

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

Table of Contents

1.0	Introduction	3
1.1	Scope of RHSC Duties	3
	General Duties of the Research Health and Safety Committee (RHSC)	3
1.2	Scope of BSO Duties	4
	Qualifications	4
	Duties	4
2.0	Membership and Organization of RHSC	4
2.1	Number of Members	4
2.2	Alternate Members	4
2.3	Ex Officio Members	5
2.4	Member(s) of the OC	5
2.5	RHSC Chair and Co-Chair	5
2.6	RHSC Executive Secretary	5
3.0	Membership Terms and Conditions	7
4.0	Projects Requiring Submission to the RHSC and Review	8
4.1	Definitions Pertinent to this Section	8
4.2	Is RHSC review required?	9
4.3	What Type of RHSC Review Process is employed?	9
4.4	Biological Registration	10
4.5	Tracking of Research Projects	10
4.6	Initial Review by BSO	10
4.7	Assignment for Presentation	10
4.8	Presentation at the RHSC Meeting	10
4.9	Notification of the PI	11
4.10	Amendments to Projects	11
4.11	Amendment Status	11
4.12	Project Renewal	13
4.13	Periodic Review	13
4.14	Project Terminations	14
4.15	Transferring a Project to another Investigator	14
5.0	Review by Other Emory Committees	14
5.1	Other Committees	14
5.2	Coordination Among Committees	14
6.0	Responsibilities of PIs	15
6.1	General Responsibilities	15
6.2	Specific Responsibilities of the PI with Regards to the RHSC	15
6.3	Specific Responsibilities of PI with Regard to the Laboratory Staff Prior to and During Conduct of Research	16
6.4	PI Reporting of Adverse Events and other Events to Biological Safety Officer	16
7.0	Recordkeeping	16
8.0	Review and Update of these Policies and Procedures	17
9.0	Condition of Approval	17



TITLE:

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

9.1 Training.....17
9.2 Lab Inspection17
9.3 Occupational Health17

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

1.0 Introduction

1.1 Scope of RHSC Duties

General Duties of the Research Health and Safety Committee (RHSC)

The RHSC's general duties shall include the following:

- 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).
- Identifying substantive research and operational areas in which biological, chemical or other health hazards may exist.
- 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.
- Reviewing Biosafety Office (BSO) 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.
- Upon its own initiative, or upon the request of the Director of the EHSO or the BSO, 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.
- 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.
- 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).
- 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).
- The RHSC may investigate issues of noncompliance or accidents, involving matters that fall within the RHSC's purview.
- Carrying out such other duties as may be assigned from time to time by the President, or his/her designee.
- Reviews all research involving Dual Use Research of Concern (DURC).

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

1.2 Scope of BSO Duties

Qualifications

The BSO 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 BSO shall be trained in and receive on-going training in laboratory safety. The BSO shall be on the staff of Emory's EHSO and shall be a voting member of the RHSC.

Duties

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

- Making periodic inspections of laboratories at which research subject to the jurisdiction of the 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).
- 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 BSO becomes aware, unless a report has previously been filed with the RHSC by a Principal Investigator (PI).
- 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 BSO, Chair of the RHSC. OC will be sent copies of the reports.
- Developing an emergency plan for handling accidental spills and personnel contamination and investigating laboratory accidents, such plans shall be reviewed and approved by the RHSC.
- Reviewing project-specific plans for handling incidents/accidents developed by the PI that the RHSC has set as requirement for project approval.
- Providing advice on laboratory security.
- Providing technical advice to PIs and the RHSC on research safety procedures.
- Carrying out such other duties as may be assigned from time to time by the RHSC, EHSO or other appropriate Emory administrative units.

2.0 Membership and Organization of RHSC

2.1 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).

2.2 Alternate Members

Alternate members may serve in place of a regular member when the regular member is

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

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 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.

2.3 Ex Officio Members

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

- **BSO:** Emory's BSO shall be a voting member of the RHSC and also shall serve as Executive Secretary to the RHSC.
- **Associate BSO:** Emory's Associate BSO 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 BSO is not in attendance.
- **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 BSO nor the Associate BSO 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 BSO.
- **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.

2.4 Member(s) of the OC

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

2.5 RHSC Chair and Co-Chair

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

2.6 RHSC Executive Secretary

- The BSO shall serve as the Executive Secretary for the RHSC. At any RHSC meeting at which the BSO is not in attendance, the Associate BSO or the Director of EHSO shall serve as alternate Executive Secretary for purposes of that meeting, in accordance with Section 2.3 above.

TITLE:

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

- **Duties:** The Executive Secretary shall be responsible for performing the following duties:
- **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. 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.
- **Attendance:** Keeping accurate attendance of all members at each meeting of the RHSC.
- **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).
- **Keeping of Minutes:** Keeping accurate minutes of each RHSC meeting, including, but not limited to the following:
 - (a) date, time and place of the meeting;
 - (b) list of all individuals in attendance and a record of the presence of a quorum in accordance with the Section **Quorum** above, including a record of any persons who leave or enter during the course of the meeting and any resulting failure in quorum;
 - (c) 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) description of all items of old and new business discussed;
 - (e) description of all project reviewed and of all items of discussion regarding each such project;
 - (f) record of all motions made and whether the motions were approved/disapproved;
 - (g) record of the votes taken with regard to each project 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) description of any changes in RHSC membership, including beginning and ending dates of members' terms;
 - (i) listing of RHSC officers, including beginning and ending dates of

TITLE:

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

officers' terms; and

(j) time of the meeting's adjournment.

- **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.
- **Records:** Collecting and maintaining all records of any actions and activities of the BSO and the RHSC, including the Official Minutes as set forth in Sections **Keeping Minutes** and **Circulation and Approval of Minutes** above. All records shall be kept for the longest of any retention period required by applicable federal, state, local or university requirement.

3.0 Membership Terms and Conditions

- **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).
- **Officer Terms:** The Chair and Co-Chair(s) shall be appointed to serve for a term of 3-years from the effective date of appointment.
- **Additional Terms:** 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.
- 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

TITLE:

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

until their appointment has become effective and have been announced to the other RHSC members.

- **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.
- **Conflicts-of-Interest:** No RHSC member may be involved in the review or approval of a project 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 project/s. Any such RHSC member shall recuse himself/herself from the portion of the RHSC meeting in which any such project is considered; shall not vote on the project or be present for the vote; and shall not be counted towards a quorum necessary for the consideration of the project/s.
- **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.

4.0 Projects Requiring Submission to the RHSC and Review

4.1 Definitions Pertinent to this Section

- **Biological Toxins:** "Toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, or protozoa) or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology; produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance." [See 42 CFR § 73.1].
- **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)].
- **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

TITLE:

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

cause disease or adverse health impacts on humans, plants or animals. [See, F. Lisella, VNR DICTIONARY OF ENVIRONMENTAL HEALTH AND SAFETY, 165 (1994).]

- **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).
- **NIH Guidelines Research:** All research involving recombinant and synthetic nucleic acids is subject to the NIH Guidelines. Please refer to the IBC Charter and SOP for review of these projects.
- **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 projects 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 Project Guidelines (excluding research involving recombinant or synthetic nucleic acid molecules) as those terms are defined above, must be reviewed by the RHSC.

- **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?

- **Research that Involves Biological Toxins, or Infectious Agents:** If the research to be conducted involves Biological Toxins, Infectious Agents or includes recombinant or synthetic nucleic acid molecules but is exempt from the NIH Guidelines, then the following review processes are employed:
- **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 completing the electronic registration. EHSO will review the research to assign a preliminary biosafety level determination; to determine if the research falls under the NIH Guidelines; and to determine which type of review process should be employed.
- **BSL2 Enhanced and Higher Biosafety Levels (i.e., BSL 3 & BSL4):** If the research is exempt from the NIH Guidelines (III-F) and is classified as requiring BSL2 containment following BSL3 practices (enhanced) or higher

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

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 RHSC for review.

- **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 Biological Registration

All PIs who plan to work with Biological Toxins, Infectious Agents, Select Agents or Recombinant DNA Molecules must complete the electronic biological registration, including the project form, and submit it to the BSO for review by RHSC in accordance with Section 4.3 above. In addition, the processes for the submission of amendments to and annual updates of research projects are explained in the Biosafety Approval Guidelines. In order to conduct research at Emory involving Recombinant DNA covered by the NIH Guidelines, personnel must also follow the requirements of the Emory IBC Reference: NIH Guidelines, Section IV-B-2-a-(5); Biosafety Protocol Guidelines.

4.5 Tracking of Research Projects

Upon completion and certification of the electronic biological registration and specific project form, the BSO shall assign a number to the research project/s, which shall be used for tracking. The PI should refer to the assigned project number in all correspondence with the BSO and the RHSC regarding the research project.

4.6 Initial Review by BSO

The BSO shall review each certified biological registration and associated project/s 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 biological registration or project shall be returned to the PI for completion prior to being presented to the RHSC for review. Electronic files of the biological registration, project and supporting documents to be reviewed by the RHSC shall be provided to each member of the RHSC.

4.7 Assignment for Presentation

For all projects for which full RHSC review is required, the BSO with the concurrence of the RHSC Chair shall assign a reviewer(s) for each biological registration or amendment to be reviewed; provided, however, that the following project amendments may be reviewed solely by the Chair of the RHSC or his/her designee:

- A change in the title of a project, that does not involve any other changes to the project or personnel involved in the project,
- A change to a project for research when the change pertains only to a change in research personnel, other than the PI, assigned to the project, or
- A change that does not modify the current biosafety assignment (e.g. no change in Biosafety level or change in animal species).

4.8 Presentation at the RHSC Meeting

TITLE:

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

All electronic biological registrations or amendments 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 biological registration or amendment to be reviewed, a reviewer must be present at the meeting otherwise it 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 biological registration and associated project/s or project amendment have been received, along with the type of review process that the project will undergo, and if full RHSC review is required, the date of the RHSC meeting at which the project or amendment is scheduled for review. The biological registration or amendment must be received at by the submission deadlines posted on the EHSO website in order to be reviewed at that meeting. After the biological registration, associated projects, or amendment has been reviewed, the PI shall be notified by the RHSC as to the status assigned per Section 4.11 below.

4.10 Amendments to Projects

If a PI makes any change (addition, removal, or modification, referred to herein as an “amendment”) to the biological registration in BioRAFT after it has been approved the biological registration must be certified electronically. The certification of the biological registration will change the status from Approved to Awaiting EHSO review. As appropriate under [Section 4.3](#), the BSO or the full RHSC must review and approve the Amendment before the additions/modifications can be implemented. The minor amendments to biological registrations, as described in [Section 4.7](#), that initially received full RHSC review may be reviewed and approved by the BSO with the concurrence of the RHSC Chair.

- All other amendments that initially required full RHSC review must be approved by the full RHSC utilizing the same procedure followed for the original review of biological registrations. 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.
- Notwithstanding anything to the contrary set forth in Section 4.10 above, all Project forms using laboratory animal must be submitted for IACUC review, and all projects involving human subjects must be submitted to IRB for review.

4.11 Amendment Status

As a part of its review of a project within a biological registration or an amendment, the RHSC will assign one of the following statuses to the project under review:

- **Approved:** This status is given if the RHSC approves the project or amendment as reviewed without the need for any additional changes by the PI. An approval is good for one year, unless a shorter timeframe is specified by the RHSC. The approval letter is contingent to completion of all administrative requirements (e.g. training, Hepatitis B documentation, Corrective Action Plan, etc.). The approval of the amendment will be reflected in the electronic registration accordingly.

TITLE:

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

- **Pending Approval:** This status is given if the RHSC has just a few minor questions or issues about the project/amendment that the PI must resolve before the project 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 project/amendment will be withdrawn by the RHSC. The PI's response to the questions/issues will be given to the reviewers assigned to the project. They will review these responses and report to the RHSC Chair as to whether the response is adequate, and if so, the project/amendment will be granted the "Approved" status. No work under the project/amendment may take place until the project/amendment is Approved.
- **Re-Review/Deferred:** This status is given if the RHSC has a significant number of questions or issues regarding a project/amendment, or if the RHSC has questions or issues of a substantive nature regarding the project/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 project/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 project/amendment may take place until the project/amendment is Approved. Project approval periods shall be measured from the date of the meeting at which the RHSC granted Full Approval or Pending Approval; provided, however, that in the case of Pending Approval, work under the project cannot begin unless and until the PI receives a final approval letter from the RHSC. The project form will be archived electronically if it is not approved.
- **Disapproved:** This status is given if the RHSC has major substantive concerns with the project/amendment. For example, the project/amendment may not be justified; it may pose severe or unnecessary risk; it may have been deferred on several occasions; or the PI may have failed to adequately address issues or questions about the project/amendment. Further revisions to a Disapproved project/amendment will not be accepted by the RHSC. The PI may re-write the project/amendment with substantial changes and submit it as a new project/amendment. The status of the project form will be changed to "Denied" in the electronic registration if it is not approved. **Withdrawn:** The status is given to projects/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. The project form will be archived in BioRAFT if it is not approved.
- **Suspended:** This status is given if the RHSC determines that serious questions or issues have arisen with regard to a project, or the manner in which the project 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 project that the project has been suspended by that group. The RHSC may, in its discretion, suspend

TITLE:

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

all or part of a project. 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 project (or suspended portion of the project) 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 project should be Suspended, or to determine if a Suspended project may have its Approved status reinstated. OC will be notified about the suspension. The status of the project form will be changed to "Denied" in the electronic registration, if it is not approved.

- **Terminated:** This status is given to projects that are no longer active. Research may not be conducted under projects that are terminated. The project form will be archived in BioRAFT.
- The PI may terminate a project by writing to the RHSC Chair or his/her designee.
- If a PI does not take proper steps to renew a project when its Approved status is set to expire, then the project will be Terminated.
- The RHSC may also take steps to Terminate a project that has been Suspended, based on the results of appropriate inquiries/investigations conducted by the RHSC or other appropriate Emory University committees or units with jurisdiction over the project. The RHSC shall send out a written notice of Termination to the PI of any project that is Terminated. This notice may be copied to other University committees or units, as appropriate. No work shall continue under a project after it is Terminated. If the PI wishes to conduct future work under a Terminated project, he/she must submit the project for approval as a new project.

4.12 Project Annual Update

- Each project that is Approved by the RHSC is approved for one year. Projects that have been reviewed by the full Committee will return to the committee every three years and must be updated by the PI every year.
- Reminders for annual review are sent automatically in BioRAFT at 90, 60, 30 and 2 weeks intervals.
- The RHSC shall notify the PI as to the results of the RHSC's vote regarding the renewal of the project. If a PI fails to certify the electronic biological registration by the 10th of the month prior to the expiration of their existing project, or if the RHSC denies the renewal of the project, then the project 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 project after it is Terminated. If the PI wishes to conduct future work related to the Terminated project, he/she must review and certify the electronic biological registration to initiate the review by the RHSC.

4.13 Periodic Review/Update

On behalf of the institution, the RHSC is responsible for periodically reviewing research conducted at the institution as described in Section 4.2. All registrations subject to RHSC

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

review must be reviewed and updated annually. The annual update consists of verification of biological agents used, personnel included in a project/s, occupational health requirements, engineering controls, and completion of annual laboratory self-inspections. The annual review and update is completed in BioRAFT. The PI must certify the biological summary at the end of the review to prompt EHSO review.

4.14 Project Terminations

- A PI should request that the RHSC Terminate a project when the project 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 project should be Terminated or is being transferred to another PI at Emory in accordance with Section 4.15 below.
- The RHSC may Terminate a Project as set forth above in Section 4.11

4.15 Transferring a Project to another Investigator

If a PI desires to transfer his/her project to another PI at Emory, the transfer must be initiated by notifying the Biosafety Office via email to biosafe@emory.edu. The BSO will confirm with the transfer and make the changes in the electronic registration accordingly. No work may take place on a transferred project 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 project is no longer at Emory University and that PI had made no attempt to transfer the project to another PI at Emory, then the RHSC will contact the chair of the respective department and inquire as to whether they would like the project transferred to them as PI. Until a new PI has agreed to and received a transfer of the project, the project will be Suspended, and no work can take place on it. The participants who are eligible to serve as a PI will then have 30 days in which to review, update, and certify the registration or project. If the forms are not certified the electronic registration during this period, then the project will be Terminated.

5.0 Review by Other Emory Committees

5.1 Other Committees

Projects reviewed by the RHSC may require review and approval by other University Committees as well before the work under the Project can begin. For example, if the Project utilizes laboratory animals then the project will require review by the Emory University IACUC. Similarly, if the Project 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 projects at Emory shall coordinate among themselves the review of projects requiring approval by multiple committees. Committees shall also coordinate among themselves the communication of any Terminations or Suspensions regarding Projects under the jurisdiction of multiple committees. In general, if a project is subject to the jurisdiction of and requires review by either the IRB or the IACUC, the RHSC shall communicate any decision on its part regarding the approval of that project to either or both of the committees, and the approval by the IRB and/or the

TITLE:

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

IACUC must be in place before the PI can proceed with the project.

6.0 Responsibilities of PIs

6.1 General Responsibilities

- **PI is Responsible for Compliance with University Policies:** Each PI at Emory University is fully responsible for ensuring that his/her research that is subject to these Policies and Procedures is in full compliance therewith, as well as with any other applicable laws and regulations or University policies and procedures. Any failure on the part of the PI to comply with such applicable laws, regulations, policies and procedures may result in Suspension or Termination of the research and/or other appropriate actions, including disciplinary actions, being taken regarding the research or the PI by appropriate University Committees or officials.
- **Research Subject to RHSC Review:** The PI shall be responsible for ensuring that all research under a project requiring RHSC review is properly submitted to the RHSC for review and that RHSC approval is granted before any research under the project 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.).
- **Reporting Responsibilities:** The PI shall fulfill all reporting responsibilities placed upon him/her per Section 6.4 below.
- **Training:** The PI shall be adequately trained in good microbiological techniques and laboratory practices 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 BSO for additional information regarding training and training requirements.
- **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

- **Initial Submission to RHSC:** The PI shall submit and maintain up to date the BioRAFT electronic biological registration to the RHSC for review and approval/disapproval. Consult with the BSO for additional information.
- **Continuing Communication with the RHSC:** The PI shall be responsible for remaining in communication with the RHSC throughout his/her conduct of any project subject to the RHSC's jurisdiction; following any required procedures for renewal or amendment of the project; and immediately advising the RHSC of any adverse events, significant problems, significant research-related accidents or illnesses related to the project.

TITLE:**SAF-111, POLICIES & PROCEDURES OF THE EMORY UNIVERSITY RESEARCH HEALTH & SAFETY COMMITTEE****6.3 Specific Responsibilities of PI with Regard to the Laboratory Staff Prior to and During Conduct of Research**

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

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

- The PI shall immediately report the occurrence of the following events to the BSO who in turn shall report such events to the RHSC Chair and determine further reporting requirements:
- Significant problems pertaining to any project subject to the RHSC's jurisdiction, including problems pertaining to the operation and implementation of containment practices and procedures.
- 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. See the PeopleSoft reporting system website for reporting incidents.
- Further Reporting: The PI shall then, in conjunction with the Biological Safety Officer, further report any of the events set forth in the section above as follows:
- To the RHSC by letter to the Chair of the RHSC – immediately.
- To any Greenhouse/Animal Facility Director – immediately.
- To any other appropriate authorities within legally prescribed times or 30 days, whichever is less.

7.0 Recordkeeping

The RHSC meeting minutes are maintained by the Executive Secretary as set forth in Section 2.6 above. Correspondence sent to researchers, regulatory agencies or other persons concerning any of the RHSC's duties set forth hereunder is maintained electronically. All records shall be kept for the longest of any retention period required by any applicable federal, state, local or university requirement.

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

8.0 Review and Update of these Policies and Procedures

On a periodic basis, the BSO, 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 BSO 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.

9.0 Condition of Approval

9.1 Training

- As a condition of approval for all RHSC projects and biological registration, the personnel and the PI must have up to date training determined by the type of research to be conducted.

9.2 Lab Inspection

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

9.3 Occupational Health

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