KENNESAW STATE UNIVERSITY
OFFICE OF RESEARCH
Research Compliance

Policy Title	Reporting
Last Updated	12/21/2021
Responsible Office	IRB Office
Contact Information	IRB Office Email: irb@kennesaw.edu Phone: 470-578-4941

1. Policy Purpose Statement

Federal regulations require that institutions engaging in human subjects research have written procedures to ensure investigators properly report certain events to the Institutional Review Board (IRB). This policy defines those events that require prompt reporting to the Kennesaw State University (KSU) IRB.

2. Scope

This policy applies to all research studies that are overseen by the KSU IRB. For studies involving KSU investigators where KSU has designated another IRB as the IRB of record, investigators must still report to the KSU IRB in accordance with this policy.

3. Definitions

3.1. **Prompt reporting**: within 3 days of an occurrence or within 3 business days of the principal investigator becoming aware of an occurrence.

3.2. **Unanticipated problems involving risks to subjects or others (UPIRSO)**: Any incident, experience, or outcome that meets all the following criteria:

3.2.1. Is 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; This may include any other safety findings (e.g. animal data) that would necessitate additions to the investigator brochure, protocol and/or informed consent to ensure protection of human subjects.

3.2.2. Is related or possibly related to an individual's participation in the research; and

3.2.3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, social, economic, legal, or informational harm) than was previously known.

3.3. **Related or possibly related to the research:** An event is considered related to the research if, in the opinion of the investigator, it was more likely than not the result of the research interventions/interactions, or the result of the collection/use of identifiable private information for the research (i.e., there is a reasonable possibility that the event may have been caused by participation in the research).

3.4. **Adverse event**: Any untoward or unfavorable occurrence in a research participant that is temporally associated with the participant's involvement in the research. An adverse event encompasses physical, psychological, social, economic, legal, or informational harms. It may or may not be directly related to the individual's participation in the research.

3.5. Serious adverse event: Any adverse event temporally associated with the individual's participation in research that meets any of the following criteria:
  3.5.1. Results in death;
  3.5.2. Is life threatening (places the subject at immediate risk of death from the event as it occurs);
  3.5.3. Requires inpatient hospitalization or prolongation of existing hospitalization;
  3.5.4. Results in a persistent or significant disability/incapacity;
  3.5.5. Results in a congenital anomaly/birth defect;
  3.5.6. Based upon appropriate medical judgment, may jeopardize the individual's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition;
  3.5.7. Results in a breach of confidentiality that is damaging to the participant's rights, employment, financial standing or reputation; or
  3.5.8. Causes significant psychological, social, economic, or legal harm to the participant or others.

3.6. Unexpected adverse event: Any adverse event occurring in one or more participants when the nature, severity, or frequency is not consistent with either
  3.6.1. the known or foreseeable risk described in (a) the protocol-related documents (e.g., the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document) and (b) other relevant sources of information (e.g., product labeling and package inserts);
  3.6.2. the expected natural progression of any underlying disease, disorder, or condition of the individuals(s) experiencing the adverse event and the individual's predisposing risk factor profile for the adverse event.

3.7. Unanticipated adverse device effect (UADE): For studies of medical devices, the investigational device exemption regulations define an unanticipated adverse device effect as any serious effect on health or safety or any life threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects (21 CFR 812.3(s)).

4. Policy
4.1. Events that must be promptly reported to the IRB:
  4.1.1. Any serious adverse event that is related or possibly related to the research (see definition 3.5);
  4.1.2. Any event that meets the definition of an unanticipated problem (UPIRSO) (see definition 3.2);
  4.1.3. Any event that meets the definition of serious or continuing non-compliance (IRB Policy: Non-Compliance);
  4.1.4. Potential breaches of confidentiality
    4.1.4.1. Potential breaches of confidentiality that involve protected health information (PHI) must also be reported promptly to the covered entity
  4.1.5. Incarceration of a participant in a study not approved by the IRB to involve prisoners and the study team plans to continue study activities with prisoners while incarcerated.
  4.1.6. Unexpected adverse events

4.1.7. Complaints of subjects which may indicate an unexpected adverse event or cannot be resolved by the research team.
4.1.8. Voluntary suspension or termination of an IRB approved research project by the principal investigator or study sponsor.
4.1.9. Unanticipated adverse device effect (UADE)

4.2. If the problem is or poses an immediate risk of serious harm to a participant or others, it must be reported immediately (within 24 hours) to IRB@kennesaw.edu or by phone (470) 578-2106.

4.3. Events that do not meet the above criteria should be summarized and reported to the IRB at the time of continuing review, administrative check in, or study closure, whichever occurs first.

4.4. If applicable, results of all data safety monitoring board (DSMB) meetings must be reported to the IRB and must also follow the requirements and timelines set forth in the DSMB charter that are in place for the research.

5. How to report to the IRB

5.1. Events identified in this policy are reported to the IRB by submitting an Incident Report in Cayuse. In addition, PIs should use their discretion to call or email the IRB Chair or IRB Office Director.
5.1.1. Log in to Cayuse and select the study related to the incident to be reported.
5.1.2. From the Study Details page, click blue box labeled "+ New Submission" on the right side of the screen and select "Incident". This will create the Incident submission.
5.1.3. From the cover page of the Incident submission, select "Edit" to open the form and answer provided questions and attach any supporting materials, if necessary.
5.1.4. Upon completion of the form, click "Submit" and then "Certify".

5.2. Incident report must include study ID, study title, PI name, detailed description of the event, description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the event.

5.3. The PI must

6. Procedures: IRB

6.1. Upon receipt of an Incident Report, IRB/Human Subjects Office (HSO) staff conduct a pre-review to ensure adequacy of information provided and determine appropriate routing.
6.1.1. Incident reports received that do not meet criteria for prompt reporting are acknowledged.
6.1.1.1. A copy of the report is placed in the IRB record associated with the incident.
6.1.1.2. A letter of acknowledgement is sent to the PI.
6.1.2. IRB Policy: Non-Compliance is followed when an Incident Report reports an incident of non-compliance.
6.1.3. Incident Reports of adverse events are reviewed by the IRB/HSO Director for initial determination of serious or unexpected adverse event.
6.1.3.1. IRB/HSO Director may request additional information from the PI.
6.1.3.2. Incident Reports determined to be potentially serious and/or unexpected are added to the agenda for the next meeting of the convened IRB.
6.1.3.2.1. The convened IRB makes determinations for serious adverse event or UPIRSO and appropriate course of action which may include, but is not limited to, suspension and/or termination of the project (IRB Policy: Suspensions and Terminations of IRB Approved Research)
6.1.3.2.2. The PI is informed in writing.
6.1.3.2.3. A copy of the incident report and related materials is placed in the IRB record associated with the incident.
6.1.4. All other Incident Reports are reported to the IRB Chair.

6.1.4.1. The IRB Chair (or designee) determines actions to be taken by the IRB, IRB Office Staff, and/or PI.
6.1.4.2. The PI is informed in writing.
6.1.4.3. A copy of incident report and related materials is placed in the IRB record associated with the incident.

6.2. If the research is conducted, funded, or overseen by DHHS, is regulated by FDA, and/or other agencies that are signatories to the Common Rule, KSU must report to each respective agency, IRB findings of UPIRSO, serious or continuing non-compliance, (IRB Policy: Non-Compliance) and determinations that a study is to be suspended or terminated (IRB Policy: Suspensions and Terminations of IRB Approved Research)

6.3. Following IRB determination that an incident is a UPIRSO, serious non-compliance, continuing non-compliance, and/or IRB approval of a study is suspended or terminated, IRB/HSO staff prepare a report to the IO which must include:
6.3.1. The nature of the event;
6.3.2. The findings of the IRB;
6.3.3. The actions taken by the IRB, including plans to protect the rights and welfare of the participants, and;
6.3.4. Any plans for additional oversight, investigation, or corrective and preventative action.

6.4. The IO (or designee) submits the final report to OHRP

6.5. A copy of the final report is sent to Sponsored Programs Administration if the project is funded by an outside sponsor or agency. If the event involves the unauthorized use or disclosure of PHI, a copy will be sent to the appropriate covered entity.

Reference Materials:

45 CFR 46, especially 46.108(a)(3) and 46.111

21 CFR 56, especially 56.108(b)

FDA Guidance: Guidance for Clinical Investigators, Sponsors and IRBs: Adverse Event Reporting to IRBs – Improving Human Subject Protection

OHRP Guidance: Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events (2007)