External Appendix A
for EHS-00056 BIO-SAFETY POLICY

Institutional Biosafety Committee Charter

REVISION

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1	DCN1628	Initial Release	11-28-18	K. Rhodes	T. Diamond

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1 PURPOSE

Provide guidance and standardized protocol for the Institutional Biosafety Committee (IBC) to facilitate efficient review of biohazardous research and materials.

2 SCOPE

The Institutional Biosafety Committee (IBC) is charged by the SUNY Polytechnic Vice President of Environmental, Health & Safety to provide oversight of all research involving recombinant or synthetic nucleic acid molecule technology in compliance with *National Institutes of Health (NIH) Guidelines*. The Committee is further charged with oversight of research involving biohazardous material to protect public health and the environment.

3 ASSOCIATED DOCUMENTS

3.1 **EHS-00056** Biosafety Policy

3.2 **EHS-00056-F3** Biological Risk Assessment

4 PROCEDURE

4.1 Committee Structure

In accordance with *NIH Guidelines* (IV-B-2), the Committee shall be constituted as follows:

4.1.1 There shall be at least five members, selected so that they collectively have experience and expertise in recombinant and synthetic nucleic acid molecule research and to identify any potential risk to public health or the environment.

4.1.2 At least two members shall not be affiliated with SUNY Polytechnic, and who represent the interest of the surrounding community with respect to health and protection of the environment.

4.1.3 When actively used on site, at least one member shall have expertise in plant, plant pathogen, or plant pest containment principles (ad hoc consultant, as needed).

4.1.4 When actively used on site, at least one member shall have expertise in animal containment principles (ad hoc consultant, as needed).

4.1.5 When actively used on site, at least one member shall have human gene transfer expertise (ad hoc consultant, as needed).

4.1.6 The SUNY Poly Biosafety Officer (BSO) shall hold an ongoing membership position.

4.1.7 Unless otherwise specified, appointment term is for three years and will be renewed annually.

4.1.8 Potential IBC members are recommended by committee members to the IBC Chair/ BSO for selection.

4.2 **Committee Responsibilities**

The Committee shall:

4.2.1 Verify the appropriate biosafety containment level for each research protocol has been selected.

4.2.2 Review all new and modified research protocols involving the use of recombinant or synthetic nucleic acid molecules, infectious agents, and select agents (as defined by CDC and USDA). Differing levels of review will be used depending on the potential hazards.

4.2.3 Notify Principal Investigators (PI) of the results of each research protocol review.

4.2.4 Conduct periodic reviews of all research protocols involving the non-exempt use of recombinant or synthetic nucleic acid molecules to ensure compliance with *NIH Guidelines*.

4.2.5 Verify emergency plans covering accidental spills and personnel contamination resulting from recombinant and synthetic nucleic acid molecule research are sufficient.

4.2.6 Investigate any research-related accidents or illnesses involving potential biological hazards and file reports, as required, with the NIH Office of Biotechnology Activities.

4.2.7 Ensure that the annual report containing the IBC roster is filed in a timely manner with National Institutes of Health/Office of Biotechnology Activities (NIH/OBA) by the BSO as required under the *NIH Guidelines*. The deadline for the annual update is one year after the approval date of the last report submission.

4.2.8 Investigate allegations of noncompliance with *NIH Guidelines* or other unsafe acts.

4.2.9 Provide a forum for development and modification of campus biosafety policies.

4.3 **Principal Investigator Responsibilities**

Principal Investigators shall comply with the *NIH Guidelines* and:

4.3.1 Submit new and modified (renewal or amendment) Biological Risk Assessment (**EHS-00056-F3**) to the Committee, as required.

4.3.2 Not commence research on new or modified protocols prior to the receipt of written approval from the Committee for protocols falling under Sections III-A, III-B, III-C, or III-D of the *NIH Guidelines*.

4.3.3 Participate in the annual review of each of their research protocols involving the use of recombinant or synthetic nucleic acid molecules.

4.3.4 Ensure they and all laboratory staff are appropriately trained including, at a minimum: containment methods, disinfectant and disposal practices, utilization of personal protective equipment, and required actions in the event of a spill.

4.3.5 Ensure required safety practices and techniques are employed in the space for which they are responsible.

4.3.6 Comply with all other requirements of the IBC approval, inspections and SUNY Poly Biosafety Program.

4.4 **General Committee Procedures**

4.4.1 Meetings shall be held, as dictated, by need, but no less than once per calendar year.

4.4.2 A quorum consists of fifty percent of the Committee membership, plus one.

4.4.3 In the event that the IBC chair must be absent, he/she will request another committee member to serve as chair during the absence.

4.4.4 Meetings held may be open to the public, when consistent with protection of privacy and proprietary interests. Meeting minutes are available for public review.

4.4.5 Meeting minutes may be redacted as appropriate, before being made public. Redaction will be based on a legal review by appropriate internal parties.

4.4.6 If urgently required, approvals associated with recombinant DNA activities may be obtained when a majority of members approve in writing without a meeting.

4.5 Research Protocol Review Procedures

4.5.1 Protocols involving:

a) non-exempt recombinant or synthetic nucleic acid molecule research and
b) blood borne pathogens or
c) other biohazardous material that are determined to present significant potential for human and environmental impact such as BSL2 or greater and/ or select agent materials (defined by 42 CFR Part 73, 9 CFR Part 121 and 7 CFR Part 331).

4.5.1.1 These protocols shall be submitted using the Biological Risk Assessment (**EHS-00056-F3**) then reviewed and approved by the FULL committee and discussed at a Committee meeting. Protocols may be approved, conditionally approved, or disapproved. Approval is by majority vote of those present.

4.5.2 Protocols involving:

a) exempt recombinant or synthetic nucleic acid molecule research,
b) non-recombinant synthetic nucleic acid molecule BL1 classification research and
c) other non-research BL1 operations.

4.5.2.1 These protocols are submitted using the Biological Risk Assessment (**EHS-00056-F3**) then reviewed and approved by the IBC Chair/ Biosafety Officer, but are NOT generally subject to full Committee review.

4.5.3 Protocol Modification

4.5.3.1 Major modifications or renewal protocols require a new Biological Risk Assessment (**EHS-00056-F3**) and full Committee review and approval.

4.5.3.2 Minor modifications require amendment with review and approval by the IBC Chair/ Biosafety Officer.

4.5.4 Protocols Containing Proprietary Information

4.5.4.1 Principal Investigators who believe that their research protocols contain proprietary information shall identify such research in writing to the IBC Chair/ Biosafety Officer at the time the protocol is submitted for review.

4.5.4.2 Grounds for classifying information as proprietary include, but are not limited to: new and/or novel ideas; it is specified as such in a written contract or agreement; new commercial uses of a process, device or chemical; and potentially patentable items.

4.5.4.3 Protocols identified as containing proprietary information may be discussed in closed session. Records of votes and discussion that do not reveal the proprietary information will be maintained.

4.6 Conflict of Interest Policy

4.6.1 It is the policy of this committee that no member of the IBC may be involved (except to provide information requested by the IBC) 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.

4.6.2 Each member is expected to notify the IBC chair in these circumstances and recuse themselves when such proposals are being discussed and are up for a vote.

4.7 Appeals

4.7.1 Principal Investigators who disagree with Committee decisions may request an audience at a Committee meeting for the purpose of presenting evidence that supports their position.

4.7.2 Should there still be disagreement; the Principal Investigator may appeal to the SUNY Polytechnic Vice President of Environmental, Health & Safety; who shall make the final decision.

4.8 Charter Amendments

4.8.1 Charter amendments may be made by the SUNY Polytechnic Vice President of Environmental Health and Safety to keep the committee in compliance with changes to the *NIH Guidelines*.

4.8.2 IBC members may recommend an amendment to the charter if the amendment is approved by 75 percent of voting IBC members. The recommended amendment must be presented to the Vice Provost for Research and the Provost.

4.8.3 Recommended amendments become effective upon approval of the administration.

4.8.4 All charter amendments must maintain SUNY Poly's compliance with *NIH Guidelines*.