UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

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Title:	USM Institutional Biosafety Committee (IBC) Policy and Procedures

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1. General Biosafety Program

1.1. Biosafety Policy Statement

1.1.1. General

It is the policy of University of Southern Maine (USM) to provide a safe, healthy and secure work environment for all faculty, staff, students, collaborators, visitors, contract employees and human subject participants. All persons involved in activities with recombinant DNA (rDNA), infectious materials, USDA-defined select agents and toxins, or human/animal blood, bodily fluids, or tissues (use of human blood and body fluid for clinical, diagnostic, and treatment purposes is excluded) at USM must abide by the regulatory and policy requirements pertaining to the acquisition and use of these materials used for research, teaching, or testing (hereto referred to as activities) as outlined in the:

1.1.1.1. NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), April 2019;

1.1.1.2. CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition, 2020;

1.1.1.3. Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information; 2007

1.1.1.4. Public Health Security and Bioterrorism Preparedness and Response Act of 2002;

1.1.1.5. NSABB - Addressing Biosecurity Concerns related to the Synthesis of Select Agents;

1.1.1.6. Applicable federal, state and local laws;

1.1.1.7. Contents of this policy; and

1.1.1.8. Policies of the University of Southern Maine and the University of Maine System.

The safe conduct of activities involving biological agents depends on the individual(s) conducting such activities. These policies and procedures cannot anticipate every possible situation; therefore, good judgment is key to the protection of USM personnel and the environment.

The Institutional Biosafety Committee (IBC) is responsible for ensuring that all activities involving rDNA and biological agents conducted at, or sponsored by USM are conducted in compliance with the National Institutes of Health (NIH) Guidelines, Federal, State, and Local Laws and Regulations, and University of Maine System Policies.

Note: These policies and procedures are always evolving to meet emerging changes in science, research methodologies, and the law. The following policies and procedures delineate the roles, responsibilities, and the administrative framework involved in providing for and maintaining a safe work environment, an essential and integral part of the research activities outlined herein. Further clarifications, interpretations, and guidance will be issued by USM as necessary.

1.1.2. Purpose

This policy has been prepared in an effort to prevent injuries, illnesses, and death from causes related to working with biohazardous materials, and to minimize the loss of material resources and resulting interruptions from accidental occurrences. It is part of a continuing safety and informational program for all USM personnel, students, and visitors, and is meant to be used as a guide for working safely with these materials. All individuals share in the responsibility of protecting the health and safety of our employees, collaborators, contractors, and visitors.

This policy provides personnel, students, faculty, staff, collaborators and visitors with general guidelines for implementing an effective high quality Biosafety program. It is not an exhaustive document but rather an outlined approach to providing a safe work environment, well-controlled

research study areas, and protection for the local community. The policy brings together information that will assist employees and supervisors in carrying out their responsibility in ensuring a safe environment at USM for visitors, contractors, students, and employees. All personnel should read this manual and conduct their work accordingly.

1.1.3. **Scope**

All persons involved in activities using rDNA or biohazardous materials at USM, regardless of funding, must abide by the NIH Guidelines and other regulatory and policy requirements pertaining to the acquisition and use of these materials as outlined by this policy. However, this policy is not a substitute for special operation manuals used in certain buildings or laboratories designed to address specific situations. This policy serves as a basis to which supervisors shall add safety measures relevant to their laboratory or work operations.

1.2. Policy Development, Maintenance, and Revision Process

All materials in this manual have been developed and are maintained under the supervision and direction of the IBC and the Office of Research Integrity and Outreach (ORIO). The IBC has provided guidance for all policy issuances contained in this manual, and has reviewed all policy and guidance material. The materials contained in this manual replace any previous policies on Biosafety issued by these bodies. Any substantive revisions to this policy will only be made with the advice, review, and approval of those listed above.

1.3. Occupational Health Program

1.3.1. **General**

Exposure to rDNA, biological agents, and toxins presents a risk of developing adverse health outcomes. The risks of associated illness include transmission of infection, respiratory illness, allergies, asthma, and others. However, these risks can be minimized with proper procedures and personal protective equipment. All persons involved in potentially biohazardous activities are encouraged to participate in the USM Occupational Health Program. The program provides educational information on the health risks associated with handling chemicals and biological agents as well as ways to minimize the chance of developing illness as a result of prolonged contact. The program also offers ongoing monitoring of chemical or biologic agent related health statuses. The Office of Research Integrity and Outreach (ORIO) may be contacted for comprehensive information about the Occupational Health Program.

1.3.1.1. Faculty, staff, and students conducting biological research under the following conditions **may** participate in the Occupational Health Program:

1.3.1.1.1. Working in a BSL 1 or 2 laboratory; or

1.3.1.1.2. Working with Risk Group 1 and 2 agents.

1.3.1.2. Faculty, staff, and students conducting biological research under the following conditions **must** participate in the Occupational Health Program:

1.3.1.2.1. Research that is governed by the USM IACUC (regardless of ABSL level);

1.3.1.2.2. Working in a BSL 3 or 4 laboratory;

1.3.1.2.3. Working with Risk Group 3 and 4 agents;

1.3.1.2.4. Working with Select Agents, including exempt amounts;

1.3.1.2.5. Personnel with known animal allergies; and

1.3.1.2.6. Research in which the PI receives funding from the Federal Government (PHS, NIH, CDC, etc.).

1.3.2. **Occupational Health Questionnaire**

1.3.2.1. General

The Occupational Health Questionnaire was developed by ORIO in order to identify and address any special needs of personnel, required immunizations, or other safety precautions necessary in order for biological research activities to be safely conducted and to further reduce the risks of illnesses or injuries. In the event that a biological research activity or researcher requires any of the above (as determined by the Health Questionnaire, use of specific or contagious biological agents, or as required by other regulations), ORIO will contact the particular individual, personnel, or Principle Investigator (PI) directly.

Note: This questionnaire is further a legal requirement under USM's Federal Assurance with the Office of Laboratory Animal Welfare (OLAW) for individuals at USM working directly or indirectly with animals (1.3.1.2.1.).

1.3.2.2. Confidentiality of Health Information

USM will only use the information provided in the form for official Occupational Health Program functions, and the information will otherwise remain confidential. Privacy rights will be maintained to the fullest extent allowed by law. The questionnaire will not:

1.3.2.2.1. Become part of the employment record,

1.3.2.2.2. Be shared with Human Resources,

1.3.2.2.3. Be used in employment decisions, or

1.3.2.2.4. Be shared with supervisors.

This information may only be used in cases of public health emergencies, if emergency medical treatment is needed, or as required and/or allowed by law (for example, workers compensation claims).

1.4. Program Roles and Responsibilities

1.4.1. General

Biosafety can only be accomplished in a cooperative environment. As a researcher or any personnel working with biohazards, it is the responsibility of <u>every</u> member of a research/lab team to:

1.4.1.1. Watch out for possible hazards;

1.4.1.2. Report suspected or known hazards to the appropriate authority;

1.4.1.3. Follow all necessary and required lab or research protocols;

1.4.1.4. Report suspected or known violations of lab or research protocols;

1.4.1.5. Take appropriate steps to prevent potential hazards;

1.4.1.6. Make sure all required safety equipment is present and functional before starting work;

1.4.1.7. Use universal precautions;

1.4.1.8. Utilize all appropriate safety equipment; and

1.4.1.9. Follow the guidance of the designated lab supervisor.

1.4.2. The Office of Research Integrity and Outreach (ORIO)

ORIO provides management and administrative support to the IBC. Staffing of the IBC and the Biosafety program will be proportional to the volume of activity and levels of risk associated with rDNA and biological agent activities at USM. As part of its general staffing duties, ORIO will prepare and maintain records of IBC activities for at least 3 years and records related to protocols for at least 3 years after the completion/termination of the research. ORIO will keep written IBC records of the following items:

1.4.2.1. Copies of all IBC Application and supporting materials that are reviewed;

1.4.2.2. Summaries of the IBC meetings in sufficient detail to show attendance, actions taken at the meeting and votes on actions, the basis for requiring changes in research, and a summary of the IBC discussion of controversial issues and its resolution;

1.4.2.3. Records of initial reviews and continuing review activities;

1.4.2.4. Copies of lab safety reviews, surveys and security protocols;

1.4.2.5. Copies of all correspondence between the IBC, PI's and ORIO;

1.4.2.6. A list of IBC members and their qualifications for serving on the board;

1.4.2.7. Written IBC policies and procedures;

1.4.2.8. Statements of significant new findings on the safety of biological activities at USM;

1.4.2.9. Standard Operating Procedures approved by the IBC;

1.4.2.10. Biosafety training materials, dates, and names of all persons who have completed Biosafety training; and

1.4.2.11. Annual Reports to the Institutional Official and NIH/OBA.

1.4.3. **IBC Administrator**

The IBC Administrator, through ORIO, provides administrative support to the IBC and researchers by:

1.4.3.1. Conducting analysis of Federal, State, and local regulations pertaining to the handling, disposition, and use of rDNA molecules and biological agents in IBC covered activities;

1.4.3.3. Developing and maintaining databases of information related to rDNA and biological agent material holdings on USM campuses;

1.4.3.4. Maintaining records of IBC approvals for usage of biohazardous materials;

1.4.3.5. Providing guidance and assistance to investigators with respect to institutional and regulatory filings related to Biosafety;

1.4.3.6. Maintaining confidential information related to USM's Biosafety programs;

1.4.3.7. Providing technical information on Biosafety training, and IBC resource materials;

1.4.3.8. Performing periodic facilities inspections to monitor and verify IBC recommendations; and

1.4.3.9. Providing updates on biohazardous activities and Biosafety correspondence with the IBC and the Assistant Provost for Research Integrity.

1.4.4. **Biosafety Safety Officer (BSO)**

The institution will appoint a Biosafety Officer (BSO) if it engages in large-scale research or production activities involving viable organisms containing recombinant or synthetic nucleic acid molecules, biological agents in RG3 or RG4, or Select Agents. The institution must appoint a BSO if it engages in rDNA research at BSL3 or BSL-4. The BSO will also be a member of the IBC.

The Biosafety Officer is responsible for overall compliance and administrative oversight of USM's Biosafety Program. The BSO works in cooperation with the IBC and other USM departments to coordinate the campus-wide Biosafety Program. The BSO's duties, powers, and Federal functions include:

1.4.4.1. Developing Policies and Procedures for USM's Biosafety Program, and developing communications programs related to policy and procedure changes;

1.4.4.2. Conducting periodic inspections to ensure laboratory standards are rigorously followed;

1.4.4.3. Investigating accidents;

1.4.4.4. Record keeping;

1.4.4.5. Assessing University facilities to determine suitability for use in potentially hazardous biomedical research operations; and

1.4.4.6. Advising professional and technical staff regarding Biosafety practices, procedures, and regulatory requirements.

1.4.4.7. Coordinating the development of IBC resources including content for the IBC web page and Biosafety training modules;

1.4.4.8. Coordinating with campus colleges, IRB, IACUC, and other groups in order to maintain consistent policies and procedures, sharing of information, maintaining a free flow of communication and acting as a resource conduit between groups; and

1.4.4.9. Reporting to the IBC and the institution any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses of which the BSO becomes aware unless the BSO determines that a report has already been filed by the Principal Investigator;

1.4.4.10. Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant or synthetic nucleic acid molecule research;

1.4.4.11. Providing technical advice on laboratory security and research safety procedures to Principal Investigator's and the IBC; and

1.4.4.12. Providing monthly updates on biohazardous activities and Biosafety correspondence with USM's ORIO.

1.4.5. **Principal Investigator**

1.4.5.1. General

The Principal Investigator (PI) is responsible for full compliance with the NIH Guidelines and USM Biosafety Policies and Procedures in the conduct of rDNA and biological agent activities. The PI is responsible for ensuring that all reporting requirements are fulfilled and will be held accountable for any reporting lapses. The PI will:

1.4.5.1.1. Not initiate or modify rDNA or Biologic Agent activities that require IBC approval until the activities or modification to the activities have been approved by the IBC;

1.4.5.1.2. Report any significant problems or violations of the NIH Guidelines to ORIO immediately;

1.4.5.1.3. Report any new information about the safety of biological agents or rDNA under their purview that may have bearing on the NIH Guidelines to ORIO. ORIO will communicate this information to the IBC and to NIH/Office of Science Policy (OSP) preferable by email to: NIHGuidelines@od.nih.gov (if applicable);

1.4.5.1.4. Be adequately trained in standard techniques related to the use of rDNA and biological agents within their purview;

1.4.5.1.5. Adhere to IBC approved emergency plans for handling accidental spills and personnel contamination;

1.4.5.1.6. Comply with shipping/disposal requirements for rDNA and biological agents;

1.4.5.1.7. Remain in communication with the IBC throughout the conduct of the project; and

1.4.5.1.8. Conform to NIH Guidelines, Section IV-B-7-d and Section IV-B-7-e (Responsibilities of the Principle Investigator Prior to and During the Conduct of the Research).

1.4.5.2. Dissemination of Information

The PI will:

1.4.5.2.1. Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken;

1.4.5.2.2. Ensure proper training of laboratory staff in the practices and techniques required to ensure safety, and the procedures for dealing with accidents; and

1.4.5.2.3. Inform laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).

1.4.5.3. PI Oversight of rDNA or Biological Agent Activities

The PI will:

1.4.5.3.1. Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed;

1.4.5.3.2. Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the BSO, IBC, IACUC and IRB (where applicable);

1.4.5.3.3. Correct work errors and conditions that may result in the release of rDNA materials or biological agents;

1.4.5.3.4. Ensure the integrity of the physical containment (e.g., Biological safety cabinets) and the Biohazard containment (e.g., purity and genotypic and phenotypic characteristics);

1.4.5.3.5. Comply with reporting requirements for human gene transfer experiments conducted in compliance with the current NIH Guidelines; and

1.4.5.3.6. Submit information, as applicable, to the NIH OSP via ORIO.

1.4.5.4. Specific NIH Requirements

Where applicable, the PI will:

1.4.5.4.1. Submit information to the NIH OSP for certification of new host-vector systems;

1.4.5.4.2. Petition the NIH OSP, with notice to the IBC, for proposed exemptions to the NIH Guidelines;

1.4.5.4.3. Petition the NIH OSP or to another Federal agency that has jurisdiction for review and approval with concurrence of the IBC, for approval to conduct activities specified in NIH Guidelines; Once approvals or other applicable clearances have been obtained from a Federal agency other than NIH (whether the experiment is referred to that agency by NIH or sent directly there by the submitter), the

experiment may proceed without the necessity for NIH review or approval.

1.4.5.4.4. Petition the NIH OSP for determination of containment for experiments requiring case-by-case review;

1.4.5.4.5. Petition the NIH OSP for determination of containment for experiments not covered by the NIH Guidelines;

1.4.5.4.6. Ensure that all aspects of the NIH Guidelines have been appropriately addressed prior to submission of a human gene transfer experiment to the NIH OSP; and

1.4.5.4.7. Obtain approval from the IBC and all other applicable institutional and regulatory authorizations prior to the initiation of experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules into human research participants (human gene transfer). No human gene transfer experiment shall be initiated until the IBC approval has been obtained and all other applicable institutional and regulatory authorizations and approvals have been obtained.

1.4.5.4.8. When registering agents or toxins that are regulated by the Select Agent Program under Federal Law (7 C.F.R. part 331, 9 C.F.R. part 121, 42 C.F.R. part 73), as having the potential to pose a severe threat to human, animal, or plant health, or to animal and plant products are subject to having their proposed research subject to review by the NIH. (See Dual Use Research Section 1.6)

1.5. Training Requirements

1.5.1. General

All personnel involved in the use of biohazardous materials at USM are required to complete an approved biosafety training program. USM will provide or make available training on the appropriate use of rDNA and Biologic agents to ensure that all individuals working with these materials are adequately informed about the work in the laboratory, its risks, and what to do if an accident occurs. All training records are kept on file at ORIO. Acceptable forms of basic biosafety training include, but are not limited to:

1.5.1.1. A presentation through ORIO, Safety Management; and/or

1.5.1.2. The appropriate CITI Online Biosafety Modules/Courses.

Dependent upon the biohazard involved and level of exposure/involvement with the material(s), training generally includes, but is not limited to the following information:

1.5.2.3. Exposure limits and symptoms;

1.5.2.4. Biohazard reference material(s);

1.5.2.5. Biohazard detection;

1.5.2.6. Employee protection;

1.5.2.7. Blood borne pathogens;

1.5.2.8. Emergency and personal protection procedures; and

1.5.2.9. Stockroom/storeroom receiving and personal protection procedures.

1.5.2. **Training Frequency**

Appropriate Biosafety training will be required:

1.5.2.1. At the time of an individual's initial assignment to a work or research area where rDNA, infectious material, select agents or toxins, or human/animal bodily fluids or tissues are present;

1.5.2.2. Prior to new assignments exposing individuals to other biohazardous situations or materials; and

1.5.2.3. When new Biosafety regulations, policies, and/or procedures go into effect.

The appropriate training and education program must be repeated at least every four years, or annually, depending upon the materials involved.

Note: It is the responsibility of the PI of any activity involving biohazards to recognize when training is needed for their employees/personnel and to arrange for such training through the appropriate training opportunity. The PI is not responsible for developing and presenting training, but he or she must recognize and address the need for and frequency of biosafety training.

1.6. Dual Use Research

1.6.1 General

Dual use research is defined by the National Science Advisory Board for Security (NSABB) as "research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or materiel." Pursuant to the recommendations found in the National Research Council report "Biotechnology Research in an Age of Terrorism: Confronting the Dual Use Dilemma", biohazardous research at USM should be screened for dual use concerns by both the PI and the IBC by asking the following seven questions about whether the research is designed to:

1.6.1.1. Enhance the harmful consequences of a biological agent or toxin;

1.6.1.2. Disrupt immunity or the effectiveness of an immunization without clinical and/or agricultural justification;

1.6.1.3. Confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection methodologies;

1.6.1.4. Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin;

1.6.1.5. Alter the host range or tropism of a biological agent or toxin;

1.6.1.6. Enhance the susceptibility of a host population; and/or

1.6.1.7. Generate a novel pathogenic agent or toxin or reconstitute an eradicated or extinct biological agent.

Any PI who feels the research in question can or does satisfy one of the above questions/designs should contact ORIO as soon as possible in order to facilitate a process to address, mitigate, or alleviate the circumstances of the research of concern.

2. Institutional Biosafety Committee (IBC)

As part of the University's research compliance program, USM will maintain a standing Institutional Biosafety Committee (IBC). The IBC's mission is to oversee and implement safe practices and procedures in research that

involve the use of rDNA, biological agents, and transgenic animals. Participation on the IBC is a voluntary public service activity, and USM does not provide monetary compensation for service on the Committee.

The IBC may be contacted through the USM Office of Research Integrity and Outreach by email at usmorio@maine.edu, or by mail at The Office of Research Integrity and Outreach, 126 Bedford St., Portland, ME 04101.

2.1. IBC Membership

2.1.1. General

Successful membership on the IBC is achieved by appointing personnel who have expertise, experience, educational background, and/or specialized training that gives them with the ability to analyze and comprehend safety procedures for use with Biological Agents and rDNA, and to identify any potential risks to public health or the environment. Nominations for service on the committee or volunteers interested in IBC membership should contact the IBC Chair. The Chair, in consultation with the ORIO Assistant Provost for Research Integrity, will review the prospective member's qualifications to determine if the nominee is suited to serve on the committee, and if the nominee can satisfy one of the roles listed below. If there is a need for additional members and the nominee is qualified, the Chair or Assistant Provost will discuss the nomination with the prospective member's Department Chair, Dean, or Direct Supervisor for clearance to participate on the Committee. The Institutional Official appoints members for up to 3-year terms. One member of the committee may fulfill more than one membership role as required and indicated below.

2.1.2. IBC Composition

The IBC will have no fewer than five members, each whose expertise/role, when applicable to USM's current teaching, funding and research activities, will satisfy the following requirements:

- 2.1.2.1. One individual with expertise in plant, plant pathogen, or plant pest containment principles;
- 2.1.2.2. One scientist with expertise in animal containment principles;
- 2.1.2.3. One Biological Safety Officer (where BSL3 facility is required or large scale research is conducted);
- 2.1.2.4. One person with expertise in rDNA technology, biosafety, and physical containment;
- 2.1.2.5. One individual that represents USM's Facilities Management;
- 2.1.2.6. One individual who represents Safety Management; and
- 2.1.2.7. At least two members shall not be affiliated with the institution in any way other than their membership on the Committee.

2.1.3. Resignation of Membership

IBC members may voluntarily resign their position for any reason. As a matter of courtesy, however, a minimum of 30-day notice should be given to the IBC Chair, Assistant Provost for Research Integrity, or IBC Administrator.

If a member is considering resignation for any reason (i.e. too much time commitment, heavy workload, sabbatical, etc.), he or she should discuss those reasons with the IBC Chair or the Assistant Provost for Research Integrity for possible alternative options.

2.2. IBC Roles and Responsibilities

2.2.1. General

The IBC will have the following responsibilities and powers:

2.2.1.1. Review and approve, require modifications (to secure approval), table, or withhold approval of activities (or changes to approved activities) related to rDNA molecules and use of rDNA or Biological agents in teaching, testing or research consonant with NIH Guidelines, USDA, CDC recommendations, ORIO Policy or new data on safety;

2.2.1.2. Inspect at least once annually all of the institution's Biosafety facilities (including satellite facilities) or designate this function to the appropriate Biosafety official or Safety Management;

2.2.1.3. Suspend any activity that is considered unsafe or a threat to public or employee health and safety or any activity not conducted in accordance with IBC requirements (this may only take place at a convened meeting with a quorum of members present, or by the Chair in emergency situations);

2.2.1.4. Develop criteria for identifying dual-use research and research results;

2.2.1.5. Develop guidelines for the oversight of dual-use research, including guidelines for the risk/benefit analysis of dual-use biological research and research results;

2.2.1.6. Provide recommendations on the development of a code of conduct for scientists and laboratory workers; and

2.2.1.7. Provide recommendations for education and training in biosecurity issues for all scientists and laboratory workers at USM.

2.2.2. **IBC Program Review**

ORIO, in conjunction with the IBC, will review all policies and procedures outlined in this manual and in facilities where rDNA and Biological Agent activities occur on a need to know basis. The purpose of the program review is to assess the overall policies and procedures for Biosafety at USM and ensure that they meet all regulatory requirements and community needs. Any deficits in policy will be brought to the IBC for comment and suggestions. ORIO may revise policies and procedures in order to comply with new statutory or regulatory requirements.

2.2.3. **IBC Power to Lower Containment Levels**

The IBC may lower containment levels for certain activities with the following guidance (specified in the NIH Guidelines):

2.2.3.1. NIH Guidelines, Section IV-B-2-b-(4). Setting containment levels as specified in NIH Guidelines, Sections III-D-4-b, Experiments Involving Whole Animals, and III-D-5, Experiments Involving Whole Plants.

2.2.3.2. NIH Guidelines, Section IV-B-2-b-(5). Periodically reviewing recombinant synthetic nucleic acid molecule research conducted at the institution to ensure compliance with the NIH Guidelines.

2.2.3.3. NIH Guidelines, Section IV-B-2-b-(6). Adopting emergency plans covering accidental spills and personnel contamination resulting from recombinant or synthetic nucleic acid molecules research.

2.2.4. **Responsibilities of the IBC Chair**

The chief responsibility of the IBC Chair is to provide leadership to the IBC. The Chair is responsible for:

2.2.4.1. Recruiting new members in cooperation with the Assistant Provost for Research Integrity;

2.2.4.2. Leading and convening meetings (not to overlap with the Administrator's responsibilities);

2.2.4.3. Providing orientation on IBC Policies and Procedures to new members;

2.2.4.4. Coordinating with the Assistant Provost for Research Integrity on all IBC subcommittees, working groups, and projects; and

2.2.4.5. Ensuring IBC members are properly trained.

Note: The Chair also plays a significant role in the assessment of Biosafety misconduct, Serious Adverse Biosafety Events, and relaying information on Biosafety to the USM Community.

2.3. IBC Member Registration with NIH

ORIO will register the USM IBC with the NIH Office of Science Policy (OSP) Institutional Biosafety Committee Registration Management System. In addition to the registration, ORIO shall file the institution's annual report with the NIH OSP that includes:

2.3.1. A roster of all IBC members clearly indicating their roles and expertise on the IBC;

2.3.2. Biographical sketches, resumes, CV's, etc. of all IBC members (including community members); and

2.3.3. Member contact information including name, title, business mailing address, telephone number, fax number and email address.

2.4. Training of IBC Members

All IBC members are required to undergo the following trainings prior to voting on an IBC matter:

2.4.1. CITI Online Biosafety Course for IBC Members (every 4 years); and/or

2.4.2. Other required USM Biosafety Training.

Note: On an ongoing basis, ORIO will provide educational sessions on various Biosafety topics relevant and pertinent to the responsibilities of the IBC.

2.5. Meetings and Meeting Minutes

2.5.1. General

Although the NIH Guidelines do not set a minimum threshold for meeting frequency, IBCs are expected to meet as often as necessary to carry out the functions prescribed in Section IV-B-2-b of the NIH Guidelines. The USM IBC is scheduled to meet every 6 months but this schedule may be adjusted based on the amount of activity and IBC business to be conducted. A quorum of members must be present at these meetings. A quorum is a simple majority of members present in person for face-to-face discussion, and votes, when necessary.

Note: No member of the IBC may vote on or be present for IBC review and discussion of a proposal in which the member has a financial or institutional conflict of interest. In such instances the IBC member will voluntarily declare the conflict and excuse herself/himself from the meeting until after the IBC takes action on the proposal.

2.5.2. Agenda

ORIO sets the IBC meeting agendas in cooperation with the IBC Chair. The agenda must include a review of the previous meeting minutes, a summary of activities reviewed or exempted since the last meeting, and administrative updates.

2.5.3. Meeting Minutes

Meeting minutes will be drafted after the completion of an IBC meeting by ORIO, to be reviewed and approved at the next scheduled IBC meeting. These minutes will include date, attendance, absentees, motions, results of votes, and a synopsis of meeting activities and discussions.

When the IBC reviews research utilizing rDNA, the following additional information will be incorporated into the minutes:

2.5.3.1. Agent characteristics (pathogenicity, virulence, etc.);

2.5.3.2. Types of planned manipulations;

2.5.3.3. Source(s) of inserted DNA sequences;

2.5.3.4. Nature of inserted DNA sequences;

2.5.3.5. Host(s) and vector(s) to be used;

2.5.3.6. Containment conditions to be utilized;

2.5.3.7. Whether an attempt will be made to obtain expression of a foreign gene and if yes, the protein that will be produced; and

2.5.3.8. Applicable section(s) of NIH Guidelines.

Note: These minutes are for official documentation purposes only and not for general distribution or public access without formal written requests (see below).

2.5.3.9. External Requests for Meeting Minutes

Section IV-B-2-a-(7) of the NIH Guidelines states upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public. If public comments are made on Institutional Biosafety Committee actions, the institution shall forward both the public comments and the Institutional Biosafety Committee's response to the Office of Science Policy, National Institutes of Health, preferably by email to: NIHGuidelines@od.nih.gov. Any requests must be made in writing to ORIO, Assistant Provost for Research Integrity. The IBC at

2.5.3.9.1. Rosters submitted to the NIH;

2.5.3.9.2. Biographical sketches;

2.5.3.9.3. Documents that would be public access under the Freedom of Information Act; and

2.5.3.9.4. Other information as required by federal or state law.

As part of USM's dedication to maintaining high levels of safety and security for all members of the USM community, the IBC Chair and/or the Assistant Provost for Research Integrity will verify the request and assure that the request is legitimate. This process can be accomplished by any reasonable and legal means available. The verification and verification method must be documented. Once verification is completed, the IBC Chair, the IBC, and/or the Assistant Provost for Research Integrity will notify the University's System Counsel Office of the request and comply with any directives from the Counsel's Office.

Certain information, though part of the IBC meeting minutes, is not to be made available to the public. Redaction of information must be made judicially, using clearly articulated criteria or justification and be applied consistently.

Types of redacted information include:

2.5.3.9.5. Trade secrets or other confidential commercial information;

2.5.3.9.6. Proprietary information;

2.5.3.9.7. Information pertaining ongoing research, where the research data or results are not publicly available or have not been published (unless disclosure of such information is required by law or the funding agency);

2.5.3.9.8. Personal information such as home phone #s, addresses, e-mails, etc. of IBC members, staff or other representatives;

2.5.3.9.9. Information that would compromise institutional, local or national security;

2.5.3.9.10. Protected Health Information (PHI) as defined under HIPAA; and/or

2.5.3.9.11. Personally identifiable information (PII) as defined in federal and state laws.

Note: The IBC, through ORIO, may charge a reasonable amount sufficient to cover the costs of providing the minutes. Excessive charges or charges used to deter access are not allowed and will be considered a violation of this policy and subject to disciplinary review.

3. IBC Procedures

3.1. What Must Be Reviewed By The IBC

Research, teaching or testing activities involving any of the following must be reviewed by the IBC before approval to commence these activities at any USM location is granted:

3.1.1. Any Recombinant DNA activity;

3.1.2. Any transgenic animal[1] (cross-over review with IACUC);

3.1.3. Human or animal blood, bodily fluids, or tissues (use of human blood and body fluid for clinical, diagnostic, and treatment purposes is excluded);

3.1.4. Known infectious materials;

3.1.5. Select Agents, including exempt amounts;

3.1.6. Any biological agent in Risk Group 2, 3 or 4; and/or

3.1.7. Experiments with transgenic[2] plants.

Note: Activities involving biohazardous materials will often require cross review by other USM research oversight boards and committees (IACUC, IRB, and RSC). Please contact ORIO for guidance on these review requirements.

3.2. Definition of rDNA[3] and Classifications

3.2.1. **Recombinant DNA molecules are defined as either:**

3.2.1.1. molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or

3.2.1.2. molecules that result from the replication of those described in (a) above.

Note(s): Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed in vivo as a biologically active polynucleotide or polypeptide product, it is exempt from the NIH Guidelines.

Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the NIH Guidelines unless the transposon itself contains recombinant DNA.

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[1] Under APHIS (The Animal and Plant Health Inspection Service) Guidance, this includes any vertebrate or invertebrate organism and laboratory mammals (mice, rabbits, rats) which are altered through the introduction of foreign DNA from another species by genetically manipulating the egg or embryo.

[2] Including plants that are altered (by genetic manipulation) by introducing foreign DNA from another species and are not controlled under the Controlled Substances Act or other federal regulation.

[3] NIH Guidelines, Section 1-B.

3.2.2. **Classification of Risk Groups**

The World Health Organization (WHO), the American Biological Safety Association (ABSA), and many other organizations have established a mechanism for defining biological agent risks, based on the agent's unique characteristics and its effects on humans or animals. In accordance with regulatory requirements and these guidelines, the IBC has adopted this mechanism for biological agent risk classification. The Risk Groups (RG's) are defined below:

3.2.2.1. Illustration

Characteristic	Risk Group 1	Risk Group 2	Risk Group 3	Risk Group 4
Severity of Disease	Unlikely to cause human disease	Can cause human disease, but is generally not serious	Serious	Very Serious or lethal
Effective treatments or preventions available	Generally not needed	Yes	Usually	Generally no
Communicability	Unlikely	Possible	Probable	Yes
Exposure route(s)	NA	Direct, most common	Direct, inhalation most common	Direct, indirect, inhalation common
Host range	Humans and animals	Humans and animals	Humans and animals	Humans and animals
Individual risk	Low	Moderate	High	High
Community (group) risk	Low	Low	Low-Moderate	High
Example: Bacteria	E-coli K-12	Salmonella (various types)	Rickettsia (various types)	NA
Example: Virus	Bovine Leukemia Virus (BLV)	Coronaviruses	HIV types 1 and 2	Herpesvirus simiae (B virus)
Example: Fungi	NA	Crytoccus neoformans	Histoplasma capsulatum	NA
Example: Parasite	Naegleria gruberi	Ascarius, various types	NA	NA

Note: For a complete searchable list of the current infectious agents and their Risk Group classification, go to the ABSA's website or click below for a direct link:
ABSA Risk Group Database

3.2.3. **Biosafety Levels (BSL); Defined**

BSL's are not the same thing as Risk Groups. BSL's establish the defining characteristics of the work environment and required containment levels. Risk Groups, on the other hand, define the characteristics of individual agents.

3.2.3.1. BSL-1: Suitable for work involving well-characterized biological agents not known to consistently cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment. The laboratory is not necessarily separated from the general traffic patterns in the building. Work is generally conducted on open

bench tops using standard microbiological practices. Special containment equipment or facility design is neither required nor generally used. Laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised by a scientist with general training in microbiology or a related science.

3.2.3.2. BSL-2: Similar to BSL-1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs from BSL-1 in that:

3.2.3.2.1. Laboratory personnel have specific training in handling pathogenic agents and are directed by qualified scientists;

3.2.3.2.2. Access to the laboratory is limited when work is being conducted;

3.2.3.2.3. Additional precautions are taken with contaminated sharp items; and

3.2.3.2.4. With the following procedures:

3.2.3.2.4.1. Where infectious aerosols or splashes may be created;

3.2.3.2.4.2. That are conducted in biological safety cabinets; or

3.2.3.2.4.3. That uses other physical containment equipment.

Whenever there is a high potential for aerosol or droplet production, a biological safety cabinet will be used. The IBC does not allow the use of vertical or horizontal laminar flow clean benches for biohazardous agent work.

3.2.3.3. BSL-3: Applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents, and are supervised by competent scientists who are experienced in working with these agents.

All procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices, and by personnel wearing appropriate personal protective clothing and equipment. The laboratory has special engineering and design features.

It is recognized, however, that some existing facilities may not have all the facility features recommended for Biosafety Level 3 (i.e., double-door access zone and sealed penetrations). In this circumstance, an acceptable level of safety for the conduct of routine procedures, (e.g., diagnostic procedures involving the propagation of an agent for identification, typing, susceptibility testing, etc.), may be achieved in a BSL-2 facility, provided that:

3.2.3.3.1. The exhaust air from the laboratory room is discharged to the outdoors,

3.2.3.3.2. The ventilation to the laboratory is balanced to provide directional airflow into the room,

3.2.3.3.3. Access to the laboratory is restricted when work is in progress, and

3.2.3.3.4. The recommended Standard Microbiological Practices, Special Practices, and Safety Equipment for Biosafety Level 3 are rigorously followed.

Note: The decision to implement this modification of BSL-3 recommendations should be made only by the laboratory director, following IBC approval and the notification of facilities personnel.

3.2.3.4. BSL-4: Required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease. Agents with a close or identical antigenic relationship to Biosafety Level 4 agents are handled at

this level until sufficient data are obtained either to confirm continued work at this level, or authorization is granted to work with them at a lower level. Members of the laboratory staff have specific and thorough training in handling extremely hazardous infectious agents and they understand the primary and secondary containment functions of the standard and special practices, the containment equipment, and the laboratory design characteristics. They are supervised by competent scientists who are trained and experienced in working with these agents. Access to the laboratory is strictly controlled by the laboratory director. The facility is either in a separate building or in a controlled area within a building, which is completely isolated from all other areas of the building. A specific facility operations manual is prepared or adopted for each lab/facility.

Within work areas of the facility, all activities are confined to Class III biological safety cabinets, or Class II biological safety cabinets used with one-piece positive pressure personnel suits ventilated by a life support system. The BSL-4 laboratory has special engineering and design features to prevent microorganisms from being disseminated into the environment.

3.2.4. **Animal Biosafety Levels (ABSL); Defined**

ABSL's are not the same thing as Risk Groups. ABSL's establish the defining characteristics of the work environment and required containment levels. Risk Groups, on the other hand, define the characteristics of individual agents.

3.2.4.1. ABSL-1: Animal Biosafety Level 1 (ABSL-1) is suitable for work involving well characterized agents that are not known to cause disease in healthy adult humans, and that are of minimal potential hazard to laboratory personnel and the environment.

3.2.4.2. ABSL-2: Animal Biosafety Level 2 involves practices for work with those agents associated with human disease. It addresses hazards from ingestion as well as from percutaneous and mucous membrane exposure. ABSL-2 builds upon the practices, procedures, containment equipment, and facility requirements of ABSL-1.

3.2.4.3. ABSL-3: Animal Biosafety Level 3 involves practices suitable for work with animals infected with indigenous or exotic agents that present the potential of aerosol transmission and of causing serious or potentially lethal disease. ABSL-3 builds upon the standard practices, procedures, containment equipment, and facility requirements of ABSL-2.

3.2.4.4. ABSL-4: Animal Biosafety Level 4 involves practices suitable for addressing dangerous or exotic agents that pose high risk of life threatening disease, aerosol transmission, or related agents with unknown risk of transmission. ABSL-4 builds upon the standard practices, procedures, containment equipment, and facility requirements of ABSL-3. Procedures must be developed locally to address specific operations of the Class III cabinet line or the suit laboratory.

3.3. IBC Application Submission Procedures & Resources

Any PI, whenever involved in research, teaching, or testing activities working with those materials listed in Section 3.1 of this policy, must contact ORIO to determine whether IBC approval is required. The PI must submit a signed IBC Application to ORIO, which can be found on the ORIO Website under Research Compliance.

3.3.1. **Instructions/Considerations for PI's Development and Submission of Biosafety Proposals**

When developing and submitting a Biosafety proposal, an approved protocol submission form with the following information must be included:

3.3.1.1. Purpose;

3.3.1.2. Location of activities;

3.3.1.3. Initial risk assessment;

3.3.1.4. Initial estimate of the required BSL (or ABSL) in accordance with NIH guidelines and the contents of this policy;

3.3.1.5. Outline of standard operating procedures for good lab practice and techniques to be followed (e.g., waste procedures, decontamination procedures, personal protective equipment);

3.3.1.6. Who is involved and their credentials/training;

3.3.1.7. Specific additional training requirements that may be needed; and

3.3.1.8. Any additional requirements that may be needed (i.e. specialized equipment, facilities, etc.)

Note: PI's are strongly encouraged to include a process for **authenticating cultured cell lines** that they plan on using in a proposed research project. The PI and their team are free to choose which method to employ. The chosen method, however, must be currently accepted within the scientific community and reasonable for the proposed research project.

Note: Any time researchers utilize human blood, tissues, DNA, saliva, etc., there is a chance that the research will engage the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as these materials may contain **protected health information (PHI)** (information that could be used to identify who the materials came from). It is the responsibility of the PI to contact ORIO to assess materials for PHI.

3.3.2. **Informational Sources for PI's: Biosafety & Grants**

3.3.2.1. General

The following informational links are provided to assist researchers while preparing IBC protocol submissions in order to better understand the issues, safety guidelines, and general policies surrounding Biosafety:

3.3.2.1.1. Association for Biosafety and Biosecurity

3.3.2.1.2. Center for Disease Control

3.3.2.1.3. CDC The National Institute for Occupational Safety and Health (NIOSH)

3.3.2.1.4. Food and Drug Administration

3.3.2.1.5. US DHHS Office for Civil Rights

3.3.2.1.6. NIH Office of Science Policy

3.3.2.1.7. National Institutes of Health

3.3.2.1.8. Occupational Safety and Health Administration

3.3.2.1.9. HHS HIPAA

3.3.2.1.10. "The Common Rule"- 45 CFR 46, Protection of Human Subjects

3.3.2.1.11 NIH_Guidelines.pdf

3.3.2.1.12. Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition (PDF Download)

3.3.2.1.13. Select Agents Program and Regulations

3.3.2.1.16. HIPAA Privacy Rule

3.3.2.1.17. HIPAA Security Rule

Note: For more information, please contact ORIO.

3.3.2.2. Grant Information and Preparation

Research involving biohazardous activities is often initiated through granting agencies. Grants are one of the most important parts of research funding for the University System. It is important to note, however, that many competitive grants have very specific requirements for Biosafety. To further help researchers in grant preparations, please use the following references for more information from specific granting agencies:

3.3.2.2.1. National Institutes of Health (NIH): To find out what NIH looks for in grants and about grant basics go to NIH Grant Basics. For more information on NIH grant opportunities, policies, forms, etc., go to NIH Grant information.

3.3.2.2.2. US Dept of Health and Human Services (DHHS): For general information on the DHHS grant process and funding, go to HHS Grant information.

3.3.2.2.3. National Science Foundation (NSF): For general information on the NSF grant process and funding, go to NSF Grant Proposal Guide; NSF Grant Policy Manual and NSF FAQ on Proposal Preparation.

Note: For more information about grant preparation, please contact the USM Office of Sponsored Programs.

3.4. Review of Biohazardous Activities

3.4.1. General

In order to approve biohazardous activities or changes to those biohazardous activities ongoing, the IBC, in coordination with ORIO, will conduct a review of the required components of the proposal, and determine if the proposed activities are in accordance with this Policy. In making this determination, the proposed activities must be conducted in accordance with NIH Guidelines for Recombinant DNA, CDC guidance, and all Federal, State and local laws and regulations, and the activity must be consistent with these requirements unless acceptable justification for a departure is presented and proper federal approval is secured.

3.4.2. ORIO Preliminary Review and Exemption Determination

Upon receipt of an application, ORIO, along with the IBC Chair, will assess the proposal for completeness of information and provide a preliminary review of the activities based on NIH, CDC, USDA requirements. If the activities are eligible for an exemption from IBC review, an exemption determination letter will be issued at that time by ORIO and the IBC Chair. This letter will include the basis for the exemption determination. **Please note that an annual continuing review is still required for exempt protocols**. Upon receiving a notification of exemption, if the investigator makes any change to what was provided in the original protocol, the PI must submit a revision/amendment form and receive approval prior to initiating the change.

Even if the proposed research project is exempt from IBC review, the PI may still have to comply with other Federal or State laws, funding mandated requirements, and/or regulations outside of the IBC's control.

If the activities do not qualify for exemption status, the application and ORIO's preliminary review will be forwarded to the full IBC for further review and determination.

3.4.3. Full IBC Review

Research protocols given a non-exempt determination will go to the IBC for further review. Full

IBC review can also be initiated if the IBC Chair or any other individual having taken part in the preliminary review has decided that the protocol should go before the full IBC. In the case of a Full IBC review, a quorum of IBC members must be present to meet face to face to discuss, review, and vote on a research proposal.

3.4.4. **Criteria for Review**

ORIO and the IBC will determine that the research proposal conforms to the institution's NIH Assurance and meets the following criteria:

3.4.4.1. The hazards and risks associated with the project or activity are appropriately minimized by safe procedures;

3.4.4.2. The risk to personnel, students or visitors is reasonable in relation to the threats and hazards associated with use of the materials;

3.4.4.3. The risk to the community's health and environment is reasonable;

3.4.4.4. The facilities are adequate to minimize the risks of using the materials;

3.4.4.5. Preventative medical measures are taken to minimize risks associated with breeches in safety procedures. This includes any required occupational health consultations;

3.4.4.6. Proof that research and support personnel have completed the initial Occupational Health Screening Questionnaire;

3.4.4.7. That the lab/PI has established any required security measures that may be required by State or Federal law;

3.4.4.8. That the proposed research conforms to acceptable research methodology(s) and laboratory procedures; and

3.4.4.9. Documentation of PI and staff credentials, certifications, and any required licenses.

3.4.5. **Biosafety Risk Assessment**

3.4.5.1. General

The term risk, as used in a Biosafety activity, is the probability of harm, injury, illness, or death occurring. Typically the risk assessment for microbiological or biomedical research focuses on the possibility and subsequent preventative measures of laboratory associated accidents or infections. A thorough risk assessment by the PI, ORIO, Safety Management, and the IBC is essential to the overall IBC submission and review process, as well as to the general safety of all involved in biohazardous activities at the University.

It is the responsibility of all lab directors, lab supervisors, and PI's to provide an initial assessment of the risk factors and risk levels involved in their proposed activities. In many instances, the PI/Supervisor has significant experience working with similar biological agents or rDNA and is in the best position to estimate appropriate Biosafety level for the lab and immediate work environment. This assessment must be done in collaboration with ORIO.

A thorough risk assessment, therefore, involves two stages: a PI/ORIO risk assessment and a Safety Management/ORIO/IBC risk assessment. The PI/ORIO risk assessment looks at factors such as the research protocol, the agent(s) used, available protective measures, data from other studies, etc. The Safety Management/ORIO/IBC risk assessment looks at factors such as the safety aspects of the physical lab layout/building, appropriate policies and procedures, and available safety equipment.

3.4.5.2. Biosafety Risk Assessment Factors

3.4.5.2.1. The collaborative PI/ORIO risk assessment should consider the following list of important risk factors:

3.4.5.2.1.1. Nature and characteristics of Biohazardous agents used:

3.4.5.2.1.1.1. Pathogenicity (severity),

3.4.5.2.1.1.2. Virulence,

3.4.5.2.1.1.3. Route(s) of transmission,

3.4.5.2.1.1.4. Agent stability,

3.4.5.2.1.1.5. Infectious or intoxication dose,

3.4.5.2.1.1.6. Route(s) of exposure,

3.4.5.2.1.1.7. Concentration(s), and

3.4.5.2.1.1.8. Origin of materials;

3.4.5.2.1.2. Availability of effective prophylaxis and/or other therapeutic interventions, such as:

3.4.5.2.1.2.1. Universal precautions,

3.4.5.2.1.2.2. Vaccinations,

3.4.5.2.1.2.3. Availability of medical surveillance programs, and

3.4.5.2.1.2.4. Other medical services;

3.4.5.2.1.3. Availability of data from animal or other research studies;

3.4.5.2.1.4. Personnel factors:

3.4.5.2.1.4.1. Experience and skill levels of all personnel,

3.4.5.2.1.4.2. Receipt of proper training(s); and

3.4.5.2.1.5. Availability, feasibility, and proper use of safety equipment:

3.4.5.2.1.5.1. Gloves & Goggles,

3.4.5.2.1.5.2. Respirators,

3.4.5.2.1.5.3. Aprons/gowns, and

3.4.5.2.1.5.4. Personal containment suits.

3.4.5.2.2. The collaborative Safety Management /ORIO/IBC risk assessment should consider the following list of important risk factors:

3.4.5.2.2.1. Availability of appropriate policies and procedures, such as:

3.4.5.2.2.1.1. Reporting of accidents,

3.4.5.2.2.1.2. Proper laboratory operations,

3.4.5.2.2.1.3. Proper care and handling of animal subjects and human subjects involved in the activities,

3.4.5.2.2.1.4. Sanitation/decontamination protocols,

3.4.5.2.2.1.5. Emergency evacuation,

3.4.5.2.2.1.6. Handling, destruction and transportation of pathogens or hazardous chemicals,

3.4.5.2.2.1.7. OSHA compliance levels,

3.4.5.2.2.1.8. Ventilation,

3.4.5.2.2.1.9. Proper use and installation of containment equipment,

3.4.5.2.2.1.10. Proper use of warning signs.

3.4.5.2.2.2. Known threats to personnel or the building, such as:

3.4.5.2.2.2.1. National Terrorist Alert Levels,

3.4.5.2.2.2.2. Policy reports or issued warnings,

3.5.2.2.2.2.3. Known or suspected threats (ex. threats by animal rights groups), and

3.4.5.2.2.2.4. Known injuries to staff or other personnel; and

3.4.5.2.2.3. The environmental impact if containment is breached.

(See EPA Environmental Management Information for more assistance; or the World Health Organization's Communicable Disease Surveillance and Response)

Note: All risk factors shall be assessed pursuant to established guidelines provided for by the CDC, DOD, NIH and/or USDA in estimating both the likelihood and magnitude of risk.

3.4.5.3. PI Guidance for Risk Assessment

The following guidance on risk assessment is provided to assist PI's in conducting an accurate and effective risk assessment. The steps listed below are modified excerpts from the *The Biosafety in Microbiological and Biomedical Laboratories* (BMBL 6th Edition):

3.4.5.3.1. Step 1: Identify agent hazards and perform an initial assessment of risk.

Consider the principal hazardous characteristics of the agent, which include its capability to infect and cause disease in a susceptible human host, severity of disease, and the availability of preventive measures and effective treatments.

3.4.5.3.2. Step 2: Identify laboratory procedure hazards.

The principal laboratory procedure hazards are agent concentration, suspension volume, equipment and procedures that generate small particle aerosols and larger airborne particles (droplets), and use of sharps. Procedures involving animals can present a number of hazards such as bites and scratches, exposure to zoonotic agents, and the handling of experimentally generated infectious aerosols.

3.4.5.3.3. Step 3: Make an [initial] determination of the appropriate biosafety level and select additional precautions indicated by the risk assessment.

Note: ORIO and the IBC will make the final biosafety level determination.

3.4.5.3.4. Step 4: Evaluate the proficiencies of staff regarding safe practices and the integrity of safety equipment.

In conducting a risk assessment, the laboratory director or PI should ensure that laboratory workers have acquired the technical proficiency in the use of microbiological practices and safety equipment required for the safe handling of the agent, and have developed good habits that sustain excellence in the performance of those practices.

3.4.5.3.5. Step 5: Review the risk assessment with the USM Biosafety Officer (where applicable), subject matter expert, and the IBC.

3.4.6. **Approval Period and Continuing Review**

The IBC can approve a research protocol for up to one year. If an applicable statute, regulation or Federal Agency rule allows for a longer approval period, the IBC may take this into consideration. If an applicable statute, regulation or Federal Agency rule requires a shorter approval period, then the IBC must follow that requirement.

PI's may renew their approval period by filling out the IBC Continuing Review form and submitting it to the ORIO at least 30 calendar days prior to the protocol's expiration date. A 60 calendar day submission period is preferable.

Note: If the original protocol was reviewed and approved by the full IBC, then the Continuing Review may need to be reviewed by the full IBC at the next available meeting. PIs are encouraged to keep the scheduled meeting dates (found on the ORIO website) in mind when submitting for a Continuing Review.

3.5. **Dispute Resolution**

If an investigator disagrees with the IBC required revisions or specifications required for approval or continuation of research activities, the investigator may bring his or her concerns to the Chair of the IBC or ORIO for discussion, reconsideration, and/or due process investigation. The final decision, however, regarding approval of activities involving biohazardous materials rests with the IBC and may not be overturned by the Institutional Official, IBC Chair, or ORIO personnel.

4. Transportation and Disposal of Biohazardous Materials

The standard operating procedure (SOP) for transportation and disposal of biohazardous materials can be found in IBC SOP # IBC-001 Transportation and Disposal of Biohazardous Materials, incorporated herein by reference.

5. Research Misconduct and Biosafety Violations

5.1. **Definition**

Research Misconduct (as defined under federal regulation and USM's policy for "*Alleged Research Misconduct"*) means:

5.1.1. The knowing fabrication, falsification, or manipulation by a researcher of data or information;

5.1.2. The knowing theft by a researcher of data, materials, or information, including but not limited to plagiarism; and

5.1.3. Implicit in this definition of misconduct is that a preponderance of the evidence proves that fabrication, falsification, or plagiarism; theft; non-compliance with legal requirements; or disregard of associate conduct was committed intentionally, knowingly, or recklessly, and not merely carelessly.

5.2. **Reporting Alleged Research Misconduct**

At any time, a USM community member may have confidential discussions and consultations concerning possible research misconduct with the Research Integrity Officer (RIO) and will be counseled about appropriate procedures for reporting allegations. According to USM's anti-retaliation procedures, individuals who have in good faith made an allegation of research misconduct ("whistle-blower") will not be subject to disciplinary action or retaliation.

5.3. **Procedures for Biosafety Violations**

5.3.1. **General Procedures**

A biosafety violation occurs when there is a variance between the activity that has been reviewed and approved by the IBC and the actual activities being performed. A violation may be minor or major in nature. All incidents of alleged or known protocol violations may be investigated using the following procedures:

5.3.1.1. A fact-finding process may be initiated by ORIO in cooperation with the IBC Chair;

5.3.1.2. The IBC Chair and ORIO will then analyze all information gathered regarding the protocol violation and compare it to the approved protocol. When necessary, the IBC Chair and ORIO will consult with experts in the particular area of research to make definitive, unbiased and educated decisions regarding the violation; and

5.3.1.3. A conclusion may then be made regarding whether there was a protocol violation, and if so, whether the violation is "major" or "minor" in nature (see below).

If the findings from this procedure do not support that a violation has occurred, then the matter will be dropped.

5.3.2. **Minor Biosafety Violation**

A Minor Biosafety violation:

5.3.2.1. Has no substantive effect on the risks to those conducting rDNA and Biological agent activities; and/or

5.3.2.2. Results in a non-serious adverse event occurring; and

5.3.2.3. Does not result from willful or knowing misconduct on the part of the investigator(s).

In such cases, the following steps will be taken:

5.3.2.4. The IBC Chair will notify the PI in writing what must be done (if anything) to correct the conditions that led to the violation, and

5.3.2.5. The IBC Chair will present a summary of the violation, process, facts, and conclusions at the next scheduled IBC meeting.

5.3.3. **Major Biosafety Violations**

A Major Biosafety violation:

5.3.3.1. Has or poses a significant risk of substantive harm to the health or safety of personnel, students, the public or the environment; or

5.3.3.2. Seriously deviates from either the established protocol or those practices that are commonly accepted by the scientific community; or

5.3.3.3. Results in a serious adverse biosafety event; or

5.3.3.4. Results if the investigator(s) demonstrates other serious or continued noncompliance with federal, state or local research policy, laws or regulations; and

5.3.3.5. Results from a willful or knowing misconduct on the part of the investigator.

In the case that the fact-finding committee finds any of the four criteria noted above, the following steps will be taken:

5.3.3.6. The IBC Chair or Institutional Official (if applicable) may suspend the protocol pending IBC review. If suspension of the protocol or study procedures would result in harm to the enrolled research participants, the Chair will request that the PI's department chair assign PI duties to another qualified person and submit an IBC Protocol Revision/Amendment Form explaining this substitution, and indicating temporary closure of the study. In this situation the official action will be the suspension of the protocol.

5.3.3.7. If requested by the Biosafety Officer, the IBC Chair, or the PI, the IBC chair may convene a hearing committee to consider all facts of the case and to meet with the

investigator(s). The hearing committee will be held within 10 days of being requested and may consist of the following individuals:

5.3.3.7.1. The IBC Chair,

5.3.3.7.2. USM Biosafety Officer,

5.3.3.7.3. One or more representatives from the PI's department or discipline,

5.3.3.7.4. The Dean or other representative from the PI's college,

5.3.3.7.5. One or more representatives from the IBC, and

5.3.3.7.6. Any additional persons as necessary.

The IBC Chair will notify the PI in writing within 14 days of the conclusion of fact-finding what must be done to correct the conditions that led to the violation.

5.3.3.8. Any protocol or PI suspension will be reported directly to ORIO, which will determine the appropriate federal agencies or sponsors to notify, and ORIO will prompt the IO to make such notification in writing.

5.3.3.9. Depending on the nature or the seriousness of the violation, the hearing committee may elect to direct the IBC to audit all protocols that involve the PI in question. The IBC Chair may delegate this duty to a designee or appropriate third party.

5.3.3.10. If the findings of the hearing committee support possible research misconduct (as defined under federal regulation and USM's policy for "*Alleged Research Misconduct*"), the Research Integrity Officer shall be notified and will conduct a preliminary inquiry.

5.3.3.11. A summary of the issue, process, facts, conclusions and actions will be presented at the next scheduled IBC meeting. A written summary will be forwarded to the Institutional Official, PI, the PI's department chair, and the appropriate dean or director. A copy will be retained in the IBC study file.

5.3.4. **Investigator Right to Appeal**

If an investigator disagrees with the findings or requirements of the fact-finding or hearing committees, the investigator has the right to appeal the decision to the Institutional Official. The IBC Chair will forward all information gathered by the inquiry or hearing process to the Institutional Official, who will consider it along with any additional information provided by the investigator.

6. Biosafety Adverse Events

6.1. Mandatory Reporting of Adverse Biosafety Events

6.1.1. All unanticipated serious biosafety adverse events must be communicated to ORIO. A serious biosafety adverse event is defined as any injury, illness, or accident that results in any of the following:

6.1.1.1. Death;

6.1.1.2. Life-threatening event;

6.1.1.3. In-patient hospitalization or prolongation of existing hospitalization;

6.1.1.4. Persistent or significant disability/incapacity;

6.1.1.5. A congenital anomaly/birth defect; or

6.1.1.6. An important medical event that may not result in death, be life threatening, or require hospitalization, though, based upon appropriate medical judgment, may jeopardize the participant and may require medical or surgical intervention to prevent one of the previously identified outcomes[4].

[4] Based on NIH Policy 6.1, Serious Event Reporting.
[5] Based on NIH Guidelines Incident Reporting Appendix G-II-D-2-k May 2019

6.1.1.7. Spills or accidents in BL2 laboratories resulting in an overt exposure and Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure[5].

6.1.1.7. Any spill or accident involving recombinant or synthetic nucleic acid molecule research of the nature described above or that otherwise leads to personal injury or illness or to a breach of containment

In addition, unanticipated research events in federally sponsored research must be disclosed to the grantor via ORIO.

6.1.2. The PI must submit the IBC Adverse Event Report Form to ORIO within 7 days of an injury and within 24 hours of a death. The chair of the IBC and the BSO (if applicable) will review all reports of adverse events. All serious biosafety adverse events will be communicated to the IBC at either a regularly convened meeting or one convened by the IBC Chair, at which time the IBC may require additional safeguards or changes in procedures.

6.1.3. In the event of a death or life-threatening research event, a full IBC, (and if applicable additional research committees), meeting will be convened to discuss the adverse event, and all Biosafety procedures associated with the event. In some instances the Chair of the IBC may suspend all rDNA or Biological Agent use by the Principle Investigator pending clearance from the IBC and consultation with medical specialists.

6.1.4. Once ORIO has been notified of a serious biosafety adverse event, the Assistant Provost for Research Integrity will notify the Institutional Biosafety Committee, Institutional Animal Care and Use Committee (when applicable), the Institutional Review Board, NIH/OSP, and other appropriate authorities (if applicable) within 30 days. Certain types of accidents must be reported on a more expedited basis. Spills or accidents in BL2 laboratories resulting in an overt exposure and accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately (within 24 hours) reported to NIH. Reports to NIH/OSP will be sent to (via the ORIO) The Office of Science Policy. Reports of incidents can be emailed to NIHGuidelines@od.nih.gov

6.2. **IBC Review of Adverse Biosafety Events**

6.2.1. Upon receipt of an IBC Adverse Event Report Form (see section VII. A. for definition of serious adverse biosafety event), the original IBC review forms, the original approval letter, continuing approvals, and any IBC or ORIO monitoring notes, along with the report form, will be submitted to the IBC for review. As necessary, an advisor or expert in the field will be consulted if the needed expertise is not available, for any reason, within the IBC.

6.2.1.1. Procedures

6.2.1.1.1. The IBC Chair, and BSO, if applicable, will discuss the protocol in light of the adverse event(s) and re-assess the current Biosafety procedure to determine if it adequately protects employees, students, and the public. The Chair or BSO may require the IBC to review the event and provide additional safeguards and/or changes in the previously approved procedures to prevent additional adverse events. If the IBC finds the risks of the activities unacceptable, the IBC may vote to suspend or terminate the protocol with a majority IBC vote. In emergency situations, the Chair may be compelled to immediately suspend activities to protect the safety of personnel and the community at large.

6.2.1.1.2. If the findings of the review suggest possible research misconduct (as defined under federal regulation and USM's policy for "*Alleged Research*

Misconduct"), the Research Integrity Officer shall be notified in order to conduct a preliminary inquiry.

6.2.1.2. Communications and Reporting Requirements

6.2.1.2.1. The PI will be notified in writing of the following:

6.2.1.2.1.1. The scheduled IBC review of the relevant adverse event(s);

6.2.1.2.1.2. Any changes/modifications required by the IBC for the existing protocol; and/or

6.2.1.2.1.3. Any other actions taken by the IBC in reviewing the adverse event(s).

6.2.1.2.2. Unforeseen adverse research events will be reported to all appropriate officials.

6.2.1.3. Follow-up Procedures

The PI must submit a follow-up adverse event report 30 days following IBC review of the adverse event. ORIO or IBC members are required to observe the new procedures implemented and a follow up report will be reviewed by the IBC at the next convened IBC meeting to assess the adequacy and effectiveness of the protocol protections. If necessary, the IBC may require additional changes. The investigator will be notified in writing if any additional changes are then required.

6.2.2. **Near Adverse Biosafety Events**

A near adverse biosafety event is any circumstance that:

6.2.2.1. Does not meet the criteria of a serious biosafety adverse event, but still results in some form of accident, illness or injury; or

6.2.2.2. Was avoided, prevented, or mitigated by some means.

Near adverse biosafety events must be tracked for many reasons, including improving safety procedures, creating new policies, identifying possible future problems, illustrating the need for additional trainings and so forth. Near adverse biosafety events should be reported to the PI or the assigned lab supervisor.

Appendix 1: Glossary of Acronyms

ABSA	American Biological Safety Association
ABSL	Animal Biosafety Level
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BSL	Biosafety Level
BSO	Biosafety Officer
CDC	Centers for Disease Control
UEH&S	(USM's) University Environmental Health and Safety
DHHS	(US) Department of Health and Human Services
EPA	Environmental Protection Agency
FDA	(US) Food and Drug Administration
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IRB	Institutional Review Board
NIH	National Institutes of Health
NIH-OBA	National Institutes of Health, Office of Biotechnology Activities
NIOSH	National Institute of Occupational Safety and Health
NSABB	National Science Advisory Board for Biosecurity
NSF	National Science Foundation
OLAW	Office of Laboratory Animal Welfare
ORIO	(USM's) Office of Research Integrity and Outreach
ORI	Office of Research Integrity
OSHA	Occupational Safety and Health Administration
PI	Principle Investigator
rDNA	Recombinant Deoxyribonucleic Acid
RG	Risk Group or Risk Group Classification (usually accompanied by a number 1-4)
RSC	Radiation Safety Committee
USDA	US Department of Agriculture
USDA-APHIS	US Department of Agriculture-Animal and Plant Health Inspection Service
WHO	The World Health Organization