|  |  |  |  |
| --- | --- | --- | --- |
|  | Additional information or instructions |  | Link to information or additional forms |
|  |  Only type into shaded rows that include this pencil icon |  | External document may need to be submitted |
|  |  |  |  |
| **SECTION 1: Study Title and PI** |
| 1 | Study Number |
|  | Insert response here |
| 2 | Study Title |
|  |  |
| 3 | Name of Principal Investigator  |
|  |  |
|  | Submissions will only be reviewed when received *directly* from the PI. |
| **SECTION 2: Event Details** |
|  | **Note about reporting timeframe:** Incidents may constitute more than one type of reportable event. Report within the shortest applicable timeframe.**Note about content:** Do not provide the Human Research Protection Program with individually identifiable information about study participants. Narratives and supporting documents should be de-identified prior to submission. |
| 1 | What was the date of the occurrence? |
|  |  |
| 2 | When did you discover this occurrence?  |
|  |  |
| 3 | Describe the occurrence (problem, event, deviation, etc.): |
|  |  |
| 4 | What, if anything, has been done to address this occurrence? |
|  |  |
| 5 | What is the current status of the study? For example, is recruitment ongoing, are participants still taking part in study activities, or is the study closed to enrollment? |
|  |  |
| 6 | How will you prevent a recurrence in this or other studies on which you are the principal investigator? |
|  |  |
|  | Attach any reports of this occurrence that have been sent to collaborators, the funding agency, the FDA, or other outside entity. |
| **Event Type Descriptions** |
|  | **UNANTICIPATED PROBLEM****Reporting Timeframe**Report this to the HRPP Office within 24 hours if the incident involved a death; otherwise report within 3 business days of discovery.**Definitions***Unanticipated problems* include any incident, experience, or outcome that meets **all** of the following criteria:* Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
* Related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
* Suggests that the research places subjects or others (investigators, students, the public, subjects’ family members) at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

**Examples*** Information that indicates a change to the risks or potential benefits of the research, such as:
	+ An interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the IRB.
	+ A paper is published from another study that shows that the risks or potential benefits of your research may be different than initially presented to the IRB.
* A breach of confidentiality. This includes reporting to the Office of Equal Opportunity and Access triggered by Title IX; reporting to state or federal authorities triggered by a mandatory reporting law; disclosures required by subpoena; and other similar disclosures. Other breaches include loss of a field notebook; theft of a research computer; or a security violation in a locked space or restricted drive. Breach of confidentiality is considered to place subjects at risk, but is only unanticipated if it was not described as a risk in the consent form.
* Incarceration of a participant in a protocol not approved to enroll prisoners.
* Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.
* Complaint from a participant that cannot be resolved by the research team.
* Sponsor imposed suspension.
* Any other event that indicates participant(s) or others might be at risk of serious, unanticipated harms that are reasonably related to the research.

**ADVERSE EVENT****Reporting Timeframe**Report this to the HRPP Office within 30 business days of discovery.**Definitions**An Adverse Event is an event that occurs during the course of a research protocol that either causes physical or psychological harm, or increases the risk of physical or psychological harm, or results in a loss of privacy and/or confidentiality to a research participant or others (such as family members). A *reportable* adverse event is one that meets all three of the following criteria: * Temporally associated with the subject’s participation
* Related or possibly related to the research
* Moderate to severe in nature

Mild: Event results in transient discomfort; does not influence performance or functioning; does not require intervention or treatment; does not limit or interfere with daily activities; expected to resolve quickly with no physical, psychological, social, or economic consequences. Moderate: Of sufficient severity to make the patient uncomfortable; may include worsening of conditions present at the onset of the study; treatment of symptom(s) may be needed; expected to resolve but short term physical, psychological, social, or economic consequences are possible.Severe: Event results in significant symptoms that prevents normal daily activities; may require hospitalization or invasive intervention. Long term physical, psychological, social, or economic consequences are possible.**Examples**An **Anticipated Adverse Event** is one that is listed in the protocol and consent form as a risk of participating in the research, such as:* A participant experiences a muscle strain during research-related exercise
* A participant faints during a research blood draw
* A participant becomes upset during an interview and requires a referral to a counselor

An **Unanticipated Adverse Event** is one that was not listed in the protocol and consent form as a risk of participating in the research, such as:* A participant requires hospitalization after an experimental device they are asked to use breaks during a study visit
* A participant reports distress when her classmates ostracize her for choosing to be in a study

**DEVIATION****Reporting Timeframe**Report this to the HRPP Office within 10 business days of discovery.**Definition**A deviation is any alteration or modification of an IRB-approved protocol made without prior IRB approval. A deviation that increases risk, has the potential to recur, or is undertaken to eliminate an immediate hazard, may also be an *Unanticipated Problem*.**Examples*** Replacing the principal investigator without prior approval
* Modifying the consent document without prior approval
* Adding a new funding source without submitted a revision for review
* Enrolling a 16 year old when the study was only approved for adult participants
* Using a survey or test instrument that was not previously reviewed and approved by the IRB
* Adding compensation or study incentives without prior approval

**Significant New Findings that Require Notification to Research Participants****Reporting Timeframe**These reports may be submitted to the IRB as a project revision, as part of the continuing review process, or as an unanticipated problem; whichever is most appropriate to the findings and the related timeframe will apply. **Definition**A significant new finding is anything that develops during the course of the research which may relate to a subject's willingness to continue participation; may impact their rights or welfare; increases the risks to subjects or others; or decreases the benefits to the subjects or of the study in general. **Examples*** Changes in standard of care, such that participation in research can increase risk to subjects (i.e., subjects would be deprived of the standard of care by continuing to take part in the research study)
* Identification of new risks to subjects currently receiving the study treatment
* Identification of potential late-term effects for subject who completed study treatment
* Discovery that a research-related risk occurs more frequently than previously expected or disclosed
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**PI should email completed form and all relevant attachments to** **IRB@oregonstate.edu**