Binghamton University
Institutional Biosafety
Policy and Procedures

1. Purpose

Binghamton University will provide oversight in the safe handling, storage, and disposal of potentially bio-hazardous materials, recombinant DNA (rDNA) and gene drive modified organisms (GDMO's) used in research or instruction. Providing the necessary expertise, training, support, and surveillance, Binghamton University will ensure safe practices to protect campus constituencies, the community, and the environment from biological hazards and will abide by all biosafety regulations and guidelines. The NIH Guidelines require an Institutional Biosafety Committee (IBC) be established

by the University or in activities sponsored by the University involving any of the aforementioned substances. All activities involving substances that fall under this policy will be performed under the supervision of the Principal Investigator (PI) who is designated as the principal user and who is responsible for proper acquisition, use, handling, storage, transportation and disposal.

C. All research deemed non-exempt by the IBC is required to be performed using BSL-2 laboratory practices unless otherwise specifically stated. It is the

E. The IBC will convene, at a minimum, once per semester and supplement as needed to

University stakeholders, including senior officials, deans, department chairs, investigators, laboratory staff. BSO duties include, but are not be limited to:

a. Inspecting laboratory to ensure that standards are rigorously followed;
b. Reviewing laboratory facility design plans for research involving biological hazards and ensuring current certification of laboratory biological safety cabinets;
c. Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant or synthetic nucleic acid molecule research;
d. Providing technical advice on research safety procedures, laboratory security, biosafety administrative controls and compliance requirements, and assistance in the development of SOPs;
e. Perform Continuing Reviews
f. Investigating laboratory accidents and report to the IBC Chair, the Assistant Vice President for Research Compliance, and when applicable the Occupational Health Specialist, any significant problems or viol.3 (c)-4.9 (a)-3.2 (c)-4.9bo0.8 (m)-6,ealthois6no

ii. The PI is to make an initial determination of the required levels of physical and biological containment in accordance with the NIH Guidelines, and submit the initial research protocol including to SOPs, MSDSs, MTAs, etc. Initial and all subsequent submissions to the IBC are via PACS for review and approval, modification, or disapproval.

iii. Prior to initiating research that falls under the purview of the IBC, the PI is to ensure that laboratory staff are appropriately trained in the techniques required to ensure safety and in dealing with incidents that may cause harm. Other pre approval responsibilities include:

   a. Make available to all laboratory staff the protocols that address the potential biohazards and the precautions to be taken;
   b. Determine and secure the necessary personal protective equipment (PPE) required for lab staff and provide training on the proper s Td10.6 (oMC 6.29roI 1.29 TDe)7candtt90.olabtoot12Sctoslab

i. Studies involving GDMO's, rDNA, Select Agents or Biohazardous Materials must be submitted to the Office of Research Compliance for review through PACS.
ii. The IBC review process is coordinated by the Office of Research Compliance. The BSO will make the determination on whether the proposed research falls under the purview of the IBC.

iii.

iv. The IBC approves protocol applications by a majority vote during such meetings.

v. The IBC will discuss each protocol application during the convened meeting. This discussion focuses on an assessment of the safety of each research protocol and the identification of any potential risk to workers, other persons, or the environment, and protocol revisions and/or clarifications made in response to reviewer comments.

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The timeline for review and approval of Significant Amendments will be the same as an initial protocol submission (5.A.v.-vi). All annual Continuing Reviews are to be submitted via PACS at least fourteen (14) days prior to the annual expiration date for review and approval. Continuing Reviews will be reviewed by the BSO.

6. Conflict of Interest Policy

The Binghamton University IBC Conflict of Interest (COI) Policy states that committee members will neither review nor vote on any research protocol for which they have a COI. A member that has a COI may be asked to provide the IBC information concerning the research, however they shall recuse themselves from the final discussion and vote of all such research, and are not counted toward quorum.

For the purposes of this policy, a "conflict of interest" shall be defined as any factor, event or interest, whether of a financial or non-financial nature that could reasonably influence, or be

meeting minutes and any associated documents submitted to or received from funding

agencies. Documents may be redacted, as necessary to protect confidentiality and/or proprietary information.

8. Reporting Concerns

a. Concerns involving the safe and ethical use of GDMO's, rDNA, Select Agents, and/or Biohazardous Materials are to be communicated directly to the BSO.
b. When the BSO cannot address such concerns, these concerns need to be forwarded to the IBC Chair and discussed at the next convened IBC meeting, or more immediate when necessary.
c. Following this discussion, the IBC will vote on measures deemed appropriate to resolve the concern. These actions are to be reported to the Assistant Vice President for Research Compliance who serves as the Institutional Official (IO).
d. If the concerns are significant in nature, the IO will submit a report to the NIH OSP as per the NIH Guidelines and notify the IBC of the submission of the report to the NIH OSP.

Note: The NIH Guidelines require that "any significant problems, violations, or any significant