

Kennesaw State University Institutional Biosafety Committee

I. Mission

The charge of the Institutional Biosafety Committee (IBC) is to assure the safe acquisition, use, and disposal of all biological agents at Kennesaw State University. It is the responsibility of the Committee to establish appropriate health and safety policies in accordance with federal, state, and local regulations and guidelines that cover biological safety, and to evaluate work being conducted at Kennesaw State University for biological safety considerations.

II. Purpose and Scope

- A. Kennesaw State University (KSU) is committed to the highest standards of safe and ethical research and complies with all federal, state, and local laws and regulations and University System of Georgia policies. For this purpose and to comply with the National Institutes of Health (NIH) *Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*, KSU has established an Institutional Biosafety Committee (IBC). The NIH Guidelines apply to all recombinant DNA research that is conducted at or sponsored by any institution that receives support from the NIH. Thus these guidelines apply to everyone who participates in research, instruction, or work at KSU.
- B. The IBC is responsible for local oversight and review of activities that use the following potentially bio-hazardous materials or procedures:
 - Recombinant or synthetic nucleic acid molecules (rDNA/RNA)
 - Select agents and toxins, as determined by the [Federal Select Agent Program](#)
 - Biological agents that require Biosafety Level 2 containment or higher, including
 - Agents in Risk Group 2, 3, and 4
 - Blood borne pathogens (from human and non-human primates)
 - All other biological agents that can cause disease in humans
 - Stem cell research
 - Biological Nanotechnology (e.g., drug delivery via nanoparticles, etc.)
 - Importing/Exporting of etiologic agents (which require BSL-2 and or BSL-3 containment) into/out of the campus
 - Xenotransplantation

III. IBC Responsibilities

For activities listed in section II.B, the IBC shall be responsible for the following functions:

- Recommending or prescribing, and publishing for the KSU community, the appropriate requirements, conditions, and restrictions necessary (e.g. – training, vaccinations, work practices, control measures, personal protective equipment [PPE], etc.) according to NIH guidelines; federal, state, and local laws and regulations; and University System of Georgia (USG) policies.
- Certifying and assigning investigators/teachers/workers, their laboratories or other workspaces, and/or their practices for work, at appropriate biological safety levels prescribed in the latest edition of the Center for Disease Control (CDC)/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL). Activities identified as Biological Safety Level 2 (BSL 2) and greater may not proceed without the written consent of the IBC prior to initiation of work.
- Reviewing and approving protocols/proposals for activities listed in Section IIB.
- Notifying each applicant of the IBC's decision regarding his/her protocol(s)/proposal(s)
- Conducting annual reviews of protocols/proposals and recertification every three years for activities listed in section IIB to ensure compliance with NIH guidelines and all federal, state, and local regulations and USG policies.
- Keeping the KSU community aware of any changes/updates in the NIH guidelines, laws, policies, and regulations associated with biosafety
- Reviewing reports from the Biosafety Officer concerning instances of urgent issues, including personnel exposure, loss/theft of biological agents, breaches in biosafety containment, and accidental spills involving rDNA, synthetic nucleic acids, and other biohazards; reporting such instances to the NIH and regulatory agencies as necessary.
**Reportable incidents must be reported to NIH/Office of Biotechnology Activities within 30 days*
- Overseeing the monitoring follow-up of those persons testing positive for identified pathogens resulting from confirmed laboratory acquired infections.
- Implementing corrective actions when KSU policies, NIH Guidelines, federal, state, and/or local regulations are not followed. These actions may include (not limited to):
 - Termination of authorizations
 - Restricting the receipt of biological agents
 - Ordering the removal of biological agents from laboratories
 - Termination of access to laboratories and/or other facilities**The IBC may choose to reverse these penalties after a thorough review finds that all operations are in compliance with NIH Guidelines, and all applicable policies and regulations*
- Maintaining records of all IBC meeting minutes, protocol reviews, and any other documents associated with the IBC or the use of biological agents at KSU.
- Periodic review of IBC policies and procedures.

IV. IBC Committee Procedures

A. Membership

The IBC size and composition shall be large enough to represent the range of personnel who perform activities listed in Section IIB across Kennesaw State University and will include KSU scientists and administrators and community representatives. Based on NIH Guidelines (section IV-B-2-a-(1)), the minimum number of IBC members is five. An effort is made to represent all major units served, to have a mix of technical expertise characteristic of the research protocols being reviewed, and to epitomize the diversity of the University community. Committee configuration will be kept in accordance with NIH Guidelines (section IV-B-2-a).

- **Full Members:** The committee shall consist of no fewer than five full members, of whom;
 - at least two members with a PhD and appropriate infectious disease and recombinant DNA expertise, and/or biological safety and containment expertise;
 - at least two community members (not affiliated with the university) who represent the interests of the surrounding community with respect to health and protection of the environment;
 - a biological safety officer, Environmental Health & Safety Office;
 - a research compliance officer (NIH/OBA contact person), University Office of Research;
 - a research administrator, University Office of Research;
 - at least one scientist with expertise in plant containment principles when experiments utilizing NIH Guidelines [Appendix P](#), Physical and Biological Containment for Recombinant DNA Research Involving Plants, require IBC approval.
 - at least one scientist with expertise in animal containment principles when experiments utilizing NIH Guidelines [Appendix Q](#), Physical and Biological Containment for Recombinant DNA Research Involving Animals, require IBC approval.
- **Ex Officio Voting Members**

In addition, the following are designated as voting members:
Vice President of Research, institutional authorized signing official.
- **Subject Matter Expertise**

If a protocol registration is outside the area of expertise of IBC members, the IBC Chair is authorized to seek counsel from an individual knowledgeable in the subject matter to allow for appropriate review and approval or disapproval.
- **Appointment to the IBC**

The Vice President of Research appoints members for a renewable term of three years. Terms of appointment are staggered in a manner such that one-third of the committee is appointed or renewed each year.
- **The IBC Chair**

The Vice President of Research appoints the Chair from within the membership of the IBC for a term of three years. The Chair has the responsibility for prescreening submitted registrations as necessary; approving registrations or recommending review by full committee; reviewing and approving amendments and updates as necessary; ensuring

member training (this task may be designated to another qualified individual); setting meeting agendas and establishing meeting dates; and conducting/managing meetings.

B. IBC Member Training

All members are required to complete training on the regulatory responsibilities and function of the IBC. The Collaborative Institutional Training Initiative (CITI) online training program is the official certification program for KSU's IBC and will require recertification every three years.

C. Meeting Frequency

The Committee shall meet no less than two times per year; however, the IBC Chair can call additional meetings as needed throughout the year.

D. Quorum

A quorum is greater than 50% of the Committee membership; written proxies do not count toward a quorum. A quorum may also be established if meetings of the IBC occur via conference phone calls, or via electronic media, as long as the following requirements are met:

- a. Accurate attendance records are kept.
- b. All materials for examination are available to all participating IBC members.
- c. All participants have full and equal opportunity for interactive discussion.

E. Proceedings

Meetings will be conducted in accordance with Robert's Rules of Order. The Chair will issue all points of order, summarize registrations as necessary, moderate discussions, and call for motions. Motions, seconds, and/or other propositions may be made by any voting member of the IBC. Motions pass by a simple majority of the quorum present. Votes may be conducted by email.

F. Meeting Minutes

Minutes of IBC meetings will be kept and will include the names of members attending; summaries of discussions, actions taken and the numerical vote on these actions; dissenting reports and opinions, and the basis for any required change in or disapproval of a proposal. Records will be maintained for at least three years.

G. Conflict of Interest

A conflict of interest is loosely defined as financial involvement with a commercial sponsor or a personal relationship with an investigator or a sponsor. No member of the IBC may be involved in the review or approval of a project in which he/she has been, is, or expects to be engaged or in which he/she has professional or financial interest, except to provide information requested by the IBC. Any IBC member with financial or other interests with the investigator or a research sponsor should inform the IBC and, if necessary, follow the procedures in the policies referenced below to manage or resolve the conflict, if any.

Federal government policy on disclosure of financial conflict of interest differs among the various agencies. For more information on the university's conflict of interest in research and sponsored programs policies, please click [here](#).

H. Removal of a Member

Removal of a member from the IBC typically requires documented and substantiated "just cause" that demonstrates the member to be unfit or unable to serve on the IBC. "Just cause" for removal may include, but is not limited to, lack of regular attendance at meetings, a finding of misconduct, or an unresolved conflict of interest. Members may also be removed to allow for fresh perspectives on the committee. The ultimate decision to remove a member is made by the Vice President of Research.

Individuals who cannot attend an IBC meeting because of a leave of absence should request a replacement be appointed to serve during their absence. If a replacement cannot be found, the member will be temporarily removed from the IBC (during their absence) and will not be considered a member of the IBC when determining if a quorum is present. The individual is expected to return to the IBC upon their return to the University.