

The University of Tulsa Institutional Biosafety Committee –Standard Operation Procedures (SOPs)

SOP Title: **IBC Membership, Annual IBC Registration, and Member Confidentiality**

SOP Number: **IBC-SOP-001**

Revision Number: 1

Effective Date: 9/20/2019

1. **PURPOSE**

- 1.1 The purpose of this document is to describe the process of annual IBC roster submission to the Office of Biotechnology Activities (OBA), new and continuing IBC membership, and member confidentiality.

2. **KEY WORD DEFINITIONS:**

- 2.1 IBC: Institutional Biosafety Committee
- 2.2 RCC: Research Compliance Coordinator
- 2.3 BSO: Biological Safety Officer
- 2.4 NIH OBA: National Institutes of Health Office of Biotechnology Activities
- 2.5 IBC-RMS: The Institutional Biosafety Committee Registration Management System
- 2.6 IO: Institutional Official
- 2.7 NIH Guidelines: *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (last revised April 2019)

3. **RESPONSIBILITIES AND AUTHORITIES**

Research Compliance Coordinator (RCC):

- 3.1 Maintains the current TU IBC membership list;
- 3.2 Submits the annual TU IBC membership roster to NIH OBA
- 3.3 Maintains records related to reports;
- 3.4 Collects and stores CITI TU IBC member training and biographical sketches of all new TU IBC members;
- 3.5 Maintains TU IBC member Confidentiality Forms

4. **IBC MEMBERSHIP COMPOSITION**

- 4.1 The University of Tulsa has established an Institutional Biosafety Committee (TU IBC) whose responsibilities are restricted to the oversight of recombinant DNA or synthetic nucleic acid molecule research.
- 4.2 **Per NIH Guidelines, Section IV-B-2-a-(1)** - The University of Tulsa Institutional Biosafety Committee (TU IBC) is comprised of no fewer than five members so selected that they collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecule research and to identify any potential risk to public health

or the environment. At least two members are not affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and represent the interest of the surrounding community with respect to health and protection of the environment (e.g., officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community). The Institutional Biosafety Committee includes at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing **Appendix L**, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants*, require prior approval by the Institutional Biosafety Committee. The Institutional Biosafety Committee has at least one scientist with expertise in animal containment principles when experiments utilizing **Appendix M**, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals*, require Institutional Biosafety Committee prior approval.

When the University of Tulsa participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human research participants, the institution will ensure that the Institutional Biosafety Committee has adequate expertise and training (using *ad hoc* consultants as deemed necessary) and no research participant shall be enrolled until the TU IBC, TU Institutional Review Board (IRB) and all other applicable institutional and regulatory authorization(s) approvals have been obtained.

Section IV-B-2-a-(2). In order to ensure the competence necessary to review and approve recombinant or synthetic nucleic acid molecule activities, the Institutional Biosafety Committee should (i) include persons with expertise in recombinant or synthetic nucleic acid molecule technology, biological safety, and physical containment; (ii) include or have available as consultants persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment, and (iii) include at least one member representing the laboratory technical staff.

Section IV-B-2-a-(4). No member of an Institutional Biosafety Committee may be involved (except to provide information requested by the Institutional Biosafety Committee) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.

- 4.3 **Biosafety Officer:** Per *NIH Guidelines*, when an institution conducts recombinant or synthetic nucleic acid molecule research at BL3, BL4, or Large Scale (greater than 10 liters), a Biological Safety Officer is mandatory and shall be a member of the Institutional Biosafety Committee (see **Section IV-B-3**, *Biological Safety Officer*).

4.3.1. Currently, The University of Tulsa does not conduct research activities that meet the criteria needed to appoint a Biological Safety Officer (BSO).

- 4.4 IBC Membership Appointments: TU IBC Members will be recruited to serve three-year term appointments, with starting dates coinciding with the start of the academic year (i.e. August 15, 2018-August 14, 2021)
- 4.4.1. TU IBC Members can be recruited to serve multiple term appointments.
- 4.4.2. TU IBC member appointment terms will be staggered so that only a minority of members' terms will be up at any given academic year end, to retain continuity and experience on the Committee.

5. ANNUAL IBC MEMBERSHIP

- 5.1 **Registration:** Each year the RCC will submit the annual IBC Report to the NIH Office of Biotechnology Activities on the Registration Management System (IBC-RMS).
- 5.1.1. This electronic annual report contains:
- An updated committee roster indicating the role of each committee member and expertise
 - Bio-sketches (curricula vita, resume, etc.) of any new members or
 - Continuing members who have been on the roster over three years and when NIH-OBA requests updated bio-sketches.
- 5.1.2. The RCC will collect and upload the bio-sketches (curricula vita, resume, etc.) of any new members or continuing members.
- 5.1.3. The Annual IBC Membership report is due one year after the approval receipt of the previous year's report to NIH-OBA.
- The RCC will calendar the annual report deadline, with ample time to collect any information needed to submit the current year's report.

6. CONFIDENTIALITY FORMS

- 6.1 All members of the TU IBC will be provided with a confidentiality agreement and will agree to adhere to the confidentiality policy and sign the form at the beginning of their service term and again at the beginning of each subsequent 3-year term.
- 6.2 In reviewing an application, if the IBC or an individual member feels that additional expertise is needed, the IBC Chair will solicit a subject matter expert or consultant. Consultants will adhere to the TU IBC confidentiality policy and will sign the confidentiality agreement.
- 6.3 No Information about the proceedings and deliberations of the TU IBC may be discussed except with other TU IBC members, the RCC, the Institutional Official (Vice President for Research), or others to assist in the conducting of official TU IBC business. All discussions will occur in a secure location.

7. **REVISION HISTORY**

7.1 Version 9.20.2019 approved 10/1/2019

8. **STANDARD OPERATION PROCEDURES APPROVAL**

Approved by: Estelle Levettin Date Approved: 10-1-19
TU IBC Chair

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf