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| **For Reporting Adverse Consequences to Humans Participating in Research** |
| **All forms must be completed, signed, and submitted via email to** [**irb@ualr.edu**](mailto:irb@ualr.edu)**.**  **If there are multiple participants with adverse events then complete multiple forms.** |

**DEFINITIONS**

**Unanticipated Problem Involving Risks to Participants or Others (Unanticipated Problem):** Any event or problem that (1) was **unforeseen** in terms of nature, severity, or frequency given the approved research protocol and participant population; (2) **related** **or probably related** to participation in the research or if the incident probably or definitely affects participants even if the event does not appear to be associated with the research protocol and (3) suggests that the research places participants or others at a **greater risk of harm** than was previously known or recognized.

Examples include: Adverse events, a breach of confidentiality or privacy that involves real or potential risk, data and safety monitoring reports that indicate the frequency or magnitude of harms or benefits may be different than initially presented to the IRB, incarceration of a participant in a protocol not approved to enroll prisoners, complaints from participants or others involved in the research that indicate unexpected risks or that cannot be resolved by the research team. This is not an exhaustive list.

**Adverse event:** Any physical, psychological or social harm to participants during the course of research. Unexpected: An event is “unexpected” when its specificity and severity are not accurately reflected in the informed consent document.

**Related to the research:** An event is “related to the research procedures” if in the opinion of the principal investigator, it was more likely than not to be caused by the research procedures or if it is more likely than not that the event affects the rights and welfare of current participants.

The problems or events above may be unanticipated risks to participants or others. The IRB needs this information to determine that risks to participants are minimized and are reasonable in relation to the anticipated benefits.

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| **When to Use this Form:**  The Principal Investigator (PI) should complete and sign this form and submit it with related attachments for any event that falls into either Category A or Category B, below. If the PI is a student, the advisor must also sign. |

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| **Category A: Any *Serious Adverse Event* that Occurs within 48 Hours of Participation in the Research**  Serious adverse events are those resulting in death, a life-threatening experience, hospitalization or prolongation of existing hospitalization, a persistent or significant disability or incapacity. Every serious adverse event must be reported on this form, even if the event does not appear to be associated with the research protocol. In addition, the IRB Office (at 501-916-6207) or [irb@ualr.edu](mailto:irb@ualr.edu) ) should be notified within 24 hours of discovery of any serious adverse event. |
| **Category B: Any Event for which *All Three* of the Following are True:**   1. **Risks to Participants or others have increased.** An event or outcome has occurred that has *resulted in harm* to the participant, has *affected the participant detrimentally*, has *worsened* a condition of the participant as a result of participation in the research, or that has resulted in *increased risk to the participant or to others,* whether or not the risk has actually resulted in harm (for example, misplacing a Participant’s research records would constitute an increased risk event that should be reported). 2. **Unexpected Event**: An event or outcome that *was not described as a risk* of participation in the research, or, though described as a risk, has occurred with *unexpected severity or frequency.* 3. **Possibly, Probably, or Definitely Related Event:** An event or outcome that was *definitely related* to participation in the research or that it is *reasonable to conclude* was related to participation, or *that it is possible* to conclude was related to the research, but for which there is not enough information available at this time to assess the likelihood of this possibility. |

**PROBLEM / ADVERSE EVENT (AE)**

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| **Check the applicable boxes for the problem/adverse event:** | | |
| **1.** |  | The problem/adverse event suggests that the research places Participants at a greater risk of harm than was previously known or recognized (including physical, psychological, economic, or social harm); **and** |
| **2.** |  | The problem/adverse event was unexpected; **and** |
| **3.** |  | The problem/adverse event is related or possibly related to participation in the research. |
| **4.** |  | The problem/adverse event involves a death which is related to participation in the research. |
| **5.** |  | The problem/adverse event does not fall under the IRB’s prompt reporting requirements, but **in the PI's judgment**, prompt reporting of the event(s) is in the best interest of the participant(s) because it may affect the safety and/or welfare of Participants and/or change the risk level of the study. |

**Section 1. PROTOCOL INFORMATION**

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| **1A. Principal Investigator:** |
| **Co-Investigator(s):** |
| **Advisor (If PI is a student):** |
| **1B. Protocol Number:** |
| **1C. Project Title:** |

**Section 2. TIMING OF EVENT**

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| **2A. Date of adverse event:** |
| **2B. Date of its discovery by research personnel:** |
| **2C. Date report submitted to IRB:** |

**Section 3. LOCATION**

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| **3A. Where was the research activity conducted?** |
| **3B. Where did the incident (or consequent events) occur?** |

**Section 4. RESEARCH PERSONNEL**

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| **Who was present when the incident (or consequent events) was (were) discovered?** |

**Section 5. EVENT TYPE** (definitions are at the top of page 1)

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| Category A—Serious Adverse Event  Category B—Other Unanticipated Event Adversely Affecting Participant or Others |

**Section 6. PARTICIPANT INFORMATION** (If there are multiple participants with adverse events then complete multiple forms.)

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| **6A. Participant ID number:** |
| **6B. Age:** |
| **6C.**  Male  Female  Other, *please specify*: |
| **6D. Known pre-existing condition(s), if any:** |

**Section 7. DESCRIPTION OF EVENT**

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| **7A. This event (check all that apply):**  caused psychological harm or injury.  caused physical harm or injury.  caused social harm or injury.  caused economic harm.  caused a breach of confidentiality.  increased risk of psychological, social, or economic harm or injury.  increased risk of breach of confidentiality.  was a life-threatening experience.  required emergency treatment.  required transport to hospital.  required hospitalization.  Other: |
| **7B. Provide a brief narrative of the event:** |

**Section 8. RESOLUTION**

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| **Describe any and all steps and actions taken in response to the incident or to resolve the issue:** |

**Section 9. PARTICIPANT STATUS**

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| **9A. What was participant’s participation level after the event?**  Participant stopped research participation  Participant withdrew from further participation  Investigator withdrew participant from further participation  Participant had already completed research  Participant continued research participation  Participant continued participation with follow-up only  Other: |
| **9B. Describe the participant’s prognosis:** |

**Section 10. PREVIOUS RESEARCH**

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| **10A. Has any previous research conducted by the PI or others produced this type of event or outcome?**  Yes  No  Unsure |
| **10B. If yes, describe and reference previous reports:** |

**Section 11. EVENT CATEGORIZATION**

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| **11A. The event is:**  Expected  Unexpected |
| **11B. The event is:**  Serious  Not serious |
| **11C. In the PI’s judgment, was there a relationship between the event and the research?**  Definitely: clearly related to the research  Probably: likely related to the research  Possibly: may be related to the research but not enough information is available to assess this  Probably not: doubtfully related to the research  Definitely not: clearly not related to the research |

**Section 12. RELATION TO RISKS**

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| **12A. In the PI’s judgment, was this event related to the risks as presented in the protocol or consent documents?**  Yes No. If no go to #13 below. |
| **12B. If yes, attach copies of the research protocol and consent document(s) with relevant sections highlighted.**  Attached |

**Section 13. REVISIONS**

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| **13A. In the PI’s judgment, should the research protocol or consent form(s) be revised?**  Yes No |
| **13B. If yes, complete and attach a Modification form and revised materials, as applicable.**  Attached Will Follow What is the estimated date? |
| **13C. If no, provide an explanation.** |

**Section 14. NOTIFICATION OF PARTICIPANTS AND OTHERS**

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| **14A. In the PI’s judgment, which of the following participant groups, legally authorized representative, or parents/guardians should be notified? Check all the apply**  New participants  Currently enrolled participants  Participants that have completed the research  Legally authorized representatives or parents/guardians  None |
| **14B. If any but “None” are marked, complete and attach a Modification form and revised consent or assent form(s).**  Attached Will Follow What is the estimated date? |
| **14C. In the PI’s judgment, is it necessary to obtain a new consent or assent of participants, legally authorized representative, or parents/guardians who have already given their consent or assent to participate?**  Yes No |
| **14D. If “Yes” is marked, complete and attach a Request for Protocol Modification form and revised consent or assent form(s).**  Attached Will Follow - What is the estimated date? |

**Section 15. IMPACT ON RESEARCH**

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| **In the PI’s judgment, the research should:**  **Continue as planned** with no changes to the research protocol or consent process.  **Continue with changes** to the research protocol or consent process, as previously noted on this form.  **Suspend new Participant enrollment** until the event is assessed further.  **Be terminated** (stopped completely), with all participants removed from research. |

**Section 16. REPORTS FILED**

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| **16A. Has the event been reported to any other organizations or regulatory bodies?**  Yes No |
| **16B. If “Yes” is marked, list all that apply and attach copies of the reports submitted to these places.** |

**Section 17. INVESTIGATOR ASSURANCES**

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| I have reviewed the contents of this form, with attachments, and I certify that the information provided is complete and accurate to the best of my knowledge. |
| **The original signature of the PI is required before this form can be processed (electronic signatures are acceptable).**    Principal Investigator Date |
| Co-Principal Investigator(s) Date |
| Advisor (If PI is a student) Date |

After receiving the form, the IRB will review it and the following outcomes are possible:

a. a decision that no further action is required

b. a decision to suspend the research until the problem is resolved

c. a decision to terminate the research

The IRB will decide if non-compliance has occurred and in that case the noncompliance policy will be followed. The IRB will also decide whether OHRP, any funding agencies, the Chancellor, legal counsel, and department heads need to be notified.