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1.0 Introduction

1.1 Purpose of Policies and Procedures

The purpose of these Policies and Procedures is to set forth the charge of Emory University's Institutional Biosafety Committee (IBC). The IBC is charged with:

- Reviewing and approving any proposed IBC Research prior to its Initiation.
- Determining what types of IBC Research that involve recombinant or synthetic nucleic acid molecules fall within the scope of the NIH Guidelines (such research referred to herein as "IBC NIH Guidelines Research") and must be reviewed in accordance with the NIH Guidelines.
- Establishing policies and procedures that the IBC will follow in its initial and continuing review of IBC Research, including IBC NIH Guidelines Research.
- In connection with the University's EHSO, establishing and implementing policies and procedures that investigators at Emory should follow to provide for the safe conduct of IBC NIH Guidelines Research (IBC Research), and the establishment and implementation of policies and procedures to ensure that the IBC Research is carried out in compliance with the NIH Guidelines
- Reporting any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to NIH OSP within thirty days, unless the institution determines that a report has already been filed by the Principal Investigator or Institutional Biosafety Committee.

Reference: NIH Guidelines, Sections IV-B-1-a & IV-B-1-j; Charter of the Emory University Institutional Biosafety Committee.

1.2 Scope of Policies and Procedures

- These policies and procedures apply to all persons, who are involved in the conduct of any research sponsored by Emory University ("Emory") and/or conducted at Emory facilities (regardless of its funding source) that involves recombinant nucleic acid molecules, synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules and/or other genetically altered organisms, cells, or agents, including organisms and viruses containing such molecules
- Throughout these Policies and Procedures, all research described within this Section shall collectively be referred to herein as "IBC Research".

Reference: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, Section I-C General Applicability; Charter of the Emory University Institutional Biosafety Committee.

1.3 Definitions

In addition to terms that are defined within these Policies and Procedures, the following additional terms are define below.

Biological Safety Officer or Biosafety Officer. Person appointed by Emory University in

accordance with NIH Guidelines to fulfill duties set forth in Section 3.0 of these Policies and Procedures.

EHSO. Emory University Environmental Health and Safety Office

Human Gene Transfer Experiment (HGT). HGT is the deliberate transfer into human research participants of either:

- Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or
- Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:
  - Contain more than 100 nucleotides; or
  - Possess biological properties that enable integration into the genome (e.g., cis elements involved in integration); or
  - Have the potential to replicate in a cell; or
  - Can be translated or transcribed.

IACUC. Emory University Institutional Animal Care and Use Committee.

IBC. Institutional Biosafety Committee (IBC) established in accordance to NIH Guidelines to perform duties set forth in Section 3.0 of these Policies and Procedures.

IBC Research. All research that falls within the review jurisdiction of the Emory University IBC, including research that the Emory IBC is to review pursuant to the requirements of NIH Guidelines and research required to be reviewed per the Emory University charter establishing the IBC.

IRB. Emory University Institutional Review Board.

NIH. National Institutes of Health.

"NIH Guidelines" or the "Guidelines". The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules found at the following website: https://osp.od.nih.gov/biotechnology/nih-guidelines/

NIH OSP. The OSP is the office within the NIH that is responsible for: (i) reviewing and coordinating all activities relating to the NIH Guidelines, and (ii) performing other duties as defined in Section IV-C-2, Office of Science Policy (OSP). https://osp.od.nih.gov/about-us/

NIH Recombinant DNA Advisory Committee (NIH RAC). In April of 2019, NIH published an amendment of the NIH Guidelines whereby the RAC review, protocol registration, and reporting requirements associated with gene therapy research were removed. Concurrently, the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) was introduced as the NIH Director's go-to advisory committee for advice and transparent discussions about the scientific, safety, ethical, and social issues associated with emerging

biotechnologies.

OC. Emory University Office of Compliance.

Emergency Use Authorization: Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA may *authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by Chemical Biological Radiological, and Nuclear threat agents when certain criteria are met, including there are no adequate, approved, and available alternatives.*

1.4 Institutional Responsibilities

Responsibilities Regarding IBC Research (i.e. Research involving Recombinant or Synthetic Nucleic Acid that is Subject to IBC review and falls within the Scope of the NIH Guidelines)

To ensure that all IBC Research is carried out in accordance with the NIH Guidelines, Emory, acting through these Policies and Procedures, and through the committees and positions established by these Policies and Procedures, has performed the responsibilities set forth below and continues to carry out any such ongoing responsibilities:

- Establish an IBC.
- Appoint appropriate members to the IBC in accordance with Section 4 below.
- Appointment of a Biological Safety Officer (also referred to herein as a "Biosafety Officer" (BSO)).
- Establish and implement a policy and procedure for review of recombinant or synthetic nucleic acid molecules research involving human research participants in which Emory participates or sponsors that falls within the purview of the NIH Guidelines (i.e., constitutes IBC Research). ***All HGT studies to be conducted at Emory University must be registered with the biosafety office.*** http://www.ehso.emory.edu/documents/guidance-document-ibc-review-of- human-gene-transfer.pdf
- Assist Principal Investigators (PI) at Emory who are conducting research activities which fall under the NIH Guidelines to ensure that these investigators comply with the NIH Guidelines.
- Ensure that appropriate training in laboratory safety and the implementation of the NIH Guidelines is in place for: (i) IBC members, including the Biological Safety Officer; and (ii) PIs carrying out research that is subject to the NIH Guidelines. Retraining will be required every three years.
- Ensure that Emory PIs, in turn, provide appropriate training to their laboratory staff regarding laboratory safety and implementation of the NIH Guidelines. This obligation shall be carried out by ensuring the implementation of training requirements established by the IBC and other appropriate Emory departments and units responsible for research compliance training.
- Evaluate the necessity for health surveillance of personnel conducting research involving the use of recombinant or synthetic Nucleic Acids, and, if appropriate,

recommend a health surveillance program for such projects.

- When appropriate, in accordance with the NIH Guidelines, establish and maintain a health surveillance program for personnel engaged in large scale research or production activities involving viable organisms, or engaged in animal research involving viable recombinant DNA containing microorganisms, that require Biosafety Level (BSL) 3 or greater containment in the laboratory. These responsibilities are carried out primarily through the cooperative efforts of the IBC, the EHSO and Occupational Injury Management (OIM). The IBC, at its discretion, may require the PI to enroll personnel conducting research subject to IBC jurisdiction in the Employee Health Program as a condition of project approval.
- The PI reports to the Biosafety Officer any significant problems, violations, of NIH Guidelines or any significant research related accidents and illnesses within 1 business day of occurrence.
    - Copies of any such reports shall be provided by the Biosafety Officer to the Emory University OC and the Chair of the IBC.
      Based on reports received, the Biosafety Officer shall report any significant problems, violations of the NIH Guidelines or any significant research-related accidents and illnesses to the NIH OSP via e-mail to: NIHGuidelines@od.nih.gov. Such reports shall be made within 30 days of the occurrence, unless it is determined that a report has already been filed by the PI involved or by the IBC. Copies of any reports made by Biosafety Officer shall be provided to the Chair of the IBC.

Reference:
Responsibilities of the Institution: NIH Guidelines, Sections IV-B-1
Responsibilities of the PI: NIH Guidelines, Sections IV-B-7

1.5 Establishment of the IBC and Biological Safety Officer Position

Institutional Biosafety Committee (IBC):

In accordance with the requirements of the NIH Guidelines, Emory has established an IBC. The IBC shall meet all requirements and perform all responsibilities of an IBC as set forth in the NIH Guidelines. The IBC shall operate in accordance with these Policies and Procedures; provided, however, that if the terms and conditions of these Policies and Procedures ever conflict with the terms and conditions of the NIH Guidelines (or any amendments to the NIH Guidelines) then the terms and conditions of the NIH Guidelines shall control, and these Policies and Procedures shall be conformed to the NIH Guidelines. The IBC also shall be authorized to provide recommendations to Emory's President or his/her designee on matters relating to research described in Section 1.2 of these Policies and Procedures and on any matters falling within the IBC's purview under the Charter of the Emory University Institutional Biosafety Committee.
Reference: NIH Guidelines, Section IV-B-1-b

Biological Safety Officer (BSO):

In accordance with the NIH Guidelines, Emory has established the position of Biological Safety Officer (also sometimes referred to herein as the "Biosafety Officer") and appointed an appropriate person to fill this position. The Biosafety Officer shall meet all requirements and perform all responsibilities of a Biosafety Officer as set forth in the NIH Guidelines, including any amendments

thereto; provided, however, that if there is any conflict between these Policies and Procedures and the NIH Guidelines, as amended, the NIH Guidelines shall control, and these Policies and Procedures shall be conformed to the NIH Guidelines. The Biosafety Officer shall appoint a qualified designee from within the EHSO to serve as an alternate Biosafety Officer in the appointed Biosafety Officer's absence. Throughout these Policies and Procedures, the term Biosafety Officer shall refer to the appointed Biosafety Officer or his/her designee.
Reference: NIH Guidelines, Sections IV-B-1-c.

1.6 Recordkeeping

The IBC meeting minutes are maintained by the Executive Secretary as set forth in Section 4.7 below. Correspondence sent to researchers, regulatory agencies or other persons concerning any of the IBC's duties set forth hereunder is maintained electronically. All records shall be kept for the longest of any retention period required by NIH Guidelines, or any other applicable federal, state, local or university requirement.

1.7 Review and Update of these Policies and Procedures

On a periodic basis, the Biosafety Officer, in conjunction with the participation of at least one other member of the IBC, shall review these Policies and Procedures to ensure that they are in conformance with current laws, regulations and Emory University policies and procedures, and to suggest for the IBC Chair's consideration any proposed improvements thereto. The IBC Chair will consider all suggested modifications and/or additions to these Policies and Procedures and decide whether to accept the changes. All modifications and additions to these Policies and Procedures approved by the IBC Chair will be communicated to the IBC at a regularly convened meeting of the IBC. Amendments to the Policies and Procedures shall become effective upon the specified effective date set forth in the amendment. The Biosafety Officer shall be responsible for providing notice of these Policies and Procedures, and any changes thereto, to the affected members of the research community at Emory.

2.0 Scope of the Biosafety Officer Duties

2.1 Qualifications

The Biosafety Officer shall have the experience, education and background that make him/her knowledgeable about laboratory research, biohazards, containment and recombinant or synthetic nucleic acid molecule technology and give him/her the capability to assess the safety of recombinant DNA research and identify potential risks to public health and/or the environment. The Biosafety Officer shall be trained in and receive on- going training in laboratory safety and topics necessary for the implementation of the NIH Guidelines. The Biosafety Officer shall be on the staff of Emory's EHSO and shall be a voting member of the IBC.

2.2 Duties

The Biosafety Officer's duties shall include, but shall not be limited to, the following:

- Making periodic inspections of laboratories at which research subject to the jurisdiction of the IBC is being conducted to ensure that laboratory standards are rigorously

followed and reporting the results of such inspections to the IBC, as well as to any other appropriate compliance units or committees at Emory (e.g., OC).

- Reporting to the IBC, as well as to any other appropriate compliance units or committees at Emory (e.g., OC, IACUC, IRB) any significant problems involving or violations of the NIH Guidelines, and any significant accidents or illnesses related to research under the IBC's jurisdiction of which the Biosafety Officer becomes aware, unless a report has previously been filed with the IBC by a PI. The Biosafety Officer also shall be responsible for confirming that the PI (or other appropriate individual or committee) has made any reports to NIH OSP or other governmental agencies or sponsors that are required by the NIH Guidelines, or other applicable laws or regulations (see Sections 1.4 and Section 7.1 and 7.5) and that copies of any such reports have been provided to the Biosafety Officer, and the Chair of the IBC. OC will receive copies of the reports.
- Developing an emergency plan for handling accidental spills and personnel contamination and investigating laboratory accidents that concern recombinant or synthetic nucleic acid molecules, these plans shall be reviewed and approved by the IBC. In addition, as a condition of project approval, the IBC may require PIs to develop project specific plans for handling such incidents.
- Providing advice on laboratory security.
- Providing technical advice to PIs and the IBC on research safety procedures.
- Carrying out such other duties as may be assigned from time to time by the IBC, EHSO or other appropriate Emory administrative units.

Reference: NIH Guidelines, Section IV-B-3.

3.0 Scope of IBC Duties

3.1 General Duties of the IBC

The IBC's general duties shall include the following:

- Conducting any functions required of an IBC, as set forth in NIH Guidelines, and as more particularly described under Section 4.2 below.
- The IBC may investigate issues of noncompliance or accidents, involving IBC Research.

Reference: NIH Guidelines, Section IV-B-2-b; Charter of the Emory University Institutional Biosafety Committee.

3.2 Duties of the IBC Under the NIH Guidelines

The IBC's specific duties under the NIH Guidelines shall include the following:

- Reviewing recombinant or synthetic nucleic acid molecules research conducted at or sponsored by Emory to determine if it constitutes research under the NIH Guidelines, Section III, Experiments Covered by the NIH Guidelines, and if so reviewing the research for compliance with the NIH Guidelines. The IBC may grant approval only to those research projects for IBC NIH Guidelines Research that it finds to be in conformance with the NIH Guidelines and any other applicable legal or University

requirements. The IBC will assign an exemption category to recombinant or synthetic nucleic acid molecule research conducted at or sponsored by Emory, if applicable. At the discretion of the Biosafety Officer, that exempt research can be referred to the Emory University Research Health and Safety Committee (RHSC).

- Notifying the PI of the results of the IBC's review and approval or disapproval.
- Reviewing and approving any request for the lowering of containment levels for certain experiments as specified in NIH Guidelines, Section III-D-2-a, Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4 or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems.
- Setting containment levels for projects as set forth in NIH Guidelines, Sections III-D-4, Experiments Involving Whole Animals, and III-D-5, Experiments Involving Whole Plants.
- Establishing and implementing a method whereby the IBC periodically reviews recombinant or synthetic nucleic acid molecules research conducted at Emory to ensure compliance with NIH Guidelines (e.g., through conduct of compliance review, inspections, audits, etc.).
- Reviewing and adopting emergency plans covering accidental spills and personnel contamination resulting from DNA research. Such plans shall follow recommendations found in NIH's Laboratory Safety Monograph and shall include provisions for cooperating with state and local public health departments by reporting any significant research-related illness or accident that may be hazardous to the public health.
- Reporting any significant problems with or violations of the NIH Guidelines and any significant research related accidents or illness to the appropriate institutional officials and NIH OSP within 30 days of occurrence unless the IBC determines that a report has already been filed with the institutional official and the NIH OSP by the PI or other Emory official. Reports shall be sent to NIH OSP at the address specified in Section 1.4 above. Copies of any such reports shall be sent to the Biosafety Officer and to the OC. Performing such other duties and functions as may be delegated to the IBC in accordance with NIH Guidelines, Section IV-B-2, and the Charter of the Emory University Institutional Biosafety Committee.

Reference: NIH Guidelines, Section IV-B-2-b.

4.0 Membership and Organization of the IBC

4.1 Number of Members

- The IBC shall have no less than five (5) members. Each member shall be appointed by Emory's President or his/her designee. The President, or his/her designee, may increase or decrease the number of members on the IBC, but in no event shall the number of members be less than five (5).
- **Alternates**: A member may suggest one or more alternate members to serve in his/her stead. An alternate shall have substantially similar qualifications to the member for whom he or she is serving as an alternate. At meetings in which the alternate is serving for the regular member, the alternate shall be counted towards quorum and shall have

such voting rights and privileges as the member would have. Alternates also may attend IBC meetings along with the member for whom they serve as an alternate, but in such instances, they attend the meeting as guests and do not have any voting rights or responsibilities and are not counted towards establishment of quorum. Alternates shall be appointed by Emory's President or his/her designee. The Executive Secretary shall include in the membership roster the names, contact information and CVs for any alternates. Unless otherwise stated, throughout this document, the term "member" shall refer to a member and/or his/her alternate.

Reference: NIH Guidelines, Section IV-B-2-a-(1); Charter of the Emory University IBC.

4.2 General Qualifications of Members

The IBC membership shall be composed of persons who collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecule research and to identify any potential risk to public health or the environment. In addition to including members with expertise in recombinant or synthetic nucleic acid molecule technology, the IBC also shall include members with expertise in biological safety and physical containment, as well as including, or having available as ex officio members or consultants, persons who are knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community standards and the environment. Each IBC member shall provide the Executive Secretary with a copy of his/her CV or resume on an annual basis.

Reference: NIH Guidelines, Sections IV-B-2-a-(1) & IV-B-2-a-(2).

4.3 Specific Qualifications of Particular Members

Based on a total membership of at least five (5) persons, the ***IBC*** members shall have the following qualifications:

- One (1) member shall be a non-doctoral staff member from an Emory biomedical laboratory who represents laboratory technical staff.
- At least two (2) members will be selected from the community (hereinafter the "Community Members") and shall have no present affiliation with Emory apart from their membership on the IBC. These members shall represent the interests of the surrounding community with respect to health and protection of the environment, and they may be individuals such as state or local public health or environmental agency officials, members of local governmental bodies or persons active in medical, occupational health or environmental concerns in the community.
- In addition to members with the foregoing qualifications, the IBC shall ensure that it includes persons with the following qualifications as members when the types of research specified below are being considered by the IBC:
- At least one (1) member shall have expertise in plant, plant pathogen or plant pest containment principles (said member hereinafter referred to as the "Plant Expert") at any time at which the IBC is considering for approval projects involving experiments that utilize NIH Guidelines, Appendix P, Physical and Biological Containment for Recombinant DNA Research Involving Plants.
- At least one (1) member will be a scientist with expertise in animal containment

principles (said member hereinafter referred to as the "Animal Expert") when the IBC is considering for approval experiments that utilize NIH Guidelines, Appendix Q, Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals.

- Sufficient members with adequate expertise and training to evaluate recombinant DNA research involving human research participants (one or more) and to ensure that all aspects of NIH Guidelines, *Section III-C Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation* and the supplementary information provided by NIH as *Points to Consider Institutional Biosafety Committee (IBC) Review of Human Gene Transfer Protocols* have been appropriately addressed by the PI when the IBC is considering for approval such research involving human participants in which Emory is participating or sponsoring. Alternatively, the IBC may, as necessary, appoint an ad hoc consultant(s) to the IBC to provide such expertise.
- Members meeting the qualifications specified in this Section may be existing members, who also meet other IBC member qualifications, or they may be members appointed specifically to fulfill these qualifications.

Reference: NIH Guidelines, Sections IV-B-2-a-(1), IV-B-4, IV-B-5, & IV-B-6; Charter of the Emory University Institutional Biosafety Committee.

4.4 Ex Officio Members

The following persons shall be members of the IBC by virtue of the positions that they hold at Emory.

- **Biosafety Officer:** Emory's Biosafety Officer shall be a voting member of the IBC and shall serve as Executive Secretary to the IBC.
- **Associate Biosafety Officer:** Emory's Associate Biosafety Officer shall be a voting member of the IBC and shall serve as alternate Executive Secretary to the IBC at any meeting of the IBC at which the Biosafety Officer is not in attendance.
- **Director of the EHSO:** The Director of the EHSO shall be a non-voting member of the IBC. In addition, the Director of the EHSO shall serve as an alternative Executive Secretary to the IBC at any meeting of the IBC at which neither the Biosafety Officer nor the Associate Biosafety Officer are in attendance. At any meeting in which the Director of the EHSO serves as Executive Secretary to the IBC, he/she shall also serve as a voting alternate for the Biosafety Officer.
- **Additional Ex-Officio Member:** The President or designee, in its discretion, may appoint up to one additional person from any component or discipline at Emory to serve as a non-voting, ex-officio member of the IBC.

4.5 Member(s) of the OC

Member(s) of the OC may attend the meeting and give input as a guest. **Reference:** NIH Guidelines, Section IV-B-2-a-(2); Charter of the Emory University Institutional Biosafety Committee.

4.6 IBC Chair and Co-Chair

- **Chair:** Emory's President, or his/her designee, shall appoint a Chair of the IBC from among the members appointed to the IBC.
- **Co-Chair:** Emory's President or his/her designee shall appoint a Co-Chair(s). The Co-Chair shall exercise all rights and responsibilities of the Chair in the event of the absence or unavailability of the Chair. The IBC may make recommendations as to who could serve as Co-Chair.

Reference: Charter of the Emory University Institutional Biosafety Committee.

4.7 IBC Executive Secretary

- The Biosafety Officer shall serve as the Executive Secretary for the IBC. At any IBC meeting at which the Biosafety Officer is not in attendance, the Associate Biosafety Officer, or the Director of EHSO shall serve as alternate Executive Secretary for purposes of that meeting, in accordance with Section 2.2 above.
- **Duties:** The Executive Secretary shall be responsible for performing the following duties:
- **Membership Roster:** Keeping a current roster of all members (including the Community Members) of the IBC that specifies for each member (and any alternate members): (a) name; (b) title; (c) contact information; (d) biographical sketch; (e) effective date of appointment and ending date of member's term; (f) specification of whether member is appointed or ex-officio; (g) specification of whether member is voting or non-voting; (h) specification of any office or post held within the IBC by the member (e.g., Chairperson, Co-Chairperson, etc.), including effective date and ending date of terms for which office or post is held;
  (i) specification of whether a member is a Plant Expert, Animal Expert or has human gene transfer expertise; specification of any consultant appointed to the IBC to provide any necessary human gene therapy expertise (see Section 4.3 above).
- **Attendance:** Keeping accurate attendance of all members at each meeting of the IBC.
- **Quorum:** Keeping track to ensure that there is a quorum of members at the beginning and throughout the course of each IBC meeting, including noting within the meeting minutes when any IBC member leaves the meeting and when he/she returns. A quorum shall be constituted when a majority of the voting members of the IBC are present. No IBC business shall be conducted unless a quorum is present. (Note: In the case of an odd number of voting members on the IBC, the number that constitutes a majority shall be ½ of the committee membership rounded up to the nearest whole number, e.g. if there are 13 voting members on the committee, 7 members would constitute the majority).
- **Keeping of Minutes:** Keeping accurate minutes of each IBC meeting, including, but not limited to the following: (a) the date, time and place of the meeting; (b) a list of all individuals in attendance and a record of the presence of a quorum in accordance with Section 4.7 above, including a record of any persons who leave or enter during the course of the meeting and any resulting failure in quorum; (c) a description of any discussion regarding the prior meeting's minutes, including any recommendations for corrections thereto, and a description of the vote as to whether the prior meeting's

minutes were approved or disapproved; (d) a description of all items of old and new business discussed; (e) a description of all projects reviewed and of all items of discussion regarding each such project; (f) a record of all motions made and whether the motions were approved/disapproved;
(g) a record of the votes taken regarding each project or any other item of business requiring a vote by the IBC, including the number of members in favor, those opposed and those who abstained; (h) a description of any changes in IBC membership, including beginning and ending dates of members' terms; (i) a listing of IBC officers, including beginning and ending dates of officers' terms; and (j) the time of the meeting's adjournment.

- **Circulation and Approval of Minutes:** Drafting minutes of each IBC meeting promptly after the conclusion of each such meeting and circulating these minutes to all IBC members at least one week prior to the next scheduled IBC meeting for comment and a vote of approval at that meeting. Final copies of each IBC meeting minutes (including any comments or changes suggested at the meeting at which approval was voted) shall be maintained in a record of "Official Minutes" by the Executive Secretary.
- **Availability of Minutes:** The IBC Official Minutes shall be made available to the public upon request in accordance with NIH Guidelines, Section IV-B-2-a-(7), along with any documents that the IBC has submitted to or received from funding agencies that the funding agencies are required to make public. If the IBC receives any public comments regarding its actions, the Executive Secretary shall forward such comments and the IBC's response to the NIH OSP preferably by e-mail to NIHGuidelines@od.nih.gov.
- **Redacting Meeting Minutes:** Public requests for copies of IBC meeting minutes along with any documents that the IBC has submitted to or received from funding agencies that the funding agencies are required to make public must be promptly forwarded by the Biosafety Officer to the Committee.
- Once received by the Committee, the meeting minutes in question will be reviewed in conjunction with the Biosafety Officer and IBC Chair as necessary, for purposes of identifying information that may be redacted. The Committee may consult with other offices for input/assistance (e.g. Office of the General Counsel). OC will be informed of any request made.
- Information subject to redaction includes, but is not limited to:
    - Trade secret information and other confidential commercial information.
    - Personal information of IBC members (for example, home telephone numbers and addresses).
    - Specific information whose disclosure would directly compromise institutional or national security.
    - Once the information has been redacted, the Biosafety Officer will be responsible for making the redacted minutes available in response to the request.
- **Annual Report:** On behalf of the IBC, and subject to IBC approval, compiling and submitting an annual report to the NIH OSP preferably by e-mail to NIHGuidelines@od.nih.gov. The Annual Report shall contain (i) a roster of all Institutional Biosafety Committee members clearly indicating the Chair, contact person,

Biological Safety Officer (if applicable), plant expert (if applicable), animal expert (if applicable), human gene therapy expertise or ad hoc consultant (if applicable); and (ii) biographical sketches of all Institutional Biosafety Committee members (including community members).

- **Contact Person:** Serving as a "Contact Person" for the IBC, as required by the NIH Guidelines and including contact information and specification as the Contact Person within the Annual Report, as specified in Section 4.7 above.
- **Records:** Collecting and maintaining all records of any actions and activities of the Biosafety Officer and the IBC, including the Official Minutes as set forth in Sections 4.7 above. All records shall be kept for the longest of any retention period required by the NIH Guidelines, or any other applicable federal, state, local or university requirement.

Reference: NIH Guidelines, Sections IV-B-2-a-(3) & IV-B-2-a-(7); Charter of the Emory University Institutional Biosafety Committee; NIH OSP FAQs About IBC Meeting and Minutes - https://osp.od.nih.gov/biotechnology/faqs-about-ibc-meetings-and-minutes/

4.8 Membership Terms and Conditions

- **Member Terms:** Each appointed member of the IBC (excluding ex-officio members) shall be appointed to serve for a term of two (2) or three (3) years from the effective date of appointment (so that member rotation on and off the IBC can be staggered). Alternates' terms shall be concurrent with the member for whom they serve as a member.
- **Officer Terms:** The Chair and Co-Chair(s) shall be appointed to serve for a term of 3-years from the effective date of appointment.
- **Additional Terms:** IBC members, Chair and Co-Chair(s) may be appointed to serve an unlimited number of additional three (3) year terms, whether consecutive or non-consecutive.
- **Appointment/Resignation/Removal:** All members and officers of the IBC, aside from ex officio members/officers, serve at the discretion of Emory's President (or his/her designee) and may be removed from membership and/or have their term as an officer terminated by the President (or his/her designee) at any time by written notice from the President (or his/her designee), to the Executive Secretary of the IBC. If a member or officer is removed or resigns from membership/office prior to the expiration of his/her term, the President (or his/her designee) shall appoint a replacement to serve for the remainder of that person's term. Members and officers may resign by submitting their written resignations (including the effective date of their resignation) to the Executive Secretary. If possible, resigning members/officers may provide the Executive Secretary with the names of potential successors who are interested in serving on the IBC. The Executive Secretary, in turn, may pass such names onto the President, or his/her designee, for consideration. The Executive Secretary shall announce any appointment/resignations, along with their effective dates, at the soonest possible IBC meeting or by written communication to IBC members. Members shall not be permitted to vote or take place in IBC activities until their appointment has become effective and been announced to the other IBC members.

- **Voting:** Each member shall be entitled to one vote. In order to vote, a member must be present at a duly constituted IBC meeting at which a quorum is present; there shall be no voting by proxy.
- **Conflicts-of-Interest:** No IBC member may be involved in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest, except to provide information to the IBC regarding the project. Any such IBC member shall recuse himself/herself from the portion of the IBC meeting in which any such project is considered; shall not vote on the project or be present for the vote; and shall not be counted towards a quorum necessary for the consideration of the project/s. Reference: Section IV-B-2-a-(4)
- **Attendance at Meeting via Computer or Telephonic Means:** An IBC member may attend a meeting of the IBC via conference call, video teleconference or webcam, provided that the member has received in advance the materials to be reviewed at the meeting; the member can hear the meeting and be heard by the other members; the member advises the Executive Secretary if he/she needs to leave at any time during the meeting or conference call; and the member votes by voice on matters submitted for a vote. Members who attend the IBC in this manner may be counted toward establishing quorum for the meeting.
- **IBC Requirements under the NIH Guidelines during a public health emergency** Convening the IBC by teleconference or videoconference is permissible as these modes enable a live meeting to be conducted, thereby fulfilling the expectations of the NIH Guidelines. IBC requirements, such as a quorum present for the conduct of official IBC business and documentation of the meeting (e.g., meeting minutes), still apply regardless of the mode of convening. https://osp.od.nih.gov/biotechnology/interim-lab-biosafety-guidance-for-research-with-sars-cov-2/

Reference: Charter of the Emory University Institutional Biosafety Committee.

5.0 Projects Requiring Submission to the IBC and Review Process

5.1 Definitions Pertinent to this Section

Recombinant and Synthetic Nucleic Acids as defined in the NIH Guidelines:

> Molecules that (a) are constructed by joining nucleic acid molecules and (b) that can replicate in a living cell, i.e., recombinant nucleic acids;
> 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
> molecules that result from the replication of those described in (i) or (ii) above.
> [NIH Guidelines, Section I-B].

5.2 Is IBC Review Required?

- Per the Charter of the Emory University Institutional Biosafety Committee and/or the NIH

Guidelines, all research projects sponsored by Emory University or conducted at Emory facilities that involve work with "Recombinant or Synthetic Nucleic Acid Molecules," as that term is defined above, must be registered with the Biosafety Office. Such research projects that involve IBC NIH Guidelines Research must be reviewed in accordance with and comply with all requirements of the NIH Guidelines. A table setting forth those experiments covered by the NIH Guidelines, along with a grid showing which NIH units and other Emory committees (e.g., IRB, IACUC) must review projects containing such experiments is set forth in rDNA Experiments Covered by the NIH Guidelines. **See Appendix 1** for experiments covered by the NIH Guidelines and the required review.

- **Collaborative Research:** Collaborative research that takes place at Emory and non-Emory facilities may require similar review by appropriate oversight bodies at the non-Emory site.

5.3 What type of IBC Review Process is Employed?

The type of review process used by the IBC is described below:

- NIH Guidelines Research: All research that involves procedures that are covered by the NIH Guidelines (see rDNA Experiments Covered by the NIH Guidelines, including the use of recombinant or synthetic nucleic acids in human research participants) is reviewed by the IBC. In addition, the IBC is responsible for fulfilling all duties assigned to it by the NIH Guidelines, as set forth in Section 3.0 above.

Reference: NIH Guidelines, Section III; Charter of the Emory University Institutional Biosafety Committee, Preamble.

5.4 Registration of biological materials

Each PI who plans to work with Recombinant or Synthetic Nucleic Acid Molecules must complete the electronic registration including project forms and complementary pathogen and/or viral vector forms as requested by the Biosafety Officer. Certified biological registrations will be reviewed by the Biosafety Officer and the IBC in accordance with Section 5.2. Amendments to add biological materials will be completed using the electronic registration.
Reference: NIH Guidelines, Section IV-B-2-a-(5).

5.5 Tracking of Research Projects

Once the PI certifies the biological registration (new, annual update, or amendment), the status will change to "Awaiting EHS review" or "Awaiting Amendment Review". The Biosafety Officer shall assign a number to the project form, which shall be included in the Approval letter. The PI should refer to the assigned project number in all correspondence with the Biosafety Officer and the IBC regarding the research project.
Reference: NIH Guidelines, Section IV-B-2-a-(5).

5.6 Initial Review by Biosafety Officer

The Biosafety Officer, or a designee, shall review each submitted biological registration for completeness and make a preliminary determination as to the type of review that should be provided per Section 5.3 above. The IBC Chair shall reserve the right to review this determination and concur or assign a different type of IBC review. An obviously incomplete biological registration

shall be returned to the PI for completion prior to being presented to the IBC for review. IBC members shall be provided access to the biological registrations to be reviewed by the Committee prior to the meeting.
Reference: NIH Guidelines, Section IV-B-2-a-(5).

5.7 Assignment for Presentation

For biological registrations requiring IBC review, the Biosafety Officer with the concurrence of the IBC Chair shall assign a reviewer(s) for each biological registration to be reviewed; provided, however, that the following project amendments may be reviewed solely by the Chair of the IBC or his/her designee:

- A change in the title of a project;
- A change to a project for research when the change pertains only to a change in research personnel, other than the PI, assigned to the project; or
- An amendment that does not change the biosafety profile (e.g. no change in Biosafety level or change in animal species).

Reference: NIH Guidelines, Section IV-B-2-a-(5).

5.8 Presentation at the IBC Meeting

All biological registrations (new, annual update, or amendment) that require review by the full IBC shall be scheduled for presentation by the assigned reviewer(s) at an upcoming IBC meeting. For the biological registration to be reviewed, a reviewer must be present at the meeting otherwise the project shall be deferred until the next meeting of the IBC at which a reviewer can be present.
Reference: NIH Guidelines, Section IV-B-2-a-(5).

5.9 Notification to the PI

The PI shall receive notice from the IBC indicating that his/her biological registration has been received, along with the type of review process that the project will undergo, and if full IBC review is required, the date of the IBC meeting at which the biological registration or amendment is scheduled for review. Certification of the biological registration (new, annual update, or amendment) must be received by the submission deadlines posted at on the EHSO website to be reviewed at that meeting. After the biological registration (new, annual update, or amendment) is reviewed, the PI shall be notified by the IBC as to the status assigned to the protocol per Section 5.11 below.
Reference: NIH Guidelines, Section IV-B-2-b-(2); Section IV-B-2-a-(5).

5.10 Amendments to Biological registrations or projects

If a PI adds or modifies an (referred to herein as an “amendment”) approved biological registration, then the PI must certify the Summary of Biological Use page including changes to the project form [certification status changes to *Awaiting EHS review* or *Awaiting Amendment Review*]. The Biosafety Office is notified of a modification made to a biological registration only after it is certified by the PI. As appropriate under Section 5.3, the Biosafety Officer or the IBC must review and approve the amendment before the additions/modifications can be implemented. The minor amendments to projects, as described in Section 5.7, that initially were reviewed by the IBC may be reviewed and approved by the Biosafety Officer with the concurrence of the IBC Chair.

- All other amendments to the approved registration that initially required IBC review must be approved by the IBC utilizing the same procedure followed for the original review of the registration requiring full IBC review must be received by the submission deadlines posted on the EHSO website to be reviewed at the meeting. After the amendment is reviewed, the PI shall be notified by the IBC as to the status granted to the Amendment per Section 5.9.
- Notwithstanding anything to the contrary set forth in Section 5.3 above, all projects associated with other institutional approvals, such as IACUC and IRB, must also follow that Institutional Committee review process independent of the IBC review.

Reference: NIH Guidelines, Section IV-B-2-a-(5).

5.11 Project/Amendment Status

As a part of its review of a new, updated or amended biological registration, the IBC will assign one of the following statuses to the project or amendment:

- **Approved:** This status is given if the IBC approves the project /amendment without the need for any changes to the project/amendment by the PI. An approval is good for one year, unless a shorter timeframe is specified by the IBC.
- **Pending Approval:** This status is given if the IBC has minor questions or issues about the project/amendment that the PI must resolve before the project can receive the approval letter. The IBC shall provide the PI with a list of these questions or issues, and the PI must respond to each of these questions/issues in full within 30 days after receiving the list. If the PI fails to respond within this period, then the project/amendment will be withdrawn by the IBC. The PI's response to the questions/issues will be given to the reviewer(s) assigned to the project. They will review these responses and report to the IBC Chair or the IBC Chair's designee as to whether the response is adequate, and if so, the project/amendment will be granted the Approved status. No work under the project/amendment may take place until the project/amendment is Approved.
- **Re-Review/Deferred:** This status is given if the IBC has a significant number of questions or issues regarding a project/amendment, or if the IBC has questions or issues of a substantive nature regarding the project/amendment. The IBC shall provide the PI with a list of its questions or issues and the PI must respond to each of these questions/issues in full within 30 days after receiving the list. If the PI fails to respond to the list within this time the project/amendment will be Withdrawn. The PI's response to the questions/issues must go back to the full IBC for review and a vote as to approval/disapproval. No work under the project/amendment may take place until the project/amendment is Approved.
  Project approval periods shall be measured from the date of the meeting at which the IBC granted Approval or Pending Approval; provided, however, that in the case of Pending Approval, work under the project cannot begin unless and until the PI receives a final approval letter from the IBC.
- **Disapproved:** This status is given if the IBC has major substantive concerns with the project/amendment. For example, the project/amendment may not be justified; it may pose severe or unnecessary risk; it may have been deferred on several occasions; or the PI may have failed to adequately address issues or questions about the

project/amendment. Further revisions to a Disapproved project/amendment will not be accepted by the IBC. The PI may re-write the project/amendment with substantial changes and submit it as a new project/amendment.

- **Withdrawn**: The status is given to projects/amendments that the IBC has removed from further consideration by the IBC. This may occur at the PI's request or when the PI has failed to respond to questions from the IBC in the allotted time.
- **Suspended:** This status is given if the IBC determines that serious questions or issues have arisen about a project, or the manner in which the project is being conducted that should cause its Approved status to be removed. For example, the IBC may receive allegations that the project is not being conducted in accordance with the NIH Guidelines or it may receive notice from another University committee with jurisdiction over the project that the project has been suspended by that group. The IBC may, in its discretion, suspend all or part of a project. The IBC, in connection with the General Counsel, shall immediately notify the PI of any suspension, and the PI shall immediately stop any work under the suspended project (or suspended portion of the project) until clearance to resume work is received from the IBC. The IBC may conduct or cooperate in such inquiries/investigations as it deems necessary to determine if a project should be Suspended, or to determine if a Suspended project may have its Approved status reinstated. OC will be notified about the suspension.
- **Terminated:** This status is given to projects that are no longer active. The electronic project form will be archived. Research may not be conducted under projects that are terminated. The PI may terminate a project by writing to the IBC Chair or his/her designee. If a PI does not take proper steps to renew a project when its Approved status is set to expire, then the project will be Terminated. The IBC may also take steps to Terminate a project that has been Suspended, based on the results of appropriate inquires/investigations conducted by the IBC or other appropriate Emory University committees or units with jurisdiction over the project. The IBC shall send out a written notice of Termination to the PI of any project that is Terminated. This notice may be copied to other University committees or units, as appropriate. No work shall continue under a project after it is Terminated. If the PI wishes to conduct future work under a Terminated project, he/she must submit the project for approval as a new project.

Reference: NIH Guidelines, Section IV-B-2-b-(2).

5.12 Project Renewals

Each project that is Approved by the IBC is approved for one year. The IBC will review the biological registration, including all projects, every three years. PIs shall receive automated reminders 90 days prior to that deadline and continue with reminders approximately every 30 days month until the biological registration is certified. The IBC shall notify the PI as to the results of the IBC's vote regarding the renewal of the protocol. If a PI fails to certify the biological registration by the 10th of the month prior to the expiration of their existing protocol, or if the IBC denies the renewal of project, then the projects included in the biological registration is Terminated, the electronic biological registration will be set to "Denied" and the IBC will send out a notice of Termination. This notice of Termination may be copied to other University committees or units as appropriate. No work should continue under a project after it is Terminated. If the PI wishes to

conduct future work under a Terminated project, he/she must re-certify the biological registration for approval as a new protocol.
Reference: NIH Guidelines, Sections IV-B-2-b-(2) & IV-B-2-b-(5).

5.13 Periodic Review

On behalf of the institution, the IBC is responsible for periodically reviewing recombinant and synthetic nucleic acid molecule research conducted at the institution to ensure compliance with the NIH Guidelines. The PI of an approved IBC project is responsible for providing an annual update on the status of the project. The annual update consists of verification of personnel training, occupational health requirements, engineering controls, and completion of annual laboratory self-inspections.
Reference: NIH Guidelines, Section IV-B-2-b-(5).

5.14 Project Terminations

A PI should request that the IBC Terminate a project when the project has ended and Recombinant or Synthetic Nucleic Acid Molecules are no longer being used. The PI should notify the IBC in writing of the request for Termination. If a faculty member leaves the University, he/she should notify the IBC in writing that his/her project should be Terminated or is being transferred to another PI at Emory in accordance with Section 5.15 below. In addition, the IBC may Terminate a Project as set forth above in Section 5.11. Terminated projects will be archived in the electronic biological registration.
Reference: NIH Guidelines, Sections IV-B-2-b-(2).

5.15 Transferring a Project to Another Investigator

If a PI desires to transfer his/her project to another PI at Emory, the transfer must be processed as an amendment pursuant to Section 6.10 above, and the amendment must be accompanied by letter describing the planned transfer signed by both the current PI and the prospective PI. No work may take place on a transferred project unless and until the IBC has approved the transfer through the applicable review process set forth in Section 5.3 If the IBC is notified, or otherwise becomes aware, that a PI on an Approved project is no longer at Emory University and that PI had made no attempt to transfer the project to another PI at Emory, then the IBC will contact the chair of the respective department and inquire as to whether they would like the project transferred to them as PI. Until a new PI has agreed to and received a transfer of the project, the project will be Suspended, and no work can take place on it. The participants who are eligible to serve as a PI will then have 30 days in which to submit an amendment to have the project transferred to one of them as PI. If no amendments are received during this period, then the project will be Terminated.
Reference: NIH Guidelines, Sections IV-B-2-b-(2).

6.0 Review by Other Emory Committees

6.1 Other Committees

Projects reviewed by the IBC may require review and approval by other University Committees before the work under the project can begin. For example, if the project utilizes animals, then the project will require review by the Emory University Institutional Animal Care and Use Committee (IACUC). Similarly, if the project involves human research participants, then review by the Emory University Institutional Review Board (IRB) will be required.

6.2 Coordination Among Committees

Committees involved in the review of research projects at Emory shall coordinate among themselves the review of projects requiring approval by multiple committees. Committees shall also coordinate among themselves the communication of any *Terminations or Suspensions* regarding Projects under the jurisdiction of multiple committees. In general, if a project is subject to the jurisdiction of and requires review by either the IRB or the IACUC, the IBC shall communicate any decision on its part regarding the approval of that project to either or both committees, and the approval by the IRB and/or the IACUC must be in place before the PI can proceed with the project. **Reference:** NIH Guidelines, Sections IV-B-2-b-(2); Section IV-B-2-a-(5).

7.0 Responsibilities of PIs

7.1 General Responsibilities

- PI is Responsible for Compliance with NIH Guidelines and University Policies: Each PI at Emory is responsible for ensuring that his/her research covered by the NIH Guidelines (i.e., IBC NIH Guidelines Research) is in full compliance with those NIH Guidelines. Each PI also is fully responsible for ensuring that his/her research that is subject to these Policies and Procedures is in full compliance therewith, as well as with any other applicable laws and regulations or University policies and procedures. Any failure on the part of the PI to comply with such applicable laws, regulations, policies and procedures may result in Suspension or Termination of the research and/or other appropriate actions, including disciplinary actions, being taken regarding the research or the PI by appropriate University committees or officials.
- **Research Subject to IBC Review:** The PI shall be responsible for ensuring that all research under a project requiring IBC review is properly submitted to the IBC for review and that IBC approval is granted before any research under the project is initiated. If the PI may be doing research covered in Appendix C and/or F of the NIH Guidelines, the PI is required to consult with the Biosafety Officer before commencing the work. The PI shall also be responsible for ensuring that any required approval from other University Committees is obtained before initiating the research (e.g., IRB approval, IACUC approval, etc.). The PI shall also make any proper notification to IBC of the initiation of any Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation in accordance with Section III-E of the NIH Guidelines.
- **Reporting Responsibilities:** The PI shall fulfill all reporting responsibilities placed

upon him/her per Section 7.2 below.

- **Training:** The PI shall be adequately trained in good microbiological techniques and shall adhere to such techniques in his/her research. The PI also shall ensure that his/her employees and assistants are adequately trained (the training is documented with dates and subject matter covered) and follow appropriate lab techniques. See Section 1.4 for additional information regarding training.
- **Adherence to IBC and Other University Safety Plans:** The principal investigator shall adhere to all IBC-approved and other University-approved plans for handling, managing, using, storing and shipping Recombinant or Synthetic Nucleic Acid Molecules, including plans regarding the handling of accidental spills and personnel contamination.
  Reference: NIH Guidelines, Sections IV-B-7

7.2 Specific Responsibilities of the PI regarding the IBC

- **Initial Submission to IBC:** The PI shall make an initial determination of the required level of physical and biological containment required for the work in his/her project in accordance the NIH Guidelines and select appropriate microbiological practices and lab techniques to be used for the research. The PI shall submit his/her initial research project and any subsequent amendment to that project to the IBC for review and approval/disapproval in accordance the requirements of the NIH Guidelines (including the requirements of Sections III-A, III- B, III- C, III- D and III-E).
- **Continuing Communication with the IBC**: The PI shall be responsible for remaining in communication with the IBC throughout his/her conduct of any project subject to the IBC's jurisdiction; following any required procedures for renewal or amendment of the project; and immediately advising the IBC of any adverse events, significant problems, violations of NIH Guidelines or significant research-related accidents or illnesses related to the project.
- **Human Gene Transfer Experiments:** The PI shall ensure that no human research participant shall be enrolled in a Human Gene Transfer Experiment until the IBC has reviewed and issued an approval letter.
  According to the NIH Guidelines (2019), human gene transfer is the deliberate transfer into human research participants of either:
  1. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or
  2. Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:
     a. Contain more than 100 nucleotides; or
     b. Possess biological properties that enable integration into the genome (e.g., cis elements involved in integration); or
     c. Have the potential to replicate in a cell; or
     d. Can be translated or transcribed.

  All clinical trials involving recombinant or synthetic nucleic acids in humans to be conducted at Emory University will undergo IBC review via the process described in the Guidelines for IBC Review of Human Gene Transfer:

http://www.ehso.emory.edu/documents/guidance-document-ibc-review-of- human-gene-transfer.pdf

- The focus of the IBC review of HGT research should be equivalent to their review of the biosafety aspects of another covered research, for example:
  - required containment levels
  - potential for shedding
  - 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
- Documents required for IBC review:
  - Scientific abstract
  - Clinical Study Protocol
  - Product description:
  - Pharmacy Manual (delivery
  - Investigational Brochure
  - Consent (if available)

Reference: Points to Consider: Institutional Biosafety Committee (IBC) Review of Human Gene Transfer Protocols

See **Appendix 2** for Human Gene Transfer involving investigational products with FDA Emergency Use Authorization

7.3 Specific Responsibilities of PI regarding Laboratory Staff Prior to and During Conduct of Research

Prior to initiating research, the PI shall:

- Make available to all laboratory staff the projects that describe the potential biohazards and the precautions to be taken;
- Instruct and train laboratory staff in the practices and techniques required to ensure
- safety, as well as in the procedures for dealing with accidents; (the training is documented with dates and subject matter covered); and
- Inform the laboratory staff of the reasons and provision for any precautionary medical practices in which they are advised or requested to participate, e.g., vaccination, serum collection.
- During the Conduct of the Research the PI shall:
  - Be responsible for supervising the safety performance of the laboratory staff to ensure that the required safety practices and techniques are followed;

- Correct work errors and conditions that may result in the release of recombinant or synthetic nucleic acid materials;
- Ensure the integrity of the physical containment and the biological containment used in the project.

Reference: NIH Guidelines, Sections IV-B-7-d and IV-B-7–e.

7.4 Specific Responsibilities of PI regarding Submission of Information/Petitions to NIH OSP

- The PI shall be responsible for submitting the following information/petitions to NIH OSP regarding the PI's projects, and unless otherwise specified, copies of all such information/petitions shall also be provided to the IBC:
- Certification of new host-vector systems;
- Petitions for proposed exemption from the NIH Guidelines, along with a copy of notice of the request for the exemption sent to the IBC;
- Petition, with a copy of the IBC's concurrence, for approval to conduct experiments specified in NIH Guidelines, Section III-A-1, Major Actions Under the NIH Guidelines and III-B, Experiments that Require NIH OSP and IBC Approval before Initiation;
- Petition for determination of containment for experiments requiring case-by-case review; and
- Petitions for determination of containment for experiments not covered by the NIH Guidelines.

Reference: NIH Guidelines, Section IV-B-7-b.

7.5 PI Reporting of Exposures, Incidents other Events to Biological Safety Officer

- The PI shall immediately report the occurrence of the following events to the Biological Safety Officer who in turn shall report such events to the IBC Chair and determine further reporting requirements:
  - Significant problems pertaining to any project subject to the IBC's jurisdiction, including problems pertaining to the operation and implementation of containment practices and procedures.
  - Violations of NIH Guidelines.
  - Any significant research-related accidents and illnesses, including work-related exposures, injuries, illnesses, and/or laboratory accidents. Any such events concerning human subjects also shall be reported to the Emory IRB and events involving animal subjects also shall be reported to the Emory IACUC using the PeopleSoft reporting system.
- **Further Reporting:** The PI shall then, in conjunction with the Biological Safety Officer, further report any of the events set forth in the section above as follows:
  - To the IBC by letter to the Chair of the IBC – immediately
  - To any Greenhouse/Animal Facility Director; - immediately
  - To NIH OSP - Reports to the NIH OSP shall be sent to the Office of Science Policy, National Institutes of Health, preferably by e-mail to: NIHGuidelines@od.nih.gov within 30 days.

- To any other appropriate authorities within legally prescribed times or 30 days, whichever is less.

- For Human Gene Transfer Experiments, Principal Investigators must report to the biosafety officer exposures and accidents involving the recombinant or synthetic product. The *NIH Guidelines* require that "…any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" be reported to NIH. Reports of incidents can be emailed to NIHguidelines@od.nih.gov. Relevant incidents would include spills and accidents that result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of HGT research.

Reference: NIH Guidelines, Section IV-B-7-a-(3); IV-B-7-e-(2) to (4).

8.0 Conditions of Approval

8.1 Lab Inspections

As a condition of approval for all IBC projects, the lab(s) at which the projects are to be carried out must have completed an annual laboratory self-inspection in accordance with criteria established by the Biosafety Office. The Biosafety Officer shall establish the intervals at which labs must be re-inspected, which shall be no less than annually.

8.2 Occupational Health

As a condition of approval for IBC projects, the IBC may establish occupational health requirements that must be fulfilled by the personnel working on the project, including, but not limited to coordination with Employee Health; obtaining certain immunizations (or signing declination statements, as appropriate); and obtaining certain health screening or testing.

9.0 Dual Use Research of Concern (DURC)

DURC is 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. Per United States Government requirements, all research conducted at the University involving DURC agents are subject to Institutional oversight regardless of funding source. Emory University's policy for institutional oversight of life sciences dual use research of concern is located at Appendix 1 of Emory University Policy for Oversight of Life Sciences Dual Use Research of Concern. IBC projects that require DURC review will undergo DURC review via the process described in Appendix 1 of Emory University Policy for Oversight of Life Sciences Dual Use Research of Concern. http://www.ehso.emory.edu/content-manuals/DURC-policy.pdf

10.0 Externally Administered IBC

An externally administered IBC is an IBC that is administered by an entity (i.e. institution, commercial entity, university, etc.) other than the institution performing research subject to the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). Per direction from NIH, Emory University IBC may serve as an External IBC to specific Emory projects administered offsite.

Reference: https://osp.od.nih.gov/biotechnology/faqs-on-externally-administered-ibcs/?pdf=10455

Appendix 1. Guidelines for Experiments Covered by the NIH Guidelines

	NIH Director approval	NIH OSP approval	IBC approval before initiation	IBC notice upon initiation	IACUC approval	IRB approval
Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture) [III-A-1-a]	■	■	■			
Transfer of a drug resistant gene to microorganisms compromising the use of veterinary medicine	■	■	■		■	
Cloning of toxin molecules with LD50 of less than 100 ng/kg body weight [III-B-1]		■	■			
Deliberate transfer of recombinant or synthetic nucleic acid molecules into one or more human research participant [III-C-1]			■			■
Using risk group 2, 3, 4 or restricted agents as host-vector systems [III-D1]			■			
Experiments in Which DNA From Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems [III-D2]			■			

	NIH Director approval	NIH OSP approval	IBC approval before initiation	IBC notice upon initiation	IACUC approval	IRB approval
Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems [III-D-3]						
Experiments using recombinant or synthetic nucleic acids in Whole Animals [III-D-4]						
The creation of transgenic or knock-out rodents, arthropods, nematodes, or other animals						
The breeding of transgenic or knock-out rodents, arthropods, nematodes, or other animals housed at ABSL-2 and above						
Use of recombinant or synthetic nucleic acids in animals (transgenic or otherwise)						
Purchase or transfer of transgenic animals housed at ABSL-2 or higher						
Plant experiments with animals or arthropods						
Experiments Involving Whole Plants [III-D-5]						

	NIH Director approval	NIH OSP approval	IBC approval before initiation	IBC notice upon initiation	IACUC approval	IRB approval
Experiments with more than 10L of culture [III-D-6]			■			
The use of influenza viruses [III-D-7]			■			
Experiments that do not fall under Sections III-A, B, C, D, F or Appendix C of the NIH Guidelines (e.g. Use of RG1 microbes or viral vectors for in vitro or in vivo research) [III-E]				■		
Experiments Involving the Formation of Recombinant or Synthetic Nucleic Acid Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus [III-E-1]				■		
Breeding and creation of transgenic rodents housed at ABSL-1 [III-E3]				■	■	

NIH OSP = National Institutes of Health Office of Science Policy

IBC = Institutional Biosafety Committee

IACUC = Institutional Animal Care and Use Committee

IRB = Institutional Review Board

Appendix 2. IBC review of studies involving Emergency Use Authorization

- Per the NIH Guidelines, Section III-C-1 Research cannot be initiated until Institutional Biosafety Committee and all other applicable institutional and regulatory authorization(s) and approvals have been obtained.

- The deliberate transfer of recombinant or synthetic nucleic acids **into one** human research participant, conducted under an FDA regulated individual patient expanded access IND or protocol, including for emergency use, is not research subject to the NIH Guidelines and thus does not need to be submitted to an IBC for review and approval. FAQs on the NIH Guidelines Q10 https://osp.od.nih.gov/biotechnology/faqs-on-the-nih-guidelines-research-synthetic-nucleic-acid-molecules/

- Investigational products which have received FDA's Emergency Use Authorization and will be used in more than one participant must be submitted for IBC review

- Amendments to an investigational brochure already reviewed by the IBC whereby the additional product shares the same properties as the one reviewed by the Committee, will be reviewed by the biosafety office and deferred to the IBC chair for final approval.