KENNESAW STATE UNIVERSITY
OFFICE OF RESEARCH
Research Compliance

Policy Title	Responsibilities of the IRB
Last Updated	10-19-2021
Responsible Office	IRB Office
Contact Information	IRB Office Email: irb@kennesaw.edu Phone: 470-578-4941

1. **Policy Purpose Statement**

The purpose of this policy is to define the role and responsibilities of the Kennesaw State University Institutional Review Board. This Policy applies to individuals formally appointed as members of Kennesaw State University IRB.

2. **Definitions**

Institutional Official (IO): The individual identified on KSU's Federalwide Assurance with the Office for Human Research Protections who is legally authorized to act for and on behalf of KSU, and who obligates the University to the Terms of the Assurance.

Convened IRB: A meeting of the IRB at which a majority of IRB members are present.

Federalwide Assurance: The Federalwide Assurance (FWA) is granted by the Department of Health and Human Service's (DHHS) Office for Human Research Protections (OHRP). It is the only type of assurance of compliance accepted and approved by OHRP for institutions engaged in non-Exempt human subjects research conducted or supported by DHHS. Under an FWA, an institution commits to DHHS that it will comply with the requirements set forth in 45 CFR Part 46, as well as the Terms of Assurance.

Alternate IRB Member: Alternate members are appointed to serve as a substitute for a regular IRB member and/or to ensure that the IRB has the appropriate expertise to review research (e.g., prisoner representative, pharmacy representative, etc.).

Primary IRB Member: Primary members are charged with review of proposed human research protocols in order to ensure that the rights of participants are protected, and that risk of harm is minimized. They must adhere to the requirements set forth by this policy.

3. **Policy**

3.1. As Institutional Official for Kennesaw State University, the Vice President for Research appoints the IRB and ensures there are resources sufficient to protect the rights and welfare of research subjects for the research activities that KSU conducts or oversees, including meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

3.2. The IRB prospectively reviews and makes decisions concerning Human Subjects research conducted by agents of the university. The IRB discharges its duties in compliance with the

requirements of the Federal Policy for Protection of Human Research Subjects (45 CFR Part 46), applicable State regulations, the Federalwide Assurance, and Kennesaw State University policies.

3.3. The IRB is authorized to do the following:

3.3.1. Provide evaluation of the risks and potential benefits, if any, of research projects and proposed amendments and determine whether the rights and welfare of Human Subjects are adequately protected.

3.3.2. Approve, Contingently Approve, Defer, Disapprove, or Table KSU Human Subjects research protocols including exempt research for which Limited IRB Review is required;

3.3.3. Require that information given to subjects (or legally authorized representatives, when appropriate) as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

3.3.4. Require documentation of informed consent or may waive documentation in accordance with §46.117.

3.3.5. Review Reportable Events as set forth in the Institutional Review Board Policy on Reportable Events and Noncompliance;

3.3.6. Suspend or Terminate KSU Human Subjects research projects being conducted in conflict with the Federal Policy for Protection of Human Research Subjects, applicable State regulations, the Federalwide Assurance, and/or KSU University policies;

3.3.7. Observe, or arrange for a third party to observe, the consent process for research participants in KSU Human Subjects research studies; and

3.4. Observe, or arrange for a third party to observe, the conduct of any Human Subjects research under its oversight. The IRB notifies investigators and the institution in writing of its decision to approve or disapprove a proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it includes in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

3.5. The IRB Chair and the Director of the IRB Office will review the activity of the IRB on at least an annual basis and make a recommendation to the IO regarding the appropriate number of IRBs that are needed for the institution. This recommendation will be based on the volume of IRB applications and related post-approval activities subject to its review (e.g., Reportable Events) and the scientific diversity and complexity of the Human Subjects research studies the IRB reviews (e.g., social behavioral research, clinical trials, biomedical research). If additional IRBs are formed, the Chairs of each IRB will work together to ensure cross-coordination across IRBs.

3.6. The IRB Chair is responsible for conducting all Convened IRB meetings and ensuring the IRB is fair, impartial, and immune to pressure from the institution's administration, the PIs whose IRB applications it reviews, and other professional and nonprofessional sources.

3.7. The IRB Vice Chair serves as the IRB Chair in the IRB Chair's absence. When acting as the IRB Chair, the IRB Vice Chair has the same authority and duties as the IRB Chair.

3.8. Regardless of appointment type, all IRB members must adhere to the following requirements:

3.8.1. Execute their responsibilities in accordance with KSU policies and applicable federal, state, and local laws;

3.8.2. Complete the IRB Member module of the human subjects protection training in the Collaborative Institute Training Initiative (CITI) system and additional training as assigned;

3.8.3. Provide a resume or Curriculum Vitae to the IRB Office every 2 years or at a time it has been updated;

3.8.4. Ensure that the criteria for IRB approval are met for all reviewed assignments by using the Reviewer Checklist;

3.8.5. Maintain confidentiality for all matters related to service on the IRB, including shredding or otherwise securely destroying any physical or electronic files following review completion; and

3.8.6. Comply with the Conflict-of-Interest Policy.

3.9. Primary and alternate IRB members serve the same functions on the IRB, with differing attendance requirements as set forth in their respective appointment letters. Primary and alternate IRB members are voting members of the IRB; however, when the primary member and corresponding alternate member(s) are present at a Convened IRB meeting, only the primary IRB member's vote is counted. If a primary member is recused from a vote at a Convened IRB meeting or is not present at a Convened IRB meeting, the alternate member's vote will be counted.

3.10. The IRB roster identifies the primary member for whom each alternate member may substitute. The IRB minutes will document when an alternate member's vote replaces that of a primary member. Alternate IRB members are matched to primary members with similar member roles (e.g., non-scientist, scientist) and, when applicable, with similar expertise.

3.11. When necessary, the IRB Chair or designee may solicit individuals from KSU or outside KSU with specialized knowledge in certain areas to assist in the review of Human Subjects research studies that require expertise beyond or in addition to that available among appointed IRB Members.

3.11.1. Consultants will be bound by the same confidentiality obligations of IRB members.

3.11.2. Consultants will receive the IRB Member Conflict of Interest Policy and be required to abide by the policy.

3.11.3. Consultants are not voting members of the IRB and may not observe the Convened IRB's vote.

3.11.4. Consultants will present recommendations to the Convened IRB for consideration either in person or in writing. These recommendations will be documented in the IRB meeting minutes.

3.12. Primary members are required to attend at least 75% of Convened IRB meetings on an annual basis. Alternate members must attend at least 50% of Convened IRB meetings on an annual basis.

Materials

Reviewer Checklist