USM Institutional Biosafety Committee

Biosafety Policy Manual

Office of the President

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I. General Biosafety Policies

A. Biosafety Policy Statement

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, 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 (hereeto referred to as activities) as outlined in the:

- NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), May 2011;
- CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition, 2009;
- NSABB’s proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information (2007);
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002;
- NSABB- Addressing Biosecurity Concerns related to the Synthesis of Select Agents;
- All federal, state and local laws;
- The contents of this policy; and
- All 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 the 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 is conducted in compliance with the National Institutes of Health (NIH) Guidelines, Federal, State and Local Laws and Regulations and University of Maine System Polices.

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 an administrative framework in which safety is an essential and integral part of research. Further clarifications and interpretations of roles and responsibilities will be issued by USM as necessary.

2. Purpose

This policy has been prepared in an effort to prevent injuries, illnesses, death from work related causes, and to minimize loss of material resources and interruptions from accidental occurrences. It is directed toward the control of all types of biohazards encountered in the performance of official duties. This policy is a part of a continuing safety and informational program for all USM personnel, students and visitors. All share in the responsibility for the health and safety of our employees, contractors, and visitors. This manual is meant as a guide for working safely in your workplace.

This policy provides personnel, students, faculty, staff and visitors with general guidelines for implementing a high quality Biosafety program. It is not an exhaustive source document but rather an
approach to safety. The policy brings together information that will assist employees and supervisors in carrying out their responsibility of ensuring a safe environment at USM for visitors, contractors, and employees.

All personnel should read this manual and conduct their work accordingly.

3. Scope

The information and requirements given in this policy are applicable to all areas of USM and represent only general minimum standards. They are not a substitute for special operation manuals used in certain buildings or laboratories to meet specific situations. This policy will serve as a basis to which supervisors shall add safety measures relevant to their laboratory or work operations.

This policy contains the objectives, policies, standards, and procedures that pertain to all employees working with or around biological agents and rDNA. The specific responsibilities, administrative procedures, and operational requirements that are described in this policy are designed to prevent laboratory illness and injury, and maintain laboratory safety. This policy replaces all previously issued memorandums concerning biosafety.

B. Policy Development, Maintenance, and Revision Process

1. General

All materials in this manual have been developed and maintained under the supervision and direction of the IBC, the Office of Research Integrity and Outreach (ORIO), and the Office of University Environmental Health and Safety (UEH&S). 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 previous policies on Biosafety.

C. Occupational Health Program

1. General

Exposure to rDNA, biological agents and toxins includes a risk of developing some adverse health outcomes. The risks of associated illness include transmission of infection, respiratory illness, allergies and asthma among others. However, these risks can be minimized by 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 and 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 status. The Office of University Environmental Health and Safety (UEH&S) or the Office of Research Integrity and Outreach (ORIO) may be contacted for comprehensive information about the Occupational Health Program.

Faculty, staff and students conducting biological research in the following situations may participate in the Occupational Health Program:

- Working in a BSL 1 or 2 laboratory;
- Working with Risk Group 1 and 2 agents.

Faculty staff and students conducting biological research in the following situations must participate in the Occupational Health Program:
- Research is governed by the USM IACUC (regardless of ABSL level)
- Working in a BSL 3 or 4 laboratory;
- Working with Risk Group 3 and 4 agents;
- Working with Select Agents, including exempt amounts;
- Personnel have known animal allergies;
- PI receives funding from the Federal Government (PHS, NIH, CDC, etc.)

2. Occupational Health Questionnaire

In addition to possible inclusion into the Occupational Health Program, any person working directly, indirectly, or adjacent to the USM Animal Facility, or working directly with animals, must fill out the USM Occupational Health Questionnaire.

This questionnaire is part of USM’s Occupational Health Program and is a legal requirement of USM’s Federal Assurance with the Office of Laboratory Animal Welfare (OLAW). All persons working in the Science Building or who use the Animal Facility, are required to fill out this questionnaire. Failure to fill out the questionnaire and return it to USM’s University Environmental Health and Safety (UEH&S) office within two weeks will have access to the Facility and the Science Building denied.

The questionnaire will help UEH&S identify any special needs or requirements personnel may have in order to do their job safely and to further reduce the risks of illnesses or injuries. This questionnaire and each annual follow-up will also help UEH&S track any occupational health related issues that may happen over time as a result of working in or near the Animal Facility.

USM will only use the information provided for official Occupational Health Program functions and will remain confidential. Privacy rights will be maintained to the fullest extent allowed by law. The questionnaire will not:
- Become part of the employment record,
- Be shared with Human Resources,
- Be used in employment decisions, or
- Be shared with supervisors.

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

UEH&S will maintain the questionnaires and keep them secured in their offices. Access to these record will be very limited and only on a “need to know” basis. If any special equipment, immunizations, and so on, is needed UEH&S will contact that person directly and make the necessary arrangements.

In the event that a research activity requires immunization(s) (as determined by the Health Questionnaire, use of specific or contagious biological agents or as required by other regulations), the IBC, through the ORIO will contact the Principle Investigator (PI) and notify him/her that all involved personnel will need to have an occupational health consultation prior to beginning the research. In the event that a particular person requires immunization(s), as determined by the Health Questionnaire, UEH&S will contact that person directly and notify that person as to what immunization(s) are required. At that point, if immunizations are required, all involved personnel will need to have the required immunization prior to beginning of the research. PIs and supervisors should allow 4 weeks for immunizations to be accomplished and 30 days for IBC approval before commencement of their research.
D. Training Program for Biosafety

As part of the Biosafety Program, USM will provide or make available, training on the appropriate use of rDNA and Biologic agents to ensure that all individuals at risk are adequately informed about the work in the laboratory, its risks, and what to do if an accident occurs. In many instances the supervisor or PI is the best source for direct training to learn how to handle biological agents and rDNA.

1. Acceptable forms of basic biosafety training include, but not limited to:
   - A presentation arranged or presented by the ORIO;
   - A presentation arranged or presented by the PI/lab supervisor; or
   - The CITI Online Biosafety Course

Basic Training must include, but is not limited to the following information:

1. **Exposure Limits**
   The permissible exposure limits of regulated chemical substances as set by the Occupational Safety and Health Administration (OSHA) and/or the maximum infectious dose limits (when available) for biological agents as established by the Canadian Material Safety Data Sheets (Infectious Substances);

2. **Exposure Symptoms**
   Signs and symptoms associated with exposures to biological agents used in the laboratory;

3. **Biohazard Reference Materials**
   The location and availability of known reference materials on hazards, safe handling, storage and disposal of biological agents found in the laboratory including, but not limited to, Material Safety Data Sheets received from the supplier;

4. **Biohazard Detection**
   Methods and observations that may be used to detect the presence or release of biological agents (such as monitoring continuous monitoring devices, visual appearance or odor of biological agents when being released, etc.);

5. **Employee Protection**
   The measures employees can take to protect themselves from biohazards, including specific procedures USM has implemented to protect lab members from exposure to biological agents, such as appropriate work practices, emergency procedures, and personal protective equipment to be used.

6. **Emergency and Personal Protection Procedures**
   Every laboratory member should know the location and proper use of available protective apparel and equipment. Some of the full-time personnel of the laboratory should be trained in the proper use of emergency equipment and procedures. Such training as well as first aid instruction should be available to and encouraged for everyone.

   Basic information on emergency and personal protection procedures is covered as part of Welcome Matters (new employee orientation). Additional or more advanced trainings are available from the USM UEH&S office.

7. **Receiving and Stockroom/Storeroom Personnel Protection**
   Receiving and stockroom/storeroom personnel should know about hazards involved in handling biological agents, including equipment, protective apparel, and relevant regulations required for
safe transfer of materials, and what to do in case of a breech in containment.

2. Frequency of Training

Appropriate Biosafety Training will be conducted:

- At the time of an employee’s initial assignment to a work area where rDNA, infectious material, select agents or toxins, or human/animal bodily fluids or tissues are present;
- Prior to assignments involving new exposure situations; and
- When new Biosafety policies and procedures go into effect;

The training and education program must be repeated at least every four years. Supervisors are reminded that training and education is a regular, continuous activity not just an annual presentation.

E. Dual Use Research

The term Dual Use is a general term that covers any research or technology that has a bona fide research purpose or use, but in the wrong hands could be misused or used for military purposes.

The National Science Advisory Board for Biosecurity (NSABB) is the federal agency charged with providing advice, guidance, and leadership regarding biosecurity oversight of dual-use research of concern. As policies and advice become available from NSABB, the IBC and ORIO will develop appropriate policies, procedures and guidance to respond to these requirements.

Dual use research in biology encompasses biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security. According to NSABB’s Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information the following are considered to be dual use research of concern:

1. Enhancing the harmful consequences of a biological agent or toxin;
2. Disrupting immunity or the effectiveness of an immunization without clinical and/or agricultural justification
3. Conferring 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
4. Increasing the stability, transmissibility, or the ability to disseminate a biological agent or toxin
5. Altering the host range or tropism of a biological agent or toxin
6. Enhancing the susceptibility of a host population
7. Generating a novel pathogenic agent or toxin or reconstitute an eradicated or extinct biological agent

In addition to NSABB’s recommendations for research of concern, the National Research Counsel (NRC) issued the Fink Report which outlines “experiments of concern”. Experiments of concern are those research activities that:

- Demonstrate how to render a vaccine ineffective
- Confer resistance to therapeutically useful antibiotics or antiviral agents
- Enhance the virulence of a pathogen or render a nonpathogen virulent
- Increase transmissibility of a pathogen
- Alter the host range of a pathogen
- Enable the evasion of diagnostic or detection modalities
- Enable the weaponization of a biological agent or toxin

When considering whether or not research could be “dual use” or “experiments of concern” researchers must consider two threshold points:
   1. Results can be directly misapplied (immediacy); and
   2. Misapplication would have broad consequences (scope)

If these two considerations are met (or are highly probable) then the PI must contact the IBC or the ORIO as soon as possible in order to facilitate actions that will help alleviate and/or mitigate the circumstances.
II. 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 safety practices and procedures that involve the use of rDNA and biological agents. The IBC also oversees research with biological agents and research involving transgenic animals. Participation on the IBC is voluntary public service activity and USM does not provide monetary compensation for service on the Board.

The IBC may be contacted through the USM Office of Research Integrity and Outreach at (207) 228-8279 or by email at ibc@usm.maine.edu.

US Mail Address:
Office of Research Integrity and Outreach
P.O. 9300
Portland, ME 04104-9300

Campus Address:
7 Chamberlain Ave.
Portland, ME 04101

A. IBC Membership

1. General

IBC membership is based on appointing personnel who have expertise, experience, educational background, and specialized training that give them the ability to analyze safety procedures used with Biological Agents, rDNA, and to identify any potential risk to public health or the environment. Nominations/volunteers for service on the committee may be made to 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 fits 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 perspective member’s Department Chair, Dean, or Direct Supervisor for clearance to participate on the Committee. The President or the President’s official designee appoints members for up to 3-year terms. One member of the committee may fulfill more than one of the membership categories indicated below.

The IBC will have no fewer than five members whose expertise will be in the following areas, as determined by the USM research and teaching agenda:

a. Two people who are not employed by USM and who represent the interest of the surrounding community with respect to health and protection of the environment (e.g., officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community);
b. One person with expertise in plant, plant pathogen, or plant pest containment Principles;
c. One scientist with expertise in animal containment principles;
d. One Biological Safety Officer;
e. One person with expertise in rDNA technology, biosafety, and physical containment;
f. One person that represents USM’s Facilities Management;
g. One person who represents the Executive Administration; and
h. One person who represents the CES&H office.
3. Termination of Membership

An IBC member may be terminated for serious misconduct or breach of membership requirement. Absenteeism due to conflicts of interests does not count as a breach of membership requirements. A termination action may only be initiated by the IBC Chair, the Assistant Provost for Research Integrity or the Institutional Official (Provost). Termination of an IBC member must be approved by a simple majority of the IBC. This action may only be taken at a convened IBC meeting.

4. Resignation of Membership

IBC members may voluntarily resign their position for any reason. As a matter of courtesy, however, a minimum of 30 days notice should be given to the IBC board or other authorized representative.

If a member is considering resignation for any reason (i.e. too much time commitment, heavy work load, sabbatical, etc.), they should discuss this with the IBC Chair or the Associate Director of ORIO for possible alternative options.

B. IBC Responsibilities and Powers

1. The Powers of the IBC are limited to the following:

   a. Review and approve, require modifications in (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, NIH RAC reviews, USDA, CDC recommendations, ORIO Policy or new data on safety;
   b. Inspect at least once annually all of the institution’s Biosafety facilities (including satellite facilities) or designate this function to the appropriate Biosafety official;
   c. Report annually to the President and Institutional Official (Provost) on the adequacy of the Biosafety program, facilities, review activities, personnel training, and compliance with IBC recommendation. The ORIO will prepare this annual report;
   d. 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);
   e. Develop criteria for identifying dual-use research and research results;
   f. Develop guidelines for the oversight of dual-use research, including guidelines for the risk/benefit analysis of dual-use biological research and research results;
   g. Provide recommendations on the development of a code of conduct for scientists and laboratory workers; and
   h. Provide recommendations for education and training in biosecurity issues for all scientists and laboratory workers at USM.

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 the IBC takes action on the proposal.

2. Scope of power to lower containment levels

The IBC may lower containment levels for certain activities, as specified in the NIH Guidelines,
utilizing the following guidance:

a. 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.

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

c. NIH Guidelines, Section IV-B-2-b-(6). Adopting emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research.

The IBC may not authorize initiation of activities that are not explicitly covered by the NIH Guidelines until NIH, with the advice of the NIH-RAC when required, establishes the containment requirement.

3. Responsibilities of the IBC Chair

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

- Recruiting new members in cooperation with the Associate Director of the ORIO;
- Leading meetings (not to overlap with Associate responsibilities);
- Providing orientation on IBC Policies and Procedures to new members;
- Coordinating with the Associate Director of the ORIO on all IBC subcommittees, working groups and projects.
- Convening meetings; and
- Ensuring IBC members are properly trained.

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.

C. Rules for IBC Program Review

1. Program Review

The ORIO will review all policies and procedures outlined in this manual and facilities where rDNA and Biological Agent activities occur on an as needed 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. The ORIO or University of Maine System Legal Counsel may revise policies and procedures in order to comply with new statutory or regulatory requirements.

D. IBC Member Registration with NIH

The ORIO will register the USM IBC with the NIH Office of Biotechnology Activities. In addition to the registration, the ORIO will file the President and the Provost’s annual report, on behalf of the IBC, with NIH/OBA that includes:

1. A roster of all IBC members clearly indicating their roles and expertise on the IBC.
2. Biographical sketches, resumes, CV’s, etc. of all IBC members (including community members).
3. Member contact information including name, title, business mailing address, telephone
E. Education of IBC Members

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

- CITI Online Biosafety Course
- Other USM Biosafety Training.

On an ongoing basis the Office of Research Integrity and Outreach staff will provide ongoing educational sessions on various Biosafety topics germane to the responsibilities of the IBC.

F. Meetings and Meeting Summaries

The IBC meets a minimum of once every 6 months (typically in the spring and fall semesters) or as needed to review proposed rDNA and biological agent activities. 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 discussions.

The ORIO is responsible for the administrative aspects of IBC meetings, including setting the meeting agenda, scheduling the room, announcing and coordinating meetings, preparing paperwork, taking notes, sending out copies of the meeting minutes to IBC members, etc.

1. Agenda

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

2. Meeting Summaries

Meeting summaries will be written up and sent out to all IBC members after the completion of the IBC meeting. These summaries 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:

1. Agent characteristics (pathogenicity, virulence, etc.);
2. Types of planned manipulations;
3. Source(s) of inserted DNA sequences;
4. Nature of inserted DNA sequences;
5. Host(s) and vector(s) to be used;
6. Containment conditions to be utilized;
7. Whether and attempt will be made to obtain expression of a foreign gene and if yes, then the protein that will be produced; and
8. Applicable section of NIH Guidelines.

These summaries are for official documentation purposes only and not for general distribution or public access without formal written requests.

3. External requests for Meeting Summaries

Section IV-B-2-a-(7) of the NIH Guidelines allows people and organization outside of USM to request access/copies of the IBC meeting summaries. These requests must be made in writing to the USM Provost, IBC Chair or the ORIO Associate Director. Upon written
request, the IBC will make available to the public any or all requested meeting minutes and any other public access documents. These other documents can include:

- Rosters submitted to the NIH;
- Biographical sketches;
- Documents that would be public access under the Freedom of Information Act; and
- 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 and/or the ORIO Assistant Provost for Research Integrity (or their designee) will verify the request and assure that the request is legitimate. This process can be accomplished by any reasonable and legal means available. Verification and verification method must be documented. Once verification is completed, the IBC and/or the ORIO Associate Director (or their designee) 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 summary, 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:
- Trade secrets or other confidential commercial information;
- Proprietary information;
- 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);
- Personal information such as home phone #s, addresses, e-mails, etc. of IBC members, staff or other representatives;
- Information that would compromise institutional, local or national security;
- Protected Health Information (PHI) as defined under HIPAA;
- Personally identifiable information (PII) as defined in federal and state laws

The IBC, through the ORIO, may charge a reasonable cost for photocopying of documents. Excessive costs or costs used to deter access is not allowed and will be considered a violation of this policy and subject to disciplinary review.
III. IBC Procedures

A. What Must Be Reviewed By The IBC

The following category/groups of items must be reviewed by the IBC before approval is granted for the commencement of research, teaching or testing activities that include:

- Any Recombinant DNA activity.
- Any transgenic animal1 (cross-over review with IACUC)
- Human or animal blood, bodily fluids, or tissues (use of human blood and body fluid for clinical, diagnostic, and treatment purposes is excluded)
- Known infectious materials
- Select Agents, including exempt amounts (see Select Agent Policies and Procedures)
- Any biological agent in Risk Group 2, 3 or 4
- Experiments with transgenic2 plants

B. Definition of rDNA3

Recombinant DNA molecules: Are defined as either:
- 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
- molecules that result from the replication of those described in (i) above.

Notes:
A. 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.

B. 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.

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:

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

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

**ABSA’s Risk Group Tables**

3. Biosafety Levels (BSL); Defined

**Note:** 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.

a. 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.

b. 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:

- Laboratory personnel have specific training in handling pathogenic agents and are directed by qualified scientists;
- Access to the laboratory is limited when work is being conducted;
- Additional precautions are taken with contaminated sharp items; and
- With the following procedures:
  - Where infectious aerosols or splashes may be created;
  - That are conducted in biological safety cabinets; or
  - 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 Biosafety Committee does not allow the use of vertical or horizontal laminar flow clean benches for Biohazardous agent work.

c. 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, providing:

i. The exhaust air from the laboratory room is discharged to the outdoors,
ii. The ventilation to the laboratory is balanced to provide directional airflow into the room,
iii. Access to the laboratory is restricted when work is in progress, and
iv. The recommended Standard Microbiological Practices, Special Practices, and Safety Equipment for Biosafety Level 3 are rigorously followed.

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.

d. 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.

4. Animal Biosafety Levels (ABSL); Defined

**Note:** 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.

a. **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.

b. **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.

c. **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.

d. **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.

**C. Procedure for Filing an IBC Application**
The Principle Investigator (PI) must contact the ORIO to determine whether approval is required. The PI should submit a signed IBC Application to the ORIO.
1. Instructions for Developing and Submitting Biosafety Proposals

The PI or supervisor will:

- Remain in communication with the IBC throughout the conduct of the project; and
- Conform to NIH Guidelines Section IV-B-7-d (Responsibilities of the Principle Investigator Prior to Initiating Research)

When developing and submitting a Biosafety proposal, a project summary with the following items must be included:

a. Introduction
b. Purpose
c. Location of Activities
d. Initial risk assessment
e. Initial estimate of the required BSL (or ABL) in accordance with NIH guidelines and the contents of this policy;
f. Outline SPECIFIC standard operating procedures for good lab practice and techniques to be followed (e.g., waste procedures, decontamination procedures, personal protective equipment);
g. Who is involved and credentials (if applicable);
h. Training of staff (or plans to train);
i. Specific additional training requirements that may be needed;
j. Any additional requirements that may be needed (i.e. specialized equipment, facilities, etc.)

2. Sources of Information for Biosafety

The following informational links provided below are here to help any researcher better understand issues and general policies surrounding Biosafety. Several of the links refer to actual statutes and guidelines commonly used in research and Biosafety. For more information, please contact the Office of Research Integrity and Outreach

Organizational links
- American Biosafety Association
- Center for Disease Control
- CDC-Office of Health and Safety
- Food and Drug Administration
- US DHHS Office for Civil Rights
- Office of Biotechnology Activities
- National Institutes of Health
- Occupational Safety and Health Administration
- DHHS Office for Civil Rights (HIPAA)

Select statutes and reference links
- “The Common Rule” - 45 CFR 46, Protection of Human Subjects
- NIH Guidelines for Research Involving Recombinant DNA
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) 4th Edition (PDF Download)
- Select Agents Program and Regulations
- OSHA-Occupational Exposure to Hazardous Chemicals in Laboratories
- OSHA-Bloodborne Pathogens
- FDA Compliance References
3. Grant Information and Preparation

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 check out the following sites for more information from specific granting agencies.

People wishing more information about grant preparation should contact the Office of Sponsored Programs. For basic information, researchers may want to review the following sites:

- **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](#).

- **US Dept of Health and Human Services (DHHS)**
  For general information on the DHHS grant process and funding, go to [DHHS Grant Information](#). To find information on DHHS supported grants, go to [DHHS GrantsNet](#).

- **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](#).

D. Review of Proposed Activities

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

1. ORIO Preliminary Analysis and IBC Exemption Determination

Upon receipt of application, the ORIO will assess the proposal for completeness of information and provide a preliminary assessment 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 the appropriate ORIO personnel. This letter will include the basis for the exemption determination. 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, they must submit a revision/amendment form and receive approval prior to initiating the change.

**Note:** 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 comply with regulations outside of the IBC’s control.
If the activities require review, then the application and the ORIO’s preliminary analysis will be forwarded to the full IBC.

The IBC will evaluate the project’s protocol, equipment, work space, and other pertinent information for safety. The investigator will be advised concerning the acceptability of the proposal and any modifications, additions, etc. required. The IBC Chair will issue the investigator an approval notification to begin work when all work hazards are satisfactorily controlled.

2. IBC Review Method

A research protocol will go to the IBC for review once the ORIO has made a non-exempt determination. All protocols that are not exempt will be submitted to the full IBC membership for review. Full IBC review will occur under three conditions:

1. There is an automatic triggering condition (such as meeting NIH Guidelines for reviewable rDNA research);
2. At least one IBC member feels that there are issues or concerns that need discussion/evaluation by the full IBC membership; or
3. The IBC Chair has decided that the protocol will go before the Full Board for review.

3. Criteria for Biosafety Proposal Approval

The IBC will determine that the research proposal conforms to the institution’s NIH Assurance and meets the following Criteria:

a. The hazards and risks associated with the project or activity are appropriately minimized by safe procedures;
b. The risk to personnel, students or visitors is reasonable in relation to the threats and hazards associated with use of the materials;
c. The risk to the community’s health and environment is reasonable;
d. The facilities are adequate to minimize the risks of using the materials;
e. Preventative medical measures are taken to minimize risks associated with breeches in safety procedures. This includes any required occupational health consultations;
f. Proof that research and support personnel have completed the initial Occupational Health Screening Questionnaire;
g. That the lab/PI has established any required security measures that may be required by State or Federal law;
h. That the proposed research conforms to acceptable research methodology(s) and laboratory procedures; and
i. Documentation of PI and staff credentials, certifications and any required licenses.

4. 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 than one year 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. PI's are encouraged to keep the scheduled meeting dates (found on the ORIO website) in mind when submitting for a Continuing Review.

**E. Biosafety Risk Assessment**

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 prevention of laboratory associated accidents or infections.

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 they are in the best position to estimate appropriate Biosafety level for the lab and their immediate work environment. This assessment must be done in collaboration with the ORIO, the IBC and the UEH&S.

1. BMBL (5th) Approach to Risk Assessment for PI’s (modified excerpts from BMBL Section II)

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

Consider the principle 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.

**Step 2:** Identify laboratory procedure hazards

The principle 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.

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

Note: The ORIO/IBC will make the final biosafety level determination

**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 principle investigator 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.
**Step 5:** Review the risk assessment with the USM Biosafety Officer, subject matter expert, and the IBC

2. Biosafety Risk Assessment Factors

A thorough risk assessment includes two parts; a PI/ORIO risk assessment and a UEH&S/ORIO risk assessment. The PI/ORIO risk assessment looks at such items as the research protocol, the agent(s) used, available protective measures, data from other studies and so forth. The UEH&S/ORIO risk assessment looks at such items as safety aspects of the physical lab layout/building, appropriate policies and procedures, and available safety equipment.

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

**Nature and characteristics of Biohazardous agents used:**
- Pathogenicity (severity)
- Virulence
- Route(s) of transmission
- Agent stability
- Infectious or intoxication dose
- Route(s) of exposure
- Concentration(s)
- Origin of materials

**Availability of effective prophylaxis and/or other therapeutic interventions, such as:**
- Universal precautions
- Vaccinations
- Availability of medical surveillance programs
- Other medical services

**Availability of data from animal or other research studies:**

**Personnel factors:**
- Experience and skill levels of all personnel involved
- Receipt of proper training(s)

**Availability, feasibility, and proper use of safety equipment:**
- Gloves & Goggles
- Respirators
- Aprons/gowns
- Personal containment suits

b. The collaborative UEH&S/ORIO risk assessment should consider the following lists of important risk factors:

**Availability of Appropriate polices and procedures, such as:**
- Reporting of accidents
- Proper laboratory operations
- Proper care and handling of animal subjects & human subjects involved in the activities
• Sanitation/decontamination protocols
• Emergency evacuation
• Handling, destruction and transportation of pathogens or hazardous chemicals

Physical layout of lab or research area;
• OSHA compliance levels
• Ventilation
• Proper use and installation of containment equipment
• Proper use of warning signs

Known threats to personnel or the building, such as
• National Terrorist Alert Levels
• Policy reports or issued warnings
• Known or suspected threats (ex. Threats by animal rights groups)
• Known injuries to staff or other personnel

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

All of the above mentioned risk factors will be assessed by the IBC using a reasonable lay standard
that estimates both the likelihood and magnitude of the risk. In all instances USM will follow
established guidelines provided by the CDC, DOD, NIH and or USDA.

F. Additional Review Considerations

1. Cross Board Reviews

In many instances activities will require additional committee review by other committees
(IACUC, IRB, and RSC). Contact the Office of Research Integrity and Outreach for guidance
on these review requirements.

2. Protected Health Information

Any time researchers utilize human blood, tissues, DNA or any other product that comes from a
human, there is a chance that the research will over-lap with the Health Insurance Portability and
Accountability Act of 1996 (HIPAA). When received, these materials may contain protected health
information (PHI) or information that could be used to identify who the materials came from. Please
contact the Office of Research Integrity and Outreach to assess your materials for PHI.

3. Authentication of Cultured Cell Lines

PI’s are strongly encouraged to include a process for authenticating cultured cell lines they are
planning on using in a proposed research project. The PI and their team are free to choose which
method to employee. The chosen method, however, must be currently accepted within the scientific
community and reasonable to the proposed research project.
**Note:** Any PI applying for NIH funding should note that according to a recent NIH Notice⁴:

> "Grant applications that fail to employ such practices would not be considered of the highest quality and such manuscripts would not fare well in the journal review process. We encourage all reviewers to consider these issues carefully in order to protect and promote the validity of the science we support."

**G. Procedures for Handling Concerns or Discrepancies**

If an investigator disagrees with the IBC required revisions or specifications, the investigator may bring his or her concerns to the Chair of the IBC, the ORIO or the University Ombudsman for discussion and due process investigation.

It must be noted, however, that the final decision rests with the IBC and may not be overturned by any other Institutional Official.

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⁴ Notice # NOT-OD-08-017, Release date November 28, 2007. Signed by Norka Ruiz Bravo, Ph.D. NIH Deputy Director for Extramural Research and Michael Gottesman, M.D. NIH Deputy Director for Intramural Research
IV. Transportation and Disposal of Biohazardous Materials

A. General Purpose

This policy is intended to serve as guidelines for the safe transportation and disposal of biohazardous materials at the University of Southern Maine (USM). The purpose of this policy is to minimize the amount of waste disposed of as biohazardous. Although biohazard waste containers are often conveniently placed in all of the laboratories, it is important to remember that these bags are for biohazard and contaminated wastes only, and are not to be used for regular trash. Disposal of non-biohazard waste in a biohazard waste container adds significant costs to waste management.

B. Definitions (For use of Section IV of this policy only)

a. **Biohazardous**: Infectious agents or hazardous biological materials that present a risk or potential risk to the health of humans, animals or to the environment. The risk can be direct through infection or indirect through damage to the environment. Types of biohazardous materials include, but are not limited to:
   i. Human or non-human primate blood, body fluids or tissues
   ii. Animal blood, body fluids, tissues, carcasses, bedding, and other waste that contain organisms or agents not usual to the normal animal environment AND that are pathogenic or hazardous to humans
   iii. Recombinant DNA and/or transgenic materials: 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 molecules that result from the replication of those described above.
   iv. Infectious materials: organisms and viruses infectious to humans, animals or plants (e.g. parasites, viruses, bacteria, fungi, prions, rickettsia)
   v. Toxins: Poisonous substances produced within living cells or organisms
   vi. Select Agents: as defined by the United States Department of Agriculture
   vii. Cell Cultures or Cell Lines of human origin, or that are known to contain an agent that is pathogenic to humans, animals or to the environment or has a causative association to such a pathogen.

b. **Contaminated**: Direct contact with a biohazardous agent.

c. **Incidental Exposure**: A release of human blood, body fluids or tissues that is limited in quantity and exposure potential, and which does not pose a significant safety or health hazard to any persons or the environment. An incidental spill may be safely cleaned up by employees who are familiar with the hazards of the substance. This does not include disposable laboratory equipment such as pipette tips that were purposely used to transfer human blood, body fluids, or tissues.

d. **Uncontaminated**: Any item that has not had direct exposure to a biohazardous material, or that has had only incidental exposure consistent with Section B(c).
C. Transfer and Transportation
   a. Chain of Custody
      i. In any transfer of biohazardous materials inter or intra-university, there shall be appropriate documentation of:
         1. The transferor and transferee of such materials
         2. The date and time of transfer
         3. A detailed description of what is being transferred
         4. Any comments regarding the condition and nature of the material
   b. Equipment
      i. In any transportation of biohazardous materials, the proper vehicle and safety equipment must be used by all parties. The biohazardous material must be effectively contained so as to prevent any leakage.
   c. Safety
      i. Appropriate safety precautions must be taken in any transfer or transport of biohazardous materials. This includes personal protective equipment for anybody handling containers holding biohazardous materials.

D. Disposal
   a. Uncontaminated Materials
      i. Regular Waste: Place in wastebaskets with plastic liners.
         1. These are collected nightly by the Department of Facilities Management (DFM).
      ii. Recyclable Materials: Place in blue recycle containers. This includes universally recyclable glass, paper, cardboard, plastic, and metal materials.
         1. These are collected nightly by DFM
      iii. Ordinary Glass: Place into regular trash or recyclable container if applicable
      iv. Broken Glass: Place into a cardboard box with plastic liners that are clearly marked “BROKEN GLASS”. Once full, seal the box with tape.
         1. These are collected by DFM on an as-needed basis.
      v. Liquid Waste: Pour down the sink, flush with a copious amount of tap water and rinse the container.
      vi. Uncontaminated Animal Carcasses: If the conditions of Section B(a)(ii) are not met, package the carcass in air-tight, opaque plastic bags. They should be frozen if possible, and must be discarded in the normal trash
      vii. **UNCONTAMINATED ITEMS ARE NOT TO BE DISPOSED OF AS BIOHAZARDOUS WASTE**
   b. Disposing of Biohazardous Waste
i. Only waste that has had direct contact with the materials defined as biohazardous in Section B(a)(i) – B(a)(vii) may be disposed of as biohazardous waste

ii. Solid Biohazardous Waste: Must be placed in a biohazard container (with lid) lined with a red autoclave bag. When these containers are full they are to be sealed and removed by the appropriate laboratory or DFM personnel to Basement Room 89 of the Science Building. This waste must be autoclaved and placed in the receptacle for pickup by USM’s outside contractor

iii. Liquid Waste: All liquid biohazardous waste must be collected in local, labeled waste containers. Appropriate bleach must be added into the waste containers; after 10 minutes, the liquid waste must be poured down a laboratory sink and flushed with a copious amount of tap water.

iv. Sharps Waste: All needles, scalpels, razor blades, contaminated glass pipettes, microscope slides, contaminated broken glass, or other sharps must be disposed of in a closeable, puncture resistant, leak proof container (red or clear plastic “sharps” containers). When full, these containers must be closed up and removed by the appropriate personnel to the autoclave in Basement Room 89 of the USM Science Building. This waste must be autoclaved and placed in the receptacle for pickup by USM’s outside contractor

v. Biohazardous waste is collected by an outside contractor at a frequency consistent with USM’s need.
Guidelines for the Disposal of Biohazardous Materials

Did the waste have any direct exposure to a Biohazardous Material?

NO

YES

Was it an incidental exposure to human blood, body fluids or tissues (not including disposable laboratory equipment)?

YES

Decontaminate with bleach for at least ten minutes, and then dispose down drain with copious amounts of tap water

NO

Is the waste a:

Solid

Liquid

Sharp or Broken Glass

Is the waste a:

Solid

Liquid

Broken Glass

Discard into blue recycle container if recyclable, otherwise discard into normal trash

Discard into “Sharps” Container

Discard into “Sharps” Container

Discard into “Sharps” Container

Drain disposal with copious amounts of tap water

Place waste into a RED autoclave bag, autoclave if possible, and then discard into designated biohazard waste container in Room 89
V. Biosecurity

A. Definitions

**Biosecurity:** The protection of microbial agents from loss, theft, diversion or intentional misuse.\(^5\)

Note: Biosafety and biosecurity are not the same thing, though they share many aspects in common. The goal of biosafety is to reduce risk and individual/environmental exposure to biological agents whereas the goal of biosecurity is to reduce risk and deter/prevent theft, loss and misuse of biological agents.

B. Biosecurity Risk Assessment and Management Process\(^6\)

1. Identify and Prioritize Biological Materials
   - Identify the biological materials that exist at USM, including the form of the material, location and quantities, including non-replicating materials (i.e., toxins).
   - Evaluate the potential for misuse of these biologic materials.
   - Evaluate the consequences of misuse of these biologic materials.
   - Prioritize the biologic materials based on the consequences of misuse (i.e., risk of malicious use).

2. Identify and Prioritize the Threat to Biological Materials
   - Identify the types of “Insiders” who may pose a threat to the biologic materials at USM.
   - Identify the types of “Outsiders” (if any) who may pose a threat to the biologic materials at USM.
   - Evaluate the motive, means, and opportunity of these various potential adversaries.

3. Analyze the Risk of Specific Security Scenarios
   - Develop a list of possible biosecurity scenarios/events, that could occur at USM, considering the following:
     - access to the agent within your laboratory;
     - how the event could occur;
     - protective/security measures in place to prevent occurrence;
     - how the existing security measures could be breached (i.e., internal vulnerabilities).
   - Evaluate the probability of each scenario happening and the associated consequences. Considerations should include:
     - the threats that are more probable than others;
     - the “attractiveness” of the agents/assets to an adversary; and
     - valid and credible threats, existing precautions, and the potential need for additional or specialized precautions.

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\(^6\) Based on section VI of the BMBL 5th Edition; Principles of Biosecurity
• Prioritize or rank the scenarios by risk for review by the IBC/ORIO/CES&.

4. Develop an Overall Risk Management Program
   • USM, through the IBC, is committed to oversight, implementation, training and maintenance of the biosecurity program.
   • USM will develop a biosecurity risk statement, documenting which biosecurity scenarios represent an unacceptable risk and must be mitigated versus those risks appropriately handled through existing protection controls.
   • USM will develop a biosecurity plan to describe how the institution will mitigate those unacceptable risks including:
     ▪ a written security plan, standard operating procedures, and incident response plans; and
     ▪ written protocols for employee training on potential hazards, the biosecurity program and incident response plans.
   • USM will ensure necessary resources to achieve the protection measures documented in the biosecurity plan.

5. Reevaluation of the Risk Posture and Security Protections
   • USM, through the IBC, ORIO and CES&H, will regularly reevaluate the biosecurity plan(s) and makes necessary modifications to the biosecurity:
     ▪ risk statement;
     ▪ risk assessment process;
     ▪ program/plan;
     ▪ information systems.
   • USM and PI’s assures the daily implementation, training and annual re-evaluation of the security program.
VI. Research-Related Misconduct and Biosafety Violations

For purposes of this policy, Misconduct or Misconduct in Science is defined as “fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.”

A. Biosafety Misconduct

Biosafety misconduct is defined as a willful disregard of USM’s Policies and Procedures for Biosafety. Anyone found guilty of willful misconduct is subject to disciplinary action by the IBC and the University’s Conduct Officer.

The USM is committed to the highest degree of integrity in all University activities. Therefore, as a means of maintaining confidence, professional integrity and high ethical standards in research at USM, all allegations of misconduct will be thoroughly investigated and taken with utmost seriousness. These policies are designed to ascertain the truth and to protect the rights both of those accused of misconduct and those whose reputations may be at stake.

B. Reporting a Research-Related Misconduct Allegation

Faculty, staff, and students may confidentially disclose what they honestly and in good faith believe to be research misconduct to the College Deans or Chairs, faculty, Administrative Directors, the USM Ombudsperson, or directly to the Associate Director of the ORIO. Deans, Directors and faculty are required to report all allegations of research-related misconduct to the Assistant Provost for Research Integrity to begin a confidential assessment. The procedures for misconduct assessment will follow the USM Policy on Alleged Misconduct in Research and Other Professional Activities. Anyone who wishes to make an anonymous report may complete a Misconduct Allegation Form and submit it to the ORIO via campus mail or US mail.

Individuals who have in good faith reported an allegation of misconduct will not be the object of retaliation. Retaliation against such individual will be construed as an act of misconduct. Any individual that acts in bad faith or knowingly makes a false accusation of Biosafety misconduct will be subject to USM disciplinary actions and/or civil liabilities under state law (such as defamation of character, libel, or other possible torts).

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7 42 CFR Part 50 Subpart A §50.102.
VII. Biosafety Adverse Events

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

- Death;
- Life-threatening event;
- In-patient hospitalization or prolongation of existing hospitalization;
- Persistent or significant disability/incapacity;
- A congenital anomaly/birth defect; or
- 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.

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

All other types of biosafety adverse events, including near accidents and minor injuries, must be reported to the Principle Investigator (PI).

The PI/Supervisor must submit the Serious Biosafety Adverse Event Report Form to the Office of Integrity and Outreach within 7 days of an injury and within 24 hours of a death. The chair of the IBC and the Biosafety Officer 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.

In the event of a death or life-threatening research event, a full IBC, and if applicable additional research committee meetings, 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/Supervisor pending clearance from the IBC and consultation with medical specialists.

Once the ORIO has been notified of a serious biosafety adverse event, the Associate Director of the ORIO will notify the USM Animal Facility Manager, Institutional Biosafety Committee, Institutional Animal Care and Use Committee (where applicable), the Institutional Review Board, NIH/OBA, and other appropriate authorities (if applicable) within 30 days. Reports to NIH/OBA will be sent to (via the ORIO):

The Office of Biotechnology Activities,
National Institutes of Health,
6705 Rockledge Drive,
Suite 750, MSC 7985,
Bethesda, MD 20892-7985 (20817 for non-USPS mail),
301-496-9838, 301-496-9839 (fax);

B. IBC Review of Adverse Biosafety Events

1. Serious Adverse Biosafety Events

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8 Based on NIH Policy 6.1, Serious Event Reporting.
Upon receipt of a Serious Adverse Biosafety Event Report Form (see section I. E. for definition of serious adverse biosafety event), the adverse event report form, the original IBC review forms, the original approval letter, continuing approvals, and any IBC or ORIO monitoring notes will be submitted to the IBC for review. As necessary, an advisor or expert in the field will be consulted if such expertise is not available from among the IBC members or a perceived or actual conflict of interest exists for IBC members with such expertise.

a. Procedures

The BSO and IBC Chair will discuss the protocol in light of the adverse event(s) and re-assess the current Biosafety procedure to determine if they adequately protect 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 approved procedures to prevent additional adverse events. If the IBC finds the risks of the activities are unacceptable, the IBC may vote to suspend or terminate the protocol 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.

b. Communications and Reporting Requirements

The PI will be notified in writing of the Scheduled IBC review of adverse events and any changes or actions taken by the IBC as a result of the adverse event. Unforeseen adverse research events will be reported to all appropriate officials. Adverse events that involve Alleged Misconduct will be reported to the Public Health Service Office of Research Integrity.

c. 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. The 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 required.

2. Near Adverse Biosafety Events

A near adverse biosafety event is any circumstance that:

- Does not meet the criteria of a serious adverse event, but still results in some form of accident, illness or injury; or
- 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.
VIII. Personnel Responsibilities

Biosafety can only be accomplished in a cooperative environment. All faculty, staff, students and contractors have a responsibility to uphold good safety and use practices with respect to handling rDNA and Biological Agents. It is up to every member of a research/lab team to:

- Watch out for possible hazards
- Report suspected or known hazards to the appropriate authority
- Follow all necessary and required lab or research protocols
- Report suspected or known violations of lab or research protocols
- Take appropriate steps to prevent potential hazards
- Make sure all required safety equipment is present and functional before starting work
- Use universal precautions
- Utilize all appropriate safety equipment
- Follow the guidance of the designated lab supervisor

A. Administration of the Biosafety Program and Technical Support of the IBC

The ORIO will provide 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, the 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. The ORIO will keep written IBC records of the following items:

1. Copies of all IBC Application and supporting materials that are reviewed;
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 their resolution;
3. Records of initial reviews and continuing review activities;
4. Copies of lab safety reviews, surveys and security protocols;
5. Copies of all correspondence between the IBC, PI's and the ORIO;
6. A list of IBC members and their qualifications for serving on the board;
7. Written IBC policies and procedures;
8. Statement of significant new findings on the safety of biological activities at USM;
9. Standard Operating Procedures approved by the IBC;
10. Biosafety training materials, dates, and names of all persons who have completed Biosafety training;
11. Annual Reports to the President, Institutional Official and NIH/OBA.

1. Biosafety Safety Officer (BSO)

A. General

The institution will appoint a Biosafety Officer (BSO) if it engages in large-scale research or production activities involving viable organisms containing rDNA molecules, biological agents in RG-3 or 4, or Select Agents. The institution must appoint a BSO if it engages in rDNA research at BSL-3 or 4. The BSO will 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, including:

- Risk-based laboratory inspections;
- Accident investigations;
- Record keeping;
- Assessment of University facilities to determine suitability for use in potentially hazardous biomedical research operations; and
- Advising professional and technical staff regarding Biosafety practices, procedures, and regulatory requirements.

The BSO’s responsibilities also include:

- Developing Policies and Procedures for USM’s Biosafety Program, and developing communications programs related to policy and procedures changes;
- Coordinating the development of IBC resources including content for the IBC web page and Biosafety training modules;
- Coordinating with other 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
- Conducting inquiries and investigations into research related misconduct, protocol violations and adverse events.
- Suspending or shutting down any lab or research project that the BSO deems unsafe, hazardous to the facilities, personnel or the environment or is in violation of approved IBC approved protocol.

B. BSO Specific Federal Functions

The BSO’s specific duties include, but are not be limited to:

- Periodic inspections to ensure that laboratory standards are rigorously followed;
- Report 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 Principle Investigator;
- Develop emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving rDNA research;
- Provide advice on laboratory security;
- Provide technical advice to PI’s and the IBC on research safety procedures;
- Provide updates of monthly Biohazardous activities and Biosafety correspondence with USM’s Director of UEH&S and the Chemical Hygiene Officer;
- Conduct risk-based inspections of BSL1 and 2 laboratories and ABSL 1 and 2 animal facilities (biomedical facilities utilizing moderate level microbial pathogens);
- Conduct routine inspections of BSL3 laboratory(s) and animal facilities (biomedical facilities utilizing high level microbial pathogens, toxins, and Select Agents);
- Perform on-site regulatory/policy compliance review(s) of all facilities for rDNA or biological agent manipulations; inspects, assesses, and reports on suitability for use, and coordinates with lab personnel, investigators, and others as needed to ensure follow up and correction of problems.
2. The Biosafety Administrator’s duties include but are not limited to:

- Conduct analysis of Federal, State, and local regulations pertaining to the handling, disposition, and use of rDNA molecules and biological agents in IBC covered activities;
- Initiate and conduct literature and Internet research to obtain scientific information related to specific microorganisms, rDNA molecules, toxins;
- Develop and maintain databases of information related to rDNA and biological agent material holdings around the University; maintains records of IBC approvals for usage of biohazardous materials;
- Provide guidance and assistance to investigators with respect to institutional and regulatory filings related to Biosafety;
- Maintain confidential information related to USM’s Biosafety programs and Select Agent holdings;
- Provide technical information on Biosafety training, and IBC resource materials;
- Perform periodic facilities inspections to monitor and verify IBC recommendations;
- Provide updates on monthly Biohazardous activities and Biosafety correspondence with the IBC, USM’s Director of UEH&S, the Chemical Hygiene Officer, and the Associate Director of the ORIO.

B. Principle Investigator/Supervisor Responsibilities

The PI or Supervisor (hereo referred to as Supervisor) is responsible for full compliance with the NIH Guidelines in the conduct of rDNA and biological agent activities and USM Biosafety Policies and Procedures. A supervisor engaged in human gene transfer research may delegate to another party, such as a corporate sponsor, the reporting functions set forth in Appendix M, with written notification to the NIH OBA of the delegation and of the name(s), address, telephone, and fax numbers of the contact. The supervisor is responsible for ensuring that the reporting requirements are fulfilled and will be held accountable for any reporting lapses.

1. General Responsibilities

The supervisor will:

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;
2. In cooperation with ORIO staff, determine whether activities are covered by NIH Guidelines Section III-E or USM Biosafety Policies and Procedures and that approved procedures are followed;
3. Report any significant problems or violations of the NIH Guidelines to the ORIO immediately;
4. Report any new information about the safety of biological agents or rDNA under the Supervisor’s responsibility that may have bearing on the NIH Guidelines to the ORIO. The ORIO will communicate this information to the IBC and to NIH/OBA (if applicable);
5. Be adequately trained in standard techniques related to the use of rDNA and biological agents under their supervision;
6. Adhere to IBC approved emergency plans for handling accidental spills and personnel contamination; and
7. Comply with shipping requirements for rDNA and biological agents.

2. Dissemination of Information

The supervisor will:
1. Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken;
2. Instruct and train laboratory staff (or arrange for proper training by a third party) in the:
   - Practices and techniques required to ensure safety, and
   - Procedures for dealing with accidents;
3. Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection); and
4. Conform to NIH Guidelines, Section IV-B-7-e (Responsibilities of the Principle Investigator During the Conduct of the Research)

3. Responsibilities of the Supervisor during the conduct of rDNA or biological agent activities

a. Oversight of rDNA or biological agent activities

   The Supervisor will:
   1. Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed;
   2. Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the BSA, Animal Facility Director (where applicable), IBC, and IRB (if applicable);
   3. Correct work errors and conditions that may result in the release of recombinant DNA materials or biological agents; and
   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);
   5. Comply with reporting requirements for human gene transfer experiments conducted in compliance with the NIH Guidelines; and
   6. Submit all information to NIH OBA via the ORIO.

b. NIH Requirements

   The Supervisor will:
   1. Submit information to NIH/OBA for certification of new host-vector systems;
   2. Petition NIH/OBA, with notice to the IBC, for proposed exemptions to the NIH Guidelines;
   3. Petition NIH/OBA, with concurrence of the IBC, for approval to conduct activities specified in NIH Guidelines;
   4. Petition NIH/OBA for determination of containment for experiments requiring case-by-case review; and
   5. Petition NIH/OBA for determination of containment for experiments not covered by the NIH Guidelines.
   6. Ensure that all aspects of Appendix M have been appropriately addressed prior to submission of a human gene transfer experiment to NIH OBA, and provide a letter on institutional letterhead acknowledging that the documentation being submitted to NIH OBA complies with the requirements set forth in Appendix M. No research participant will be enrolled in a human gene transfer experiment until the RAC review process has been completed; IBC approval (from the clinical trial site) has been obtained; Institutional Review Board (IRB) approval has been obtained; and all applicable regulatory authorization(s) have been obtained.
   7. For a clinical trial site that is added after the RAC review process, no research participant will
be enrolled at the clinical trial site until the following documentation has been submitted to NIH OBA:

- IBC approval (from the clinical trial site);
- IRB approval;
- IRB-approved informed consent document;
- Curriculum vitae of the principle investigator(s) (no more than two pages in biographical sketch format); and
- NIH grant number(s) if applicable.

4. Training

It is the responsibility of the supervisor to recognize when training is needed for his/her employees and to arrange for such training. The supervisor is not responsible for providing training in the sense that he/she must develop and present the training program, but rather, the supervisor must recognize the need for training and arrange for their employees to receive it.
### Appendix 1: Glossary of Acronyms

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