Event Report Form

For use by ORI only

Review by IRB Chair:

Review by convened IRB:

Risk level:

Date:

HS

(*For use by UCR faculty researchers, students, visiting professors, and postdocs*)

**I – General information**Principal Investigators must report all complaints and concerns, non-compliance by the research staff, protocol deviations, and Unanticipated Problems to the IRB **within ten (10) working days** of discovery or awareness. Exceptions to the reporting deadlines may be made for emergency situations (e.g., COVID-19 outbreak).

This form must be typed out and submitted via e-mail to [irb@ucr.edu](mailto:irb@ucr.edu) along with all relevant materials and required signatures. All the applicable questions should be answered.

**1. IRB Application Number: HS**

**2. Title of Research Study:**

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| --- |
|  |

**3. Researcher (e.g., UCR faculty, student, postdoc, visiting professor):**

|  |  |  |  |
| --- | --- | --- | --- |
| Title (e.g., Dr., Mr. Mrs., etc.): | Name: | | |
| Faculty (50% f/t)  Doctoral  Masters  Undergrad  Post-Doctoral  Visiting professor/External researcher  Other (specify:      ) | | | |
| Department: | | | |
| Phone: | | Institutional e-mail: | |
| Alternate contact (e.g., research coordinator, department administrator) name: | | | Alternate contact Institutional e-mail: |

**4. UCR Faculty Advisor or Sponsor**

1. **List the UCR Faculty Advisor or Sponsor. (Q4a is to be filled out only if person in Q3 is a UCR student, trainee, postdoc, or visiting scholar; for faculty research, this question should be blank):**

|  |  |  |
| --- | --- | --- |
| Title (e.g., Dr., Prof): | Name: | |
| Department: | | Email: |

**5. Funding Source**

|  |
| --- |
| Is the project supported by funding?  Yes  No |
| If “yes”, provide all related funder(s) name and type:  Name:  Industry  Non-Profit sponsor  Government funding  Departmental funds  Other (describe): |
| If “yes”, was the funder notified of the event referenced below?  Yes  No |

**II. Summary of Event**

**6. Event Overview**

**Identify the categories that represent the event**: *(check all that apply)*

|  |  |
| --- | --- |
|  | **Non-compliance:** Non-compliance with the federal regulations governing human research, institutional policies, or the requirements and determinations of the IRB. Examples include, but are not limited to, failure to obtain IRB approval, inadequate supervision, failure to report unanticipated problems and adverse events, interaction with/or collection of data from an incarcerated individual in a project not IRB approved to involve prisoners, or protocol changes made without IRB approval. |
|  | **Emergency Protocol Deviation:** A protocol deviation taken without prior IRB review to eliminate an apparent immediate hazard to a research participant (e.g., response to COVID-19 outbreak). |
|  | **Protocol Deviation:** Prospective departure from the defined procedures sent forth in the IRB-approved protocol without prior IRB review. |
|  | **Confidentiality breach:** Breach of research data confidentiality; loss or destruction of research data not in accordance with IRB approval, institutional policy or federal regulations (e.g., HIPAA). |
|  | **New or increased risk:** Information that indicates a new or increased risk of harm, or a safety issue. For example:   1. New information (e.g. an interim analysis, safety monitoring report, publication in the literature, funder report, or researcher finding) indicates an increase in the frequency or magnitude of a previously known risk or uncovers a new risk. 2. Protocol violation that harmed participants or others, or that indicates participants or others might be at increased risk of harm. 3. Complaint from a participant or other that indicates participants/others might be at increased risk of harm or at risk of a new harm. |
|  | **Unanticipated problem involving risk to participants or others:** Any incident that, in the opinion of the researcher, is unexpected, possibly related to the research procedures, and suggests that participants or others are at a greater risk of harm than was previously known.   1. A harm is **“unexpected”** when its specificity or severity is inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, or characteristics of the research population (e.g., no listed as a risk in the consent form). 2. A harm is **“possibly related”** to the research procedures if there is a reasonable possibility that the incident, experience, or outcome was more likely than not to have been caused by the research procedures. |
|  | **Suspension:** Premature suspension or termination of the research by the funder, researcher, or institution. |
|  | **Other** *Describe***:** |

**7a. Description of event**

**Timing of Event**

|  |
| --- |
| **Date of event:** |
| **Date of its discovery:** |
| **Date of this report:** |
| **Was IRB/ORI made aware of this event (describe):** |

**Describe the event below as comprehensively as possible. Include attachments as necessary.**

|  |
| --- |
|  |

**Event Categorization**

|  |  |
| --- | --- |
| **The event is:**   Expected  Unexpected | |
| **The event is:**  Serious  Not serious | |
| **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 |

**7b. Event Resolution**

**Describe any and all steps and actions taken in response to the event or to resolve the issue.**

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|  |

**Revisions**

|  |  |  |
| --- | --- | --- |
| **Yes** | **No** | **In the PI’s judgement…** |
|  |  | Is the risk of this event contained in the current approved consent form? |
|  |  | Should the consent form or any portion of the study be revised as a result of this event? If yes, enclose the revised documents with all revisions as part of a study amendment |
|  |  | Will currently enrolled participants be notified of this event?  If yes, describe method of notification:  If no, please indicate why: |
|  |  | Should enrolled participants be re-consented? If yes, enclose the revised consent form as part of a study amendment  If no, please indicate why: |

**Effect on Research**

|  |  |
| --- | --- |
| **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. |

**III. Signatures**

**IRB submission instructions:** All event report forms must be submitted via email to [irb@ucr.edu](mailto:irb@ucr.edu), **with the required signatures** in place. Signatures whether electronic or scanned signatures are acceptable.

If this form is a revision of an incident report form for this incident which included signatures, there is no need to complete this section again. Taking a single picture of all the signatures in place as well as inserting a jpeg of the signature is also acceptable. Typed-in signatures only, will not be accepted.

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

My signature as researcher, confirms that the information provided in this report is true and accurate to the best of my knowledge. I am responsible for the scientific and ethical conduct of the research and providing all reports and information to the IRB, as well as other related groups.

**Researcher’s signature: Date:**

My signature as UCR faculty advisor and/or supervisor, confirms that the information provided in this report is true and accurate to the best of my knowledge. I have read and reviewed all aspects of this report. As a UCR faculty supervisor, I am ultimately responsible for the scientific and ethical conduct of the research and providing all reports and information to the IRB, as well as other groups.

**UCR faculty advisor and/or supervisor signature: Date:**