Institutional Biosafety Committee Policies and Procedures

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Applies To: Faculty, Staff, Students, and Others
For More Information contact: RICS, IBC at 860-486-1838

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Acronyms

APHIS  Animal and Plant Health Inspection Service
AVPR  Associate Vice President for Research Integrity and Regulatory Affairs
BMBL  Biosafety in Microbiological and Biomedical Laboratories
BSL  Biosafety Level
BSO  Biological Safety Officer
CDC  Centers for Disease Control and Prevention
CFR  Code of Federal Regulations
EHS  Environmental Health & Safety
EPA  Environmental Protection Agency
ESTA  Employee Safety Training Assessment
FDA  Food and Drug Administration
IACUC  Institutional Animal Care and Use Committee
IBC  Institutional Biosafety Committee
IRB  Institutional Review Board
LSBM  Laboratory-Specific Biosafety Manual
NIH  National Institutes of Health
OSP  Office of Science Policy
OVPR  Office of the Vice President for Research
PAM  Post Approval Monitoring
PI  Principal Investigator
PPE  Personal Protective Equipment
RAC  Recombinant DNA Advisory Committee
RICS  Research Integrity & Compliance Services
rsNA  Recombinant or Synthetic Nucleic Acids
RG  Risk Group
SCRO  Stem Cell Research Oversight Committee
SOP  Standard Operating Procedures
SPS  Sponsored Programs Services
UConn  University of Connecticut
VPR  Vice President for Research
Definitions

**Biological Material:** Biological materials requiring IBC oversight will include but not be limited to: recombinant or synthetic nucleic acid molecules (rsNA), bacteria and their phages and plasmids, viruses, fungi, biological toxins, mycoplasmas, prions, and parasites; human and non-human primate tissues, body fluids, blood, blood byproducts, and cell lines, transgenic and wild type animals and plants, animal remains and insects that may harbor zoonotic pathogens.

**Biohazardous Biological Agents:** As outlined in title 18 United States Code (U.S.C) §178, any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance, capable of causing: death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; or deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

**Biological Select Agent or Toxin:** Specifically regulated pathogens and toxins as defined in Titles 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121, Possession, Use, and Transfer of Biological Agents and Toxins regulated by both DHHS and USDA (i.e., overlapping agents or toxins) and plant pathogens regulated by USDA alone.

**Exposure:** Any eye, nose, other mucous membrane, skin, or parenteral contact with any biohazardous material.

**Gene Transfer:** As defined by (NIH), the deliberate transfer into human research participants of either:
1. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or
2. Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:
   a. Contain more than 100 nucleotides; or
   b. Possess biological properties that enable integration into the genome (e.g., cis elements involved in integration); or
   c. Have the potential to replicate in a cell; or
   d. Can be translated or transcribed.

**Laboratory Personnel:** Refers to anyone, including students of any kind, conducting research on, or otherwise handling biological material.
Recombinant and synthetic nucleic acid molecules: As defined by the NIH Guidelines,
1. molecules that a) are constructed by joining nucleic acid molecules and b) that can
   replicate in a living cell, i.e., recombinant nucleic acids;
2. 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
3. molecules that result from the replication of those described in (1) or (2) above.

Toxin: As outlined in Title 18 United States Code (U.S.C) §178, toxic material or product
of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi,
rickettsiae or protozoa), or infectious substances, or a recombinant or synthesized
molecule, whatever their origin and method of production, and includes: any poisonous
substance or biological product that may be engineered as a result of biotechnology
produced by a living organism; or any poisonous isomer or biological product, homolog,
or derivative of such a substance.
A. Mission Statement

The Institutional Biosafety Committee (IBC) of the University of Connecticut (UConn) is committed to promoting the advancement of research and teaching activities, by ensuring that all experiments involving biological materials are conducted in full compliance with local, state, and federal regulations and guidelines. As required by the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), all institutions that conduct research with recombinant/synthetic nucleic acids (rsNA) and receive NIH funding, must maintain an active IBC. With the cooperative effort of Principal Investigators (PIs), the IBC conducts risk assessments for hazards associated with the use of biological materials, and promotes the safe use of such materials by enhancing lab personnel’s understanding of biosafety practices and procedures, as defined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) issued by the Centers for Disease Control and Prevention (CDC).

B. Introduction

This document sets forth the standard operating policies and procedures for the IBC reporting to the Vice President for Research (VPR) at UConn. These policies and procedures apply to the Storrs campus, five regional campuses (Avery Point, Hartford, Stamford, Waterbury), and non-University entities utilizing the University’s laboratory space under the Technology Incubator Program (TIP). Compliance with the provisions of this policy will provide a safe working environment for personnel, as well as ensure the safety of the surrounding community and the protection of the environment. This document also describes the relationships of the IBC with other internal and external agencies. All members of the IBC and research personnel are expected to be familiar with these policies.

1. Program Elements
   a. Institutional Biosafety Committee
   As a recipient of NIH funding, UConn is mandated to establish an IBC, as outlined in the NIH Guidelines. The charge of the IBC is to ensure the safe handling, storage, and disposal of biological materials used in University research or teaching activities, through the review of protocols, which shall be referred to as registrations. The IBC also assists the University and its employees in their compliance with federal, state, and local regulations on the use of biological materials.
Upon notification of a new award or new funding, forms must be submitted for IBC review and approval, prior to the initiation of research associated with the project. The IBC transmits registration review status to the PIs and to Sponsored Program Services (SPS) in order to satisfy the requirements for the release of funding. For certain types of research, awards will not be released until the IBC registration is approved in accordance with NIH guidelines, the BMBL, and institutional policy. Additional information regarding the University’s Biosafety Practices can be found in the Biological Safety Manual.

The IBC has the authority to enforce the NIH Guidelines and ensure that IBC registration approval conditions are adhered to. The IBC has the appropriate authority to fully investigate any potential violations or issues of non-compliance. The IBC may work with RICS to determine appropriate administrative actions as deemed necessary in the event of non-compliance issues.

b. Research Integrity & Compliance Services (RICS)
RICS is the institutional entity that ensures that the policies and procedures detailed in this document are observed. RICS and Environmental Health and Safety (EHS) shall act on behalf of the IBC to monitor and conduct annual reviews of all research and teaching activities involving the use of biological materials. RICS has the authority to inspect research facilities as a part of the Post Approval Monitoring (PAM) program. RICS may obtain records and other relevant information relating to the use of biological materials, and reserve the right to have a third party inspect activities related to the use of biologicals.

RICS and EHS have express authority (1) to monitor research related to biological materials and (2) to enforce biosafety requirements, which may include the suspension of research, or recommending to the VPR penalties and sanctions for non-compliant PIs.

2. Policy Implementation
The authority to create, modify and implement policies is shared by RICS, EHS, and the IBC. Every three years the IBC, and the Biosafety Officer (BSO) will review all biosafety policies. Such review will include an assessment of the accuracy and relevancy of the policies, whether the policies are in-line with other institutional policies, and whether there is a need for new policies. New policies shall be reviewed and approved by the IBC at full committee review, prior to implementation. RICS, the IBC Chair, and BSO shall have the authority to modify existing policies. Together they will review and approve modifications prior to
C. Institutional Biosafety Committee (IBC)

The IBC is charged with reviewing research and teaching activities that involve biological materials conducted by faculty, students or staff that is performed at, or makes use of the UConn facilities.

1. Membership of the IBC

The membership of the IBC is in accordance with the NIH Guidelines, section IV-B-2-a-(1). The IBC shall maintain a minimum of five voting members who have experience and expertise in biohazardous materials and the capability to assess the safety of research projects and/or biological safety issues and to identify any potential risk to public health or the environment.

A minimum of two members shall not be affiliated with the institution (apart from their membership on the IBC). Un-affiliated members will represent the interest of the surrounding community with respect to health and protection of the environment.

At least one member shall serve as an expert in plant, plant pathogen, or plant pest containment principles to assess physical and biological containment for experiments that utilize biological materials or rsNA in plant research.

At least one member shall have sufficient expertise in animal research to assess physical and biological containment in experiments that utilize biological materials in or from animals.

Other members shall be appointed as necessary to ensure the competence necessary to review any activities involving biological materials. Alternate members from certain departments may be sought to ensure that quorum is met. The IBC shall make every effort to include persons with a wide range of expertise in rsNA technology, biological safety, and physical containment; include or have available as consultants persons knowledgeable in institutional commitments and policies, applicable regulations and guidelines, standards of professional conduct and practice, community viewpoints on research, and the environment, and may include members representing the laboratory technical staff.
Ex officio members are selected from the following areas.

- Associate Vice President for Research Integrity and Regulatory Affairs
- Director of Animal Care Services or designee
- Environmental Health & Safety Director
- Biological Safety Officer

*Ex officio* members will be assigned voting rights based on their committee role. The BSO and *Ex officio* members fulfilling one of the expertise roles as required by the NIH Guidelines will be assigned full voting rights.

The membership of the IBC is registered with the NIH, Office of Science Policy (OSP). Changes in IBC membership shall be reported to OSP in a timely manner.

2. Appointment of IBC Members

When necessary, RICS will seek input from IBC members and Department Heads regarding appointment of new members. Potential new members will be identified to fulfill the needs of the IBC. The Chair, in coordination with RICS and the BSO, will identify preferences from those recommended. RICS will contact the candidate and discuss his/her appointment to the IBC. Upon agreement of the candidate to serve on the IBC, an appointment letter will be issued from the OVPR. Appointment periods are up to three years but are determined in accordance with the availability of the new member.

At the conclusion of the three-year term, members may elect to continue for an additional three-year term or to rotate off the committee. The length of service for community members is indeterminate. *Ex officio* members serve as long as they are in their respective positions.

The AVPR appoints the IBC Chair and Vice Chair. Appointment periods are up to three years, but are determined in accordance with the availability of the member. The Chair will be a tenured or tenure-track faculty at UConn, have at least one year of previous IBC experience, and have expertise in rsNA technology, biological safety, and physical containment. Preference will be given to senior/tenured faculty with extensive familiarity with the NIH Guidelines. Other considerations include the length of time served (or the length of past membership) on the IBC, thoroughness of reviews and attendance at meetings.

A member selected by the Chair, in consultation with RICS and the BSO, shall serve as Vice-Chair. The Vice-Chair must be a UConn employee and have at least one year...
of previous IBC experience. The OVPR will issue an official appointment letter to the Chair and Vice-Chair.

3. **Ad-Hoc Consultants**
At its discretion, the IBC may enlist the help of an internal or external reviewer who is not a member of the IBC. Such reviewers will be called upon when, in the opinion of the IBC, someone with a specific expertise is needed to conduct a thorough review of a registration or to address specific questions related to a project in a registration. Ad-hoc consultants will be sought by the Chair and asked to provide the review as a courtesy to the IBC. If appropriate expertise cannot be identified within the University, ad-hoc consultation may be sought from an external source. Conflict of interest for an ad-hoc consultant is defined in the same manner as a conflict of interest for an IBC member. The Chair, Vice Chair, or designee will determine that no conflict exists in the course of communication with the consultant and document that such determination was made.

4. **Responsibilities of IBC Members**
IBC members shall attend regularly scheduled meetings, thoroughly review all materials, participate in the discussions of all registrations, apply their understanding of the regulations pertaining to use of biohazardous materials to the review process, review IBC minutes, and provide input/feedback on new policies that relate to the IBC. Members shall recuse themselves from the deliberation and voting on any registration for which they have a conflict of interest, as detailed below.

The Chair is responsible for running the convened IBC meetings, serving as a resource to investigators, IBC members, and RICS. If the Chair determines that the IBC does not have the appropriate expertise, the review of the registration shall be referred to an outside expert. The Chair or designee has the authority to give final approval to revised registrations that had been previously recommended by the IBC for approval pending minor modifications.

A member not fulfilling his/her obligations may be asked to step down by the Chair or the (A)VPR. Any member of the IBC may express a concern related to the performance of another member to the Chair or (A)VPR. Based upon findings, the Chair and/or (A)VPR may take no action, hold a discussion with the member regarding expectations and performance, or require the member to step down.
5. Voting by IBC Members
All members present at a meeting are expected to vote on registrations presented to the full committee. If a member abstains from voting, that abstention will be counted and the member’s presence will count towards quorum.

A member cannot review or vote on a registration, if: 1) the member is involved with the project as an investigator, co-investigator, or collaborator, 2) the member has a conflict of interest with the project (financial or otherwise), and/or 3) the member arrived late to the meeting after discussion of the project was complete. Members who cannot vote on a specific project for reasons 1 or 2 above, may provide information to and/or answer questions from the committee, but cannot be present for the deliberation or vote for that registration/amendment. Since that member recuses themselves from the deliberation and vote, their attendance cannot count towards quorum for that particular vote.

A majority vote of the members present will be required to carry a motion. The Chair reserves the right to use an alternate method of voting, such as by ballot, if it is deemed necessary. The Chair shall not preside over the review or approve any registration for which they have any conflict as noted above and must designate the task to the Vice Chair or designee.

6. IBC Relationships with Other Institutional Oversight Committees

Institutional Animal Care and Use Committee (IACUC)
The IACUC has the responsibility for reviewing the University of Connecticut's program for the humane care and use of animals in research and teaching activities, as described in its Assurance and University Policy. As part of the review process, the IBC ensures that projects that involve vertebrates are submitted for review and approval by the IACUC.

Institutional Review Committee (IRB)
All human protocols involving gene transfer or gene therapy, as defined by the NIH Guidelines, must be reviewed by the IBC in coordination with the IRB. Final approval for human participant studies is contingent upon the approval by the NIH Recombinant DNA Advisory Committee (RAC).

Stem Cell Research Oversight Committee (SCRO)
The SCRO provides oversight to ensure that human embryonic stem cell (hESC) and human induced pluripotent stem cell (iPSC) research is well-justified and that inappropriate and/or unethical research is not conducted. Its mandate is to provide
oversight of ethical issues related to the derivation and research use of human stem cell lines at all schools, colleges, campuses, and research arms of the University of Connecticut/UConn Health regardless of the source of funding, and to review all proposals from University of Connecticut/UConn Health investigators funded by the State of Connecticut’s Regenerative Medicine Research Fund. Review by the SCRO committee supplements but does not replace the usual reviews for compliance with federal, state, and local regulations (e.g., reviews by IACUC, IRB, IBC, etc.).

Environmental Health & Safety (EHS)
EHS provides expertise in evaluating laboratory and occupational risks in areas of biological, chemical, and radiation safety. The biosafety program is designed to introduce and/or recommend procedures, practices, equipment and/or facility designs that promote, containment of biological materials, contamination control, and/or risk mitigation and to help assure University compliance with local, state, and federal regulations.

Sponsored Program Services (SPS)
The AVPR and RICS works closely with SPS to ensure that sponsored research is reviewed by the IBC as required. The AVPR and RICS is informed of pre and post award reportable instances of non-compliance, unanticipated problems, suspensions or terminations of IBC registrations for sponsored research.

D. IBC Meetings
The IBC shall convene regularly, approximately once every six weeks. RICS will supply the agenda and meeting materials to IBC members electronically via secure website after an administrative preliminary review has been completed.

1. Quorum
A quorum shall consist of the (1) Chair, Vice-Chair or designee and (2) four other voting committee members for a total of five. The final motion regarding a registration/amendment requires a majority vote of IBC members present and voting. If a quorum is lost at any time during the meeting, the meeting shall be adjourned and no further action shall be taken by the IBC until a quorum is attained.

2. Attendance
Members are expected to attend a majority of IBC meetings. Members who attend less than 50% of meetings will be contacted and encouraged to increase their attendance. Anticipated absences from an IBC meeting should be communicated to the RICS as soon as possible before the meeting.
3. Conflict of Interest (COI)
IBC members who have a COI (as described above in section C-5, Voting by IBC Members) with a registration/amendment to be reviewed shall not be present during the deliberation or vote for that registration/amendment. Those with a COI may address questions or provide information requested by the IBC. Since that member recuses themselves from the deliberation and vote, their attendance cannot count towards quorum for that particular vote.

4. Registration and Biosafety Meetings
The Registration meeting is an open session where registrations and amendments are reviewed, discussed and voted on by the IBC. When protection of privacy or proprietary interests is deemed necessary, that portion of the meeting will be closed to the public.

The Biosafety meeting is a closed session in which areas of safety, polices, procedures, and other concerns are reviewed, discussed, and/or decided upon by the IBC.

5. Agendas
The Registration meeting agenda shall include:
- Conflict of interest and confidentiality statement
- Minutes of previous meeting for review and approval
- Report of administrative actions taken by the IBC Chair and IBSO since the previous meeting
- Review of new registrations, renewals, and amendments that require full committee review

The Biosafety meeting agenda shall include:
- Conflict of interest and confidentiality statement
- Minutes of previous meeting for review and approval
- The BSO’s report of administrative actions taken since the previous meeting
- New business and old business to be discussed
- Items from the floor
- Training for IBC Members (as needed)

6. Meeting Minutes
Minutes will be taken at all convened Registration and Biosafety meetings. Minutes will include:
- Members, staff and guests present
- Date and start and stop time
- Minutes of the previous month’s meeting for review and approval
- Brief description of discussion
• Vote to approve, request revisions, reject or abstain
• Interval of IBC approval
• Maintenance of quorum, and a notation of when a member leaves or joins a meeting
• Identity of any IBC member recused from deliberations and voting because of a conflict of interest

Under unusual circumstances, the Chair may call an emergency meeting of the committee. An emergency meeting may be called, for example to prevent lapse of a project when a quorum for the originally scheduled meeting was not met or if an investigator failed to submit a registration in time for IBC approval due to a situation beyond his/her control. However, such a meeting will not be called if the PI failed to submit a registration due to negligence. The meeting materials must be distributed to members as soon as possible to allow sufficient time for review. The investigator may be asked to attend the meeting to address questions, or provide time for information or clarification.

In the event of a Freedom of Information Act (FOIA) request to release any records regarding the IBC, RICS will work with applicable departments (e.g. Public Records, OVPR, etc.), to ensure FOIA requests are addressed in accordance with state and federal law, and institutional policy and procedure. Once compiled, the records will then be reviewed to determine if there are any applicable exemptions under state or federal law that might be cause for non-disclosure or redaction of certain records. Records may be redacted if it is determined that such action is necessary to protect sensitive and/or protected information.

E. Roles and Responsibilities

1. University of Connecticut
   It is the institution’s responsibility to:
   • Establish an Institutional Biosafety Committee that meets the requirements set forth in the NIH Guidelines
   • Establish and implement policies in consultation with the IBC for the safe conduct of biohazardous material research
   • Ensure appropriate training for the IBC Chair and members, BSO and other containment experts (when applicable), PIs, and laboratory personnel
   • Assist and ensure compliance with the NIH Guidelines and other government regulations by PIs and laboratory personnel conducting research at UConn that involves the use of biohazardous materials
• Determine the necessity for health surveillance of personnel involved in connection with individual biohazardous material projects; and if appropriate, conduct a health surveillance program for such projects
• Assist and ensure that all requirements for reporting to NIH/OSP and other federal and state agencies are met, including violations, accidents, and illnesses related to the use of biohazardous materials

2. **Institutional Biosafety Committee**
   It is the IBC’s responsibility to:
   • Review and approve research or teaching activity conducted at or sponsored by UConn that use biohazardous materials through the review of registrations
   • Determine containment levels for experiments as specified within the *NIH Guidelines* and the BMBL
   • Periodically review research involving biohazardous materials conducted at UConn to ensure compliance with the NIH Guidelines and other government regulations (through post-approval monitoring)
   • Notify the PI of the results of the IBC’s review and approval
   • In collaboration with Biosafety and other institutional agencies, develop emergency response plans in the event of incidents that might occur from activities involving the use of biological materials
   • Annually file a report with the NIH/OSP
   • Report any significant problems with or violations of the *NIH Guidelines* and any significant accidents or illnesses stemming from the use of biohazardous materials at UConn to the appropriate institutional official and NIH/OSP within 30 days
   • In cooperation with RICS and SPS, suspend, terminate approval, and/or halt funding in the event research is not being conducted in accordance with the NIH Guidelines or institutional policy and procedure
   • The committee also has the independent authority to take appropriate administrative action (e.g. suspend or terminate research, etc.) when research is deemed non-compliant with local, state, or federal regulations, and/or institutional policy and procedure

3. **Biological Safety Officer (BSO)**
   It is the BSO’s responsibility to:
   • Conduct periodic inspections of laboratories
   • Report to the IBC any problems, violations, and accidents or illnesses from activities that involve the use of biohazardous materials
• Develop emergency response plans for handling incidents that might occur from activities involving the use of biological materials, and investigate all reported incidents
• Provide advice on lab security
• Provide technical advice to PIs, lab personnel, and the IBC on biosafety procedures

4. Principal Investigator
It is the PI’s responsibility to:
• Fully comply with applicable local, state, and federal regulations and guidelines, including, but not limited to the current editions of NIH Guidelines and the CDC/NIH BMBL
• Conduct a risk assessment to make an initial determination of containment level required, and work with BSO to certify the lab for the appropriate level of containment
• Limit access to laboratories and equipment where rsNA materials and biological agents are used and/or stored
• Submit an IBC Registration, and complete applications with IRB, IACUC, and SCRO, as required
• Be adequately trained in standard lab techniques (aseptic technique, decontamination practices, etc.)
• Ensure all personnel have completed all appropriate EHS and compliance committee training prior to initiating work in the lab (i.e. Bloodborne Pathogens Training, Biosafety General Training, etc.) – personnel must complete the EHS Employee Safety Training Assessment (ESTA) to determine which trainings are necessary (https://ehs.uconn.edu/esta/)
• Instruct and train personnel on laboratory specific standard operating procedures which should include safety, security, incident response procedures, and emergency preparedness; all laboratory training of laboratory personnel should be documented
• Supervise personnel to ensure proper safety practices and procedures are followed
• Provide appropriate personal protective equipment (PPE) to personnel
• Inform personnel of precautionary medical practices that are advised or requested (i.e. vaccinations or serum collections)
• If biosafety level 2 (BSL-2) containment is used, PI must have an updated Laboratory-Specific Biosafety Manual (LSBM) readily accessible to personnel and inspectors upon request; PI must also train personnel on the LSBM on an annual basis, and use the Training Verification Form to document completion
• Adhere to UConn’s Biological Safety Manual (http://media.ehs.uconn.edu/Biological/BiologicalSafetyManual.pdf)
• Restrict experimental activities to those which have been approved by the IBC
• Notify the IBC of any proposed changes to approved registrations (e.g. experimental activities, personnel, funding sources, etc.)
• Comply with shipping regulations, permit requirements, and Material Transfer Agreements
• Investigate and report any significant NIH Guideline violations, problems, or incidents to BSO and the IBC, see the Incidents Involving Biological Materials section of this document

5. Laboratory Personnel
It is the laboratory personnel's responsibility to:
• Complete the training required by EHS and other appropriate compliance committees – complete ESTA to determine which EHS trainings are required (https://ehs.uconn.edu/esta/)
• Know and adhere to all laboratory biosafety policies and emergency procedures
• Receive an overview of the LSBM on an annual basis from the PI or Laboratory Supervisor, and follow all established laboratory practices
• Inform the PI of any personal health requirements that may require implementation of additional safety precautions
• Report to the PI or the lab supervisor all problems, deviations in procedure, spills involving biohazardous materials, exposures, and/or safety or security concerns (e.g., suspicious persons or activities)

F. Registration Submission to the IBC
All laboratories performing biological research or teaching activities are required to complete a registration. Full committee review and approval is required prior to initiating research involving risk group 2 (RG2) organisms and rsNA research that is subject to the NIH Guidelines (see #2 – Materials Which May Require Full Committee Approval). Administrative review and approval by the BSO may be appropriate for research materials that are exempt from the NIH Guidelines, and do not involve RG2 organisms (see #4.d.i below). For changes to an existing registration, the IBC Amendment Form should be completed and submitted prior to the initiation of any changes (e.g. addition of experimental activities, update personnel or funding sources, locations, etc.). If the amendment contains revisions that require full committee review and approval, those changes must not be implemented until the PI has received approval.
1. **Eligibility for Registration Submission**

PIs shall submit a completed registration form along with applicable appendices, to the IBC to obtain approval to work with biological materials. In general, a PI is a tenured, tenure track, or research faculty with assigned research or teaching space, including those who manage support labs (e.g. Flow Cytometry). Exceptions to this policy will be considered by the IBC on a case-by-case basis.

2. **Materials Which May Require Committee Approval**
   a. Recombinant or Synthetic Nucleic Acid Molecules
   b. Genetically Modified Organisms (GMO) including:
      - Transgenic and Knock-out/in vertebrates and invertebrates
      - Transgenic field trials, any GMO to be introduced into the environment, including planting of deregulated* items in the field by UConn staff or students and/or on UConn property
   c. Any organism, agent, or toxin requiring federal permits (including but not limited to APHIS, CDC, EPA, FDA)
   d. Human and non-human primate cells, tissues, organs, blood, blood byproducts and potentially infectious fluids
   e. Work with infectious organisms (bacteria and their phages and plasmids, mycoplasmas, fungi, parasites, prions, rickettsias, viruses, and toxins)
   f. Human gene transfer
   g. Exempt quantities of Select Agents and Toxins, as specified by the IBC’s policy on Working with Exempt Quantities of Select Agents and Toxins

The IBC Registration form serves as a tool to gather relevant information about research and teaching activities at UConn that involve the use of biological materials. The form is available upon request by emailing ibc@uconn.edu.

*Deregulated- An approval process by which genetically engineered plants are no longer subject to APHIS regulations under 7 CFR Part 340.

Note: Biosafety level 3 and 4 activities require specially engineered laboratory facilities. UConn currently does not have these facilities. No work will be permitted with biohazard materials requiring BSL-3 or 4 containment at the Storrs or regional campuses. PIs who anticipate working with organisms that require BSL-3 or 4 containment at a collaborator’s facility must follow the policies and procedures outlined in the [IBC Review of Research at Off-Campus Institutions](#) section of this document.
3. Meeting Schedule and Submission Deadline
The meeting schedule and submission deadlines are posted on the [OVPR website](https://ovpr.uconn.edu/services/rics/safety-in-research/ibc/). Adjustments to the meeting schedule may be made due to inclement weather or other unanticipated circumstances. Meetings may be cancelled if it is unlikely that quorum will be met, or if there is not enough business to be conducted. Committee members and PIs will be notified of schedule changes as soon as possible. The submission deadline for full committee review is 28 working days prior to the meeting date.

4. Submission of IBC Registration
PIs are asked to submit new IBC Registration forms via Word Document format, to [ibc@uconn.edu](mailto:ibc@uconn.edu). The PI is responsible for submitting a complete registration and any relevant supporting documentation.

   a. Notification of Receipt of Registration
   A unique registration number is assigned to all new or renewal submissions. The PI will receive an email that the registration has been received. The e-mail will include the newly assigned registration number and the date of the upcoming IBC meeting.

   b. Preliminary Review
   All registrations will be pre-reviewed by RICS, the BSO and when necessary an assigned IBC Primary Reviewer. The PI will be notified by e-mail of any comments or suggested revisions to submit by a specified date prior to the IBC meeting. Registrations missing information needed to conduct a proper risk assessment may be deferred to the next convened meeting or until such details have been included in the registration.

   c. Classification of Experiments
   Investigators should make an initial classification of their experiments based on the NIH Guidelines. RICS and the BSO will verify or modify the classification and determine the level of review required, as described below according to the NIH Guidelines. In the event RICS and the BSO are unable to determine an initial classification for a registration/amendment, a Primary Reviewer may be asked to conduct a preliminary review to assist in determining the level of review required.
d. IBC Review

Once the registration has been preliminarily classified, it is placed into one of the two review categories below:

i. Administrative Approval by the BSO

The IBC has delegated authority to the BSO to approve certain types of activities with notification to the IBC. Minor administrative matters or registrations that do not require full committee review and approval include but are not limited to:

- Research activities that are classified as III-F exempt under the NIH Guidelines
- Activities using biological materials that do not pose a risk to the health and safety of the PI, staff and students or the environment (e.g. RG1 agents)
- Non rsNA registrations/amendments (e.g. human materials, animals, plants, etc.)
- Minor amendments that do not alter the originally assigned biosafety level(s), risk group(s), or NIH classification(s)

ii. Full Committee Review and Approval

With the exception of research activities described above which can be approved administratively, all registrations shall be reviewed by the full IBC at its regularly scheduled meetings. As part of its review, the IBC shall:

- Ensure that proposed activities that use biological materials are in compliance with applicable federal, state, and institutional requirements
- Conduct an assessment of the facilities, procedures, practices, training and expertise of personnel involved in the experimental activities
- Assign appropriate containment levels for all proposed experimental activities, according to the NIH Guidelines and the BMBL
- Ensure that all required approvals in accordance with federal and state regulations have been obtained prior to initiation of research

5. Review of Human Gene Transfer Registrations

Registrations that involve human gene transfer are subject to dual review by the IBC and the IRB, reviewing compliance with biosafety and human subject regulations, respectively. The UConn IBC reserves the right to receive internal or external consultation on areas of needed expertise pertaining to the registration (see Ad-hoc Consultant). All human gene transfer registrations will be reviewed on a case by case basis in accordance with the NIH Guidelines, Section III-C.
6. Level of Review and NIH Classifications

Following discussion of each registration, the proposed activities will be classified according to the *NIH Guidelines*. More than one of the following subsections may apply to a given registration.

*It should be noted that violations of the NIH Guidelines could result in the loss of NIH funding for the institution, regardless of the funding sources for the PI involved in the violation. Since UConn receives NIH funding, all PIs conducting research subject to the Guidelines must comply with the requirements outlined in the NIH Guidelines.*

**NIH Guidelines Classifications and Level of Review at UConn**

- **SECTION III-A (Major Actions):** IBC, RAC, and NIH Director review and approval prior to initiation of experiments
- **SECTION III-B:** IBC approval and NIH review for containment determination before initiation
- **SECTION III-C:** IBC and IRB approvals, and RAC review (if applicable) before research participant enrollment
- **SECTION III-D:** IBC approval before initiation

For III-A to III-D experiments: Registration renewals must be approved before the expiration date of the current registration in order to avoid interruption of research activities

- **SECTION III-E:** Requires IBC notice simultaneous with initiation (i.e. submission of complete registration/amendment)
- **SECTION III-F:** Exempt from NIH Guidelines, requires IBC notice simultaneous with initiation (i.e. submission of complete registration/amendment)
- Experiments with **non-rsNA** RG2 biological agents or toxins (not subject to *NIH Guidelines*) requires IBC approval before initiation; when experimental activities can be administratively approved, research can begin once the PI has been notified of the level of review required

For III-E, III-F, and **non-rsNA** biological agent and toxin experiments, PIs must submit a renewal registration by the expiration date of the current registration.
7. Full Committee Decisions for Registrations
The Committee shall make one of the following determinations in regard to the registration/amendment:

**APPROVED AS WRITTEN:** IBC approval indicates that the Committee has concluded that the proposed procedures meet the regulatory criteria for approval. No modifications to the registration are necessary.

**APPROVED WITH ADMINISTRATIVE EDITS:** The IBC approves the registration pending minor administrative edits by RICS. In some instances, clarification with the PI may be conducted via email, and RICS will update the forms administratively. The approval letter indicates the documented changes. The approval date of record will reflect the date the Committee voted to approve the registration/amendment.

**APPROVED WITH REQUEST MINOR REVISIONS BY THE PI:** A vote for approval with modifications by the PI, indicates the IBC has given the chair or designee the authority to administratively approve the required minor revisions. The approval date of record will reflect the date the Committee voted to approve the registration/amendment.

**DEFERRED/REQUEST MAJOR REVISIONS BY THE PI:** The IBC withholds approval pending submission of major revisions/additional information, or further review by an expert who is not an IBC member. This decision may occur in the event of a registration/amendment not containing enough information to conduct a proper risk assessment or to assign NIH classifications. For some studies, the IBC may appoint one or more members of the IBC to further discuss the registration with the investigator. Once adequate revisions have been made by the PI and submitted to RICS, review of the revised registration will be added to the agenda for the next scheduled IBC meeting.

*It should be noted that if requested revisions are not received within six months of the initial request, the PI must re-submit the registration/amendment for full committee review.*

**REJECTED:** The IBC will vote to reject a registration when the IBC determines that the risk of the procedures is deemed too hazardous or when the proper expertise or containment facilities are not available.
States of registration under which the PI cannot continue his/her activities involving biological materials

CLOSED: This designation is used when a registration is closed or the project completed. An investigator may request closure of a registration when the research project will no longer be pursued, or when data collection is finished, and the essential work of the project is completed. **All activities with biological materials must cease.**

TERMINATED: This designation is used when the registration has been terminated by the IBC. A project may be terminated due to (1) failure to resubmit a renewal by the project expiration date and (2) non-compliance or occurrence of serious or unexpected risks to participants. Termination of previously approved research is defined as a permanent withdrawal of project approval that requires all project-related activity to cease. The OVPR, SPS, Department Head, and the PI will be notified of studies terminated by the IBC. **All activities with biological materials must cease.**

SUSPENDED: This designation is used when a 30 day temporary hold is placed on any or all activities associated with a project, or when a permanent stop is placed on some portion of a previously approved registration. In some cases the suspension period may equal the amount of time from the expiration date (**Lapse in Approval**) to the next convened IBC meeting. **All activities with biological materials must cease.**

8. **Notification of Committee Decision**
IBC actions that occur during meetings are promptly conveyed to the PI in writing, electronically, or by phone from RICS. Approval letters will be signed by the IBC Chair, and the approval documents will be sent by RICS. Minor revision request letters will be sent by RICS. Major revisions request letters will be signed by the IBC Chair, and sent by RICS.

9. **Length of Approval**
Each registration shall be active for a maximum of three (3) years.

When a registration receives final approval, RICS assigns the start of the approval period as the date of the convened IBC meeting. If a registration was determined to require administrative edits or minor revisions to secure approval and the PI submits the requested revisions to the IBC, the registration will expire 3 years from the date of the convened meeting. If a registration that was initially deferred/required major
revisions receives final approval, RICS assigns the start of the approval period as the date of the meeting the registration was approved or required modifications to secure approval.

10. Appeals Against IBC Decision
In the event that an application is rejected, suspended, or terminated by the IBC, the PI may appeal the decision in writing to the IBC. The appeal will be referred to the full committee for consideration. At the discretion of the Chair, the PI may be invited to attend the next regularly scheduled IBC meeting or one convened specifically for the appeal purpose. The PI shall explain to the IBC the reason and justification for the appeal and approval/reinstatement of approval for the project, and may provide and discuss additional information. The PI will be excused prior to deliberations and voting by the IBC. The PI will be informed in writing of the final decision of the IBC. The letter signed by the IBC Chair will be transmitted to the PI, OVPR, and Department Head.

When the IBC has determined that serious or continuing non-compliance or issues are present, the decision of the IBC to terminate or suspend approval of such a project is effective immediately upon such determination. A PI must comply with the decision, but may make an appeal to the IBC to lift the suspension or termination.

The PI may also appeal modifications required by the IBC for approval. The appeal will be made as a written response to the requested modifications, explaining why the modifications requested by the IBC are not appropriate. The Chair may elect to agree with the PI, disagree with the PI and continue to require that modifications be addressed, or refer the matter back to a full committee meeting for review and vote, (e.g. if the Chair and PI cannot come to an agreement.)

11. Undue Influence
The AVPR shall report to the VPR any instance of an individual(s) attempting to influence RICS, any IBC member or the IBC if, in the opinion of the AVPR, the attempt to create the influence is willful and knowing. The AVPR may exercise the authority to conduct an audit or investigation, suspend or terminate activities previously approved for that individual, or to suspend that individual’s involvement in activities for which s/he is a Co-PI or collaborator. The AVPR may also take other appropriate administrative actions based on the findings, including recommending disciplinary action to the VPR. Such instances may be reportable to federal or state agencies for which s/he receives funding as issues of serious non-compliance.
G. Renewals, Amendments, and Lapses in Approval

1. Submission of Renewals
Registration approval must be obtained before expiration of the current registration for III-A to III-D experiments. For III-E, III-F, and non-rsNA biological agent and toxin experiments, PIs must submit a renewal registration by the expiration date of the current registration. Requests for renewals are submitted using the registration form. As a courtesy, RICS will send a reminder notice by e-mail to the PI at least three months before the registration expires, requesting submission of a renewal. A second notice will be generated one month prior to the requested submission date. The PI is responsible for submitting, in a timely manner, a renewal registration for activities that will continue beyond the currently approved term. PIs who fail to submit a renewal registration form in time for IBC review shall receive an expiration notice the day their registration expires, see Lapses in Approval. If a request for renewal is received immediately after the three month request, the registration may be reviewed at the closest convened meeting or held until the next convened meeting prior to the expiration date. The PI may request an earlier review when the renewal includes new experimental activities.

2. Requests for Amendments
Prior to initiating new research activities a PI must amend their approved registration. All amendments must be submitted on the IBC amendment form. Activities that add new NIH classifications III-A through III-D must receive approval by the IBC prior to implementation.

An exception may be made when the changes are necessary to eliminate apparent immediate hazards to human health or the environment. Amendments include but are not limited to additions/deletions in research activities, biological materials utilized (genetic materials, vectors, microorganisms, etc.), and/or laboratory location or room updates. Substantial changes may require modifications to the original registration.

The procedures for approving amendments are the same as those described above for new registrations, with the exception that minor changes may be administratively approved by the BSO or IBC Chair acting on behalf of the IBC.

3. Annual Review Form
Annually, PIs will receive an email regarding their approved registration, requiring them to complete an Annual Review Form. This form helps the PI remain compliant and aids in determining if major changes have been made which would require an amendment. Some PIs will be selected for Post Approval Monitoring (PAM) during
their annual review period and will complete the form during their laboratory biosafety audit instead of via email.

If there is no response from the PI after two notices the IBC may take actions deemed appropriate, such as project suspension, until receipt of the annual review form. The decision to suspend the project may depend on the biosafety level of the laboratory, history of registration lapses, or other non-compliance issues.

4. Lapse in Approval
When a renewal is not obtained by the expiration date, RICS will send the investigator the standard notification letter or e-mail that a lapse in approval has occurred.

a. III-A to III-D Experiment
Activities previously classified as III-D and above shall be suspended until IBC approval is obtained. The PI must secure approval by the first convened meeting following the expiration date. If approval is not secured by the next convened meeting the registration will be administratively terminated and a written notification will be sent to the PI. Any research involving biological materials must be suspended until the IBC receives renewal forms.

b. III-E, III-F and non-rsNA Experiments
Activities previously approved as III-E, III-F or as a non-rsNA experiments at BSL-2 may continue to be conducted when the IBC has been notified by the expiration date. The PI must secure approval by the first committee meeting following the expiration date. If approval is not secured by the expiration date, the registration will be administratively terminated, and research involving biological materials must be suspended until the IBC receives renewal forms.

H. IBC Review of Research Conducted at Off-Campus Institutions
UConn’s institutional policy requires that all research activities involving the use of biological materials be reviewed by the IBC. Some PIs at UConn are engaged in activities involving biological materials outside of the institution. To ensure that all activities involving biological materials conducted at an “off-campus institution” conforms to UConn’s biosafety standards, the UConn IBC adopts the following procedures:

1. Research Involving Biohazardous Materials Risk Group 2 or Below
The UConn IBC will serve as the compliance committee of record for the review of activities involving RG1 or RG2 biohazardous materials conducted at off-campus
institutions. As part of the review process UConn’s IBC requires the off-campus institution to have an EHS Biosafety program in place which conducts regular audits/inspections of the locations to be utilized by the UConn PI.

2. Research Involving Risk Group 3, 4, or Restricted Agents (including the use of Select Agents and Toxins)

The UConn IBC will not serve as the compliance committee of record for the review of activities involving RG3, RG4, non-exempt select agents and toxins or those requiring BSL-3 or above at off-campus institutions. The IBC of the hosting institution must review and approve the research to be conducted by UConn’s PI. It is up to the hosting facility to ensure the PI has all of the appropriate clearances and training for activities involving highly pathogenic organisms and the possession, use, and transfer of select agents and toxins. UConn’s IBC will require an IBC Registration and the appropriate supporting documents from the host institution to verify outside research; upon the completion of the off-campus institution’s IBC review.

I. Record Retention

Research Integrity & Compliance Services will retain records in accordance with Federal and state regulations.

1. IBC Files

IBC files and documentation are considered privileged information. Every effort will be made to maintain confidentiality and non-disclosure of this information. RICS will maintain a file (electronic and hard copy) containing the minutes and the agenda for each convened meeting.

RICS will also maintain files related to registration in chronological order by assigned registration numbers. The electronic files will contain all documentation submitted by the investigator for IBC review (initial review, renewal, amendments), correspondence from the IBC to the investigator, and correspondence from the investigator to the IBC. Files may also contain reports of injuries and other accidents, audit reports, copies of permits, and may contain grant applications.

RICS will maintain complete files of all active registrations on site. Closed files may be archived in a permanent, secure location. Files shall not be destroyed until after applicable state and federal retention requirements have been met. Closed files will be made available for inspection and copying by regulatory agencies.
2. IBC Meeting Documentation
RICS shall maintain hard copy files of meeting documentation on site for at least three years, after which the files may be archived. Files shall not be destroyed until after applicable State and Federal retention requirements have been met. Archived files will be made available for inspection and copying by regulatory agencies.

J. Research Activities Requiring Permits
Many biohazardous materials and research activities require federal or state permits. These permits are required for a wide range of activities, which state many of the stipulations required to maintain approval. Biohazardous activities that require federal or state permits should be registered with the IBC, using the IBC Registration form. A copy of the permits must be appended to the IBC Registration form.

K. Environmental Health and Safety Laboratory Audits
The laboratory in which the research and teaching activities involving biohazardous materials will take place, must be audited by the Biosafety Officer or designee, and approved prior to commencing work. If the audit is satisfactory, the BSO or designee will send a letter specifying the biosafety level and the period of compliance. The IBC will not approve activities in non-compliant laboratories. See UConn Biological Safety Manual for additional information on laboratory audits.

L. Post Approval Monitoring (PAM)
The purpose of conducting post approval monitoring is to ensure that all work is performed in accordance to the current editions of NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules, CDC’s Biosafety in Microbiological and Biomedical Laboratories (BMBL) and UConn policies and procedures. Compliance with other applicable federal, state and local regulations is also required. UConn is actively committed to preserving the health and safety of its students, staff, and faculty. RICS will conduct post-approval monitoring of selected laboratories with active registrations, in addition to ensuring the completion of the annual review form. The principal purpose of a PAM program is to monitor approved IBC registrations and gather information for continuous improvement of IBC processes, promote the safe use of biohazardous materials, increase the investigator’s understanding of federal/state regulations, and verify that the registration accurately describes the current research being conducted, see the IBC’s Post Approval Monitoring Policy, regarding this audit process.
M. Training

Training is required for all PIs and laboratory personnel registering and/or working with biological materials. Completion of training courses is a requirement for the approval of registrations and amendments.

1. Training of IBC Members
All members of the IBC will receive initial and on-going training on the possession and use of biological materials. An initial orientation to the IBC Policies will be given. IBC members shall receive updates at IBC meetings on changes affecting the possession and/or use of biological materials. IBC members will also receive training on the NIH Guidelines initially, and whenever there are significant changes to the Guidelines.

2. Training of Principal Investigators
EHS will provide initial training and subsequent refresher training to faculty and laboratory personnel on all applicable trainings, which will be determined when personnel complete the ESTA. RICS will provide training on the orientation to the NIH Guidelines and a general overview of the IBC Policies and Procedures. All PIs utilizing RNA molecules subject to the Guidelines are required to complete the online NIH Guideline Training for PIs via Husky CT. The PI must review the training slides, and complete the quiz with a 100% to ensure understanding of course material. Retraining will only be required when there are significant changes to the Guidelines applicable to the work conducted at UConn. To access this training, submit a request to ibc@uconn.edu to be added to the course.

3. Training by the Principal Investigator or Laboratory Supervisor
The PI or designee will provide their laboratory personnel with the necessary training of the Laboratory-Specific Biosafety Manual, which includes the risks associated with all biological materials used in the laboratory, security, accident procedures, and emergency preparedness. All PI or Laboratory Supervisor training for laboratory personnel must be documented.

N. Incidents Involving Biological Materials

All PIs conducting research involving biological materials are required to report any problems or accidents promptly to the BSO and IBC. Examples of reportable incidents include but are not limited to overt exposures, such as needle sticks, contact of the mucous membranes, release/loss of transgenic organisms, or other potentially biohazardous materials.
1. Principal Investigator Reporting

It is the responsibility of the PI, to complete an IBC Incident Reporting Form in consultation with the person involved in the incident, and submit the completed form to the IBC office within the time frames per the table below. If assistance is needed with completing the form contact the BSO at 6-3180 or the IBC office at 6-1838. All incidents shall be investigated by biosafety and reviewed at the subsequent IBC or Biosafety meeting. When appropriate, the IBC will suggest the necessary corrective actions. Final reports will be submitted to applicable federal or state agencies as warranted. These incidents must be reported as follows:

<table>
<thead>
<tr>
<th>Type of spill or exposure</th>
<th>Reporting time frame</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure to a RG2 or RG3 agent</td>
<td>Report <em>immediately</em> to the Biosafety Officer. Submit Incident Reporting Form to the IBC <em>within 5 days</em> of exposure.</td>
</tr>
<tr>
<td>Exposure to rsNA molecules</td>
<td></td>
</tr>
<tr>
<td>Spill outside the biosafety cabinet (BSC) with RG2 or RG3 agents</td>
<td>Report <em>immediately</em> to the Biosafety Officer. Incident Reporting Form must be submitted to the IBC <em>within 7 days of incident</em>. If an exposure has occurred, see above. Only immediate notification at BSL-2 and overt exposure.</td>
</tr>
<tr>
<td>Spill outside the BSC with rsNA molecules</td>
<td></td>
</tr>
</tbody>
</table>

Failure by PIs and laboratory personnel to follow federal and state regulations, guidelines, and institutional policies and/or procedures will require reporting to the IBC and if necessary the appropriate government agencies. Incidents will also include conducting new or ongoing research without appropriate federal or state permit, or an approved IBC registration.

Completed Incident Reporting forms may be emailed to: *ibc@uconn.edu*; faxed: 860-486-1106; or sent via campus mail to Unit 4097, Attn: IBC.

2. Laboratory-Specific Biosafety Manual (LSBM)

The Laboratory-Specific Biosafety Manual (LSBM) is a guide used to minimize the risk of injury or illness to laboratory personnel, and to ensure the best practices for research and teaching laboratories are met. For BSL-2 laboratories, CDC and NIH require an LSBM be readily available, and reviewed by lab personnel on an annual basis. The manual should outline the hazards of biological agents and toxins used in the lab, handling procedures, training records, and incident response plans for biological spills, exposures. All BSL-2 laboratories are required to have an LSBM. At a minimum the contents should include the aforementioned topics of interest.
The LSBM must be available to all laboratory personnel. The PI must document initial review and any modifications made, ensuring everyone is aware of the changes. Templates of the LSBM can be requested by emailing ibc@uconn.edu. The LSBM procedure can be found on the IBC website. Examples of laboratory responses to accidents and spills have been provided. Each PI may write and/or revise the standard operating procedures (SOPs) to meet the constraints of parameters that are unique to the research environment; however the IBC reserves the right to require modifications of the SOPs to ensure the safety of staff.
Appendix A: Supplemental Policies and Supportive Documents

1. Amendment Form
2. Annual Review Form
3. Biohazardous Material Incident Management
4. Incident Reporting Form
5. Laboratory-Specific Biosafety Manual Procedure
6. Post Approval Monitoring Policy
7. Exempt Biological Select Agents and Toxins Policy
Appendix B: Useful Resources

1. National Institute of Health Guidelines:

2. Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5TH Edition:
   http://www.cdc.gov/biosafety/publications/bmbl5/

3. Plant Containment Guide:

4. Select Agent and Toxins:
   https://www.selectagents.gov/SelectAgentsandToxinsList.html

5. United States Department of Agriculture/ APHIS Permits and Certifications:
   https://www.aphis.usda.gov/aphis/resources/permits

6. Centers for Disease Control and Prevention (CDC) Import Permit Program
   https://www.cdc.gov/cpr/ipp/index.htm

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