



I. Background

The University of South Carolina (USC) research laboratories conduct a broad range of biological research. All projects involving recombinant or synthetic nucleic acid molecules must comply with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*. The *NIH Guidelines* require the university to establish an Institutional Biosafety Committee (IBC) whose responsibilities need not be restricted to research explicitly covered by the guidelines. The University's IBC has an expanded scope of oversight to review and approve protocols for all research involving recombinant or synthetic nucleic acid molecules (all research subject to section III-A through III-F of the *NIH Guidelines*), infectious agents, human-derived materials, and HHS/USDA select agents and toxins. Principal Investigators are notified of the IBC review and approval results. The IBC website (https://sc.edu/about/offices_and_divisions/ehs/research_and_laboratory_safety/biological_safety/ibc/index.php) contains resources and guidance documents to assist the University's research community with understanding and adhering to biological safety and compliance requirements. IBC meetings are scheduled at least quarterly.

II. Purpose Statement

The Institutional Biosafety Committee (IBC) provides local review and oversight for research involving recombinant or synthetic nucleic acid molecules. The IBC ensures that research conducted at or sponsored by the university is in compliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*. This requirement is primarily fulfilled through the IBC's review and approval of protocols for all research subject to the *NIH Guidelines*. Members of the IBC provide the collective experience and expertise in research involving these materials and the capability to assess the safety of research protocols and to identify any potential risk to workers, other persons, or the environment. The University's IBC has an expanded scope of oversight to review protocols for all research involving recombinant or synthetic nucleic acids, transgenic animals or plants, infectious agents, human-derived materials, and HHS/USDA select agents and biological toxins.

The IBC shall provide an annual report to the Enterprise Risk Management and Oversight Committee via the Research Safety and Compliance Oversight Committee. This report shall include notable areas of success and best practices, critical areas of risk or needs for improvement (facilities, training, resources, personnel), and specifically identify the top three to five institutional risks associated with research involving biological hazards.

III. Terms of Appointment

IBC members are appointed for a period of three years, and consecutive terms are permissible when necessary to maintain a collective experience and expertise to effectively review all research protocols. The one exception is the Biological Safety Officer (BSO) who manages the Biological Safety Program and serves as a permanent member of the IBC. If an IBC member does not attend at least 50% of the scheduled IBC meetings in a calendar year, the IBC Chair or BSO may request to nominate a replacement. The University maintains a list of all Special Advisory Committees. This list includes the IBC's purpose statement and membership requirements.

IV. IBC Authority

The IBC is empowered with the authority to enforce the *NIH Guidelines* and to ensure that IBC approved conditions are fulfilled. The IBC may fully investigate potential violations or compliance problems. In the event of a significant research-related incident, the IBC may suspend, limit, or terminate a Principal Investigator's authorization to use biological materials pending a formal investigation. The IBC and/or Biosafety Officer may take further actions deemed appropriate if a Principal Investigator has repeated compliance violations that are not corrected, or serious safety violations are identified that create a significant risk to laboratory workers, other persons, or the environment. If required as a condition of compliance with the *NIH Guidelines*, these significant incidents will be reported to the NIH Office of Science Policy (OSP).

V. IBC Membership Requirements

In accordance with NIH requirements, the USC Institutional Biosafety Committee (IBC) will be comprised of no fewer than seven members, and members are selected to ensure they collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of research and to identify potential risks to public health or the environment. Membership is by nomination from the current IBC members with approval from the IBC Chair. The Chair and Biological Safety Officer (BSO) ensure membership compliance with the NIH requirements.

The IBC membership will consist of:

- 1) A Chair of the IBC
- 2) A Biological Safety Officer (BSO)
- 3) At least two members not affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and these individuals will represent the interest of the surrounding community with respect to health and protection of the environment (e.g., officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical,

occupational health, or environmental concerns in the community).

- 4) At least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing *Appendix P* require prior approval by the IBC.
- 5) At least one scientist with expertise in animal containment principles when experiments utilizing *Appendix Q* require prior approval by the IBC.
- 6) Additional members will be selected in order to ensure the competence necessary to review and approve work involving recombinant or synthetic nucleic acid molecules. In an effort to accomplish this diverse experience and expertise, the IBC will seek to:
 - a) Include persons with expertise in recombinant or synthetic nucleic acid molecule technology, biological safety, and physical containment;
 - b) Include or have available as consultants persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment;
 - c) Include or have available as a consultant one person with expertise in recombinant or synthetic nucleic acid molecule research involving human subjects, or other studies involving the deliberate exposure of humans to biological agents, when the University engages in or sponsors research utilizing *Appendix M*;
 - d) Include at least one member representing the laboratory technical staff.

IBC Membership (2018–2019)

IBC Member	Department / Member Role
Lydia Matesic	IBC Chair; Faculty member in Biological Sciences
Shayne Barlow	Director & Attending Veterinarian, Laboratory Animal Resources
Beth Krizek	Faculty member in Biological Sciences; Plant Expert
Mark Robbins	Biological Safety Officer; Environmental Health and Safety
Seungjin Shin	Director of USC School of Medicine’s Viral Vector Core Facility
Michael Shtutman	Faculty member in Drug Discovery and Biomedical Sciences
Daping Fan	Faculty member in Cell Biology and Anatomy
Sean Norman	Faculty member in Environmental Health Sciences
Amanda Moore	Community member; SC Dept. of Health & Environmental Control
Vida Mingo	Community member; Faculty member at Columbia College
Kris Kaigler	Lab technical staff; Pharmacology, Physiology and Neuroscience
P. Logan Schuck	Graduate student member in Biological Sciences

VI. Roles and Responsibilities

Responsibilities of the Vice President for Research

- 1) Establish an Institutional Biosafety Committee with the authority and resources to fulfill all compliance responsibilities required in the *NIH Guidelines*.
- 2) Ensure the IBC maintains a protocol management system for biosafety protocol review, approval and records management as required in the *NIH Guidelines*.
- 3) Ensure a written policy is established that addresses the appointment of IBC members. Determine if the appointment of IBC members is made by a senior institutional official, and if members of the IBC are appointed for a fixed term.
- 4) Ensure an appropriate research occupational health and medical surveillance program is established for laboratory personnel conducting research involving recombinant DNA or other biological hazards. This includes establishing policies, procedures, and occupational health services for lab workers with potential exposure on the USC's main campus and School of Medicine campus.
- 5) Determine how IBC members will be recognized for service to enable the committee to recruit and retain qualified members and acknowledge institution-wide the value that the institution places on the IBC's role (e.g. IBC service counts toward service requirements considered for promotion and tenure).

Responsibilities of the Director, Office of Research Compliance

- 1) Assist the IBC and BSO to ensure that research at the University is conducted in compliance with the *NIH Guidelines* and other biosafety requirements. As required by NIH, encourage grantees to meet applicable Federal, State, and local health and safety standards and adhere to the OSHA Bloodborne Pathogens Standard and the BMBL (5th Edition). Assist to ensure that grantees understand that by drawing funds from the HHS system, the grantee agrees to these terms and conditions.
- 2) Assist the IBC and BSO to implement federal biosafety guidance and standards such as the *APLU Guide to Implementing a Laboratory Safety Culture* and *FESAP Guiding Principles for Biosafety Governance*, and participate in National Biosafety Month when NIH encourages institutions to highlight and strengthen biosafety.
- 3) Ensure appropriate training for the Institutional Biosafety Committee Chair and members, Biological Safety Officer and other containment experts (when applicable), Principal Investigators, and lab staff regarding laboratory safety and implementation of the *NIH Guidelines*. This includes encouraging professional development particularly for IBC members and staff, such as attendance at professional conferences related to biosafety or the *NIH Guidelines*. Also ensure a system is established for maintaining training records for individual personnel.

- 4) Report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the Vice President for Research (VPR), the PI's Department Chair or Dean, and NIH OSP within thirty days unless a report has already been filed by the Biosafety Officer or IBC Chair.
- 5) Conduct a thorough annual assessment of the resources necessary for the IBC to fulfill all of its responsibilities as articulated in the *NIH Guidelines*, taking into account not only the protocol submission and review process, but also training and surveillance responsibilities as required under the *NIH Guidelines*.

Responsibilities of the Director, Department of Environmental Health & Safety

- 1) In 2014, the Director for EHS committed to invest the resources necessary for a multi-year project to establish and maintain a bio-risk management system. This project is also supported by the Office of the Vice President for Research. The system will evolve over time to include specialized modules that support new and expanded biosafety program operations to improve safety and compliance, and adapt to ongoing changes in the university's research and regulatory environment.
- 2) Periodically assess the resources required to establish and maintain a bio-risk management system to fulfill the following safety and compliance objectives:
 - I. Establish an infrastructure to achieve and maintain research safety and compliance in an evolving research and regulatory environment.
 - II. Reduce institutional risk and the high cost of non-compliance
 - III. Improve program operational efficiency and data management
 - IV. Minimize the compliance burden on the IBC and lab researchers
 - V. Utilize responsible planning and management of resources
 - VI. Support projects to improve biological safety and compliance
- 3) Provide guidance or direction regarding safety and compliance strategic planning, priorities, objectives, and timelines associated with biological risk management. Promote a shared responsibility and commitment to compliance and creating a culture of safe biological research among all University stakeholders, including senior officials, deans, directors, department chairs, faculty, and laboratory staff.

Institutional Biosafety Committee Responsibilities

- 1) Review recombinant or synthetic nucleic acid molecules research conducted at or sponsored by the university to determine compliance with the *NIH Guidelines*, and approve 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 DNA research; (iii) ensuring that all aspects of Appendix M have been

- appropriately addressed by the Principal Investigator. The *NIH Guidelines* require IBC review of all research involving recombinant DNA materials or technology. The University's IBC also reviews research involving infectious agents, human-derived materials, and HHS/USDA select agents and toxins.
- 2) Establish procedures that the IBC will follow in its initial and continuing review and approval of applications, proposals, and activities.
 - 3) Notify the Principal Investigator of the results of the Institutional Biosafety Committee's review and approval.
 - 4) Lower containment levels for certain experiments specified in Section III-D-2-a, *Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems*.
 - 5) Set containment levels as specified in Sections III-D-4-b, *Experiments Involving Whole Animals*, and III-D-5, *Experiments Involving Whole Plants*.
 - 6) Periodically review recombinant or synthetic nucleic acid molecules research conducted at the institution to ensure compliance with the *NIH Guidelines*. This includes verification that Principal Investigators submit a protocol amendment prior to conducting experiments requiring IBC review and approval.
 - 7) Adopt emergency plans covering accidental spills and personnel contamination resulting from recombinant or synthetic nucleic acid molecules research. Emergency plans will emphasize the prevention of occupational infections or environmental contamination.
 - 8) In the event of a significant research-related incident, the IBC may suspend, limit, or terminate a Principal Investigator's authorization to use biological materials pending a formal investigation. The University may also take further actions deemed appropriate if a Principal Investigator has repeated compliance violations that are not corrected, or serious safety violations are identified that create a significant risk to laboratory workers, other persons, or the environment.
 - 9) The Institutional Biosafety Committee will not authorize the initiation of experiments which are not explicitly covered by the *NIH Guidelines* until NIH (with advice of the RAC when required) establishes the containment requirement.
 - 10) Open IBC meetings to the public when possible and consistent with protection of privacy and proprietary interests.
 - 11) Make meeting minutes available to the public upon request.
 - 12) Perform other functions as delegated to the Institutional Biosafety Committee.

IBC Chair Responsibilities

- 1) Verify that Institutional Biosafety Committee members are appropriately trained.

- 2) Direct and prioritize IBC activities and serve as IBC Chair for all meetings.
- 3) Ensure the IBC fulfills all of its responsibilities as stated in the IBC Charter.
- 4) Report any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the Vice President for Research (VPR), Director of the Office of Research Compliance (ORC), the PI's Department Chair/Dean, and NIH OSP within 30 days, unless a report has already been filed by the Biosafety Officer or Director of the ORC.
- 5) Assess the resources necessary for the IBC to fulfill all of its responsibilities as articulated in the *NIH Guidelines*, taking into account not only the protocol submission and review process, but also training and surveillance responsibilities. Make recommendations to the Vice President of Research, Director of Research Compliance, or Director of Environmental Health and Safety when additional resources are required to fulfill IBC responsibilities and to ensure safe research.
- 6) If public comments are made on IBC actions, the IBC Chair will forward both the public comments and IBC's response to the NIH Office of Science Policy (OSP).
- 7) Provide leadership for the IBC to identify, develop and adopt policies or programs to promote safe biological research and compliance with the *NIH Guidelines*.
- 8) Perform other functions as required to promote compliance with *NIH Guidelines*.

Biological Safety Officer (BSO) Responsibilities

- 1) Ensure periodic inspections are conducted to verify lab standards are rigorously followed, and compliance with USC policies and biosafety regulations/guidelines.
- 2) Investigate laboratory accidents and report to the IBC Chairperson any significant problems or violations, and any significant research-related injuries or illnesses associated with biological research. Following each investigation, the research personnel involved will be notified of the recommended corrective actions.
- 3) Report any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the NIH OSP within 30 days, unless a report has already been filed by the IBC Chair or other institutional official.
- 4) Develop and implement emergency plans for handling accidental spills and personnel contamination resulting from work with biological hazards. Assist occupational health services to determine the necessity for health surveillance of personnel conducting research with recombinant DNA or other biological hazards.
- 5) Provide technical advice on laboratory security, research safety procedures, biosafety administrative controls, and compliance requirements.
- 6) Review laboratory facility design plans for research involving biological hazards.
- 7) Ensure general biosafety level 2 training is provided to personnel in BSL-2 labs.

- 8) Manage the contract for the certification of laboratory biological safety cabinets.
- 9) Assist with development of SOPs for the use of biohazards in animals for DLAR.
- 10) Provide training on the *NIH Guidelines* for new IBC members when appointed.
- 11) Coordinate posting of policies, guidance documents, and other resources on the IBC website to promote safe research and compliance with the *NIH Guidelines*.
- 12) Serve as a permanent ex-officio member of the Institutional Biosafety Committee.
- 13) In collaboration with the IBC Chair, identify IBC members with the collective experience and expertise in research involving biological hazards used in USC labs.
- 14) Periodically conduct an IBC self-assessment for compliance with NIH Guidelines, and provide compliance assessments to the VP for Research Office upon request.
- 15) Schedule IBC meetings, verify quorum attendance, and prepare meeting agendas.
- 16) Facilitate protocol review and approval process, including protocol modifications.
- 17) Notify Principal Investigators of the results of IBC protocol review and approval.
- 18) Prepare IBC meeting minutes to include information required in *NIH Guidelines*.
- 19) Submit annual report to NIH OSP in the IBC Registration Management System.
- 20) Maintain records (e.g. approved protocols, meeting minutes, membership roster)
- 21) Provide updated IBC membership roster to the USC's Provost Office upon request.
- 22) Post public notification regarding access to convened IBC meetings and minutes. Upon request, make the following information conveniently available to the public through U.S. mail, email or the IBC website:
 - A. All requested Institutional Biosafety Committee meeting minutes
 - B. Rosters and biographical sketches that have been submitted to NIH

IBC Member Responsibilities

- 1) Provide knowledge and expertise to the broad scope of biosafety issues, with primary responsibility for providing guidance in acknowledged areas of expertise.
- 2) Attend and participate at IBC meetings. All members are encouraged to attend every meeting. The Chair may nominate a replacement for any IBC member that does not attend at least 50% of the scheduled IBC meetings in a calendar year.
- 3) Perform a comprehensive and timely review of protocol applications, and follow all protocol review and approval procedures as defined in this document.
- 4) Contribute expertise and assist with efforts to identify, develop and adopt policies to promote safe biological research and compliance with the *NIH Guidelines*.

- 5) Perform other functions as required to promote compliance with *NIH Guidelines*.

Principal Investigator Responsibilities

- 1) Ensure that laboratory staff is appropriately trained in the practices and techniques required to ensure safety and the procedures for dealing with accidents.
- 2) Never initiate or modify research involving biological materials which requires IBC approval prior to initiation until that research or the proposed modification has been approved by the IBC and met other requirements of the *NIH Guidelines*;
- 3) Determine whether experiments are covered by Section III-E of the *NIH Guidelines, Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation*, and ensure that appropriate procedures are followed;
- 4) Report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the BSO and IBC.
- 5) Be adequately trained in good microbiological techniques;
- 6) Adhere to IBC approved emergency plans for handling accidental spills and personnel contamination; and
- 7) Comply with shipping requirements for recombinant or synthetic nucleic acids

Submissions by the Principal Investigator to the Institutional Biosafety Committee

- a) Make an initial determination of the required levels of physical and biological containment in accordance with the *NIH Guidelines*;
- b) Select appropriate microbiological practices and laboratory techniques to be used for the research;
- c) Submit the initial research protocol and any subsequent changes (e.g., changes in the source of DNA or host-vector system) to the IBC for review and approval or disapproval; and
- d) Remain in communication with the IBC throughout the conduct of the project.

Responsibilities of the Principal Investigator Prior to Initiating Research

- a) Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken;
- b) Determine the minimal personal protective equipment (PPE) required for lab staff and provide training on the proper use of PPE;

- c) Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents; and
- d) Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).

Responsibilities of the Principal Investigator During the Conduct of the Research

- a) Supervise the safety performance of the lab staff to ensure that the required safety practices and techniques are employed (this includes monitoring PPE compliance)
- b) Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the IBC;
- c) Correct work errors and conditions that may result in the release of recombinant or synthetic nucleic acid molecules; and
- d) Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics). This includes ensuring that any biological safety cabinet used to conduct the research has received annual certification by a USC approved vendor.

VII. Conduct of Committee Business

- 1) The IBC reviews research with recombinant or synthetic nucleic acids (e.g. all research subject to section III-A through III-F of the *NIH Guidelines*), infectious agents, human-derived materials, and HHS/USDA select agents and toxins.
- 2) The IBC will meet at least once every quarter throughout the calendar year. Additional meetings may be scheduled when necessary to ensure the timely review of research, to provide training for IBC members, or address IBC business.
- 3) IBC meetings will be open to the public except when there are privacy or proprietary issues that preclude an open meeting. The IBC meeting dates, times and locations will be advertised to the public on the university's IBC website at https://sc.edu/about/offices_and_divisions/ehs/research_and_laboratory_safety/biological_safety/ibc/index.php
- 4) The IBC Chair and Biological Safety Officer (ex-officio) both have the same rights and privileges as all other members, including the right to make motions, to speak in debate, and to vote on all protocol approvals or issues discussed.
- 5) The IBC will not allow the transaction of substantive business to continue in the absence of a quorum. If the Chair notices the absence of a quorum, he or she will declare this fact before taking any vote or stating the question on any new motion.
- 6) Proxy voting is not permitted for any official IBC business (i.e. a member who expects to be absent from an IBC meeting may not authorize someone else to act in

- his or her place at the meeting). Proxy voting is incompatible with the essential characteristics of a convened meeting.
- 7) Committee quorum consists of a numerical majority of IBC members. Each IBC meeting also requires sufficient members to ensure the collective experience and expertise to assess the safety and identify any potential risk involved with the research under review. Consultants may occasionally be invited to attend an IBC meeting due to specialized knowledge on a specific topic that will be discussed during the meeting (e.g. persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct or practice, community attitudes, and the environment). An IBC consultant may provide professional guidance on the topic of interest, but will not have rights to make motions or vote.
 - 8) The *NIH Guidelines* do not permit expedited reviews or approvals by a subgroup of the IBC on behalf of the entire IBC for research subject to the *NIH Guidelines*. Formal business will only be conducted when a quorum of the IBC is present at a convened meeting. The IBC approves protocol applications by a majority vote of the membership during the meeting.
 - 9) The Biosafety Officer prepares the proposed agenda prior to the meeting after consulting with the IBC Chair regarding agenda items that should be included. For a proposed agenda to become the official agenda for a meeting, it must be adopted by the committee at the outset of the meeting. At the time that an agenda is presented for adoption, it is in order for any member to move to amend the proposed agenda by adding any item that the member desires to add, or by proposing any other change.
 - 10) Protocols and research information is shared between the IBC, IACUC, IRB, and Sponsored Awards Management (SAM). The IBC and IRB review recombinant DNA or other potentially infectious materials research involving human subjects. The University currently does not have active research involving the deliberate transfer of recombinant or synthetic nucleic acid molecules into research participants (i.e. human gene therapy). The IBC and IACUC both review research involving transgenic animals or experimentally infected animals. This collaborative effort between research compliance committees helps to ensure that Principal Investigators do not initiate or modify research involving biohazardous materials which require IBC approval until the research or proposed modification has been approved by the IBC and met other requirements of the *NIH Guidelines*.

VIII. Conflict of Interest

Members of the IBC shall not participate in the review and approval of applications under consideration by the IBC when a conflict of interest exists. This includes, but is not limited to, the following:

- 1) The IBC member has been engaged, or expects to be engaged, in the research project under review, as defined in the *NIH Guidelines*.

- 2) The IBC member has a direct financial interest in the PI or the entity funding the research proposed by the PI, as defined by the institution and/or *NIH Guidelines*.
- 3) The IBC member and the PI of the application under consideration share a familial relationship.
- 4) The IBC member has other reasons to feel that he/she cannot render an impartial assessment of an application.

The IBC member shall disclose the conflict of interest at the following time:

- 1) When the IBC member is contacted to participate in the review of a project from a PI with whom the IBC member has a conflict of interest.
- 2) Prior to the discussion at a convened meeting of a project for which the IBC member has a conflict of interest.

Although an IBC member shall be recused from voting on the final disposition of projects for which she/he has a conflict of interest, the IBC member shall nevertheless remain eligible to provide information related to the review of the project to the IBC.

IX. Meeting Minutes

- 1) Meeting minutes reflect the date and place of the meeting, whether minutes of the prior meeting were approved, individuals in attendance, whether and why the meeting was open or closed, a list each protocol reviewed (including the IBC protocol number, protocol title, description of materials involved, approved biosafety level, and applicable section of *NIH Guidelines*), all major motions, and whether motions were approved, and the time of meeting adjournment.
- 2) Meeting minutes offer sufficient detail of the IBC's rationale for particular decisions by documenting any significant discussions of the following matters:
 - Conducting an assessment of the containment levels required by the *NIH Guidelines* when reviewing proposed research
 - Assessing the facilities, procedures, practices, and training and expertise of personnel involved in recombinant or synthetic nucleic acids research
 - Periodically reviewing recombinant or synthetic nucleic acid molecules research to ensure compliance with the *NIH Guidelines*
 - Agent characteristics (e.g. virulence, pathogenicity, environment stability)
 - Types of manipulations planned
 - Source(s) of the inserted DNA sequences (e.g., species)
 - Nature of the inserted DNA sequences (e.g., structural gene, oncogene)
 - Host(s) and vector(s) to be used
 - Whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced

- Containment conditions to be implemented
 - Applicable section of the *NIH Guidelines* (e.g., Section III-D-1)
- 3) Meeting minutes will reflect the IBC voting decision for all protocols reviewed. Each protocol will be assigned one of the following status options:
- Approved
 - Returned for Modification
 - Tabled
 - Denied
- 4) Meeting minutes and other required public information will be provided upon request by sending the requested information through U.S. mail, email, or making information available on the university's IBC website.
- 5) The IBC may not document certain information in the meeting minutes. Examples of information that may not be captured in the minutes includes Select Agent information, location of agents, trade secrets and other confidential commercial information, and information whose disclosure may directly compromise institutional security. Since the information described is not documented in the meeting minutes, the IBC does not anticipate the need to redact information from the minutes before they are released to the public upon request. In the event that unanticipated information must be redacted from the minutes before they are provided to the public, this decision will be made carefully to ensure maximum transparency and any redactions must be approved by the Chair.

X. Protocol Application Review and Approval Procedures

- 1) IBC meetings are scheduled at least quarterly. Additional meetings may be scheduled, when necessary, based on the volume of research requiring IBC review and approval, and to ensure a timely protocol review and approval process.
- 2) An IBC protocol must be submitted by the Principal Investigator for experiments involving recombinant or synthetic nucleic acid molecules (all research subject to section III-A through III-F of the *NIH Guidelines*), infectious agents, human-derived materials, and HHS/USDA regulated select agents and toxins.
- 3) The protocol application is a web-based form consisting of multiple sections that must be submitted electronically. The Principal Investigator is required to complete all sections that are applicable based on the type of biological materials that will be used for experiments involved in the projects submitted for review.
- 4) The BSO and IBC Chair will pre-review all protocol applications and provide comments or suggested revisions back to the Principal Investigator. This pre-review process is used to verify that all required sections of the protocol application have been completed and any significant safety or compliance issues have been addressed prior to the full committee's review of each protocol. Any pre-reviews are usually completed before the protocol submission deadline.

- 5) The IBC meeting dates and protocol application submission deadlines are posted on the IBC website in January of each calendar year. The Biosafety Officer will send a reminder notification to Principal Investigators about six weeks prior to the protocol submission deadline when the PI has a protocol that is due to expire. The PI must notify the Biosafety Officer in writing if they do not plan to renew their protocol and will no longer be conducting experiments in the protocol that are subject to the *NIH Guidelines*. Protocols received after the submission deadline will not be reviewed by the full committee until the next quarterly meeting. Exceptions to this procedure must be approved by the BSO and IBC Chair. Principal Investigators are encouraged to submit their applications as many days in advance of the scheduled IBC meeting as possible. This procedure helps expedite the protocol review process and ensure that all protocols are not submitted close to the submission deadline. The quarterly IBC meetings are usually scheduled for the third Wednesday of the month.
- 6) The day after the protocol submission deadline, all protocols are made available to the full committee for review. All IBC members have access to the IBC protocol management system, and committee members can review all agenda protocols in this system. Members can also add their comments, requests for clarification, or required revisions directly to the applicable question in each protocol form. Review comments are posted to the protocol form and visible to all other members during the review period. The protocol reviews due date is usually set for two weeks after all protocols are assigned to the full committee for review. Members must complete all assigned protocol reviews and submit their comments prior to the requested due date.
- 7) The Biosafety Officer will return all protocols for modification following the due date for completion of the full committee's reviews. Principal Investigators will be given at least five business days to complete the required protocol revisions and return the revised protocol for final review during the convened IBC meeting.
- 8) The Biosafety Officer will finalize the meeting agenda no later than the Monday morning prior to the Wednesday afternoon scheduled meeting. The full committee will be sent a notification that the meeting agenda has been completed and is available for review in the IBC protocol management system. Members can review all protocols on the agenda, see comments made by other reviewers, and evaluate the Principal Investigator's revisions made in response to these comments. The meeting agenda includes the following information:
 - Date, time and location of the scheduled meeting
 - List of all IBC members scheduled to attend (including guest attendees)
 - Copy of previous meeting minutes for review and approval
 - Announcements by the Chair, Biological Safety Officer or other attendees
 - Old business items that are still open for discussion
 - Description of any training that will be provided to IBC members
 - All biosafety protocol applications under review during the meeting
- 9) The full committee will discuss each protocol application during the convened

meeting. This discussion focuses on an assessment of the safety of each research protocol and the identification of any potential risk to workers, other persons, or the environment. The IBC Administrator presents a summary of all protocol revisions made in response to the member's review comments. Following a request by the IBC Chair for additional comments and discussion, the full committee will vote on each protocol and assign the protocol status as one of the following: Approved; Returned for Modification; Tabled; or Denied.

- 10) The Principal Investigator will be notified of his/her application's status via a written letter or email notification sent by the Biosafety Officer. This notification usually is communicated within one week of the meeting date, and will include the following information based on IBC's voting decision:
 - Approved: The IBC approved the application with no revisions necessary.
 - Returned for Modification: The application requires additional revisions based on comments made by IBC members during the protocol review process. Protocol approval will be granted once the Principal Investigator adequately addresses each issue identified during the review.
 - Tabled: The protocol review process is administratively suspended due to the Principal Investigator not responding to IBC notifications or not meeting protocol deadlines. A protocol may be *Tabled* if the PI does not re-submit a protocol that has been *Returned for Modification* by the due date. The *Tabled* protocol will be reviewed during the next IBC meeting if the PI has submitted a revised protocol by the next submission deadline.
 - Denied: The IBC does not approve the protocol because the research experiments may pose a significant safety risk to workers, other persons or the environment; the risks outweigh the benefits; or other reasons the IBC cannot justify granting approval.

Note: Conditional Approval is an informal approval status between the time the IBC meets to discuss the protocol and the time any stated conditions are fulfilled. Final approval is not granted until the Biosafety Officer verifies all approval conditions have been fulfilled. If approval conditions are not met, the protocol remains unapproved until the PI or lab addresses any required conditions.

- 11) All protocol applications are approved for a period of three years from the initial approval date. A Principal Investigator is required to submit a *Protocol Renewal* prior to the expiration date for any protocol that will be continued beyond the expiration date of the initial application approval.
- 12) Principal Investigators must submit any subsequent research protocol changes (during the three year approval period) to the IBC for review and approval or disapproval. Protocol changes must be submitted using the *Amendment Protocol*. All amendments must be approved prior to initiating the proposed changes. The IBC review will focus on reviewing content that has changed since the original protocol was approved. However due to periodic changes in IBC membership, committee expertise, and biosafety policies, it is possible that modifications may be required to sections that were approved in the original protocol application. When this occurs, the PI must make necessary revisions to any section of the

protocol application that is required to obtain the *Amendment Protocol* approval.

- 13) Principal Investigators are encouraged to attend IBC meetings where their research is discussed when unique circumstances arise and their attendance can be beneficial to assist the IBC in understanding the nature and risk of the proposed experiments. Although PI attendance at IBC meetings is rare, it will be requested when useful for projects that are especially complex, when proposed experiments are not conducted by other University investigators and when the IBC does not have unique expertise required to independently assess the safety of the research.

XI. APHIS/CDC Select Agents and Biosafety Level 3 (BSL-3) Research

The CDC and/or APHIS regulate the possession, use, and transfer of select agents and toxins. Research involving select agents and research conducted at biosafety level 3 (BSL-3) requires additional training, enhanced medical surveillance plans, complex facility maintenance and operations, and other specialized biosafety, security, and incident response plans. A research summary must be submitted to the Institutional Biosafety Committee (IBC) Chair and USC's Biological Safety Officer prior to any faculty member submitting a grant for this type of research, or any department hiring a new faculty member to conduct select agent or BSL-3 research. This notification will initiate a risk assessment for the proposed research, and an evaluation of the resources necessary for the IBC to fulfill all of its responsibilities under the *NIH Guidelines*, and the Environmental Health and Safety Department to provide adequate safety and compliance oversight. All research involving select agents or BSL-3 containment that is conducted at or sponsored by the university must be reviewed and approved by the Institutional Biosafety Committee prior to initiating research.

XII. Complaints Involving IBC Actions or Protocol Applications

- 1) Complaints involving the use of recombinant or synthetic nucleic acid molecules or other biological hazards should be communicated directly to the Biological Safety Officer or IBC Chair. Under most circumstances, one of these individuals will be able to resolve the complaint by taking appropriate actions.
- 2) In the event that a complaint cannot be resolved by the BSO or IBC Chair, a report will be prepared to document the nature of the complaint and any actions taken. This report will be discussed with the full IBC at the next convened meeting. Following this discussion, the IBC will vote on measures deemed appropriate to either resolve the complaint, or request further review of the complaint by other University administrators (e.g. Vice President for Research, General Counsel, Director of EHS, or Director of Research Compliance).
- 3) The IBC and other University administrators that have reviewed the complaint will collaborate to determine the best course of action. All final decisions will be conveyed to the individual or group that originally filed the complaint.

- 4) If any complaint involves public comments regarding actions taken by the IBC, the IBC Chair will forward both the public comments and IBC's response to NIH Office of Science Policy (OSP).

XIII. Biological Safety Regulations and Guidelines

During the IBC protocol review and approval process, the committee strives to ensure compliance with applicable biological safety regulations, guidelines and standards, including:

- ❖ *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids*
- ❖ *Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition*
- ❖ *OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030)*
- ❖ *IATA Dangerous Goods Regulations (Infectious Substances Transport)*
- ❖ *Infectious Waste Management: SC Department of Health & Environmental Control*
- ❖ *Pathogen Safety Data Sheets and Risk Assessment: Public Health Agency of Canada*
- ❖ *General Microbiology Fact Sheet: OSHA/ABSA Alliance Program*
- ❖ *Primary Containment: Selection, Installation and Use of Biological Safety Cabinets*
- ❖ *EPA's Registered Disinfectants Effective Against HIV-1, HBV, TB, and MRSA*
- ❖ *HHS and USDA Select Agents Regulations*

XIV. IBC Charter Approval

The IBC Charter is reviewed and updated by the Biological Safety Officer. The updated Charter will be distributed to the IBC Chair, Director of Research Compliance and Director of Environmental Health and Safety for review and comments. The IBC Charter must be approved by a full committee vote during a convened meeting. Then the approved Charter will be posted on the IBC website.