KENNESAW STATE UNIVERSITY
OFFICE OF RESEARCH
Research Compliance

Policy Title	Non-Compliance
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

This policy addresses non-compliance as it pertains to the conduct of research involving human participants at Kennesaw State University (KSU). Incidents of non-compliance must be reported both to ensure the protection of the rights of human participants and to uphold KSU's assurance to the federal government. The purpose of this policy is to define non-compliance, provide procedures for reporting non-compliance to the Institutional Review Board (IRB), and describe actions for the IRB.

2. Definitions

2.1. Allegation of Non-Compliance: an assertion or report of non-compliance

2.2. Non-Compliance: the failure to follow federal, state, or local regulations governing human subject research, institutional policies related to human subject research, an IRB-approved research protocol, or the requirements or determinations of the IRB. This may pertain to the principal investigator, research staff, or any member or component of the Human Research Protection Program (HRPP).

2.3. Minor Non-Compliance: Any behavior, action, or omission in the conduct or oversight of research involving human participants that deviate from the approved research plan, federal regulations, or institutional policies but, because of its nature, the research project, or subject population, does or did not:

2.3.1. Harm or pose an increased risk of substantive harm to a research participant;
2.3.2. Result in a detrimental change to a participant's clinical or emotional condition or status;
2.3.3. Have a substantive effect on the value of the data collected; and
2.3.4. Result from willful or knowing misconduct on the part of the investigator(s) or study staff.

2.4. Serious Non-Compliance: Any behavior, action, or omission in the conduct or oversight of research involving human subjects that, in the judgment of a convened IRB, has been determined to:

2.4.1. Adversely affect the rights and welfare of participants;
2.4.2. Harm or pose an increased risk of substantive harm to a research participant;
2.4.3. Result in a detrimental change to a participant's clinical or emotional condition or status;
2.4.4. Compromise the integrity or validity of the research; or
2.4.5. Result from willful or knowing misconduct on the part of the investigator(s) or study staff.

2.5. Continuing Non-Compliance: a pattern of non-compliance that, in the judgment of a convened IRB:

2.5.1. Indicates a lack of understanding or a disregard for the regulations or institutional requirements that protect the rights and welfare of participants;
2.5.2. Suggests a likelihood that non-compliance will continue without intervention;
2.5.3. Involves frequent instances of minor non-compliance, such as repetitive protocol deviations.

3. Policy
   3.1. All research team members are required to conduct research in accordance with the protocol as approved by the IRB, and in accordance with federal regulations, state law, and University policy. Failure to do so constitutes non-compliance in the research endeavor, irrespective of the magnitude or intent of the deviation from the approved protocol.
   3.2. Principal Investigators are responsible for reporting all incidents of non-compliance to the IRB along with a corrective action plan ensuring the safety of research subjects and others, future compliance with the approved protocol, and prevention of reoccurrence.
   3.3. Reports of non-compliance may be made from anyone inside or outside of the University community who has reason to believe that non-compliance with human subject research regulations and/or IRB policies and procedures has occurred.
      3.3.1. University personnel, who believe in good faith that they are aware of an instance of non-compliance, are responsible for reporting such incidents to the IRB office.
   3.4. The IRB is responsible for:
      3.4.1. Investigating allegations of non-compliance;
         3.4.1.1. During the investigation the IRB Chair may impose restrictions on the research study as deemed appropriate or necessary to protect the rights and welfare of research participants.
      3.4.2. Determining serious and/or continuing non-compliance;
      3.4.3. Determining appropriate actions for any findings of non-compliance. The IRB will take into consideration the nature, severity, and frequency of the non-compliance and the risk that non-compliance poses to human subjects in determining corrective action.
      3.4.4. Reporting findings of serious and/or continuing non-compliance. (IRB Policy: Reporting).
   3.5. If the IRB determines that the reported incident constitutes serious and/or continuing non-compliance, it is authorized to take any action it deems necessary to protect the rights and/or welfare of the research participants involved and/or restore the validity/integrity of the research (if possible), including, but not limited to:
      3.5.1. Remediation or educational measures for the research team;
      3.5.2. Monitor research activities;
      3.5.3. Monitoring the informed consent process;
      3.5.4. Require notification of past or current research participants;
      3.5.5. Require re-consent of participants;
      3.5.6. Require modifications to the research protocol;
      3.5.7. Require more frequent continuing review (renewal of approval) or administrative check in schedule;
      3.5.8. Periodic audits by the IRB administrator or appointed member of the IRB.
      3.5.9. Restrict the PI's research practice, such as limiting the privilege to minimal risk or supervised projects.
      3.5.10. Suspension of approval for one or more of the PI's studies.
      3.5.11. Termination of approval for one or more of the PI's studies.
      3.5.12. Referral to other University authorities or committees for possible further review and resolution by those bodies including possible disciplinary action up to and including termination in accordance with the appropriate disciplinary procedures for faculty, staff, and students

4. Procedures
   4.1. Reports of non-compliance must contain enough information to determine whether the report is sufficiently credible and specific so that it may be identified and acted upon.
   4.2. PI and study staff report incidents of non-compliance by submitting an Incident Report in Cayuse.

4.2.1. IRB/Human Subjects Office (HSO) Staff use the Incident report to document the investigation and communicate with the PI.

4.3. Non-study staff report non-compliance or suspected non-compliance by emailing or calling the IRB/Human Subjects Office or by using the Compliance and Ethics Reporting Hotline https://www.kennesaw.edu/hotline/index.php.

4.3.1. For allegations of non-compliance that are received by non-study staff, IRB/HSO staff create an Incident Report in Cayuse to document the allegation of non-compliance and subsequent investigation.

4.4. Upon receipt of an allegation of non-compliance, IRB/HSO Director and/or IRB Chair conducts initial investigation to determine validity of the allegation.

4.5. Upon validation of the allegation, IRB/HSO staff assists IRB Chair in conducting full investigation.

4.5.1. A sub-committee may be formed for the purpose of conducting the investigation and formulation of recommendations for action items to be considered by the full committee.

4.6. Following investigation, Incident Report is added to the agenda for the next scheduled meeting of the convened IRB for determination of serious or non-serious, continuing or non-continuing, and any actions the IRB may wish to make or require of the PI resulting from these determinations.

4.6.1. If the IRB Chair determines the nature of the non-compliance requires immediate action by the IRB, an ad hoc meeting may be scheduled.

4.7. The IRB's determination is communicated to the PI in writing via Cayuse through the Incident Report. IRB requirements of remediation or corrective actions, if any, is included in this communication.

4.8. Determinations of serious or continuing non-compliance are reported to Institutional Official (IO).

4.9. The PI must provide the IRB with written documentation that the remediation or corrective actions have been completed in the time frame designated by the IRB.

4.10. Once the PI has satisfied the IRB's requirements, the matter will be considered resolved. A final written communication indicating resolution will be provided to the PI and others as appropriate.

4.10.1. The IRB may audit the research study after non-compliance resolution.

4.11. A copy of all correspondence regarding the issue is maintained in the IRB records.

Reference Material:

21 CFR 56.108(b)(2), 56.113
45 CFR 46.113

Examples of Non-Compliance

Conducting research with human participants without IRB approval:

"Conducting research" includes recruitment, consent, data collection and analysis, and writing up findings or research related reports. Engaging in these activities before IRB approval is obtained or after IRB approval expires constitutes non-compliance and may result in sanctions against the use of data obtained before or after IRB approval.

Changing or deviating from the IRB-approved research plan:

Failure to implement research activities according to the IRB-approved research plan constitutes non-compliance. The IRB must approve all changes to non-exempt human research before the changes are initiated unless changes are necessary to eliminate immediate harm to participants. In the latter case, the Principal Investigator (PI) may implement the changes but must report them to the IRB within five days of implementation by submitting an Incident Report and modification submission.

Common changes include the following:

- Increasing or decreasing participant enrollment by greater than 10% of the anticipated number;
- Editing materials to which participants will be exposed (e.g., recruitment, educational, and consent materials);
- Adding, removing, or editing questions on surveys or interview guides;
- Collecting information that could identify participants when the research plan stated that no personal identifiers would be collected;
- Removing study activities. In the approval process, the IRB assesses research benefits. Removing components of a research study may affect the IRB's assessment of study benefits.

Implementing study procedures with a participant who did not agree to the specific activity:

Some research is designed to allow participants to agree to some aspects of the study and to decline to participate in other aspects (e.g., videotaping). Involving a participant in an activity to which she/he/they has not consented constitutes non-compliance and may constitute an Unanticipated Problem if the activity involves risks to the participant or others.

Failing to record, code, store, or destroy data as described in the IRB-approved research plan:

PIs provide specific information in the IRB application about their plans for data management and storage, and for removing or coding personally identifiable information. Failure to adhere to the stated plans constitutes non-compliance and may constitute an Unanticipated Problem if unauthorized disclosure may harm a participant or others.

Initiating research prior to receiving notification of IRB approval:

The IRB may approve research with conditions. Before any research activities may commence under these conditions, researchers must provide the IRB with the requested revisions for review. Once the IRB determines the revisions are satisfactory, the PI will receive formal notification of IRB approval. Initiating any research activities prior to notification of IRB approval constitutes non-compliance and may result in restrictions in the use of any data collected before notification of IRB approval.

Using data from a minor who did not have parental permission to participate in the research study:
This may occur in classroom research activities when not all parents agree to their child's participation in research, or when minor undergraduate students engage in research that was not designed to include minors and consequently, did not include processes for obtaining parent permission.

Changing or adding study locations:
The IRB considers study locations in assessing equity in participant enrollment. Changing or adding study sites may alter the IRB's assessment. Failure to obtain acknowledgment or approval for changes or additions to study locations constitutes non-compliance.

Not using the IRB-approved, date-stamped consent document when enrolling participants:
Research Integrity staff electronically "stamp" the IRB approval date in the footer of approved versions of consent documents/materials. Researchers must use the stamped, approved versions when enrolling research participants. Failure to do so constitutes non-compliance.

Pre-testing or piloting research materials or activities without IRB approval:
The definition of "research" in the federal regulations includes "research development, testing, and evaluation" among activities that may be considered research. Pre-testing or piloting materials or activities before obtaining IRB approval may constitute non-compliance.