

**KANSAS STATE UNIVERSITY INSTITUTIONAL BIOSAFETY COMMITTEE
STANDARD OPERATING PROCEDURES**

I. INTRODUCTION

The Kansas State University (K-State) Institutional Biosafety Committee, hereafter referred to as the IBC, is charged by federal law to review and approve elements of a campus biosafety program. The purpose of this program is to ensure the health and safety of all personnel working with biohazardous materials. The Institutional Official (IO) appoints membership on the IBC. Membership consists of the Chairperson, faculty, and at least two community members, all of which serve at the pleasure of the IO.

The IBC as a whole represents collective expertise and research experience in biohazardous materials and biosafety in experiments that may pose potential risks to health or the environment. The IBC is responsible for ensuring that research conducted at K-State is in compliance with applicable regulations and guidelines, including the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid molecules (NIH Guidelines), the Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition, and the Federal Select Agents Regulations. These form the basis for campus biosafety policies and procedures, and reviewing individual research proposals for biosafety concerns.

II. REQUIREMENTS OF THE IBC

A. According to the NIH Guidelines, K-State must

1. Establish an IBC.
2. Ensure that the IBC has adequate expertise and training
3. Provide appropriate training for the IBC Chair and members, Biological Safety Officer, principal investigators, and laboratory staff
4. File an annual report with the NIH Office of Biotechnology Activities that includes 1) a roster of IBC members clearly indicating the Chair, contact person, and, as applicable, the biological safety officer, plant expert, animal expert and 2) biographical sketches of all IBC members, including community members.
5. Establish procedures that the IBC shall follow in its initial and continuing review and approval of applications, proposals, and activities; and making available to the public, upon request, all IBC meeting minutes and any documents submitted to or received from funding agencies that those agencies must make available to the public.

B. Membership Requirements

1. The IBC must be comprised of no fewer than five members so selected that they collectively have experience and expertise in recombinant or synthetic nucleic acid technology and the capability to assess the safety of recombinant and

synthetic nucleic acid research and to identify any potential risk to public health or the environment:

- i. At least two members shall not be affiliated with the institution (apart from their membership on the IBC) and represent the interest of the surrounding community with respect to health and protection of the environment.
- ii. At least one member must have expertise in plant, plant pathogen, or plant pest containment principles.
- iii. At least one member with expertise in animal containment principles.
- iv. And a Biological Safety Officer if institution conducts recombinant or synthetic nucleic acid molecule research at BL-3, BL-4, or Large Scale (greater than 10 liters) experiments.
- v. No member of the IBC may be involved in the review or approval (except to provide information requested by the IBC) of a project in which he/she has been or expects to be engaged or has a direct financial interest

C. Functions

1. Reviewing recombinant or synthetic nucleic acid molecule research conducted at or sponsored by the institution for compliance with the NIH Guidelines as specified in Section III, Experiments Covered by the NIH Guidelines, and approving those research projects that are found to conform with the NIH Guidelines. This review shall include:
 - i. Independent assessment of the containment levels required by the NIH Guidelines for the proposed research.
 - ii. Assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant or synthetic nucleic acid molecule research.
 - iii. Review infectious disease research using as a guide the 5th Edition of the BMBL.
 - iv. Notify the Principal Investigator (PI) of the results of the IBC's review and approval.
 - v. Lower containment levels for certain experiments as specified in Section III-D-2-a, Experiments in which DNA from Risk Group 2, Risk Group 3, or Risk Group 4, or Restricted Agents Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems.
 - vi. Setting containment levels as specified in Sections III-D-4-b, Experiments Involving Whole Animals, and III-D-5, Experiments Involving Whole Plants.
 - vii. Periodically reviewing recombinant or synthetic nucleic acid molecule research conducted at the institution to ensure compliance with the NIH Guidelines.
 - viii. Adopting emergency plans covering accidental spills and personnel contamination resulting from recombinant or synthetic nucleic acid molecule research.
 - ix. Report any significant problems with or violations of the NIH Guidelines

and any significant research-related accidents or illnesses to the appropriate institutional official and NIH/OBA within 30 days.

- x. The IBC may not authorize initiation of experiments which are not explicitly covered by the NIH Guidelines until NIH establishes the containment requirement.
- xi. Visit labs as appropriate to verify compliance with applicable laws, rules, regulations, and guidelines.
- xii. Perform other such function as may be delegated to the IBC under Section IV-B-2, Institutional Biosafety Committee

D. Role of Principal Investigator

1. The PI is responsible for compliance with the NIH Guidelines in the conduct of recombinant or synthetic nucleic acid molecule research:
 - i. No recombinant or synthetic nucleic acid molecule research may be initiated or modified prior to approval of the IBC and insurance that it meets all other requirements of the NIH Guidelines.
 - ii. The PI must determine whether experiments are covered by Section III-E, Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation, and ensure that the appropriate procedures are followed.
 - iii. Report any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to the Biological Safety Officer, Greenhouse/Animal Facility Director, IBC, or other appropriate authorities within 30 days.
 - iv. Report any new information bearing on the NIH Guidelines to the IBC.
 - v. Be adequately trained in good microbial techniques.
 - vi. Adhere to emergency plans for handling accidental spills and personnel contamination.
 - vii. Comply with shipping requirements for recombinant or synthetic nucleic acid molecules.
2. Requirements of PI prior to initiating research:
 - i. Determination of required levels of physical and biological containment in accordance with the NIH Guidelines.
 - ii. Select appropriate microbiological practices and laboratory techniques to be used for research.
 - iii. Submit an initial registration Document (RD) and any subsequent changes to the IBC for review and approval or disapproval.
 - iv. Remain in communication with the IBC throughout the conduct of the project.
 - v. Make available to all laboratory staff the protocols that describe potential biohazards and the precautions to be taken.
 - vi. Instruct and train laboratory staff in 1) practices and techniques required to ensure safety and 2) procedures for dealing with accidents.
 - vii. Inform laboratory staff of the reasons and provisions for any precautionary

- medical practices advised or requested.
3. Requirements of PI during conduct of research:
 - i. Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
 - ii. Investigate and report any significant problems pertaining to operation and implementation of containment practices and procedures in writing to appropriate authority.
 - iii. Correct work errors and conditions that may result in release of recombinant or synthetic nucleic acid molecule materials.
 - iv. Ensure the integrity of physical containment and biological containment

III. Administrative Processes

A. Electronic submission of Registration Documents for Review

1. PIs are asked to submit new RDs to the URCO in electronic form. Pdf applications are found on the URCO IBC webpage, <https://www.k-state.edu/comply/>, and should be sent to comply@KSU.edu. This allows the URCO to facilitate distribution of RD proposals to IBC members for review.
2. Before approval, the URCO requires an electronic signature on the Assurances Page or a signed original of the Assurances Page be sent to 203 Fairchild. The Assurances page is the last page of the Registration Document.

B. URCO Initial Administrative Review of Registration Documents

1. There is no requirement for the IBC to formally review recombinant or synthetic nucleic acid molecule activities categorized as exempt under the NIH Guidelines. In addition, the IBC will not formally review Biosafety Level -1 activities (as defined in the 5th Edition of the BMBL) in full committee. Therefore, the URCO will perform an administrative review of registration documents to determine if the activity warrants formal convened IBC review. Upon receipt of a RD by the URCO, it will be logged in, assigned a number, and reviewed by the URCO (URCO Administrative Review of RD - Form 1). The initial, administrative review will determine whether the RD should be:
 - i. Reviewed in Full Committee: Non-exempt recombinant or synthetic nucleic acid molecule activity, or BSL – 2 and higher biocontainment. The RD will be reviewed at the next available IBC meeting.
 - ii. Administratively reviewed – not committee reviewed: BSL-1 or exempt recombinant or synthetic nucleic acid molecule activity. The Chair will sign a letter notifying the PI of the determination of the URCO administrative review. A copy of the approval/notification letter, the administrative review sheet and the RD will be maintained in the URCO files for documentation purposes. As long as the activity does not significantly change, no additional action is required by the IBC or the PI. nor will the activity be included in the annual review.

C. IBC Committee Meetings

1. The IBC chair, in collaboration with the URCO, is responsible for setting agendas and calling convened meetings every month, or as often as necessary to accomplish the business of the IBC. Meetings are open to the public except for those discussions the Chair determines deal with private or confidential information. Full IBC committee actions require the presence of a quorum of the voting members, defined as majority of the membership (more than half).
2. Principal Investigators (PIs) may present new protocols at IBC meetings, and respond to questions from IBC members as appropriate. To ensure that committee members feel free to express their views and or concerns freely, PIs, or other non-committee members are excused from the meeting prior to final deliberations and the formal vote of the IBC on a specific activity.
3. Full committee IBC meetings are conducted in accordance with Roberts Rules of Order. That is, at a minimum, the Chair conducts the meeting, there is a predetermined agenda, the minutes of the prior meeting are voted upon, and all actions and resolutions require a voice or show-of-hands vote of the members present, following pertinent discussion and the making and seconding of a motion. A majority vote carries the decision.
4. During the committee meetings, a proposal can be approved, approved with conditions or stipulations, or not approved. The PI will be notified in writing of the decision by the Committee with a letter signed by the Chair. This letter will include any stipulations that need to be met before initiating research, if applicable. Once the stipulations are resolved to the satisfaction of the committee, the Chair signs an approval letter. Registration Documents are approved for 3 years from the date of the approval letter. Additionally, there is an annual review of activities performed by the URCO/IBC.

D. Modifications

1. Changes to an approved activity must be approved by the IBC prior to initiating the proposed changes. To change an approved IBC protocol, the level of modification must be determined. Major or minor modifications are to be submitted on the latest approved version of the registration document with a complete explanation/justification for the change, and emailed [d to URCO at comply@ksu.edu](mailto:comply@ksu.edu). In all modifications, a letter documenting the final decision will be sent to the PI.
 - i. Minor changes (personnel additions, room number changes, or modifications that do not change the overall risk of a project) are approved by the Chair.
 - ii. Major or significant changes may require review by the full IBC committee, and could result in the request of a new IBC registration document regardless of the date of expiration of the current version.

E. Appeal of IBC Actions

1. By federal regulation and guidance, and in accord with the K-State procedures, institutional officials may not approve recombinant or synthetic nucleic acid molecule or infectious agent research that has not been approved by the K-State IBC. IBC disapproval of a proposed biotechnology or recombinant or synthetic nucleic acid molecule activity cannot be appealed to, or reversed by, the institutional official.

2. Principal investigators may request the IBC reconsider a decision regarding recombinant or synthetic nucleic acid molecule or infectious agent research. However, investigators do not have the option to seek the reversal of an IBC decision by a route other than IBC re-review and approval.

F. IBC Minutes and Records

1. The minutes of the IBC meetings must be recorded in sufficient detail to show: attendance at the meetings, actions taken by the IBC, the vote on actions including the number of members voting for, against, and abstaining, including the reasons for any opposing vote, the basis for requiring changes in or disapproving research, and a written summary of the discussion of controversial issues and their resolution.
2. The URCO maintains copies of IBC RDs and applicable documents that it has reviewed, including annual reviews, scientific evaluations, if any that accompany RDs, minutes of its meetings, a current approved membership list, progress reports submitted by investigators, copies of all correspondence between the IBC and Principal Investigators, and documentation of collaborative and cooperative research activities occurring at other institutions. All results of deliberations and decisions by the IBC are communicated in writing to the Principal Investigator. Records and documents must be retained for at least three years after completion of the research.

G. Annual Review

1. Registration Documents are approved for three years from the original date of approval. The URCO/ IBC perform an annual review of approved activities. This review assesses: the progress of the activity; whether or not changes to the activity are pending or have been made; and changes of personnel associated with the activity. Annual review records will be maintained in the original RD file.

H. Select Agents

1. The Federal Select Agent Program oversees the activities of possession of biological agents and toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. Activities that involve agents identified by the NIH or the USDA as Select Agents (SA) will be reviewed by the IBC using the same procedures as other biological agents. However, the SA Responsible Official (RO) administers a comprehensive program that oversees all SA campus activities. The IBC will cooperate closely with the RO to ensure that SA activities are properly performed.

I. Records

1. The URCO will maintain all records pertinent to all recombinant or synthetic nucleic acid molecule or biological agent activity that is covered by the IBC. Once an approved RD activity concludes, expires, or is inactivated, the URCO will maintain records for three years. At this time the files will be purged.

J. Accident/Incident Investigation

1. If an accident/incident occur during the execution of an IBC approved activity, it is the PI's responsibility to report the incident to the proper entities. The IBC should be included in the reporting scheme. The URCO/IBC have developed a review strategy to deal with accident on a case-by-case basis. Accident reports will be maintained for 5 years.

K. Training

1. A number of forms of training for activities involving recombinant or synthetic nucleic acid molecule and biological agents are in use. These include:
 - i. Online training: Online training modules through the University's subscription to the CITI training program are mandatory for IBC approval of RDs.
 - ii. Didactic training: In certain cases, didactic training is provided either by safety/biosafety specialists, URCO personnel, or other appropriate subject matter experts.
 - iii. Procedure specific training: Investigators provide training that is specific to activities performed in the approved activity. Documentation is maintained by the PI.
 - iv. Webinars, continuing education, seminars, etc.: various training strategies are used as appropriate for the personnel and activities.

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