Bylaws

Regis University Institutional Biosafety Committee (RUIBC)

Article I - Name

The name of this Committee shall be the "Regis University Institutional Biosafety Committee" (RUIBC).

Article II - Charge

The charge of this Committee shall be to:

- 1. Develop institutional policy for the safe use, handling, and storage of hazardous chemical and biological materials, including, but not limited to recombinant DNA;
- 2. Advise the Institution/Investigators on regulations and policies involving biologically and chemically hazardous materials;
- 3.. Certify to granting agencies, as requested, that facilities, procedures, and practices for handling biologically and chemically hazardous material have been reviewed and approved by the Committee, and certify that the training and expertise of personnel is sufficient and appropriate;
- 4. Provide timely review of and make approve/deny decisions for any protocols submitted to the IBC;
- 5. Make recommendations to the Institutional Official (IO) concerning the biohazards program. Provide notification of any concerns to the Institutional Official regarding safety issues, adverse events, or other significant concerns;
- 6. Provide documents regarding processes and procedures for review by the Research Protection Committee upon request.

Article III - Members

Section 1. The membership of this Committee shall consist of at least five individuals with pertinent expertise as follows:

The Chair of the Committee

The Chair of the Committee shall be a ranked faculty member of Regis University who is professionally knowledgeable about one or more aspects of biosafety. S/he must be a scientist with applied research experience with recombinant DNA. The chair is the only non-voting member of the regular committee who shall vote only in the case of a tie vote among IBC members.

The Chair shall serve a two-year term and preside at all meetings of the committee. He/she may assign such additional duties to other members of the committee as deemed necessary for the conduct of the work of the committee and which are not inconsistent or conflicting with the duties otherwise prescribed.

The Chair of the IBC is appointed by the Institutional Official and is expected to actively participate in the Research Protection Committee.

University Members

Approved: March 16, 2018

There shall be a **minimum of three** Regis University faculty and staff members, including the chair. Faculty members must be ranked. Areas of expertise desirable (but not required) of the committee members include: microbiology, infectious disease, recombinant DNA technology, animal experimentation, plant experimentation, medicine, current clinical practice, chemistry, toxicology, occupational health and safety, public health, community attitudes, applicable law.

Members will be nominated by their respective Academic Dean and approved by the Institutional Official.

Community Members

There shall be **two** committee members, not affiliated with the University, who represent the community with respect to health and protection of the environment, herein called "community members". The community members shall be voting members of the IBC.

Ex-Officio Members

The Compliance Coordinator will serve as an *Ex-Officio* committee member. Other *Ex-Officio* members with expertise pertinent to committee business shall be recruited as needed.

Administrative responsibilities for the Committee, which will include taking notes, recording votes, drafting agendas, assisting with research, tracking/verifying CITI training certification, maintaining bylaws, and convening the meetings will be the responsibility of the University's research compliance coordinator, an individual under the approval of the IO. Secretarial duties need not be executed by a member of the committee.

Terms of Office

Section 2. Each member's annual term shall coincide with the start of the Regis academic year. If notice of resignation by the member or non-reappointment by the IO is not given by July 1 of each year, each member's appointment shall be automatically renewed on a year-to-year basis.

Resignation

Members may resign at any time, but should provide sufficient notice such that a suitable replacement may be appointed so as to not impede RUIBC processes.

Removal

If a member can no longer serve because of a change in eligibility status or inability/unwillingness to participate fully in the required activities of the committee, the committee shall recommend removal of the member.

Article IV – Meetings

Section 1. The Committee will meet at least annually and as needed to conduct business.

Section 2. Quorum for this committee to conduct business is defined as fifty percent of members, plus one. Quorum may be established in person or via phone.

Section 3. An expedited or other special meeting may be called by the Chairperson to review a new application, renewal of an established protocol, or an amendment if a grant transfer or grant award is pending, and approval must be granted prior to the next scheduled IBC meeting. All members are invited, and a minimum of three members is required to approve the protocol under review. Action is approved by majority vote. Business conducted at an expedited meeting is reported to the full committee at the next scheduled meeting.

Approved: March 16, 2018

Section 4. Meeting minutes will be retained for three years following the meeting (or as consistent with Regis policy and 2 CFR 200.333). Any printed or electronic documents related to a protocol will be retained for three years following termination/completion of the protocol.

Notice of Meeting

Each member of the committee shall be notified in writing or via e-mail of all regularly scheduled meetings at least two weeks prior to the date of the meeting. Notification of meetings scheduled on short notice shall be via e-mail or phone.

Each voting member shall have one vote, which shall be exercised only by that member either in person or by phone during the meeting in which the motion is put to a vote. Motions may be made by any IBC member. Approval of all motions shall be gained with a simple majority.

Article VI – Review and Approval of Bylaws

These bylaws shall be reviewed at **least every two years** by the Chairperson of the Committee, and the IO. Proposed changes to the bylaws will be presented to the full Committee for review and comment. The IBC Chairperson has authority to provide final approval of the Bylaws.

Article VII - Amendment of Bylaws

These bylaws may be modified or amended as needed at the request of the IO or designee in consultation with the IBC Chairperson.

Article VIII – Confidentiality of Records – The principle investigator (PI) is responsible for complying with HIPAA regulations and guidelines, as well as with those of the Regis University IRB. All documents submitted to RUIBC will be treated as confidential, with their discussion being limited to the scope of official committee business conducted among committee members, the Institutional Official, the secretary, and external expertise as needed.

Article VIII - Conflict of Interest

A conflict of interest situation exists when the committee is requested to deliberate and recommend action regarding a particular biohazardous agent user who is also a member of the committee. This member will be allowed to participate in the discussion of the issue but shall not be permitted to make any formal motions or to cast a vote concerning the topic at hand. The member shall be asked to leave the room during any vote affecting the conflict of interest area.

Approved: March 16, 2018