TEMPLE UNIVERSITY
INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) CHARTER

I. PURPOSE

This chartering document (hereinafter, this "Charter") defines the charge, responsibility and authority of the Temple University Institutional Biosafety Committee ("IBC")

II. SCOPE

The IBC is an advisory committee at Temple University dedicated to excellence in the science and practice of biological safety, established as mandated in section IV-B-2 of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*. Committee members are involved in evaluating risks from recombinant or synthetic nucleic acid molecules, biohazardous materials, and biologically-derived toxins. The activities of the IBC are those appropriate to accomplish its role in ensuring the safe acquisition, storage, use, and disposal of recombinant or synthetic nucleic acid molecules, biohazardous materials and biologically-derived toxins at Temple University, and in monitoring and recommending as necessary, modifications to the Biological Safety program. Provisions of this Charter shall apply to all instructional and research projects conducted in Temple University facilities or on Temple University property, including all rented or leased facilities or properties, as well as to all such projects carried out by faculty, staff, or students in connection with University responsibilities, regardless of location. If work is being done off site, the Temple University IBC may accept the approval of another IBC.

III. CHARGE

Temple University hereby charges the IBC to:

1. Ensure that all instructional and research projects involving the acquisition, use, storage, or disposal of recombinant or synthetic nucleic acid molecules are in compliance with the *NIH Guidelines* as mandated by NIH Office of Science Policy (NIH-OSP), as well as all applicable federal, state, and local regulations and guidelines.

2. Ensure that all instructional and research projects involving the acquisition, use, storage, or disposal of biohazardous materials are in compliance with the National Institutes of Health (NIH)/ Centers for Disease Control (CDC) publication *Biosafety in Microbiological and Biomedical Laboratories 5th Edition (BMBL6)* as well as all applicable federal, state, and local regulations and guidelines. For this purpose, biohazardous materials include, but are not limited to all infectious agents, infected or potentially infected animals, infectious material, recombinant or synthetic nucleic acid

molecules, and biologically-derived toxins that present either a risk or a potential risk to the health of humans, animals, or plants either directly through infection or indirectly through damage to the environment. Materials that may harbor biohazardous agents such as human and non-human primate blood, body fluids, tissues, primary cells, or tissue culture cells must also be considered biohazardous materials.

3. Ensure that all instructional and research projects involving the acquisition, use, storage, or disposal of biologically-derived toxins are in compliance with the NIH/CDC publication *BMBL6* as well as all applicable federal, state, and local regulations and guidelines.

4. Advise the Vice President for Research on the development of policies and procedures concerning the use of recombinant or synthetic nucleic acid molecules, biohazardous materials, and biologically -derived toxins in instructional and research laboratories.

5. Advise the Vice President for Research regarding training, experience, and qualifications of individuals who work with or in the vicinity of recombinant or synthetic nucleic acid molecules, biohazardous materials, and biologically-derived toxins in instructional and research laboratories.

6. Recommend to the Vice President for Research sanctions on any individual whom the IBC determines has violated the terms of an approved protocol, has conducted projects subject to its authority without gaining appropriate IBC approval, or has otherwise violated any provision of applicable federal, state, and local regulations and guidelines, or institutional policies regarding subjects under its purview.

IV. RESPONSIBILITIES AND AUTHORITY

1. Review and approve all instructional and research projects involving the acquisition, use, storage, or disposal of recombinant or synthetic nucleic acid molecules, biohazardous materials, hazardous drugs, or biologically-derived toxins in accordance with all applicable federal, state and local regulations and guidelines.

2. For human gene transfer experiments, the IBC will meet and review all project applications in accordance with all aspects Section III-C of the *NIH Guidelines.*

3. Ensure that IBC members are appropriately trained with respect to all applicable federal, state, and local regulations and guidelines.

4. Verify that all laboratory procedures, facilities, and safety equipment are consistent with the University's written policies and procedures concerning the generation and/or use of recombinant or synthetic nucleic acid molecules, biohazardous materials, and biologically-derived toxins in instructional and research laboratories.

5. Review reports from Temple University Environmental Health and Radiation Safety department (EHRS) on unsafe practices and safety hazards in the laboratory and make recommendations to the Vice President for Research regarding these hazards.

6. Advise the Institutional Review Board (IRB) and the Institutional Animal Care and Use Committee (IACUC) for work involving recombinant or synthetic nucleic acid molecules, biohazardous materials, and biologically-derived toxins.

7. Establish a *Procedures Manual*[1] that the IBC will follow in its initial and continuing review and approval of project applications, proposals, and activities.

8. The IBC may delegate its authority to the Chair or the University Biosafety Officer for routine matters, to include approval of exempt recombinant or synthetic nucleic acid molecules projects.

V. MEMBERSHIP:

1. At a minimum, individuals holding the following positions or titles at Temple University shall be appointed by the Vice President for Research to the IBC as voting members:

   a) At least three (3) members of the University research faculty
   b) Two persons not affiliated with the University
   c) University Biosafety Officer
   d) Animal Containment Expert
   e) Additional members may be appointed based on specific future research project(s) review by the IBC.

2. Faculty members shall be appointed to the IBC by the Vice President for Research for renewable terms of three years. Initial membership may be for periods of less than three years to stagger periodic replacements.

VI. OFFICERS AND SUBCOMMITTEES

1. The officers of the IBC are the Chair, the Vice Chair, and the University Biosafety Officer.

2. The Chair is the principal administrative officer of the IBC and presides over all meetings and oversees all IBC activities.

3. The Chair shall be appointed by the Vice President for Research to serve a term

[1] The Procedures Manual is referenced herein and attached hereto and may be modified, addended, altered, changed, or revised without modification of this Charter

of one year and may be re-elected to consecutive terms.

4. The Vice Chair shall be appointed by the Vice President for Research to fulfill the duties of the Chairperson in his or her absence or recusal.

5. The University Biosafety Officer is responsible for implementing institutional biosafety policies and coordinating IBC activities.

6. The IBC coordinator is responsible for maintaining the official records of the IBC.

7. Subcommittees consisting of at least three members may be formed to address specific issues.

8. In the event that a subcommittee is formed, the Chair will select members (including the University Biosafety Officer) with experience relevant to the specific issues. Subcommittees may include individuals who are not IBC members but who possess expertise relevant to the project being considered.

VII. MEETINGS

1. The IBC shall meet monthly and additionally at the call of the Chair or the Vice President for Research.

2. A quorum shall consist of a simple majority of voting members (including the Chair and/or the Vice Chair), though a vote on a pending project approval will still be valid should a voting member need to be recused. To take action, a quorum must be present in person or through telephone or video conferencing.

3. The IBC shall follow standard operating procedures throughout the review of research and instructional projects as specified in the *Temple University Institutional Biosafety Committee Procedures Manual*.

4. Decisions and project approvals shall be made based on a majority vote of voting members present at the time a vote is taken.

VIII. HEARINGS AND APPEALS

1. Any individual who may be the subject of a disciplinary action by the IBC shall have the right to appear before the IBC and to present evidence to the IBC for its consideration before any decision, appeal decision, or final decision is made by the Vice President for Research.

2. Decisions of the IBC may be appealed first to the IBC, and then, if necessary, to the Vice President for Research, whose decisions shall be final.

IX. AMENDMENTS AND REVIEW

1. Amendments to the Charter may be proposed at any meeting of the IBC.
2. The IBC Charter shall be reviewed by the IBC annually or as needed.

X. EFFECTIVE DATE

This Charter shall take effect immediately upon receipt of the signatures listed below.

XI. APPROVAL