University of Louisiana at Lafayette
Institutional Biosafety Committee
Policy and Procedures

UNIVERSITY OF LOUISIANA Lafayette™

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Acknowledgements

This document is drafted as a guide to all University employees and students engaged in research with "biological agents". The content of this document meets, but does not supercede, criteria set forth by The National Institute of Health (NIH), Office of Biotechnology Activities (OBA), and its agents. The University acknowledges the LSU Occupational and Environmental Safety Department, the LSU IBRDS Committee, NIH, OBA, and the Center for Disease Control (CDC) for their assistance in preparing this document.

1.0 EMERGENCY INFORMATION

Information given in this section primarily refers to biosafety incidents, excluding those involving "select agents and toxins." Additional information on fire-based emergencies, chemical spills, emergency response, and general laboratory safety procedures can be found in the University's Environmental Health and Safety (EH&S) Policy, which can be viewed at www.safety.louisiana.edu.

Incidents involving "select agents and toxins" should be handled according to specifications from the CDC Select Agent Program (http://www.cdc.gov/od/sap/), and the specific laboratory's approved "Select Agent Policy & Emergency Plan."

1.1 Biosafety Incidents

Researchers performing work with biological agents should have an agent- (or risk group-) specific contingency plan for addressing material spills and other emergencies, and personnel should have received training in handling such spills and emergencies. Researchers working with Recombinant DNA (not exempt from NIH Guidelines) must have these spill/emergency SOPs (standard operating procedures) and up-to-date record of employee training approved as part of an individual laboratory's inspection by the university's Biosafety Officer.

When dealing with a spill or sudden release of any biological material, always notify the laboratory supervisor. Consider the following guide to determine incident severity and best response:

Minor - Small spill controlled within the lab. No University Police response is necessary.

Moderate - Laboratory personnel are unable to control the spill or clean up with resources inside the laboratory. Evacuate the laboratory and contact University Police for assistance. Contact the BSO and other regulatory agencies as specified by federal regulations.

Large - Spill or release has spread to many areas of the building and requires a building evacuation. Pull the fire alarm to initiate building evacuation and contact University

Police immediately. Notify others in the vicinity to avoid exposure. Contact the BSO and other regulatory agencies as specified by federal regulations.

Major - Spill or release has spread to other areas of campus outside of the building, affecting or threatening neighbors. Pull the building fire alarm and contact University Police. Contact the BSO and other regulatory agencies as specified by federal regulations.

In all cases, injured persons should be decontaminated before transport. Technical information regarding the agent should be provided to medical and emergency response personnel.

1.2 Emergency Phone Numbers

Each person working with biological agents shall be familiar with a list of emergency numbers specific to that laboratory and the line of authority for the laboratory. Such information shall be posted adjacent to every telephone in the laboratory. For additional requirements, such as door posting requirements, see the NIH Guidelines and the CDC BMBL manual.

FIRE/FIRST AID/POLICE	DIAL 911 University Police From off campus: (337) 482-6447
HOSPITAL/EMS	DIAL 911 University Police From off campus: (337) 482-6447
STUDENT HEALTH SERVICES	482-5464
POISON CONTROL	Call 911 (provide name of material for reference purposes) 1-800-256-9822 (Poison Control Center)
EMERGENCY SERVICES	DIAL 911 University Police (337) 482-6447
CHEMICAL/BIOLOGICAL ACCIDENTS AND SPILLS OR RELEASES	**DIAL 911 University Police** **From off campus: (337) 482-6447**

2.0 General Information

For the purpose of this document, a biological agent is defined as a biological material that can directly or indirectly spread in humans, animals and plants. Such agents include: infectious organisms of bacterial, viral, prional, parasitic or fungal origin that can independently infect and spread in humans, animals or plants. Other biological agents include those that can potentially change the genetic make up of an animal or plant by becoming a permanent part of their genetic make up, and any other biological agent that can indirectly spread by physical means or through

any other biological vector system. All "Select Agents and Toxins" (as defined by CDC/USDA) are included.

Key abbreviations to be used throughout this document are as follows:

BMBL	Biosafety in Microbiological and Biomedical Laboratories (CDC/NIH publication)
BSO	Biological Safety Officer
CDC	Center for Disease Control and Prevention
HHS	(United States Department of) Health and Human Services
IBC	Institutional Biosafety Committee
IRB	Institutional Review Board
NIH	National Institutes of Health (in HHS)
OBA	Office of Biotechnology Activities (in NIH)
RAC	Recombinant DNA Advisory Group (appointed under NIH/HHS procedures)
USDA	United States Department of Agriculture
ORSP	Office of Research and Sponsored Programs (at UL Lafayette)

2.1 Purpose

The purpose of this document is to aid researchers and the UL Lafayette Institutional Biosafety Committee (IBC) in:

- Recognizing and assessing any dangers associated with biological research.
- Assuring Federal CDC and NIH compliance with regard to biological research.
- Providing assistance to UL Lafayette researchers in conducting biological research in a safe manner.

Knowledge and understanding of this document are required for investigators using biological agents in their research. The contents of this manual are derived from directions established by the IBC, existing University policies, and guidelines from the CDC and NIH. Specifically, investigators must comply with the most current version of the following documents (where applicable):

- The UL Lafayette EH&S Policy, which can be viewed at http://www.safety.louisiana.edu.
- The UL Lafayette Office of Research and Sponsored Programs (ORSP) Internal Proposal Approval Form, which can be viewed at http://orsp.louisiana.edu/proposal/IPAF.shtml.
- The CDC manual entitled ***"Biosafety in Microbiological and Biomedical Laboratories, 5th Edition***", which can be viewed at http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm
- The ***NIH Guidelines For Research Involving Recombinant DNA Molecules***, available for download at http://oba.od.nih.gov/rdna/nih_guidelines_oba.html.
- The CDC/USDA Select Agent Program, which can be viewed at http://www.selectagents.gov/

2.2 Scope
The IBC, through this document, provides guidance to University researchers who use biological agents and recombinant DNA within the scope of their work.

2.3 Authority
Administration: UL Lafayette administrators, which include the Vice President for Research, the Vice President for Academic Affairs, and all Deans and Department Heads, shall give the IBC the authority to review all applicable proposals and assess regulatory compliance.

3.0 Policy and Procedures for the IBC

3.1 Appointments
The Vice President for Research shall appoint the IBC including its chairperson. At least five (5) people are appointed including two individuals who are not associated with the University (outside scientific professionals with experience and knowledge in biological materials). The Environmental Health and Safety Director shall serve continually on the committee and will be primarily responsible for reporting and record keeping purposes and will not serve as a technical consultant.

IBC members are appointed for 3-year terms and are required to sign a legally-binding confidentiality agreement before service on the committee may begin. No member of the IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he/she serves as Principal Investigator or has a direct financial interest.

In order to ensure the competence necessary to review and approve recombinant DNA activities, the IBC should include, or have available as consultants, persons with expertise in recombinant DNA technology, biological safety, and physical containment.

3.2 Responsibilities of the IBC
The mission of the IBC is to ensure that research involving biological agents and/or recombinant DNA is conducted within existing Federal and State laws and guidelines that aim to protect the safety of workers, the general public, and the environment. This objective is achieved through careful planning. Specifically, the IBC is required to:

- Review technical and safety-related aspects of the use of all biological agents.
- Develop and maintain policies and procedures for use of biological agents (i.e. this document).
- Ensure compliance with State and Federal reporting requirements for research with biological agents.
- Maintain records of all committee meetings, inspections, protocols, and personnel training.

- Review protocols and facilities upon request and periodically as adopted by the committee.
- Classify and (if necessary) inspect facilities with respect to appropriate biosafety levels.
- Identify members of the IBC to the NIH Office for Biotechnology Activities (OBA) in accordance with NIH guidelines.

3.3 IBC Review Protocol and Procedures

Principal investigators conducting any research involving biological agents and/or recombinant DNA shall submit an application to the IBC for review. Research involving biological agents and/or recombinant DNA cannot be started before IBC approval has been granted.

Initial Application and Review

The IBC is responsible for reviewing and approving, requiring modification to (to secure approval), or withholding approval of those activities related to research involving biological agents and/or recombinant DNA.

The IBC procedures for protocol review are:

1. IBC Applications are submitted to the office of the IBC Chair and assigned a unique IBC number. The Chair, the Biosafety Officer or a designated member of the IBC will be available to assist investigators in the preparation of IBC Applications or revisions.

2. The IBC Chair will make an initial evaluation of the Application and determine whether the Application will require an expedited or full review. In general, all proposed work involving recombinant DNA will undergo full review, as will all work with RG3, RG4 or "Select" agents.

3. An expedited review is an in-depth review conducted by three IBC members (the Chair, the Biosafety Officer, and at least one member who is familiar with the study topic or proposed procedures). The expedited reviewers may elect to approve, request revision(s) prior to approval, or call for a full IBC review meeting for the proposed research. Expedited reviewers are required to complete reviews within 8 business days of receipt of the application. The IBC Chair will notify the PI in writing of the review decision.

4. During the review process, the Chair may request that the IBC Biosafety Officer evaluate the Application in regard to the availability of appropriate facilities and policies and procedures to conduct the proposed research. If needed facilities are available and policies and procedures appropriate, the Biosafety Officer will attest to these by signature.

5. An application will undergo full IBC review if so decided by the Chair in the initial evaluation of the application or if any designated reviewer (during the expedited review) calls for a full IBC review of the Application. A quorum (majority of members) must be present for full review of a research Application. The Biosafety Officer must attend the Application review meeting. The PI will be notified and asked to be available for

questions. In some instances, the PI will be requested to present the protocol to the Committee.

6. In a full IBC Application review, approval of the Application is afforded only when the majority of a convened members vote in favor of approval. The minority view, if any, is recorded in the minutes of the review meeting.

7. No IBC member will be allowed to be involved (except to provide information requested by the IBC) in the review or approval of a project in which he/she serves as Principal Investigator or has a direct financial interest. In the event that the Biosafety Officer has such a conflict of interest, another IBC member will be given the facility, policy and procedure review task. Should the IBC Chair have a conflict of interest, a designated Committee member will assume the duties of the Chair for the purpose of Application review.

8. After final decision on the Application, and (where appropriate) facilities, policies, and procedures, a copy of the application cover page (which includes application and approval numbers) will be signed and dated by the IBC Chair.

9. Notice of the Committee's decision (approval, request revision, or disapproval) will be mailed to the PI. The Chair will notify the Office of Research and Sponsored Programs of the Committee's action. All documents related to the review process will be filed by IBC number.

10. IBC approval of an Application expires on the stated date of completion on the Application or one calendar year from the approval date on the Application document, whichever occurs sooner. If the program is to continue (other than just maintaining or monitoring of research subjects), it is the responsibility of the PI to maintain uninterrupted IBC approval (see "Continuing Research Application and Review" below). Renewal Application forms can be used for renewal on uneven years (e.g. 1 year after the initial approval), while full applications are needed for renewal on uneven years (years 2, 4 etc.).

11. IBC records (all application and review documents and related correspondence, irrespective of whether applications were approved) will be retained within the IBC files for a period of five years.

Proposal Modifications Application and Review

The IBC has the authority to review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes in research using biological agents.

The IBC procedures for reviewing proposed significant changes in ongoing research projects are:

1. For Select Agents and non-exempt recombinant DNA, all changes to the original application must be submitted to the IBC for re-approval.

2. For all other research involving biological agents and/or recombinant DNA, the following modifications require IBC review and approval:
    - A change that increase the required Biosafety or Animal Biosafety Level.
    - A change in species not previously approved.
    - A modification of the biological agent that may expand its host range.
    - A change in the overall objective of the research.
    - A change in federal regulations (i.e. CDC, NIH, BMBL, etc.) that affects the research.

3. It is the responsibility of the PI to inform the IBC and await IBC approval for a significant protocol change prior to initiating the change.

4. The PI will complete the "IBC Project Change / Renewal Form" and submit it to the IBC Chair. The Chair and Biosafety Officer can approve the requested change, or request a new application. If a new application is requested, it will be subject to the same review procedures used for new applications. The Chair will notify the PI accordingly.

Continuing Research Application and Review
The IBC shall conduct continuing review of each previously approved, ongoing activity covered by IBC policy at appropriate intervals as determined by the IBC.

The IBC procedures for conducting continuing review are:

1. The IBC shall conduct annual reviews of previously approved protocols.

2. Continuing review is not needed if the active experimental phase of a research project is completed and research organisms are only maintained and monitored.

3. The PI is to submit a "IBC Project Change/Renewal Form" for renewal on uneven years (e.g. 1 year after the initial approval), while full applications are needed for renewal on even years (years 2, 4 etc.). The PI should provide a full description of planned changes and state any problems or adverse events encountered during the previous study interval.

4. Renewals submitted using the “IBC Project Change/Renewal Form will undergo an initial review by the IRB Chair and Biosafety Officer, who can approve the requested renewal or request a full application. Full applications will be handled as a first-time submission (see above).

Notifying Investigators of the Outcome of Application Review
The IBC shall notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the use of biological agents.

3.4 Administrative Actions

The IBC is authorized to withdraw approval for an ongoing research project. The IBC procedures for withdrawing approval for an ongoing activity are:

1. The IBC has set the following criteria for investigating the possibility of withdrawing approval for an ongoing project involving biohazard agents. These are:

    - Noncompliance with the NIH Guidelines for Research with Recombinant DNA.
    - Noncompliance with the CDC/USDA Select Agent Program.
    - A deviation from the BMBL that was not specified in the IBC Application.
    - Failure to comply with the Institution's IBC Policies and Procedures document.
    - Report of concerns involving the use of biological agents.

2. Should any of these occur, the PI will be given an opportunity to respond to the allegation(s) in writing.

3. If the outcome of items #1 and 2 above support possible withdrawal of approval of the project, the Chair will inform the ORSP and the PI in writing of this possibility, and call a full IBC meeting to review the case. The PI will be invited to attend and reply to concerns of the Committee.

4. The Committee will vote whether or not to withdraw approval for the project. A majority vote of the full Committee will be required for withdrawing approval. The minority view, if any, will be recorded.

5. The vote of the Committee will be reported in writing to the PI and the ORSP. If the vote is to withdraw approval for the project, a report of the Committee investigation and details of the occurrence, with all supporting documents will be sent to the VP for Research, the Department Head, the funding agency and the appropriate government agency with oversight over the specific research.

6. If a report of non-compliance with the criteria in section 3.4.1 is received that requires immediate action, the IBC Chair, with the concurrence of the Biosafety Officer and following notification of the IBC committee and the Vice President for Research, may temporarily suspend any ongoing research until the IBC committee has reviewed and voted on the matter as stated in section 3.4.

3.5 Meetings

The IBC shall meet once monthly unless there are no applications subject to full review. Any IBC member may call for a special meeting if so desired. Minutes will be recorded by the EH&S Director and submitted to the Chair for initial approval. Minutes will then be distributed to the committee for review and adoption at the next IBC meeting.

3.6 Reporting Requirements

The IBC shall file an annual report with NIH/OBA, which includes:

- A roster of all IBC members, indicating the Chair, contact person, BSO, and specific expertise.
- A biosketch of all IBC members
- Incident reports as needed by regulatory agencies.

4.0 Procedures for Researchers

4.1 Requirements for a Principal Investigator (PI).

The PI of a research protocol using biological agents must be an employee of UL Lafayette (fulltime, part-time, or contract employee). A visiting scientist may be eligible to use biological agents; but the PI on an IBC application must be an employee of UL Lafayette. The PI has authority over all other personnel listed on the application, and is responsible for the use of biological agents. The PI is responsible for obtaining IBC approval and approval from specific regulatory agencies as needed for the proposed research.

4.2 Training

All persons involved in the use of biological agents must have received appropriate training. The PI must be familiar with all applicable guidelines included in this document and those listed with appropriate regulatory agencies. The PI is responsible for the training of personnel potentially at risk. The IBC shall be readily available to answer questions about safe and practical handling of biological agents. Training documentation will be kept by the PI and be made available upon request by the IBC.

4.3 IBC Application Form

The PI must submit the appropriate application form for review and approval by the IBC for all research projects using biological agents. The application should be submitted at least 2 weeks prior to the IBC's monthly meeting. A copy of this document is available at http://orsp.louisiana.edu/compliance/IBC.shtml. It is strongly recommended that the PI seek consultation during the planning stage of a project involving biological agents. The UL Lafayette Office of Research and Sponsored Programs shall require any grant proposal involving biological agents to be submitted for review to the IBC.

5.0 Procedures for Experiments using Biological Agents

Knowledge and understanding of this document is required for investigators using biological agents in their research. The contents of this manual are derived from directions established by the IBC, existing University policies, and guidelines from the CDC and NIH. Specifically, investigators must comply with the most current version of the documents listed previously (under section 2.1).

6.0 Security and Emergency Response for Laboratories with Select Agents

6.1 General Information

The CDC and USDA have established laws that regulate the possession, use, disposal, and transfer of some toxins and infectious materials that may be used in the creation of weapons of mass destruction. These materials are referred to as Select Agents. Further information can be found at the website of the National Select Agent Registry (http://www.selectagents.gov/). UL Lafayette investigators must comply with the most current version of the CDC and USDA regulations on select agents (available at http://www.selectagents.gov/Regulations.html)

A current list of the select agent materials can be viewed or downloaded at: http://www.selectagents.gov/Select Agents and Toxins List.html

The principal investigator is responsible for determining if the scope of the research involves select agents and for following the federal regulations mentioned in this section. Additionally, when working with select agents, the application review procedures set forth in section 3.3 must be followed. Researchers may not receive any select agents until the CDC/USDA application has been approved.

6.2 Responsible Official

The Responsible Official (RO) is responsible for administering CDC/USDA Select Agent registration for facilities and investigators who are conducting research that involves select agents. The Environmental Health and Safety (EH&S) Director has been designated as the RO for UL Lafayette. The EH&S Director must be contacted at 482-5357 or safetyman@louisiana.edu when investigators determine that proposed research will involve select agents.

7.0 Packaging and Shipment of Biological Materials

Federal rules require that shippers of biological agents or other dangerous goods have formal training. The shipping of all biological agents must be coordinated through the EH&S office in order to ensure compliance with federal rules. The EH&S Director shall maintain current training to package biological materials.

Glossary of Terms

Application Form: The document used by the UL Lafayette Institutional Biosafety Committee to review research using biological agents. This document can be downloaded at http://orsp.louisiana.edu/compliance/IBC.shtml. See section 4.3 for more information.

Biological Agents: A biological material that can directly or indirectly spread in humans, animals and plants. This includes recombinant DNA and infectious organisms of bacterial, viral, prional, parasitic or fungal origin that can independently infect and spread in humans, animals or plants. Other biological agents include those that can potentially change the genetic make up of an animal or plant by becoming a permanent part of their genetic make up, and any other biological agent that can indirectly spread by physical means or through any other biological vector system. See section 2.0 for more information.

Biosafety officer (BSO): An individual appointed by the University to oversee the management of all biosafety risks and who is a member of the IBC.

Center for Disease Control and Prevention (CDC): The lead federal agency for protecting the health and safety of people - at home and abroad, providing credible information to enhance health decisions, and promoting health through strong partnerships. CDC serves as the national focus for developing and applying disease prevention and control, environmental health, and health promotion and education activities designed to improve the health of the people of the United States. For more information, visit www.cdc.gov or call 1-800-311-3435.

Environmental Health and Safety (EH&S) Director: Refers to the individual at UL Lafayette responsible for State and Federal compliance with regard to occupational safety.

Expedited Application Review: An in-depth review of a research proposal involving biological agents that is conducted by three IBC members (the Chair, the Biosafety Officer, and at least one member who is familiar with the study topic or proposed procedures). An expedited review does not require a full vote of the Institutional Biosafety Committee to be approved. See section 3.3 for more information.

Full Application Review: Any research involving biological agents and/or recombinant DNA in which the Institutional Biosafety Committee Chair convenes a meeting for the purpose of Application review. A quorum (majority of members) must be present for Full Application Review of a research protocol. During the meeting, the application is reviewed and voted for committee approval. See section 3.3 for more information.

Institutional Biosafety Committee: A group of individuals appointed by the University administration to review research involving biological agents and/or recombinant DNA. See section 3.1 for more information.

National Institute of Health (NIH): An agency of the Department of Health and Human Services, the NIH is the Federal focal point for health research. NIH is the steward of medical and behavioral research for the Nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability. For more information, visit http://www.nih.gov or call (301) 496-4000.

Office of Biotechnology Activities (OBA): A division of the National Institute of Health that monitors scientific progress in research involving Recombinant DNA and related biological agents. The OBA provides analytical support to NIH, develops and implements NIH policies and procedures, reviews and evaluates the composition of Institutional Biosafety Committees and develops registries of activities related to Recombinant DNA and other related biological agents. For more information, visit: http://oba.od.nih.gov/oba/index.html.

Office of Research and Sponsored Programs (ORSP): This office reviews and approves all proposals, contracts and other legal agreements relating to outside funding of research and sponsored programs for the university, and helps ensure university compliance with federal, state, and university regulations (see also: http://orsp.louisiana.edu).

Principal Investigator (PI): Also referred to as a Project Director, Study Director, Co-PI , or alternate Study Director. Such an individual is responsible for the overall implementation of a specific research project conducted at the University, and must be an employee of the University. The PI is responsible for applying to the Institutional Biosafety Committee for review of any proposals that involve the use of biological agents. See section 3 for more information.

Recombinant DNA (R-DNA): Either (1) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell or (2) molecules that result from the replication of those described in (1) above. For more information, please consult the *NIH Guidelines For Research Involving Recombinant DNA Molecules*, available for viewing or download at http://oba.od.nih.gov/rdna/nih_guidelines_oba.html

Responsible Official (RO): An individual who is responsible for registering and reporting facilities that conduct research involving select agents. The RO is responsible for ensuring that the University is compliant with the terms set forth in 42 CFR, part 73 and other documents referenced within 42 CFR, part 73. For more information, see section 6.2 and visit http://www.selectagents.gov/.

Select Agents: Any microorganism or infectious substance capable of causing death, disease, or other biological malfunction in a human, animal, plant, or other living organism; deterioration of food, water, equipment, supplies, or other material; or deleterious alteration of the environment. Includes all biological agents or toxins listed in 7 CFR Part 331, 9 CFR Part 121,or 42 CFR Part 73. Researchers must register with the

CDC through the University Responsible Official and get approval to possess or use a select agent. For more information, visit http://www.selectagents.gov/.