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)
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 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
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 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
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Examples of Non
-Compliance

Conducting research with human participants without IRB approval
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“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
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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