UNIVERSITY OF South Carolina

Institutional Biosafety Committee Charter

I. Background

The University of South Carolina (USC) research laboratories conduct a broad range of biological research activities. USC research involving biological hazards will be conducted in compliance with federal and state regulations and standards. This includes compliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*, OSHA Bloodborne Pathogens Standard, CDC Biosafety and Microbiological and Biomedical Laboratories, IATA Dangerous Goods Regulations, SC DHEC Infectious Waste Regulation, NSF/ANSI 49 Annex E, and HHS/USDA Select Agent Regulations. The *NIH Guidelines* require the university to establish an Institutional Biosafety Committee (IBC) as a condition for NIH funding for this research. The USC's IBC and Biological Safety Program services support research conducted at the USC Columbia, USC School of Medicine Columbia, USC School of Medicine Greenville, USC Aiken and USC Upstate campuses. The scope of review includes protocols for all research involving 1) recombinant or synthetic nucleic acid molecules (i.e., all research covered under sections III-A through III-F of the *NIH Guidelines*); 2) human, animal, or plant pathogens; 3) human-derived materials; and 4) HHS/USDA select agents and toxins. Principal Investigators are notified of the IBC review and approval results. The IBC may also approve new or significantly revised Biological Safety policies or plans. The IBC website and Biological Safety webpages contain guidance resources to assist researchers with understanding and adhering to biosafety 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. According to the NIH, institutions shall ensure that research complies with the *NIH Guidelines*, and the IBC shall assess the safety of research protocols to identify potential risk to workers, other persons, or the environment. This requirement is primarily fulfilled through IBC review and approval of protocols for research involving biological hazards. IBC members provide the collective experience and expertise in research involving these materials and the capability to assess the safety of research protocols and to identify potential risks to workers, other persons, or the environment.

The IBC shall provide an annual biological safety risk assessment and report to the Enterprise Risk Management Oversight Committee via the Research Safety Senior Committee. This assessment will identify the various risks associated with research involving biological hazards and will define the highest risk(s). The committee will review and update a biosafety risk matrix and heat map annually. A High-Risk Report will describe the highest biosafety risk, benefits of conducting the activity, and institutional impact. This report will also list the current risk controls and controls being

implemented to mitigate these high risks. In addition, the report outlines leading and lagging indicators associated with the highest risks, including metrics and a quarterly assessment that defines any changes to the status of risk or effectiveness of controls.

III. Terms of Appointment

The Institutional Biosafety Committee is appointed by the Vice President for Research. IBC members are appointed for a period of three years. Consecutive terms are permissible when necessary to maintain a collective experience and expertise to effectively assess the safety and risks of research proposals. The one exception is the Research Safety Bureau Chief (RSBC) / Senior Biosafety Officer who serves as the IBC Administrator and a permanent member of the IBC. Members are nominated by the RSBC/Senior BSO, IBC Chair, or any member of the committee (often to fill an area of expertise when a member rotates off the committee). New members are formally appointed by a full committee vote during a convened meeting. If an IBC member does not attend at least 50% of the scheduled IBC meetings in a calendar year, the IBC Chair or RSBC may request to nominate a replacement. The USC maintains a list of all Special Advisory Committees. This list of official committees includes the IBC's purpose statement and membership requirements. The IBC will closely collaborate with the Biological Safety Program to fulfill its functions.

IV. IBC Authority

The IBC is empowered with the authority to enforce the *NIH Guidelines* and to ensure that IBC approval conditions are fulfilled in USC Columbia, USC School of Medicine Columbia, USC School of Medicine Greenville, USC Aiken and USC Upstate laboratories. 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 conduct research pending a formal investigation. The IBC or Research Safety Bureau Chief / Senior BSO 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. Incidents will be reported to the NIH Office of Science Policy (OSP) when required for compliance. The IBC has the authority to revise and approve Biosafety policies, manuals, and plans.

The IBC can require protocol modifications to lab work practices, engineering controls, personal protective equipment, and other safety measures to reduce risk prior to protocol approval. According to the hierarchy of controls, elimination of the hazard is the most effective method for mitigating risk. Since this is often not possible due to the necessity to use biological hazards for research discovery, there is always a potential for an incident to occur. The probability or severity of an incident (e.g., exposure) occurring often depends on the laboratory experiments conducted or biological hazards involved in the research.

The IBC and Biosafety Program do not have authority to establish new programs to further reduce biomedical research risks. The IBC can advocate for or recommend implementing new programs (e.g., research occupational health program, service for laundering lab coats), but the implementation of new programs requires support from senior institutional

officials and dedicated resources. The impact of additional biosafety risk controls will vary for different research projects. The IBC will conduct a risk assessment for each project. The IBC will not approve projects with significant safety or compliance concerns. If the PI has completed an IBC protocol that conforms to current institutional biosafety policies and no significant safety or compliance risks are identified, the project will be approved. If additional risk controls are identified that are beyond the scope of current institutional services, and these risk controls are documented as not yet implemented in the ERM Biological Safety High-Risk Report (e.g., research safety responsibilities policy, training management system, research occupational health, lab coat program), then the IBC will approve the project. The IBC submits quarterly Biosafety High-Risk Report updates to the ERM Oversight Committee and Research Safety Senior Committee on risk controls being implemented, impact, implementation timelines, unit responsible and other quarterly notes. The USC and its IBC are committed to a process of continuous improvement in biosafety.

V. IBC Membership Requirements

Members are selected to ensure compliance with membership requirements articulated in the *NIH Guidelines*. The Institutional Biosafety Committee (IBC) will be comprised of no fewer than six members. Members are appointed to ensure they collectively have experience and expertise to effectively assess the safety and risks of research proposals. IBC membership must include representatives from the USC Columbia, USC School of Medicine Columbia, USC School of Medicine Greenville, USC Aiken and USC Upstate.

<u>The IBC membership will consist of:</u>

1) A Chair of the IBC

2) A Senior Biosafety Officer/Administrator

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 L* require prior approval by the IBC.

5) At least one scientist with expertise in animal containment principles when experiments utilizing *Appendix M* require prior approval by the IBC.

6) Additional members will be selected 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 persons available as consultants that are knowledgeable of institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment;

c) Include at least one member representing the laboratory technical staff.

IBC Membership (2023–2024)

IBC Member	Department / Member Role
Doug Pittman	IBC Chair; Faculty member in Drug Discovery and Biomedical Sciences
Mark Robbins	EH&S Research Safety Bureau Chief & Senior Biosafety Officer
Shayne Barlow	Associate VP for Research & Attending Veterinarian/Animal Expert
Beth Krizek	Professor in Biological Sciences; Plant Expert
Sujit Pujhari	Viral Vector Core Director in Pharmacology, Physiology and Neuroscience
Jason Kubinak	Assistant Professor in Pathology, Microbiology, and Immunology
Michael Shtutman	Associate Professor in Drug Discovery and Biomedical Sciences
Daping Fan	Professor in Cell Biology and Anatomy
Sean Norman	Associate Professor in Environmental Health Sciences
Anna Blenda	Associate Professor and Director of Research at USC SOM Greenville
William Jackson	Professor and Chair in Biology & Geology at USC Aiken
Ben Montgomery	Associate Professor in Natural Sciences and Division Chair at USC Upstate
Amanda Moore	Community member; SC Department of Health & Environmental Control
Vida Mingo	Community member; Senior Lecturer of Biology at Columbia College
Kris Kaigler	Laboratory technical staff in Pharmacology, Physiology and Neuroscience

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 federal, state and local biological safety compliance responsibilities. Encourage grantees to meet health and safety standards for drawing funds from HHS systems. Promote biosafety as part of the social responsibility of science.

2) Provide funding to maintain an IBC protocol management system for protocol review and approval, and to manage all records for *NIH Guidelines* compliance.

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 a research occupational health and medical surveillance program is established for personnel conducting research involving recombinant DNA or other biological hazards. This includes establishing policies, procedures, and occupational health services for USC lab workers with potential for exposure. A research occupational health program functions separate from the Biosafety Program but needs to collaborate closely with the Biosafety Program and IBC.

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) Promote institutional efforts to ensure 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 (6th Edition). Assist to ensure that grantees understand that by drawing funds from the HHS system, the grantee agrees to these terms and conditions. Assist the IBC to resolve issues of laboratory non-compliance with IBC requirements.

Responsibilities of the Enterprise Risk Management Oversight (Executive) Committee and ERM Research Safety Senior Committee

1) Review quarterly updates to the Biological Safety High-Risk Report, Risk Register, and Heat Map that are submitted by the IBC. Assess the status of current risk controls, controls being implemented, leading and lagging indicators, status of risk, and the effectiveness of controls. Utilize this information when making decisions regarding acceptable biosafety risk and the implementation of new risk controls.

2) Conduct a thorough annual assessment of the resources necessary for the IBC to fulfill all 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.*

Institutional Biosafety Committee Responsibilities

1) Review research projects involving biological hazards for approval or disapproval. 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; and (ii) assessment of the facilities, procedures, practices, and training and expertise of personnel involved in

recombinant DNA research. The *NIH Guidelines* require IBC review of all research involving recombinant DNA materials or technology. The University's IBC also reviews research involving human/animal/plant pathogens, human materials that may contain bloodborne pathogens, 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 IBC'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 IBC may take further actions deemed appropriate if a Principal Investigator has repeated compliance violations that are not corrected, any serious safety violations, or multiple less serious safety concerns are identified that create a significant risk to laboratory workers, other persons, or the environment.

9) The IBC may review and approve new or significantly amended biosafety policies.

10) The IBC 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) Serve as IBC Chair and prioritize activities for all convened meetings.

2) Ensure the IBC fulfills its responsibilities as stated in the IBC Charter.

3) 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.

4) Assess the resources necessary for the IBC to fulfill its responsibilities articulated in the *NIH Guidelines*. This assessment should account for 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.

5) If public comments are made on IBC actions, the IBC Chair (in consultation with the Research Safety Bureau Chief / Senior Biosafety Officer) will forward both the public comments and IBC's response to the NIH Office of Science Policy (OSP).

6) Provide leadership for the IBC to identify, develop and adopt policies or programs to promote safe biological research and compliance with the *NIH Guidelines*.

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

Research Safety Bureau Chief / Senior Biosafety Officer Responsibilities

1) Serve as a permanent member of the Institutional Biosafety Committee.

2) Serve as USC's primary expert on complex biosafety or IBC compliance issues. Provide technical advice to the IBC on research safety procedures, safety equipment, lab facilities, and lab security.

3) Develop and maintain the IBC Charter. Coordinate IBC review, suggested revisions, and approval of significant amendments to 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 NIH OSP within 30 days, unless a report has already been filed by the IBC Chair or other institutional official.

5) 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.

6) Review laboratory facility design plans for research involving biological hazards.

7) Assist with development of SOPs for the use of biohazards in animals for DLAR.

8) Provide training on the *NIH Guidelines* for new IBC members when appointed.

9) Coordinate posting of biosafety policies, plans, guidance documents, and other references on the IBC website to promote research safety and compliance.

10) In collaboration with the IBC Chair, identify IBC members with the collective experience and expertise in research involving biological hazards used at USC.

11) Periodically conduct an IBC self-assessment for compliance with *NIH Guidelines*, and provide compliance assessments to the VP for Research Office upon request.

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

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

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

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

16) Submit the IBC annual report to the NIH Office of Science Policy.

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

18) Provide updated IBC membership roster to the USC Provost Office upon request.

19) Provide guidance to Principal Investigators and the IBC on specialized biosafety issues upon request (e.g., biological agent authorizations, CDC or USDA permits, shipping specimens, transfer agreements, specialized containment requirements).

20) Serve as the primary liaison between the IBC, Biological Safety Program, IACUC, IRB, and Enterprise Risk Management (ERM) Research Safety Senior Committee.

21) Prepare the Research Safety Bureau and Biological Safety Program annual reports. Submit annual reports to the Director of EH&S to promote transparency and engage management with respect to institutional biosafety oversight and compliance.

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

Biological Safety Officer (BSO) Responsibilities

1) Maintain biological safety policies, procedures, and guidance documents. Consult with the Senior BSO when needed for specialized biosafety or compliance issues.

2) Ensure periodic inspections are conducted to verify lab standards are rigorously followed and compliance with USC biosafety policies and regulations/guidelines.

3) Investigate laboratory accidents and report to the Senior BSO and IBC Chair any

significant problems or violations, and any significant research-related injuries or illnesses associated with biological research. Following all incident investigations, notify the research personnel involved of the recommended corrective actions.

4) Ensure required biosafety training is provided to laboratory personnel. This training includes, but is not limited to, Biosafety Level 2 and bloodborne pathogens training.

5) Manage the contract and records for certification of laboratory biosafety cabinets. Provide guidance to labs on the selection, installation, and use of biosafety cabinets.

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 require IBC approval 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 containing all relevant information required for the IBC to assess the safety of the research project (experimental procedures, agents used, risks, etc.) 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 impede safety or containment for biological hazards, correct all reported safety or compliance deficiencies identified during lab inspections, and submit corrective action plan by the requested due date);

d) Ensure all laboratory personal complete required biosafety training courses; and

e) Ensure the integrity of the physical containment (e.g., annual certification of biosafety cabinets by USC approved vendor) and the biological containment (e.g., purity and genotypic and phenotypic characteristics).

VII. Conduct of Committee Business

1) The IBC scope of review includes research involving 1) recombinant or synthetic nucleic acid molecules (i.e., all research covered under sections III-A through III-F of the *NIH Guidelines*); 2) human, animal, or plant pathogens; 3) human-derived materials; and 4) 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 projects, 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.

4) IBC members have the right to make motions, to speak in debate, and to vote on all biosafety approvals or issues discussed. The IBC Chair and Senior Biosafety Officer both have the same rights and privileges as all other members.

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 (i.e., at least 50%) 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 subject-matter expertise 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). A consultant may provide professional guidance on the topic of interest but will not have rights to make motions or vote and will not be considered as an IBC member for quorum.

8) The Senior 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, any member may move to amend the proposed agenda by requesting to add any item that the member desires to add, or by proposing any other modifications to the agenda.

9) 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. If additional minor protocol revisions are required for IBC approval, these revisions must be clearly defined by committee vote and can be made by the PI after the meeting and the protocol can later be approved only after appropriate revisions are verified by the IBC Chair or Senior BSO. If any significant required revisions are identified during the convened meeting or the minor revisions made by the PI after the meeting may not fulfill the expectations of the full committee, then the protocol must be tabled for review and consideration for approval during the next convened meeting.

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 collaboration 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 decisions by documenting any significant discussions of the following matters:

    - Assessing 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) 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*), human/animal/plant pathogens, human-derived materials, and HHS/USDA regulated select agents and toxins.

2) 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.

3) The Biological Safety Officer offers to pre-review all new protocol applications and provide comments or suggested revisions back to the Principal Investigator. This pre-review process is beneficial 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.

4) The IBC meeting dates and protocol application submission deadlines are posted on the IBC website in January of each calendar year. The Senior 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 Senior BSO 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 Senior 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.

5) 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 due date.

6) The Senior Biosafety Officer will return all protocols for PI 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.

7) The Senior 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, Senior Biosafety 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

8) 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 Senior BSO 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. Protocols are often approved during the convened meeting since required PI modifications are often completed prior to the meeting during the pre-review and full committee review process.

9) The Principal Investigator will be notified of his/her application's status via a written letter or email notification sent by the Senior 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 BSO or Senior BSO verifies all approval conditions have been fulfilled. If approval conditions are not met, the protocol remains unapproved until the PI or lab properly addresses all required conditions.

10) 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.

11) 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.

12) 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 BSL-3 or ABSL-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) or animal biosafety level 3 (ABSL-3) containment requires additional training, enhanced medical surveillance plans, complex facility management 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 Research Safety Bureau Chief (Senior Biosafety 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/ABSL-3 research. This notification must be made several months in advance of any plans to initiate this type of research.

The USC will appoint a team to collaboratively evaluate the feasibility of a new facility, define general design requirements based on the proposed research, and assess the resources required for the complete planning, design, renovation or construction, management, operations, and safety/compliance oversight for a new high containment facility. This team should include, but not be limited to the Research Safety Bureau Chief, Biological Safety Officer, IBC Chair, Associate Dean for Research, Facilities Project Manager, Principal Investigator(s), and Director of DLAR (for ABSL-3 facilities). An external consultant with expertise in BSL-3/ABSL-3 facility design may be needed for the initial feasibility and planning process. If the BSL-3/ABSL-3 facility is approved, an experienced BSL-3 Facility Manager should be appointed to oversee the design, construction, commissioning, and operations of the facility. All research involving select agents, BSL-3 or ABSL-3 containment that is conducted at or sponsored by the USC must be reviewed and approved by the IBC (and IACUC for ABSL-3) 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 Senior Biosafety Officer or IBC Chair. Under most circumstances, one of these individuals will be able to resolve the complaint by taking appropriate actions.

2) If a complaint cannot be resolved by the Research Safety Bureau Chief 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 resolve the complaint or request further review of the complaint by other USC administrators (e.g., Vice President for Research, General Counsel).

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), 6th Edition*
- *OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030)*
- *IATA Dangerous Goods Regulations (Infectious Substances Shipping Guidelines)*
- *SC DHEC Infectious Waste Management Regulation (Regulation 61-105)*
- *Pathogen Safety Data Sheets and Risk Assessment: Public Health Agency of Canada*
- *General Microbiology Fact Sheet: OSHA/ABSA Alliance Program*
- *NSF/ANSI 49 (2019) – Biosafety Cabinetry: Design, Construction, Performance, and Field Certification*
- *List E: EPA's Registered Antimicrobial Products Effective Against TB, HIV-1 and HBV*
- *Arthropod Containment Guidelines, Version 3.2 (ACME)*
- *CDC Import Permit Program (IPP)*
- *CDC and USDA Select Agents Regulations*

XIV. Biosafety Governance, IBC Charter, Training, Reports and Approvals

Biosafety Governance:

The National Security Council (NSC) established guiding principles and best practices for biosafety governance. These principles and practices are intended to promote robust programs of oversight and to ensure that all those at the institution who are conducting or overseeing life sciences research are aware of their responsibilities for compliance with biosafety requirements and the importance of upholding a strong culture of biosafety. These guiding principles include, but are not limited to:

- Coordinate activities among committees, departments, offices, and staff with biosafety and biosecurity oversight and compliance responsibilities.
- Ensure senior leadership is engaged with respect to institutional biosafety and biosecurity oversight and compliance functions.
- Ensure appropriate resources are devoted to biosafety and biosecurity oversight and compliance activities at the institution.
- Promote transparency regarding institutional biosafety and biosecurity oversight.

The IBC and Biosafety Program, along with other institutional committees and officials are committed to a process of continuous improvement in biosafety and compliance.

IBC Charter:

The IBC Charter will be reviewed and updated at least annually. The IBC Charter must be approved by a full committee vote during a convened meeting. Then the approved IBC Charter will be posted on the IBC website. The Vice President for Research may propose amendments to the IBC Charter by contacting the Research Safety Bureau Chief.

Training:

The NIH Guidelines require training for the IBC Chair and members, Biological Safety Officer and other containment experts, Principal Investigators, and laboratory staff regarding laboratory safety and implementation of the *NIH Guidelines*. The Research Safety Bureau Chief / Senior Biosafety Officer provides training to all new IBC members, including the IBC Chair. The RSBC / Senior BSO has attended training provided by the NIH Office of Science Policy, and the Biological Safety Officer has been provided training. The Biological Safety Program has implemented an *NIH Guidelines* training for Principal Investigators. The Principal Investigator is responsible for ensuring that laboratory staff are appropriately trained. Other required research safety training courses are provided to research personnel on laboratory safety topics based on the type of research conducted such as General Laboratory Safety, Laboratory Biosafety Level 2, Animal Biosafety Level 2, Bloodborne Pathogens, and Shipping Infectious Substances or Related Materials.

Biosafety Reports and Plans:

The Biological Safety Officer (BSO) will prepare a Biological Safety Program Annual Report. The agenda for the first IBC meeting each calendar year will include the annual report for full committee review and an opportunity to provide feedback. The annual report will also be submitted to the Director of EH&S. Annual reports will include a summary of the following topics to ensure the IBC has updated information pertaining to their role:

1) Biosafety and IBC compliance priorities, metrics, and annual highlights
2) Updates on federal biosafety oversight and changes in university research
3) Status updates on biosafety risk controls, successes, and compliance challenges

The USC Enterprise Risk Management Oversight (Executive) Committee and ERM Research Safety Senior Committee will review updates to the Biological Safety High-Risk Report, Risk Register, and Heat Map that are submitted by the IBC. These committees will assess the status of current biosafety risk controls, controls being implemented, leading and lagging indicators, status of biosafety and compliance risks, and effectiveness of controls.

The IBC may review and approve new or significantly updated USC biosafety policies and plans, including resources such as the IBC Protocol Forms, Biological Safety Manual, Bloodborne Pathogens Exposure Control Plan, Infectious Waste Management Plan, Biological Agent Safety Guides, training requirements, and Biosafety or IBC website.