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**

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 resolut .5 (er)-12.3 (ees)-40.4 1.2 (b)-25Tc 16.22 0 Td( )Tj c.5 (er) 0.024 Tw -29.333 -1.222 Td[3.)-68.7 (5

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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