MUSC IBC Policies and Procedures

Contents

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1. Overview of IBC

1.1. IBC Charge and Authority

The Medical University of South Carolina (MUSC) Institutional Biosafety Committee (IBC) and the Department of University Risk Management are closely aligned in a partnership to administer the MUSC Biosafety Program, which aims to minimize risks to MUSC and the surrounding community from activities involving recombinant and synthetic nucleic acid molecules, microorganisms, and biological toxins.

The MUSC Institutional Official (as defined in IBC Policies and Procedures Section 2.1) has charged the IBC with reviewing all recombinant or synthetic nucleic acid molecule research conducted at or sponsored by MUSC for compliance with the current edition of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*), and approving those research projects that are found to conform with the *NIH Guidelines*. The IBC is also responsible for reviewing all research conducted with microorganisms and biological toxins (including all Select Agents) and approving those research projects that are found to conform to the regulations and guidelines described in Section 1.2 below (hereafter referred to as "Regulations and Guidelines"). All such research activities, regardless of the source of funding, must be reviewed and approved by the IBC. The IBC exercises independence as the entity authorized to oversee such research for MUSC.

The IBC is registered with the NIH Office of Science Policy (OSP) for purposes of research involving Recombinant or Synthetic Nucleic Acid Molecules.

The IBC Policies and Procedures address projects at Biosafety Levels 1 and 2[1] only. The IBC Policies and Procedures will be modified to address higher Biosafety Levels when necessary.

1.2. Regulations and Guidelines

The IBC will ensure that the proposed research is in compliance with all relevant portions of applicable federal, state and local laws, rules, regulations, and guidelines, including, but not limited to:

a. *NIH Guidelines* (current version) – NIH
b. Biosafety in Microbiological and Biomedical Laboratories (BMBL) – CDC and NIH (current version)

[1] As defined in Appendix G of the *NIH Guidelines*

c. Select Agent Regulations (7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73)
d.
e. HHS regulations Protection of Human Subjects (45 C.F.R. Part 46).
f. FDA regulations (21 C.F.R.)
g. USDA APHIS - Animal and Plant Health Inspection Service regulations
h. DHEC - S.C. Department of Health & Environmental Control regulations
i. All relevant policies and procedures of MUSC, including:
- IBC Policies and Procedures
- Biological Safety Policy of University Risk Management, Biosafety Office
- Management of HCT/P (Human Cells, Tissues, or Human Cell or Tissue-Based Products) Based Therapy
- Infection Control Standard Precautions
- Bloodborne Pathogen Protocols
- Red Bag Usage in the Disposal of Biohazardous/Regulated Waste

1.3. Definitions and Abbreviations

Biological Safety Officer (BSO) – An individual appointed by MUSC to oversee management of biosafety risks. The *NIH Guidelines* require that a BSO be appointed when the institution is engaged in large-scale research or production activities, or in research requiring containment at BL-3 or BL-4.

Biological toxin – means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.[2]

Biosafety – The discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials.[3]

Biosafety Level (BL) – A description of the degree of physical containment being employed to confine organisms containing recombinant and synthetic nucleic acid molecules and to reduce the potential for exposure of laboratory workers, persons

[2] 42 C.F.R. § 73.1 (2012)
[3] Chosewood LC, Wilson DE. 2007. Biosafety in microbiological and biomedical laboratories (BMBL), 5th ed. Centers for Disease Control and Prevention, Atlanta, GA.

outside of the laboratory, and the environment. In Appendix G of the *NIH Guidelines*, these are graded from BL-1 (the least stringent) to BL-4 (the most stringent).

Biosafety Officer (BSO)

DHHS – Department of Health and Human Services

Enrollment – The process of obtaining informed consent from a potential research participant, or a designated legal guardian of the participant, to undergo a test or procedure associated with a clinical trial.[4]

IACUC – Institutional Animal Care and Use Committee. Oversight committee for the use of laboratory animals for research or instructional purposes.

IRB – Institutional Review Board. Oversight committee for research involving human subjects.

IO – Institutional Official

NIH – National Institutes of Health

PI – Principal Investigator. See Principal Investigator.

Principal Investigator - the lead scientist on a project registered with the IBC, whose primary responsibility is to direct the proper conduct of a scientific research project or program. Only MUSC faculty are eligible to submit IBC applications. Post-doctoral fellows, graduate students and visiting faculty must have the faculty member with whom they are working with submit an IBC application(s) covering their work.

Recombinant and synthetic nucleic acid molecules – either: (i) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell (i.e. recombinant nucleic acids); (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e. synthetic nucleic acids); or (iii) molecules that result from the replication of those described in (i) or (ii) above.[5]

Select Agents - Biological agents and toxins that are defined in 42 C.F.R. §§ 73.3 and 73.4 (2012).

2. Responsibilities

The *NIH Guidelines* are intended to assist the institution, Institutional Biosafety Committee, Biological Safety Officer, and the Principal Investigator in determining safeguards that should be implemented. However, it is the responsibility of the institution and those associated with it to adhere to the intent of the *NIH Guidelines* as well as to their specifics.[6]

2.1. Institution

[4] *NIH Guidelines* Section I-E-7
[5] *NIH Guidelines* Section I-B
[6] *NIH Guidelines* Section IV-A

The MUSC President delegates the Institution's (MUSC) responsibility for the Biosafety Program to the Vice President for Research, who is the Institutional Official. The IO:

a. Ensures MUSC is compliant with *NIH Guidelines* Section IV-B (Responsibilities of the Institution).

In addition, the IO:

b. Appoints IBC members and designates the IBC Chair.
c. Annually evaluates allocation of resources to the IBC and adjusts as necessary.
d. Ensures appropriate training for the IBC Chair and members, BSO and other containment experts (when applicable), Principal Investigators, and laboratory staff regarding laboratory safety and implementation of the *NIH Guidelines* and general biosafety issues.
e. Provides administrative oversight.
f. Serves as the institutional representative responsible for reporting to the National Institutes of Health and other cognizant federal agencies in accordance with IBC Policies and Procedures (Section 8) any significant problems with or violations of the Regulations and Guidelines and any significant research-related accidents or illnesses.
g. Takes appropriate, corrective action to remedy reported safety problems or IBC Policies and Procedures violations and reports that action to the IBC.

2.2. IBC

The responsibilities of the IBC include, but are not limited to, the functions as described in Section IV-B-2 of the *NIH Guidelines*

In addition, the IBC

a. Reviews research involving recombinant and synthetic nucleic acid molecules, microorganisms and biological toxins, conducted at or sponsored by MUSC for compliance with Regulations and Guidelines, and approving those research projects that are found to conform with these Regulations and Guidelines. This pertains to the initial and renewal reviews as well as modifications to the currently approved research by amendment.
b. Makes final determination of containment levels for research involving recombinant and synthetic nucleic acid molecules, microorganisms and biological toxins, and modify containment levels as necessary.
c. Periodically reviews research involving recombinant and synthetic nucleic acid molecules, microorganisms and biological toxins, conducted at MUSC to ensure compliance with the Regulations and Guidelines.
d. Reports any significant problems with or violations of the Regulations and Guidelines and any significant research-related accidents or illnesses as outlined in section 8.
e. Suspends or terminates protocol approval for the possession or use of recombinant and synthetic nucleic acid molecules, microorganisms and biological toxins for research, where the IBC finds serious and/or repetitive

noncompliance or that such use or possession poses undue risk to research personnel or a threat to the health and safety of the community or environment.

f. Communicates and coordinates review and approval of research projects with the Institutional Animal Care and Use Committee (IACUC) and the Institutional Review Board (IRB), as applicable.
g. Provides recommendations for education and training related to biosafety for all MUSC faculty, staff, and personnel listed on the IBC registration and/or individuals that may be affected by the use of or exposure to such materials.
h. On a case by case basis, recuses any member of the IBC who is involved in the research project in question or has a real or perceived conflict of interest in accordance with Section 3.5, except to provide specific information requested by the review entity; and
i. Engages in an ongoing dialogue with the Principal Investigator of the research in question when conducting a risk assessment and developing a risk mitigation plan.

2.3. IBC Chair

The responsibilities of the Chair are to:

a. Approve the agenda for convened meetings of the IBC.
b. Call the meeting to order and direct the meeting deliberations, request motions and seconds, and close the meeting once it has concluded business.
c. Assign subcommittees as needed to review an issue prior to official committee decisions made at the convened meeting.
d. Ensure compliance with membership and procedure requirements in IBC Policies and Procedures.
e. Report any significant problems with or violations of the Regulations and Guidelines and any significant research-related accidents or illnesses as outlined in section 8.
f. Assess the resources necessary for the IBC to fulfill all of its responsibilities as articulated in Section IV-B of the *NIH Guidelines*, taking into account not only the protocol submission and review process, but also training and surveillance responsibilities. Make recommendations to the Institutional Official when additional resources are required to fulfill all IBC responsibilities and ensure compliance.
g. If public comments are made on IBC actions, the IBC Chair or their designee will forward both the public comments and IBC's response to OSP.[7]
h. Maintain a working knowledge of biosafety regulations, research involving recombinant and synthetic nucleic acid molecules, microorganisms, and biological toxins through continued education and training per *NIH Guidelines*.

[7] NIH Guidelines Section IV-B-2-a-(7)

i. Appoint another committee member to act as Chair in the event that the IBC Chair and Vice-Chair must be absent or have a Conflict of Interest in research being reviewed.
j. Perform other functions as required to promote compliance with *NIH Guidelines*.
k. Delegate duties of the BSO to qualified individuals during periods when the BSO is not available.

2.4. IBC Vice-Chair

The responsibilities of the Vice-Chair are to:

a. Preside over convened meetings of the IBC in the Chair's absence
b. Assist the Chair with review procedures as delegated
c. Perform all duties of the Chair in the Chair's absence
d. Maintain a working knowledge of biosafety regulations, research involving recombinant and synthetic nucleic acid molecules, microorganisms, and biological toxins through continued education and training per *NIH Guidelines*.

2.5. University Risk Management

The responsibilities of University Risk Management, in the context of the IBC Policies and Procedures, are to:

a. Shut down research or teaching activities in laboratories that do not meet the necessary biosafety standards for the agents being used in accordance with Section 10.1.

2.6. BSO

The BSO is a direct report of the Assistant Provost for Research Compliance and Regulatory Affairs, who will provide copies of all BSO reporting to Risk Management. The BSO responsibilities include, in the context of the IBC Policies and Procedures, the duties as described in Section IV-B-3-c of the *NIH Guidelines*
In addition, the BSO:

a. Conducts periodic inspections to ensure laboratory standards are rigorously followed, and in compliance with MUSC IBC Policies and Procedures and with the Regulations and Guidelines.
b. Reviews the PIs laboratory specific Standard Operating Procedures (SOPs) to ensure they outline the hazards involved with the proposed research, how to safely manipulate the registered agents to avoid any laboratory acquired infection, and serve as a reference in case of an emergency.
c. Investigates laboratory accidents and in accordance with Section 8 of the IBC Policies and Procedures reports any significant problems or violations, and any significant research-related injuries or illnesses associated with biological research.
d. Provides general laboratory biosafety training to research personnel.
e. Serves as a permanent voting member of the IBC.

f. Maintains a working knowledge of biosafety regulations, research involving recombinant and synthetic nucleic acid molecules, microorganisms, and biological toxins through continued education and training per *NIH Guidelines*.

2.7. IBC Member

The responsibilities of IBC members are to:

a. Provide knowledge and expertise to the broad scope of biosafety issues, with primary responsibility for providing guidance in acknowledged areas of expertise.
b. Attend and participate at IBC meetings. All members are encouraged to attend every meeting. The IBC 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.
c. Present primary reviewed protocols to the IBC as requested.
d. Perform a comprehensive and timely review of protocol applications.
e. Participate in subcommittee activities.
f. Protect the confidentiality of all materials provided and all business conducted.
g. Acquire and maintain a working knowledge of biosafety regulations, research involving recombinant and synthetic nucleic acid molecules, microorganisms, and biological toxins through education and training requirements for IBC member per *NIH Guidelines.*
h. Perform other functions as required to promote compliance with *NIH Guidelines*.

2.8. IBC Staff

IBC staff responsibilities are to:

a. Serve as liaison between the researchers and IBC.
b. Schedule IBC meetings, verify quorum attendance, and prepare meeting agendas.
c. Facilitate protocol review and approval process, including protocol modifications submitted by amendment.
d. Notify Principal Investigators of the results of IBC review.
e. Prepare IBC meeting minutes to include information required in *NIH Guidelines*.
f. Maintain records (e.g. approved protocols, meeting minutes, membership roster)
g. Interface and communicate relevant information between the BSO, IBC, and other parties.
h. Review the IBC Policies and Procedures at least once a year to determine if they meet regulatory requirements and community needs.
i. Maintain a working knowledge of biosafety regulations, research involving recombinant and synthetic nucleic acid molecules, microorganisms, and biological toxins through continued education and training.
j. Orient new IBC members to the IBC Policies and Procedures and all Regulations and Guidelines.
k. File annual reports with OSP, which includes an updated list of IBC members indicating the role of each member. The OSP is notified of any changes in IBC membership when they occur. Such notice includes a revised list of members, contact information and a biosketch for each new member.

2.9. Principal Investigator

The Principal Investigator responsibilities include the duties as described in Section IV-B-7 of the *NIH Guidelines*.

In addition, Principal Investigators are to:

a. Follow applicable Regulations and Guidelines, as well as IBC Policies and Procedures, when conducting research involving recombinant and synthetic nucleic acid molecules, microorganisms, and biological toxins.
b. Never initiate or modify research that requires IBC approval until that research or the proposed modification has been approved by the IBC and has met all other requirements of the Regulations and Guidelines.
c. Be adequately trained in good microbiological techniques.
d. Perform an initial risk assessment of the agents and procedures to determine potential safety and environmental hazards. For guidance on how to conduct a risk assessment, see BMBL.[8]
e. Develop laboratory specific Standard Operating Procedures (SOPs) based on the risk assessment, Guidelines and Regulations and ensure they outline the hazards involved with the proposed research, how to safely manipulate the registered agents to avoid any lab acquired infection, and describe emergency procedures.
f. Inform personnel of the conditions of the registered project, including any specific hazards and ensure they have received appropriate additional training.
g. Have the laboratory and facilities used in the project inspected by the Biosafety Officer (BSO) biennially or as needed e.g. when location of facilities is moved or added, or an agent is added. The PI should contact the BSO to schedule an inspection prior to moving laboratories or using or storing any agents in uninspected space.
h. Ensure that all laboratory personnel have signed the SOP in effect.
i. Comply with additional stipulations required by the IBC for approval.
j. Ensure that work with the registered agents will be done at the biosafety level specified by the IBC and will comply with all applicable Regulations and Guidelines.
k. Have any biosafety cabinets (BSCs) in the registered facilities recertified yearly, if they are moved, and if they have been damaged.
l. Provide proper surveillance of personnel and correct conditions as needed.
m. Adhere to the IBC approved MUSC Biological Safety Policy and laboratory specific safety protocols (SOPs) for handling accidental spills and personnel contamination.
l. Report any significant problems with or violations of the Regulations and Guidelines and any significant research-related accidents or illnesses in accordance with IBC Policies and Procedures Section 8.

[8] See footnote 2. p.9-21.

n. Notify the IBC of any changes in the registered project or recent findings or reports that might affect the risk analysis for work with any of these agents.
o. Update any SOPs as needed based on amendment(s) to the registration and provide them to the IBC, to replace the outdated versions.
p. Complete a termination form and submit to the IBC, as well as properly dispose of each agent, within 30 days of the date that work with the agent is completed.

3. IBC Membership

3.1. Composition

The membership of the IBC is based on the requirements set forth in the *NIH Guidelines*[9]. Specifically:

a. The IBC must be comprised of no fewer than five members so selected that they collectively have (i) experience and expertise in recombinant and synthetic nucleic acid molecules technology, microorganisms, and biological toxins, and (ii) the capability to assess the safety of research involving recombinant and synthetic nucleic acid molecules technology, microorganisms, and biological toxins, and to identify any potential risk to public health or the environment.
b. At least two members must not be affiliated with MUSC in a current capacity except for their membership on the IBC, and should represent the interest of the surrounding community with respect to health and protection of the environment.
c. The IBC membership shall include expertise in animal containment principles, clinical research with human subjects, experience with microorganisms and biological toxins, and expertise in virology or gene therapy vectors.
d. At least one member must have expertise in plants, plant pathogens, or plant pest containment principles when applications are submitted for review utilizing Appendix M, Physical and Biological Containment for Recombinant and synthetic nucleic acid molecules Research Involving Plants, of the *NIH Guidelines.*
e. One member of the IBC shall be the Institutional Biosafety Officer (BSO).

3.2. Designation (Alternates, Voting/Non-voting)

Members shall be designated as either: (1) affiliated (MUSC) or (2) unaffiliated (Community); and further designated as (1) voting member or (2) non-voting member, (3) alternate, or (4) *ad hoc* member.

1. Affiliated member refers to members who are affiliated with any component of the MUSC. "Affiliated" is defined as having a current employment relationship with, a professional relationship with, a paid consultant relationship with, a trustee/governing board member relationship with, or being a matriculated student of the entity or component.

[9] *NIH Guidelines* Section IV-B-2-a

2. Unaffiliated member refers to members, who are currently not affiliated with any component of the MUSC.
3. Voting Member refers to members who are required to vote or abstain from voting on each research activity considered by the IBC when they are present for the discussion and vote.
4. Non-Voting Member refers to members who are not allowed to vote and do not count towards quorum.
5. Alternate Members are those members that are designated to represent specific member types (e.g., affiliated, unaffiliated, Voting, Non-voting) when any member of that type is absent from a meeting. Alternates are encouraged to attend all meetings but may only count toward a quorum and vote in the absence of that type of member. Alternate members are appointed in the same manner as regular members.
6. *Ad hoc* Members are those who may be appointed to the IBC depending on their expertise and experience. *Ad hoc* members are required to be present during the discussion and vote for applications relevant to their office, expertise and experience and they are voting members of the IBC.

3.3. Appointment and Reappointment

3.3.1. Committee Members

The IBC members will be appointed by the Institutional Official (IO) for three year terms. The members will be designated as voting or non-voting by the IO. When appointing a committee member, the IO considers the following factors: experience with biosafety issues; willingness to commit the time required; and skills involved in reviewing research projects. Members may resign by notification to the IBC Chair in writing. They may serve no more than 2 consecutive terms.

3.3.2. Chair and Vice-Chair

The IBC Chair and Vice- Chair will be appointed by the Institutional Official (IO) for three year terms. The IBC Chair and Vice-Chair must have been a member of the MUSC IBC for at least one year and participated in research as an investigator. The IO is responsible for appointing a replacement if the IBC Chair or Vice-Chair cannot complete the three year term for any reason. The appointed IBC Chair and Vice-Chair are familiar with regulatory requirements related to biosafety. When appointing an IBC Chair or Vice-Chair the IO considers the following factors: academic appointment and position of leadership; experience with IBC and biosafety issues; scientific expertise; willingness to commit the time required; and skills involved in presiding over committee affairs. The Chair and Vice-Chair may resign by notification to the IO in writing. They may serve no more than 2 consecutive terms.

3.4. Consultants

IBC staff, the IBC Chair, and/or any voting IBC member may request that additional expertise be made available to supplement the expertise of the IBC members. The IBC Chair and Administrator of the IBC are responsible for securing this expertise. The required expertise will be sought among the MUSC faculty if available and without a conflict of interest in accordance with IBC Member Conflict of Interest Policy (See Section 3.5 below). If the expertise is not available within MUSC, external consultants should be secured. The IBC Chair or designee will specify the concerns/questions requiring expert review and will notify the Principal Investigator that additional expertise has been secured to review the protocol and/or related documents. IBC staff will ensure the consultant has all the materials required to review and address the concerns/questions. Depending on the request and need for the additional expertise, the IBC Chair will ask the expert(s) to discuss concerns/questions with IBC staff or member, document his/her review, and/or attend the relevant convened IBC meeting. The consultant will not be allowed a vote and will not count towards quorum.

3.5. Conflict of Interest

A member of the IBC may not participate in the initial, renewal,or amendment review of any project in which the member has a "conflict of interest," (COI) except to provide information at the IBC's request.

"Conflict of interest" is defined as:

(1) Conflict of interest in science - refers to situations in which financial or other personal considerations (i.e. service on Board of Directors, Consulting, intellectual property related to application under consideration, application submitted by members of immediate family) may compromise, or have the appearance of compromising, an IBC member's professional judgment in designing, conducting or reporting research, or

(2) Financial conflict of interest – refers to financial interest in the sponsor, product or service being tested, or competitor of the sponsor or product or service being tested.

IBC members complete the IBC Member (and Consultant) Conflict of Interest Statement annually and must update their COI Statement within 30 days of any change in their COI status.

At the start of every IBC meeting, IBC members will also be asked to disclose any conflict of interest they may have with the business before the committee. This discussion, if any, will be documented in IBC meeting minutes and actions taken to minimize the impact of this conflict. Any IBC member who is a member of the research team of a study presented to the IBC for initial, renewal, or amendment review will leave the IBC room during the IBC member's voting process. This includes the roles of principal investigator, co-investigator, mentor and consultant.

IBC members with a conflict of interest will not be counted toward quorum during discussion of the conflicted item. This action will be documented in the IBC meeting minutes.

3.6. Liability of IBC Members

IBC members and alternates fulfill their administrative and institutional service responsibilities to MUSC, in part, by serving on the IBC. Accordingly, the MUSC will indemnify IBC members in the event of a legal dispute relating to the actions of the committee, provided that the IBC member has acted in good faith and in accordance with federal requirements, state and local laws and MUSC policy.

3.7. Membership Record

The Office of Research Integrity shall be responsible for updating the membership roster and IBC registration information as needed when membership changes and submitting the updated information to NIH OSP as required by the *NIH Guidelines*. IBC rosters shall be retained a minimum of five (5) years and shall be made available upon request according to IBC Policies and Procedures Section 9.

Biosketches are on file for all current members and alternates.

3.8. Education of IBC Members

a. Orientation - IBC staff shall provide new members with the MUSC IBC Policies and Procedures and relevant Regulations and Guidelines.
b. Training - IBC Chairs, IBC members, and IBC staff involved in the review of IBC applications are required to successfully complete the appropriate training prior to serving on the committee as outlined in section 11 of the IBC Policies and Procedures.
c. Continuing Education and Training – MUSC is responsible for ensuring appropriate training for the Institutional Biosafety Committee Chair and members, Biological Safety Officer and other containment experts.[10]

4. IBC Function

4.1. Convened Meetings

The IBC shall meet monthly with meetings scheduled for the entire calendar year and posted on the IBC website. Members shall be informed of the meeting schedule prior to the end of the previous calendar year. Members must contact the IBC office if they are unable to review for a meeting. The committee may reschedule a meeting if a poll of the members indicates quorum cannot be reached for the monthly meeting. The meeting agenda is delivered to all IBC members (including those to participate via teleconference) prior to the meeting.

[10] NIH Guidelines Section IV-B

4.2. Special Meetings

These may be called by the IBC Chair or Vice Chair, or by any two IBC members, with a majority vote of approval by the Committee. Notification shall be given to the entire IBC at least seven days prior to such a meeting.

4.3. Meetings by Electronic or Telephone Conference

Any meeting, regular or special, may be held by electronic conference or similar communication equipment, so long as all members participating in the meeting can communicate with one another.

4.4. Quorum

A quorum of the membership of the IBC, including at least one scientist must be met and at least one member whose primary concerns are in nonscientific areas should be present, before a meeting can be convened. The presence of at least one-half the voting membership plus one shall constitute a quorum. Members joining by teleconference count towards quorum. Quorum shall be maintained for the discussion and vote on each research activity on the agenda. Members not present for, or recused from, the discussion shall not be counted towards the quorum. In the event an IBC member must participate by teleconference, the member will receive all pertinent material prior to the meeting and the minutes of the convened IBC meeting will reflect that the member participated by teleconference.

4.5. Attendance of those not on the IBC

IBC meetings are considered open and, as such, members of the MUSC community and the public at large may request to attend an IBC meeting. Those who wish to attend an IBC meeting must notify IBC staff in advance regarding the desire to attend. While no one will be denied access to a meeting, IBC staff must be made aware of additional attendees in order to schedule a room of appropriate size. Last minute requests may not be honored if the meeting room cannot accommodate additional attendees. PIs and personnel listed on applications under consideration may not be present for the Committee's vote. Non-members of the IBC may not be present while proprietary information is discussed. The IBC Chair shall maintain order and decorum.

4.6. Sub-Committees

Sub-committees may be formed as the nature of the application dictates. The IBC Chair will select members with experience relevant to the specific issues involved with the research being discussed.

4.7. Animal Research

When reviewing research involving administration of recombinant and synthetic nucleic acid molecules, microorganisms, or biological toxins to whole animals, at least one IBC member (or alternate or consultant) who is knowledgeable about or

experienced in animal research shall participate in the discussion at the IBC meeting.[11]

4.8. Plant Research

When reviewing research involving plants, plant pathogens or plant containment principles, at least one IBC member (or alternate or consultant) who is knowledgeable about or experienced in plant research shall participate in the discussion at the IBC meeting.[12]

4.9. Human Research

When reviewing research involving human subjects, at least one IBC member (or alternate or consultant) who is knowledgeable about or experienced in human subjects research shall participate in the discussion at the IBC meeting.

4.10. Discussion and Vote

During the convened meeting, each initial or renewal application is presented by the Chair and/or Primary Reviewer(s), discussed and voted on individually. The Principal Investigator may be present if requested by any IBC member or if the Chair/Administrator thinks the Investigator needs to be present to clarify issues/concerns. The IBC may approve, table, disapprove, or require modifications to secure approval. If the IBC requests minor modifications, which do not substantially impact the risk assessment, the IBC may approve the application contingent on final review and approval by the IBC Chair or the Chair's Designee. Changes that are substantive in nature must be brought back before the IBC at a convened meeting.

4.11. Minutes

IBC staff or someone designated by the IBC Chair prepares minutes of the convened meeting, which are approved by the convened IBC.

Minutes of each IBC meeting are recorded in writing and contain[13]:

a. Date and place of the IBC meeting
b. Record that prior minutes were approved
c. Individuals in attendance
d. All major motions
e. Major points that were approved
f. Time of the meeting opening and adjournment
g. Sufficient detail to record key discussion and the rationale for any

[11] NIH Guidelines Section IV-B-5
[12] NIH Guidelines Section IV-B-4
[13] Per NIH OSP memorandum "Guidance on the Content of Minutes of Institutional Biosafety Committee Meetings"
https://osp.od.nih.gov/biotechnology/faqs-about-ibc-meetings-and-minutes/?pdf=10458

decisions made

h. Section of the *NIH Guidelines* applicable to the proposed work

For distribution and redaction of minutes refer to Section 9.

4.12. Notification

4.12.1. PI

IBC staff will inform the Principal Investigator of the IBC review decisions and whether any special conditions for approval of work is required.

4.12.2. Other Committees

Any IBC decision or recommendation will be communicated to relevant MUSC committees by IBC staff on behalf of the IBC chair: e.g. if the IBC has made a recommendation for other committee review (e.g. IRB, IACUC, Conflict of Interest, Institutional Review Entity for Dual Use Research of Concern).

5. Review Procedures

5.1. Materials Requiring Registration with the IBC

All use of recombinant and synthetic nucleic acid molecules, as well as all use and possession of microorganisms and biological toxins needs to be registered with the IBC. All microorganisms regardless of their risk group (RG) (*Escherichia coli* and other RG 1 organisms included) must be registered with the IBC. All possession, use and transfer of Select Agents[14] at MUSC in any quantity must be registered with the IBC prior to bringing the Select Agents to MUSC.

Human blood, fresh tissue, or body fluids must be regarded as possibly infected with blood borne pathogens (BBP) as defined by OSHA Bloodborne Pathogen Standards. All research involving handling of human specimens must adhere to the standard precautions as described in the Blood borne Pathogen Exposure Control Plan (ECP). Research whereby BBPs are isolated, propagated, amplified and/or concentrated from a human specimen, must be registered with the IBC.

5.2. Review Criteria

These following review criteria are used for an initial, renewal or amendment review of research. In order for the IBC to approve research, the IBC will:

a. Review the initial risk assessment conducted by the PI of the agents and procedures to determine potential safety and environmental hazards.

[14] See CDC Select Agent and Toxins List

b. Review the PI's laboratory specific SOPs to ensure they outline the hazards involved with the proposed research, how to safely manipulate the registered agents to avoid any lab acquired infection, and serve as a reference in case of an emergency.
c. Conduct an independent assessment of the containment levels required by the applicable Regulations and Guidelines when reviewing proposed research with recombinant and synthetic nucleic acid molecules, microorganisms, or biological toxins.[15]
d. Assess the facilities, procedures, practices, and training and expertise of personnel involved in research with recombinant and synthetic nucleic acid molecules, microorganisms, or biological toxins.

In reviewing proposed recombinant and synthetic nucleic acid molecules research, the *NIH Guidelines* cite a number of matters that the IBC should consider as appropriate.[16] These matters include:

a. Agent characteristics (e.g. virulence, pathogenicity, environmental stability).
b. Types of manipulations planned.
c. Source(s) of the inserted DNA sequences (e.g., species).
d. Nature of the inserted DNA sequences (e.g., structural gene, oncogene).
e. Host(s) and vector(s) to be used.
f. Whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced.
g. Containment conditions to be implemented.
h. Applicable section of the *NIH Guidelines* (e.g., Section II-D-1. Section III-E-1, etc.).

A satisfactory laboratory (See IBC Policies & Procedures Section 7) is required before the IBC releases approval of an application.

5.2.1. Review Criteria for Human Research

The focus of the IBC review of Human Gene Transfer Trial research should be equivalent to their review of the biosafety aspects of other covered research, e.g.:

- required containment levels
- potential for shedding

[15] *NIH Guidelines* Section IV-B-2-b
[16] *NIH Guidelines* Section II-A-3 and Section III, and NIH OBA, memorandum "Guidance on the Content of Minutes of Institutional Biosafety Committee Meetings", February 23, 2007

- safety and training of laboratory/technical personnel involved in the clinical protocol
- details of the facilities
- adequacy and maintenance of safety equipment that may be used in support of the clinical protocol
- safety procedures and practices when working with the product and during administration to a protocol participant
- reporting of biosafety accidents and incidents occurring during conduct of the protocol
- approving emergency response plans for accidental spills and personnel contamination

a. .[17]

5.3. IBC Actions

When conducting an initial, renewal, or amendment review of an application the IBC can take any of the following actions:

5.3.1 Not Ready for Review.

Should in the opinion of the IBC administrator, an application, amendment, or continuing review application be deemed NOT to have yet achieved a state where an assessment of risk can be assessed the application will be returned to the PI. The IBC administrator will provide his/her comments to the applicant delineating the areas requiring modification prior to its review by the IBC.

5.3.2. Approval.

If the application is approved without requiring final modifications, the Chair or the Chair's designee will sign off on the approval and IBC staff will notify the Principal Investigator of the decision.

5.3.3. Approval with Contingency, Pending Minor Final Modifications or Additional Information or Conditions

If the application requires final modifications that are minor in nature or additional information or conditions, the IBC staff will notify the Principal Investigator of the required modifications. Upon receipt of the revised application, the Chair or the Chair's designee will review the revised application and, if deemed acceptable, sign off on the approval. IBC staff will notify the Principal Investigator of the final approval decision. Work may not begin until the final approval decision has been issued.

5.3.4. Table for Substantive Modifications or Significant Additional Information

[17] https://osp.od.nih.gov/biotechnology/faqs-on-the-nih-guidelines-research-synthetic-nucleic-acid-molecules/

If the required final modifications are substantive in nature or significant additional information is requested, the application may be tabled. The IBC staff will notify the Principal Investigator of the required modifications. Principal Investigator responses to substantive modifications are presented to the Full Committee for review, discussion and vote at a convened meeting.

5.3.5. Partial Approval
Limited approval may be granted when the IACUC has voted to approve certain aspects of the work described in the application (e.g., some experiments, some procedures, some locations). For example, if certain laboratory facilities are under construction. The IBC staff will notify the Principal Investigator of the Committee's determination of the scope of work that may be approved. Approval of the entire application will be withheld until all conditions for approval have been met.

5.3.6. Disapproval
This designation indicates that the risks of the proposed research cannot be determined or are of such significance that the committee cannot approve the project. The authority of the IBC to disapprove a study may not be overridden. The IBC staff will notify the Principal Investigator of the Committee's rationale for disapproval.

5.3.7. Responding to IBC Comments
The Principal Investigator is required to respond to committee comments within 30 calendar days. Failure to respond may result in a Final Notice letter from the IBC administrator or Chair. If the Principal Investigator fails to respond to the Final Notice letter in 30 calendar days, this may result in withdrawal of the submission.

6. Application Processing

Prior to starting work with recombinant and synthetic nucleic acid molecules, microorganisms, and/or biotoxins, the Principal Investigator will electronically submit an application to register the agents. By submitting the electronic application form, the Principal Investigator "signs" the assurance section of the electronic form. Submissions for review of a continuing review of an application, or a review of proposed changes to a previously approved application must also be submitted via the electronic registration system. The electronic registration forms must be accurately completed and submitted by the submission deadlines posted on the IBC website. The electronic registration forms will include at minimum all the elements listed under IBC Policies and Procedures Section 5.2 (Review Criteria). Signature of the electronic registration constitutes an agreement to all policies and procedures therein, including disinfection, waste disposal

and emergency plans related to personnel contamination, research related illness, accidental spills and loss of containment.

6.1. Initial and Renewal Applications

a. Applications received will be assigned a reference number and will be reviewed by the IBC staff for completeness.
b. An application is considered complete when all relevant portions of the electronic registration forms have been completed and any referenced materials is attached and a SOP covering the work described in the MUSC IBC application and specific to MUSC has been submitted.
c. For research involving administration (directly or indirectly) of recombinant and synthetic nucleic acid molecules, microorganisms and biological toxins into human research participants, no such experiment shall be initiated until IBC approval has been obtained and all applicable regulatory authorization(s) and approvals have been obtained. The following additional items need to be submitted for review:
    1. The Clinical Trial Protocol
    2. The Investigators' Brochure
    3. Informed Consent document submitted to the MUSC IRB (optional)

d. Review:
    1. Designated Review
        i. Only the following Initial or Renewal Application are eligible for Designated Review:
            1. Applications involving exclusively experiments using recombinant and synthetic nucleic acid molecules that fall under Section III-F of the NIH Guidelines
            2. Applications that do not involve experiments using any recombinant and synthetic nucleic acid molecules and exclusively uses experiments that can be conducted using BSL1 biosafety precautions.

        All other applications require Full Committee Review.
        ii. Complete Initial and Renewal Applications are processed for consideration. If incomplete, the Principal Investigator will be asked to submit additional information. An application is considered complete once all items on the form that are relevant to the proposed research have been completed and a draft SOP, that covers the agents being registered and the research to be done using them, has been submitted.
        iii. The IBC Administrator via the electronic system makes the complete application available to the IBC Chair (or his/her

designee(s)), the IBC Vice Chair, the BSO, and one other member of the IBC (collectively, the Designated Reviewers). The Administrator will request Designated Reviewers' comments by a specified deadline.

iv. Any of the Designated Reviewers may request additional expertise when reviewing a protocol. In that case, a consultant will be identified (Section 3.4) and assigned.

v. Any of the Designated Reviewers may call that the application be reviewed by the Full Committee Review process.

vi. The Designated Reviewers finalize their reviews by categorizing their recommendation as approval, approval with contingency, or disapproval and summarize the suggested modifications that may be required for the study to achieve an acceptable risk.

vii. The IBC staff enters Designated Reviewers' comments into the electronic database and discusses these comments with the reviewers and IBC Chair as necessary for clarification.

viii. The IBC staff sends all comments to the Principal Investigator electronically. A date of when his/her response is due is given based on when the comments were received and scheduled date for discussion at the convened meeting.

ix. The IBC staff checks the Principal Investigator's response and forwards via the electronic system a summary of any disparities, together with the revised application, to the Committee members for review in preparation of discussion at the convened meeting.

x. An application under Designated Review may be approved, tabled, partially approved, or require final modifications to secure approval. No Designated Review application may be disapproved. Any Designated Review application submitted that should be considered for disapproval will be sent to a meeting of the convened IBC for Full Committee Review.

xi. Experiments approved by Designated Review may not be initiated until a satisfactory inspection has been completed (if needed) and a signed SOP is in place.

xii. Applications approved by the Designated Review process will be reported to the full committee in the meeting minutes of previous convened IBC meeting. Any IBC member may request further consideration of any protocol approved by the Designated Review process.

2. Full Committee Review

i. Complete Initial and Renewal Applications received by the deadline for a given meeting are processed for consideration at that meeting. If incomplete, the Principal Investigator will be asked to submit additional information. An application is considered complete once all items on the form that are relevant to the proposed research have been completed and a draft SOP, that covers the agents being registered and the research to be done using them, has been submitted.
ii. The IBC Administrator via the electronic system makes the complete application available to all IBC members scheduled to attend the upcoming Committee meeting. The information will also indicate the Presenter. All IBC members scheduled to attend the upcoming Committee meeting are expected to review the application. The Administrator will request IBC members' comments by a specified deadline.
iii. The IBC Administrator, Chair, and/or any voting member may request additional expertise when reviewing a protocol. In that case, a consultant will be identified (Section 3.4) and assigned.
iv. The Committee members finalize their reviews by categorizing their recommendation as approval, approval with contingency, or disapproval and summarize the suggested modifications that may be required for the study to achieve an acceptable risk.
v. The IBC staff enters the members' comments into the electronic database and discusses these comments with the reviewers and IBC Chair as necessary for clarification.
vi. The IBC staff sends all comments to the Principal Investigator electronically. A date of when his/her response is due is given based on when the comments were received and scheduled date for discussion at the convened meeting.
vii. The IBC staff checks the Principal Investigator's response and forwards via the electronic system a summary of any disparities, together with the revised application, to the Committee members for review in preparation of discussion at the convened meeting.
viii. During the convened IBC meeting, each initial or renewal application is presented by the Chair and/or Primary Reviewer(s), discussed and voted on individually. The Principal Investigator will be invited if requested by any IBC member or if the Chair/Administrator thinks the

Investigator needs to be present to clarify issues/concerns and may be present for the discussion

ix. An application may be approved, tabled, partially approved, disapproved, or require final modifications to secure approval (see Section 5.3).

e. If research has been approved, but the Chair is absent or has a conflict of interest, the Vice Chair may sign the application approval notice. If the Vice Chair is also absent or has a conflict of interest, the Chair may designate the BSO to sign the approval notice.
f. A signed SOP, approved by the BSO and IBC must be uploaded as part of the application, prior to release of the approval notice by IBC staff.
g. If a Principal Investigator has appealed the IBC decision in writing to the Chair, IBC staff will place the item on the agenda for the next scheduled convened meeting for Full Committee discussion and vote. The PI will be asked to address the IBC's concerns prior to the meeting.
h. Applications (once approved called registrations) are active for three years and require annual continuing review. The calculation of the approval period is based on the date of the convened meeting at which the IBC approved the application or the date of the approval by Designated Review, and not the date when contingencies have been removed. For all approved applications (registrations), the IBC may determine that the research risk is of significant magnitude meriting review more frequently.
i. Investigators will be informed of the outcome of the IBC review via the electronic system.

6.2. Amendments

Amendments must be submitted prior to making a change in personnel, agents, procedures/practices, and/or facilities and must be submitted via the electronic registration system. The IBC may request submission of an amendment if the level of risk of the registered agents changes. The procedures for disposition of amendments are the same as for Initial or Renewal Protocols (Section 5.3). Any amendment submitted that should be considered for disapproval will be sent to a meeting of the convened IBC for consideration. All required attachments, such as updated SOPs or new references, need to be submitted for IBC review as part of the amendment. These are the following types of amendments and procedures:

6.2.1. Administrative Review

Changes made to personnel, facility location, or grant information may be reviewed and approved by IBC staff as the Chair's designee. New personnel will be approved only if the required training has been completed. A change in facility location will be approved only after the BSO has inspected the new location and deemed it satisfactory (See Section 7). IBC staff may also approve removal of genes, organisms, or biotoxins from a registration.

6.2.2. Subcommittee Review

6.2.2.1. Exempt Experiments. An amendment adding exempt experiments (See Section III-F of the *NIH Guidelines*) may be approved by the IBC chair or his/her designee. A laboratory inspection may be waived if the location is already approved for BSL-1 or BSL-2. However, the appropriate signed SOP needs to be in place before work can be initiated.

6.2.2.2. Non-recombinant Microorganism

A change in research procedures for non-recombinant microorganisms already covered by a registration, or addition of non-recombinant microorganisms may be approved after the Chair (or his designee) and either the Vice-Chair or Biosafety Officer have reviewed the amendment and recommended approval.

6.2.2.3. Reporter Genes

Addition of reporter genes (for definition, see below) to an approved Registration may be added with review and approval by two of the following IBC members: Chair, Vice-Chair, Biosafety Officer. Reporter genes are defined as:

Fluorescent proteins
Aequorea (jellyfish) derived fluorescent proteins (GFP, eGFP, YFP, RFP, etc.)
Anemones and reef coral derived fluorescent proteins (DsRed, mCherry, mPlum, etc.)

Luminescent proteins
Luciferases (firefly, sea pansy, two click beetle, etc.)

Biochemical reporter molecules
Beta-galactosidase

6.2.3. Full Committee Review

All changes not covered under IBC Policies and Procedures Section 6.2.1 (Administrative Review) or 6.2.2 (Subcommittee Review) require review by the fully convened IBC. The procedures for reviewing and approving amendments requiring Full Committee review procedures are the same as for Initial and Renewal Protocols (IBC Policies and Procedures section 6.1), except that:

a. If the proposed changes are extensive, or change the scope of the review, a new application should be submitted.

b. As part of the amendment, a signed revised SOP that covers the existing and additional agents being registered and the research to be done using them, has to be submitted for IBC review.
c. Approval of an amendment does not alter the renewal due date of a registration, unless specifically indicated otherwise by the IBC.

6.3. Continuing Reviews

a. Prior to a registration's expiration date, the IBC staff will send the Principal Investigator a timely reminder of approval expiration.
b. Continuing Reviews must be submitted annually by the Principal Investigator after a notice is received requesting their submission and by the submission deadline for the month stated in the notice. Any changes to the registered research identified as part of the Continuing Review, require submission of an amendment, reflecting those changes. Amendments associated with this Continuing Review should be submitted the same day that the Continuing Review is due, if changes are made that require Full Committee Review. Other amendments maybe submitted one week later.
c. When received, the Continuing Review application is reviewed by IBC staff for completeness and accuracy. If the application is incomplete, IBC staff will notify the Principal Investigator regarding the deficiencies.
d. If the Principal Investigator fails to provide a renewal form to the IBC by the anniversary date, a letter will be sent to the Principal Investigator, and copied to the Chair/Dean of the department. All research activities pertaining to the research described in the expired protocol must cease. If the Principal Investigator does not provide a renewal by the next IBC meeting, this issue is added to the agenda and the IBC determines whether or not to terminate the IBC protocol. Termination of the IBC protocol may require termination of any related IACUC or IRB protocols.

6.4. Change in PI on Open IBC Protocol

Transferring an open IBC protocol to another PI requires review by the fully convened IBC. The IBC will determine if the new PI's training and expertise is adequate as it relates to the project.

6.5. Completed or Inactive Projects

PI shall terminate registration within 30 days of project completion. A human gene transfer trial may be closed after the last subject enrolled at MUSC has completed the study, or if the final report for the Investigational New Drug license has been submitted to the FDA. IBC staff reviews the Termination form to make sure disposition of all registered agents has been addressed. A copy of the Termination form will be forwarded to the BSO, who will verify that all registered agents have been properly disposed of.

If an investigator leaves MUSC but does not terminate the registration, the BSO will investigate the status of registered agents and has the authority to dispose of

the remaining materials. Following BSO investigation and disposal, if applicable, the registration may be closed administratively.

6.6. Death of an Investigator

6.6.1. Upon the death of the principal investigator all approved research will cease until such time as a successor Principal investigator has submitted an amendment or new IBC application to continue the work under his/her name. The successor PI may have access to the deceased investigator's registration materials for review and modification as required.

7. Facilities Inspections

7.1. Initial Inspection

a. Facilities inspections must be successfully completed prior to the initiation of any work with agents/toxins or genes covered by the IBC application.
   i. It is the responsibility of the principal investigator (PI) to contact the BSO to schedule an inspection. The PI must be present for the first lab inspection for any new agent and must sign the checklist at the end of the inspection.
   ii. It is the BSO's responsibility to conduct lab inspections in a timely fashion.
   iii. MUSC IBC is responsible for lab space controlled by MUSC; VA IBC is responsible for lab space controlled by VA. VA lab inspections and VA IBC approvals of MUSC faculty are considered approvals by MUSC IBC. The PI is responsible for providing the MUSC IBC with current VA lab inspection and VA IBC approval. These documents should be sent as PDFs so that they can be uploaded to the PI's electronic file.
   iv. Successful completion of lab inspections requires compliance with the current edition of the BMBL as the minimum guideline that must be followed. Additional requirements may be mandated by the BSO/IBC based on an appropriate risk assessment, the specific laboratory space, and/or the "standard of the industry" in order to protect personnel, the community, the environment, and MUSC.
   v. A detailed SOP covering all aspects of the work as described in the IBC application and signed by all members of the lab is required for successful completion of a laboratory inspection. For multiple PIs working in the same space (with the exception of core facilities, which maintain their own SOP), all lab personnel must sign either a joint SOP covering all aspects of all work described in all of the pertinent IBC applications or individual SOPs for each PI.
b. Even if an inspection is satisfactory, research may not proceed until IBC approval has been obtained.

c. PIs have 30 days after the lab inspection to resolve any deficiencies. If not, the PI must justify in writing to the BSO why a satisfactory inspection has not been achieved and the written justification must be sent each successive month that the inspection has not been satisfactorily achieved.

7.2. Inspection for New Agent/Toxin or Room Change/Addition:

a. Inspections are based on PI/agent-toxin/room—if the agent-toxin or room changes, an amendment must be completed and submitted to the IBC ASAP. A new inspection may be required prior to beginning work. The need for an inspection for minimal amendment changes can be made by the BSO, but the IBC has final authority to require an inspection. The BSO is responsible for conducting inspections in a timely fashion.
b. If a PI registered with the IBC leaves MUSC but a graduate student/postdoctoral fellow remains at MUSC to finish under the supervision of a different PI, the supervising PI must register the project with the IBC and successfully complete a lab inspection prior to continuing work.
c. If a PI transfers any agent(s) to another investigator at MUSC, that individual must register the agent(s) with the IBC and successfully complete a laboratory inspection, if needed, before beginning work with it.

7.3. Re-Inspections

a. Re-inspections must be conducted no less often than every 2 years. Failure of the PI to have a lab re-inspection by the date the initial inspection lapses places the PI and his/her lab out of compliance with IBC policies. The day after the initial inspection lapses the PI and his/her lab staff cannot work with his/her agent-toxin or genes in mammalian cells until the re-inspection has been successfully completed. PIs shall be notified of this consequence if the PI does not respond to the BSO's initial lab re-inspection notification.
    i. Failure to successfully complete re-inspection by the expiration date of the original inspection will result in the BSO notifying the PI's business manager and department chair of the lack of compliance and any work involving the IBC registered agents must cease immediately.
    ii. The BSO is responsible for notifying PIs a minimum of two weeks in advance of the date that the original inspection expires that a re-inspection is needed. The BSO is also responsible for conducting lab re-inspections in a timely fashion, but the re-inspection must be performed before the expiration of the original inspection.
b. Random, unannounced laboratory inspections may be performed at any time by the BSO to ensure the safe conduct of research.
c. The PI does not need to be present for any scheduled re-inspection. However, at the end of a scheduled re-inspection, the BSO must

communicate directly to the PI any deficiencies or concerns found during the re-inspection. If no satisfactory time can be found to accommodate both PI and the BSO for the re-inspection because the PI is a clinician performing direct patient care when the BSO is available, the PI can sign the inspection checklist within 24 hours of the re-inspection.

a. Re-inspections must be satisfactorily completed same as initial inspections.
b. Inspection for a new agent/toxin can be conducted with a re-inspection at the discretion of the BSO and the PI. However, even if the lab inspection for a new agent/toxin is successfully completed prior to approval of the IBC, the PI cannot work with the new agent/toxin until IBC approval is obtained.

d. Biennial inspections of clinical facilities may be waived for human subjects research projects where the following criteria have been met:
    1. The biological product that was registered with the IBC for the project is no longer stored at MUSC, and
    2. any subjects remaining enrolled in the study at MUSC are no longer receiving the biological product, and the subjects are in follow up or data collection status only, and
    3. the study is closed to accrual at MUSC.

7.4. Animal Room Inspections

a. Animal rooms controlled by DLAR that are likely to be used for BSL2 experiments are inspected annually. No additional inspections will be conducted of animal room facilities in the interim unless specifically requested by the Director of DLAR.
b. Animal rooms controlled by PIs that are used for BSL2 experiments are inspected when the PI's lab is inspected.
c. Additional re-inspections are performed if there is suspicion that biosafety is being compromised or as deemed necessary by the BSO or the IBC.

7.5. Communication Between BSO and IBC Administrator

a. The BSO will provide the IBC administrator with the outcome of each laboratory inspection.
b. Completed inspection reports should include the following elements: Name of the PI, Agent(s) covered by the inspection [expression of mammalian genes in mammalian cell cultures should be included]; location(s) i.e. rooms [including sub-rooms e.g. A, B] and the function of each e.g. tissue culture, equipment; date the inspection was conducted; a notation that a satisfactory, signed SOP has been received and is on file; and status e.g. Satisfactorily completed.
c. Inspection with deficiencies should additionally include a brief description of the nature of deficiencies.

d. Notification of the status of all inspections should be sent within one week of the inspection.

8. Reporting of Incidents or Noncompliance with IBC Procedures, Guidelines and Regulations

Under the *NIH Guidelines* incident and violations reporting is articulated as a responsibility of the Institution, IBC, BSO, and Principal Investigator. Institutions have the discretion to determine which party should make these reports, and one report for each incident or set of information is generally sufficient.[18]
The preferred reporting mechanism pertaining to MUSC is outlined below.

The *NIH Guidelines* state that "…any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH OSP within 30 days. Certain types of accidents must be reported on a more expedited basis. Spills or accidents in BL2 laboratories resulting in an overt exposure must be immediately reported to NIH OSP. These kinds of events might include skin punctures with needles containing recombinant and synthetic nucleic acid molecules, the escape or improper disposition of an animal harboring recombinant or synthetic nucleic acid molecules, microorganisms, or biological toxins, or spills of high-risk recombinant materials occurring outside of a biosafety cabinet. Minor spills of low-risk agents not involving a breach of containment that were properly cleaned and decontaminated generally do not need to be reported.[5] The IBC will consult with NIH OSP if there is uncertainty whether the nature or severity of the incident warrants reporting to NIH OSP.[5]

For all research involving recombinant and synthetic nucleic acid molecules, microorganisms and/or certain biotoxins, the following reporting procedure will be followed:

8.1. PI Reporting of Incidents or Noncompliance with IBC Procedures, Guidelines and Regulations

The PI must ensure that his/her personnel immediately report any noncompliance with IBC Procedures, Guidelines and Regulations (including *NIH Guidelines*), significant problems, or any significant research-related accidents and illnesses to the PI. The PI must immediately report such incidents to the IBC, BSO, and Animal Facility Director (if applicable).[19]

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[18] NIH OBA faqs on "Reporting of Incidents Involving Recombinant DNA to the NIH Office of Biotechnology Activities (OBA)"
http://osp.od.nih.gov/sites/default/files/FAQs_about_Incident_Reporting.pdf

[19] NIH Guidelines Section IV-B-7-a-(3)

8.2. BSO Reporting of Incidents or Noncompliance with IBC Procedures, Guidelines and Regulations

The BSO will report to the IBC and IO any incidents or violations of which the BSO becomes aware.

8.3. IBC Reporting of Incidents or Noncompliance with IBC Procedures, Guidelines and Regulations

Should the IBC receive a report of any noncompliance with IBC Procedures, Guidelines and Regulations (including *NIH Guidelines*), significant problems, or any significant research-related accidents and illnesses, the IBC will inform the IO, BSO, Animal Facility Director (if applicable) immediately. The IBC will require the investigator to suspend all activity at once. The IBC then implements procedures for investigating, remedying, and reporting noncompliance to the IO, BSO, and Animal Facility Director (if applicable).

8.4. Institutional Official Reporting of Incidents or Noncompliance with IBC Procedures, Guidelines and Regulations

Should the IO receive a report of any noncompliance with IBC Procedures, Guidelines and Regulations (including *NIH Guidelines*), significant problems, or any significant research-related accidents and illnesses, the IO will assist the IBC with implementing procedures for investigating and remedying the incident. The IO will report any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to NIH/OSP within 30 days.

9. Response to External Request for Public Comments

9.1. Distribution of Minutes Upon Request

In accordance with *NIH Guidelines*, upon request, the IBC shall make available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies, which the latter are required to make available to the public.

9.2. Redaction of Minutes

Redaction of proprietary and private information is allowed but "must be done so judiciously and consistently for all requested documents." Information that may be redacted includes 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. Reasonable charges for photocopying of documents may be passed on to the organization or person requesting such information.

10. Compliance

10.1. Suspension or Termination

MUSC grants the IBC authority to place on administrative hold or terminate approval of research that is not being conducted in accordance with regulatory requirements of the IBC, MUSC, state and federal agencies.

Administrative hold means that the PI is instructed to temporarily halt research activities and allow for assessment of the conduct of the research and full committee review. This may, upon direction of the committee, become a termination of the registration. With corrective action on the part of the Principal Investigator the full committee may withdraw the administrative hold, request amendment of the registration and returning the registration to full active status. Under emergency circumstances, this decision may be made by the Chair, Vice-Chair or Office of Research Integrity Director.

Termination means that the PI is instructed to cease all research and destroy the registered agents as directed by the IBC. Under emergency circumstances, this decision may be made by the Chair, Vice-Chair or ORI Director.

Such actions may be based on IBC determination of reportable incidents or violations as specified in Section 8. Registration termination may also occur for serious or continuing non-compliance or other findings arising from continuing reviews, information from medical or scientific literature and/or complaints or if the research has been associated with unexpected serious harm to researchers, staff, the public and/or the environment.

Suspension or termination of IBC approval will generally be determined by a convened IBC. Under emergency circumstances, the IBC Chair, Vice-Chair or ORI director may immediately place an administrative hold on a registration or PI. At the next convened IBC meeting, the matter will be reviewed by the full IBC. Actions which the board may take include:

- Placing the study on Administrative Hold,
- Lifting the Administrative Hold or
- Continuing the Administrative Hold or
- Terminating the study

In circumstances of major concern and with sufficient evidence, the IBC will notify the investigator of the administrative hold or termination of the registration, possible remediation and of the time and date of the next convened IBC meeting where the registration will be discussed.

If the IBC becomes aware of work being done with unregistered agents recombinant and synthetic nucleic acid molecules, mircoorganisms, and/or biological toxins, the IBC will send a notice to the PI with instructions to submit an IBC application form within 30 days. All work with these agents must be immediately stopped until IBC

approval is achieved. If the PI is non-compliant, the PIs facilities will be closed by University Risk Management until IBC approval is achieved.

11. Training

11.1. IBC Members

All IBC members will receive initial training regarding the IBC Policies and Procedures and *NIH Guidelines*. Continuing education will consist of information provided at each IBC meeting. Such information will consist of official directives, relevant publications, conference announcements, seminar proceedings, compliance issues, and any other information that may increase their knowledge, understanding and awareness of current laws and regulations, new directives, best practice guidelines and institutional policies. The IBC Program Manager will document all training.

11.2. PI and Lab Personnel

It is the Principal Investigator's responsibility to complete and ensure all research personnel have received the required training prior to protocol review by IBC. Documentation of successful completion of training is required in order to receive IBC approval.

The following training is required:

a. OSHA
    1. Blood borne Pathogens
    2. Fire and Life Safety Training
    3. Hazard Communication
    4. Personal Protective Equipment
b. CITI biosafety training modules that are relevant to the individual's role in the research project.

12. Coordination with Other Compliance Committees

12.1. Animal Use

For all research involving vertebrate animals and recombinant and synthetic nucleic acid molecules, microorganisms, or biotoxins, the IBC staff will coordinate during review of the protocol with the MUSC IACUC. The laboratory animal care expert IBC member will report any animal care concerns before or at the IBC meeting during discussion of the application.

12.2. Human Subjects

For all human subjects research involving recombinant and synthetic nucleic acid molecules, microorganisms, or biotoxins, the IBC staff will coordinate during review of the protocol with the MUSC IRB.

13. Record Retention Policy

Minutes and membership rosters shall be retained by the Office of Research Integrity for at least five (5) years.

14. Amendment to the Policies and Procedures

Should any amendment to these policies and procedures be required, the Program Director of ORI and Assistant Provost for Research shall review the revision and make recommendations to the IBC. The IBC will then review and vote on acceptance of the amendment.

This document will be updated as needed, but at least reviewed by the IBC every three years.

THIS UNIVERSITY POLICY AND PROCEDURES IS EFFECTIVE AS OF:
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