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 (including transgenic animals, transgenic plants and human gene transfer), infectious agents, human-derived materials, and HHS/USDA select agents and toxins. Principal Investigators are directly notified of the IBC review and approval results. The IBC website (http://ehs.sc.edu/Biosafety/IBC.htm) contains resources and guidance documents to assist the University’s research community with understanding and adhering to biological safety and compliance requirements. The IBC reports directly to the Office of Research Compliance. IBC meetings are scheduled at least quarterly.

II. Mission Statement

The Institutional Biosafety Committee (IBC) provides local review and oversight for research involving recombinant DNA and other potentially infectious or hazardous biological materials. The NIH Guidelines require the IBC to ensure that recombinant DNA research conducted at or sponsored by the university is in compliance with the NIH Guidelines. This requirement is primarily met through the IBC’s review and approval of all research subject to the NIH Guidelines. Members of the IBC are responsible for providing 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.

III. Terms of Appointment

The Provost officially appoints members of the IBC, and designates the Committee Chair. 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 who is a staff member in the Environmental Health and Safety Department (EHS), and serves as a permanent member of the IBC. The Biological Safety Officer is appointed by the Director of Environmental Health and Safety. If an IBC member does not attend at least fifty percent of the scheduled IBC meetings in a calendar year, the IBC Chair or Biosafety Officer may request that a replacement be nominated.
IV. IBC Membership Requirements

The USC Institutional Biosafety Committee will be comprised of no fewer than seven members. Members will be selected to ensure they collectively have:

- Experience and expertise in recombinant DNA technology and work with pathogenic agents
- The capability to assess the safety of this type of research and to identify any potential risk to public health or the environment

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 Institutional Biosafety Committee.

5) At least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q require prior approval by the Institutional Biosafety Committee.

6) Additional members will be selected in order to ensure the competence necessary to review and approve work involving recombinant DNA or other pathogenic agents. In an effort to accomplish this diverse experience and expertise, the IBC will seek to:

   a) Include persons with expertise in recombinant DNA 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 DNA 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 (2015–2016)

<table>
<thead>
<tr>
<th>IBC Member</th>
<th>Department / Member Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lydia Matesic</td>
<td>IBC Chair; Faculty member in Biological Sciences</td>
</tr>
<tr>
<td>Shayne Barlow</td>
<td>University Veterinarian and Director, Animal Resource Facilities</td>
</tr>
<tr>
<td>Beth Krizek</td>
<td>Faculty member in Biological Sciences; Plant Expert</td>
</tr>
<tr>
<td>Mark Robbins</td>
<td>Biological Safety Officer; Environmental Health and Safety</td>
</tr>
<tr>
<td>Boris Kantor</td>
<td>Director of USC School of Medicine’s Viral Vector Core Facility</td>
</tr>
<tr>
<td>Michael Shtutman</td>
<td>Assistant Professor in Drug Discovery and Biomedical Sciences</td>
</tr>
<tr>
<td>Jeff Twiss</td>
<td>SmartState Chair in Biology; Childhood Neurotherapeutics</td>
</tr>
<tr>
<td>Amanda Moore</td>
<td>Community member; SC Dept. of Health &amp; Environmental Control</td>
</tr>
<tr>
<td>Vida Mingo</td>
<td>Community member; Faculty member at Columbia College</td>
</tr>
<tr>
<td>Kris Kaigler</td>
<td>Lab technical staff; Pharmacology, Physiology and Neuroscience</td>
</tr>
<tr>
<td>Heather Mentrup</td>
<td>Graduate student member in Biological Sciences</td>
</tr>
</tbody>
</table>

## V. Roles and Responsibilities

**Responsibilities of the Director, Office of Research Compliance**

1) Provide adequate supervisory oversight to ensure the IBC has established and implemented policies that provide for the safe conduct of recombinant or synthetic nucleic acid molecule research and that ensure compliance with the *NIH Guidelines*. As part of its general responsibilities for IBC compliance oversight, the Office of Research Compliance may establish or recommend additional procedures, as deemed necessary, to govern the University and its components in the discharge of its responsibilities under the *NIH Guidelines*.

2) Establish an Institutional Biosafety Committee that meets the requirements and carries out the functions detailed in the *NIH Guidelines*. This responsibility includes identifying individuals with the collective experience and expertise in research involving all biological hazards used in University labs. Members will be selected with the capability to assess the safety of research protocols and to identify any potential risk to workers, other persons, or the environment.

3) Assist the IBC to ensure compliance with the *NIH Guidelines* by Principal Investigators conducting research at the institution. This assistance includes activities such as facilitating communication between the IBC and department chairs or other administrators hiring new faculty to conduct research involving biological hazards to ensure this research can be conducted in full compliance.

4) Ensure appropriate training for the Institutional Biosafety Committee Chair and
members, Biological Safety Officer and other containment experts (when applicable), Principal Investigators, and laboratory staff regarding laboratory safety and implementation of the *NIH Guidelines*.

5) If the IBC determines the necessity for health surveillance, support policies and plans to conduct a health surveillance program, when appropriate, for personnel involved with individual recombinant or synthetic nucleic acid molecule projects.

6) Report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to NIH/OBA within thirty days unless the University determines that a report has already been filed by the Biosafety Officer, Principal Investigator or Institutional Biosafety Committee.

7) 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, Office of Environmental Health and Safety

1) In 2013, the Director for EHS committed to invest the resources (e.g. financial, specialized skills, IT support, time) 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 multiple new and expanded biosafety program operations required 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 DNA research conducted at or sponsored by the university to determine compliance with the *NIH Guidelines*, and approve 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 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 DNA research conducted at the institution to ensure compliance with the *NIH Guidelines*. This includes, but is not limited to, verification that Principal Investigators submit a protocol amendment prior to conducting experiments requiring IBC review and approval prior to initiation.

7) Adopt emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research. Emergency plans will emphasize the prevention of occupational infections or environmental contamination.

8) 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), Office of Research Compliance, the PI’s Department Chair/Dean, and NIH/OBA within 30 days, unless the IBC determines that a report has already been filed by the Principal Investigator.

9) 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.
10) 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.

11) Open IBC meetings to the public when possible and consistent with protection of privacy and proprietary interests.

12) Make meeting minutes available to the public upon request.

13) 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 appropriate institutional official(s) and NIH/OBA within 30 days, unless the IBC determines that a report has already been filed by the Principal Investigator.

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 Associate VP for Health and Safety when additional resources are required to fulfill IBC responsibilities and to ensure safe research and compliance.

6) If public comments are made on IBC actions, the IBC Chair will forward both the public comments and IBC’s response to NIH Office of Biotechnology Activities.

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) & IBC Administrator Responsibilities**

1) Conduct periodic inspections to ensure laboratory 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) Develop and implement emergency plans for handling accidental spills and personnel contamination resulting from work with biological hazards.

4) Provide technical advice on laboratory security, research safety procedures, biosafety administrative controls, and compliance requirements. Assist with the review of lab facility design plans for research involving biological hazards. Manage the contract for installation and certification of biological safety cabinets.

5) Provide general laboratory biosafety training to research personnel, and manage the vendor contract for certification of all biological safety cabinets in USC labs.

6) Coordinate posting of policies, guidance documents, and other resources on the IBC website to promote safe research and compliance with the NIH Guidelines.

7) Serve as a permanent ex-officio member of the Institutional Biosafety Committee.

8) Assist with providing general oversight of IBC operations to promote compliance.

9) Schedule IBC meetings, verify quorum attendance, and prepare meeting agendas.

10) Facilitate protocol review and approval process, including protocol modifications.

11) Notify Principal Investigators of the results of IBC review and approval.

12) Prepare IBC meeting minutes to include information required in NIH Guidelines.

13) Submit annual report to NIH/OBA (e.g. updated roster and biographical sketches)

14) Maintain records (e.g. approved protocols, meeting minutes, membership roster)

15) Post public notification regarding access to convened IBC meetings and minutes. Upon request, the IBC Administrator will make the following information conveniently available to the public:
   A. All requested Institutional Biosafety Committee meeting minutes
   B. Any documents submitted to or received from funding agencies which are required to be available to the public
   C. Rosters and biographical sketches that have been submitted to NIH

16) Provide leadership for a multi-year project to establish and maintain a sustainable biorisk management system that is modular, scalable and customized for biosafety and compliance operations. System will promote program improvement efforts to:
   A. Establish and maintain a risk assessment system
   B. Maintain an accurate biological agents and toxins inventory
   C. Develop a comprehensive Biological Safety Manual
   D. Conduct inspections for all types of biological hazards
   E. Establish and maintain all required training programs
   F. Establish a comprehensive bio-waste management policy
   G. Ensure occupational health commensurate with lab risk
   H. Provide proper medical surveillance and immunizations
I. Ensure bio-risk management of lab animal activities
J. Define scientific management responsibilities
K. Define and verify competency levels of lab staff
L. Establish incident investigation and reporting plans
M. Ensure actions to prevent lab non-compliance
N. Collect and analyze safety and compliance data
O. Add and update resources with new requirements

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.

2) Never initiate or modify research involving biohazardous materials which requires Institutional Biosafety Committee approval prior to initiation until that research or the proposed modification has been approved by the Institutional Biosafety Committee and has met all 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 Institutional Biosafety Committee.

5) Be adequately trained in good microbiological techniques;

6) Adhere to Institutional Biosafety Committee approved emergency plans for handling accidental spills and personnel contamination; and
7) Comply with shipping requirements for recombinant DNA molecules

**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 Institutional Biosafety Committee for review and approval or disapproval; and

d) Remain in communication with the Institutional Biosafety Committee 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) Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents; and

c) 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 laboratory staff to ensure that the required safety practices and techniques are employed;

b) Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Institutional Biosafety Committee;

c) Correct work errors and conditions that may result in the release of recombinant DNA materials; 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.

**VI. Conduct of Committee Business**
1) The IBC reviews research involving recombinant DNA materials or technology (e.g. transgenic animals, transgenic plants and human gene therapy), 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 times and location will be advertised to the public on the university’s IBC website at http://ehs.sc.edu/Biosafety/IBC.htm.

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. 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 IBC Administrator 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 DNA 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 prior to initiation until that research or the proposed modification has been approved by the IBC and has met all other requirements of the NIH Guidelines.

VII. 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 is currently 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.

VIII. 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 DNA research
- Periodically reviewing recombinant DNA 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 redact proprietary or private information from the meeting minutes, but must do so judiciously and consistently for all requested documents. Some examples of information that may be redacted include trade secret information and other confidential commercial information, home telephone numbers and home addresses of IBC members, and specific information whose disclosure would directly compromise institutional or national security.

**IX. Protocol Application Review and Approval Procedures**

1) IBC meetings are scheduled at least quarterly. Additional meetings may be scheduled, when necessary, to expedite the 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 (including transgenic animals, transgenic plants and human gene therapy), 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 Biological Safety Officer will pre-review all protocol applications and submit 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. The BSO’s pre-review is usually completed before the protocol submission deadline.

5) The protocol application submission deadline is usually the first day of the month when the IBC meeting is scheduled. 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 Biological Safety Officer 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 applicable 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 Topaz protocol management system. Committee members can review all protocols posted in the “My Reviews” section of the system’s Dashboard. 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 IBC Administrator will return all protocols for modification following the due date for completion of the full committee’s reviews. Principal Investigators will be given five business days to complete the required protocol revisions and return the revised protocol for final review during the convened IBC meeting.

8) The IBC Administrator 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 Topaz Dashboard section titled “My Meetings”. 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

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. 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.

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.

X. 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.

XI. Complaints Involving IBC Actions or Protocol Applications

1) Complaints involving the use of recombinant DNA 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 or Office 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 Biotechnology Activities.

XII. Evolving Research Environment

In recent years, biological research activity has increased substantially in areas such as:

- Total number of biological research labs (over 50% increase in last 6 years)
- Biological hazards use (e.g. # labs using viral vectors doubled in last 5 years)
- Collaborations, interdisciplinary/innovative research, private-public partnerships, entrepreneurship and commercialization, SmartState Program endowed chairs
- Complexity of regulatory environment and more strictly enforced oversight
- Number new laboratory designs, renovations, and new construction projects
- Global research initiatives (imports and exports of regulated dangerous goods)
- Number of new technical compliance resources to develop and maintain

XIII. Biological Safety Regulations and Guidelines

- *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*
- *APHIS/CDC National Select Agent Registry*

XIV. IBC Charter Approval

The IBC Charter is reviewed and updated annually by the Biological Safety Officer. The updated document, and all proposed amendments, will be reviewed and approved by the IBC Chair, Director of the Office of Research Compliance, and Director of Environmental Health and Safety. The IBC Charter must also be approved by a full committee vote during a convened meeting and posted on the IBC website.