Federal regulations [45 CFR 46.103(b)(5)] require the IRB to ensure that investigators promptly report any “unanticipated problems involving risk to subjects or others” (UPIRSO). The IRB defines UPIRSOs as any research related incidents that may impact the rights, safety, or welfare of subjects or others. An UPIRSO may impact the risks or harms to physical, financial, legal, social, emotional or psychological well being, privacy, or confidentiality. Although the reporting of adverse events is commonplace in biomedical research, an unanticipated problem meeting the level of an UPIRSO and prompt reporting to the IRB can occur in any type of research.

Examples of UPIRSOs are a breach of confidentiality due to the loss of a laptop; a subject complaint when the complaint indicates unexpected risks or a complaint which cannot be resolved by the investigators; or a research team member experiences harm in the conduct of the study.

Prompt reporting to the UCAIHS will be limited to events meeting the criteria of an UPIRSO. UCAIHS will return without IRB review reports of events not meeting the criteria of an UPIRSO.

**EVENT REPORTING PROCESS**

**Reporting Events to the UCAIHS IRB**

1. Any event that meets the definition of a UPIRSO must be reported to the UCAIHS IRB in writing within five business (5) days.
2. All serious unanticipated problems or adverse events that represent increases in severity or frequency of known risks should be reported within five (5) working days of discovery of the incident.
3. **Death of a NYU Subject** - Any death of a NYU subject that is unexpected and related or possibly related to the research must be reported as soon as possible, but no later than within 24 hours of discovery of the event by calling the UCAIHS Office (212-998-4808). A written summary of this event must be submitted to the UCAIHS within five (5) business days following the telephone call. The PI must complete and submit the *Event Requiring Prompt Reporting to the IRB* form.
4. The UCAIHS will return without IRB review reports of events not meeting the criteria of an UPIRSO. Examples of events that do not require prompt reporting are:
   a. adverse events and problems that are expected, unrelated, or do not involve an increase of risks to subjects or others;
   b. reports of external adverse events (non-NYU), whether serious or not, that do not meet the criteria of an UPIRSO;
   c. adverse device effects (such as MRI) that are non-serious, anticipated, or unrelated;
   d. Protocol deviations or violations not involving risks to participants or unlikely to recur;
   e. Complaints made by research participants not involving risks, or complaints that were resolved.
5. Whether or not the adverse event is an UPIRSO or requires prompt reporting to the IRB, the investigator should be aware of the potential need to still report the adverse event to one or more monitoring or regulatory entities (i.e., sponsor, data coordinating center, collaborators, other IRBs), depending on the provisions in the IRB-approved protocol.
INSTRUCTIONS:

The process for submitting a reportable event is as follows:

1. Complete the UCAIHS Event Requiring Prompt Reporting to the IRB form. **One report form must be completed for each reportable event.** You must answer the questions in all sections.
2. Attach any supporting documentation (i.e., case report form, medical transcripts, death certificates) to the report. Any identifying information (name, medical record number) about the subject should be removed and only his/her study identification number included for tracking purposes.
3. UPIRSOs are to be reported within 5 days of the Principal Investigator learning of the event, within 24 hours if the UPIRSO involves a reportable subject death (see item 3 above).
4. If the reportable event warrants change to the informed consent process/document(s) (consent, parent/guardian permission or assent documents), the research protocol application, and/or research protocol, the document “Amendments to Previously Approved Research” must also be completed and submitted for review by the IRB. See the amendment submission instructions for the appropriate submission procedures.
5. Attach copies of any amendments, revised informed consent documents, assent documents, research protocol, and/or protocol application, if applicable.
   a. If you indicated that you will notify subjects of the event, explain how they will be notified and attach a copy of the type of notification (revised consent, letter, consent addendum) that will be used. You will need to submit this information to the IRB as an amendment for review and approval. The amendment may be attached to this report, if the amendments and supporting documents are ready for submission at the same time as this report).
6. Submit the completed report form and supporting documentation to the UCAIHS Office at apply.humansubjects@nyu.edu
7. The Principal Investigator will be notified if any missing documentation or additional information is required or if the event requires review by the convened IRB.
8. **Note:** If an UPIRSO impacts the safety of subjects enrolled in the research or requires substantive revision to the research procedures or informed consent document, then the UPIRSO requires convened IRB review.

Section I – Research Protocol Information

1. Provide the following general information about the research protocol for which you are submitting this event:
   a. The date you complete the report
   b. HS number and title of the research protocol
   c. Name and Net ID for the Principal Investigator

Section II – Assessing the Event

1. To determine if the event meets the definition of an UPIRSO, answer the following questions. If you answer NO to any of the following questions, the event does not meet the definition of an UPIRSO. If you answer YES to ALL of the questions, complete the Event Requiring Prompt Reporting to the Institutional Review Board Form.
   a. Was the event unexpected (in terms of its nature, frequency or severity) at the time of its occurrence?
   b. Is the event related or possibly related to the research?
   c. Does the event suggest that subjects or others may be at greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized?
d. If the UPIRSO is an adverse event, determine which of the following best describes the event:
   i. The event is serious, unexpected (in terms of its nature, frequency or severity) and related or possibly related to participation in the research.
   ii. The event is not serious, but is unexpected (in terms of its nature, frequency or severity), related or possibly related to the research and suggests that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized.

2. If the event meets the definition of a UPIRSO, answer question #2. If needed attach applicable pages of documents showing that the consent and/or protocol are consistent with information about the event. If no, briefly explain why not.

Section II – Type of Event
1. Select the type(s) of event that is being reported
   a. **UPIRSO** (unanticipated problems involving risks to subjects or others) is any incident, experience or outcome that is not expected (in terms of nature, severity or frequency) given (a) the research procedures that are described in the protocol-related documents (such as the research protocol and informed consent document) and (b) the characteristics of the subject population being studied; is related or possibly related to participation in the research; and suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
   b. **Breach of Confidentiality** – Specify (e.g., loss of study data or forms, computer theft, etc.)
   c. **Complaint** made by a research participant indicating an unanticipated risk or one that cannot be resolved by the research staff. A subject complaint that resulted in or revealed an unexpected risk or harm to subjects.
   d. **Death of a Research Subject** – if the event meets the criteria for a reportable death of a research subject, provide any pertinent information about the event (i.e., copy of death certificate, medical records, doctor’s statement)

Section IV – Event Information
Describe the event you are reporting. Include the following:
1. Date the event occurred.
2. Event Report Status – Check the box indicating if this is an initial or follow-up report. If a follow-up report is being submitted, indicate the number of the follow-up report being submitted (1, 2, follow-up to phone report, etc.)
3. At what site was the subject enrolled? Check the box indicating if the subject was enrolled into the research on or off campus.
4. Subject study ID# - Do not use personal identifiers to identify the subject. Use only a subject’s study identification number, or if none exists, use an event report number.
5. Provide a brief description of the event being reported. Describe how it impacted the safety or welfare of the subject or other subjects participating in the research. If the event impacted the safety of someone other than the research subject (study personnel, subject’s relative, etc.) describe who was affected by this event and how they were affected.
6. Research status – indicate the subject’s level of participation following the event.
7. Number of subjects – report the total number of subjects currently enrolled.
8. Research recruitment – indicate the current status of recruitment into this research study.
9. Research interventions/interactions – indicate the current status of the interventions or interactions being taken with all other subjects in this research study. If the research has been suspended, indicate by whom.

**Section V – Actions to Be Taken**
As a result of the event indicate the status of the research protocol and any corrective actions that will be taken. Check all of the actions that apply.

Some of the actions may require additional reporting responsibilities or actions to be taken on part of the principal investigator. This will be determined after IRB review.

If changes to the research protocol and or recruitment materials (consent, assent, advertisements) are needed, then an amendment must be submitted to the IRB for review. If the event is a UPIRSO or the research requires a suspension, additional action by the UCAIHS may be required.

If an amendment is required for this event, complete an Amendment form and submit it to apply.humansubjects@nyu.edu for review by the IRB.

**Section VI – Statement of Principal Investigator/Signatures**
The statement indicates that the report form has been reviewed by the Principal Investigator. By signing the form the PI is assuring that the event report is accurate and any additional actions required (submission of an amendment, etc.) are being taken. The form must be signed by the Principal Investigator.

If the research is conducted by a NYU student under the direction of a Faculty Sponsor, the faculty sponsor must also review and sign the report form. By signing the form the faculty sponsor is assuring that the event was properly reported and any necessary corrective actions have been taken. If changes are required to the research protocol and/or recruitment materials, the faculty sponsor must assure that the student PI has submitted the required amendments to the UCAIHS.