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 to ensure that research conducted at or sponsored by the University is in compliance with the NIH Guidelines. This requirement is primarily met through the review and approval of all applicable research by this review body. Members of the IBC are responsible for providing the collective experience and expertise in research involving these materials and the capability to assess the safety of research protocols and to identify any potential risk to workers, other persons, or the environment. This policy and procedures, therein describe the functions of the Office of Research Compliance, Office of Environmental Health and Safety (EH&S), the Institutional Biological Safety Officer (BSO), and the IBC.

2. Policy

The IBC will oversee all University activities that use GDMO's, rDNA and biohazardous materials. The IBC, in conjunction with EH&S, will establish and periodically review procedures and regulations and ensure adherence to these procedures and regulations to provide for the safe use of GDMO's, rDNA and biohazardous materials at the University and in activities sponsored by and through the University. The IBC will ensure compliance with Federal and State regulations and the most current practices and procedures for the safe use of GDMO's, rDNA and biohazardous materials. All investigators will be responsible for full compliance with the NIH Guidelines, all applicable governmental rules and regulations, and applicable University policies and procedures.

A. Research involving the following must be submitted and approved by the IBC:
   i. **Recombinant DNA-**All research involving rDNA
   ii. **Gene Drive Modified Organisms-**All research involving GDMO's
   iii. **Select Agents**-All research involving Select Agents must be submitted and approved by the IBC (defined by 42 CFR Part 73, 9 CFR Part 121 and 7 CFR Part 331)
   iv. **Biohazardous Materials** -Research involving Biohazardous Materials may require IBC review and approval. The following categories represent the areas of primary concern with respect to biosafety: Infectious agents
   Biological toxins
   Certain human-derived tissues, fluids, cells
   Certain plant pathogens
   Experiments with Dual Use Research of Concern (DURC) potential

B. This policy applies to investigators engaging in research and instructional activities that involve any of the aforementioned substances. Investigators shall be defined as any student, staff or faculty of the University and anyone conducting activities either on property owned or operated

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 policy of Binghamton University that BSL-3 and 4 agents may not be used or stored on property owned or operated by the University. This policy does not cover activities that only generate human biohazardous waste and are not related to research. These activities are regulated by EH&S.
D. Approval and clearance must be obtained before any research that falls under this policy is to commence. Non-compliance with this policy or the terms of approval to conduct research that falls under this policy may result in, but not limited to: suspension of research, closure of labs, and suspension of funding.
E. All activities that fall under this policy must be reviewed and approved by the BSO and, as required, by the IBC. Projects submitted for sponsorship by external agencies will be submitted for review and receive approval prior to the acceptance of funding.

3. Committee Charge

A. The IBC of Binghamton University, holding the necessary experience and expertise in pertinent areas of biological research and safety, will provide oversight for all University activities involving the aforementioned substances. The IBC will function in accordance with the NIH Guidelines for Research involving rDNA Molecules, CDC BMBL, Code of Federal Regulations (42CFR73, 7CFR331, 9CFR121) USA Patriot Act, Public Health Security and Bioterrorism Response Act.
B. The IBC is empowered with the authority to enforce the NIH Guidelines and to ensure that IBC approved conditions are fulfilled. The IBC may fully investigate potential violations or non-compliance. In the event of a significant research-related incident, the IBC may suspend, limit, or terminate PI authorization to use biological materials pending a formal investigation. The IBC may take further actions deemed appropriate upon repeated areas of non-compliance. The IBC may delegate authority to the BSO for investigating problems and taking actions necessary to correct repeated compliance violations or serious safety violations. If required as a condition of compliance with the NIH Guidelines, these incidents will be reported to the NIH.
C. The NIH requires that the IBC must be comprised of no fewer than five members. At least two members shall not be affiliated with the institution and represent the interest of the surrounding community with respect to health and protection of the environment; at least one individual with expertise in plant, plant pathogen, or plant pest containment principles; at least one scientist with expertise in animal containment principles; andthe BSO.
D. IBC members are appointed for a period of three years, and consecutive terms are permissible when necessary to maintain a collective experience and expertise to effectively review all research protocols. The one exception is the BSO who is a staff member in EH&S and serves as a permanent member of the IBC.

E. The IBC will convene, at a minimum, once per semester and supplement as needed to review and address any proposals and campus biosafety related matters.
F. No member of an 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 conflict of interest (COI). Any questions surrounding a COI are to be addressed by the Assistant Vice President for Research Compliance.
G. A member that has a COI (see 5.C.) may be asked to provide the IBC information concerning the research, however they shall recuse themselves for the final discussion and vote of all such research, and are not counted toward quorum.
H. A quorum for decision making will be a simple majority of eligible and appropriate committee members. The quorum is to include the necessary expertise (i.e. plant, animal) in relations to the research being reviewed. The quorum is to include at least one unaffiliated member.

4. Roles

A. Office of Research Compliance

i. The Assistant Vice President for Research Compliance will provide adequate supervisory oversight, guidance, and administrative support to ensure the IBC has established and implemented policies to provide for the safe conduct of research that falls under this policy.
ii. The Research Compliance Coordinator will provide the administrative support to the IBC and investigators to ensure compliance with the NIH Guidelines, applicable governmental rules and regulations, and University policies and procedures. This support includes:
    a. Ensuring appropriate trainings are completed by IBC members and investigators;
    b. Assisting PIs in the submission of protocols, modifications, and annual reports;
    c. Managing the protocol review and approval process;
    d. Notifying the PI of IBC determinations;
    e. Committee communications, meeting scheduling and support, and records maintenance;
    f. Annual reporting to the NIH including rosters and biographical sketches updating through the NIH Registration Management System;
    g. Forwarding both the public comments and IBC actions to the Assistant Vice President for Research Compliance, IBC Chair, and the BSO to act in response to the NIH Office of Science Policy; and
    h. Reporting of significant problems or area of non-compliance to the Assistant Vice President for Research Compliance.

B. Biological Safety Officer (BSO)

i. The BSO serves as a permanent ex-officio member of the IBC and advises investigators, the IBC, and laboratory staff on appropriate safety practice to ensure the safe conduct of research that falls under this policy. The BSO is to provide guidance regarding safety, strategic planning, standard operating procedures (SOPs), and priorities associated with biological risk management creating a culture of safe biological research among all

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 violations, and any significant research-related injuries or illnesses associated with biological research. Following each investigation, the investigator involved will be notified of the recommended corrective actions;
g. Performing categorization of research to determine exemption from the NIH Guidelines;
h. Developing and implementing emergency plans for handling accidental spills and personnel contamination resulting from work with biological hazards; and
i. Conducting general laboratory biosafety training for investigators in collaboration with EH&S.

C. IBC Chair

i. The IBC Chair will preside over the meetings ensuring the committee fulfills all responsibilities as stated in this policy. The IBC Chair's responsibilities include, but are not be limited to:

a. Confirming with the Office of Research Compliance that the IBC Committee members are appropriately trained and current on applicable regulations;
b. Confirming categorization by the BSO of research deemed as exempt from the NIH Guidelines. Binghamton University requires all research that may fall under this policy be registered with the Office of Research Compliance in order to allow the BSO or IBC Chair exemption determination;
c. Reporting any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the Assistant Vice President of Research Compliance, BSO, and Occupational Health Specialist as necessary;
d. Review and approve Minor Amendments, as deemed by the BSO and IBC Chair.
e. Review and approve Protocol Renewals (exceeding three (3) year approval) that have no changes from the approved protocol.

f. Making recommendations to the Assistant Vice President of Research Compliance of the required resources necessary for the IBC to perform its duties; and
g. Providing leadership for the IBC to identify, develop and adopt policies or programs to promote safe biological research and be in compliance with the NIH Guidelines.

D. Institutional Biosafety Committee (IBC)

i. The IBC will review all research that falls under this policy to ensure compliance with the NIH Guidelines. The IBC will not authorize the initiation of experiments which are not explicitly covered by the NIH Guidelines until the NIH establishes the containment requirement. The IBC responsibilities include:
    a. Independent assessment of the containment levels required by the NIH Guidelines for the proposed research;
    b. Contribute expertise and assist with efforts to identify, develop and adopt policies to promote safe biological research and compliance with the NIH Guidelines including the assessment of the facilities, procedures, practices, and training and expertise of all engaged investigators;
    c. Establishment of procedures for initial, modification, and continuing reviews and approvals of protocols;
    d. Lower containment levels for certain experiments to lessen risk and increase safety;
    e. Periodically, and as necessary, perform post approval monitoring;
    f. Ensure emergency plans covering accidental spills and personnel contamination as developed by the BSO are adhered to by the investigators;
    g. Suspend, limit, or terminate research found to have significant non-compliance pending a formal investigation. The University may take further actions deemed appropriate in instances of repeated non-compliance, compliance violations that are not corrected, or when serious safety violations are identified that create a significant risk to laboratory workers, other persons, or the environment; and
    h. Each member is responsible to attend and be prepared to participate at IBC meetings. The IBC holds the knowledge and expertise to the broad scope of biosafety issues, with primary responsibility for providing guidance in acknowledged areas of expertise. Members are to provide a comprehensive and timely review of protocol applications, and follow all protocol review and approval procedures as defined in this policy.

E. Principal Investigator (PI)

i. Principal Investigators are never to initiate or modify research involving GDMO's, rDNA, Select Agents, or Biohazardous Materials that requires review and approval by the IBC. The PI is to determine whether the research and experiments, therein are covered by Section III-E of the *NIH Guidelines, Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation*, and ensure that appropriate procedures are followed.

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 use of PPE;
   c. Instruct and train laboratory staff on the SOPs for the research including emergency plans for handling accidental spills and personnel contamination; and
   d. Submit proof of training document described in section F. Training Requirements; and
   e. Inform the laboratory staff of necessary medical precautions (e.g., vaccinations or serum collection) that are to be taken prior to engagement.

iv. Post approval-the PI is to remain in communication with the IBC throughout the conduct of the approved research; report any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to the BSO, IBC, and when applicable, the Occupational Health Specialist; and comply with shipping parameters. The PI is to supervise the lab staff to ensure that the required safety practices and techniques are employed. Any significant issues pertaining to the physical containment procedures and equipment are to be reported to the BSO and IBC immediately.

F. Training Requirements

i. PIs, Co-Is, Faculty, Staff, and Graduate Student Study Team Members are to complete CITI Initial Biosafety Training (**required every four years**); EH&S Lab Safety Training (**required annually**); CITI OSHA Bloodborne Pathogens (if you are working with any Human derived material or under an IBC protocol that has a correlative stem cell research protocol); Working with Microorganism Workshop conducted by the BBRC (Strongly Suggested); applicable course work and research activities (Identified by the PI and/or the IBC).

ii. It is strongly suggested that Undergraduate Study Team members complete CITI Initial Biosafety Training and EH&S Lab Safety Training.

iii. It is the responsibility of the PI to ensure all Undergraduate Study Team Members working in the research lab under an approved IBC protocol are properly trained.

iv. All Undergraduate Study Team Members working under an IACUC protocol that has a correlative IBC protocol are **required** to complete Initial Biosafety Training.

v. All Undergraduate Study Team Members working under an IBC protocol that has a correlative stem cell protocol are **required** to complete OSHA Blood Borne Pathogens; in addition to Initial Biosafety Training.

5. IBC Processes

A. Committee Review

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. The IBC will meet at least once every semester. Additional meetings may be scheduled when necessary to ensure the timely review of research, to provide training for IBC members, or address IBC business. Consistent with NIH Guidelines, when possible and consistent with protection of privacy and proprietary interests, Binghamton University will open meetings to the public. IBC meetings will be open to the public except when there are privacy or proprietary issues that preclude an open meeting. The IBC meeting dates, times and locations will be advertised to the public on the Binghamton University Division of Research Biosafety website at https://www.binghamton.edu/research/compliance/institutionalbiosafety.html. In addition, upon request, the Binghamton University Office of Research Compliance shall make available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies.

iv. Once the protocol and all pertinent document are submitted via PACS, the Research Compliance Coordinator will facilitate the distribution of all materials for review.

v. The BSO, followed by the IBC Chair, will pre-review all protocol applications and provide comments or suggested revisions within three to five (3-5) working days of receipt, respectively. This pre-review process is used to verify that the protocol is non-exempt, all required sections of the protocol application have been completed, and any significant safety or compliance issues have been addressed prior to full committee review. The Research Compliance Coordinator will ensure the comments or suggested revisions are received by the PI. Once all comments and revisions are addressed by the PI and the protocol is deemed ready for full committee review, the committee will be sent the protocol for member review.

vi. All IBC members have access to PACS to review protocols. Members can add comments and/or requests for clarification through this platform. Review comments are posted and visible to all other members during the review period. The protocol reviews are expected to be received seven (7) days after all protocols are assigned to the IBC for review. Members are to complete the protocol reviews and submit their comments by the requested due date. Dependent on protocol complexity and/or submission volume, reviews may take up to fourteen (14) days.

vii. Exempt protocols will be filed. Any modification to exempt protocols will be required and reviewed by BSO and presented at applicable IBC meetings.

B. Meeting Proceedings

i. In consultation with the BSO and the IBC Chair, the Research Compliance Coordinator prepares the meeting agenda. The agenda can be formally amended at the convened meeting by committee member(s) motion and vote.

ii. The IBC must maintain a quorum to conduct pertinent activities with relation to review and approval or disapproval, or suspension of research protocols. Each IBC meeting also requires sufficient members to ensure the collective experience and expertise to assess the safety and identify any potential risk involved with the research under review. Consultants may occasionally be invited to attend an IBC meeting to provide specialized knowledge on particular areas of research but do not have rights to make motions or vote.

iii. The NIH Guidelines do not permit expedited reviews or approvals by a subgroup of the IBC on behalf of the entire IBC for research subject to the NIH Guidelines.

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.

vi. PIs will be invited to IBC meetings where their research is discussed as their attendance can be beneficial to assist the IBC in understanding the nature and risk of the proposed experiments.

vii. Following a request by the IBC Chair for additional comments and discussion, the committee will vote on each protocol and assign the protocol status as one of the following: Approved; Conditional Approval; Modifications Required; or Denied.

   a. *Approved*-Protocols are approved for a period of three (3) years from the initial approval date. The IBC has the authority to grant approval for less than three years. A PI is required to submit a Protocol Renewal prior to the expiration date for any protocol that will be continued beyond the expiration date of the initial application approval.
   b. *Conditional Approval*- Minor delineated conditions are to be met by the PI and accepted by the BSO and IBC Chair for final approval.
   c. *Modifications required*- All required modifications are to be submitted by the PI. The revised protocol will go back to the IBC for review and vote.
   d. *Denied*- When the proposed research poses significant safety risks that outweigh the benefits or other aspect to which the IBC cannot justify granting approval, the protocol will not be approved.

Note: A protocol may be tabled due lack of timely or adequate response by the PI. A tabled protocol will be reviewed during the next IBC meeting if the PI addressed the pertinent issues accordingly.

viii. PIs will be notified of the IBC determination by the IBC Chair via PACS within two (2) working days following the determination.

ix. PIs must submit all protocol Amendments to the IBC via PACS for review and approval or disapproval. The IBC review will focus on reviewing content that has changed since the original protocol was approved. However due to periodic changes in IBC membership, committee expertise, and biosafety policies, it is possible that modifications may be required to sections that were approved in the original protocol application. When this occurs, the PI must make necessary revisions to any section of the protocol application that is required in order to obtain approval.

x. When appropriate, protocols and meeting determinations are shared with other research compliance committees (i.e. IACUC, IRB, SCRO, Radiation Safety) and Sponsored Programs. The IBC and IRB review rDNA or other potentially infectious materials research involving human subjects. Binghamton University does not engage in research involving the deliberate transfer of recombinant or synthetic nucleic acid molecules into research participants (i.e. human gene therapy). The IBC and IACUC both review research involving transgenic animals or experimentally infected animals. This collaborative effort between the research compliance committees on correlative research activities support the PIs effort to remain in compliance and to gain necessary approvals at all stages of the research.

xi. All Amendments must be submitted via PACS and be approved prior to initiating the proposed changes. Minor Amendments, as deemed by the BSO and IBC Chair, will be reviewed and approved by the IBC Chair. Significant Amendments will be reviewed and approved by the IBC.

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 perceived to influence, the review of any research study. IBC members, spouses, dependent children, or partners that hold a financial interest is defined as anything of monetary value, including although not limited to, salary or other payments for services (e.g. consulting fees or honoraria); equity interests (e.g. stocks, stock options, or other ownership interest); and intellectual property rights (e.g. patents, copyrights, and royalties from such rights). IBC members are required to complete a COI disclosure annually. New interests that are acquired that may affect or have the potential to affect obligations in the review of research protocols are to be disclosed within 30 days of when identified.

7. Confidentiality

Binghamton University IBC members review information that may include Confidential Information (i.e. intellectual property) and thus are required to review and execute a Confidentiality Statement annually. IBC members are required to use all reasonable efforts to prevent the disclosure of Confidential Information. Members may not disclose any Confidential Information to third parties other than to those with a need to know and who have executed a Confidentiality Statement. If required by law or court order to disclose Confidential Information, a member may do so only upon prior written notice to the Office of Research Compliance. All obligations of confidentiality and nondisclosure survive a minimum of ten (10) years following the last date of service on the IBC.

A. Meeting Minutes

i. Meeting minutes will include the following:
   a. time, date, and place of meeting
   b. approval of agenda
   c. approval of prior meeting minutes
   d. individuals in attendance
   e. all motions and their outcome
   f. major points of discussion and rationale for decisions
   g. time of meeting adjournment
   h. documentation that the IBC has fulfilled its review and oversight responsibilities as outlined under Section IV-B-2-b of the NIH Guidelines

ii. Upon request, the Office of Research Compliance shall make available to the public all IBC

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 research-related accidents and illnesses" be reported to OSP within 30 days. Appendix G of the NIH Guidelines specifies certain types of accidents that must be reported on a more expedited basis. Specifically, Appendix G-II-B-2-k requires that spills and accidents in BL2 laboratories resulting in an overt exposure must be immediately reported to the OSP (as well as the IBC).*

9. Guidelines and Resources

Resources can be found on the Binghamton University Biosafety webpage

Additional guidelines and resources can be found through the following:

Biosafety in Microbiological and Biomedical Research Laboratories (the BMBL) from the Centers for Disease Control and Prevention (CDC)

The NIH Guidelines for Research Involving Recombinant and Synthetic DNA Molecules (the NIH Guidelines) from the National Institutes of Health (NIH)

The American Biological Safety Association (ABSA)

The US Dept. of Agriculture and the Animal and Plant Health Inspection Service - USDA/APHIS

Select Agent Regulations (42 CFR 73) or USDA (9 CFR 121)

NIH Covered Classes (III)

Regulated Medical Waste - Guidelines for the Handling and Disposal

FAQs about Biosafety and Research Registration at Binghamton University

10. Definitions

Biohazardous Materials: Infectious biological or synthetic agents, biologically derived materials and toxins that present a risk or potential risk to the health of humans, animals, or plants either directly through exposure or infection or indirectly through damage to the environment. Potentially infectious biological materials include but are not limited to the following:

- Human, animal, and plant pathogens (bacteria, parasites, fungi, viruses, prions).
- All human blood, blood products, tissues, and certain body fluids (use of human blood and body fluid for clinical diagnostic and treatment purposes is excluded).
- Cultured cells and potentially infectious agents these cells may contain.
- Infected animals and animal tissues.

Dual Use Research of Concern (DURC): DURC is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that, when directly misapplied, could pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. Research including such manipulation, including that of Select Agents, is prohibited at Binghamton University.

Recombinant DNA: In the context of the NIH Guidelines, recombinant and synthetic nucleic acids are defined as:

- Molecules that a) are constructed by joining nucleic acid molecules, and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
- Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids; or
- Molecules that result from the replication of those described above.

Select Agent- Biological agent or toxin that has the potential to pose a severe threat to public health and safety, animal or plant health, or animal or plant product.

11. Contact Information

- Information or questions about lab inspection and approval: J. Kelly Donovan, Biosafety Officer by phone at 607-777-6834 or by email at donovan@binghatmon.edu
- Information about the IBC: David Davies, Committee Chair, at dgdavies@binghamton.edu.
- All other questions or concerns: Nancy Lewis, Assistant Vice President of Research Compliance by phone at 607-777-3532 or by email at nlewis@binghamton.edu

https://www.binghamton.edu/research/compliance/institutionalbiosafety.html