The University of Vermont
Institutional Biosafety Committee
Serving The University of Vermont
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MANUAL FOR RESEARCHERS WHO USE RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES, INFECTIOUS AGENTS, BIOTOXINS, SELECT AGENTS

(Biohazardous Materials)

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Summary of Changes since the last version

5.E. Review of Dual Use Research of Concern (New Section)

Dual use research of concern (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat to public health and safety, agricultural crops and other plants, animals, the environment, material or national security. Please see this section for further information.

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1. DEFINITIONS AND REGULATORY AGENCIES

BioHazardous Materials

For purposes of the IBC Policies, biohazardous materials include, but are not limited to, the materials defined in this section.

Recombinant or Synthetic Nucleic Acid Molecules

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* defines these as (i) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell (i.e. recombinant nucleic acids);
(ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e. synthetic nucleic acids); or
(iii) molecules that result from the replication of those described in (i) or (ii) above.
http://oba.od.nih.gov/rdna/nih_guidelines_new.htm
Synthetic nucleic acid segments that 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 nucleic acid counterpart.

Infectious Biological Agents

Infectious biological agents include biological agents and biologically derived materials that present a risk or potential risk to the health of humans or animals, either directly through infection or indirectly through damage to the environment.
Categories of potentially infectious biological materials include the following:

- Human, animal, and plant pathogens (bacteria, parasites, fungi, viruses, prions).
- All human blood, blood products, tissues, and certain body fluids when used in conjunction with infectious agents or recombinant or synthetic nucleic acid molecules.
- Cultured cells and potentially infectious agents these cells may contain.
- Clinical specimens.
- Infected animal and animal tissues.

Biotoxins

A biotoxin is a poisonous substance that is a specific product of the metabolic activities of a living organism and is usually very unstable, notably toxic when introduced into the tissues, and typically capable of inducing antibody formation. Biological toxins can include metabolites of living organisms, degradation products of dead organisms, and materials rendered toxic by the metabolic activity of microorganisms. Some toxins can also be produced by bacterial or fungal fermentation, by the use of recombinant or synthetic nucleic acid moleculestechnology, or by chemical syntheses of low molecular weight toxins. Biological toxins behave like chemical toxins in that they are non-replicating and therefore are not considered infectious. Since they exert their adverse health effects through intoxication, the toxic effect is analogous to chemical poisoning rather than to a traditional biological infection.

Select Agents and Toxins

Select agents and toxins are those biological agents and toxins that are deemed to pose a threat to public, animal or plant health. The Department of Health and Human Services (HHS), Center for Disease Control and Prevention (CDC), and the United States Departmet of Agriculture (USDA) have identified those select agents and select agent toxins (“listed select agent or toxin”) that are subject to protocol and regulatory oversight. The HHS/CDC lists of select agents and toxins (include those that overlap with the USDA) are identified at 42 CFR 73.3 (HHS list) and 42 CFR 73.4 (Overlap list). The USDA list of select agents and toxins are identified at 9 CFR 121.3. The CDC list of all select agents and toxins (as of 12/04/12) is located at

http://www.selectagents.gov/resources/List_of_Select_Agents_and_Toxins_2012-12-4-English.pdf. This list is updated on an ongoing basis at http://www.selectagents.gov/.

Regulatory Agencies

Office of Biotechnology Activities (OBA)
Monitors scientific progress in human genetics research in order to anticipate future developments, including ethical, legal, and social concerns, in basic and clinical research involving Recombinant DNA, Genetic Technologies, and Xenotransplantation;

Recombinant DNA Advisory Committee (RAC)

The Recombinant DNA Advisory Committee (RAC) was established by the NIH on October 7, 1974 in response to public concerns regarding the safety of manipulating genetic material through the use of recombinant DNA techniques.

The RAC developed a set of guidelines, now known as the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*). While compliance with the *NIH Guidelines* is mandatory for investigators at institutions receiving NIH funds for research involving recombinant DNA, they have become a universal standard for safe scientific practice in this area of research and are followed voluntarily by many companies and other institutions not otherwise subject to their requirements.

In addition to seeking the RAC's advice on needed changes to the *NIH Guidelines*, the NIH asks the RAC to consider other matters pertinent to basic and clinical research involving recombinant DNA. A major responsibility of the RAC at present is to review human gene transfer research on behalf of the NIH. Human gene transfer trials conducted at, or sponsored by, institutions receiving NIH funding for recombinant DNA research are registered with OBA and reviewed by the RAC.

2. COMMITTEE MISSION

The University of Vermont (UVM) is committed to minimizing the risks to faculty, staff, students, the public, the facilities, and the environment while using biohazardous materials during research at UVM. The Institutional Biosafety Committee (IBC) is responsible for ensuring the biohazardous materials as defined above are used in research appropriately. IBC policies for review and use of these biohazardous materials apply to research that is:

- Sponsored by UVM,
- Conducted by UVM personnel, or
- Conducted using UVM's property, facilities, or non-public information.

The IBC Policies are based upon the following regulations and guidelines:

***NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines)**—
This document provides guidelines for constructing and handling recombinant and synthetic nucleic acid molecules and organisms containing recombinant or synthetic nucleic molecules. This document requires that each institution establish an Institutional Biosafety Committee with the authority to approve proposed recombinant and synthetic nucleic acid molecule research using the NIH Guidelines as a minimum standard. The NIH Guidelines publication is available at http://oba.od.nih.gov/rdna/nih_guidelines_oba.html.

***Biosafety in Microbiological and Biomedical Laboratories* (BMBL), published**

by Centers for Disease Control and Prevention (CDC) and NIH - This document contains guidelines for microbiological practices, safety equipment, and facilities that constitute the four established biosafety levels. The BMBL is generally considered the standard for biosafety. The BMBL is available at http://www.cdc.gov/biosafety/publications/bmbl5/index.htm

3. COMMITTEE RESPONSIBILITIES/AUTHORITY

The IBC is responsible for establishing and implementing policies that (1) provide for the safe use of certain biohazardous materials in research, and (2) ensure compliance with appropriate federal requirements, including the NIH Guidelines and the BMBL. The responsibilities of the IBC include, but are not limited to, the following:

- Define the basic policies, procedures and standards as required by NIH to oversee the safe use of these biohazardous materials (also referred to hereafter as "these materials".)
- Review requests for the use of these materials for compliance with NIH Guidelines and the BMBL, and approve those requests which are found to conform with NIH Guidelines and the BMBL. As part of the review process, the IBC will do the following, as applicable:
    - Conduct an independent assessment of the containment levels, as required by the NIH Guidelines for research involving recombinant and synthetic nucleic acid molecules.
    - Conduct an assessment, if applicable, of the facilities, procedures, practices, training, and expertise of personnel involved in the requested use of these materials.
    - Ensure compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the NIH Guidelines.
- Disapprove, terminate, or suspend activities involving these materials which are not in conformity with the Guidelines;
- Notify investigators in writing of its decision to approve or withhold approval of activities involving these materials, or of modifications required to secure IBC approval. All decisions will be part of the IBC records maintained by the Research Protections Office;
- Set containment levels as specified in the NIH Guidelines and BMBL;
- Conduct periodic review of the use of these materials to ensure that the requirements of the Guidelines are being fulfilled;
- Assist the University's Office of Risk Management in maintaining and following emergency plans covering accidental spill and personnel contamination resulting from use of biohazardous materials;
- Report to the Vice President for Research any significant related illness or accident resulting from use of these materials that appears to be a hazard to public health;
- Report to the Vice President for Research and the NIH Office of Biolotechnology Activities (OBA) any significant problems with or violation of the Guidelines;
- The IBC may not authorize initiation of experiments with the materials within its purvue not explicitly covered by the Guidelines until NIH (with the advice of the RAC when required) establishes the containment requirement.

4. COMMITTEE CONTACTS

The administrative office of the IBC is located in 213 Waterman, 85 South Prospect Street, 656-5040.

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All correspondence, including that directed to the Chair or other specific members of the Committee, should be sent to the above address.

Committee Chair**:** Robert J. Kelm, Ph.D.
Robert.Kelm@uvm.edu

Biosafety Officer: Jeff Labossiere
Jeff.Labossiere@uvm.edu

5. TYPES OF COMMITTEE REVIEW

Regardless of type of review, researchers must submit completed protocol forms for review if engaging in research with the materials defined above.

5.A. Full Prior Review of Non-Exempt Research

For projects requiring full IBC review (non-exempt biohazardous materials in a risk category greater than or equal to Biosafety Level 2 (BSL2), the researcher must complete a Protocol Form and submit to the IBC Committee for review. The IBC may take one or more of the following actions:

- Approve the project without modification.
- Approve the project subject to stipulations and/or minor modifications.
- Table the decision pending additional information.
- Disapprove the project.

The researcher may not initiate the project until IBC approval is given.

5.B. Review Simultaneous with Initiation

Those projects determined to have a risk category BSL1 may be initiated prior to approval. The determination that the research fits within the "review simultaneous" category will be made by the Biological Safety Officer and the Chair. The researcher will receive a memo stating that activity may begin. The project will be placed on the next available agenda for full IBC review. The researcher may be asked for further clarifications after the full review and the IBC may take one or more of the following actions:

- Approve the project without modification.
- Approve the project subject to stipulations and/or minor modifications.
- Table the decision pending additional information.
- Disapprove the project.

5.C. Review of Exempt Research

According to federal regulations, IBC review is not required for certain categories of research activities that involve little or no risk to research personnel. However, the University has an obligation to be apprised of all potentially biohazardous materials being used under its auspices in the event any questions or problems arise and in order to assure that, regardless of risk, all University personnel as well as the environment are protected. Therefore, these projects must be registered with the IBC by the submission of protocols.

Exempt status, as defined by the NIH Guidelines, will be determined by the Biological Safety Officer and confirmed by the Chair, or designee. The Chair or designee may request a review by the full IBC if there is question regarding the project's status. Exempt protocols will not be subject to further IBC review.

Note that any revisions to the research affecting the biosafety level may affect the determination of exemption and therefore must be prospectively submitted for review to confirm the status.

5.D. Designated Review (new)

Projects deemed Equivalent to a Previously Approved Project

The IBC may determine that a proposed project is equivalent to a project that has previously been approved. A project will only be considered equivalent if, as determined by the IBC, there are no substantive differences that would change the biosafety and or public health considerations for the proposed project.

The initial determination is made by the Biosafety Officer and Chair. The project will then be sent out for designated review to the full Committee for a period of 5 days. If no additional clarifications or requests for a Full Committee review at a convened meeting are received, an approval will be signed at the discretion of the chair.

5.E. Review of Dual Use Research of Concern (New Section)

Dual use research of concern (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat to public health and safety, agricultural crops and other plants, animals, the environment, material or national security.

On March 29, 2012, the U.S. Government (USG) issued its "Policy for Oversight of Life Sciences Dual Use Research of Concern" (March 29 Policy). The policy formalizes a requirement of regular Federal review of USG-funded or -conducted research with certain high-consequence pathogens and toxins. Funders and recipients of life sciences research have a shared responsibility for oversight of DURC. The oversight applies to all DURC-related projects, regardless of the source of funding.

Scope of Oversight Required Under this Policy

Consistent with the *March 29 USG Policy*, life sciences research that uses one or more of the agents or toxins listed below, and produces, aims to produce, or can be reasonably anticipated to produce one or more of the experimental effects listed below, must be evaluated for DURC potential.

Agents and toxins

Avian influenza virus (highly pathogenic)	Marburg virus
Bacillus anthracis	Reconstructed 1918 Influenza virus

Botulinum neurotoxin	Rinderpest virus
Burkholderia mallei	Toxin-producing strains of Clostridium botulinum
Burkholderia pseudomallei	Variola major virus
Ebola virus	Variola minor virus
Foot-and-mouth disease virus	Yersinia pestis
Francisella tularensis	

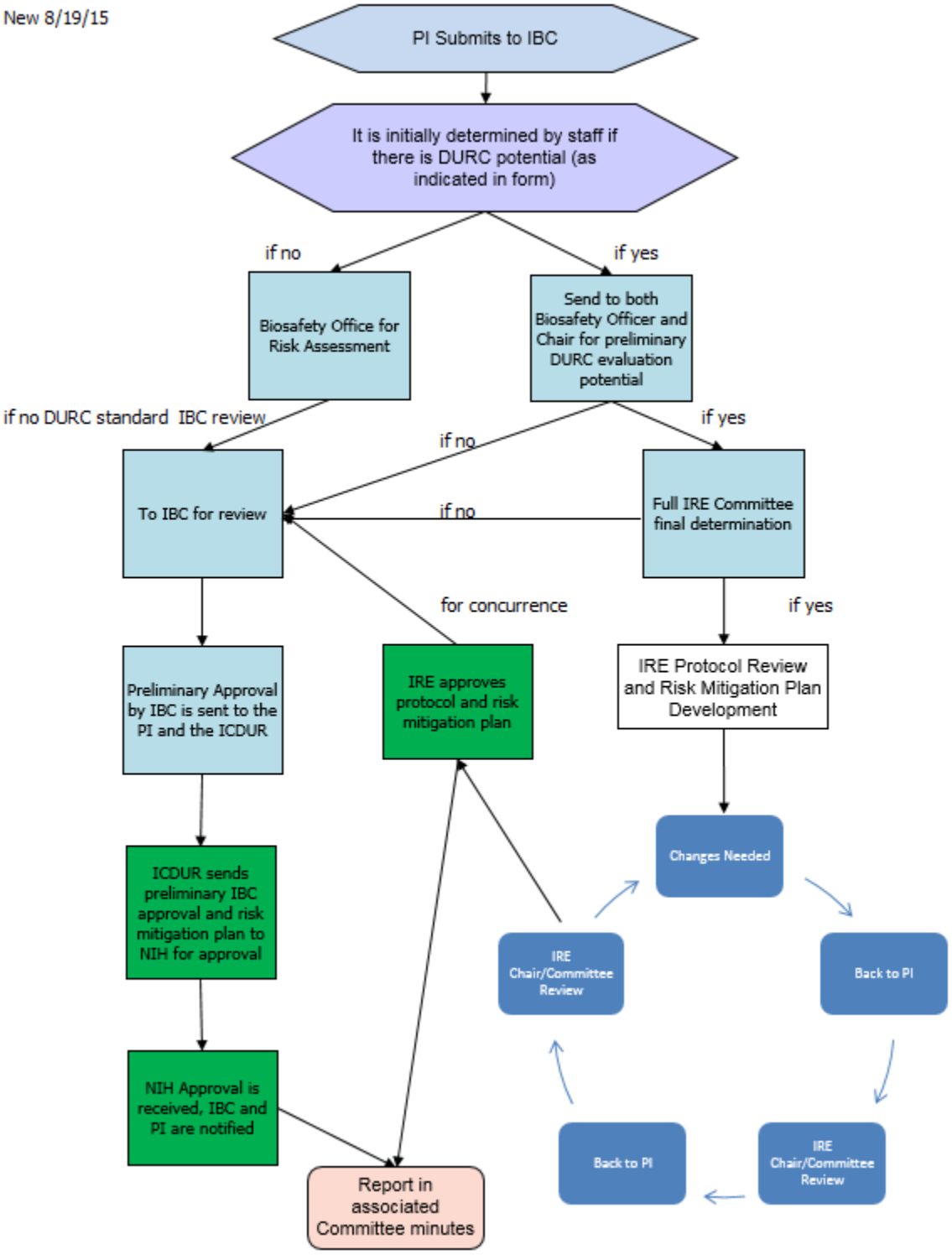
Categories of experimental effects

a) Enhances the harmful consequences of the agent or toxin
b) Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
c) Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
e) Alters the host range or tropism of the agent or toxin
f) Enhances the susceptibility of a host population to the agent or toxin
g) Generates or reconstitutes an eradicated or extinct agent or toxin listed above.

Mechanism for PIs to Submit Potential DURC

The IBC modified its protocol submission form to gather information needed to determine if the project may include DURC. Based on the information submitted in the form, if the potential for DURC exists, the project is referred to the Chair of the IBC and the Biosafety Officer, and other specialists as needed, for an initial evaluation of potential of DURC. If the potential exists, the project is then referred to the Institutional Review Entity (IRE) for further review. If the potential does not exist, the project will undergo IBC review.

The IRE is tasked with initial concurrence of DURC and then works with the PI on development of a risk mitigation plan. The following flow demontrates the review and approval flow of a DURC project.



6. RISK ASSESSMENT AND SUBMISSION OF INITIAL AND SUBSEQUENT PAPERWORK

6.A. Initial Risk Assessment

Research involving these biohazardous materials is classified on the basis of perceived risk to humans and the evironment. The risk classification determines the type of biological and physical containment level. It is the responsibility of the researcher to meet with the Biological

Safety Officer to conduct a risk assessment to determine the appropriate level of perceived risk and biological and physical containment level prior to using these biohazardous material(s). The risk assessment and the Biosafety Officer's signature are required to be on the protocol form prior to submission for review. Therefore, you should plan to complete this visit at least four weeks prior to an IBC Committee meeting date. See meeting schedules on the Committee forms page.

6.A.1. Risk Groups

Risk Groups	
Risk Group 1 (RG1)	Agents that are not associated with disease in healthy adult humans. (BSL-1)
Risk Group 2 (RG2)	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available. (BSL-2)
Risk Group 3 (RG3)	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk). (BSL-3)
Risk Group 4 (RG4)	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk). (BSL-4)

The following factors will be considered when conducting a risk assessment and determining the level of containment:

- **Pathogenicity of the biohazardous material(s)** - Consideration should include disease incidence and severity.
- **Route of transmission (e.g., parenteral, airborne, by ingestion)** - When planning to work with a relatively uncharacterized agent with an uncertain mode of transmission, the potential for aerosol transmission should be strongly considered.
- **Agent stability** - Should include a consideration of factors such as desiccation, exposure to sunlight or ultraviolet light, or exposure to chemical disinfectants.
- **Infectious dose of the agent and communicability** - Consideration should include the range from the healthiest immunized worker to the worker with lesser resistance.
- **Concentration** - Include consideration of the milieu containing the organism (e.g., solid tissue, viscous blood or sputum, liquid medium) and the activity planned.
- **Volume** - >10 liters is considered large scale and is subject to further review and higher containment level.
- **Origin of the biohazardous material(s)** - Consideration should include factors such as geographic location, host, and nature of the source.
- **Availability of data from animal studies** - This information may be useful in the risk assessment process in the absence of human data.
- **Established availability of immunization/vaccine or treatment** - The unavailability of immunization/vaccine or treatment may impact the risk involved in the use of biohazardous material(s).
- **Gene product effects, such as toxicity, physiological activity, and allergenicity**.

6.A.2. Biosafety Level (Biological And Physical Containment Level)

The final risk assessment determination (RG-1 to RG-4) is used to set the appropriate biosafety level (BSL-1 to BSL-4) for the biohazardous material(s). The biosafety level describes the degree of physical containment and biosafety practices required to confine these materials and to reduce the potential for exposure of laboratory workers, persons outside the laboratory, and the environment. Containment and biosafety practice are the same unless otherwise designated. UVM is in the midst of planning construction of a acertified BSL-3 laboratory. UVM

does not have any laboratories certified for BSL-4, therefore no use or possession of biohazardous materials requiring BSL-4 is allowed at UVM.

The IBC will make the final decision as to the level of risk and appropriate biological and physical containment levels for the biohazardous materials subject to its review and approval.

6.B. Initial Submission of Protocol

Once the Officer's risk assessment and signature have been obtained on the protocol, the researcher submits one signed original of the Protocol Form, to the IBC by the deadline which is at least two weeks prior to the next regularly scheduled IBC meeting. Deadline and meeting schedules may be found on the Committee web page. IBC approval must be obtained before using biohazardous materials. Once approved, the Committee will return a signed approval memo back to the researcher via email.

All forms can be found on the Committee website.

6.B.1. Recombinant or Synthetic Nucleic Acid Molecules

The following table summarizes experiments and the required level of review. See the NIH Guidelines (http://oba.od.nih.gov/rdna/nih_guidelines_oba.html) for more information.

Level of Review Required	Type of Experiment
NIH Director, RAC, IBC	A drug resistant gene transferred into a (new) microorganism. (NIH Section III-A)
NIH/OBA, IBC	The cloning of toxin molecules with LD_{50} < 100 ng/kg of body weight. (NIH Section III-B)
RAC, IRB, IBC	Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules transferred into humans.Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules transferred into humans, that meet any one of the following criteria: (1) Contains more than 100 nucleotides; (2) Possesses biological properties that enable integration into the genome (e.g., *cis* elements involved in integration); (3) Have the potential to replicate in a cell; (4) Can be translated or transcribed. (NIH Section III-C-1)
IBC	Recombinant or synthetic nucleic acid molecules transferred to or from whole animals, whole plants, transgenic rodents, experiments involving >10 Liters of culture, at the appropriate Biological Safety Level (BSL). (NIH Section III-D)
IBC	Recombinant or synthetic nucleic acid molecules involving no more than 2/3 eukaryotic virus agents, whole plants, arthropods, or transgenic rodents. (NIH Section III-E)
IBC	Recombinant or synthetic nucleic acid molecules not found in organisms or viruses, single monochromal or viral DNA sources, or host DNA transferred to the same host or related species. (NIH Section III-F)

6.B.2. Infectious Agents

The IBC also reviews work with biohazardous agents including virus and bacteria.

6.B.2.a. CDC/NIH Requirements

Under the CDC/NIH guidelines in the BMBL, the principal investigator must:

- Limit or restrict access to the laboratory when work with infectious agents is in progress. The PI must include a determination of who may be at increased risk and appropriately limit or deny access.
- Establish policies and procedures to limit access to those individuals who have been advised of the potential hazards and meet specific entry requirements (e.g., immunization).
- Ensure that laboratory personnel are offered, at no cost, appropriate immunizations or tests for the infectious agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine, tuberculosis skin testing).
- Select and provide appropriate personal protective equipment required for work with biohazardous materials.
- Ensure that laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, the exposure evaluation procedures, and that personnel receive annual updates or additional training as necessary for procedural or policy changes.
- Develop standard operating procedures incorporating biosafety procedures or a biosafety manual prepared specifically for the laboratory, advise personnel of special hazards, and require them to read and follow instructions on practices and procedures.

6.B.2.b. Local Requirement for Standard Operating Procedures

For projects including infectious agents and certain viral vectors, a set of standard operating procedures is required. Researchers may develop their own using a template the Committee developed. See Appendix B.

6.B.3. Biotoxins

Biological toxins can include metabolites of living organisms, degradation products of dead organisms, and materials rendered toxic by the metabolic activity of microorganisms. Some toxins can also be produced by bacterial or fungal fermentation, by the use of recombinant and synthetic nucleic acid molecule technology, or by chemical syntheses of low molecular weight toxins. Protocols utilizing biotoxins must be reviewed by the IBC prior to use.

For more information and a list of biotoxins refer to http://www.bt.cdc.gov/agent/biotoxins/.

6.B.4. Select Agents and Toxins

Currently there is no use of select agents at the University of Vermont that falls under the federal regulations. For more information and a list of select agents please go to http://www.selectagents.gov/ and http://www.selectagents.gov/resources/List_of_Select_Agents_and_Toxins_2012-12-4-English.pdf. If you intend to use a select agent, please contact the Committee for further information prior to obtaining the agent.

6.B.5. Human Gene Transfer Trials (NIH Appendix M)

Researchers planning a human gene transfer protocol should note that there is a special review process for this type of work. All human gene transfer research protocols must undergo review by the Recombinant DNA Advisory Committee (RAC) of the NIH Office of Biotechnology Activities (NIH/OBA). The RAC determination on the protocol must be obtained PRIOR to the protocol receiving local IBC approval. IBC approval needs to be obtained prior to human subjects review by the University's Institutional Review Board (IRB).

No reseach participant may be enrolled in a human gene transfer protocol until the RAC review process is complete AND IBC and IRB approvals and applicable regulatory authorizations are obtained. Furthermore, investigators may be required to submit specific additional materials to NIH OBA prior to the enrollment of any research participant. The industry sponsor should make researchers aware of their obligations in this regard.

Researchers should inform the Research Protections Office as soon as possible when considering submission of a human gene transfer protocol to RAC. The office will attempt to conduct simultaneous reviews with RAC, however no final determinations will be made until the RAC outcome is known.

The IBC requires the following materials for review of a gene transfer protocol:

1) IBC Protocol Form,
2) Clinical Protocol including tables, figures, and relevant manuscripts,
3) Investigational Drug Brochure,
4) Responses to NIH Guidelines Appendices M-II through M-V,
5) Human Subject Common Protocol Cover Form,
6) Informed consent draft, and
7) Recombinant Advisory Committee (RAC) review (if complete).

6.B.6. Animals and Recombinant or Synthetic Nucleic Acid Molecules (NIH Appendix Q)

Recombinant and synthetic nucleic acid moleculeprotocols which involve animals require review by the IBC and the Institutional Animal Care and Use Committee (IACUC) committees. The office will attempt to conduct simultaneous reviews with the IBC and IACUC committees. To protect animals, the IACUC approval will not be released until IBC approval has been obtained.

The IBC requires the following materials for review of research involving animals:

1) IBC Protocol Form,
2) Standard Operating Procedure (infectious agents and viral mediated work)

6.B.7. Projects Involving Plants (NIH Appendix P)

Projects involving plants require review by the IBC committee. Consultants may be called upon to address these types of protocols.

The IBC requires the following materials for review of this type of research:

1) IBC Protocol Form
2) Standard Operating Procedure (infectious agents and viral mediated work)

6.C. Revisions To Approved Projects

Principal investigators revising a currently approved project must complete an Amendment form, revise appropriate protocol pages, and submit one copy of each to the IBC for approval. Changes involving modification of biological agents, significant procedure changes (including change of the responsible principal investigator), changes to personnel, or changes that increase the risk of the project and/or the biosafety level must be approved by the IBC prior to implementing the changes.

Once approved, the Committee will return a signed approval memo back to the principal investigator.

NOTE: If the amendment involves vertebrate animals or human subjects, additional review by other committees may be required prior to implementation.

6.D. Continuing Review of Approved Projects

Annually, the Committee will forward to the principal investigator a Continuing Review Form which must be completed and returned to the Committee for review and continued approval.

Once approved, the Committee will return a signed approval memo to the principal investigator.

Note: The IBC may require an Investigator to complete a new IBC Protocol form when protocols continue for extended periods of time or if the version of the form template has changed significantly (e.g., substantive changes to the questions or complete reorganization of information).

6.E. Reporting

6.E.1. Laboratory Accidents and Exposures

All biological exposures (i.e., life-threatening events), illness, or significant accident leading to, or potentially leading to illness or that is environmentally dangerous to humans and/or animals must be reported to the IBC as soon as possible utilizing the Incident form.

The Chair and Biosafety Officer reviews all reports of biological exposures. All incidents will be reported to the IBC at a regularly convened meeting at which time the IBC may require additional safeguards or changes in procedures.

If a biological exposure results in death or is life-threatening, a full IBC, and if applicable, additional research committee meetings, will be convened to discuss the incident, and all biosafety procedures associated with the event. In some instances the Chair of the IBC may suspend all relevant biohazardous materials use by the PI pending clearance from the IBC and consultation with medical specialists.

The IBC will provide information about the reported event to the Office of Animal Care Management and the Institutional Animal Care and Use Committee (when applicable), and the Institutional Review Board (when applicable).

6.E.2. Additional Reporting for Protocols that Involve Recombinant and Certain Types of Synthetic Nucleic Acid Molecules

The NIH Guidelines specifically require the reporting of significant problems, violations of the NIH Guidelines, or any significant research-related accident or illness by the Institution, the Institutional Biosafety Committee, or the Principal Investigator.

The Institutional Official will report in writing incidents that involve recombinant and synthetic nucleic acid molecules to:

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

Following recommendations from the IBC the Insitutional Official will inform external agencies such as the CDC, local public health department, State agencies, and funding sources about the incident and corrective actions.

6.F. Notice of Termination

Principal investigators must notify the IBC when a project is completed or no longer active.

7. REQUIREMENTS OF THE PRINCIPAL INVESTIGATOR

The principal investigator is responsible for the following:

- Ensuring proper training and oversight of the research team;
- Ensuring protocol adherence, and;
- Providing reports on the progress of the study.

7.A. Proper Training and Oversight of the Research Team

The principal investigator is responsible for ensuring that the research team has appropriate training prior to and during the conduct of the study by:

- Making available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken (e.g., hazards and risks, immunizations, personal protective equipment required, decontamination, storage and disposal, spill procedures). Instructing staff in aseptic techniques and in the biology of the organisms used in the experiments so that the potential biohazards can be understood and appreciated.
- Faculty members, principal investigators and others responsible for directly, or indirectly, supervising labs will support and encourage a culture of safety and the use of best practices in laboratory protocols and procedures. This includes communicating safety and health as a core value, understanding the risks and requirements associated with the laboratories they oversee, assuring that appropriate precautions are taken against hazards and unsafe practices, that proper personal protective equipment is made available to all personnel, that workplace equipment and machinery is routinely maintained, that required medical surveillance of impacted employees is conducted, that regular safety inspections are performed and documented, and that students and employees receive job and hazard-specific safety training. (NOTE: This excerpt is taken from the UVM Laboratory Health and Safety Policy)
- If BSL2 or greater, the PI needs to ensure that key personnel have completed the IBC required “Biosafety in the Laboratory for BSL2 labs” in-class training **(NOTE: The IBC Committee will not approve key personnel until this requirement has been met.)**
- Instructing and training laboratory staff in the practices and techniques required to ensure safety and the procedures for dealing with accidents.
- Informing laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested.
- Supervising the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
- Investigating and reporting any significant problems pertaining to the operating and implementation of containment practices and procedures in writing to the IBC, NIH/OBA (as required), and/or other appropriate regulatory authorities.
- Correcting work errors and conditions that may result in the release of these materials.
- Ensuring the integrity of the biological and physical containment (biosafety level).

7.B. Protocol Adherence

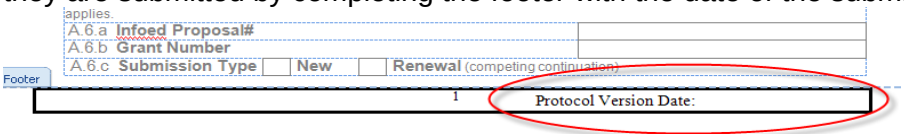
It is the principal investigator’s responsibility to ensure that the IBC-approved protocol is

being followed at all times by the research team. This includes making sure that amendments are submitted for IBC review in a timely fashion and then once approved implemented by the research team.

8. COMMUNICATION WITH THE IBC

The IBC requires investigators to submit all protocols and protocol-related submissions (e.g. amendments, key personnel changes) via an email attachment, preferably in portable document format (PDF). Investigators in turn can expect to receive their IBC correspondence via email. This change is a giant step forward and should result in less paperwork for the investigators and the IBC staff.

We continue to require protocol submissions to be signed by the Biosafety Officer and the PI. We have identified a potential pitfall with this new process to be confusion with document versions. We must all be vigilant about making sure we are always working with the currently approved version of the protocol and protocol roster. Please update your documents every time they are submitted by completing the footer with the date of the submission as shown below.



This date footer is not automatic, therefore you must change it each time you revise your protocol. You should not use the automatic date feature as this will add further confusion by changing your date every time you happen to open the document. Failure to update this protocol version date may delay review of the submission.

All submissions need to be sent to the IBC@uvm.edu email box where new submissions will be monitored and processed in the order they are received.

When you are in communication with the office, whether in writing, by telephone, fax or e-mail, you should have the following information available.

- IBC number, if assigned at the time of contact
- Principal investigator's name
- Protocol title
- Date and type of submission (if applicable)

We can more readily assist you with this information.

8.A. Written Communication of IBC Decisions

Decisions made by the IBC will be communicated to the principal investigator (or designee if provided) through a memorandum outlining the approval status and/or concerns, questions and/or comments of the IBC.

The IBC Chair will convey one of the following four decisions in writing to the principal investigator promptly after the meeting:

Approval, Review Simultaneous or Exemption Determination

The principal investigator may begin the research study upon receipt of the Approval Memo, Review Simultaneous Memo, or the Exemption Determination Memo from the Chair.

Approval Withheld Pending Stipulations/Clarifications

This designation means the protocol is recommended for approval by the IBC pending the principal investigator's satisfactory response to IBC questions and making revisions to conform to IBC-directed stipulations. The principal investigator must provide a memorandum responding to the IBC's questions and stipulations. The memo should reference the IBC number and the applicable revised protocol pages should be attached.

Tabled

This designation indicates that more substantive issues regarding the protocol must be addressed. Clarifications or necessary revisions are significant in nature. A memorandum outlining the issues is sent to the investigator. Full committee review of the investigator's response and revised protocol is required prior to approval.

Disapproved

This designation indicates that the risks of the biohazardous material are of such significance that the committee cannot approve the project. The authority of the IBC to disapprove a study may not be overridden.

NOTE: The IBC has a 30, 60, 90 day reminder system for all pending protocol items. The investigator will be reminded of an outstanding IBC request for information or modifications. If no response is received, at the 120 day mark the protocol is withdrawn from the Committee's consideration. This ensures that changes to protocols are handled in a timely fashion.

9. COMPLIANCE OVERSIGHT AND CORRECTIVE ACTION

The IBC has authority to address non-compliance with the University policies and procedures or the NIH Guidelines, the BMBL, or other legal requirements.

Appendix A - How to Determine Risk Group and Biosafety Level Containment

The following tools can help researchers make an initial determination of the appropriate risk group and containment level and practices. The Biosafety Officer, after collecting the details necessary at a lab site visit, will bring his recommendation to the full Committee who will make the final risk group and containment level determination.

Follows is a link to the NIH/CDC BMBL 5th edition table to help get you started
http://www.cdc.gov/biosafety/publications/bmbl5/index.htmhttp://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf

The American Biological Society Association maintains an excellent reference for risk groups at
http://www.absa.org/riskgroups/index.html

Appendix B – Template SOPs

The IBC Committee has developed a standard template standard operating procedures (SOPs) for your use. The template can be downloaded from the IBC forms page.

Attachment C – IBC Forms

All forms and form instructions are located in the forms section of our website and should be downloaded each time you need one. (SEE: http://www.uvm.edu/ibc and click on “Forms”)

Attachment D – Exposure Control Plan for Bloodborne Pathogens

UVM’s Risk Management and Safety Office has an appropriate bloodborne pathogen control plan which is located at http://esf.uvm.edu/uvmecp/.