Policy 2204
Policy for Institutional Biosafety

Date of Current Revision: March 2023
Primary Responsible Officer: Vice President for Research, Economic Development and Innovation

1. PURPOSE

This policy establishes the Institutional Biosafety Committee (IBC) to serve as a campus resource for investigators and instructors in developing protocols for safe handling and use of biological materials deemed potentially hazardous under the National Institutes of Health (NIH), Biosafety in Microbiological and Biomedical Laboratories (BMBL), and Centers for Disease Control and Prevention (CDC) guidelines. The IBC is dedicated to helping researchers conduct research that is safe and compliant with NIH, federal, state, and local ordinances. The IBC is governed by its Standard Operating Procedures (SOPs) which guide both the researcher and the IBC in conducting and approving research, teaching, and other activities conducted at, sponsored by, or on behalf of JMU involving any of the following:

- Infectious agents (bacteria, viruses, protozoans, fungi, prions, etc.)
- Biologically derived toxins
- Human and/or non-human primate cells, tissues, blood or body fluids
- Recombinant/Synthetic DNA/RNA
- Transgenic organisms
- Select agents
- Synthetic biology
- Human gene transfer
- Dual use technologies

The IBC SOPs help assure that the research conducted at JMU is compatible with federal guidelines from the NIH and other federal, state, and local ordinances.

The IBC also serves as an advocate to the JMU administration for infrastructure and issues pertaining to biosafety or the administration of biosafety practices on campus.

2. AUTHORITY

The Board of Visitors has been authorized by the Commonwealth of Virginia to govern James Madison University. See Code of Virginia section 23-164.6; 23-9.2:3. The board has delegated this authority to the president.

The *NIH Guidelines* detail safety practices and containment procedures for basic and clinical research involving recombinant or synthetic nucleic acid molecules, including the creation and use of organisms and viruses containing recombinant or synthetic nucleic acid molecules. Universities who receive funding from the NIH for research involving recombinant or synthetic nucleic acid molecules are subject to the *NIH Guidelines* and must establish an IBC under Section IV of the guidelines. Even if only one research project involving recombinant or synthetic nucleic acid molecules at an institution benefits from NIH support, all such projects conducted at or sponsored by that institution must comply with the *NIH Guidelines*. Adherence

to the *NIH Guidelines* may also be a condition of support from other federal agencies, or even private funders of research.

The University may also be subject to federal, state, and local guidelines that require compliance with the *NIH Guidelines*. Consequently, the university president may appoint an IBC in accordance with *NIH Guidelines*.

The IBC reviews all research, teaching, and training that involve the use of all forms of research utilizing recombinant or synthetic nucleic acid molecules and infectious agents through examining exempt and full research registrations submitted by principal investigators to ensure NIH, federal, state, and local regulations are followed, and best safety practices are maintained at JMU. The IBC has the authority to approve these registrations, require modifications to secure approval, and disapprove these research registrations and terminate research if necessary due to biosafety violations (refer to SOPs for additional details).

3. DEFINITIONS

Biosafety Levels (BSL)
Describes the general measures and infrastructure needed to work with an infectious agent. There are four levels from 1 (lowest) to 4 (highest). JMU only supports non-exempt work with infectious agents or nucleic acids that can be handled at the BSL1 and BSL2 level.

Infectious Agent
Any living organism, virus, or prion capable of producing disease in humans, posing a risk to public health and safety, or animal or plant health. This can include human and non-human primate cells, tissues, blood or body fluids - cells, blood or body fluids that can potentially harbor infectious agents. Diseases can include those which provoke an immune response, such as due to a virus or bacteria, or an altered metabolic status, such as due to cholera toxin or prion-induced protein aggregation.

Institutional Biosafety Committee (IBC)
A committee of qualified faculty, individuals from the community external to JMU, and administrators who work with investigators and instructors to identify, assess, and ameliorate any hazards that could occur due to activities using infectious agents or recombinant nucleic acids. The committee membership must be compatible with that established under Section IV of the *NIH Guidelines*.

Office of Research Integrity (ORI)
Provides the administrative oversight for the IBC. This involves serving as a resource for education and information, facilitating the creation and distribution of SOPs, maintaining communication mechanisms, such as the website, providing guidance and feedback to investigators, providing administrative support to the IBC, ensuring all requirements of the federal assurance are met, and conducting quality assurance activities.

Principal Investigator
The individual faculty member or instructor at JMU with the responsibility for conducting a scholarly or teaching activity monitored by the IBC at JMU.

Recombinant or Synthetic Nucleic Acid Molecules
According to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules,* recombinant or synthetic nucleic acid are: i. molecules that (a) are constructed by joining nucleic acid molecules and (b) can replicate in a living cell; ii. 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; iii. molecules that result from the replication of those described in i or ii. In essence, nucleic acids that can replicate, or which are replicated in cells that are distinct from the genome, fall into these categories.

Risk Groups
Infectious agents are classified into 1 of 4 levels called Risk Groups. Risk group 1 are agents not associated with disease in healthy humans. Risk group 2 are agents that can cause infections of varying severity, which are rarely lethal because the host immune system is capable of controlling the infection, or there are therapeutic strategies to prevent infection. Currently, JMU only supports work with Risk Group 1 and 2 agents.

4. APPLICABILITY

This policy is applicable to all relevant biological agent work that is conducted at or sponsored by or under the aegis of JMU. No activity involving the construction or handling of recombinant DNA molecules or organisms and viruses containing recombinant DNA molecules shall be initiated without the notification, and if necessary, review and approval, of the JMU IBC.

5. POLICY

All PIs or faculty who possess or use biological agents must register the possession and use of biological agents with the JMU IBC. Investigators and faculty are authorized to proceed with the proposed activities only after notifying the IBC and obtaining any NIH required IBC approval. PIs and faculty are responsible for ensuring that their practices, equipment, and facilities do not jeopardize the health and well-being of themselves, their personnel, or the general public. The IBC will provide consultation and assistance to PIs and faculty in this regard.

JMU will comply with all applicable federal, state, and local regulations that apply to the possession, manipulation, and disposal of biological agents. Additionally, consensus biosafety guidelines, such as those from the NIH, CDC, and other organizations, will be applied as appropriate, along with requirements established in JMU Biosafety Manuals and Standard Operating Procedures, to protect personnel and the environment from potentially adverse exposures to biological agents.

Additional explanations of the research areas covered by *NIH Guidelines* can be found in the SOPs.

6. PROCEDURES

6.1 Institutional Biosafety Committee
The membership will be drawn in compliance with the diversity, competency and professional guidelines established by the *NIH Guidelines*. The members will be appointed annually by the university president upon recommendation by the academic unit heads (AUH) and the ORI. The group's collective expertise and experience should minimally include experience with

recombinant or synthetic nucleic acid molecule research and biosafety. It also should include knowledge of institutional commitments and policies, applicable laws, and community attitudes in order to assess the safety of research involving recombinant and synthetic nucleic acid molecules, and to identify potential risks to public health and safety.

The IBC will meet at least once per fall and spring semesters, and more frequently as determined by the number of protocol registrations submitted or as IBC business requires. All protocol registrations will receive consideration within 30 days if submitted during the regular fall or spring semesters. Submissions during breaks will receive consideration as soon as possible but may be delayed if faculty or staff on the IBC are unable to meet. All protocols submitted during the breaks will receive consideration within 30 days, or within 14 days of the start of the semester if their consideration has been delayed due to the unavailability of committee members. PIs are encouraged to consult with the IBC on their submission window to avoid unnecessary delays in revision and/or approval.

The JMU ORI will administer the protocol approval, modification, renewal, and termination process.

6.2 Activities that are subject to IBC review

Upon planning an activity that uses a potentially infectious agent or recombinant nucleic acid, the PI should consult with the IBC chair or designee to determine whether registration is required, and whether the activity requires exempt registration or requires a full protocol registration. If a full protocol is required, the protocol should be submitted through the JMU electronic research administration system (eRA). Submitters are encouraged to work with IBC members and staff in the ORI to ensure efficient submission. During this consultation, the IBC will provide the PI the workspace checklist, or schedule a courtesy pre-inspection of the workspace, as part of the consultation.

Experiments or activities that use infectious agents or recombinant or synthetic nucleic acids, which can be expressed in an organism or will be used to change an organism's gene expression, are to be registered by the PI as either exempt or non-exempt from *NIH Guidelines*. Exempt experiments or activities are those that are described in Section III-F of *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.* Many activities using experimental systems such, as E. coli K-12, Saccharomyces cerevisiae, and nucleic acids that cannot be reproduced in cells, fall in this category. Work with exempt agents does not require a specific protocol for handling but does require registration with the JMU IBC. Activities that are not exempt require that a non-exempt protocol registration be submitted to JMU that is approved by the IBC. These activities include working with agents that require specific handling under NIH, BMBL, or CDC guidelines, or if working with E. coli or Saccharomyces cerevisiae using large scale culturing (>10 L) of biological agents in a single vessel.

6.3 Criteria Used by the IBC to Review Protocols and Perform Inspections

The IBC uses criteria outlined in the SOPs to review and perform inspections of laboratory space.

The IBC may be consulted for help in modifying the protocol and fixing any issues. The IBC may: 1) approve the protocol; 2) approve the protocol pending minor revisions by the PI; or 3) ask that the protocol be changed and submitted for re-review. Revised protocols will be reviewed by the IBC chair and may be redistributed to the IBC as needed for review. The IBC chair or designee will notify the PI of protocol approval.

Approved protocols are valid for three (3) years with an inspection in year two and the submission of a yearly update. If no changes have occurred, then the yearly update should state no changes have occurred. When changes need to occur, protocols can be updated. Minor changes, such as changes in student researchers or grant funding, can be approved by the IBC chair or designee. Other changes in protocol will be reviewed by the IBC chair or designee and may be passed onto all IBC members for review, depending on the scale and scope of the modifications.

Protocols may be renewed, and the IBC will review the renewal through an expedited process provided satisfactory yearly reports were submitted and a successful mid-term inspection of the workspace was conducted. If protocols are to be terminated, a closure notice must be sent to the IBC and the lab must be decontaminated, as noted in the SOPs.

The Office of Sponsored Programs will not release external funding for projects involving biological agents without evidence of IBC approval. Investigators and instructors are encouraged to consult with the IBC during the grant submission process to ease the future submission and approval of an exempt or full protocol.

7. RESPONSIBILITIES

IBC is responsible for:

- updating SOP protocols, as needed, to maintain compliance with NIH, federal, state and local guidelines;
- oversight and approval of work involving biological materials at JMU;
- advising and aiding PIs in developing safe protocols within the infrastructure available at JMU; and,
- providing training for IBC members, investigators, and individuals on an as-needed basis.

The JMU ORI is responsible for:

- Working with the department head and IBC chair to maintain a committee of appropriately qualified people on the IBC;
- Maintaining protocol registration and forms databases;
- Filing meeting notes that can be made available to the public when requested;
- Filing an annual report with the NIH OSP that includes (1) a roster of IBC members clearly indicating the chair, contact person and, as applicable, the Biosafety Officer (BSO), plant expert, animal expert, and human gene transfer expert or *ad hoc* consultant; and (2) biographical sketches of all IBC members, including community members; and,
- Filing university reports on the committee when requested.

BSO – Monitors the safety of potentially biohazardous materials. Per NIH guidelines and definitions, JMU does not need a BSO until work requiring BSL3 and above precautions or large scale (>10 L) culturing of organisms commences on campus.

All departments, offices and employees that generate, receive, or maintain public records under the terms of this policy are also responsible for compliance with Policy 1109 (Records Management).

8. SANCTIONS

If during protocol review, workspace inspections, or through other reports, violations of the safety protocol are identified, the IBC will notify the PI/instructor and work to rectify the issue. Repeated violations of the same type or willful flaunting of safety procedures will result in notification of the appropriate AUH and meeting with the IBC, AUH, and the PI, with the goal of bringing the activity into compliance with the submitted protocol. Further violations will be followed by notification and involvement of the Dean and Vice President for Research, Economic Development and Innovation (REDI). Compliance is covered in more detail in the SOPs.

Non-compliance may be subject to enforcement and penalties, as defined by Code of Virginia § 40.1-51.22 and § 40.1-51.39. Non-compliance with Occupational Safety and Health Administration (OSHA) requirements may be subject to enforcement and penalties, as defined by the United States Department of Labor (DOL) Federal Civil Penalties. Non-compliance with *NIH Guidelines* may jeopardize federally funded research. The Inspector General of the Department of Health and Human Services is delegated authority to conduct investigations and to impose civil monetary penalties against any individual or entity in accordance with regulations for violations of the regulations in this part, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188). The delegation of authority includes all powers contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.). PIs/faculty who possess or use biological agents without appropriate IBC approval are subject to suspension of research funding and laboratory closure at the discretion of the IBC, Institutional BSO, or Responsible Official (per 42 CFR Part 73).

Sanctions will be commensurate with the severity and/or frequency of the offense and may include termination of employment for employees, expulsion from the university for students, removal of affiliate status for affiliates, and loss of privileges and/or no trespass orders for any individual.

9. EXCLUSIONS

None.

10. INTERPRETATION

The authority to interpret this policy rests with the president and is generally delegated to the Director of ORI and the IBC Chair.

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