

SAF-101, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY INSTITUTIONAL BIOSAFETY COMMITTEE

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SAF-101, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY INSTITUTIONAL BIOSAFETY COMMITTEE**1. GLOSSARY**

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

1.1. Terms that Appear in Bold/Italicized Text

- 1.1.1. **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.
- 1.1.2. **Human Gene Transfer Experiment:** Research proposal involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into human subjects.
- 1.1.3. **IBC:** Institutional Biosafety Committee (**IBC**) established in accordance *NIH Guidelines* to perform duties set forth in [Section 4.0](#) of these Policies and Procedures.
- 1.1.4. **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**.
- 1.1.5. **“NIH Guidelines” or the “Guidelines”:** The *NIH Guidelines* for Research Involving Recombinant DNA or Synthetic Nucleic Acid Molecules found at the following website: <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>
- 1.1.6. **NIH Guidelines Research:** Research involving recombinant DNA or synthetic nucleic acid molecules that is subject to the *NIH Guidelines* and must be reviewed by the **IBC** in accordance with those guidelines.
- 1.1.7. **NIH Recombinant DNA Advisory Committee (NIH RAC):** *NIH* Committee responsible for advising *NIH* on current state of knowledge and technology regarding recombinant DNA and for reviewing and approving experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human research participants, prior to the human subjects enrollment.

1.2. Names/Acronyms used within these Policies and Procedures

- 1.2.1. Emory University Environmental Health and Safety Office (EHSO)
- 1.2.2. Emory University Institutional Review Board (IRB)
- 1.2.3. Emory University Institutional Animal Care and Use Committee (IACUC)
- 1.2.4. Emory University Office of Compliance (OC)
- 1.2.5. National Institutes of Health (NIH)
- 1.2.6. National Institutes of Health Office of Biotechnology Activities (NIH OBA)

SAF-101, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY INSTITUTIONAL BIOSAFETY COMMITTEE**2. SCOPE AND PURPOSE OF POLICIES AND PROCEDURES****2.1. Scope of Policies and Procedures**

- 2.1.1. 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:
- 2.1.1.1. Recombinant DNA molecules, and or synthetic nucleic acid, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules and/or other genetically altered organisms or agents, including organisms and viruses containing such molecules
- 2.1.2. Throughout these Policies and Procedures, all research described within this [Section 2.1](#) shall collectively be referred to herein as “**IBC Research**”.

Reference: *NIH Guidelines* for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, **Section I-A** (September 2012, as amended, hereinafter referred to as the “*NIH Guidelines*” or the “*Guidelines*”); Charter of the Emory University [Institutional] Biosafety Committee.

2.2. 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:

- 2.2.1. Reviewing and approving any proposed **IBC Research** prior to its Initiation.
- 2.2.2. 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*, including any required review by the *NIH Recombinant DNA Advisory Committee (NIH RAC)*.
- 2.2.3. Establishing policies and procedures that the **IBC** will follow in its initial and continuing review of **IBC Research**, including **IBC NIH Guidelines Research**.
- 2.2.4. In connection with the University’s EHSO, establishing and implementing policies and procedures that investigators at Emory should follow in order to provide for the safe conduct of **IBC Research (NIH Guidelines Research)**, and in particular, the establishment and implementation of policies and procedures to ensure that **NIH Guidelines Research** is carried out in compliance with the *NIH Guidelines*.

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

2.3. Institutional Responsibilities Under Policies and Procedures

- 2.3.1. **Responsibilities Regarding *NIH Guidelines 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*):**

In order to ensure that all **IBC/NIH Guidelines 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:

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- 2.3.1.1. Establishment of an **IBC**.
- 2.3.1.2. Appointment of appropriate members to the **IBC** in accordance with [Section 5](#) below.
- 2.3.1.3. Appointment of a **Biological Safety Officer** (also referred to herein as a “**Biosafety Officer**”).
- 2.3.1.4. Establishment and implementation of a policy and procedure for review of recombinant or synthetic nucleic acid molecules research involving human subjects in which Emory participates or sponsors that falls within the purview of the **NIH Guidelines** (i.e., constitutes **NIH Guidelines Research**). Specifically with regard to such research for which Emory is prime contractor or prime awardee, Emory will ensure that no research participant is enrolled in a **Human Gene Transfer Experiment** until the following steps have been completed: (i) the **NIH RAC** review process has been completed; (ii) Emory **IBC** approval has been obtained, as well as **IBC** approval from each institution at which the recombinant or synthetic nucleic acid molecule material will be administered to human subjects, if administration occurs at institutions other than, or in addition to, Emory; (iii) Emory IRB approval, and other institutions’ IRB approval, as applicable, has been obtained; and (iv) all applicable regulatory authorizations have been obtained.
- 2.3.1.5. Providing assistance to Principal Investigators (PI) at Emory who are conducting **IBC NIH Guidelines Research** in order to ensure that these investigators are in compliance with the **NIH Guidelines**.
- 2.3.1.6. Ensuring 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**. Re-training will be required every three years.
- 2.3.1.7. Ensuring 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.
- 2.3.1.8. Evaluating the necessity for health surveillance of personnel involved in individual recombinant DNA **IBC NIH Guidelines Research** projects and, if and when appropriate, conducting a health surveillance program for such projects.
- 2.3.1.9. If and when appropriate, in accordance with the **NIH Guidelines**, establishing and maintaining a health surveillance program for personnel engaged **IBC NIH Guidelines Research** that consists of 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 protocol approval.
- 2.3.1.10. (a) Reporting by the PI 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

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Biosafety Officer to the Emory University OC and the Chair of the **IBC**. (b) 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 OBA the following address: Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Dr., Suite 750, MSC 7985, Bethesda, MD 20892-7985 (or 20817 for mail sent by means other than the United States Postal Service); Phone – (301) 496-9838; FAX – (301) 496-9839. 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** (see [Section 4.2.7](#) below). Copies of any reports made by **Biosafety Officer** shall be provided to the Chair of the **IBC**.

Reference: *NIH Guidelines*, Sections IV-B-1 through IV-B-1-j.

2.4. *Establishment of IBC and Biological Safety Officer Position*

2.4.1. **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 2.1](#) 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.

2.4.2. **Biological Safety Officer:** 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-b & IV-B-1-c.

3. SCOPE OF BIOSAFETY OFFICER DUTIES

3.1. *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

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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*.

3.2. Duties

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

- 3.2.1. Making periodic inspections of laboratories at which research subject to the jurisdiction of the *IBC* is being conducted in order 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).
- 3.2.2. 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*, as well as 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 OBA* or other governmental agencies or sponsors that are required by the *NIH Guidelines*, or other applicable laws or regulations (see [Section 2.3](#) above and [Section 4.2.7](#) below) and that copies of any such reports have been provided to the *Biosafety Officer*, Chair of the *IBC*. OC will be sent copies of the reports.
- 3.2.3. Developing an emergency plan for handling accidental spills and personnel contamination and investigating laboratory accidents that concern recombinant or synthetic nucleic acid molecules *IBC NIH Guidelines Research*, which plans shall be reviewed and approved by the *IBC*. In addition, as a condition of protocol approval, the *IBC* may require PIs to develop protocol specific plans for handling such incidents.
- 3.2.4. Providing advice on laboratory security.
- 3.2.5. Providing technical advice to PIs and the *IBC* on research safety procedures.
- 3.2.6. 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*, Sections IV-B-2-a-(1), IV-B-3.

4. SCOPE OF *IBC* DUTIES

4.1. General Duties of the *IBC*

The *IBC's* general duties shall include the following:

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

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

4.2. Duties of the *IBC* Under the *NIH Guidelines*

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

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- 4.2.1. Reviewing recombinant or synthetic nucleic acid molecules research conducted at or sponsored by Emory to determine if it constitutes **IBC/ NIH Guidelines Research** per **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 protocols 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) if necessary.
- 4.2.2. Notifying the PI of the results of the **IBC's** review and approval or disapproval.
- 4.2.3. 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*.
- 4.2.4. Setting containment levels for protocols as set forth in **NIH Guidelines**, Sections III-D-4-b, *Experiments Involving Whole Animals* and III-D-5, *Experiments Involving Whole Plants*.
- 4.2.5. 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.).
- 4.2.6. 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.
- 4.2.7. 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 OBA** within 30 days of occurrence unless the **IBC** determines that a report has already been filed with the institutional official and the **NIH OBA** by the PI or other Emory official. Reports shall be sent to **NIH OBA** at the address specified in [Section 2.3.1.10](#) 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 IBC**.

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

5. MEMBERSHIP AND ORGANIZATION OF THE **IBC**

5.1. *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).

- 5.1.1. **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

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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 [Institutional] Biosafety Committee

5.2. *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).

5.3. *Specific Qualifications of Particular Members*

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

- 5.3.1. One (1) member shall be a non-doctoral staff member from an Emory biomedical laboratory who represents laboratory technical staff.
- 5.3.2. 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.
- 5.3.3. 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**:
 - 5.3.3.1. 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 protocols involving experiments that utilize *NIH Guidelines*, Appendix P, *Physical and Biological Containment for Recombinant DNA Research Involving Plants*.
 - 5.3.3.2. 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**

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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*.

- 5.3.3.3. Sufficient members with adequate expertise and training to evaluate recombinant DNA research involving human research participants and to ensure that all aspects of *NIH Guidelines, Appendix M, Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant or Synthetic Nucleic Acid Molecules in to One or More Human Research Participants*, 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.
- 5.3.3.4. 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

5.4. *Ex Officio Members*

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

- 5.4.1. **Biosafety Officer:** Emory's **Biosafety Officer** shall be a voting member of the **IBC** and also shall serve as Executive Secretary to the **IBC**
- 5.4.2. **Associate Biosafety Officer:** Emory's Associate Biosafety Officer shall be a voting member of the **IBC** and also shall serve as alternate Executive Secretary to the **IBC** at any meeting of the **IBC** at which the **Biosafety Officer** is not in attendance.
- 5.4.3. **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**.
- 5.4.4. **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**.

- 5.5. Member(s) of the OC may attend the meeting and give input as a guest.

Reference: *NIH Guidelines*, Section IV-B-2-a-(1); Charter of the Emory University [Institutional] Biosafety Committee.

5.6. *IBC Chair and Co-Chair*

- 5.6.1. **Chair:** Emory's President, or his/her designee, shall appoint a Chair of the **IBC** from among the members appointed to the **IBC**.
- 5.6.2. **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

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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.

5.7. **IBC Executive Secretary**

5.7.1. 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 [Sections 5.4.2](#) and [5.4.3](#) above.

5.7.2. **Duties:** The Executive Secretary shall be responsible for performing the following duties:

- 5.7.2.1. **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 (see [Section 5.3.3.1](#) above), Animal Expert (see [Section 5.3.3.2](#) above) or has human gene therapy expertise (see [Section 5.3.3.3](#) above); specification of any consultant appointed to the **IBC** to provide any necessary human gene therapy expertise (see [Section 5.3.3.3](#) above).
- 5.7.2.2. **Attendance:** Keeping accurate attendance of all members at each meeting of the **IBC**.
- 5.7.2.3. **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 $\frac{1}{2}$ 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).
- 5.7.2.4. **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 5.7.2.3](#) 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 protocols reviewed and of all items of discussion regarding each such protocol; (f) a record of all motions made and whether the motions were approved/disapproved; (g) a record of the votes taken with regard to each protocol 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'

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terms; (i) a listing of **IBC** officers, including beginning and ending dates of officers' terms; and (j) the time of the meeting's adjournment.

- 5.7.2.5. **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.
- 5.7.2.6. **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. In the event that the **IBC** receives any public comments regarding its actions, the Executive Secretary shall forward such comments and the **IBC's** response to the **NIH OBA** at the following address: Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Dr., Suite 750, MSC 7985, Bethesda, MD 20892-7985 (or 20817 for mail sent by means other than the United States Postal Service); Phone – (301) 496-9838; FAX – (301) 496-9839.
- 5.7.2.7. **Redacting Meeting Minutes**
- 5.7.2.7.1. 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.
- 5.7.2.7.2. 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.
- 5.7.2.7.3. Information subject to redaction includes, but is not limited to:
- 5.7.2.7.3.1. Trade secret information and other confidential commercial information
- 5.7.2.7.3.2. Personal information of **IBC** members (e.g. home telephone numbers and addresses)
- 5.7.2.7.3.3. Specific information whose disclosure would directly compromise institutional or national security
- 5.7.2.7.4. Once the information has been redacted, the **Biosafety Officer** will be responsible for making the redacted minutes available in response to the request.
- 5.7.2.8. **Annual Report:** On behalf of the **IBC**, and subject to **IBC** approval, compiling and submitting an annual report to the **NIH OBA** at the address specified in [Section 5.7.2.6](#) above. The Annual Report shall contain all information specified in [Section 5.7.2.1](#) above.

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- 5.7.2.9. **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 5.7.2.1](#) above.
- 5.7.2.10. **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 5.7.2.4](#) and [5.7.2.5](#) 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 OBA Questions and Answers Concerning *IBC* Meeting Minutes, May 14, 2004, guidance document; Guidance on the Content of Minutes of Institutional Biosafety Committee Meetings, NIH OBA, February 23, 2007, guidance memo.

5.8. Membership Terms & Conditions

- 5.8.1. **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.
- 5.8.2. **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.
- 5.8.3. **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.
- 5.8.4. **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*. In the event that 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.
- 5.8.5. **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.
- 5.8.6. **Conflicts-of-Interest:** No *IBC* member may be involved in the review or approval of a protocol or 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 protocol/project. Any such

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IBC member shall recuse himself/herself from the portion of the *IBC* meeting in which any such protocol is considered; shall not vote on the protocol or be present for the vote; and shall not be counted towards a quorum necessary for the consideration of the protocol/project.

5.8.7. 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.

Reference: *NIH Guidelines*, Section IV-B-2-a-(4); Charter of the Emory University [Institutional] Biosafety Committee.

6. PROTOCOLS REQUIRING SUBMISSION TO THE *IBC* & REVIEW PROCESS

6.1. Definitions Pertinent to this Section

6.1.1. Recombinant and Synthetic Nucleic Acid Molecules

6.1.1.1. Molecules that fall within one of the following groupings:

6.1.1.2. (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. [*NIH Guidelines*, Section I-B].

6.2. Is *IBC* Review Required?

Per the Charter of the Emory University [Institutional] Biosafety Committee and/or the *NIH Guidelines*, all research protocols 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 reviewed by the *IBC*. Such research protocols 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) must review protocols containing such experiments is set forth in [rDNA Experiments Covered by the NIH Guidelines](#).

6.2.1. 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.

6.3. What type of *IBC* Review Process is Employed?

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

6.3.1. NIH Guidelines Research: All research that involves procedures that are covered by the *NIH Guidelines* (see [rDNA Experiments Covered by the NIH Guidelines](#)) receives review by the full *IBC*. In addition, *NIH Guidelines* research that includes experiments that involve recombinant or synthetic nucleic acid molecules and human subjects must be reviewed by the

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RAC in accordance with the *NIH Guidelines*. In addition, the full *IBC* is responsible for fulfilling all duties assigned to it by the *NIH Guidelines*, as set forth in [Section 4.2](#) above.

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

6.4. *Notice of Intent*

Each PI who plans to work with Recombinant or Synthetic Nucleic Acid Molecules must complete the [Notice of Intent Form](#) (referred to herein as the “Notice of Intent”) and submit it, along with a copy of the research protocol, to the *Biosafety Officer* for review by *IBC* in accordance with [Section 6.3](#) above. In addition, the different processes for the submission of amendments to and renewals of research protocols are explained in the guidelines link.

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

6.5. *Tracking of Research Protocols*

Upon receipt of the Notice of Intent and accompanying research protocol, the *Biosafety Officer* shall assign a number to the research protocol, which shall be used for tracking. Any amendments/modifications received for a protocol shall be numbered sequentially upon approval. The PI should refer to the assigned protocol number in all correspondence with the *Biosafety Officer* and the *IBC* regarding the research protocol.

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

6.6. *Initial Review by Biosafety Officer*

The *Biosafety Officer* shall review each submitted research protocol for completeness and make a preliminary determination as to the type of review that should be provided per [Section 6.3](#) 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 protocol shall be returned to the PI for completion prior to being presented to the *IBC* for review. Copies of all protocols to be reviewed by the *IBC* shall be provided to each member of the *IBC*.

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

6.7. *Assignment for Presentation*

For all protocols for which full *IBC* review is required, the *Biosafety Officer* with the concurrence of the *IBC* Chair shall assign a reviewer(s) for each protocol or protocol amendment to be reviewed; provided, however, that the following protocol amendments may be reviewed solely by the Chair of the *IBC* or his/her designee:

6.7.1. A change in the title of a protocol,

6.7.2. A change to a protocol for research when the change pertains only to a change in research personnel, other than the PI, assigned to the protocol, or

6.7.3. 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)

SAF-101, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY INSTITUTIONAL BIOSAFETY COMMITTEE**6.8. Presentation at the IBC Meeting**

All protocols that require review by the full **IBC** shall be scheduled for presentation by the assigned reviewer(s) at an upcoming **IBC** meeting. In order for the protocol to be reviewed, a reviewer must be present at the meeting otherwise the protocol 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)

6.9. Notification of the PI

The PI shall receive notice from the **IBC** indicating that his/her Notice of Intent and protocol or protocol amendment have been received, along with the type of review process that the protocol will undergo, and if full **IBC** review is required, the date of the **IBC** meeting at which the protocol or amendment is scheduled for review. A Notice of Intent and the corresponding protocol must be received by the [submission deadlines](#) posted at on the EHSO website in order to be reviewed at that meeting. After the protocol (or amendment) is reviewed, the PI shall be notified by the **IBC** as to the status assigned to the protocol per [Section 6.11](#) below.

Reference: *NIH Guidelines*, Section IV-B-2-b-(2); Section IV-B-2-a-(5);

6.10. Amendments to Protocols

If a PI makes an addition or modification (referred to herein as an “amendment”) to an approved Protocol, then the PI must complete the Protocol Amendment form. This Protocol Amendment form must be submitted to the Biosafety Office. As appropriate under [Section 6.3](#), the **Biosafety Officer** or the full **IBC** must review and approve the Protocol Amendment before the additions/modifications can be implemented. The minor amendments to protocols, as described in [Section 6.7](#), that initially received full **IBC** review may be reviewed and approved by the **Biosafety Officer** with the concurrence of the **IBC** Chair.

- 6.10.1. All other amendments to protocols that initially required full **IBC** review must be approved by the full **IBC** utilizing the same procedure followed for the original review of protocols. Amendments requiring full **IBC** review must be received by the [submission deadlines](#) posted on the EHSO website in order 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 6.11](#) below.
- 6.10.2. Notwithstanding anything to the contrary set forth in [Section 6.10.1](#) above, all IACUC protocols involving animal subjects must be resubmitted as new protocols to the IACUC for review every three years and all IRB protocols involving human subjects must be resubmitted to the IRB as new protocols for review every year.

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

6.11. Protocol/Amendment Status

As a part of its review of a protocol or an amendment to a protocol, the **IBC** will assign one of the following statuses to the protocol or amendment:

- 6.11.1. **Approved:** This status is given if the **IBC** approves the protocol/amendment without the need for any changes to the protocol/amendment by the PI. An approval is good for one year, unless a shorter timeframe is specified by the **IBC**.
- 6.11.2. **Pending Approval:** This status is given if the **IBC** has just a few minor questions or issues about the protocol/amendment that the PI must resolve before the protocol can receive full

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approval. 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 protocol/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 protocol. 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 protocol/amendment will be granted the Approved status. No work under the protocol/amendment may take place until the protocol/amendment is Approved.

- 6.11.3. **Re-Review/Deferred:** This status is given if the **IBC** has a significant number of questions or issues regarding a protocol/amendment, or if the **IBC** has questions or issues of a substantive nature regarding the protocol/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 protocol/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 protocol/amendment may take place until the protocol/amendment is Approved. Protocol approval periods shall be measured from the date of the meeting at which the **IBC** granted Full Approval or Pending Approval; provided, however, that in the case of Pending Approval, work under the protocol cannot begin unless and until the PI receives a final approval letter from the **IBC**.
- 6.11.4. **Disapproved:** This status is given if the **IBC** has major substantive concerns with the protocol/amendment. For example, the protocol/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 protocol/amendment. Further revisions to a Disapproved protocol/amendment will not be accepted by the **IBC**. The PI may re-write the protocol/amendment with substantial changes and submit it as a new protocol/amendment.
- 6.11.5. **Withdrawn:** The status is given to protocols/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.
- 6.11.6. **Suspended:** This status is given if the **IBC** determines that serious questions or issues have arisen with regard to a protocol, or the manner in which the protocol is being conducted that should cause its Approved status to be removed. For example, the **IBC** may receive allegations that the protocol is not being conducted in accordance with the *NIH Guidelines* or it may receive notice from another University committee with jurisdiction over the protocol that the protocol has been suspended by that group. The **IBC** may, in its discretion, suspend all or part of a protocol. 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 protocol (or suspended portion of the protocol) 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 protocol should be Suspended, or to determine if a Suspended protocol may have its Approved status reinstated. OC will be notified about the suspension.
- 6.11.7. **Terminated:** This status is given to protocols that are no longer active. Research may not be conducted under protocols that are terminated. The PI may terminate a protocol by writing to the **IBC** Chair or his/her designee. If a PI does not take proper steps to renew a

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protocol when its Approved status is set to expire, then the protocol will be Terminated. The **IBC** may also take steps to Terminate a protocol that has been Suspended, based on the results of appropriate inquiries/investigations conducted by the **IBC** or other appropriate Emory University committees or units with jurisdiction over the protocol. The **IBC** shall send out a written notice of Termination to the PI of any protocol that is Terminated. This notice may be copied to other University committees or units, as appropriate. No work shall continue under a protocol after it is Terminated. If the PI wishes to conduct future work under a Terminated protocol, he/she must submit the protocol for approval as a new protocol.

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

6.12. Protocol Renewals

Each protocol that is Approved by the **IBC** is approved for three years. For a three year renewal of an approved IBC protocol, the deadline for submitting a new Notice of Intent form and supporting documents as appropriate is the 10th of the month immediately preceding protocol expiration. The Biosafety Office will begin sending reminders approximately 90 days prior to that deadline and continue with reminders approximately every 30 days month until the deadline if a new Notice of Intent form has not been submitted. 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 submit a Notice of Intent form by the 10th of the month prior to the expiration of their existing protocol, or if the **IBC** denies the renewal of protocol, then the protocol is Terminated 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 protocol after it is Terminated. If the PI wishes to conduct future work under a Terminated protocol, he/she must submit the protocol for approval as a new protocol.

Reference: *NIH Guidelines*, Sections IV-B-2-b-(2) & IV-B-2-b-(5)

6.13. 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 protocol is responsible for providing an annual update on the status of the protocol. 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)

6.14. Protocol Terminations

A PI should request that the **IBC** Terminate a protocol when the protocol 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 protocol should be Terminated or is being transferred to another PI at Emory in accordance with [Section 6.15](#) below. In addition, the **IBC** may Terminate a Protocol as set forth above in [Section 6.11.7](#).

Reference: *NIH Guidelines*, Sections IV-B-2-b-(2)

6.15. Transferring a Protocol to Another Investigator

If a PI desires to transfer his/her protocol 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

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describing the planned transfer signed by both the current PI and the prospective PI. No work may take place on a transferred protocol unless and until the **IBC** has approved the transfer through the applicable review process set forth in [Section 6.3](#). If the **IBC** is notified, or otherwise becomes aware, that a PI on an Approved protocol is no longer at Emory University and that PI had made no attempt to transfer the protocol 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 protocol transferred to them as PI. Until a new PI has agreed to and received a transfer of the protocol, the protocol 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 protocol transferred to one of them as PI. If no amendments are received during this period, then the protocol will be Terminated.

Reference: *NIH Guidelines*, Sections IV-B-2-b-(2)

7. REVIEW BY OTHER EMORY COMMITTEES

7.1. *Other Committees*

Protocols reviewed by the **IBC** may require review and approval by other University Committees as well before the work under the Protocol can begin. For example, if the Protocol utilizes animals then the protocol will require review by the Emory University [Institutional] Animal Care and Use Committee. Similarly, if the Protocol has human subject participants, then review by the Emory University [Institutional] Review Board will be required.

7.2. *Coordination Among Committees*

Committees involved in the review of research protocols at Emory shall coordinate among themselves the review of protocols requiring approval by multiple committees. Committees shall also coordinate among themselves the communication of any Terminations or Suspensions regarding Protocols under the jurisdiction of multiple committees. In general, if a protocol 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 protocol to either or both of the committees, and the approval by the IRB and/or the IACUC **must be in place** before the PI can proceed with the protocol.

Reference: *NIH Guidelines*, Sections IV-B-2-b-(2); Section IV-B-2-a-(5)

8. RESPONSIBILITIES OF PIS

8.1. *General Responsibilities*

8.1.1. **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.

8.1.2. **Research Subject to *IBC* Review:** The PI shall be responsible for ensuring that all research under a protocol requiring **IBC** review is properly submitted to the **IBC** for review and that **IBC** approval is granted before any research under the protocol is initiated. If the PI may be

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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*.

- 8.1.3. **Reporting Responsibilities:** The PI shall fulfill all reporting responsibilities placed upon him/her per [Section 8.5](#) below.
- 8.1.4. **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 2.3.1.6](#) for additional information regarding training.
- 8.1.5. **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 and IV-B-7-a

8.2. *Specific Responsibilities of the PI with Regard to the IBC*

- 8.2.1. **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 protocol 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 protocol and any subsequent amendment to that protocol to the **IBC** for review and approval/disapproval in accordance the requirements of the *NIH Guidelines* (including the requirements of Sections III-A, - B, - C, - D and - E).
- 8.2.2. **Continuing Communication with the IBC:** The PI shall be responsible for remaining in communication with the **IBC** throughout his/her conduct of any protocol subject to the **IBC's** jurisdiction; following any required procedures for renewal or amendment of the protocol; 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 protocol.
- 8.2.3. **Human Gene Transfer Experiments:** The PI shall ensure that no human research participant shall be enrolled in a *Human Gene Transfer Experiment* until the *NIH RAC* review process has been completed; **IBC** approval from the clinical site for the protocol has been obtained; IRB approval has been obtained; and all other applicable regulatory authorizations have been obtained. In addition, when a clinical trial site is added after the completion of the *NIH RAC* review process, the PI shall ensure that no human research participant is enrolled at the new clinical trial site until the following documentation is submitted to *NIH OBA*: **IBC** approval from the clinical trial site; IRB approval; IRB approved informed consent document; CV of PI and *NIH* grant numbers, if applicable. A copy of any approval letter(s) from another non-Emory site must be submitted to the Emory **IBC** prior to the commencement of Emory's participation in a multicenter research trial. If additional site(s) are added subsequent to Emory's participation, the approval letters from the additional site(s) must be submitted to the Emory **IBC**.

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Reference: *NIH Guidelines*, Sections IV-B-7-a-(1); IV-B-7-b; and IV-B-7-c-(1) to (4).

8.3. Specific Responsibilities of PI with Regard to Laboratory Staff Prior to and During Conduct of Research

8.3.1. Prior to Initiating Research the PI shall:

- 8.3.1.1. Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken;
- 8.3.1.2. 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
- 8.3.1.3. 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.

8.3.2. During the Conduct of the Research the PI shall:

- 8.3.2.1. Be responsible for supervising the safety performance of the laboratory staff to ensure that the required safety practices and techniques are followed;
- 8.3.2.2. Correct work errors and conditions that may result in the release of recombinant or synthetic nucleic acid materials;
- 8.3.2.3. Ensure the integrity of the physical containment and the biological containment used in the protocol.

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

8.4. Specific Responsibilities of PI with Regard to Submission of Information/Petitions to NIH OBA

The PI shall be responsible for submitting the following information/petitions to *NIH OBA* with regard to the PI's protocols, and unless otherwise specified, copies of all such information/petitions shall also be provided to the *IBC*:

- 8.4.1. Certification of new host-vector systems;
- 8.4.2. Petitions for proposed exemption from the *NIH Guidelines*, along with a copy of notice of the request for the exemption sent to the *IBC*;
- 8.4.3. 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 OBA and IBC Approval before Initiation*;
- 8.4.4. Petition for determination of containment for experiments requiring case-by-case review; and
- 8.4.5. Petitions for determination of containment for experiments not covered by the *NIH Guidelines*.
- 8.4.6. Certification that all aspects of Appendix M of the *NIH Guidelines* have been appropriately addressed prior to submission of a *Human Gene Transfer Experiment* to *NIH OBA*, including provision of a letter signed by the PI on institutional letterhead acknowledging that the document being submitted to *NIH OBA* complies with requirements set forth in Appendix M of the *NIH Guidelines*.

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

SAF-101, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY INSTITUTIONAL BIOSAFETY COMMITTEE**8.5. PI Reporting of Adverse Events and other Events to Biological Safety Officer**

8.5.1. 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:

- 8.5.1.1. Significant problems pertaining to any protocol subject to the **IBC**'s jurisdiction, including problems pertaining to the operation and implementation of containment practices and procedures.
- 8.5.1.2. Violations of **NIH Guidelines**.
- 8.5.1.3. 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. Click [here](#) to link to the PeopleSoft reporting system.
- 8.5.1.4. Failure to comply with reporting requirements for **Human Gene Transfer Experiments** as set forth in the **NIH Guidelines**, Appendix M-I-C, *Reporting Requirements*, including but not limited to reporting requirements for Serious Adverse Events associated with the use of a gene transfer product.

8.5.2. **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:

- 8.5.2.1. To the **IBC** by letter to the Chair of the **IBC** – immediately
- 8.5.2.2. To any Greenhouse/Animal Facility Director; - immediately
- 8.5.2.3. To **NIH OBA** by letter to Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Dr., Suite 750, MSC 7985, Bethesda MD 20892-7985 (20817 for non-USPS mail); Phone: 301-496-9838, Fax 301 496-9839. – within 30 days.
- 8.5.2.4. To any other appropriate authorities within legally prescribed times or 30 days, whichever is less.
- 8.5.2.5. For Human Gene Transfer Experiments, Principal Investigators must follow the Safety Reporting requirements as outlined in Appendix M-I-C-4 including the requirements on content and format, and timeframe for expedited reports.

Reference: *NIH Guidelines*, Section IV-B-7-a-(3); IV-B-7-e-(2) to (5)

9. RECORD KEEPING**9.1. Records to be kept by IBC**

In addition to keeping **IBC** meeting minutes as set forth in [Section 5.7.2.4](#) above, the **IBC** shall keep copies of all correspondence received from or sent to researchers, regulatory agencies or other persons concerning any of the **IBC**'s duties set forth hereunder. Records shall be kept in the offices of the **Biological Safety Officer** within the EHSO. 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.

SAF-101, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY INSTITUTIONAL BIOSAFETY COMMITTEE**10. 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.

11. CONDITIONS OF APPROVAL**11.1. Lab Inspections**

As a condition of approval for all **IBC** protocols, the lab(s) at which the protocols 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.

11.2. Occupational Health

As a condition of approval for **IBC** protocols, the **IBC** may establish occupational health requirements that must be fulfilled by the personnel working on the protocol, 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.

12. 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 protocols 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](#).

13. 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: http://osp.od.nih.gov/sites/default/files/External_IBC_FAQs.508.pdf