

Instructions for the Application for Teaching Activities Involving Biohazardous Agents (NIH Recombinant and Synthetic Nucleic Acid Molecules, Other Biohazardous Agents, and Human Materials)

The “Application for Teaching Activities Involving Biohazardous Agents (NIH Recombinant and Synthetic Nucleic Acid Molecules, Other Biohazardous Agents, and Human Materials)” is to be completed when an instructor is teaching a course utilizing biohazardous agents, as defined in the DePaul University Institutional Biosafety Committee (IBC) policy and procedure manual. To reiterate, the DePaul Policy defines biohazardous materials, agents, or toxins as infectious biological or synthetic agents, biologically derived materials or toxins (including endotoxins such as bacterial Lipopolysaccharide or LPS) that present a risk or potential risk to the health of humans, animals, or plants either directly through exposure or infection or indirectly through damage to the environment. Categories of biohazardous agents include the following:

- Human, animal, and plant pathogens/infectious agents (bacteria, parasites, fungi, prions, plasmids, phages, viruses, viroids, mycoplasmas, rickettsiae, Chlamydia, arboviruses and related zoonotic viruses)
- Biotoxins, such as LPS
- Genetically modified organisms, including animals, plants, invertebrates, and/or other organisms created by DePaul employees or on DePaul property, transgenic field trials or genetically modified organisms to be introduced into the environment, including planting of deregulated items in the field, and field testing of plants engineered to produce pharmaceutical and industrial compounds. **Please note:** the *NIH Guidelines* address contained research only and do not address the field release of genetically modified plants, which requires proper authorization from a responsible federal agency.
- Infected laboratory animals (including insects) or tissues that may harbor such infectious agents
- All human and non-human primate blood, blood products, tissues (unfixed tissue or organ), other than intact skin, from a human, living or dead, and certain body fluids (i.e., semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, anybody fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids) and cultured human or animal cells which may harbor infectious agents and Human Immunodeficiency virus (HIV) -containing cell or tissue cultures, organ cultures, and HIV- or hepatitis B virus (HBV) -containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV

- Recombinant or synthetic nucleic acid molecules.
 - Recombinant or synthetic nucleic acid molecules that are transferred into humans (human gene transfer)
 - Recombinant or synthetic nucleic acid molecules that are transferred into animals (transgenic animals)
- Microorganisms where there is a deliberate transfer of a drug resistant trait or of recombinant or synthetic nucleic acid molecules containing genes for the biosynthesis of products potentially toxic for vertebrates
- Centers for Disease Control (CDC) and Animal and Plant Health Inspection Service (APHIS) defined select toxins or agents
- Any organisms, or agents requiring federal permits, including but not limited to the United States Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS), CDC, Environmental Protection Agency (EPA), or the Food and Drug Administration (FDA)

The completed “Application for Teaching Activities Involving Biohazardous Agents (NIH Recombinant and Synthetic Nucleic Acid Molecules, Other Biohazardous Agents, and Human Materials)” should be submitted to the Office of Research Services/IBC for review and approval before the course is being taught for the first time. Courses that are being taught/have been taught and were not previously under the purview of the IBC, must now be reviewed and approved by the IBC. The IBC suggests that new/initial protocols for teaching be submitted at least one quarter before the class will be taught. The IBC schedules one summer meeting to assist instructors who teach classes in the fall in obtaining IBC approval before the beginning of the fall quarter.

All teaching activities are reviewed by the convened IBC. Teaching protocols are approved for 3 years; however, annual reports are required so that the IBC can follow the use of the biohazardous agents in the class and any issues that may arise while conducting the class. The instructor should complete and submit the Institutional Biosafety Committee (IBC) Annual Renewal Report Form and submit it by the annual renewal date indicated in the approval letter from the IBC. If a substantive change is made to the protocol/class during the three-year approval period, an amendment must be submitted for approval to the IBC. Substantive changes that would require an amendment include changes in the type of biohazardous agent(s) utilized and changes to laboratory operating procedures. It is possible that as Teaching Assistants and adjunct instructors change, an Amendment Changing Personnel (not the PI) for an IBC Approved Protocol may need to be submitted each quarter to keep the IBC up to date on personnel-related changes. Amendment changes limited to personnel changes do not require convened IBC review and may be reviewed administratively. However, the proper training and education must be completed in order for the personnel to be added to the protocol.

The DePaul University IBC is responsible for ensuring that activities involving recombinant and synthetic nucleic acid molecules, biohazardous agents, CDC/APHIC select agents or toxins, and biological toxins are in compliance with the *National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* (current edition), DePaul Policy and procedures related to biohazardous agents, other federal regulations, or state and local laws pertaining to biohazardous agents. Since DePaul University receives funding from NIH, the IBC is required to ensure that all experiments conducted at DePaul are in compliance with the *NIH Guidelines*, regardless of whether or not the experiment or activity is funded or who the funding source is (e.g., NIH, NSF, private, educational, etc.).

The IBC has oversight of any experiment or activity conducted on the DePaul campus that involves biohazardous agents. Biohazardous agents can include recombinant and synthetic nucleic acid molecules, CDC/APHIS select agents or toxins, biological toxins, potential biological or infectious agents, such as bacteria, virus, and prions, or other sources of potential infectious or hazardous agents such as cell cultures, tissue cultures, and human bodily fluids. Because these agents can be potentially hazardous to humans and may cause illness, disease or injury, the IBC must review research and teaching activities that involve these agents to ensure the safety and welfare of DePaul faculty, staff, and students.

The teaching lab or activity falls under the purview of the IBC when it utilizes a potentially biohazardous material or agent, whether it is a recombinant or synthetic nucleic acid molecule (NIH exempt or not) or is another type of biohazardous agent and no matter the risk level or biosafety containment level assigned to the material or agent(s). At this time only activities with agents requiring BSL1 and BSL 2 containment procedures may be conducted at DePaul.

In 2012 the American Society for Microbiology issued *Guidelines for Biosafety in Teaching Laboratories*, after a multistate outbreak of *Salmonella typhimurium* that originated in teaching and clinical laboratories in 2011 (<http://www.cdc.gov/salmonella/2011/lab-exposure-1-17-2012.html>). A similar incident occurred in 2014, which highlights the need for institutions to adopt the guidelines (<http://www.cdc.gov/salmonella/typhimurium-labs-06-14/index.html>). DePaul University has incorporated the guidelines into our policies for teaching activities that involve biohazardous agents. The *Guidelines for Biosafety in Teaching Laboratories* includes detailed guidance for BSL1 and BSL2 teaching laboratories. The purpose of *Guidelines for Biosafety in Teaching Laboratories* is to ensure that educators are aware of the risks inherent in using microorganisms in the laboratory and that when teaching the class, educators use best practices to minimize the risk to students and the community. The guidelines are designed to promote best practices in teaching laboratories. It is recognized that work with most microbes in the undergraduate non-microbiology laboratories are almost always at BSL1. Even though organisms manipulated in a BSL1 laboratory pose a low level of risk to the community and are unlikely to cause disease in healthy adults, most of the microorganisms used in microbiology teaching laboratories are capable of causing an infection given the appropriate circumstances.

The best practices outlined in the *Guidelines for Biosafety in Teaching Laboratories* are designed to minimize risks of laboratory acquired infections and to train students in the proper handling of microorganisms. The practices set forth in the guidelines are for BSL1 and BSL2 level agents and fall into six major categories: personal protections, laboratory physical space, stock cultures, standard laboratory practices, training, and documents. Refer to the IBC policy and procedure manual for detailed information on the guidelines or refer to the guidelines themselves or the *Appendix to the Guidelines for Biosafety in Teaching Laboratories* found at: http://www.asm.org/images/Education/FINAL_Biosafety_Guidelines_Appendix_Only.pdf

The types of courses/course activities that would trigger the need for IBC review and approval include:

- The collection of environmental samples for analysis for research or teaching purposes, such as collection of water from the local water ways or collection of soil samples to test for certain contaminants or substances. Instructors should follow Environmental Protection Agency (EPA) guidelines for handling of the samples. In order to keep the use of these samples at the BSL1 level, instructors and students must not subculture (i.e., isolate organisms and place them in media to promote growth) unknown microbes from the environment because they may be organisms that require BSL2 practices and facilities.
- The collection of environmental samples to be used for research or teaching purposes in which the activity involves isolation and growth of microorganisms by placing them in media conducive to their growth or enhancement.
- The use of protists (a collection of single-celled organisms that do not fit into any other category). Protists are a group made up of protozoa, unicellular algae, and slime molds, arcahea, or similar microorganisms
- Using manure for composting, fuel production, or other non-culturing experiments
- Commercially available color changing coliform water test kits. The kits must remain sealed and must be properly disposed of.
- Studies of microbial fuel cells.
- Projects involving decomposing vertebrate organisms (such as in forensic projects)

Instructor Responsibilities

Instructors who are Principal Investigators (PIs) for a particular course have several responsibilities associated with the experiments or activities as part of a course conducted on the DePaul campus when that activity involves biohazardous agents. These responsibilities include:

- Providing an initial risk assessment to the IBC and to all persons who may be exposed to the biohazardous agent for all experiments or activities being conducted in teaching labs. The risk assessment includes assignment to the appropriate Risk Group and the Biosafety Containment Level.

- Submitting a complete initial IBC protocol application, using the Application for Teaching Activities Involving Biohazardous Agents (NIH Recombinant and Synthetic Nucleic Acid Molecules [Exempt and Non-Exempt], Other Biohazardous Agents, and Human Materials), to the IBC for review and approval before the course instruction begins for the first time (or first time under the revised policy).
 - All Principal Investigators/Lead Instructors, other course instructors (including adjunct instructors), Lab Coordinators assisting with the class, and Teaching Assistants (TAs) listed on a teaching protocol are required to complete the CITI IBC Basic training course for the learner group called Faculty/Teaching Assistants/Lab Coordinators/Research Personnel (including Grad Students), which provides a basic understanding of biosafety principles. Please see the training portion of the IBC web site or the appropriate section of the IBC Policy and Procedure Manual for complete information on the training requirements.
 - When Lab Coordinators and TAs are not known at the time the protocol is initially submitted to the IBC, individuals may be added at a later date using the Application for an Amendment Changing Personnel (Not the PI) for an IBC Approved Protocol. However, the required training must be completed by these persons before they may be added to the protocol.
 - Providing initial training for any additional instructors or teaching assistants that may be required specific to the agent(s) being utilized. Additionally, training for instructors and teaching assistants should be supplemented whenever new procedures or agents are utilized.
 - Ensuring all students in the course are provided with information and training related to the risks of the agent(s) and the safety procedures for handling the biohazardous materials or agent(s). The IBC protocol should describe the procedures for providing this information and training to the students. The information can be provided to the students enrolled in the course by:
 - Creating and supplying a laboratory safety manual and training information specific to the course to the IBC for review and to all persons in the course or assisting with the course. This could be a short handout or part of the syllabus that will be provided to students enrolled in the course and instructors that explains the biohazardous agent(s) that will be used in the course, background information on the potential risks associated with working with the agent(s), what procedures to follow when working with the agent, what personal protective equipment (PPE) should be utilized when working with the agent, what procedures should be followed if there is direct exposure to an agent (i.e., hand washing, disinfection), the procedures for disposal of the agent or waste associated with the agent, and what procedures to follow in the event there is a spill or other type of

contamination event to work spaces or equipment. This information can be provided for each exercise or experiment.

- Ensuring that the appropriate procedures and practices will be followed during the conduct of the course, including the proper disposal of biological waste, biohazardous agents or materials, the proper handling (clean up, disinfection) of spills (large and small volumes), contamination of work spaces or equipment, and exposures to persons (e.g., spill on skin, splash in eye, aerosolization, breathing in, accidental injection, ingestion).
 - This can be done by having students, teaching assistants and instructors demonstrate competency in BSL1 procedures before they can work with BSL2 agents.
- Documenting students have received the information and training by having students sign safety agreements explaining that they have been informed about safety precautions and the hazardous nature of the organisms they will handle through the course.
- Maintaining the student-signed safety agreements in their class records
- Prepare, maintain, and post proper signage in compliance with the DePaul Environmental Health and Safety Office policy and which is consistent with the type of agent(s) being utilized in the laboratory space.
- Document and report all injuries and spills in compliance with DePaul's Environmental Health and Safety policies and emphasize to students the importance of reporting accidental spills and exposures.
- Make Safety Data Sheets (SDS) available at all times to students and instructors in the laboratory class for all agents utilized during the course.
- Post emergency procedures and updated contact information for people to contact in case of an emergency in the laboratory. (Suggestion: Post emergency contacts and procedures in the laboratory, in case of an emergency.)
- For BSL2 activities, keep a copy of the current version of Biosafety in Microbiological and Biomedical Laboratories (BMBL) in the laboratory or supply each student, instructor or teaching assistant with the link to the online version.

Courses Involving the Collection of Environmental or Field Samples:

The IBC recognizes that the collection and isolation of microorganisms from the environment can be both a powerful learning tool, as well as a potential biological hazard. Environmental samples such as water, air, soil, or plants may contain pathogens (i.e., bacteria, viruses, spores) that could present a health hazard to people, animals or the environment. Examples of the types of environmental samples which may harbor potentially infectious agents include:

- Human specimens (field training specimens, clinical specimens, forensic specimens)
- Animal, plant, fish, or insect parts or whole bodies
- Water samples from untreated sources, badly polluted sources, or cooling towers
- Mold or fungi

- Food (routine screening for contamination, food borne illness outbreak investigation)
- Archeological samples (retrospective investigation of illness or disease)
- Quality assurance testing (air or mold samples)

The IBC would need to be concerned about samples of this nature being transported to campus laboratories, the transfer or storage of the materials on campus, the containment procedures during transport and storage, any potential release of agents from the materials, and the disposal of waste from the work with the materials.

The DePaul IBC provides the following guidelines for courses that involve environmental samples or cultures from environmental sources (e.g., soil, water).

- Be sure all persons involved in the collection and handling of the environmental samples use appropriate Personal Protective Equipment (PPE) to reduce exposure to potential pathogens or infectious agents and to minimize the transfer of pathogens or infectious agents in the environment. Use care when handling environmental samples, especially if the sample will be enhanced or enriched in the laboratory by culturing (cultivating) or other growing mechanisms, including growing in greenhouse environments.
 1. Teaching activities with unknown microorganisms can be treated as BSL 1 when:
 - 1) organisms are cultured in a sealed Petri dish (or other standard unbreakable container).
 - 2) The experiment involves only procedures in which the Petri dish remains sealed throughout the experiment (e.g., counting the presence of organisms or colonies).
 - 3) The sealed Petri dish is disposed of via autoclaving or disinfection under the supervision of the course instructor(s).
 2. If a culture container with unknown microorganisms is opened for any purpose (except for disinfection before disposal), it must be treated as a BSL 2 activity and involve the use of BSL 2 laboratory practices.
 3. Techniques used to enhance and/or culture (i.e., isolation of organisms and placing them in media to promote growth) environmental samples should be conducted at BSL2 or higher biosafety levels in an appropriate containment device, such as a biological safety cabinet or fume hood. If the environmental sample is sterilized prior to experimentation, then the sample may be manipulated in a BSL1 rated laboratory.
 4. When possible, enrichment cultures should be incubated at 28 degrees C or cooler to reduce the risk of isolating pathogenic organisms.
 5. Direct environmental samples that are likely to contain infectious organisms should be handled using BSL-2 precautions. The instructor may justify the use of BSL-1 containment procedures in the initial IBC Protocol submission, based upon experience and expertise working with the specific environmental sample.
- Cultures containing sporulating fungal or mold colonies should be decontaminated without opening cultures. If manipulation of the culture is necessary, it must be done using BSL-2 precautions in a biosafety cabinet.

- The transport of samples back to the DePaul campus would require transportation training/education.

Courses that may involve subculturing unknown samples and teaching about differential and selective media:

The procedures needed to identify unknown microorganisms can be performed safely and with little to no risk to the students in the course. Laboratory courses may include the culturing of organisms from soil, water, food materials, and the air. Generally, activities that simply create an initial culture from these materials and which may be used to only count and understand the type of organisms in a particular environment may be conducted under BSL 1 procedures and would require IBC approval. However, if differential media and subculturing procedures are used that might allow for the selection for growth of organisms listed in Risk Group 2 or higher, then BSL 2 containment procedure must be used. If the course activities involve subculturing and isolation from environments, such as water fountains, door handles, or other areas that can harbor pathogens, IBC approval and BSL 2 containment procedures would be required. Samples must never be cultured from students themselves without appropriate approval from the IBC and possibly the Institutional Review Board (IRB) for human subject activities, as there is the potential for growing microorganisms that may require BSL2 or higher containment. It is highly recommended that the testing of unknowns should be performed from a mixture of microorganisms known to the instructor, or from a culture where the contents are known to the instructor instead of from the environment.

Courses Involving Cell or Tissue Culture:

Instructors should refer to the IBC policy and procedure manual for guidelines related to cell and tissue culture.

IBC form completion and review

An instructor who will be utilizing a biohazardous agent in teaching a course must complete the Application for Teaching Activities Involving Biohazardous Agents (NIH Recombinant and Synthetic Nucleic Acid Molecules, Other Biohazardous Agents, and Human Materials).

Section I - Principal Investigator/Lead Instructor:

The instructor should complete the requested information in the Principal Investigator/Lead Instructor section, including any training completed.

Section II - Other Faculty Instructors:

If there are other instructors for the class who are known to be teaching the class for the three-year approval period, including adjunct or part-time instructors, list them in this section. If you do not know yet who these people may be, you can add them later using the Application for an Amendment Changing Personnel (not the PI) for an IBC Approved Protocol form.

Section III - Teaching Assistants:

If the names of the Teaching Assistants are known, complete this section. Please indicate that the required training has been completed. If the names of Teaching Assistants (TA) are not known at the time of initial submission or if they change over time, the information for the TAs may be submitted at a later date. Please use the Amendment Changing Personnel (not the PI) for an IBC Approved Protocol form.

Section IV - Project Information:

The instructor should supply the title of the course, when the course will be taught, and locations of the course activities.

Section V - Protocol Summary:

The instructor should provide a short description of the type of activity that will be conducted in the lab class. The language used should be at the level of an educated lay person.

Section VI - Biohazardous Agent Information:

First, the instructor must provide a list of the biohazardous agents to be utilized in the course and basic information about each agent such as risk group, containment level, types of potential risks, and NIH category, if applicable. The next section is divided into types of agent. This allows us to collect necessary information about the differing types of biohazardous agents. There are sections pertaining to Recombinant or Synthetic Nucleic Acid Molecules, Infectious Agents, biological toxins (such as lipopolysaccharide or LPS which is present on most gram negative bacteria), biohazardous agents and human materials, human blood, blood products, human body fluids, and/or human tissue. The instructor should supply the necessary information about each type of biohazardous agent so that the IBC can understand the potential risks to humans and make the final determination regarding the risk level and containment level. If a particular type of biohazardous agent is not utilized in the course, that section may be skipped.

Section VII - Training and Safety Measures:

The instructor must provide information about the training plan for the students and the Teaching Assistants. The instructor should prepare a laboratory manual for the class that includes safety information as listed in this section. The laboratory manual may be submitted as an attachment to the form versus retyping the information into the form. A template for a possible manual can be

found in the *Appendix to the Guidelines for Biosafety in Teaching Laboratories*:

http://www.asm.org/images/Education/FINAL_Biosafety_Guidelines_Appendix_Only.pdf

Section VIII - Sanitation and Disposal:

The instructor should summarize the plans for cleaning up the lab after the agent is used and for the disposal of the waste. Include a discussion of what disinfectant agent is best suited for the type of biohazardous agent being utilized in the class and the contact time needed to kill the biohazardous agents. For example: 70 % alcohol for 15 minutes, 10% fresh bleach for 15 minutes, etc.

Section IX - Assurances:

The instructor should read the assurance statement and ensure that they understand their responsibilities related to conducting activities with biohazardous agents for the course. Please sign and date the form. The signature is an electronic signature.