from this research include [briefly describe most likely risks and if it is the case state that the risks involved in this study are not greater than everyday life].
* The possible benefits of this study include [Provide a description of potential benefits to subjects or state that there is no direct benefit for participating in this study. However, there must be indirect benefits].
* Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

More detailed information may be described later in this form.

Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

**What is the study about and why are we doing it?**

The purpose of this research is:

*The information here should be a clear and short description of the “bottom line” of the study. Briefly provide participants with some background information about why this study is being done. This can include information about what is already known and what you hope to learn.*

**What is involved in the study?**

Participation is completely voluntary. If you decide to participate you will be asked to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. We think this will take you \_\_\_\_\_\_\_\_\_\_ minutes/hours.

*Refer to participants as you. Tell participants* ***exactly*** *what to expect. Explain what will happen during the study and how the study will work. List* ***everything*** *that the participants will be asked to do. Describe all surveys and data collection instruments that the participants will experience. Indicate how long each survey or procedure will take and state how long (e.g., minutes, hours, days, months, until a certain event or endpoint) the participants will be part of the study. Include the format of the instruments (online, paper, video, etc.).*

**Risks**

This is a minimal risk research study. That means that the risks of participating are no more likely or serious than those you encounter in everyday activities.

 *OR*

This study is greater than minimal risk, meaning that the risks are [slightly/significantly] higher than those you encounter in everyday activities.

All consent forms should include:

The foreseeable risks or discomforts include \_\_\_\_\_\_\_\_.

*Even if the study is minimal risk list any foreseeable physical and non-physical risks of participating in the study. Non-physical risks may include social, psychological, or economic harm; risks of criminal or civil liability; or damage to financial standing, employability, or reputation. The risks should match what is in the protocol. Note that loss of confidentiality is nearly always a risk in research studies. Include what will be done to minimize the risks*.

*If appropriate include this information:*

To minimize those risks and discomforts, the researchers will [*list what the research team is doing to minimize those risks and ensure it is consistent with your protocol].*

*If your protocol is greater than minimal risk, you must explicitly state whether compensation and/or medical treatment is available if there is an injury and where to go or who to contact for compensation/treatment.*

*For greater than minimal risk protocols or if you feel it is applicable:*

If you are injured in any way, [compensation/medical treatment] [is/is not] available. Please [contact PERSON/go to RESOURCE] immediately if you are injured so that further information can be provided.

**Benefits**

It is reasonable to expect the following benefits from this research.

*List all the benefits that might* ***reasonably*** *be expected from participating in the study. Please do not overstate benefits. First, describe benefits to participants, and then describe benefits to others. If there are no* ***direct*** *benefits to the individual participant state:* There are no known benefits to you personally arising from this study. *Follow this with a statement about the benefits to others* ***(indirect*** *benefits): “*…information from this study may benefit other people now or in the future… *(explain) “or* “…we hope to learn more about \_\_\_\_\_\_\_ …”

*A study should have direct or indirect benefits or both. Before the research is completed actual benefits are unknown so benefits should be stated using terms such as may or might.*

**Alternative Procedures**

*Include this section if appropriate. This includes situations in which there are alternative procedures or treatments instead of those in the study. It also includes situations in which extra credit is offered for participation. In this case, describe the alternative assignment(s) that is/are available.*

**Confidentiality and Data Security**

The Freedom of Information Act in Arkansas allows for records of any research affiliated with

this institution to be requested by anyone in Arkansas.

We will make every effort to keep information about you confidential *(not anonymous), to the extent*

*allowed by law and University policy.*

Data will be stored in a secure manner *(describe security measures)* for a minimum of three years.

*Describe confidentiality and security protections here. Explain how you are protecting the participant’s information. Give details as appropriate: for example, are data files in locked cabinets, are the data stored electronically, how is the data kept secure (e.g., is a password required for getting onto the system, is the data encrypted), who has access to the data, etc. List all individuals and agencies that will have access to the data and records, and how data will be described if published or shared with others. Will you be using direct quotes, which could be traced back to the individual? Will you be aggregating the data? If you plan to separate the identifiers from the data and destroy them state when that will occur.*

*For sensitive research data with identifiers, stored in the cloud or on servers, or transmitted via the internet, consider including the following statement:*

Data may exist on backups and server logs beyond the timeframe of this research project.

*OR*

Your confidentiality will be kept to the degree permitted by the technology being used. We cannot guarantee against interception of data sent via the internet by third parties.

*When the research involves e-mail communication, include the following statement:*

Please note that email communication is neither private nor secure. Though [I am/we are] taking precautions to protect your privacy, you should be aware that information sent through e-mail could be read by a third party.

*If the PI is a student be sure to include the name of the supervising faculty and any others who will see the raw data. Also, be sure to indicate that the data will also remain in the possession of the faculty member.*

It is unlikely, but possible, that others (UA Little Rock, [funding sponsor,] or state or federal officials) may require us to share the information you give us from the study to ensure that the research was conducted safely and appropriately. We will only share your information if law or policy requires us to do so.

**Audio/Video Recording**

*If audio and/or video recordings will be made, explain why these are needed and what will be done with them upon completion of the research (kept indefinitely, archived after transcription, destroyed after X years).*

**Future Use of Identifiable Data or Specimens Collected in this Research**

*If you are collecting identifiable data or identifiable biospecimens, you must include one of the following****:***

Identifiers might be removed and the de-identified information from your *[information/biospecimens]* and used or distributed for future research without additional consent from you.

*OR*

Your *[information/ biospecimens]* will not be used or distributed for future research studies even if all of the identifying information has been removed.

***Note to PIs:*** *Any future research using this data requires IRB approval.*

**Compensation**

*If participants will receive incentives, please STATE CLEARLY. State how much participation is required to earn the incentive. The incentive must be prorated in the case of partial completion of the study. What happens if a participant drops out? If the study involves compensation through a lottery, please be sure to identify the odds of winning. If students will receive extra credit for participation, ways of earning extra credit without participating in the research should be mentioned here.*

**Your Rights as a Participant**

Please take whatever time you need to ask the researchers questions about the study. You are free to stop participation at any time without any penalty.

*Cover that the participant may refuse to participate before the study begins, can stop participating at any time, or skip questions.*

*Describe procedures for withdrawing and any follow-up that you will request for participants who withdraw early. Also, what will happen to the data if participants change their minds, will it be destroyed? Follow-ups such as questionnaires that are part of the research cannot be forced upon participants who wish to withdraw.*

*Make it clear that the participant will not be penalized or lose benefits for skipping questions, withdrawing, or not volunteering in the first place by the researchers, by UA Little Rock (if that is applicable), or by any others (list them) that are relevant to this project.*

**IRB Approval and Contacts for Questions or Problems**

This study has been reviewed and approved by UA Little Rock's Institutional Review Board (IRB). The IRB has determined that this study meets the ethical obligations required by federal law and University policies.  If you have questions or concerns regarding this study, please contact the Principal Investigator (provide university email and university phone number if available) or Advisor (If there is an advisor provide university email and phone number if available). If you have any questions regarding your rights as a research participant, please contact the Office of Research Compliance at 501-916-6209 or irb@ualr.edu.

*The IRB recommends that researchers* ***not*** *include home addresses, personal emails or private cell phone numbers.*

**Consent of participant (or legally authorized representative)**

* I affirm that I am 18 years old or older.
* I have read, understood, and agree to participate

*If appropriate*

* I consent to be recorded.
* I do not want to have this interview recorded.

*If you are requiring signed informed consent include the signature line below.*

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of participant or representative Date

*Upon signing, the participant, or the legally authorized representative, may receive a copy of this form or must have access to it. If signed, the original will be held by the PI. Signed forms must be kept for three years past the life of the study. If the researcher is a student, copies must be kept by the supervising faculty. Make sure to cover in the protocol how the participants can receive a copy of the consent form.*

*If you have permission to waive* ***signed*** *informed consent, instead of the signature line above you can use the following statement at the end of the informed consent before the participant begins the study activities.*

**If you are 18 years of age or older, understand the statements above, and freely consent to participate in the study, click on the “I Agree” button to begin the survey.**

⃝ I Agree ⃝ I Do Not Agree