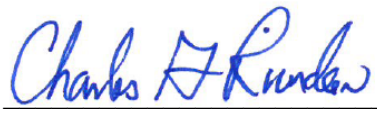
Hofstra University

Institutional Biosafety Committee

Policies and Procedures Manual

Effective Date:

APPROVED BY: **DATE:**



April 1, 2024

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1.0 HOFSTRA UNIVERSITY INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

The Hofstra University Institutional Biosafety Committee (IBC) is responsible for review and oversight of all aspects of the university's program for biological agent use in research conducted at or on behalf of Hofstra University as defined in section 3.0. The IBC ensures that research involving these agents is conducted in a manner that protects researchers, laboratory personnel, animals used in research, the public and the environment, ensuring compliance with the NIH Guidelines, federal and state regulations, and institutional policies.

1.1 Charge of the IBC

The IBC is charged with the administration and regulatory oversight of Hofstra University's research involving biological agents. The IBC has a key role in the interpretation, implementation, oversight, and evaluation of biological agent research for compliance with the requirements articulated in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules *(NIH Guidelines)*.

1.2 Authority of the IBC

The IBC shall have authority to:

- Review, approve, require modifications, place restrictions on, disapprove or suspend all biological agent research activities and dual use research of concern (DURC). This includes proposing changes in previously approved research to ensure compliance with adopted policies, regulations and guidelines.
- Develop, review and approve policies and procedures as related to research activities involving the use of biological agents and DURC. This includes establishing and monitoring policy to ensure that adopted policies meet applicable regulatory standards and guidelines.
- Participate in reviews of unanticipated problems, including serious adverse events that are unexpected and related to the research, significant violations of policies, practices and procedures, violations of the *NIH Guidelines*, or any significant research-related accidents, potential exposures, and illnesses.
- Suspend or rescind any previously approved or registered activities.
- Investigate and review any concerns related to biological research activities.
- Adopt emergency plans for accidental spills and personnel contamination resulting from all IBC registered biological agents.
- Review and assess compliance with permit-related requirements for work with materials from USDA Animal and Plant Health Inspection Service (APHIS), and other applicable requirements.
- Engage in ongoing dialogue with the Principal Investigator (PI) of the research in question when conducting a risk assessment and developing a risk mitigation plan.

1.3 Jurisdiction of the IBC

The IBC jurisdiction extends to all research (irrespective of the source of funding) involving the use of biological agents, as defined in this policy, and DURC conducted at Hofstra University. Similar research at The Zucker School of Medicine at Hofstra-Northwell is covered under the Northwell Health System IBC. Appropriate administrative and IBC approval must be obtained before engaging in such research. Research that involves collaboration with other institutions must be approved by the Hofstra University IBC, but may be subject to further administrative review at the institution where the research is occurring. These officials conducting administrative review and approval may not approve research that has been disapproved by an authorized IBC. Biological agent research or DURC activities in animals or in vitro laboratory experiments may not commence without approval of an authorized IBC. Use of any IBC other than Hofstra University IBC is not permitted without the prior written approval of the Institutional Official of the Hofstra University IBC.

2.0 APPLICABLE GUIDELINES AND REGULATIONS

The IBC shall operate in full compliance with all applicable federal, state, and local regulations and guidelines. As a condition for National Institutes of Health (NIH), funding for research involving recombinant or synthetic nucleic acid molecules, the IBC shall ensure that such research conducted at or sponsored by Hofstra University, irrespective of the source of funding, shall comply with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*. https://osp.od.nih.gov/biotechnology/nih-guidelines/

In accordance with NIH guidelines, the annual report shall be filed with NIH Office of Biotechnology Activities (OBA). This annual registration serves as assurance to OBA from the committee that local review is being conducted for biosafety risks and includes submission of a roster of the IBC members and biographical sketches of all IBC members. An annual report on the committee's activities will also be filed with the university official, HCLAS Senior Associate Dean for Budget and Finance.

3.0 DEFINITIONS OF BIOLOGICAL RESEARCH ACTIVITIES

The IBC is responsible for review and oversight of the below biological agent research defined as:

3.1 Biological Agent Research

Research involving the following: recombinant or synthetic nucleic acid molecules; potentially infectious or hazardous agents (bacteria, viruses, protozoans, fungi, prions, other microorganisms, and parasites); biological toxins; select agents; transgenic animals, invertebrates and plants; artificial gene transfer; synthetic biology; and Dual Use Research of Concern (DURC).

3.2 Dual Use Research of Concern (DURC)

Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, or national security. Agents and toxins requiring institutional oversight include those covered under the United States Government Policy for Dual use Research of Concern as outlined in section 6.2 of the United States Government Policy for Institutional Oversight of Life Sciences Dual use Research of Concern (September 2014). At the time of the preparation of this manual there are no DURC programs at Hofstra, nor is there expected to be.

3.3 Recombinant or Synthetic Nucleic Acid Molecules

In the context of the *NIH Guidelines*, recombinant and synthetic nucleic acids are defined as:

(i) molecules that a) are constructed by joining nucleic acid molecules and b) that 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.

3.4 Select Agents and Biological Toxins

Biological agents and toxins that have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. Defined by the U.S. Department of Health and Human Services (DHHS) and Agriculture (USDA) and the Centers for Disease Control (CDC): https://www.selectagents.gov/ and are subject to the National Select Agents Registry Program managed by the USDA. At the time of the preparation of this manual there is no research involving Select Agents at Hofstra, nor is there expected to be.

3.5 Synthetic Biology

Synthetic biology combines engineering and science to design and build novel and/or unknown biological functions, devices and systems.

4.0 THE RESEARCH COMMUNITY

4.1 Principal Investigator (PI)

The individual responsible for the administrative and programmatic aspects of the research or sponsored project. Every research project must have a designated Hofstra University PI and the PI must have the technical competence and substantive capabilities (scientific,

administrative, and otherwise) to carry out the project.

Primary responsibility for protecting the safety of their research study staff, study subjects, the community, and the environment rests with the principal investigator (PI). All PIs must follow the University policies. For all registrations submitted to the IBC, the PI must certify upon submission by signing an attestation on the registration form and will re-attest during annual updates/periodic reviews that he/she accepts ultimate responsibility of the research activities, including ensuring adherence to applicable federal, state and local regulations and institutional policies by the entire research team.

PIs must report any violations of the *NIH Guidelines* to the IBC Office. Any significant research-related accidents/adverse events must be reported to the Environmental Health and Safety Officer (EHSO) and the Public Safety Office of Emergency Management immediately. An incident report must be submitted within 24 hours. As part of research registration, PIs proposing biological agent research are responsible for completing a project-specific Risk Assessment developed in consultation with the Environmental Health and Safety Officer. PIs conducting biological agent research are responsible for the completion of site-specific laboratory safety training in accordance with Hofstra University policies. Refer to section 6.2: Training of IBC Members, Principal Investigators and Research Study Staff. PIs without approved training will not be allowed to submit biological agent research for IBC review. It is the responsibility of the PI to ensure that all research team members are compliant with training requirements. Additionally, research team members must be trained by the PI on the specific procedures, equipment, and policies that will be used in the laboratory or clinical environment in which the biological agent research is conducted. The IBC may terminate approved registrations in which biological agent research is conducted should investigators fail to maintain and document current training.

4.2 Research Team Members

In addition to the designation of a PI, all biological research submitted for IBC review must list all staff and students who will be handling biological material. Everyone involved in biological research is responsible for adhering to applicable federal, state and local regulations and institutional policies. Research team members are also responsible for completing all IBC and institutional training requirements prior to engaging in research. Like PIs, the research team also reports incidents or violations of IBC and other regulatory policies to the IBC.

Research staff without current training may not engage in biological agent research activities until training is complete.

5.0 IBC COMPOSITION AND MANAGEMENT

5.1 Institutional Official

The Institutional Official (IO) is responsible for ensuring that the IBC has the resources and support necessary to comply with all federal regulations and guidelines governing research activities involving recombinant or synthetic nucleic acid molecules. The IO is legally authorized to represent the institution and is responsible for:

- Reporting to NIH and other relevant federal, state and local agencies, as required.
- Investigating reports of noncompliance and reports of IBC concerns and taking corrective actions as needed.
- Holding investigators and study staff accountable for their responsibilities.
- Ensuring effective institution-wide communication and guidance on biological agent research and biological safety issues.
- Promoting an institutional culture of safety when conducting biological agent research.
- Appointing IBC members.

5.2 Membership and Structure

The IBC is comprised of no fewer than five members sufficiently qualified through experience and expertise to advise and counsel and assess the safety of biological agent research activities and DURC for safeguarding against risks.

The Hofstra IBC will be composed at minimum of the following:

- Member designated as Chair.
- At least two members not affiliated with the institution who represent the interests of the surrounding community with respect to health and protection of the environment.
- The University Health and Safety Officer.
- At least one individual with plant containment expertise, as needed.

The Institutional Official (IO) appoints the Chair, members, and alternate members to the IBC. Terms of appointment are not defined. Once appointed, a member of the IBC will remain on the Committee until s/he withdraws his/her appointment or the IBC Chair in conjunction with the IO determines that his/her appointment to the Committee is no longer required. Continued tenure on the IBC is at the discretion of the Institutional Official.

5.3 IBC Members and Alternates

IBC members (voting and alternate) are expected to attend each IBC meeting. The IBC Chair should be notified in advance of any anticipated absences (due to vacations, etc.). Absences

in excess of 50% of meetings in any given year may result in a request from the Institutional Official for resignation from the committee.

To be appointed to the IBC, a member must sign an appointment letter which also serves as a confidentiality agreement, and submit a CV to the IBC Chair. The Annual Conflict of Interest Policy that all Hofstra University employees sign also applies to their work on this committee. In addition, each member must take the required CITI training.

Alternate IBC members replace a voting IBC member when the voting member is unable to attend a convened meeting of the IBC. Alternate members have qualifications comparable to their applicable voting member(s) and may be an alternate for more than one voting member.

IBC members do not receive any compensation for participation above that received for their normal Institutional duties and responsibilities.

5.4 IBC Chair

The Chair of the IBC is a voting member of the Committee. S/he is appointed by the Institutional Official. The IBC Chair does not have a term limit. S/he can be removed at any time with written notice from the Institutional Official. The IBC Chair must have recent experience as a member of an IBC and have demonstrated regular IBC meeting attendance and active participation. In addition to the responsibilities outlined above for IBC members, chairpersons are empowered to:

- Ensure that the IBC carries out its responsibilities
- Consult with the IO or designee to review membership of the IBC to ensure scientific expertise, adequate representation, diversity, and that membership meets federal requirements. .On an ongoing basis, the IBC Chair will monitor the membership and composition of the IBC and make recommendations on the appointment of members to the IO in order to meet regulatory and organizational requirements.
- Facilitate IBC meetings.
- Will serve as the designated contact on the IBC roster
- Prepare IBC meeting agendas and meeting minutes, and make minutes available to the public upon request.
- Pre-review registrations submitted to the IBC and determining whether review can be conducted at a convened meeting or administratively reviewed.
- Notify investigators of the results of IBC reviews and provide guidance to ensure compliance.
- Complete and submit annual reports to the NIH per stipulated guidelines.
- Communicate with the institutional review boards (IRB) and institutional animal care and use committees (IACUC) regarding research requiring review by multiple committees and developing processes by which appropriate projects are reviewed by the IBC.
- Assist in investigations of research non-compliance.

- Contribute to the development of policies and procedures.
- Maintain IBC records.
- Perform other activities, as needed, to fulfill institutional responsibilities set forth in the *NIH Guidelines* and other federal, state, and local regulations.

A Scientific Member who is currently appointed to the committee will serve as the acting Chair of the IBC in the absence of the Chair or if the Chair has a conflict of interest. That member will maintain the same qualifications, authority, and duties as the IBC Chair. The acting Chair is temporary for the sole purpose of continuity of committee business and will be selected on an as needed basis by the Institutional Official.

5.5 Environmental Health and Safety Officer

The Environmental Health and Safety Officer (EHSO) is responsible for development, implementation, and maintenance of the comprehensive Hofstra University Safety program, including but not limited to establishing programs, procedures, training, occupational monitoring, hazard risk assessments, and audits. S/he ensures compliance with local, state, and federal biosafety regulations/best practices. To this end, the EHSO is responsible for:

- Periodic inspection of labs.
- Verify that PI and staff have appropriate training approvals.
- Verify that IBC approved modifications or stipulations are implemented.
- Monitoring national, state and local regulatory trends and communicating regulatory changes to institutional officials and the institutional biosafety officer as necessary.
- Immediately reporting to the IBC any significant problems, violations, or any significant research-related accidents or illnesses.
- Monitoring national, state and local regulatory trends and communicating regulatory changes to institutional officials and the institutional biosafety officer as necessary.
- Developing emergency plans and procedures for handling accidental spills and personnel contamination.
- Monitoring national, state and local regulatory trends and communicating regulatory changes to institutional officials and the institutional biosafety officer as necessary.
- Investigating and reporting to the IBC and institution any problems, violations, research-related accidents or illnesses.
- Developing and overseeing training on biosafety and laboratory safety and ensuring compliance with training requirements.
- Providing advice and guidance on laboratory security.

- Providing technical advice and guidance to investigators and the IBC on research safety procedures and personal protective equipment.

5.6 IBC Consultants

When necessary, the IBC shall utilize consultants with the appropriate expertise to evaluate/review registrations. In addition, the IBC invites individuals with competence in special areas to assist in the review of the program which require expertise beyond or in addition to that available on the IBC. Consultants will be required to abide by all institutional policies regarding conflict of interest questionnaire and confidentiality prior to reviewing a registration. IBC consultants will not participate in any IBC action in which the consultant has a conflicting interest as outlined in section 7.0.

Consultants will be provided with the same information that primary and secondary reviewers receive. At minimum, consultants will be asked to provide a written statement documenting review and recommendations to the IBC. Consultants are not voting members of the IBC and their presence does not count toward quorum. The IBC is not bound by the opinion or review of the consultants, but takes their reviews into consideration. Consultant reviews will be maintained by the IBC office with the files of the registration under review.

5.7 Guests and Non-IBC Members

IBC meetings are open to the public and any Hofstra University staff or student who wants to attend. The IBC Chair should be notified in advance to prepare for guest attendance. Guests shall be reminded that the discussions that take place at the meeting are confidential and should not be disclosed to others. Guests are not members of the IBC by virtue of their attendance and are not eligible to vote. In the event that the committee goes to executive session to discuss confidential matters, such as those of noncompliance or when proprietary information is being discussed, guests will be asked to leave. In addition, they will be asked to leave the meeting if any protocol on which they are a co-investigator is discussed. All guests will be asked to sign the attendance sheet which will serve as a confidentiality agreement.

6.0 ORIENTATION AND TRAINING

6.1 IBC Member Orientation

IBC member orientation consists of reviewing the following at a convened meeting or with the IBC Chair: functions, roles and responsibilities of the IBC; *NIH Guidelines*; criteria for membership; authority of the IBC; registration review process; periodic review; federal regulations and web-based Collaborative Institutional Training Initiative (CITI) curriculum for IBC members. As part of orientation, IBC members are required to complete CITI training for IBC members before performing member duties.

New IBC members will not be asked to serve as a primary reviewer until they have attended at least one meeting. Ongoing training will occur periodically.

6.2 Training of IBC Members, Principal Investigators and Research Study Staff

All individuals involved in research using biological agents must comply with applicable training requirements outlined in federal guidelines (such as NIH Guidelines), Hofstra University Biosafety Policy, and Hofstra University Chemical Hygiene Plan.

IBC members are required to complete the following CITI web-based training courses:
- Institutional Biosafety Committee Member Training (must be renewed every 5 years)
- Conflict of Interest (must be renewed every 5 years)

Principal Investigators, Research Study Staff and Graduate Students are required to complete CITI web based training courses:
- NIH Recombinant DNA Guidelines (must be renewed every 5 years)
- Basic Biosafety Training (must be renewed every 5 years)
- Conflict of Interest (must be renewed every 5 years)

Undergraduate Students
- Initial Biosafety Training

6.3 Project-Specific Training

Principal Investigators are responsible for training laboratory and research staff in the proper handling of all biological agents as outlined in the approved IBC Registration/Risk Assessment including the proper use of all safety and bio-containment equipment.

Documentation of training must be maintained by the PI and be available upon request. Training must be completed prior to the initiation of any experiments. The Hofstra University SOP template may be used by PIs to document training for all students and staff for each lab-specific procedure.

7.0 CONFLICTS OF INTEREST

All members of the IBC and consultants shall be required to disclose conflicts of interest prior to the meeting and recuse themselves from participating in the discussion and vote. When members recuse themselves because they are investigators in the study or have a financial conflict, they shall leave the room during discussion and vote on the research, except to provide information at the IBC's request prior to the discussion and vote. Recusals shall be documented in the minutes of the meeting as not present for the discussion and vote.

The minutes will record the number voting for, against, abstaining and recused for each agenda item. They will also include the names of recused members. Chairs vote on all protocols for which they do not have a real or perceived conflict of interest.

An individual is considered to have a significant interest when their spouse or dependent children:

- Has an involvement in (or is directly supervising) a research project being reviewed by the IBC.
- Is the project manager, or a member of the research team.
- Has a financial interest (for example, a financial interest in the sponsor or the product or service being tested) in the research whose value cannot be readily determined or whose value may be affected by the outcome of the research.
- Has a financial interest in the research with value that exceeds $5,000 or 5% ownership of any single entity when aggregated for the consultant and their immediate family.
- Has received or will receive any compensation whose value may be affected by the outcome of the study.
- Has a proprietary interest in the research (property or other financial interest in the research including, but not limited to, a patent, trademark, copyright or licensing agreement).
- Has received payments from the sponsor that exceed $5,000 in one year when aggregated for the consultant and their immediate family.
- Is an executive of the agency or company sponsoring the research.
- Any other situation where a consultant believes that another interest conflicts with his or her ability to deliberate objectively on a protocol.

8.0 CONVENED MEETINGS

8.1. Regular Scheduled Meetings

Meetings will occur in person, via conference call, or other digital means. At least 6 meetings will be scheduled each year, though if there are no new registrations to consider or no other business the meeting will be cancelled. Meetings will be held a minimum four times per year. Meeting dates will be posted on the Hofstra IBC webpage. The agenda is developed by the IBC Chair and distributed to the IBC with all relevant meeting material at least a week in advance of the scheduled meeting.

8.2 Quorum

A quorum is a majority of the total number of IBC members present. The IBC Chairperson must confirm quorum prior to calling a meeting to order and ensure quorum is maintained during the meeting.

Members may not participate in the review or approval of a project in which they have a conflict of interest, except to provide information, and may not contribute to the quorum for the vote on that project. Abstentions from voting (for reasons other than conflict of interest) do not alter the quorum and do not change the number of votes required for approval. Recusal of a member due to a conflict of interest does alter the quorum.

Reasonable efforts will be made to ensure that at least one unaffiliated member is present at each meeting. The presence of half plus one of the voting membership shall constitute a quorum. Alternate voting members can be counted towards a quorum when they are attending

as a replacement to a voting member. A quorum shall be maintained for the discussion and vote on each research activity on the agenda. The Chairperson or designee shall be responsible for ensuring that quorum is achieved before the meeting begins and is maintained throughout the meeting when each registration on the agenda is voted upon. The Chair or designee shall be responsible for recording attendance and vote on each registration.

9.0 REGISTRATION SUBMISSION AND REVIEW

The IBC has the authority to and shall be responsible for determining appropriate biological safety requirements for biological agent research performed at Hofstra University. The IBC shall be guided by the CDC-NIH Biosafety in Microbiological and Biomedical Laboratories, 5th Edition (or any updates as available),the *NIH Guidelines, OSHA Bloodborne Pathogens, 29 C.F.R. Part 1910, 7 C.F.R. Part 331, 9 C.F.R. Part 121, 42 C.F.R. Part 73, United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern: Sept. 24, 2014* . The IBC shall conduct reviews of recombinant or synthetic nucleic acid molecules research that are not exempt from the *NIH Guidelines* consistent with the requirements set forth in the *NIH Guidelines*. Registrations are valid for three years subject to periodic review. After the 3 year term has expired, a new registration will be required.

9.1 Program Participation Requirements

Prior to submitting a registration for IBC review, program requirements must be met.

MEDICAL CLEARANCE: All research personnel participating in biological agent research must complete the Biohazards Research Health Questionnaire. The questionnaire serves to allow self-screening of students and staff who have health conditions which are incompatible with biological agent research.

TRAINING: All applicable training must be completed for all individuals listed on this registration prior to initiation of experimentation. Refer to sections 6.2 and 6.3.

9.2 Registration Submission

Registration forms can be found at IBC website. Completed registrations and all required appendices are to be submitted to the committee chair at IBC@hofstra.edu. The deadline for submission is 10 business days prior to the next scheduled meeting.

9.3 Registration Review

The registration will undergo pre-review by the Chairperson and based on the activity, will be referred for review at a convened meeting of the IBC or dealt with administratively by the Chairperson or EHSO. Research involving recombinant or synthetic nucleic acids that is not exempt from the *NIH Guidelines* is required to be reviewed by a convened IBC. This review shall include an independent assessment of the biological containment required, an

assessment of the facilities, training and expertise of personnel involved in the research, and risk of biological agent to the research staff. The Chairperson will assign the registration to a primary reviewer within 2 business days of receiving the registration. Both voting members and alternates may serve as primary reviewers.

If applicable, documentation that an Institutional Animal Care and Use Committee (IACUC) protocol has been submitted should accompany a registration.

9.4 Possible IBC Actions

The reviewer(s) will present their assessment and lead the discussion. The IBC Chairperson will open the review for discussion by the members. At the end of the discussion, any member may make one of the following motions to be voted on by the IBC:
Members shall be required to vote or abstain from voting on each research activity considered by the IBC when they are present for the discussion and vote.

- **Approve:** The research is approved.
- **Require Modifications:** Modifications need to be made in the submission in order to secure approval.
- **Withhold Approval:** When substantive information is lacking from a protocol, including questions raised by the committee requiring response from the PI.
- **Disapprove:** This action is taken if the IBC determines approval of the study is unwarranted due to the risks involved in conducting the biological agent research.

A vote on the motion shall be taken by a show of hands or voice vote, and the number of votes for, against, and abstentions from voting shall be recorded in the minutes. All motions shall be decided by a majority vote of the members present for the review.

When deliberating, the IBC will ensure:

1. Motion and vote are clear.
2. Minority opinion, if held, is clearly noted.
3. Topic of deliberation is clear.

9.5 Registrations Requiring Notification Only

For research described in the *NIH Guide* section III-E as research about which the IBC should be notified, but does not require prior approval, the same registration procedure should be followed and submitted to the IBC chair. The chair will present the registration to the committee for confirmation that they fall into NIH category III-E.

9.6 Periodic Review

PIs are required to conduct an annual self-assessment of their biological agent registrations and submit an update if there are any changes to previously approved registrations. Each laboratory may be subject to a review and inspection of all registered research activities.

9.7 Voluntary Registration Termination

Approved registrations may be terminated by the PI at any time.

9.8 Appeal of an IBC Decision

The decision of the IBC to disapprove the research cannot be overruled by any other institutional body or individual(s); however, an investigator may appeal the decision of the IBC in writing and submit to the Chairperson at IBC@hofstra.edu. The deadline for submission is 10 business days prior to the next scheduled meeting. The appeal is then scheduled for review at a convened meeting. Investigators are encouraged to present appeals to the IBC in person at a convened meeting.

9.9 Add Personnel to Approved Registrations

To add personnel to IBC approved research registrations, change the administration of an approved registration or amend responsibilities of personnel, PIs must submit an Administrative Change Request Form - Add Personnel. This form can be obtained from the IBC website or the IBC Chairperson. Requests are to be submitted to IBC@hofstra.edu. Requirements to participate in research activities involving biological agents must be satisfied before an Administrative Change Request will be approved. Administrative changes, personnel additions and amended responsibilities as listed on an Administrative Change Request Form can be approved by majority vote of IBC voting members via e-mail.

9.10 Holding of Previously Approved Materials in the Absence of Active Research

If materials listed on an approved registration are to be retained on site but not as part of an active research project, a separate registration form must be submitted detailing the current status of the materials; this form retains the original number of the approved registration to preserve continuity. If previously approved materials are being held in the absence of active research as specified on a new registration form, this is treated as a modification to the original registration form and the new form can be approved by majority vote of voting IBC members via e-mail. No new active research program registrations can be approved via e-mail.

10.0 IBC RECORDS

The IBC records include:

- IBC meeting minutes
- IBC registrations; including any administrative changes, annual reports, adverse or unanticipated events, risk assessment, informed consent(s) and SOPs
- IBC membership and member training
- IBC policies and procedures
- IBC documentation related to unanticipated problems, including serious adverse events that are unexpected and related to the research, significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents, potential exposures, and illnesses.
- Reports to internal, state and/or federal entities.

11.0 MEETING MINUTES

The minutes shall include the following:

- Voting members present
- Presence of unaffiliated member(s)
- Voting members absent
- Staff and guests, including consultants present for each Biological Research Activity reviewed at each meeting.
- Title, layman's description and Biosafety level of each registration being considered.
- Motion(s) and action(s) voted on by the IBC
- Number of votes for, against, and the number of abstentions from voting (documentation of quorum)
- Members attending the meeting but not present for the discussion and vote.
- Recusals of voting members due to conflicts of interest
- When applicable, summary of information presented by IBC member(s), ad hoc consultants, or guest(s)
- Summary of the discussion of issues and their resolution, if any
- Modifications required and/or additional information requested by the IBC
- Basis for requiring changes or withholding approval of the research

Minutes shall be made available to the IBC members for review and approval and shall not be altered once approved. Minutes shall be retained by the IBC Office for at least seven (7) years and shall be maintained in a secure area within the IBC Office or secure shared filed area on the Hofstra network.

The IBC minutes document when an alternate member substitutes for a voting member. When an alternate member substitutes for a voting member, s/he receives and reviews the same material the voting member would have received.

11.1 Access to Meeting Minutes

In accordance with the *NIH Guidelines*, the IBC shall allow for public review of its actions through the provision of meeting minutes to those that have requested such documentation.

The IBC, in consultation with legal, shall review and respond to all written public requests for meeting minutes in a manner consistent with any redaction policy noted in Section 11.2. Public comments and the IBC response shall be forwarded to the NIH OSP by the IBC Director.

All IBC records, as outlined above, shall be available for inspection by the Institutional Officials and their designees and designated federal agencies. As described in Section 13.1.1, IBC shall make available all IBC meeting minutes, per the *NIH Guidelines*.

11.2 Redaction of Meeting Minutes

Consistent with Section IV-B-2-a-(6) of the *NIH Guidelines* as well as subsequent letters of interpretation from NIH OSP, the IBC reserves the right to redact proprietary or private information when minutes are released to the public. This information may include trade secret information, confidential commercial information, personal information of IBC members, and specific information whose disclosure would directly compromise institutional security.

11.3 Retention

The IBC shall retain the following records for at least seven (7) years after the completion of the research activity:

- IBC meeting minutes.
- IBC registrations and attachments thereto.
- IBC Membership and training records.
- IBC policies and procedures.
- IBC documentation related to unanticipated problems, including serious adverse events that are unexpected and related to the research, significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents, potential exposures, and illnesses.
- Reports to internal, state and/or federal entities.

12.0 INCIDENTS, VIOLATIONS AND SERIOUS ADVERSE EVENTS

The IBC will review concerns involving biological research activities, DURC exposure and spills of potentially biohazardous materials in laboratories. When a potential concern is

reported, it will initially be evaluated by the IBC Chair and Environmental Health and Safety Officer, to substantiate concern and determine significance. If the concern is substantiated and significant, suspension of the use of biological agents, termination of use, confiscation, destruction and any other actions necessary to protect the public, staff, including any restriction of access to the lab in order to suspend activities, will immediately occur and the incident will be evaluated by the IBC.

12.1 Reporting Incidents, Violations and Serious Adverse Events

Concerns may be reported to the IBC Chair, Institutional Official, EHSO, Laboratory Director, any member of the IBC, or Research Leadership. Principal Investigators and their study staff are required to report instances of possible non-compliance to the IBC Chair or the Department Chairperson as soon as possible. No facility employees, committee members or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulations, standards or concerns.

As part of the PI's responsibilities, PIs are required to notify the EHSO as soon as possible in the event of a potential or overt exposure to biological agents, suspected laboratory acquired infection, and research-related accidents or illnesses or violations of the NIH Guidelines. This is required even if the staff was not seen by Student Health Services or the Emergency Department. On behalf of the PI, the IBC will report to the appropriate agency as required. Additional information regarding reporting is provided below.

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) states that "...any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses" must be reported to NIH OBA 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 OBA.

Under the NIH Guidelines incident reporting is articulated as a responsibility of the Institution, IBC, EHSO, 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.

Once the report has been received by the IBC Chairperson, a file will be opened on the matter. The IBC Chairperson is responsible for maintaining documentation of the reporting process.

12.2 Definitions of Non-Compliance

Non-Compliance: Failure to adhere to regulations (e.g. NIH Guidelines), institutional policies, federal, state and local regulations, or requirements or determinations of the IBC. This includes deviations from approved procedures, regulations or guidelines. This may pertain to the Principal Investigator or the investigator's research staff.

Minor Non-Compliance: Non-compliance that does not pose a significant potential for causing harm to the health or safety of personnel.

Serious Non-Compliance: Non-compliance that may pose an 1) increased risk to personnel, 2) adversely affects the safety or welfare of personnel. Serious deviations from IBC registration or determinations and willful violation of the *NIH Guidelines,* institutional policies and/or federal regulations may also constitute serious non-compliance.

Continuing Non-Compliance: A pattern of non-compliance that, if allowed to continue, is likely to increase risks to personnel and the environment, adversely affect the safety of personnel. This includes minor or serious non-compliance occurring repeatedly without efforts to correct the non-compliance.

12.3 Review of Allegations of Non-Compliance, Incidents Violations and Serious Adverse Events

Upon notification of an allegation of non-compliance or incidents the following will occur:

1) The IBC Chair and EHSO will promptly evaluate the concern. If it is determined that there is no substantive concern, or that the concern is minor, the IBC Chair will document the findings and notify the parties involved. Recommendations for training or process changes may be made at this time. The IBC will be informed at the next business meeting and the findings will be documented in the meeting minutes.

2) If the IBC Chair and EHSO determine that there are substantive allegations of serious or continuing noncompliance or that the concern is significant, the Institutional Official will be notified and with his/her approval the following procedure will be used:

    a. For concerns that may potentially jeopardize the safety or welfare of staff, study activities (including the research project in question and other research projects conducted by the investigator in question) may be suspended immediately. This initial decision is based on preliminary review of available information, communication with the PI and/or staff involved in the alleged non-compliance or incident and the seriousness of the allegations. The PI will be notified of any study activity suspension in writing.

    b. The Institutional Official, IBC Chair, and EHSO will review the allegation or incident and request additional information from the investigator or an audit of the research in question within 5 business days.

3) If the Institutional Official, IBC Chair, and Safety Officer determine that the allegation of serious or continuing noncompliance or incident was not substantiated or of minor concern, this determination will be reported to the Principal Investigator, and

if applicable, the reporting party. At this stage, study activities may resume.

Recommendations for training or process changes may also be made at this time. The IBC determination letter will be copied to the Institutional Official and any other parties notified at the outset. The IBC Committee will be informed at the next business meeting and the findings will be documented in the meeting minutes.

4) If the Institutional Official, IBC Chair, and EHSO determine that the allegation of serious non-compliance is substantiated or concern is significant, the IBC is informed at the next convened meeting (or convened for special consideration). The PI involved in the alleged non-compliance or incident will be notified and provided with an opportunity to discuss the allegations or incident with the IBC. The report of the investigation conducted by the IBC will be presented at a convened IBC meeting.

    a. The committee will review the allegation of non-compliance or significant concern and decide whether there is an issue of non-compliance, and if so, whether it is serious or continuing in nature. The committee can request additional information from the investigator.
    b. If the committee determines that the findings constitute serious or continuing non-compliance, the committee can request a corrective and preventive action (CAPA) plan from the principal investigator, education and training for staff, additional monitoring of the study, suspension or termination of the study or studies on which the investigator is participating, restriction on serving as an investigator or any other actions deemed appropriate.
    c. The IBC Chair will document the outcome of committee deliberations and communications in writing. This report will include any sanctions, CAPA required on the part of the investigator and the time frame for the CAPA to occur and any other requirements of the committee. The PI is informed of the IBC determination and the basis for the determination in writing and is given a chance to respond. The CAPA must be implemented within the timeframe determined by the IBC committee. Failure to do so may lead to suspension of IBC registration approval and recommendations for punitive action. A copy of the final report will be sent to the PI, associated research staff and others as appropriate. The complainant will be provided information regarding the outcome of the investigation, as deemed appropriate by the IBC Director.

12.4 Reporting to External Agencies

The IBC Chair shall work with the Institutional Official to promptly report to NIH OSP, other federal agency reporting (e.g. OSHA, CDC), sponsors, and accrediting agencies as appropriate any serious or continuing non-compliance with the regulations or requirements of the IBC, any suspensions of IBC-approved registrations as determined by a convened IBC and any significant research-related incidents such as accidents or illnesses. This includes preliminary and final reports.

Significant research-related violations, accidents and illnesses will be reported to OSP in writing within 30 days or immediately depending on the nature of the incident. Spills and accidents in biosafety level 2 laboratories resulting in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules will be reported immediately.

Individuals will be copied on the correspondence as appropriate including the PI, Chairman or supervisor of the PI, Grants Management Office, Office of Post-Award Management and others deemed appropriate by the Institutional Official.

13.0 DISCIPLINARY ACTIONS

The IBC can launch investigations, and suspend or rescind registrations based on noncompliance and/or unacceptable risk. In addition, the IO may place limitations or conditions on an investigator's or research study staff's privilege to conduct biological agent research upon the recommendation of the IBC, where such actions are required to maintain compliance with federal, state, local, and/or institutional requirements.

14.0 MONITORING

Periodic inspections to ensure that laboratory standards are rigorously followed will be conducted by the EHSO. Any significant problems that are encountered as a result of these inspections will be promptly reported to the IBC by the EHSO.

15.0 FINAL DISPOSITION OF REGISTERED MATERIAL

Upon termination of IBC registrations, PI's are required to submit in writing to the IBC identifying the final disposition of registered material. The final disposition may include destruction via autoclaving or transfer to a collaborator. When transferring the material to an internal collaborator, the collaborator will need to register the material with the IBC. If the material is being transferred to an external collaborator, the recipient institution should provide documentation that they are equipped to safely store and work with the material.

16.0 CONFIDENTIALITY

Proprietary or private information and information that is critical to institutional security that is discussed during IBC meetings and records of review activities shall be considered confidential and protected from access except as provided in Section 11.2. IBC members or others with access to proprietary or private information and information that is critical to institutional security shall not use them for any purpose other than to carry out their review responsibilities and shall not disclose them to others who are not authorized under these procedures to have access.

Without limiting any of the above, the Chairperson shall specifically prohibit distribution of documents and records containing confidential and proprietary information of Hofstra University without prior written approval.

17.0 POLICIES AND PROCEDURES

The IBC, in conjunction with others as necessary, shall develop and maintain Policies and Procedures as well as provide guidance as may be necessary for the review of biological agent research in compliance with federal, state, and local laws and regulations. Policies and procedures will be amended to comply with changes in the regulatory and scientific environment. Such policies, procedures and guidance shall be approved by the IO. Policies which intersect with or affect other institutional offices or processes may be developed in consultation and coordination with those offices or institutional research leadership and are generally approved by the IO. All policies and procedures of the IBC are available to the Hofstra community through the University website.

Any revisions to IBC policies and procedures will be developed and approved by the IBC Chair and Institutional Official. Adoption of the revised policy & procedure manual will be considered final when the Institutional Official accepts the revisions, and signs and dates the document.

The IBC Policies and Procedures, including IBC guidance documents and significant policy-related communications to the research community, shall be made available on the IBC website and shall be maintained by the IBC Office for at least seven (7) years from the date of their adoption/distribution and shall be made available upon request to authorized representatives of the sponsor and, when applicable, authorized representatives of NIH and other federal agencies.

In addition, all applicable Hofstra University policies must be adhered to and can be found on the Hofstra website under Research and Sponsored Programs.

18.0 PROGRAM CONTACTS

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