

SAF-111, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY RESEARCH HEALTH & SAFETY COMMITTEE**TABLE OF CONTENTS**

TABLE OF CONTENTS	1
1. Scope of RHSC Duties	2
1.1. General Duties of the Research Health and Safety Committee (RHSC)	2
2. Scope of Biosafety Officer Duties	3
2.1. Qualifications	3
2.2. Duties	3
3. Membership and Organization of RHSC	3
3.1. Number of Members	3
3.2. Alternate Members	3
3.3. Ex Officio Members	4
3.4. RHSC Chair and Co-Chair	4
3.5. RHSC Executive Secretary	4
3.6. Membership Terms & Conditions	6
4. Protocols Requiring Submission to the RHSC and Review	6
4.1. Definitions Pertinent to this Section	6
4.2. Is RHSC Review Required?	7
4.3. What type of RHSC Review Process is employed?	7
4.4. Notice of Intent	8
4.5. Tracking of Research Protocols	8
4.6. Initial Review by Biosafety Officer	8
4.7. Assignment for Presentation	8
4.8. Presentation at the RHSC Meeting	9
4.9. Notification of the PI	9
4.10. Amendments to Protocols	9
4.11. Protocol/Amendment Status	9
4.12. Protocol Renewals	11
4.13. Periodic Review	11
4.14. Protocol Terminations	11
4.15. Transferring a Protocol to Another Investigator	11
5. Review by Other Emory Committees	12
5.1. Other Committees	12
5.2. Coordination among Committees	12
6. Responsibilities of PIs	12
6.1. General Responsibilities	12
6.2. Specific Responsibilities of the PI with Regards to the RHSC	13
6.3. Specific Responsibilities of PI with Regard to Laboratory Staff Prior to and During Conduct of Research	13
6.4. PI Reporting of Adverse Events and other Events to Biological Safety Officer	13
7. Record Keeping	14
7.1. Records to be kept by RHSC	14
8. Review and Update of these Policies and Procedures	14
9. Condition of Approval	14
9.1. Lab Inspections	14
9.2. Occupational Health	14

SAF-111, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY RESEARCH HEALTH & SAFETY COMMITTEE**1. SCOPE OF RHSC DUTIES*****1.1. General Duties of the Research Health and Safety Committee (RHSC)***

The RHSC's general duties shall include the following:

- 1.1.1. Making policy recommendations regarding laboratory research safety (biological, chemical, and animal safety) and related occupational health and safety matters to the President of the Emory, or his/her designee, for approval and implementation by appropriate units, including, but not limited to, Emory's Environmental Health and Safety Office (EHSO).
- 1.1.2. Identifying substantive research and operational areas in which biological, chemical or other health hazards may exist.
- 1.1.3. Recommending procedures for approval of activities involving biological hazards and hazardous chemicals that require special containment facilities or practices, which, in the judgment of the RHSC, may constitute a hazard to faculty, staff, students or the environment.
- 1.1.4. Reviewing Biosafety Officer reports of significant accidents or other incidents resulting in the exposure of personnel working or performing research activities, or the environment to infectious microorganisms or hazardous chemicals, as well as reports of non-compliance with established Emory policies and regulatory requirements regarding the safe conduct or research or use of these materials.
- 1.1.5. Upon its own initiative, or upon the request of the Director of the EHSO or the Biosafety Officer, the RHSC also may participate in any inquiry or investigation into suspected incidents of laboratory acquired infections. In particular, the expertise of selected RHSC members may be utilized to investigate specific epidemiologic features of the suspected agent and to prepare appropriate prevention strategies.
- 1.1.6. Establishing working subcommittees within the RHSC and/or appointing to the RHSC, as necessary, ad hoc consultants with particular expertise that is deemed necessary by the RHSC to effectively carry out the duties of the RHSC.
- 1.1.7. Collaborating with EHSO on the implementation of local, state and federal regulatory requirements as they relate to the purchase, use, storage and disposal of hazardous chemicals or biological materials (including, but not limited to, Select Agents).
- 1.1.8. Maintaining an effective liaison with pertinent Emory administrative units, department and committees, including, but not limited to, the Institutional Animal Care and Use Committee (IACUC), Emory Institutional Review Board (IRB), Institutional Biosafety Committee (IBC), Division of Animal Resources (DAR), Campus Services, and the Emory Office of Compliance (OC).
- 1.1.9. The RHSC may investigate issues of noncompliance or accidents, involving matters that fall within the RHSC's purview.
- 1.1.10. Carrying out such other duties as may be assigned from time to time by the President, or his/her designee.

SAF-111, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY RESEARCH HEALTH & SAFETY COMMITTEE**2. SCOPE OF BIOSAFETY OFFICER DUTIES****2.1. Qualifications**

2.1.1. The Biosafety Officer shall have the experience, education and background that make him/her knowledgeable about laboratory research, laboratory hazards, and containment and give him/her the capability to assess 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. The Biosafety Officer shall be on the staff of Emory's EHSO and shall be a voting member of the RHSC.

2.2. Duties

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

- 2.2.1. Making periodic inspections of laboratories at which research subject to the jurisdiction of the RHSC is being conducted in order to ensure that laboratory standards are rigorously followed and reporting the results of such inspections to the RHSC, as well as to any other appropriate compliance units or committees at Emory (e.g., IACUC, OC).
- 2.2.2. Reporting to the RHSC, as well as to any other appropriate compliance units or committees at Emory (e.g., IACUC, OC, IRB) any significant accidents or illnesses related to research under the RHSC's jurisdiction of which the Biosafety Officer becomes aware, unless a report has previously been filed with the RHSC by a Principal Investigator (PI). The Biosafety Officer also shall be responsible for confirming that the PI (or other appropriate individual or committee) has made any reports as required by applicable laws or regulations and that copies of any such reports have been provided to the Biosafety Officer, Chair of the RHSC. OC will be sent copies of the reports. The Biosafety Officer also shall be responsible for developing an emergency plan for handling accidental spills and personnel contamination and investigating laboratory accidents, which plans shall be reviewed and approved by the RHSC. In addition, as a condition of protocol approval, the RHSC may require PIs to develop protocol specific plans for handling such incidents, as necessary.
- 2.2.3. Providing advice on laboratory security.
- 2.2.4. Providing technical advice to PIs and the RHSC on research safety procedures.
- 2.2.5. Carrying out such other duties as may be assigned from time to time by the RHSC, EHSO or other appropriate Emory administrative units.

3. MEMBERSHIP AND ORGANIZATION OF RHSC**3.1. Number of Members**

The RHSC 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 RHSC, but in no event shall the number of members be less than five (5).

3.2. Alternate Members

Alternate members may serve in place of a regular member when the regular member is unavailable. 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 RHSC meetings along with the member for whom they serve as an alternate, but in such instances

SAF-111, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY RESEARCH HEALTH & SAFETY COMMITTEE

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.

3.3. Ex Officio Members

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

- 3.3.1. **Biosafety Officer:** Emory's Biosafety Officer shall be a voting member of the RHSC and also shall serve as Executive Secretary to the RHSC.
- 3.3.2. **Associate Biosafety Officer:** Emory's Associate Biosafety Officer shall be a voting member of the RHSC and also shall serve as alternate Executive Secretary to the RHSC at any meeting of the RHSC at which the Biosafety Officer is not in attendance.
- 3.3.3. **Director of the EHSO:** The Director of the EHSO shall be a non-voting member of the RHSC. In addition, the Director of the EHSO shall serve as an alternative Executive Secretary to the RHSC at any meeting of the RHSC 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 RHSC, he/she shall also serve as a voting alternate for the Biosafety Officer.
- 3.3.4. **Additional Ex-Officio Member:** The President or his/her designee, in their discretion, may appoint additional persons from any component or discipline at Emory to serve as a non-voting, ex-officio member of the RHSC.

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

3.5. RHSC Chair and Co-Chair

- 3.5.1. **Chair:** Emory's President, or his/her designee, shall appoint a Chair of the RHSC from among the members appointed to the RHSC.
- 3.5.2. **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 unavailability of the Chair. The RHSC may make recommendations as to who could serve as Co-Chair.

3.6. RHSC Executive Secretary

- 3.6.1. The Biosafety Officer shall serve as the Executive Secretary for the RHSC. At any RHSC 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 3.3.2](#) and [3.3.3](#) above.
- 3.6.2. **Duties:** The Executive Secretary shall be responsible for performing the following duties:
 - 3.6.2.1. **Membership Roster:** Keeping a current roster of all members of the RHSC 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 RHSC by the member (e.g.,

SAF-111, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY RESEARCH HEALTH & SAFETY COMMITTEE

Chairperson, Co-Chairperson, etc.), including effective date and ending date of terms for which office or post is held; specification of any consultant appointed to the RHSC to provide any necessary expertise.

- 3.6.2.2. **Attendance:** Keeping accurate attendance of all members at each meeting of the RHSC.
- 3.6.2.3. **Quorum:** Keeping track to ensure that there is a quorum of members at the beginning and throughout the course of each RHSC meeting, including noting within the meeting minutes when any RHSC member leaves the meeting and when he/she returns. A quorum shall be constituted when a majority of the voting members of the RHSC are present as a part of that majority. No RHSC business shall be conducted unless a quorum is present. (Note: In the case of an odd number of voting members on the RHSC, 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).
- 3.6.2.4. **Keeping of Minutes:** Keeping accurate minutes of each RHSC 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 3.6.2.3](#) 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 RHSC, including the number of members in favor, those opposed and those who abstained; (h) a description of any changes in RHSC membership, including beginning and ending dates of members' terms; (i) a listing of RHSC officers, including beginning and ending dates of officers' terms; and (j) the time of the meeting's adjournment.
- 3.6.2.5. **Circulation and Approval of Minutes:** Drafting minutes of each RHSC meeting promptly after the conclusion of each such meeting, and circulating these minutes to all RHSC members at least one week prior to the next scheduled RHSC meeting for comment and a vote of approval at the next appropriate meeting. Final copies of each RHSC 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.
- 3.6.2.6. **Records:** Collecting and maintaining all records of any actions and activities of the Biosafety Officer and the RHSC, including the Official Minutes as set forth in [Sections 3.6.2.4](#) and [3.6.2.5](#) above. All records shall be kept for the longest of any retention period required by applicable federal, state, local or university requirement.

SAF-111, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY RESEARCH HEALTH & SAFETY COMMITTEE**3.7. Membership Terms & Conditions**

- 3.7.1. **Member Terms:** Each appointed member of the RHSC (excluding ex-officio members and alternates) 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 RHSC can be staggered).
- 3.7.2. **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.
- 3.7.3. **Additional Terms:** RHSC 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.
- 3.7.4. **Appointment/Resignation/Removal:** All members and officers of the RHSC, 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 RHSC. 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 being appointed to the RHSC. 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 RHSC meeting or by written communication to RHSC members. Members shall not be permitted to vote or take place in RHSC activities until their appointment has become effective and been announced to the other RHSC members.
- 3.7.5. **Voting:** Each member shall be entitled to one vote. In order to vote, a member must be present at a duly-constituted RHSC meeting at which a quorum is present; there shall be no voting by proxy.
- 3.7.6. **Conflicts-of-Interest:** No RHSC 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 RHSC regarding the protocol/project. Any such RHSC member shall recuse himself/herself from the portion of the RHSC 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.
- 3.7.7. **Attendance at Meeting via Computer or Telephonic Means:** An RHSC member may attend a meeting of the RHSC 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 RHSC in this manner may be counted toward establishing quorum for the meeting.

4. PROTOCOLS REQUIRING SUBMISSION TO THE RHSC AND REVIEW**4.1. Definitions Pertinent to this Section**

- 4.1.1. **Biological Toxins:** "Toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsia, or protozoa) or infectious substances, or a

SAF-111, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY RESEARCH HEALTH & SAFETY COMMITTEE

recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology; produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.” [See 42 CFR § 73.1].

- 4.1.2. **Hazardous Chemicals:** Any chemical that is a health hazard or physical hazard and for which there is statistically significant evidence, based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed individuals. Included in this terminology are chemicals which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic system, and agents which damage the lungs, skin, eyes, or mucous membranes. [See 29 CFR 1910.1200 (C)].
- 4.1.3. **Infectious Agent:** An organism, usually a microorganism, but including helminthes, that is capable of producing infection or infectious disease, and any organism (such as a virus, rickettsia, bacteria, fungus or parasite) that is capable of invading and multiplying in tissues and having the capacity to cause disease or adverse health impacts on humans, plants or animals. [See, F. Lisella, *VNR DICTIONARY OF ENVIRONMENTAL HEALTH AND SAFETY*, 165 (1994).]
- 4.1.4. **Select Agent:** All biological agents or toxins listed at 42 CFR §§ 73.3 & 73.4. [See 42 CFR § 73.1; see also list at [The National Select Agent Registry Website](#)] (not including any exempt types or amounts of Select Agents as specified in applicable USDA and/or CDC regulations).
- 4.1.5. **NIH Guidelines Research:** All research that involves procedures that are covered by the NIH Guidelines receives review by the full IBC. In addition, NIH Guidelines research that includes experiments that involve recombinant DNA and human subjects must be reviewed by the RAC in accordance with the NIH Guidelines. Please consult the Policies and Procedures of the Emory University IBC for additional information and guidance. [See [NIH Guidelines](#)].
- 4.1.6. **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 requirement, 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 .

4.2. Is RHSC Review Required?

Per the [Charter of the Emory University Research Health and Safety Committee](#), all research protocols sponsored by Emory University or conducted at Emory facilities that involve work with “Biological Toxins,” “Infectious Agents,” “Hazardous Chemicals,” “Select Agents,” or other materials as described in the [Biosafety Protocol Guidelines](#) (excluding research involving recombinant or synthetic nucleic acid molecules) as those terms are defined above, must be reviewed by the RHSC.

- 4.2.1. **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.

4.3. What type of RHSC Review Process is employed?

- 4.3.1. **Research that Involves Biological Toxins, or Infectious Agents:** If the research to be conducted involves Biological Toxins, Infectious Agents or recombinant or synthetic nucleic

SAF-111, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY RESEARCH HEALTH & SAFETY COMMITTEE

acid molecules but does not fall within the category of NIH Guidelines Research, then the following review processes are employed.

- 4.3.2. **Registration:** All research involving the use of Biological Toxins, Infectious Agents or recombinant DNA, whether or not covered by the NIH Guidelines, must be registered with EHSO by the investigator filing a notice of intent with that office. EHSO will review the research to assign a preliminary biosafety level determination; to determine if the research is NIH Guidelines Research; and to determine which type of review process should be employed.
- 4.3.3. **BSL2 Enhanced and Higher Biosafety Levels (i.e., BSL 3 & BSL4):** If the research is not NIH Guidelines Research and is classified as BSL2 Enhanced or higher under the *CDC/NIH, Biosafety, Microbiology and Biomedical Laboratories Guidelines* (most recent edition), Sections 5 and 6 then the research shall be submitted to the full RHSC for review
- 4.3.4. **Select Agents:** If the research is not NIH Guidelines Research but involves Select Agents in type and amount regulated under the USDA or CDC regulations, then the research shall be submitted to the full RHSC for review.

4.4. *Notice of Intent*

Each PI who plans to work with Biological Toxins, Infectious Agents, Select Agents or Recombinant DNA Molecules must complete the [Biosafety Notice of Intent Form](#) to work with Biological Toxins, Infectious Agents or Recombinant or Synthetic Nucleic Acid Molecules (referred to herein as the “Notice of Intent”), and submit it to the Biosafety Officer for review by RHSC in accordance with [Section 4.3](#) above. In addition, the different processes for the submission of amendments to and renewals of research protocols are explained in [Biosafety Protocol Guidelines](#). In order to conduct research at Emory involving Recombinant DNA covered by the NIH Guidelines, personnel must also follow to the requirements of the Emory IBC. **Reference:** *NIH Guidelines*, Section IV-B-2-a-(5); [Biosafety Protocol Guidelines](#).

4.5. *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 RHSC regarding the research protocol.

4.6. *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 4.3](#) above. The RHSC Chair shall reserve the right to review this determination and concur or assign a different type of RHSC review. An obviously incomplete protocol shall be returned to the PI for completion prior to being presented to the RHSC for review. Copies of all protocols to be reviewed by the RHSC shall be provided to each member of the RHSC.

4.7. *Assignment for Presentation*

For all protocols for which full RHSC review is required, the Biosafety Officer with the concurrence of the RHSC 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 RHSC or his/her designee:

SAF-111, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY RESEARCH HEALTH & SAFETY COMMITTEE

- 4.7.1. A change in the title of a protocol, that does not involve any other changes to the protocol or personnel involved in the protocol,
- 4.7.2. 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
- 4.7.3. An amendment that does not change the biosafety profile (e.g. no change in Biosafety level or change in animal species).

4.8. *Presentation at the RHSC Meeting*

All protocols that require review by the full RHSC shall be scheduled for presentation by the assigned reviewer(s) at an upcoming RHSC 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 RHSC at which a reviewer can be present.

4.9. *Notification of the PI*

The PI shall receive notice from the RHSC 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 RHSC review is required, the date of the RHSC meeting at which the protocol or amendment is scheduled for review. A Notice of Intent and the corresponding protocol must be received at by the submission deadlines posted at: in order to be reviewed at that meeting. After the protocol (or amendment) is reviewed, the PI shall be notified by the RHSC as to the status assigned per [Section 4.11](#) below.

4.10. *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 4.3](#), the Biosafety Officer or the full RHSC must review and approve the Protocol Amendment before the additions/modifications can be implemented. The minor amendments to protocols, as described in [Section 4.7](#), that initially received full RHSC review may be reviewed and approved by the Biosafety Officer with the concurrence of the RHSC Chair.

- 4.10.1. All other amendments to protocols that initially required full RHSC review must be approved by the full RHSC utilizing the same procedure followed for the original review of protocols. Amendments requiring full RHSC review must be received by the submission deadlines listed in the [IBC & RHSC Meeting Schedule](#) in order to be reviewed at the meeting. After the amendment is reviewed, the PI shall be notified by the RHSC as to the status granted to the Amendment per [Section 4.11](#) below.
- 4.10.2. Notwithstanding anything to the contrary set forth in [Section 4.10.1](#) 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.

4.11. *Protocol/Amendment Status*

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

SAF-111, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY RESEARCH HEALTH & SAFETY COMMITTEE

- 4.11.1. **Approved:** This status is given if the RHSC 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 RHSC.
- 4.11.2. **Pending Approval:** This status is given if the RHSC has just a few minor questions or issues about the protocol/amendment that the PI must resolve before the protocol can receive full approval. The RHSC 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 RHSC. The PI's response to the questions/issues will be given to the reviewers assigned to the protocol. They will review these responses and report to the RHSC Chair 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.
- 4.11.3. **Re-Review/Deferred:** This status is given if the RHSC has a significant number of questions or issues regarding a protocol/amendment, or if the RHSC has questions or issues of a substantive nature regarding the protocol/amendment. The RHSC 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 RHSC 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 RHSC 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 RHSC.
- 4.11.4. **Disapproved:** This status is given if the RHSC 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 RHSC. The PI may re-write the protocol/amendment with substantial changes and submit it as a new protocol/amendment.
- 4.11.5. **Withdrawn:** The status is given to protocols/amendments that the RHSC has removed from further consideration by the RHSC. This may occur at the PI's request or when the PI has failed to respond to questions from the RHSC in the allotted time.
- 4.11.6. **Suspended:** This status is given if the RHSC 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 RHSC may receive notice from another University committee with jurisdiction over the protocol that the protocol has been suspended by that group. The RHSC may, in its discretion, suspend all or part of a protocol. The RHSC, 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 RHSC. The RHSC 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.

SAF-111, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY RESEARCH HEALTH & SAFETY COMMITTEE

4.11.7. **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 RHSC Chair or his/her designee. If a PI does not take proper steps to renew a protocol when its Approved status is set to expire, then the protocol will be Terminated. The RHSC may also take steps to Terminate a protocol that has been Suspended, based on the results of appropriate inquires/investigations conducted by the RHSC or other appropriate Emory University committees or units with jurisdiction over the protocol. The RHSC 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.

4.12. Protocol Renewals

Each protocol that is Approved by the **RHSC** is approved for three years. For a three year renewal of an approved RHSC 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 **RHSC** shall notify the PI as to the results of the **RHSC**'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 **RHSC** denies the renewal of protocol, then the protocol is Terminated and the **RHSC** 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.

4.13. Periodic Review

On behalf of the institution, the **RHSC** is responsible for periodically reviewing research conducted at the institution as described in Section 4.2. The PI of an approved **RHSC** 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.

4.14. Protocol Terminations

A PI should request that the RHSC Terminate a protocol when the protocol has ended and Biological Toxins, or Infectious Agents are no longer being used. The PI should notify the RHSC in writing of the request for Termination. If a faculty member leaves the University, he/she should notify the RHSC in writing that his/her protocol should be Terminated or is being transferred to another PI at Emory in accordance with [Section 4.15](#) below. In addition, the RHSC may Terminate a Protocol as set forth above in [Section 4.11.7](#).

4.15. 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 4.10](#) 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 protocol unless and until the RHSC has approved the transfer through the applicable review process set forth in [Section 4.3](#). If the RHSC 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

SAF-111, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY RESEARCH HEALTH & SAFETY COMMITTEE

transfer the protocol to another PI at Emory, then the RHSC 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.

5. REVIEW BY OTHER EMORY COMMITTEES**5.1. Other Committees**

Protocols reviewed by the RHSC 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 IACUC. Similarly, if the Protocol has human subject participants, then review by the Emory University IRB will be required.

5.2. 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 RHSC 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.

6. RESPONSIBILITIES OF PIS**6.1. General Responsibilities**

- 6.1.1. **PI is Responsible for Compliance with University Policies:** Each PI at Emory 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.
- 6.1.2. **Research Subject to RHSC Review:** The PI shall be responsible for ensuring that all research under a protocol requiring RHSC review is properly submitted to the RHSC for review and that RHSC approval is granted before any research under the protocol is initiated. 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.).
- 6.1.3. **Reporting Responsibilities:** The PI shall fulfill all reporting responsibilities placed upon him/her per [Section 6.4](#) below.
- 6.1.4. **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. Contact the Biosafety Officer for additional information regarding training and training requirements.

SAF-111, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY RESEARCH HEALTH & SAFETY COMMITTEE

6.1.5. **Adherence to RHSC and Other University Safety Plans:** The principal investigator shall adhere to all RHSC-approved and other University-approved plans for handling, managing, using, storing and shipping of infectious biological agents, including plans regarding the handling of accidental spills and personnel contamination. See the [PeopleSoft website](#) for reporting incidents.

6.2. Specific Responsibilities of the PI with Regards to the RHSC

6.2.1. **Initial Submission to RHSC:** The PI shall submit his/her initial research protocol and any subsequent amendment to that protocol to the RHSC for review and approval/disapproval. Consult with the Biosafety Officer for additional information.

6.2.2. **Continuing Communication with the RHSC:** The PI shall be responsible for remaining in communication with the RHSC throughout his/her conduct of any protocol subject to the RHSC's jurisdiction; following any required procedures for renewal or amendment of the protocol; and immediately advising the RHSC of any adverse events, significant problems, significant research-related accidents or illnesses related to the protocol.

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

6.3.1. Prior to Initiating Research the PI shall:

- 6.3.1.1. Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken;
- 6.3.1.2. 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
- 6.3.1.3. 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.

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

- 6.3.2.1. Be responsible for supervising the safety performance of the laboratory staff to ensure that the required safety practices and techniques are followed.
- 6.3.2.2. Ensure the integrity of the physical containment and the biological containment used in the protocol.

6.4. PI Reporting of Adverse Events and other Events to Biological Safety Officer

6.4.1. 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 RHSC Chair and determine further reporting requirements:

- 6.4.1.1. Significant problems pertaining to any protocol subject to the RHSC's jurisdiction, including problems pertaining to the operation and implementation of containment practices and procedures.
- 6.4.1.2. 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

SAF-111, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY RESEARCH HEALTH & SAFETY COMMITTEE

involving animal subjects also shall be reported to the Emory IACUC. See the [PeopleSoft reporting system website](#) for reporting incidents.

6.4.2. **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:

6.4.2.1. To the RHSC by letter to the Chair of the RHSC - immediately

6.4.2.2. To any Greenhouse/Animal Facility Director - immediately

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

7. RECORD KEEPING

7.1. *Records to be kept by RHSC*

In addition to keeping RHSC meeting minutes as set forth in [Section 3.6.2.4](#) above, the RHSC shall keep copies of all correspondence received from or sent to researchers, regulatory agencies or other persons concerning any of the RHSC'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 any applicable federal, state, local or university requirement.

8. 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 RHSC, 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 RHSC Chair's consideration any proposed improvements thereto. The RHSC 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 RHSC Chair will be communicated to the RHSC at a regularly convened meeting of the RHSC. 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.

9. CONDITION OF APPROVAL

9.1. *Lab Inspections*

As a condition of approval for all RHSC 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.

9.2. *Occupational Health*

As a condition of approval for RHSC protocols, the RHSC 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.