DePaul University

Institutional Biosafety Committee (IBC)

Policy and Procedure Manual

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Prepared in collaboration with the DePaul University's Office of Research Services, Institutional Biosafety Committee (IBC), and Environmental Health and Safety

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Institutional Biosafety Committee (IBC)
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Definitions

Blood borne pathogen (BBP) - Pathogenic microorganisms that may be present in human blood or other human source materials (i.e., tissue, cultured cells, other bodily fluids) and can cause diseases in humans. These pathogens include, but are not limited to, Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and the Human Immunodeficiency Virus (HIV).

The Occupational Health and Safety Administration (OSHA) has established blood borne pathogens standard 29 CFR 1910.1030 (OSHA Blood borne Pathogens Standard, 29CFR 1910.1030) for personnel working with human-derived blood, body fluids, tissues, or primary human cell lines or explants where the presence of an infectious agent may be unknown. Persons working with these materials must use Biosafety Level 2 (BSL-2) containment procedures and Universal Precautions as defined by the Centers for Disease Control (CDC) (http://www.cdc.gov/niosh/topics/bbp/universal.html).

Biohazardous materials, agents, or toxins- Infectious biological or synthetic agents, biologically derived materials or toxins (including endotoxins such as bacterial Lipopolysaccharide or LPS, present on most gram negative bacteria) 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 present on most gram negative bacteria
- 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, any body 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)

Biosafety Level – Four levels that describe the combination of laboratory practices and techniques, safety equipment, and laboratory facilities needed to create conditions under which the agent ordinarily can be safely handled.

Biotoxins – Biotoxins are poisonous substances produced by living organisms (animals, plants, microbes) and are not man-made. Unlike most other biohazards biotoxins do not replicate and, in some instances, are comparable to classic organic chemicals. However, biotoxins differ from chemical toxins in that they do not pose a vapor hazard and are not usually dermally active (mycotoxins are the exception).

Centers for Disease Control and Prevention (CDC) - A division of the US Department of Health and Human Services concerned primarily with the control and eradication of human disease. The CDC is headquartered in Atlanta, Georgia.

Containment – The safe methods, facilities, and equipment for managing infectious materials in a laboratory environment where they are being handled or maintained.

Decontamination and cleaning – Procedures and methods used to render an area, device, item, or material safe to handle. The primary objective is to reduce the level of microbial contamination so that infection transmission is eliminated and to protect the laboratory worker, the environment, and anyone who enters the laboratory or handles laboratory products away from the laboratory. Decontamination may include washing, cleaning, disinfection, or sterilization.

Disinfection: A process by which viable biohazardous agents are reduced to a number unlikely to produce disease in healthy people, plants or animals. It is less lethal than sterilization and may not eliminate all microbial forms (i.e., bacterial endospores) on inanimate objects and therefore, lacks the margin of safety of sterilization.

Inactivation: Any process that destroys the ability of a specific biohazardous agent to self-replicate.

Infectious agent- Any microorganism, or a toxin produced by a microorganism, that is pathogenic to humans, animals, or plants.

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)-The document published by NIH that classifies the different types of research involving recombinant or synthetic nucleic acid molecules, sets containment requirements, and provides the framework for project review, authorization, and monitoring at the government and institution levels.

Occupational Safety and Health Administration (OSHA): The main federal agency charged with the enforcement of safety and health legislation.

Recombinant and Synthetic Nucleic Acids – Are defined as: (i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids; (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or (iii) molecules that result from the replication of those described in (i) or (ii) above.

Risk Group (RG) - Based on the NIH definition; one of four levels of risk that a biological agent presents to human health. Infectious agents are ranked in ascending order of biohazard: (1) Risk Group 1 (RG1) agents are not associated with disease in healthy adult humans. (2) Risk Group 2 (RG2) agents are associated with human disease which is rarely serious and for which preventive or

therapeutic interventions are *often* available. (3) Risk Group 3 (RG3) agents are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available. (4) Risk Group 4 (RG4) agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available. **Work with RG-3 and RG-4 agents is currently prohibited at DePaul.**

Select agent - The federal government decides which agents are at high risk of being used in terrorist activities and refers to them as "select agents". Select agents are subject to additional federal oversight. Select agents can either be pathogens or biological toxins. Even though biological toxins are derived from animals and plants, they are included in the highly hazardous chemical list because they have no pathogenic potential.

Sterilization – A procedure (physical, chemical, or otherwise) used to destroy all microbial life including bacterial endospores. Any item, device, or solution is considered to be sterile when it is completely free of all living microorganisms and viruses.

Universal Precautions - As defined by CDC, a set of precautions designed to prevent transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other blood borne pathogens when providing first aid or health care.

Zoonosis - A disease that can be transmitted from an animal species to a human.

Common Acronyms

BMBL- Biosafety in Microbiological and biomedical Laboratories

BPP – Bloodborne pathogen

BSL – Biosafety Level

BSO - Biosafety Officer

CDC - Centers for Disease Control

DHHS - (US) Department of Health and Human Services

EHS – DePaul Environmental Health and Safety Office

FDA – (US) Food and Drug Administration

HBV – Hepatitis B virus

HCV – Hepatitis C virus

HIV – Human Immunodeficiency Virus

IACUC – Institutional Animal Care and Use Committee

IBC - Institutional Biosafety Committee

IRB – Institutional Review Board

NIH – National Institutes of Health

NIH OBA - National Institutes of Health Office of Biotechnology Activities

NIOSH – National Institute of Occupational Safety and Health

NIH-RAC - National Institutes of Health Recombinant DNA Advisory Committee

NSABB - National Science Advisory Board for Biosafety

NSAR - National Select Agent Registry

NSF - National Science Foundation

OSHA - Occupational Health and Safety Administration

PI - Principal Investigator

RDNA - Recombinant deoxyribonucleic acid

RG – Risk Group classification usually accompanied by a number

USDA-APHIS – United States Department of Agriculture Animal and Plant Health Inspection Service

Regulations and Guidelines

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

- *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* - This document specifies the NIH rules for constructing and handling: (i) recombinant nucleic acid molecules, (ii) synthetic nucleic acid molecules, including those that are chemically or otherwise modified, but can base pair with naturally occurring nucleic acid molecules, and (iii) cells, organisms, and viruses containing such molecules. The document outlines institutional responsibilities related to

research covered by the *NIH Guidelines*, including the establishment of an IBC and policies that ensure that research is conducted in compliance with the *NIH guidelines.* Under the *NIH Guidelines*, institutions must oversee and review research that is conducted at or sponsored by the institution when it receives any support for recombinant or synthetic nucleic acid research from NIH to ensure safety and compliance with the *Guidelines*. The *Guidelines* are frequently amended to reflect evolving scientific understanding of recombinant or synthetic nucleic acid molecules and its applications. The *Guidelines* include Appendices M, P, and Q which discuss special consideration for experiments involving humans, containment considerations for research involving plants, and containment considerations for research involving animals, respectively. The *Guidelines* can be viewed in its entirety at: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines
The DePaul IBC is registered with the Office of Biotechnology Activities (OBA) for the purposes of recombinant or synthetic nucleic acid molecule research and in compliance with the *NIH Guidelines*.

- The Office of Research Safety, National Cancer Institute, and the Special Committee of Safety and Health Experts, *Laboratory Safety Monograph: A Supplement to the NIH Guidelines for Recombinant DNA Research*, NIH, Bethesda, Maryland 1978. – This document describes basic elements for developing specific procedures dealing with major spills or potentially hazardous materials in the laboratory, including information and references about decontamination and emergency plans, and the roles and responsibilities of the Institution and the Biological Safety Officer (BSO) for these types of events.
http://offices.depaul.edu/ors/research-protections/ibc/Documents/NIH-Lab_Safety_Monograph.pdf

- *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* - This document is published by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). It contains guidelines for microbiological practices, safety equipment and facilities that constitute four established biosafety levels. The BMBL is considered the standard for biosafety and is periodically revised to ensure it remains current.
http://www.cdc.gov/biosafety/publications/bmbl5/

- *Guidelines for Biosafety in Teaching Laboratories* and *Appendix to the Guidelines for Biosafety in Teaching Laboratories*, American Society for Microbiology, 2012- These guidelines are used as the basis for best practices in teaching laboratory classes in order to protect the health and wellness of students enrolled in classes. The guidelines provide standards for Personal Protection Requirements, Laboratory Physical Space Requirements, Stock Culture Requirements, Standard Laboratory Practices, Training Practices, and Document Practices for Biosafety Level 1 and 2 activities that generally occur in teaching laboratory classes. The Appendices provide expanded information, as well as sample forms, such as a Biosafety Manual for a class.
  http://www.asm.org/index.php/education2/22-education/8308-new-version-available-for-comment-guidelines-for-best-biosafety-practices-in-teaching-laboratories

- *OSHA Blood borne Pathogen regulations (29 CFR Part 1910. 1030) –*
  This regulation refers to an organization's responsibilities related to occupational exposure to blood or other potentially infectious materials as defined in the regulations (human blood, human blood component, and products made from human blood, (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV).
  https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10051

- *OSHA Occupational Safety and Health Standards, Hazard Communication (29 CFR 1910.1200)-*
  The purpose of this regulation is to ensure that the hazards of all chemicals produced or imported are classified, and that information concerning the classified hazards is transmitted to employers and employees. Classifying the potential hazards of chemicals and communicating information concerning hazards and appropriate protective measures to employees, may include, for example, but is not limited to, provisions for: developing

and maintaining a written hazard communication program for the workplace, including lists of hazardous chemicals present; labeling of containers of chemicals in the workplace, as well as of containers of chemicals being shipped to other workplaces; preparation and distribution of safety data sheets to employees and downstream employers; and development and implementation of employee training programs regarding hazards of chemicals and protective measures. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10099

- *CDC Select agent regulations (42CFR Part 73), Possession, Use, and Transfer of Select Agents and Toxins*- The CDC Select Agents Regulations govern the possession, use and transfer of Select Agents that have the potential to pose a severe threat to public health and safety. The select agent list is periodically revised.
  List of Agents:
  http://www.selectagents.gov/SelectAgentsandToxinsList.html
  Regulations: http://www.selectagents.gov/Regulations.html

- *Animal and Plant Health Inspection Service (APHIS) Select Agents Regulations (7 CFR Part 331 [Possession, Use, and Transfer of Select Agent and Toxins] and 9 CFR Part 121 [Possession, Use, and Transfer of Select Agent and Toxins])* regulates biological agents and toxins (Select Agents) that pose a potential threat to animal and plant health or to the safety of animal or plant products. The APHIS select agent list is periodically revised.
  List of agents:
  http://www.selectagents.gov/SelectAgentsandToxinsList.html
  Regulations:
  http://www.selectagents.gov/Regulations.html

  These regulations together establish requirements regarding the possession, use, receipt, and transfer of listed select agents and select agent toxins. The regulations set forth the requirements for registration of listed agents and select agent toxins, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications.

- *United States Department of Agriculture (USDA)/APHIS 7 CFR Part 340, Introduction of Organisms and Products Altered or Produced through*

Genetic Engineering. The Animal and Plant Health Inspection Service (APHIS) regulates genetically engineered (GE) organisms that may pose a risk to plants or animal health. APHIS uses the term biotechnology to mean the use of recombinant DNA technology, or genetic engineering to modify living organisms. Permits are required for the importation, transit, domestic movement, and environmental release of organisms that impact plants or are believed to be plant pests.
http://www.aphis.usda.gov/brs/pdf/7cfr340.pdf .

- Biotechnology regulatory requirements: Within the USDA the Animal and Plant Health Inspection Service (APHIS) has regulatory oversight over products of biotechnology that could pose a risk by being a product or organism that is known or suspected to be a plant pest or to pose a plant pest risk. This would include organisms that have been altered or produced through genetic engineering. These are called "regulated articles." APHIS regulates the import, handling, interstate movement, and release into the environment for regulated organisms that are products of biotechnology, including organisms undergoing confined experimental or field trials, Regulated articles are reviewed to ensure that, under the proposed conditions of use they do not present a plant pest risk through ensuring appropriate handling, confinement, and disposal. APHIS requires a permit or notification for the importation, interstate movement, or release of genetically engineered organisms considered to be "regulated articles."
  http://www.aphis.usda.gov/biotechnology/index.shtml

- Biotechnology and Plant permits: Plant Protection and Quarantine requires permits for importation into and transit though the United States of plants and plant products; and the importation into, transit through, and interstate movement within the United States of plant pests (plant feeding insects, mites, snails, slugs, and plant pathogens), biological control organisms of plant pests and weeds, parasitic plants and Federally listed noxious weeds under regulatory authorities.
  http://www.aphis.usda.gov/permits/index.shtml

IBC shipping, transport and receiving policies are based upon the following Regulations and Guidelines:

- *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* – Appendix H of the *Guidelines* indicate that Recombinant or synthetic nucleic acid molecules contained in an organism or in a viral genome shall be shipped under the applicable regulations of the U.S. Postal Service (39 CFR, Part 3), the PHS (42 CFR, Part 72), the U.S. Department of Agriculture (9 CFR, Subchapters D and E, 7 CFR, Part 340), and the U.S. Department of Transportation (49 CFR, Parts 171-179). In addition, the *Guidelines* note that host organisms or viruses will be shipped as etiologic agents, regardless of whether they contain recombinant or synthetic nucleic acid molecules, if they are regulated as human pathogens by PHS under 42 CFR, Part 72) or as animal pathogens or plant pests under the U.S Department of Agriculture, Animal and Plant Health Inspection Service (Titles 9 and 7 CFR, respectively). Host organisms and viruses will be shipped as etiologic agents if they contain recombinant or synthetic nucleic acid molecules when: (i) the recombinant or synthetic nucleic acid molecules include the complete genome of a host organism or virus regulated as a human or animal pathogen or a plant pest; or (ii) the recombinant or synthetic nucleic acid molecule codes for a toxin or other factors directly involved in eliciting human, animal, or plant disease or inhibiting plant growth, and is carried on an expression vector or within the host chromosome and/or when the host organism contains a conjugation proficient plasmid or a generalized transducing phage; or (iii) the recombinant or synthetic nucleic acid molecule comes from a host organism or virus regulated as a human or animal pathogen or as a plant pest and has not been adequately characterized to demonstrate that it does not code for a factor involved in eliciting human, animal, or plant disease. The *Guidelines* can be viewed in its entirety at: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines

- *Federal Hazardous Materials Transportation Act (49 U.S.C. 5101 et. Seq)*—The Hazardous materials regulations regulate the safe and secure transportation of hazardous materials in commerce. The administrative unit within DOT responsible for oversight of hazardous materials, known as Hazmat, is the Pipeline and Hazardous Materials Safety Administration (PHMSA). When you prepare, mark, label, certify packages or sign shipping papers, including hazardous waste manifests and air waybills, for transportation by a non-governmental agency (e.g., waste contractor, FedEx, UPS), you are in commerce and the regulations apply. These regulations also apply to shipping biological specimens containing

chemical preservatives such as ethanol, formaldehyde, or formalin, and shipment of samples packed with dry ice. The hazardous materials regulations are subdivided by function into four basic areas:

- Procedures and/or Policies: 49 CFR Parts 101, 106, and 107
- Material Designations: 49 CFR Part 172
- Packaging Requirements: 49 CFR Parts 173, 178, 179, and 180
- Operational Rules: 49 CFR Parts 171, 173, 174, 175, 176, and 177

The training requirements under these regulations are outlined at: http://www.gpo.gov/fdsys/pkg/USCODE-2011-title49/html/USCODE-2011-title49-subtitleIII-chap51.htm

- *United States Postal Service (USPS) 39 CFR Part 20, International Postal Service (International Mail Manual), and Part 111, General Information on Postal Service (Domestic Mail Manual)* – Regulations on transporting infectious substances through the USPS are codified in Section 601.10.17 of the Domestic Mail Manual and Section 135 of the International Mail Manual. Manuals can be ordered from the USPS website: http://bookstore.gpo.gov/subjects/sb-169.jsp http://bookstore.gpo.gov/actions/GeneralSearch.do

- *Occupational Health and Safety Administration (OSHA), 29 CFR part 1910.1030, Occupational Exposure to Bloodborne Pathogens*. These regulations provide minimal packaging and labeling requirements for blood and body fluids when transported within a laboratory or outside of it. http://www.osha.gov/SLTC/bloodbornepathogens/index.html

- *Technical Instructions for the Safe Transport of Dangerous Goods by Air (Technical Instructions). International Civil Aviation Organization (ICAO).* These rules apply to the shipment of infectious substances by air and are recognized in the United States and by most countries worldwide. http://www.icao.int/safety/DangerousGoods/Pages/technical-instructions.aspx

- *Dangerous Goods Regulations. International Air Transport Association (IATA)*. These regulations are issued by an airline association, are based on the International Civil Aviation Organization (ICAO) Technical Instructions, and are followed by most airline carriers. These regulations

also apply to shipping biological specimens containing chemical preservatives such as ethanol, formaldehyde, or formalin and shipment of samples packed with dry ice.
http://www.iata.org/Pages/default.aspx

Section 1: Introduction

1.0 Purpose

It is the responsibility of the DePaul University Institutional Biosafety Committee (IBC) to review, approve, and oversee the use of recombinant or synthetic nucleic acid molecules, biohazardous agents (as defined by this policy), and select agents or toxins in all research or teaching activities conducted by DePaul University faculty, staff, and students at DePaul University or at DePaul owned facilities.

The Institutional Biosafety Committee (IBC) Policy and Procedure Manual provides information regarding the relevant regulatory and local requirements for research or teaching activities that are under the purview of the IBC. It is important to remember that since laboratory work can involve exposure not only to recombinant or synthetic nucleic acid molecules, biohazardous agents, or select agents or toxins, but also to chemical, radiological, or blood borne pathogen hazards, the IBC policies should be used in conjunction with other policies at DePaul University that may apply to hazards that are not covered by IBC policy and procedures (i.e., policies under Environmental Health and Safety covering chemical hazards and spills or radiation safety).

1.1 Mission

The IBC is a university-wide committee granted the authority by DePaul's President to ensure the safe acquisition, storage, use, and disposal of all biohazardous agents at DePaul University. The DePaul IBC safeguards human health and the environment by maintaining adherence to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*, the *Biosafety in Microbiological and Biomedical Laboratories (BMBL),* the Occupational Health and Safety Administration (OSHA) Blood borne Pathogen regulations and Occupational Safety and Health Standards, Hazard Communication regulations, and the CDC/HHS/USDA-APHIS Select Agents and Toxins regulations.

Through outreach and support for research and teaching personnel at DePaul, the IBC has the responsibility for and will:

- Assure that research and teaching activities that involve recombinant or synthetic nucleic acid molecules, biohazardous agents, and select agents or toxins meet the ethical and legal requirements for the responsible use of these agents by evaluating the activities for biological safety considerations.
- Establish appropriate health and safety policies and procedures in accordance with federal regulations, guidelines, and laws that cover biological safety and make recommendations, when necessary to ensure compliance with policy. and
- Minimize risks to DePaul faculty, staff, and students, the community, and the environment by educating the DePaul community regarding the regulatory requirements for activities involving recombinant or synthetic nucleic acid molecules, biohazardous agents, and select agents or toxins.

1.2 Scope

The IBC policies apply to all DePaul faculty, staff, or students engaged in research or teaching activities involving recombinant or synthetic nucleic acid molecules, biohazardous agents, or select agents or toxins under their role or duties as a DePaul employee or student at DePaul (i.e., teaching or research), including listing their affiliation with DePaul in any resulting publications, presentations, or other method of disseminating research results when the projects meet one or more the following criteria:

- They are Federally funded, funded by other external sources, are sponsored (funded) by DePaul University, or unfunded (no funds of any kind will be utilized to conduct the activity),
- They are conducted using DePaul owned property and facilities or under the direction of DePaul personnel off DePaul's campus or in non-DePaul facilities when these activities are not covered under the policy of another institution's IBC or the site is otherwise not regulated.
- They involve receiving, storing, using, transferring, or disposing of these materials at DePaul owned facilities or on DePaul property,
- They involve research at other institutions conducted on behalf of DePaul, such as when grant work is sub-contracted and DePaul is the lead site.

1.3 Background

In March 2005 the DePaul IBC was created when it registered with the National Institutes of Health's (NIH) Office of Biotechnology Activities (OBA) and was charged with ensuring that all research (funded or unfunded) conducted by DePaul University faculty, staff, and students is in compliance with the *NIH Guidelines*. The role of the IBC was expanded to ensure all activities involving

any type of biohazardous agent and select agents and toxins are in compliance with additional federal regulations, laws and guidelines governing biohazardous agents and select agents and toxins.

The IBC is also responsible for the review of activities that involve the use of materials potentially containing blood borne pathogens to ensure compliance with the OSHA regulations. The IBC works closely with DePaul's Environmental Health and Safety to ensure institutional compliance with the OSHA blood borne pathogen regulations.

The DePaul IBC is registered with the NIH Office of Biotechnology Activities (OBA) for the purposes of reviewing and approving research involving recombinant and synthetic nucleic acid molecules. An annual report is filed with the OBA, which includes an updated list of IBC members (a roster) indicating the role of each member and a biosketch (NIH-specific requirement for curriculum vitae information, a sample can be found at: http://grants.nih.gov/grants/funding/2590/biosketchsample.pdf) or resume/curriculum vitae for each member. The OBA is notified of any changes in IBC membership at least annually with the annual report or when changes in membership occurs in-between annual reports. Such notification includes a revised list of members, contact information and a biosketch or resume/curriculum for each new member. The Office of Research Services takes responsibility on behalf of the IBC for notifying OBA of changes to IBC membership and submitting the annual report.

DePaul University does not currently work with any select agents as defined by the Center for Disease Control (CDC) or United States Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS) guidelines. However, before any work involving such agents can occur at DePaul, DePaul must have a certificate of registration for Select Agents and Select Agent Toxins with the CDC or the USDA/APHIS for the possession, use, receipt, or transfer of listed select agents or select agent toxins. For more information visit http://www.cdc.gov/od/sap/. The CDC or HHS/USDA/APHIS registration would need to be maintained by an office at DePaul such as Environmental Health and Safety on behalf of the institution. The registration cannot be held and maintained by an individual at DePaul. During the review process for the Select agent and toxin use by the CDC or HHS/APHIS, other documentation may be needed, such as import/export permits.

1.4 Charge and Authority

The IBC is charged with the review, approval, and oversight of research and teaching activities involving recombinant or synthetic nucleic acid molecules, biohazardous agents, and select agents or toxins. The responsibilities of the IBC include assessment of facilities, procedures, and practices, and the training of personnel to assure compliance with the *NIH Guidelines* and other pertinent guidelines and regulations. In order to successfully carry out these responsibilities, the appointed IBC members must have knowledge and expertise in biomedical research and biosafety concerns and procedures. IBC members are appointed by the DePaul University President in consultation with the Office of Research Services and the current IBC Chair.

The IBC has the authority to approve, require modifications to secure approval, disapprove, suspend, or terminate research or teaching activities, as needed, and to investigate potential violations or non-compliance related to this policy in order to assure adherence to the appropriate regulations and guidelines. The IBC has been charged with these duties as part of the planning and implementation of the DePaul University Biosafety Program which has the overall purpose and goal of ensuring the health and safety of all persons working with recombinant or synthetic nucleic acid molecules, biohazardous agents, and select agents and toxins. Activities that have been approved by the IBC may be subject to further review and disapproval by institutional officials (e.g., President, Provost, AVP for Research, Deans of the Colleges). **However, those officials do not have the authority to approve of activities for the IBC or instead of the IBC or to approve of activities specifically disapproved by the IBC.** The IBC is responsible for establishing and implementing policies that provide for the safe conduct of activities involving recombinant or synthetic nucleic acid molecules, biohazardous agents, and select agents or toxins to ensure adherence to the *NIH Guidelines*, the *BMBL*, OSHA blood borne pathogen regulations, OSHA Occupational Safety and Health Standards, Hazard Communication, and CDC/USDA/APHIS regulations. The IBC reviews individual proposals using these materials in compliance with the established policies and procedures. The IBC has the authority to require progress reports from investigators and oversee the conduct of any activity, as well as to approve or disapprove of amendments or changes to activities.

The IBC's regulatory responsibilities in regards to recombinant or synthetic nucleic acid molecules activities are outlined in the *NIH Guidelines*. The IBC is given the authority to oversee all research and teaching activities involving other biohazardous agents, select agents or toxins by the DePaul's President. The IBC

has the authority to suspend or terminate any activity that is not in compliance with IBC policies.

Section 2: Responsibilities

2.0 Institutional Responsibilities

Under the *NIH Guidelines*, as a condition to receive federal funding for recombinant or synthetic nucleic acid molecule research, the institution must ensure that all research conducted at, sponsored by, or affiliated with the institution, regardless of the source of the funding, will comply with the *NIH Guidelines*. In order to meet their obligations under the guidelines an institution must:

- Establish and implement policies that provide for the safe conduct of recombinant or synthetic nucleic acid molecule research and that ensure compliance with the *NIH Guidelines*, including accurate determinations of NIH exempt activities.
- Establish an Institutional Biosafety Committee (IBC) that meets the membership requirements set forth in the *Guidelines*. **The IBC's responsibilities need not be restricted to recombinant or synthetic nucleic acid molecules, but may also include other biohazardous agents.**
- Establish policies for the IBC to follow in the initial and continuing review and approval (and changes to) of applications, grant/funding proposals, and activities involving research.
- Having procedures that ensure that no IBC member is involved in the review or approval of a project which he/she has been or expects to be engaged or has a direct financial interest.
- Appoint a Biological Safety Officer (BSO), who is a member of the IBC, if the institution conducts recombinant or synthetic nucleic acid molecule research that requires BSL3 or BSL 4 level containment procedures or engages in large scale (greater than 10 L) research. The BSO carries out duties as defined in the *Guidelines*. DePaul University has chosen to appoint a BSO even though DePaul University does not currently conduct research that requires BSL3 or BSL 4 level containment procedures or engage in large scale (involving greater than 10 L of agent) research.
- Appoint at least one individual to the IBC with expertise in plant, plant pathogen, or plant pest containment principles, if the institution conducts recombinant or synthetic nucleic acid molecule research involving plants that requires IBC review and approval under Appendix P of the *Guidelines*.
- Appoint at least one individual to the IBC with expertise in animal containment principles, if the institution conducts recombinant or synthetic nucleic acid molecule research involving animals that requires IBC review and approval under Appendix Q of the *Guidelines*.

- Ensure that if the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human subjects that the IBC has appropriate expertise and training by appointing an IBC member who has experience and training in the field of human gene transfer (and using *ad hoc* consultants as deemed necessary), that all aspects of Appendix M are addressed, and that no human subjects will be enrolled in a human gene transfer experiment until NIH Recombinant DNA Advisory Committee (RAC), IBC, and Institutional Review Board (IRB) approval has been obtained. Additionally, the IBC must review the informed consent document for human gene transfer protocols prior to initiation to ensure that the risks associated with the use of the recombinant and synthetic nucleic acid molecules are accurate and complete.
- Assist in and ensure compliance with the *Guidelines* by Principal Investigators conducting research covered by the *Guidelines.*
- Ensure appropriate training for the IBC Chair, IBC members, the Biological Safety Officer (BSO) and other containment experts (when applicable), Principal Investigators (PIs) and all research or laboratory staff regarding laboratory safety and implementation of the *NIH Guidelines.* The IBC Chair is responsible for ensuring IBC members are appropriately trained. The institution is responsible for ensuring that the PI is sufficiently trained. The PI is responsible for ensuring all laboratory staff is appropriately trained.
- Determine the necessity for health surveillance of personnel involved in connection with individual recombinant or synthetic nucleic acid molecule projects; and if appropriate, conduct a health surveillance program for such projects.
- Report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to NIH/OBA within thirty days; unless the institution determines that a report has already been filed by the Principal Investigator or Institutional Biosafety Committee.
- When possible and consistent with protection of privacy and proprietary interests, open its Institutional Biosafety Committee meetings to the public.
- Upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes and any documents submitted to or received from funding agencies (which may be required to make them available to the public). If public comments are made on Institutional Biosafety Committee actions, the institution shall forward both the public comments and the Institutional Biosafety Committee's response to the OBA.
- Maintain an active IBC registration with the Office of Biotechnology Activities (OBA) at NIH utilizing the Institutional Biosafety Committee Registration Management System (IBC-RMS).
- File an annual report to NIH/OBA which includes: a roster of all IBC members clearly indicating the Chair, contact persons, BSO, plant expert, animal expert, human gene therapy expert or ad hoc consultant (if

applicable), and non-affiliated members and biographical sketches for all IBC members including non-affiliated members. The OBA must be notified of any membership changes when they occur. Each notification of membership change includes the new membership list, contact information, and a biosketch for the new members.

- Ensure when laboratories are renovated or constructed that the IBC reviews plans and has input for plans in order to ensure conditions and containment measures are appropriate.
- Ensure the institution has written policy regarding the certification of biosafety cabinets,
- Ensure the institution has written policies regarding the verification of autoclaves to ensure they are working properly and effectively.

Currently, DePaul University does not have any work involving select agents or toxins. However, before any such work can be conducted at DePaul, the institution must obtain a certificate of registration for Select Agents and Select Agent Toxins with the Centers for Disease Control (CDC) or APHIS for the possession, use, receipt, or transfer of any agents or toxins on the current CDC or APHIS list. Individual PIs cannot obtain and maintain the registration on behalf of the institution.

For activities involving other biohazardous agents as defined by this policy, but which are not recombinant or synthetic nucleic acid molecules covered under the *NIH Guidelines*, the DePaul IBC has the responsibility to ensure a safe environment for DePaul faculty, staff, and students and ensure there are policies and procedures in place for the safe handling, storage, use, and disposal of biohazardous agents utilized in research and teaching activities. The DePaul IBC accomplishes this goal by utilizing the IBC review system implemented for ensuring compliance with the *NIH Guidelines* and applying other regulations and guidelines pertaining to other types of biohazardous agents, as defined in this policy.

The institution recognizes the importance of the IBC committee members to ensuring compliance and ensuring the health and welfare of DePaul faculty, staff, and students. An appointment to the IBC membership is recognized as service to the University community and counts towards service requirements in consideration for faculty tenure and promotion.

2.1 President, Provost, and Institutional Official Responsibilities

The responsibility for the Biosafety Program at DePaul University rests with the President, Provost and Assistant Vice President (AVP) for Research, who is the Institutional Official (IO).

The President has charged the IBC with the authority to review, approve, and provide oversight and guidance to faculty, staff, and students conducting research or teaching activities with recombinant or synthetic nucleic acid molecules or biohazardous materials, select agents, and toxins. The President charges the IBC with ensuring that any use, storage, transfer, or disposal of recombinant or synthetic nucleic acid molecules or biohazardous agents is conducted in compliance with federal regulations, guidelines, and with appropriate safeguards. Membership appointments to the IBC are made by the President, based upon recommendations from the IBC Chair, IBC members, and the Office of Research Services. IBC members are appointed for a three-year term, which may be renewed.

The Provost is responsible for allocation of resources to the AVP for Research in the Office of Research Services and the IBC to aid in ensuring that resources are sufficient to enforce the *NIH Guidelines* and other applicable federal guidelines and regulations. The budget is reviewed annually for appropriate allocation of funds.

The AVP for Research as the IO has direct supervisory authority over the Office of Research Services staff and serves as an ex-officio advisor to the IBC. The IO works with the Office of Research Services staff to ensure there is adequate allocation of resources to maintain the Biosafety Program. The IO has directly charged the IBC to review, approve, and provide oversight and guidance to research personnel who seek to use recombinant or synthetic nucleic acid molecules, biohazardous agents, or select agent or toxins at DePaul on the behalf of DePaul and to ensure that research, teaching, and other activities utilizing these agents are conducted with appropriate safeguards and in accordance with federal guidelines and regulations, and institutional policy at DePaul.

The IBC will provide the IO with a report at least annually that will allow the IO and senior administrative officials to assess the performance of the IBC.

2.2 Office of Research Services Responsibilities

The Office of Research Services (ORS) provides administrative support for the IBC. ORS staff aids the IBC in the day to day management of the Biosafety Program by:

- Being a liaison between the research personnel, the IBC, and federal and regulatory agencies
- Scheduling the IBC meetings and arranging for meeting space
- Creating meeting agendas
- Taking meeting notes and preparing meeting minutes
- Providing resource binders to each IBC member

- Providing educational materials and information regarding continuing education opportunities to IBC members and PIs
- Preparing and submitting the annual report to OBA
- Obtaining BSL2 laboratory inspection reports from Environmental Health and Safety and matching them to active IBC protocols
- Maintaining the training records for IBC members, PIs, and all personnel involved in research or teaching activities that involve recombinant or synthetic nucleic acid molecules, biohazardous agents, select agents, or toxins at DePaul
- Maintaining the IBC administrative records (i.e., rosters, protocol lists, copies of annual reports), IBC registration with NIH/OBA, and individual protocol files
- Tracking all protocols submitted to the IBC for review to ensure compliance with annual renewal and triennial review requirements
- Creating and sending correspondence to investigators related to the IBC's determinations regarding protocol-related activities
- Drafting and maintaining IBC policy, guidelines, submission forms, and maintaining the IBC website to remain compliant with Federal or state regulations and guidance
- Communicating with the Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) when protocols involve human subjects or animals, respectively
- Communicating with the grants section of the Office of Research Services to ensure any funding proposals involving recombinant or synthetic nucleic acid molecules and biohazardous agents are reviewed by the IBC prior to the release of funding to the researchers
- Coordinating outreach (e.g., Emails, Newsletters, presentations) to faculty, staff, and students to ensure awareness of the IBC, IBC policy, and the requirement for IBC review and approval of all activities involving recombinant or synthetic nucleic acid molecules and other biohazardous agents
- Conducting an assessment, at least annually, of the IBC program to ensure the resources allocated to supporting the IBC (including, but not limited to staff) are adequate. The assessment will include the number of protocol submissions, the review process, policy and procedures, training requirements, and surveillance responsibilities.

2.3 IBC Responsibilities

The IBC reviews protocols that fall under the IBC's jurisdiction, specifically research and teaching activities involving recombinant or synthetic nucleic acid

molecules, biohazardous agents, select agents and toxins. IBC review includes assessing the Risk Group (RG) and Biosafety level (BSL) containment requirements and procedures for each type of agent utilized. The IBC makes the final determination for the RG and BSL after the PI's prosed initial assessment is reviewed by the IBC. Any violations, accidents, or other issues of concern raised by any member of the IBC may be reported to the Office of Biotechnology Activities.

Under the *NIH Guidelines* the IBC is responsible for:

- Reviewing recombinant or synthetic nucleic acid molecule research conducted at or supported by DePaul for compliance with the *NIH Guidelines.* The review process shall include:
    - Independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research and making final determinations of containment level and risk group;
    - Assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant or synthetic nucleic acid molecule research;
    - When applicable, ensuring that all aspects of Appendix M have been appropriately addressed by the Principal Investigator;
    - When applicable, ensuring that no research participant is enrolled in a human gene transfer experiment until the RAC review process has been completed, Institutional Biosafety Committee approval has been obtained, Institutional Review Board approval has been obtained, and all applicable regulatory authorizations have been obtained;
    - When applicable, for human gene transfer protocols selected for public RAC review and discussion, consideration of the issues raised and recommendations made as a result of this review and consideration of the Principal Investigator's response to the RAC recommendations;
    - When applicable, ensuring that final IBC approval is granted only after the RAC review process has been completed and
    - Ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines*.
- Notifying the Principal Investigator of the results of the Institutional Biosafety Committee's review and approval.
- Lowering containment levels for certain experiments as specified in Section III-D-2-a, *Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems*.

- Setting containment levels as specified in Sections III-D-4-b, *Experiments Involving Whole Animals*, and III-D-5, *Experiments Involving Whole Plants*.
- Periodically (at least annually) reviewing recombinant or synthetic nucleic acid molecule research conducted at the institution to ensure compliance with the *NIH Guidelines*.
- Adopting emergency plans covering accidental spills and personnel contamination resulting from recombinant or synthetic nucleic acid molecule research.
- Reporting any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the appropriate institutional officials within 72 hours and to NIH/OBA within 30 days, unless the Institutional Biosafety Committee determines that a report has already been filed with NIH/OBA by the Principal Investigator or Environmental Health and Safety.
- Ensuring the Institutional Biosafety Committee does not authorize initiation of experiments which are not explicitly covered by the *NIH Guidelines* until the NIH (with the advice of the RAC, when required,) establishes the containment requirement.
- Reviewing and approving plans for renovation and construction of laboratories planning on working with agents under the IBC's purview in order to ensure that the facilities where the activities will be conducted are compliant with the conditions and containment measures described in the *NIH Guidelines*.
- Performing such other functions as may be delegated to the IBC.

In addition to IBC responsibilities under the *NIH Guidelines*, the IBC is responsible for the following:

- Reviewing all activities, including research and teaching activities that include the receipt (possession), transport, shipping, disposal, and/or use of biohazardous agents (including recombinant and synthetic nucleic acid molecules), select agents or toxins for compliance with the *BMBL* and Select Agent and Toxins regulations, state and local laws and regulations. As part of the review, the IBC will:
    - Conduct an independent assessment of the risk group and containment level required for the agent
    - Conduct an assessment of the facilities, procedures, practices, training, and expertise of the personnel conducting the activity with the agents
    - Ensure adherence with all surveillance, data reporting, and adverse event reporting requirements set forth in the regulations and guidelines.
- Establishing policies and procedures for the safe acquisition, use, storage, and disposal of all biohazardous agents, select agents and toxins at DePaul University

- Periodically (at least annually) review the IBC policies and procedures and modify them as necessary to ensure appropriate biosafety measures and adherence with federal and state requirements
- Reviewing reports of inspections of research laboratories and facilities by Environmental Health and Safety to ensure compliance with *BMBL* safety standards and the IBC assigned BSL containment standards
- Helping to prepare the annual reports to the NIH Office of Biotechnology Activities (OBA) for the institution
- Reviewing and documenting findings for research and teaching activities that involve non-recombinant or synthetic nucleic acid molecule biohazardous agents, select agents and toxins
- Notifying the researchers and faculty regarding their review determinations related to the use of biohazardous agents not covered by the *NIH Guidelines*
- Educating the DePaul community about the safe use of biohazardous agents, select agents and toxins in research and teaching activities
- Monitoring compliance with institutional policy, federal regulations, guidelines, and laws and alerting the IBC and the IO to concerns regarding compliance
- Suspending or terminating protocol approval for the possession or use of recombinant or synthetic nucleic acid molecules, biohazardous agents, or toxins, where the IBC finds noncompliance or that such use or possession poses undue risk to research personnel or a threat to the health and safety of the community, and/or the environment
- Ensuring that all personnel working with biohazardous agents, select agents, and toxins are properly trained and are knowledgeable about the *NIH guidelines*, the *BMBL*, and DePaul's policies regarding biohazardous agents, select agents and toxins
- Ensuring, when applicable, that all personnel involved in shipping, transport, and receiving of biohazardous materials are properly trained or have appropriate knowledge pertinent to their role in the activity and the type of hazard involved in the activity in compliance with federal and international shipping regulations, and
- Working on established subcommittees assigned to special tasks, such as policy review or form revision, when applicable

IBC members are expected to attend the majority of the convened meetings during the academic year unless notifying the Office of Research Services staff ahead of time that they will be unable to attend the meeting. Members failing to attend meetings on a regular basis may be removed from the committee.

2.4 IBC Chair Responsibilities

The IBC Chair's responsibilities include:

- Serving as one of the IBC contacts for the regulatory agencies
- Acting as a liaison between research and teaching personnel and the IBC

- Reviewing and confirming the NIH exempt status of protocols submitted as activities limited to the use of NIH exempt agents
- Calling the IBC convened meeting to order and directing the meeting discussions and deliberations, requests motions and seconds, and closing the meeting once the IBC business has been concluded
- Assigning subcommittees and designated reviewers, as needed
- Running investigations of allegations of non-compliance
- Approving meeting minutes by signing and dating the documents after IBC requested changes has been included
- Delegating the responsibility to ORS staff for sending correspondence to investigators when the IBC requests revisions or additional information through Full Committee Review of Designated Member Review
- Signing (via electronic signature after content review) all approval memos for protocols documenting the IBC's decisions made at convened meetings and after review of responses from investigators to requests for modifications reviewed through designated member review (DMR).

2.5 Environmental Health and Safety Responsibilities

Environmental Health and Safety (EHS) is responsible for the development and coordination of DePaul's Occupational Health and Safety Program and environmental compliance programs, including radiation safety. EHS works closely with the IBC in creating policy and procedures for the safe acquisition, use, storage, and disposal of all biohazardous agents, select agents, and toxins at DePaul University. Staff members of EHS are voting members of the IBC. EHS has several manuals (i.e., Bloodborne Pathogens Exposure Plan, Chemical Hygiene Plan, Controlled Substances Program, Radiation Safety Manual, Respiratory Protection Program, and Waste Disposal Guide) available on their website which may be relevant to persons conducting activities with biohazardous agents.

The principal responsibility of the BSO is to advise the personnel working on an IBC covered protocol, the IBC, and laboratory staff concerning the most appropriate safety practices that will assure the safe conduct of research, teaching, or other activities involving recombinant or synthetic nucleic acid molecules, biohazardous agents, or select agents and toxins. In addition, the BSO is also responsible for maintenance of the sections of the DePaul Emergency Operation Plan pertaining to hazardous chemical spills and the release of hazardous materials, the Chemical Hygiene Plan, and the Waste Disposal Guide.

The IBC membership requirements under the *NIH Guidelines* include the need to have a Biological Safety Officer (BSO). The DePaul BSO is a staff member in Environmental Health and Safety. Although the *NIH Guidelines* do not require the IBC to have an appointed BSO unless the institution engages in large-scale research or production activities involving viable organisms containing recombinant or synthetic nucleic acid molecules or when the institution engages in recombinant or synthetic nucleic acid molecule research requiring BSL 3 or BSL 4 containment level procedures, DePaul University has chosen to have BSO representation on the IBC even though the activities at DePaul are currently limited to BSL 1 and BSL 2 containment level activities in order to ensure adequate expertise on health and safety issues for all activities at DePaul.

The responsibilities of the BSO include:

- Serving as a voting member of the IBC
- Conducting initial laboratory inspections (before work with BSL-2 agents begins) and conducting periodic (not less than annually) inspections of laboratories working with BSL 2 agents to ensure that laboratory standards are rigorously followed
- Reporting results of inspections to the IBC, any issues found during laboratory inspections, and the resolution of any issues
- Reporting to the IBC and the institution any significant problems, violations of *NIH Guidelines*, and any significant research-related accidents or illnesses of which the BSO becomes aware, unless the PI has already filed a report with the IBC
- Aiding the IBC in making the required risk assessment to determine appropriate biosafety containment levels for handling of organisms
- Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant or synthetic nucleic acid molecules, biohazardous agents, or select agents or toxins
- Providing advice on laboratory security
- Providing technical advice to PIs and the IBC on research safety procedures
- Developing and implementing a comprehensive Biosafety program for DePaul University.

Environmental Health and Safety inspects all laboratory space utilizing biohazardous materials that require BSL-2 containment procedures on an annual basis. Environmental Health and Safety is also responsible for institutional compliance with the OSHA Blood borne Pathogen and OSHA Occupational

Safety and Health Standards, Hazard Communication requirements and works closely with the IBC when activities involving materials that may possibly contain blood borne pathogens are conducted at DePaul.

2.6 Principal Investigator Responsibilities

On behalf of DePaul University, the Principal Investigator (PI) is primarily responsible for ensuring full compliance with the *NIH Guidelines* and other applicable regulations and policies in the conduct of research or teaching activities involving recombinant or synthetic nucleic acid molecules, Biohazardous agents (as defined in this policy), select agent, and toxins. All such activities require IBC review as indicated in DePaul policy. This means the PI is ultimately responsible for proactively seeking advice and assistance from the IBC and obtaining IBC review and approval for all activities falling under the IBC's purview. An informational brochure is available from NIH summarizing the PIs responsibilities under the *NIH Guidelines* at: http://osp.od.nih.gov/sites/default/files/resources/InvestigatorEducationalBrochureRecombinant%20DNA_0.pdf. For the purposes of this policy the PI's responsibilities and duties include:

- Not initiating any activity involving biohazardous agents (as defined in this policy), including NIH exempt activities, before IBC approval has been obtained
- Maintaining IBC approval for the use of recombinant or synthetic nucleic acid molecules, biohazardous agents, select agents, or toxins through timely submissions of annual updates and, when applicable, protocol amendments
- Determining whether experiments are covered by Section III-E, *Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation*, and being sure the appropriate submission procedures, as defined by DePaul policy, are followed. DePaul does not allow simultaneous submission. IBC approval must be obtained before activities begin.
- Reporting any significant problems, violations of the *NIH Guidelines*, or research-related accidents and illnesses to the Biological Safety Officer (when applicable), the Research Support Facility (RSF) Director (when applicable), the IBC within 24-72 hours, and potentially to NIH/OBA, and other appropriate authorities (when applicable) within 30 days
- Reporting any new information learned during the experimentation bearing on the *NIH Guidelines* (such as changes to the Biosafety Level of an organism) to the IBC and to NIH/OBA

- Being adequately trained in good microbiological techniques, laboratory safety in accordance with the *BMBL* and the *NIH Guidelines*
- Ensuring that all laboratory staff are adequately trained in practices and techniques required for ensuring personnel safety
- Ensuring that all staff working on a specific protocol or with biohazardous agents has read the protocol, Standard Operating Procedures (SOPs), and other information related to the agents being used (i.e., safety sheets) and understand the steps necessary for dealing with any spills or potential exposures to the agents being used in the protocol
- Ensuring that all procedures described in the protocol (especially for dealing with and reporting spills, accidents, injuries, or potential exposure to agents) are being utilized
- Adhering to the IBC approved emergency plans for handling accidental spills, containment of potential exposures, and personnel contamination
- Complying with shipping requirements for recombinant or synthetic nucleic acid molecules as described in Appendix H of the *NIH Guidelines* and the Laboratory Safety Monograph (referenced in the *NIH Guidelines*) and all federal shipping regulations related to biohazardous agents
- Adhering to the requirements of shipping, transport, and receiving training for all biohazardous agents as indicated in DePaul policy
- Making the initial risk group assessment and determination for the level of physical containment required for the biohazardous agent(s) in accordance with the *NIH Guidelines* and the most recent edition of the *BMBL*
- Selecting the appropriate microbiological practices and laboratory techniques to be used for each specific protocol and ensuring the integrity of the physical containment equipment, including having laboratory equipment periodically certified and maintained per DePaul policy, when applicable
- Determining the minimal required Personal Protective Equipment (PPE) for the laboratory staff working with the agents for each protocol, including the PPE requirements in the IBC protocol and Standard Operating Procedures (SOPs) submitted to the IBC with each protocol, training each person working in their lab regarding the appropriate PPE to utilize for specific agents, and monitoring the laboratory personnel for PPE compliance. The IBC requires when cuts, open wounds, or abrasions are present when working with BSL 2 agents, that all personnel double glove. Double gloving is highly recommended for BSL1 work as well in these instances.
- Disclosing any financial or personal conflicts of interest to the IBC for each protocol submitted to the IBC. Financial conflicts of interest must

also be reported to appropriate institutional officials following the University Financial Conflict of Interest policies.

The PI must ensure that their laboratories have a standard operating procedure manual kept in the laboratory which contains the procedures specific to the activities occurring or agents utilized in that laboratory. A template for an acceptable format for laboratory SOPs is available on the IBC website. The SOP template was developed in cooperation with Environmental Health and Safety.

Individuals working with human immunodeficiency virus (HIV), hepatitis B virus (HBV) or other blood borne pathogens should consult with the Occupational Safety and Health Administration (OSHA) regulations and DePaul Environmental Health and Safety for rules related to working with such agents. BSL 2 containment is recommended for activities involving blood-contaminated clinical specimens, body fluids, and tissues from all humans, or from HIV- or HBV-infected or inoculated laboratory animals.

2.6.1 Who can be a Principal Investigator

The Principal Investigator (PI) for a protocol should be a person who is knowledgeable regarding the agents being utilized and the proper laboratory techniques and containment procedures for the agent(s) being utilized. A PI is generally a tenured, tenure track, adjunct, or research faculty member with assigned laboratory research or teaching space at DePaul. If the PI does not have his/her own research space and the agents being utilized require BSL2 containment procedures, the PI must provide to the IBC a written Email statement from the person(s) sharing the space that they are aware of the potentially biohazardous activity that will occur in that space, the type of biohazardous agent(s) being utilized, and agree to share the space and adhere to the *NIH guidelines* and institutional policy regarding safety procedures for the agents utilized in that shared space. Additionally, the PI must include appropriate signage on the door to the work area and indicate to the faculty member sharing the space that all of their lab personnel (staff or students) must be informed about the biohazardous agent(s) being utilized and the potential risks related to the agent(s).

If the research space is a laboratory classroom, the PI is the primary course instructor. No written agreement with other users of the classroom is required provided that the activities are in compliance with the Biosafety Level 1 (BSL-1) standards described in this document. Notification of other space users may be required when the agents utilized in the teaching or classroom activity require BSL 2 containment procedures.

2.7 Responsibilities of Laboratory Workers, Postdocs, Students, Individuals

All individuals working in laboratories at DePaul utilizing biohazardous agents must adhere to biological safety practices and techniques, including using the appropriate containment procedures and personal protective equipment (PPE) as directed by the supervisor or PI and as outlined in the protocol approved by the IBC and the specific laboratory SOPs.

Anyone working in the laboratory in a technical capacity versus a purely administrative capacity is defined as a laboratory worker, which includes faculty members, students, research assistants, visiting scholars, or staff. Each person must look out for his/her own safety and that of their co-workers. Every laboratory worker must:

- Complete required IBC training through the CITI program, when listed as personnel on a research protocol or as personnel on a teaching protocol
- Complete annual Laboratory Safety Training offered by Environmental Health and Safety
- Conscientiously follow lab-specific biosafety practices and procedures
- Inform the PI of any health condition that may be a result of or complicated by their work in the lab
- Report to the PI or the lab supervisor all problems, procedural discrepancies, spills, or accidental releases as soon as they occur
- Report to the appropriate institutional office or officials any significant violations in biosafety policy, practices, or procedures that are not resolved by the PI
- Refuse to take any adverse action against any person for reporting real or perceived problems or violations of procedures to supervisors, the PI, the Office of Research Services or members of the IBC.

Section 3: Education and Training

3.0 Introduction

The *NIH Guidelines* require that the institution provide training for IBC members and investigators to ensure the safe implementation of the *NIH Guidelines* for working with recombinant or synthetic nucleic acid molecules. The DePaul IBC has extended oversight responsibilities beyond those outlined in the *NIH Guidelines*. Therefore, additional regulatory requirements for training or education related to the use, storage, shipping, transport, or receiving of biohazardous agents other than recombinant or synthetic nucleic acid molecules have been adopted by the IBC. DePaul requires that all faculty, staff, and students working with biohazardous agents must complete biosafety training and other

required training, as necessary, in order to ensure that individuals are knowledgeable regarding the risks related to the specific agent(s) being utilized, recommended safety practices for the agent(s), and agent-specific containment procedures. The biosafety training requirements also extend to all IBC members and ORS staff with responsibilities related to the IBC. DePaul provides training access to the Collaborative Institutional Training Initiative (CITI) online training program and the IBC is a resource to investigators who may need assistance in creating protocol-specific or biohazard-specific training to their research staff.

Training requirements and the requirements for IBC review in general, are communicated to faculty, students and staff through the Office of Research Services web site, at new faculty orientation each fall, and through additional outreach and communication (e.g., Emails, newsletters, etc.).

3.1 IBC Member and Office of Research Services Staff Training

3.1.1 Initial Basic Training for IBC members and ORS Staff

IBC members are required to take basic initial biosafety training before they can vote on protocols at a convened IBC meeting. Office of Research Services (ORS) staff who have responsibilities related to the IBC are required to take biosafety training at the time of initial orientation to the staff position or at the time they are assigned IBC-related duties.

Each IBC member or ORS staff member will be provided with a resource binder that includes information and resources such as:

- A copy of DePaul's OBA registration
- A copy of the current IBC Policy and Procedure Manual and any other pertinent policies
- Copies of current regulations and guidance
- CDC and APHIS select agent and toxin information
- Information about the location of safety training, forms, templates, etc. currently listed on DePaul's IBC website.

DePaul currently utilizes the Collaborative Institutional Training Initiative (CITI) online training program to provide the required education to IBC members and ORS staff. "IBC members/Staff" is one learner group within the CITI program. The number of modules that an individual is required to complete is defined by their learner group. The exact number of modules and the module titles may change over time as regulations and guidance change or the training program is

improved. The topics covered in the required basic biosafety training in the CITI program for IBC members and ORS staff includes the following topics:

- Biosafety Course Overview
- Laboratory-Associated Infections
- Biohazardous Risk Assessment
- Medical Surveillance
- Risk Management
    - Work Practices
    - Personal Protective Equipment
    - Engineering Controls
    - Laboratory Design
    - Emergency & Spill Response Procedures
- NIH Guidelines for Research Involving DNA molecules
- Human Gene Transfer Research
- Select agents
- Bioterrorism
- Shipping Regulated Biological Materials
    - Overview
    - Security awareness
- Animal Biosafety
- Biosecurity
- Working Safely with Sharp Instruments
- Disinfection & Sterilization
- Centrifuge Precautious
- Safe Sharps Devices
- Understanding Nanotechnology & its Implications

In addition to the required modules, other modules in the CITI program have been designated as optional. Optional modules may be taken at the individual's discretion, but are not required. Optional modules become available to the user after completing the required modules.

At the end of most modules there is a multiple choice quiz that relates to that module content. In order to obtain credit for the training, individuals must complete the quiz after each module and obtain an overall average passing score of 80%. Individual quizzes may be re-taken, if necessary, in order to obtain a passing score.

If an individual is both an IBC member and an investigator, he/she would be required to take the modules in the IBC member learner group instead of investigator learner group, as this learner group has the largest number of modules and provides the training necessary to be an IBC member. If an individual were to become an IBC member after having completed the modules in the investigator learner's group, he/she would then need to complete any additional modules listed for IBC members.

3.1.2 Continuing Education and Training for IBC Members and ORS Staff

IBC members and ORS staff will receive continuing education and training through a combination of the following:

- Regularly scheduled education sessions during IBC meetings
- Just in time education sessions at IBC meetings, as needed, to enhance the protocol review process, and
- Attendance at local or national conferences pertaining to biosafety, webinars involving biosafety topics, or other professional level training programs.

When education sessions are presented at IBC meetings, educational materials are meant to be added to the member's resource binder for future reference.

3.2 Principal Investigator and Protocol Personnel Training

3.2.1 Biosafety Training

3.2.1.1 Initial Basic Training for PIs and Protocol Personnel

All persons working with biohazardous agents for research or teaching purposes must complete Basic Initial Biosafety Training. DePaul currently utilizes the Collaborative Institutional Training Initiative (CITI) online training program to provide the required training to faculty, staff and students at DePaul.

DePaul has created different learner groups within the CITI training program for people working on protocols requiring IBC review and approval. The learner groups relate to the role the individual has in the laboratory. The number of modules that an individual is required to complete is defined by their learner group. The exact number of modules and the module titles may change over time as regulations and guidance change or the training program is improved. The learner groups for investigators and research personnel are:

- Faculty/Teaching Assistants/Lab Coordinators/Research Personnel (including Grad Students)

- Undergraduate Students

Persons in the Faculty/Lab Coordinators/Research Personnel (including Grad students) learner group would be required to take modules in CITI covering the following topics:

- Biosafety Course Overview
- Laboratory-Associated Infections
- Biohazard Risk Assessment
- Medical Surveillance
- Risk Management
    - Work Practices
    - Personal Protective Equipment
    - Engineering Controls
    - Laboratory Design
    - Emergency Spill Response
    - NIH Guidelines for Research Involving rDNA
    - Work Safely with Sharp Instruments
    - Disinfection & Sterilization
    - Centrifuge Precautious
    - Safe Sharps Devices

Persons in the Undergraduate Students learner group would be required to take modules in CITI covering the following topics:

- Biosafety Course Overview
- Laboratory-Associated Infections
- Risk Management
    - Work Practices
    - Personal Protective Equipment
    - Engineering Controls
    - Laboratory Design
    - Emergency & Spill Response
    - NIH Guidelines for Research Involving rDNA
    - Work Safely with Sharp Instruments
    - Disinfection & Sterilization
    - Centrifuge Precautious
    - Safe Sharps Devices

At the end of most modules there is a multiple choice quiz that relates to that module content. In order to obtain credit for the training, individuals must complete the quiz after each module and obtain an overall average passing score of 80%. Individual quizzes may be re-taken, if necessary, in order to obtain a passing score.

Additional modules designated as optional are available in CITI. Optional modules may be completed at the discretion of the individual, but they are not required. Optional modules become available after completion of the required modules.

3.2.1.2 Continuing Education for PIs and Protocol Personnel

Continuing education may be required for the PI and protocol personnel based upon the protocol activities, the type of agents used in the activity and any changes to the protocol, policy, regulations or guidelines over time.

3.2.2 Shipping/Transporting Training for All Personnel Responsible for Shipping or Transporting Biohazardous Agents

Shipping or transporting infectious substances or materials, select agents, chemical preservatives, or dry ice is regulated as hazardous materials by the United States Department of Transportation (DOT), foreign governments, and the International Civil Aviation Organization. The regulations are designed to prevent the release of these materials in transit in order to protect the public, workers, property, and the environment from the harmful effects that may occur from exposure to these materials. Additional regulatory requirements apply to the transport of Select Agents or Toxins. The desired result is that training will result in a performance standard of safe shipping and handling of the biohazardous agents. The federal regulations for shipping and handling training hold the employer responsible for ensuring training of all personnel, maintaining records of training, and ensuring initial and ongoing training. It is possible that individuals who do not fall under the purview of the IBC due to the IBC definition of biohazardous agent may still require shipping or transport training in order to be compliant with federal regulations for shipping of biohazardous materials based upon the definition of biohazardous agent in the shipping regulations (See the regulation section in this manual). When that is the case, training is provided by Environmental Health and Safety.

In order to meet regulatory requirements for training of personnel involved in the shipping and transport of certain biohazardous agents (as defined in IBC policy), DePaul requires individuals involved in the shipping and transport of

biohazardous agents to complete shipping/transporting training in the CITI program. Shipping/transporting training and certification must be completed every 2 years for investigators and their staff directly involved or having a role in the shipping and transporting of biohazardous materials.
Documentation of completion of training must be available to the IBC/ORS during the review process for a specific protocol and before final IBC approval can be provided for the activity.

Written records of training must be received and retained by the DePaul ORS when related to an IBC protocol. The training records may include the individual's name, completion date of training, description of the training materials, the name of the trainer (if applicable), and certification that the DePaul individual has been trained and performance tested for their specific role by the person providing the training.

Shipping is defined as preparing a package to be carried by a commercial transport vendor such as Federal express, DHL, or international carriers. It also refers to preparing diagnostic samples for transport by a courier not employed by the laboratory doing the packaging, i.e., a courier from a diagnostic laboratory.

Transport is defined as preparing a package to be taken from one laboratory to another laboratory by personnel who understand the hazards or characteristics of the package contents. Transport can occur within one campus site, between campuses, or from campus to a non-campus location (i.e., collaborating institution).

Shipping/Transporting training covers the following topics:

- Shipping Regulated Biological materials
    - Overview
    - Classifications
    - Packaging requirements
    - Shipping papers
    - Permits for restricted shipments & transfers
    - Security awareness
    - Emergency response information
    - Refrigerants
    - Appendix

The exact module names and the number of modules may change over time as the training is revised and improved and as regulations change. At the end of most modules there is a multiple choice quiz that relates to that module. In order to obtain credit for the training, individuals must complete the quiz after each module and obtain an overall average passing score of 80%. Individual quizzes may be re-taken, if necessary, in order to obtain a passing score.

3.2.3 Receiving Training/Education for All Personnel Responsible for Receiving Shipments of Biohazardous Agents

Individuals whose role is limited to only receiving biohazardous agents are not required to take shipping training. However, receiving training/education must be completed by any individual who is delegated the responsibility of receiving, opening, and unpacking packages containing biohazardous agents. Individuals who are receiving shipments of biohazardous materials must complete training/education by reading the "Training/Education and Guidance for Receipt of Biohazardous Materials" document on the IBC website and provide their assurance of completing training/education following the instructions on the document. The training/education is required in order to ensure that the individual is knowledgeable regarding the risks related to the agent they are receiving, the appropriate storing and handling requirements (i.e., how to unpack properly) for the agent, and the appropriate packaging requirements for the agent in case of receipt of damaged packages.

Documentation of completion of the training/education will be maintained by the ORS. Copies of documentation should be kept by the Principal Investigator for each IBC protocol.

3.2.4 Blood Borne Pathogen Training For Individuals Working with Human Blood and Other Materials Potentially Containing Blood-borne Pathogens

Individuals working with human blood or other materials from humans covered by the OSHA blood borne pathogen regulations (e.g., human body fluids, human tissues, cultured human cells, or primary human cell lines or explants where the presence of an infectious agent may be unknown) must complete blood borne pathogen training offered by Environmental Health and Safety. The IBC will confirm with the office of Environmental Health and Safety that appropriate training of all personnel listed on a protocol has been completed before activities involving these materials will be approved by the IBC or before personnel are approved to work on a specific protocol.

3.2.5 Other Training Required for Laboratory Personnel

In addition to the general biosafety training through the CITI program, PIs are responsible for providing their laboratory personnel with training specific to the type of biohazardous agent(s) being utilized and with detailed information pertaining to the procedures to follow in the event of protocol-related accidents and spills or illnesses. The training should focus on the individual demonstrating proficiency with the necessary procedures and use of proper PPE to ensure their safety. The plan for provision of training by the PI is reviewed during the protocol review process and it is understood that all personnel who may work on a project may not necessarily have completed the protocol/agent-specific training at the time the protocol is submitted for IBC review. However, the training must be completed before an individual person may begin working with an agent on their own without supervision. The PIs must review the written laboratory Standard Operating Procedures (SOPs) with each laboratory worker. The written SOPs for each laboratory pertaining to biohazardous agents are reviewed by the IBC at the time of IBC protocol review. The written SOPs for a particular laboratory are for the laboratory as a whole and may contain reference to agents or procedures that relate to multiple IBC protocols.

3.3 Biosafety Training Record Requirements

Training records for all training including CITI and laboratory-specific training conducted by the PIs must be maintained by the PI and made available upon request to ORS or the IBC. The Office of Research Services will maintain all training records related to modules completed in CITI for Biosafety and shipping and for internal receiving education/training. The ORS will coordinate with DePaul's Environmental Health and Safety to ensure there is documentation of blood borne pathogen training or other training provided through that office, when required and related to a protocol being reviewed by the IBC. PIs are responsible for providing and documenting the provision of laboratory-specific training to all laboratory personnel. PIs must document the date of training and the content of training provided to each of their personnel. These training documents must be made available to the IBC upon request.

Section 4: IBC Membership and Meeting Procedures

4.0 IBC Composition

Under the *NIH Guidelines*, the IBC must:

- Be comprised of no fewer than five members, selected such that they collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of

recombinant or synthetic nucleic acid molecule research and identify any potential risk to public health or the environment.

- At least two members shall not be affiliated with the institution (apart from membership on the IBC) and who represent the interest of the surrounding community with respect to health and protection of the environment.
- At least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants* are conducted at the institution. The IBC must ensure that the transgenic plants and organism are decontaminated in accordance with Appendix P. Investigator SOPs must specifically indicate the plans for decontamination and disposal.
- At least one member with expertise in animal containment principles when recombinant or synthetic nucleic acid molecule research in accordance with Appendix Q, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals* is conducted at the institution.
- One member shall be a Biological Safety Officer, which is required under the *NIH Guidelines* when recombinant or synthetic nucleic acid molecule research involves BSL 3, BSL4, or large scale research (greater than 10 liters of volume in a single containment vessel). The DePaul IBC membership includes a BSO even though we do not currently conduct BSL3 or BSL4 activities.

Currently, DePaul does not conduct research that involves transferring recombinant or synthetic nucleic acid molecules into human subjects. In the future, if DePaul participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human subjects, the IBC will have adequate expertise and training by appointing an IBC member who has experience and training in the field of human gene transfer (and using *ad hoc* consultants when necessary), and DePaul will ensure that all aspects of Appendix M, *Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant or Synthetic Nucleic Acid Molecules into One or More Human Subjects (Points to Consider)*, have been addressed by the PI.

4.1 Ad hoc Consultants

When the IBC does not have the requisite experience and expertise to review a protocol, they will identify and utilize *ad hoc* consultants. The consultants will provide information at the IBC meetings, but may not participate in deliberations

or voting on a protocol. Consultants do not affect meeting quorum, since they are not voting members of the IBC and are not listed on the IBC roster.

4.2 Conflict of Interest

No Principal Investigator, research staff member, or IBC member will participate in the review, deliberations, or final determinations related to a protocol on which he/she or his/her spouse is listed as personnel, or if they are otherwise expected to be engaged in the conduct of the project, or has a financial or personal conflict of interest in the project. All Principal Investigators and/or IBC members are required to disclose any conflicts of interests related to a particular protocol either on the form or at the meeting that the protocol is reviewed. An IBC member with a conflict will be recused (leave the room) during deliberations and voting on their protocol.

4.3 Meeting procedures

A meeting agenda is prepared by an ORS staff member. The agenda lists the protocol submissions requiring review, educational materials, discussion items, minutes approved by the Chair via signature, and actions taken on behalf of the IBC under Designated Member Review (DMR) or Administrative Review (AR). All research and teaching activities that require IBC review and approval (other than those specifically noted as not needing convened IBC review and approval elsewhere in this policy) will be reviewed at a convened IBC meeting with a quorum of members present. When necessary, individual members may attend the meeting through teleconferencing procedures and need not attend the meeting in-person. However, teleconferencing procedures must allow for the members to interact fully in the meeting similar to when they attend in-person.

The IBC Chair will call the meeting to order when a quorum is present and follow the prepared agenda. A member of the ORS staff will take notes regarding the discussion and determinations and then prepares draft minutes. When all protocol items have been reviewed and all discussion items have been addressed, the Chair closes the meeting. Meeting agenda items may be addressed out of agenda order, when necessary.

4.4 Meeting Frequency

The IBC meets once per month, September through June for the academic year unless no protocols are submitted or otherwise require convened review. Rescheduling may occur due to an inability to achieve a quorum of members or additional meetings may be called if there are protocols or issues that arise that require immediate resolution. Meetings during the summer will be scheduled in the event that research or teaching protocols requiring approval before the beginning of the fall quarter are submitted, if outstanding protocol revisions

require review at the convened meeting, or if there is an urgent issue, such as potential noncompliance to review. If no protocol submissions or issues require review during the summer, the summer meetings will not be held.

4.5 Quorum requirements

A quorum of the IBC members must be in attendance at each convened meeting, either in-person or via teleconference, in order for official IBC business (protocol review and determinations) to be conducted. A quorum is defined as more than half (>50%) of the voting members of the IBC. In addition, at least one unaffiliated member must be present at each meeting to meet the quorum requirement. When applicable to the type of protocol being reviewed, a plant expert must be present when protocols involving activities under Appendix P are reviewed and an animal containment expert must be present when research covered under Appendix Q is being reviewed.

Members may attend the meeting in-person or via teleconference. An official protocol action, such as approval or requesting revisions, may only occur when a quorum of the voting members are present at the meeting and vote in favor of the determination. Abstentions from voting do not alter the quorum or change the number of votes required to make an action. When members are recused (leave the room during discussion and voting, are muted or disconnected for teleconferencing attendees) due to a conflict of interest, the quorum is affected and it is necessary to ensure that when the member with the conflict leaves the room or is muted/disconnected, there is still a quorum present to vote on any protocol actions.

4.6 Attendance by Non-Members

IBC meetings are open to the public or anyone at DePaul who wishes to attend the meetings, including members of the DePaul community and the public at large. The IBC may request that an investigator be available during a meeting to answer questions about their protocol. Investigators may also request that they attend a meeting at which their protocol is being reviewed to answer questions the IBC may have at the time of review. Anyone wishing to attend an IBC meeting should contact the Office of Research Services Research Protections staff via telephone or Email orp@depaul.edu. Last minute requests may not be honored if the meeting room cannot accommodate additional attendees.

4.7 Meeting minutes

The IBC meeting minutes serve as DePaul's record of the IBC's proceedings and document for the NIH/OBA and the public that the IBC is fulfilling the performance expectations of the *NIH Guidelines*. The *NIH Guidelines* requires that the IBC create and maintain meeting minutes that contain sufficient detail

about the discussion of the protocols and protocol issues in order to document the IBC's rationale for making their determinations. The IBC minutes are meant to be a record of the substantive issues discussed at the convened IBC meetings. Minutes are written such that they contain a sufficient level of detail so that a reasonable person could understand the nature of the discussion from reading the minutes. Minutes are not meant to be transcripts or kept at a level of detail that attributes each remark to a specific individual. The IBC should discuss and document the following related to each protocol reviewed:

- The date and place of the IBC meeting
- Whether the minutes of the prior IBC meeting(s) were approved
- Individuals in attendance at the IBC meeting
- The time (when) the meeting was opened and the time the meeting was adjourned, and when applicable, why the meeting was opened or closed (i.e., loss of quorum)
- The PI name
- Project title
- Verification that the PI and laboratory staff performing the activity have been appropriately trained in the safe conduct of the research
- The applicable section of the *NIH Guidelines* the activity falls under
- All major motions, major points of order, and whether motions were approved
- The agent characteristics (e.g., virulence, pathogenicity, environmental stability)
- Types of manipulations planned
- Source(s) of the nucleic sequences (e.g. species)
- Nature of the nucleic acid sequence (e.g. structural gene, oncogene)
- Host(s) and vector(s) to be used
- Whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced
- An assessment of the Risk Group of the agent(s) being utilized in the activity
- An assessment of the containment level required by the *NIH Guidelines* or the *BMBL* for the biohazardous agent being utilized and the containment conditions to be implemented (Biosafety level and any special provisions)
- An assessment of the facilities, procedures, practices, and training and expertise of the personnel involved in the research or teaching activity
- Demonstrate a periodic review (through annual renewal and triennial *de novo* review) of the recombinant or synthetic acid research to ensure ongoing compliance with the NIH Guidelines.

Additionally, the IBC is required to make the meeting minutes and any documents submitted to or received from funding agencies (e.g., rosters, biographical sketches, reports) available to the public (all people and entities). Methods for access to minutes must not be burdensome to either the public or the institution and may include U.S. mail, Email, or physical copies. DePaul University may charge the public to recover the cost of providing minutes, but the cost charged will be limited to the cost of copying and delivery. DePaul University reserves the right to redact information of a private or proprietary nature (e.g., trade secret information, confidential commercial information, research activities of a confidential nature, home telephone numbers and home addresses of IBC members, and specific information that if disclosed would directly compromise institutional, personal, or national security).

If public comments are made on IBC actions, DePaul must forward both the public comments and the IBC's response to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985.

ORS staff complete the meeting minutes shortly after the meeting. The completed meeting minutes are brought to the next available convened meeting for review and comment by the committee members. Any changes or revisions suggested at the meeting or by members are incorporated into the minutes. The final version of the minutes is ratified (approved) when the IBC Chair signs and dates the final corrected document. Ratified minutes are maintained in ORS with other IBC regulatory documents and files.

Section 5: Protocol Review Procedures

5.0 Activities that require IBC review and approval

The IBC evaluates and provides oversight to all aspects of research, teaching and other activities that involve recombinant or synthetic nucleic acid molecules, biohazardous agents, or select agents and toxins to ensure that these activities are compliant with federal regulations and guidelines and state and/or local laws.

No one shall obtain or use recombinant or synthetic nucleic acid molecules, biohazardous agents, or select agents and toxins at DePaul or on behalf of DePaul without obtaining written approval from the IBC or written confirmation of the NIH exempt category from ORS on behalf of the IBC Chair or designee. Modifications or changes to approved protocols must not be implemented until submitted to the IBC as an amendment and approved by the IBC.

Activities requiring IBC review and approval include, but are not limited to:

- All work with recombinant or synthetic nucleic acid molecules that potentially meet the exempt criteria in the *NIH Guidelines* must be submitted for exempt status confirmation (and receive written confirmation of exempt status from the IBC) before work can begin. The exempt status of the research will be confirmed through IBC Chair (or designee) exempt confirmation review. There is a short IBC form specific for this process.
- All work with recombinant or synthetic nucleic acid molecules covered under *NIH Guidelines* Section III A through III E.
    - The deliberate transfer of a drug resistance trait to micro-organisms that are not known to acquire the trait naturally
    - The deliberate transfer of recombinant DNA (rDNA) or RNA derived from rDNA into human research subjects (human gene transfer). Currently, research of this nature is not conducted at DePaul.
    - The deliberate formation of recombinant or synthetic nucleic acid containing genes for the biosynthesis of toxin molecules
    - The use of Risk Group 2 (RG-2) or RG-3 agents as host-vector systems. **Please note DePaul does not currently allow work with RG-3 agents.**
    - The use of human etiologic (disease causing) and animal viral etiologic agents
    - The cloning of DNA from RG-2 or greater agents into non-pathogenic prokaryotes or lower eukaryotic host-vectors systems
    - The use of infectious or defective RG-2 or greater agents
    - Whole animals in which the animal's genome has been altered by stable introduction of rDNA or DNA derived into the germ-line (transgenic animal)
    - Viable rDNA or synthetic nucleic acid -modified micro-organisms or cell lines tested on whole animals.
    - Genetically engineered plants by recombinant methods
    - More than 10 liters of recombinant or synthetic nucleic acid molecule culture in a single vessel
    - The formation of recombinant or synthetic nucleic acid molecules containing one-half or more of the genome of a eukaryotic virus from the same virus family
    - Activities requiring BSL-2, BSL-3, or BSL-4 containment procedures. **Note DePaul currently does not allow BSL-3 or BSL-4 work to be conducted at DePaul.**

- Non-recombinant research or teaching activities using biohazardous agents, select agents or toxins as defined in this policy.
- Research or teaching activities collecting or analyzing human or non-human primate cell lines, tissues, blood, blood components, blood products, or other bodily fluids or other potentially infectious material.

5.0.1 Recombinant and Synthetic Nucleic Acid Molecules

According to the *NIH Guidelines* there are six categories of experiments involving recombinant or synthetic nucleic acid molecules:

1. Those that require IBC approval, RAC review, and NIH Director approval before initiation and as described in **Section III-A** of the *NIH Guidelines*.
    - Experiments in this category are considered Major Actions under the *NIH Guidelines.*
    - The containment conditions or stipulation requirements for such experiments will be recommended by RAC and set by NIH at the time of approval.
    - **Section III A-1-a:** The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine or agriculture, will be reviewed by the RAC.
2. Those that require NIH/OBA and IBC approval before initiation and as described in **Section III-B** of the *NIH Guidelines.*
    - The containment conditions for such experiments will be determined by NIH/OBA in consultation with *ad hoc* experts.
    - **Section III-B-1:** Experiments Involving the Cloning of Toxin Molecules with LD_{50} of Less than 100 nanograms (ng) per kilogram (kg) body weight. This section involves deliberate formation of recombinant or synthetic nucleic acid molecules containing genes for biosynthesis of toxin molecules lethal for vertebrates at an LD_{50} of less than 100 nanograms per kilogram of body weight.
    - **Section III-B-2:** Experiments that have been approved under Section III-A-1 as Major Actions. This category includes experiments that the NIH/OBA determines is equivalent to an experiment previously approved by the NIH Director as a Major Action.
3. Those that require IBC and IRB approvals and RAC review before research participant enrollment as described in **Section III-C** of the *NIH Guidelines.*

- **Section III-C-1**-Experiments Involving Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into one or more human participants

4. Those that require IBC approval before initiation as described in **Section III-D** of the *NIH Guidelines.*
    - The Principal Investigator must submit a protocol application to the IBC which contains the following information: (i) the source(s) of DNA; (ii) the nature of the inserted DNA sequences; (iii) the host(s) and vector(s) to be used; (iv) if an attempt will be made to obtain expression of a foreign gene, and if so, indicate the protein that will be produced; and (v) the containment conditions that will be implemented as specified in the *NIH Guidelines*.
    - The IBC protocol application shall be dated, signed by the Principal Investigator, and filed with the Institutional Biosafety Committee.
    - **Section III-D-1**: Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems.
    - **Section III-D-2**: Experiments in Which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems.
    - **Section III-D-3**: Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems.
    - **Section III-D-4**: Experiments Involving Whole animals in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (transgenic animals) and experiments involving viable recombinant or synthetic nucleic acid molecule- modified microorganisms tested on whole animals.
    - **Section III-D-5**: Experiments Involving Whole Plants. This section includes experiments to genetically engineer plants by recombinant or synthetic nucleic acid molecules, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid molecules.

- **Section III-D-6**: Experiments Involving More than 10 Liters of Culture. The IBC determines the appropriate containment level using Appendix K as a guide.
- **Section III-D-7**: Experiments Involving Influenza Viruses. Experiments with influenza viruses generated by recombinant or synthetic methods shall be conducted at the containment level corresponding to the Risk Group of the virus that was the source of the majority of the sections of recombinant or synthetic virus.

5. Those that require IBC notification simultaneous with initiation as described in Section III-E of the *NIH Guidelines.* **Although the *NIH Guidelines* allow for simultaneous submission to the IBC and initiation of the activity, the *Guidelines* still require that the IBC review and approve any such registration type submissions. In order to ensure that activities in this category are appropriate for this category, DePaul IBC policy requires IBC review and confirmation of the NIH category and the BSL-1 containment requirements before initiation of the activity at DePaul.**
   - Protocols in this category only require BSL-1 containment procedures.
   - The protocol application sent to the IBC shall be dated and signed by the investigator.
   - **Section III-E-1:** Experiments Involving the Formation of Recombinant or Synthetic Nucleic Acid Molecules Containing No More than Two-Thirds of the Genome of a Eukaryotic Virus.
   - **Section III-E-2**: Experiments Involving Whole Plants. Includes experiments with modified arthropods or small animals associated with plants.
   - **Section III-E-3**: Experiments Involving Transgenic Rodents. Experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acid molecules derived therefrom, into the germ-line (transgenic rodents). *Experiments involving breeding of certain BL1 transgenic rodents are exempt under Section III-F.*
6. Those that are exempt from the *NIH Guidelines* as described in Section III-F. **Although the *NIH Guidelines* do not require prospective IBC approval for activities under this category, DePaul IBC policy requires IBC review and confirmation of the NIH exempt categorization before initiation of the activity.**

- In order for an entire protocol to be exempt all agents utilized in that protocol must meet the exemption criteria.
- Other federal and state standards of biosafety may still apply to such activities (for example, the Centers for Disease Control and Prevention (CDC)/NIH publication *Biosafety in Microbiological and Biomedical Laboratories* and because of this, the DePaul IBC requires review of NIH exempt activities through a Chair (or designee) confirmation process..
- **Section III-F-1**: Those synthetic nucleic acids that : 1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and 2) are not designed to integrate into DNA, and 3) do not produce a toxin that is lethal for vertebrates at an LD_{50} of less than 100 nanograms per kilogram body weight. Synthetic nucleic acid deliberately transferred into one or more human research subjects is not exempt.
- **Section III-F-2**: Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes.
- **Section III-F-3**: Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously (existing, occurring, or originating during the same time) in nature.
- **Section III-F-4**: Those that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host or when transferred to another host by well-established physiological means.
- **Section III-F-5**: Those that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
- **Section III-F-6**: Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of these Natural Exchangers can be found in Appendices A1-VI and will be updated periodically by NIH.

- **Section III-F-7**: Those genomic DNA molecules that have acquired a transposable element provided the transposable element does not contain any recombinant and/or synthetic DNA.
- **Section III-F-8**: Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with advice of the RAC, and following appropriate notice and opportunity for public comment. Appendix C of the *NIH Guidelines* lists for a list of exemptions under this section.

Any containment level changes for organisms which are different that those specified in the *NIH Guidelines* may not be initiated without specific approval from NIH/OBA.

5.0.2 CDC (HHS)/APHIS and USDA Select Agents and Biological Toxins

The transfer of select agents is regulated by 42 CFR Part 72 RIN 0905-AE70 "Interstate Shipment of Etiologic Agents" (see http://www.cdc.gov/od/ohs/biosfty/shipregs.htm). This rule places shipping and handling requirements on facilities that transfer or receive select agents listed in the rule that are capable of causing substantial harm to human health. Prior to transferring or receiving a select agent listed, a facility must register with the CDC through the DePaul Environmental Health and Safety. An individual person may not register; the registration must be from the institution. The registration form can be found at: http://www.selectagents.gov/forms.html . The following is a representative list of the CDC/APHIS select agents:

HHS (CDC) Agents and Toxins

- Abrin
- Botulism neurotoxins, Botulism neurotoxin producing species of *Clostridium*
- Conotoxins
- *Coxiella burnetti*
- Crimean-Congo hemorrhagic fever virus
- Diacetoxyscirpenol
- Eastern Equine Encephalitis virus
- Ebola virus
- *Francisella tularensis*
- Lassa fever virus
- Lujo virus
- Marburg virus
- Monkeypox virus

- Reconstructed replication competent forms of 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments.
- Ricin
- *Rickettsia prowazekii*
- SARS-associated coronavirus (SARS-Co-V)
- Saxitoxin
- South American Haemorrhagic Fever Viruses: Chapare, Guanarito, Juni, Machupo, Sabia
- Staphylococcal enterotoxins A, B, C, D, E subtypes
- T-2 toxin
- Tetrodoxin
- Tick-borne encephalitis complex (flavi) viruses: Far Eastern subtype, Siberian subtype
- Kyasanur Forest disease virus
- Omsk hemorrhagic fever virus
- Variola major virus (Smallpox virus)
- Variola minor virus (Alastrim)
- *Yersinia pestis*

<u>Overlap Select Agents and Toxins</u>

- *Bacillus anthracis*
- *Bacillus anthracis Pateur strain*
- *Brucella abortus*
- *Brucella melitensis*
- *Brucella suis*
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- Hendra virus
- Nipah virus
- Rift Valley fever virus
- Venezuelan equine encephalitis virus

<u>USDA Select Agents and Toxins</u>

- African horse sickness virus
- African swine fever virus
- Avian influenza virus
- Classical swine fever virus
- Foot and mouth disease virus
- Goat pox virus

- Lumpy skin disease virus
- *Mycoplasma capricolum*
- *Mycoplasma mycoides*
- Newcatle disease virus
- Peste des petits ruminants virus
- Ridnerpest virus
- Sheep pox virus
- Swine vesicular disease virus

USDA Plant Protection and Quarantine (PPQ) Select Agents and Toxins

- *Peronosclerospora phillippinesis (Peronosclerospora sacchari)*
- *Phoma glycincola (formerly Pyrenechaeta glycines)*
- *Ralstonia solanacearum*
- *Rathayibacter toxicus*
- *Scleropthora rayssiae*
- *Synchytrium endobioticum*
- *Xanthomonas oryzae*

The CDC/APHIS/USDA may inspect the facility using a Select Agent. Once a registration number has been provided from the CDC/APHIS/USDA to the University, all additional forms currently required by the CDC/APHIS to transfer the Select agent or toxins must be completed. Forms must be provided to the CDC/APHIS/USDA and be retained for five years after the shipment or after the agents are consumed or properly disposed, whichever is longer.

The list of select agents and toxins that includes the CDC, APHIS, and USDA agents can be found at: http://www.selectagents.gov/SelectAgentsandToxinsList.html . **The list is updated periodically, as needed.**

Currently, no research conducted at DePaul University is covered by this rule.

5.0.3 Other Biohazardous Agents, Infectious Agents and Pathogens

Other biohazardous agents such as bacterial agents, fungal agents, parasitic agents, rickettsial agents, viral agents, Arbovirus and related zoonotic viruses, toxin agents, and prion diseases will be reviewed and assigned Risk Groups and BSL containment levels utilizing the *BMBL* as guidance.

5.0.4 Biotoxins and Chemical toxins

Chemical toxins are only reviewed by the IBC as Biohazardous agents if the substances have (1) a significant risk of bioaccumulation (e.g. polychlorinated

biphenyls and polyfluoroalkyl substances) and the procedures may reasonably expose researchers. Qualifying chemical toxins must be used in accordance with the University Chemical Hygiene Plan and should be categorized as RG-1 and BSL-1 for administrative purposes on IBC protocol applications.

Biotoxins are toxins produced by a living organism. The IBC regulates the possession, use, and transfer of biotoxins, especially those with an LD_{50} of less than or equal to 100 mg/kg, and the organisms that produce these biological toxins. Some biotoxins are select agents and would be reviewed as such. For all types of biotoxins, the IBC risk assessment involving biotoxins will take into consideration the following:

- Biotoxin characteristics (e.g., LD_{50}, in solution or dry form, solubility)
- Risks inherent to experimental procedures and manipulations (e.g., auto inoculation, inhalation of unintentional aerosols, static build-up when working with powders)
- Total amount of toxin used relative to the estimated human lethal or cytotoxic dose
- Volume of the material manipulated
- Exposure route
- Availability of successful treatment, vaccines, or antitoxins
- Training and experience of personnel.

The risk assessment determines the risk group and the required containment level for work with biotoxins.

Biotoxins with an LD_{50} of less than 50 mg/kg (e.g., cholera toxin, microcystin, aflatoxin, and ricin) are classified as risk group 2 biotoxins requiring Biosafety Level 2 containment procedures. Biotoxins with an LD_{50} greater than 50 mg/kg, such as Lipopolysaccharide (LPS), may be downgraded to Biosafety Level 1 depending on the procedures utilized and how the biotoxin is being used.

Biotoxins are frequently stored in a lyophilized powder form. Solubilizing powder to formulate a stock solution presents a risk to the researcher because of the possibility of dispersal of the powder into the air. Procedures must be designed to minimize the risk of aerosol disbursement and the likelihood of inhalation of the toxin. For example, work should be conducted in a chemical fume hood, appropriate PPE must be worn, dilution should occur using a syringe and needle. Once the needle has been used to wet the powder, the needle and syringe should be disposed of properly and not reused. If the biotoxin solution is created in micro centrifuge tubes, the use of static guard on gloves is recommended, gloves should be resistant to the diluent, and full-face PPE should be utilized. In addition, the

vials should be opened in an isolated portion of the lab with limited airflow and any adding of diluent, mixing, or vortexing should be done in a chemical fume hood. Once the powder is wetted the tube can be opened carefully without concern about air dispersal.

5.0.5 Human Blood, Blood Components, Blood Products, Human Fluids, Human Tissue, and Other Potential Blood Containing Materials

The Occupational Safety and Health Administration (OSHA) issued Blood Borne Pathogens (BBP) Standard to protect employees who have occupational exposure to human blood or other potentially infectious materials. Protocols that involve the use of these human materials must be reviewed by the IBC. In addition, there must be a Blood Borne Pathogen Plan and written laboratory SOPs for BSL2 containment procedures for any laboratory utilizing human blood, tissue, or fluids following the content requirements set by DePaul Environmental Health and Safety. Additionally, each laboratory working with BSL2 agents must have and pass a lab inspection before work begins and annually to ensure that the BSL2 containment standards are being utilized.

Blood borne pathogen training is required for all personnel working with these agents. The training is offered through DePaul Environmental Health and Safety. Confirmation of completed training must be received by the Office of Research Services before final IBC approval for a protocol involving these types of materials can be issued.

5.0.6 Human Cell Lines and Cultures

The Occupational Safety and Health Administration (OSHA) issued Bloodborne Pathogens (BBP) Standard to protect employees who have occupational exposure to human blood or other potentially infectious materials. Human blood, most body fluids, unfixed human tissues and organs are clearly included in the OSHA standard, but whether or not human cell lines are included was ambiguous.

In 1994, OSHA issued an interpretation of the applicability of the BBP standard towards human cell lines. According to the interpretation, human cell lines, human cell explants from tissues and subsequent *in vitro* passages of human tissue explant cultures are considered to be potentially infectious and within the scope of the BBP Standard unless the specific cell line has been characterized to be free of hepatitis virus, HIV, Epstein-Barr virus, human papilloma viruses and other recognized blood borne pathogens. In alignment with OSHA's interpretation, the American Type Culture Collection (ATCC) recommends that all human cell lines be accorded the same level of biosafety consideration as a line known to carry HIV. The *BMBL* recommends that human and other primate cells should be handled using Biosafety Level 2 (BSL-2) practices and containment. Likewise,

animal tissues, explants, or cell cultures known to be contaminated by deliberate infection with human immunodeficiency virus or Hepatitis B virus are also subject to OSHA Bloodborne Pathogen regulations.

The revised *NIH Guidelines* indicate workers who handle or manipulate human or animal cells are at risk for possible exposure to potentially infectious latent and adventitious agents that may be present in these cells and tissues. For example, there is documented reactivation of herpes virus from latency, transmission of disease to organ recipients, and the persistence of human immunodeficiency virus (HIV), HBV, and hepatitis C virus (HCV) within infected individuals, and accidental transplantation of human tumor cells to healthy recipients which indicates potential hazards to workers who handle them. In addition, human or animal lines that are not well characterized or are obtained from secondary sources may introduce an infectious agent into the laboratory. It is this potential for human cell lines to harbor blood borne pathogens that lead OSHA to interpret that the final guidelines for occupational exposure would include primary human cell lines and explants.

If the non-transformed human cells strains are documented to have undergone reasonable laboratory testing to be free of HIV, hepatitis viruses, or other blood borne pathogens they may be exempted from the OSHA Bloodborne Pathogen regulations.

Based upon the regulatory interpretation and guidelines, the DePaul IBC has adopted the following policy regarding the use of human cell lines.

- Unless the researcher or investigator has written documentation of screening for blood borne pathogens, all cell and organ cultures of Human or Non-Human Primate origin, including established cell lines, must be handled in accordance with the OSHA Bloodborne Pathogens Standard and under BL-2 containment procedures.
- Researchers and investigators are required to:
    - Post appropriate signage in the areas where work will be conducted
    - Complete Biosafety training as required by Environmental Health and Safety
    - Prepare laboratory Standard Operating Practices (SOPs) and a Blood Borne Pathogens plan following guidance from Environmental Health and Safety.
    - Submit the activity to the DePaul IBC for review and approval
    - Ensure compliance with OSHA required Occupational Health and Safety practices for blood borne pathogens

OSHA Letter of Interpretation:
https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=21519

American Type Culture Collection Frequently Asked Questions:
https://www.atcc.org/support/faqs/26699/Biosafety%2blevel%2bfor%2bATCC%2bcultures-9.aspx

BMBL, 5th Edition:
http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5_appendixH.pdf

5.0.7 Transgenic Plants and Animals

The *Guidelines* require physical and biological containment for experiments involving the use of transgenic plants, animals, and insects. The *Guidelines* do not permit experiments involving deliberate release of transgenic organisms into the environment unless another Federal agency has jurisdiction over the experiment and has approved of the release. Investigators must be knowledgeable regarding the proper containment levels and disposal procedures for transgenic plants, animals, and insects.

5.0.8 Chemical Biohazardous Agents

OSHA Occupational Safety and Health Standards, Hazard Communication (29 CFR 1910.1200) require that all chemicals produced or imported are classified, and that information concerning the classified hazards is transmitted to employers and employees. Classifying the potential hazards of chemicals and communicating information concerning hazards and appropriate protective measures to employees is the responsibility of the PI. This may be done by providing copies of the Safety Data Sheets (SDS) sheets to laboratory personnel and maintaining laboratory SOPS that inform the laboratory personnel of information to handle spills or exposure.

5.0.9 Teaching Protocols

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, biological toxins, select agents or 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. It does not matter who conducts the experiment (researcher, student, or teacher) or why the experiment is being conducted (research or teaching purposes). A teaching lab or activity falls under the purview of the IBC when it utilizes a biohazardous agent, whether NIH

exempt or not and no matter the risk level or containment level. At this time only activities with agents requiring BSL1 and BSL 2 containment procedures may be conducted at DePaul. 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 this policy and procedure manual.

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)

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. To provide the required annual report, 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 by ORS. However, the proper training and education must be completed in order for the personnel to be added to the protocol.

On the application, the instructor must make an initial risk assessment for the agent(s) being utilized in the class or experiment based on the Risk Group for the agent and also make the initial biosafety containment level assessment. DePaul only allows the use of agents that are in Risk Group 1 and 2 and that require biosafety containment procedures at the BSL 1 and BSL 2 level.

In addition to the general biosafety practices outlined in the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* DePaul also follows the recommendations for safety in teaching laboratory classes as outlined by the *Guidelines for Biosafety in Teaching Laboratories* and the *Appendix to the Guidelines for Biosafety in Teaching Laboratories* as published by the American Society for Microbiology in 2012. http://www.asm.org/index.php/education2/22-education/8308-new-version-available-for-comment-guidelines-for-best-biosafety-practices-in-teaching-laboratories. These guidelines were developed after a multistate outbreak of *Salmonella typhimuirium* which originated in teaching and clinical laboratories in 2011. A similar incident occurred in 2014, which reinforced the need for these guidelines and the need for institutions with teaching laboratory classes to implement these practices. The *Guidelines for Biosafety in Teaching Laboratories* include recommendations for activities at the BSL1 and BSL2 levels.

As stated in the *Guidelines for Biosafety in Teaching Laboratories*, "Educators need to be aware of the risks inherent in using microorganisms in the laboratory and must use best practices to minimize risk to students and the community." It is understood that undergraduate non-microbiology laboratories would almost always involve agents requiring only BSL1 containment procedures. However, it is also noted that that most microorganisms used in microbiology teaching laboratories are capable of causing an infection in the appropriate circumstances. The *Guidelines for Biosafety in Teaching Laboratories* present best practices that should be adopted to minimize the risk of an acquired infection and to train

students properly in handling of microorganisms. Several of the guidelines are similar to those found in the *BMBL*, but these recommendations are specific to microorganisms that may be utilized in microbiology laboratory classes.

The *Guidelines for Biosafety in Teaching Laboratories* make the following recommendations for BSL 1 activities:

Personal Protective Requirements for Students and Instructors

- Wear safety goggles or safety glasses when handling liquid cultures, when performing procedures that may create a splash hazard, or when spread plating.
- Wear close-toe shoes that cover the top of the foot
- Students and instructors should wear gloves when their hands have fresh cuts, open wounds, or abrasions, when staining microbes, and when handling hazardous chemicals. Double gloving is highly recommended when cuts, open wounds, or abrasions are present. Gloves are not required for standard laboratory procedures if proper hand hygiene is performed. Proper hand hygiene involves thorough hand cleansing prior to and immediately after finishing handling microorganisms and any time microbes accidently contact the skin. Hand cleansing is performed by washing with soap and water or rubbing with an alcohol-based hand sanitizer.
- Recommended: Wear laboratory coats.

Laboratory Physical Space Requirements

- Require all laboratory space to include:
    - Nonporous floor, benchtops, chairs, and stools.
    - Sink for hand washing.
    - Eyewash station.
    - Lockable door to the room.
- Follow Proper pest control practices.
- Recommended: Keep personal belongings in an area separate from the work area.
- Recommended: Use a working and validated autoclave.

Stock Culture Requirement

- Only use cultures from authorized, commercial, or reputable sources (e.g., an academic laboratory or state health department). Do not subculture unknown microbes isolated from the environment, because they may be organisms that require BSL2 practices and facilities.

- Maintain documents about stock organisms, sources, and handling of stock cultures.
- Obtain fresh stock cultures of microorganisms annually (e.g., purchased, revived from frozen stock cultures, etc.) to be certain of the source culture, minimize spontaneous mutations, and reduce contamination.

Standard Laboratory Practices

- Wash hands after entering and before exiting the laboratory.
- Tie back long hair
- Do not wear dangling jewelry.
- Disinfect bench before and after the laboratory session with a disinfectant known to kill the organisms handled.
- Use disinfectants according to manufacturer instructions
- Do not bring food, gum, drinks (including water), or water bottles into the laboratory.
- Do not touch the face, apply cosmetics, adjust contact lenses, or bite nails.
- Do not handle personal items (cosmetics, cell phones, calculators, pens, pencils, etc.) while in the laboratory.
- Do not mouth pipette.
- Label all containers clearly.
- Keep door closed while the laboratory is in session. Laboratory director or instructor approves all personnel entering the laboratory.
- Minimize the use of sharps. Use needles and scalpels according to appropriate guidelines and precautions.
- Use proper transport vessels (test tube racks) for moving cultures in the laboratory, and store vessels containing cultures in a leak-proof container when work with them is complete.
- Use leak-proof containers for storage and transport of infectious materials.
- Arrange for proper (safe) decontamination and disposal of contaminated material (e.g., in a properly maintained and validated autoclave) or arrange for licensed waste removal in accordance with local, state, and federal guidelines.
- Do not handle broken glass with fingers; use a dustpan and broom. The instructor or Teaching Assistant should clean up the broken glass.
- Notify instructor of all spills or injuries.
- Document all injuries according to school, university, or college policy.
- Use only institutional-provided marking pens and writing instruments.
- Teach, practice, and enforce the proper wearing and use of gloves.

- Advise immune-compromised students (including those who are pregnant or may become pregnant) and students living with or caring for immune-compromises individuals to consult physicians to determine the appropriate level of protection in the laboratory.
- Recommended: Keep note-taking and discussion practices separate from work with hazardous or infectious materials.
- Recommended: Use microincinerators or disposable loops rather than Bunsen burners.

Training Practices

- Be aware that student assistants may be employees of the institution and subject to OSHA, state, and/or institutional regulations.
- The PI of the IBC protocol related to the teaching activity or his/her designee (e.g., lead instructor for the class) should conduct extensive initial training for instructors and student assistants to cover the safety hazards of each laboratory. The institution's biosafety officer or microbiologist in charge of the laboratories could conduct the training.
- The PI of the IBC protocol or his/her designee (e.g., lead instructor) should conduct training for all instructors whenever a new procedural change is required.
- Require students and instructors to handle microorganisms safely and responsibly.
- Inform students of safety precautions relevant to each exercise before beginning the exercise.
- Emphasize to students the importance of reporting accidental spills and exposures.

Document Practices

- Require students to sign safety agreements explaining that they have been informed about safety precautions and the hazardous nature of the organisms they will handle throughout the course.
- Maintain student-signed safety agreements at the institution.
- Prepare, maintain, and post proper signage.
- Document all injuries and spills; follow university policy, if available.
- Make Material Safety Data Sheets (MSDS) available at all times; follow institutional documentation guidelines regarding number of copies, availability via print or electronic form, etc.
- Post emergency procedures and updated information in the laboratory.

- Maintain and make available (e.g., in a syllabus, in a laboratory manual, or online) to all students a list of all cultures (and their sources) used in the course.

The *Guidelines for Biosafety in Teaching Laboratories* indicates for BSL2 activities, BSL2 is suitable for organisms that pose a moderate individual risk and low community risk of infection. When good microbiological techniques are used, these organisms rarely cause serious disease, and effective treatment for laboratory-acquired infections is available. Best practices must be adopted to minimize the risk of laboratory-acquired infections and to train students in the proper handling of organisms that require BSL2 procedures. Students should always demonstrate proficiency in laboratory technique using organisms that require BSL1 practices before being allowed to handle organisms that require BSL2 practices.

The *Guidelines for Biosafety in Teaching Laboratories* make the following recommendations for BSL 2 activities:

<u>Personal Protective Requirements for Students and Instructors</u>

- Wear safety goggles or safety glasses for normal laboratory procedures involving liquid cultures that do not generate a splash hazard (e.g., proper pipetting, spread plats, etc.). Use safety goggles and face shields or safety goggles and masks when performing procedures that may create a splash hazard. If work is performed in a biological safety cabinet, goggles and face shields/masks do not need to be worn.
- Wear closed-toe shoes that cover the top of the foot.
- When appropriate, wear gloves when handling microorganisms or hazardous chemicals,
    - If open wounds, cuts, or abrasions are present, then double gloving should be utilized for BSL-2 activities.
- Wear laboratory coats

<u>Laboratory Physical Space Requirements</u>

- Require all laboratory space to include:
    - Nonporous floor, bench tops, chairs, and stools.
    - Sink for hand washing.
    - Eyewash station.
    - Lockable door to the room.
- Follow proper pest control practices.
- Keep the storage area for personal belongings separate from work area.

- Keep a working and validated autoclave in the building or arrange for licensed waste removal according to local, state, and federal regulations.
- Post biohazard signage
    - Wherever cultures are used and stored.
    - On the door to the room.
    - On any containers used to transport cultures.
- Recommended: Have a biological safety cabinet. The biological safety cabinet is required when large volumes of culture are used or when a procedure will create aerosols.

Stock Culture Requirements

- Only use cultures from authorized, commercial, or reputable sources (e.g., an academic laboratory or state health department). Maintain documents about stock organisms, sources, and handling of stock cultures.
- Obtain fresh stock cultures of microorganisms annually (e.g., purchased, revived from frozen stock cultures, etc.) to be certain of the source culture, minimize spontaneous mutations, and reduce contamination.
- Keep stock cultures in a secure area.

Standard Laboratory Practices

- Wash hands after entering and before exiting the laboratory.
- Tie back long hair.
- Do not wear dangling jewelry.
- Disinfect bench before and after the laboratory session with a disinfectant known to kill the organisms handled.
- Use disinfectants according to manufacturer instructions.
- Do not bring food, gum, drinks (including water), or water bottles into the laboratory.
- Do not touch the face, apply cosmetics, adjust contact lenses, or bite nails.
- Do not handle personal items (cosmetics, cell phones, calculators, pens, pencils, etc.) while in the laboratory.
- Do not mouth pipette.
- Label all containers clearly.
- Keep door closed while the laboratory is in session. Laboratory director or instructor approves all personnel entering the laboratory.
- Minimize use of sharps. Use needles and scalpels according to appropriate guidelines and precautions.

- Use proper transport vessels (test tube racks) for moving cultures in the laboratory and store vessels containing cultures in a leak-proof container when work with them is complete.
- Use leak-proof containers for storage and transport of infectious materials.
- Use microincinerators or disposable loops rather than Bunsen burners.
- Arrange for proper (safe) decontamination and disposal of contaminated material (e.g., in a properly maintained and validated autoclave) or arrange for licensed waste removal to local, state, and federal regulations.
- Do not handle broken glass with fingers; use a dustpan and broom. It is recommended the instructor or Teaching Assistant should clean up the broken glass.
- Notify instructor of all spills or injuries.
- Document all injuries according to university or college policy.
- Keep note-taking and discussion practices separate from work with hazardous or infectious material.
- Use only institution-provided marking pens and writing instruments when handling BSL-2 agents.
- Teach, practice, and enforce the proper wearing and use of gloves.
- Advise immune-compromised students (including those who are pregnant or may become pregnant) and students living with or caring for an immune-compromised individual to consult physicians to determine the appropriate level of participation in the laboratory.

<u>Training Practices</u>

- Be aware that student assistants may be employees of the institution and subject to OSHA, state, and/or institutional regulations.
- The PI of the IBC protocol for the teaching activity or his/her designee (e.g., lead instructor) should conduct extensive initial training for instructors and student assistants to cover the safety hazards of each laboratory. The institution's biosafety officer or microbiologist in charge of the laboratory may conduct the training.
- The PI of the IBC protocol for the teaching activity or his/her designee (e.g., lead instructor) should conduct training for instructors whenever a new procedural change is required.
- The PI of the IBC protocol covering the teaching activity or his/her designee (e.g., lead instructor) should conduct training for student assistants annually.
- Require students and instructors to handle microorganisms safely and responsibly.

- Require students to demonstrate competency at BSL1 before working in a BSL2 laboratory.
- Inform students of safety precautions relevant to each exercise before beginning the exercise.
- Emphasize to students the importance of reporting accidental spills and exposures.

Document Practices

- Require students to sign safety agreements explaining that they have been informed about safety precautions and the hazardous nature of the organisms they will handle throughout the course.
- Maintain student-signed safety agreements at the institution.
- Prepare, maintain, and post proper signage.
- Document all injuries and spills; follow university policy, if available.
- Make Material Safety Data Sheets (MSDS) available at all times; follow institutional documentation guidelines regarding number of copies, availability via print or electronic form, etc.
- Post emergency procedures and updated contact information in the laboratory.
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- Maintain and make available (e.g., in a syllabus, in a laboratory manual, or online) to all students a list of all cultures (and their sources) used in the course.
- Keep a biosafety manual specific to the laboratory and/or course in the laboratory.
- Keep a copy of the current version of the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* in the laboratory.

The *Appendix to the Guidelines for Biosafety in Teaching Laboratories* provides expanded discussions or the information in the *Guidelines for Biosafety in Teaching Laboratories*, but also provides additional guidance in topics, such as Biological safety cabinets, microincinerators, disinfectants, decontamination and disposal procedures, isolation of unknown microbes from the environment, cultivation of fungi, autoclave validation, pet control, substitution of organisms, and sample forms for use by instructors in the laboratory to implement the practices outlined in the guidelines.

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 gents.
- 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.
- 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.

5.0.9.1 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 IBC is also concerned for the health and safety of the individuals working in the field with such samples.

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

- When possible, enrichment cultures should be incubated at 28 degrees C or cooler to reduce the risk of isolating pathogenic organisms.
- Direct environmental samples that are likely to contain infectious organisms should be handled using BSL-2 precautions. Plating isolates from environmental samples can be done in a BSL1 lab. These plates should be sealed, stored in a secure location, and only observed, not opened or subcultured. After observation, the plates must be decontaminated by autoclaving and properly disposed of. Subculturing of environmental samples (enriching organisms derived from environmental

samples) should only be performed in a BSL 2 lab using BSL 2 precautions.

- When possible, culture media used for the enrichment of environmental isolates should contain an anti-fungal agent.
- 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.
    - Teaching activities with unknown microorganisms can be treated as BSL 1 when: 1) organisms are cultured in a Petri dish (or other standard unbreakable container) which is sealed. 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).
    - 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.
    - 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.
    - When possible, enrichment cultures should be incubated at 28 degrees C or cooler to reduce the risk of isolating pathogenic organisms.
    - Direct environmental samples that are likely to contain infectious organisms should be handled using BSL-2 precautions, unless the instructor justifies the use of BSL 1 containment procedures in the initial IBC protocol submission based upon experience and expertise working with the specific environmental sample.
- If you cultivate fungi in the laboratory, it is highly recommended that you keep them in separate incubators and/or refrigerators dedicated for fungal growth and storage. These storage units should be frequently cleaned with

bleach. Fungal cultures should be opened and transferred in a dedicated area or biological safety cabinet, away from bacterial cultures and it must be done using BSL 2 precautions.
    - 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.

5.0.9.2 Courses Involving Cell or Tissue Culture

Instructors should refer to the sections of this IBC policy and procedure manual for guidelines related to cell and tissue culture when these agents are utilized as part of a course. The same guidelines for research activities utilizing these agents applies when these materials are utilized for teaching activities.

5.1 Risk Group Assessment

The assignment of the risk group is a subjective process. The investigator must make an initial risk assessment based on the guidance about the Risk Groups (RG) of agents in the *NIH Guidelines*, the *BMBL*, and other sources (i.e., agent vendor catalogs, SDS, literature, etc.). The investigator should provide the IACUC with the materials used to make the initial Risk Group assessment, such as providing the literature citation or a copy of any other sources (i.e., SDS, vendor catalogs, etc.). The IBC must make the final determination of the Risk Group (RG) during the IBC review process and has the final word regarding the assigned Risk Group determination. The IACUC will utilize the materials provided by the investigator to make the final determination and these materials will be kept as a part of the protocol record. Appendix B of the *NIH Guidelines* can be used as a resource for making this determination. Under the *NIH Guidelines* and the *BMBL* there are four Risk Groups, according to their relative pathogenicity for healthy adult humans. DePaul University currently can only support research or other activities within Risk Groups 1 or 2. The following represents a summary of the combination of the *NIH Guidelines* and *BMBL* standards:

Risk Group 1 (RG1): Risk Group 1 agents are not associated with disease in healthy human adults. A complete list of these agents can be found in the *NIH Guidelines* under Appendix B (Classification of Human Etiologic Agents on the Basis of Hazard). Examples include asporogenic *Bacillus subtilis or Bacillius lichenformis.* A strain of *E. coli* is considered RG1 if it does not possess a complete lipopolysaccharide (lacks the O antigen) and does not carry any active

virulence factor or colonization factors and does not carry any genes encoding these factors.

Risk Group 2 (RG2)*:* Risk Group 2 agents are associated with human disease which is rarely serious and for which preventative or therapeutic interventions are *often* available.

Risk Group 3 (RG3): Risk Group 3 agents are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available. (High individual risk, but low community risk)

Risk Group 4 (RG4): RG4 agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available. (High individual risk and high community risk)

It is important to remember that the Risk Groups are based upon the potential risk to persons based upon the effect of the biological agent on a healthy human adult and they do not account for instances in which an individual may have increased susceptibility to such agents due to preexisting medical conditions or diseases, medications, compromised immunity, or during pregnancy or breastfeeding.

During the protocol review process, the IBC must make an independent determination of the Risk Group of the agent(s) being utilized. The risk assessment process should begin with identifying the risk group of the agent, then considering how the agent will be manipulated. For example the final agent may be more or less virulent than the parent strain and the Risk Group may need to be adjusted accordingly. The process of risk assessment involves identifying the hazardous characteristics (e.g., routes of infection, infectious dose, stability in the environment, host range, and endemic nature) of a known infectious or potentially infectious agent or material, the activities that can result in a person's exposure to an agent, the likelihood that such exposure will cause an adverse event, reaction, or infection, and the probable consequences of such a reaction.

PIs should use the risk assessment to alert staff members to the hazards related to working with the agents and the need for developing proficiency in the practices and equipment required to contain the agent(s).

When work involves the use of laboratory animals, the hazardous characteristics of zoonotic agents should be carefully considered in the risk assessment. Animals may shed zoonotic agents and other infectious agents in saliva, urine, or feces and these agents may then infect humans.

Once the final risk group determination is made, the IBC must then make a determination for the appropriate containment conditions. The RG assessment is documented in the IBC meeting minutes and communicated to the PI in the approval letter.

5.2 Biosafety Level Containment Determination

Biosafety containment levels consist of a combination of laboratory practices and techniques, containment or safety equipment, laboratory design, and laboratory facilities that are appropriate to the type of activity being performed and based upon the potential hazard of the agent being used. The PI makes an initial determination regarding the Biosafety Level (BSL). The IBC makes the final BSL determination during the review process. The *NIH Guidelines* (in Appendix G, *Physical Containment* and Appendix I, *Biological Containment*) and the *BMBL* (in Section IV, *Laboratory Biological Safety Criteria*) have established four levels of protection for research and other activities involving infectious microorganisms, biohazardous agents and laboratory animals. The levels are designated in ascending order, by degree of protection provided to personnel, the environment, and the community. It is important to note that the Risk Group and the BSL containment level are not always directly comparable. In other words, the RG may be RG1, but the containment level may be BSL2.

Biosafety levels were created to represent the conditions under which the agent ordinarily can be safely handled. Generally, biological safety cabinets are not required for activities involving Risk Group 1 agents requiring Biosafety Level 1 (BSL 1) containment procedures. At this time, research and other activities involving biohazardous agents at DePaul University may only be conducted under BSL 1 and BSL 2 levels.

The *NIH Guidelines* also describe specific biosafety containment levels for research involving plants (Appendix P of the *Guidelines*) and for research involving animals (in Appendix Q of the *Guidelines*). Additionally, the *BMBL* includes additional Biosafety Level information for work with vertebrate animals referred to as Animal Biosafety Levels (ABSLs). Investigators working with plants or animals should refer to these reference materials for additional guidance on containment procedures.

The following Biosafety level descriptions are a combination of the *NIH Guidelines* and the *BMBL* standards:

Biosafety Level 1 (BSL1): BSL 1 is suitable for work involving well characterized agents not known to consistently cause disease in immunocompetent adult humans and present minimal potential hazard to laboratory personnel and the environment. The laboratory is not separated from the general traffic patterns in the building. Work is typically conducted on open bench tops using standard microbiological practices. Special containment equipment or laboratory design is not required, but may be used if appropriate. Laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised by a scientist with general training in microbiology or a related science. The following standards apply to BSL 1:

- Standard Microbiological Practices for BSL 1
    - Access to the laboratory is limited or restricted at the discretion of the PI when experiments are in progress and in compliance with institutional policies.
    - Signage incorporating the universal biohazard symbol must be posted at the entrance of the laboratory when infectious agents are present. The sign may include the name of the agent(s) in use, and the name and phone number of the laboratory supervisor or other responsible personnel. The signage should be posted in accordance with institutional policy.
    - Work surfaces are decontaminated once a day and after any spill of viable material.
    - All cultures, stocks, and other potentially infectious materials are decontaminated before disposal using an effective method.
    - All contaminated liquid or solid wastes are decontaminated before disposal.
    - Mechanical pipetting devices are used; mouth pipetting is prohibited.
    - Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal. Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.

    - Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible.
    - Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the work area. Food may be stored outside the laboratory in cabinets or refrigerators designated and used for that purpose only.
    - Persons wash their hands after they handle materials involving organisms containing recombinant or synthetic nucleic acid molecules, other biohazardous agent, and animals, and before exiting the laboratory.
    - All procedures are performed carefully to minimize the creation of aerosols and/or splashes.
    - In the interest of good personal hygiene, facilities (e.g., hand washing sink, shower, changing room) and protective clothing (e.g., uniforms, laboratory coats) shall be provided that are appropriate for the risk of exposure to viable organisms containing recombinant or synthetic nucleic acid molecules or other biohazardous agents.
    - The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of childbearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.
- Special Practices for BSL 1
    - Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak-proof container which is closed before being removed from the laboratory.
    - An insect and rodent control program is in effect.
- Containment Equipment for BSL 1

    - Special containment equipment is generally not required for manipulations of agents assigned to BSL 1.
- Safety Equipment (Primary Barriers and Personal Protective Equipment)
    - Protective coats, gowns, or uniforms are recommended to prevent contamination of personal clothing.
    - Wear protective eyewear when conducting procedures that have the potential to create splashes or microorganisms or other hazardous materials. Persons who wear contact lenses in the laboratory should also wear eye protection.
    - Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based upon the risk assessment. Alternatives to latex gloves should be available. The IBC requires that when BSL 2 agents are being utilized, any person with cuts, open wounds, or abrasions use double gloving. Double gloving is highly recommended when working with BSL1 agents I these instances.
    - Hands should be washed before leaving the laboratory.
- Laboratory Facilities (Secondary Barriers) for BSL 1
    - Laboratories should have doors for access control.
    - The laboratory is designed so that it can be easily cleaned. Carpets and rugs in laboratories are not appropriate.
    - Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, other chemicals, and moderate heat.
    - Laboratory furniture is sturdy and capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning.
    - Chairs used in the laboratory must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
    - Each laboratory contains a sink for hand washing.
    - If the laboratory has windows that open, they are fitted with fly screens.

Biosafety Level 2 (BSL 2): Biosafety Level 2 builds upon BSL 1 and is suitable for working with agents of moderate potential hazard to personnel and the environment. It differs from BSL 1 in that: 1) laboratory personnel have specific training in handling pathogenic agents and are directed or supervised by scientists competent in handling infectious agents and associated procedures, 2) access to the laboratory is limited (restricted) when work is being conducted, and 3) all procedures in which infectious aerosols or splashes may be created are conducted

in biological safety cabinets or other physical containment equipment. The following standards apply to BSL 2:

- Standard Microbiological Practices for BSL 2
    - Access to the laboratory is limited or restricted by the PI when work with organisms containing recombinant or synthetic nucleic acid molecules or other biohazardous agents is in progress and in compliance with institutional policies.
    - Work surfaces are decontaminated with an appropriate disinfectant at least once a day and after any spill or splash of viable or infectious material.
    - All contaminated liquid or solid wastes are decontaminated before disposal.
    - Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending upon where the decontamination will be performed, the following methods should be used prior to transport:
        - Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
        - Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
    - Mechanical pipetting devices are used; mouth pipetting is prohibited.
    - Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the work area and storing food for human consumption in the laboratory is not permitted. Food may be stored outside the laboratory in cabinets or refrigerators designated and used for that purpose only.
    - Persons wash their hands after handling potentially hazardous materials and before exiting the laboratory.
    - All procedures are performed carefully to minimize the creation of aerosols and/or splashes.
    - Experiments of lesser biohazardous potential can be conducted concurrently in carefully demarcated areas of the same laboratory.
    - Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Laboratory supervisors should adopt work practices

and controls to reduce the risk of sharps injuries. The following precautions should be implemented:

- Careful management of needles should be implemented. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
- Used disposable syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
- Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
- Broken glassware must not be handled directly. It must be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible.

  - The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of childbearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

- Special Practices for BSL 2
  - Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak proof container which is closed before being removed from the laboratory.
  - The PI limits access to the laboratory. The PI has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.
  - The PI establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any

specific entry requirements (e.g., immunization) may enter the laboratory or animal rooms.

- Laboratory personnel must be provided medical surveillance, as appropriate, and offered available immunizations for agents handled or potentially present in the laboratory.
- When organisms containing recombinant or synthetic nucleic acid molecules or other biohazardous agents in use in the laboratory require special provisions for entry (e.g., vaccination), a hazard warning sign incorporating the universal biosafety symbol is posted on the access door of the laboratory work area. The hazard warning sign identifies the agent, lists the name and telephone number of the PI or other responsible person(s), and indicates the special requirement(s) for entering the laboratory.
- An insect and rodent control program is in effect.
- Laboratory coats, gowns, smocks, or uniforms are worn while in the laboratory. Before exiting the laboratory for non-laboratory areas, the protective clothing is removed and left in the laboratory or covered with a clean coat not used in the laboratory.
- Animals or plants not involved in the work being performed are not permitted in the laboratory.
- Special care is taken to avoid skin contamination with biohazardous agents or materials; appropriate gloves should be worn when handling experimental animals and when skin contact with the agent is unavoidable.
- All wastes from laboratories and animal rooms, including transgenic animal carcasses, are appropriately decontaminated before disposal.
- All potentially infectious material must be placed in a durable, leak-proof container during collection, handling, processing, storage or transport within a facility.
- Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluid from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units are used for the injection or aspiration of fluids containing organisms that contain recombinant or synthetic nucleic acid molecules. Extreme caution should be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Needles should be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe following use. The needle and syringe should be

promptly placed in a puncture-resistant container and decontaminated, preferably autoclaved, before discard or reuse.
    - Spills and accidents which result in overt exposure to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to Public Safety, the IBC, DePaul Environmental Health and Safety, and NIH/OBA, when necessary.
        - Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to the procedures described in the laboratory-specific biosafety manual (SOPs). All incidents must be reported to the laboratory supervisor and appropriate institutional officials. Medical evaluation, surveillance, and treatment must be provided and records must be maintained.
    - When appropriate, considering the agent(s) handled baseline serum samples for laboratory and other at risk personnel are collected and stored. Additional serum specimens may be collected periodically depending on the agents handled or the function of the facility.
    - A laboratory-specific biosafety manual (SOP) is prepared and adopted as policy. The manual must be available and accessible. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.
    - The Laboratory supervisor must ensure that the laboratory personnel demonstrate proficiency in the standard and special microbiological practices before working with any BSL2 agents.
    - Laboratory equipment should be routinely decontaminated, as well, after spills, splashes, or other potential contamination.
        - Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
        - Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.
    - All procedures involving manipulation of infectious materials that may generate an aerosol should be conducted within a Biological Safety Cabinet or other physical containment devices.
- Containment Equipment (Primary Barriers and Personal Protective Equipment) for BSL 2
    - Biological Safety Cabinets (Class I or II) or other appropriate personal protective or physical containment devices are used whenever:

        - Procedures with a high potential for creating infectious aerosols or splashes are conducted. These include centrifuging, pipetting, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of materials whose internal pressure may be different from ambient pressures, intranasal inoculation of animals, and harvesting infected tissues from animals or eggs.
        - High concentration or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory if sealed beads or rotor heads or centrifuge safety cups are used and if they are opened only in a biological safety cabinet.
    - Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous materials. Protective clothing must be removed before leaving for non-laboratory areas (e.g., cafeteria, library, and administrative offices). Protective clothing must be disposed of appropriately, or deposited for laundering. Laboratory clothing should not be taken home.
    - Eye and face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials when the microorganisms or materials must be handled outside of the biological safety cabinet or containment device. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses in the laboratory should also wear eye protection.
    - Gloves should be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Gloves must not be worn outside the laboratory. BSL 2 laboratory personnel must:
        - Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.
        - Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
        - Not wash or reuse disposable gloves or used gloves exposed to other contaminated waste. Hand washing protocols must be rigorously followed.

    - Eye, face, and respiratory protection must be used in rooms containing infected animals as determined by the risk assessment.
- Laboratory Facilities (Secondary Barriers) for BSL 2
    - The laboratory is designed so that it can be easily cleaned and decontaminated. Carpets and rugs in laboratories are not permitted.
    - Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, other chemicals, and moderate heat.
    - Laboratory furniture is sturdy and capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning.
    - Chairs used in the laboratory must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
    - Each laboratory contains a sink for hand washing. The sink may be manual, hands-free, or automatically operated. It should be located near the exit door.
    - Laboratory windows that open to the exterior are not recommended. However, if the laboratory has windows that open to the exterior, they are fitted with fly screens.
    - An autoclave for decontaminating laboratory wastes is available.
    - Laboratory doors should be self-closing and have locks in accordance with institutional policies.
    - Biological safety cabinets (BSCs) must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.
    - Vacuum pumps should be protected with liquid disinfectant traps.
    - An eyewash station must be readily available.
    - When planning facilities, a mechanical ventilation system that provides inward flow of air without recirculation to spaces outside the laboratory should be considered.
    - HEPA filtered exhaust air from a Class II BSC can be safely re-circulated back into the laboratory if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or directly exhausted to the outside through a hard connection. Provisions to assure proper safety cabinet performance and air system operation must be verified.

- A method of decontaminating all laboratory wastes should be available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination methods.

Biosafety Level 3 (BSL 3): Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is conducted with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route of exposure. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents and are supervised by competent scientists who are experienced in handling infectious agents and associated procedures. All procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices or by personnel wearing appropriate personal protective clothing and devices. The laboratory has special engineering and design features, such as access zones, sealed penetrations, and directional airflow.

Currently, no work involving agents that require BSL3 containment procedures may be conducted at DePaul. For details regarding the standard microbiological practices for agents requiring BSL3 containment procedures, refer to the *NIH Guidelines* and the *BMBL*.

Biosafety Level 4 (BSL 4): Biosafety Level 4 is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that is frequently fatal, for which there are no vaccines or treatments, or a related agent with unknown risk of transmission. Agents with a close or identical antigenic relationship to agents requiring BSL4 containment must be handled at this level until sufficient data are obtained either to confirm continued work at this level, or re-designate the level. Laboratory staff must have specific and thorough training in handling extremely hazardous infectious agents. Laboratory staff must understand the primary and secondary containment functions of standard and special practices, containment equipment, and laboratory design characteristics. All laboratory staff and supervisors must be competent in handling agents and procedures requiring BSL4 containment. The laboratory supervisor in accordance with institutional policies controls access to the laboratory.

There are two models for BSL 4 laboratories: 1) Cabinet laboratory- Manipulation of agents must be performed in a Class III Biological Safety Cabinet, and 2) Suite Laboratory-Personnel must wear a positive pressure supplied air protective suit. BSL 4 cabinet and suit laboratories have special engineering and design features to prevent microorganisms from being disseminated into the environment.

Currently, no work involving agents that require BSL4 containment procedures may be conducted at DePaul. For details regarding the standard microbiological practices for agents requiring BSL4 containment procedures, refer to the *NIH Guidelines* and the *BMBL*.

5.3 IBC Protocol Review Processes

It is the responsibility of the Principal Investigator (PI) to submit any protocol involving recombinant or synthetic nucleic acid molecules, biohazardous agents, select agents or toxins as defined in this policy, to the IBC for the appropriate level of review. When the IBC receives a new protocol, amendment, resubmission, or amendment for changing personnel (not the PI), the submission is checked by the Office of Research Services staff for completeness and, if applicable, is assigned a protocol number. The ORS staff makes a preliminary decision regarding the level of review required: Full Committee Review, Designated Member Review, or Administrative Review. The submissions are sent for review through the appropriate process. The IBC Chair and the other IBC members may make a determination that a higher level of review is required for any submission. There are three possible methods of review for submissions to the IBC, Full Committee Review (FCR), Designated Member Review (DMR), and Administrative Review (AR).

5.3.1 Full Committee Review

Full Committee Review (FCR): Research, teaching, or other activities that involve recombinant or synthetic nucleic acid molecules, biohazardous agents, or select agents and toxins, must be submitted to the IBC for review and approval prior to the receipt of biohazardous materials or initiation of the research, teaching, or other activity that utilizes the agent(s).

IBC review is initiated when a researcher or other personnel submits an IBC protocol and relevant supplemental materials to the Office of Research Services. All protocol submissions must use the current version of the submission forms, available on the IBC webpage at https://offices.depaul.edu/ors/research-protections/ibc/Pages/default.aspx , as the IBC forms are periodically revised to ensure that the IBC receives all information necessary for a complete review of the research under the current *NIH Guidelines* and the standards of the *BMBL*. Submission of incomplete applications may result in the delay of IBC review.

Protocol submissions that must be reviewed by full committee review are the following:

- All protocol submissions (new, annual renewals, triennial resubmissions) involving recombinant or synthetic nucleic acid molecules, that are not NIH exempt as defined in section III-F of the *NIH Guidelines*.
- All protocols submissions (new and annual renewals) involving biohazardous agents, and select agents and toxins (excluding any recombinant or synthetic nucleic acid molecules).
- All protocols involving agents that require BSL 2 containment procedures.
- Any type of activity or submission that does not fit the criteria for either administrative review or designated member review.
- Three-year resubmission (*de novo* review) for protocols involving recombinant or synthetic nucleic acid molecules, biohazardous agents, and select agents and toxins.
- Any amendment to the approved protocol that includes substantive changes, such as a change in the risk group or an increase in the biosafety containment level, or an increase in the amount of biohazardous agent used in the activity,
- Changes to an approved protocol that now includes human subjects or animals and therefore requires IRB or IACUC review.

New protocols or other submissions that require full committee review are forwarded to all the IBC members. Two members of the IBC, who are qualified to conduct the review due to their area of expertise, will serve as primary reviewers for each protocol submission and will be asked to make initial recommendations regarding the IBC's action on the submission. The ORS staff assigns the primary reviewers based upon known expertise of the members.

Protocols reviewed at the convened IBC meeting through FCR will have determinations documented in meeting meetings.

5.3.2 Designated Member Review

Designated Member Review (DMR): Designated member review cannot be used for proposals involving recombinant or synthetic nucleic acid molecules, except for activities that are NIH exempt as defined in section III-F of the *NIH Guidelines*. Protocol submissions that qualify for a designated member review are reviewed by a subcommittee of the IBC based upon the expertise required to review the protocol. The ORS staff assigns the primary reviewers based upon known expertise of the members.

The following types of submissions qualify for designated member review:

- An annual renewal with no changes to biohazardous agents and select agent or toxins, and activities involving recombinant or synthetic nucleic acid molecules that are not NIH exempt as defined in section III-F of the *NIH Guidelines*.

- Amendments or renewals with minor changes that do not alter the agents utilized, and that have no impact on the Risk Group or Biosafety Containment Level required for the agent utilized, or on the classification of approved NIH exempt activity as defined in section III-F of the *NIH Guidelines*. For example, adding a funding source or changing the funding status.
- Recombinant or synthetic nucleic acid molecule activities that are limited solely to the NIH exempt categories as defined in section III-F of the *NIH Guidelines* and for which BSL 1 containment procedures apply. Protocols that are limited solely to NIH exempt activities covered under section III-F may be reviewed and confirmed as exempt by the IBC Chair, or designee using a short specialized form. Protocols that are limited solely to agents that require BSL 1 containment procedures may be reviewed by a subcommittee of the IBC through a DMR process.
- The addition of rooms for approved research that involves BSL-2 activities. The BSO must be consulted and confirm the room has been inspected and approved for BSL 2 level activities.
- A change in or addition of a new Biosafety hood, as a measure of ensuring that certification or re-certification has occurred before work begins or continues.
- IBC requested revisions subsequent to convened review, when the IBC has requested minor or non-substantive changes or information from the investigator and when a quorum of the IBC present at the meeting makes the determination that the revisions may be reviewed through the DMR process (usually by the primary reviewers).

To satisfy the requirement that all IBC members are involved and have the chance to comment on the protocol submission being considered for DMR, the Office of Research Services staff will first send the protocol submission and notification of proposed DMR review to all members by Email. Members have 5 business days to comment or request a full committee review. All members must respond to the DMR request Email before the submission may move to the DMR process. If a full committee review is called, the protocol submission is placed on the next IBC meeting's agenda. Protocols revisions in response to the IBC's request for modifications of minor or non-substantive nature, do not require the five-day waiting period and will be sent directly for review to the IBC members chosen to review the revisions (usually the primary reviewers) as approved during the meeting at which the revisions were requested.

If no member calls for a full-committee review, then the ORS staff on behalf of the Chair will assign the review to a selected subcommittee (the "designated reviewers") with the expertise to review the protocol submission. The subcommittee will be composed of two IBC members and assisted by the Office of Research Services staff member (non-voting).

The subcommittee has an additional 7 business days to review the protocol on behalf of the entire IBC, meeting in person or by conference call, or making a determination in writing via Email or a review guide. The subcommittee has the authority to approve (by unanimous agreement of the 2 members), request modifications, or request full committee review. If the DMR decision is split or the members believe the submission should be rejected, then the protocol submission must go to the full committee for review.

The subcommittee determination will be recorded in written documentation and the Office of Research Services staff will inform the PI of the decision (approval, comments/concerns and/or required modifications). The PI then has 30 business days to respond to the subcommittee. The PI can also ask for a full committee review at any time in the review process.

Designated member review has equal validity to full-committee review approval and does not require subsequent re-approval by a convened meeting. However, the results of approval actions made under DMR and Administrative Review (AR) will be included in the next agenda and meeting minutes as the method of notifying the convened IBC regarding decisions made under these processes in the name of the full IBC. It is always possible for any member of the IBC to discuss any protocol submissions reviewed by any method at any convened meeting, and to have those comments entered into the minutes, as a form of continuing review or in response to biosafety concerns.

5.3.3 Administrative Review

Administrative Review (AR): Protocol submissions that qualify for administrative review are reviewed by the IBC Chair or designee (a voting member with the appropriate expertise), or the Office of Research Services staff (when limited to an amendment changing personnel not involving the PI or change in title as detailed below).

The following types of submission qualify for administrative review:

- A change in personnel on an existing approved protocol, when the change pertains only to personnel other than the PI. In this instance the PI must submit an Application for an Amendment Changing Personnel (not the PI) for an IBC Approved Protocol to the Office of Research Services. The Office of Research Services will verify personnel training documentation and immunization records are on file before approving the addition of personnel.
- A change in title of the protocol that does not involve any other changes to the protocol or personnel involved in the protocol,

- The addition of new rooms to an approved protocol for BSL1 related activities

5.3.4 Chair (or Designee) Confirmation of NIH Exempt Status for Research Solely Involving NIH Exempt Agents

All research activities with recombinant or synthetic nucleic acid molecules that potentially meet the exempt criteria in the *NIH Guidelines* must be submitted for exempt status confirmation and be approved before work can begin. The exempt status of the research will be confirmed through IBC Chair (or designee) exempt confirmation review. There is a short IBC form specific for this process. After review of the information provided in the form, the Chair or designee will inform ORS that the activity has been confirmed as being limited to NIH exempt activities and ORS will prepare an approval letter. The PI should not begin working on the protocol until written approval is received.

5.4 Possible IBC Determinations

5.4.1 Convened meetings (FCR)

At a convened meeting of the IBC, the primary reviewers will present the project to the remainder of the IBC members. Each member will have reviewed the protocol submissions in detail prior to the meeting. The IBC will discuss the project, a motion is made and seconded, and a vote on a determination regarding the submission is called. The following are the possible determinations that may be made by the convened IBC when reviewing a protocol:

- *Approved* - If full approval is granted, the investigator may begin the research or other activity as outlined in the protocol once they receive written approval from the IBC. Protocols are approved for 3 years. Annual updates in the way of a renewal application must be filed to maintain approval.

- *Modification Required* - This status indicates that there are questions or issues of a minor or non-substantive nature that the investigator must resolve before the protocol can receive full approval. No research may be initiated until all conditions have been met and the researcher receives formal written notice of final IBC approval.

  The investigator's response to the IBC is assessed by either the convened IBC or a subcommittee through the DMR process, who will determine whether the IBC's concerns have been addressed in a satisfactory manner. Once the IBC's concerns have been addressed, the protocol will be given final approval and the researcher will receive a written notice of the approval.

- *Deferred: Additional Convened Review Required* - Investigators that receive a "Deferred" notification are required to address concerns of a more substantive nature. For example, there is not enough information available to assess the Risk Group or the Biosafety Containment Level of the agent(s). Once an investigator responds to this type of notification, the revised protocol materials must be reviewed a second time by the convened IBC, rather than by the primary reviewers. The investigator's response to the IBC is assessed by the full IBC to determine whether the previously raised concerns have been addressed in a satisfactory manner. Once the IBC's concerns have been addressed, the protocol may be given full approval.

  No protocol-related activity may be initiated until all conditions have been met and the investigator receives formal written notice of full IBC approval. If all the conditions have not been met, the IBC may request additional modifications and indicate that the modifications may be reviewed through the DMR process.

- *Tabled* – This status is applied to protocols that have come to the committee missing substantive information or supporting materials such that the protocol cannot be reviewed or when a protocol cannot be reviewed due to lack of quorum or time at a convened meeting.

- *Rejected/Disapproved* - This status is assigned to protocols only when the IBC has major concerns with the protocol. The activity may be at a biosafety level that DePaul cannot support or may exceed the amount of culture that can be housed within DePaul's laboratories. When the IBC rejects or disapproves the protocol, the PI is provided with a written determination letter outlining the reasons why the determination was made.

- *Withdrawn* - This designation applies to protocols or amendments that have been removed from further consideration by the IBC. This occurs when an investigator fails to respond to IBC questions within the allotted time or when an investigator initiates withdrawal of a protocol or amendment. Protocols may be withdrawn administratively by ORS staff.

- *Terminated* - Terminated protocols are no longer active, and the activity outlined in such protocols must not be conducted. Investigators who fail to provide annual reports or 3-year *de novo* resubmissions in a timely fashion may have their protocols terminated by the IBC. Protocols may also be terminated for safety reasons, due to adverse events, or non-compliance. Termination is an action taken by the IBC usually to address a concern and termination differs from simply closing the protocol. Investigators may close a protocol at any time by submitting a Final Closure Report to

the Office of Research Services. Investigators may also close protocols during the annual renewal process.

The IBC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an activity or vote with the IBC unless they are also members of the IBC.

All investigators are informed of the status of their protocol application, as well as the concerns and revisions requested by the IBC in a formal Email or letter compiled by the Office of Research Services staff. Approval letters compiled by the Office of Research services staff are signed by the IBC Chair after review. Communications will be sent to the researcher usually within 5 business days after the date of the review. The researcher may Email or phone the Chair of the IBC or the Office of Research Services for an informal notification of review outcome prior to this time. The researcher will have 30 days from the date of receipt of the letter to respond to the concerns cited in the letter. The project or changes to a protocol should not begin before all revisions have been received and approved by the IBC.

5.4.2 Designated Member Review (DMR)

The following are the possible determinations that may be made by the IBC when reviewing a protocol submission under DMR:

- *Approved* - If full approval is granted, the investigator may begin the research or other activity as outlined in the protocol once they receive written approval from the IBC.
- *Modification Required* - This status indicates that there are questions or issues that the investigator must resolve before the protocol or submission can receive full approval. No research may be initiated until all conditions have been met and the researcher receives formal notice of full IBC approval.

All investigators are informed of the status of their protocol application as well as the concerns and revisions requested by the Committee in a formal letter compiled by the Office of Research Services staff and sent via Email. Approval letters compiled by ORS staff are signed by the IBC Chair after review. Notifications of actions will be sent to the researcher usually within 5 business days after the date of the review. The researcher may Email or phone the Chair of the IBC or the Office of Research Services for an informal notification of outcome prior to this time. The researcher will have 30 days from the date of receipt of the letter to respond to the concerns cited in the letter. The project or changes to a protocol

should not begin before all revisions have been received and approved by the IBC.

5.4.3 Administrative Review (AR)

The following are the possible determinations that may be made by the IBC when reviewing a protocol submission under AR:

- *Approved* - If full approval is granted, the investigator may begin the research or other activity as outlined in the protocol once they receive written approval from the IBC.
- *Modification Required* - This status indicates that there are questions or issues that the investigator must resolve before the protocol can receive full approval. No research may be initiated until all conditions have been met and the researcher receives formal notice of full IBC approval.

All investigators are informed of the status of their protocol application as well as the concerns and revisions requested by the Committee in a formal letter compiled by the Office of Research Services staff and sent via Email. Approval letters are signed by the IBC Chair after review. Notifications of actions will be sent to the researcher usually within 5 business days after the date of the review. The researcher may Email or phone the Chair of the IBC or the Office of Research Services for an informal notification of outcome prior to this time. The researcher will have 30 days from the date of receipt of the letter to respond to the concerns cited in the letter. The project or changes to a protocol should not begin before all revisions have been received and approved by the IBC.

5.4.4 Chair (or Designee) Confirmation of NIH Exempt Status

The following are the possible determinations that may be made by the IBC Chair or designee when reviewing a protocol submission that was submitted for NIH exempt status confirmation:

- *Approved* - If full approval is granted, the investigator may begin the research or other activity as outlined in the protocol once they receive written approval from the IBC.
- *Referred for IBC Review*- If the research in its entirety does not meet the criteria for the NIH exempt categories, the IBC Chair will refer the research for review by the IBC. The PI will be contacted about this decision in writing via Email and instructed to submit the appropriate IBC review form.

5.5 Initial Review of New Submissions

The PI for a protocol should complete the appropriate form for the type of work being conducted and the type of agent. The following are the types of forms:

- Application for Research Activities Involving Recombinant and Synthetic Nucleic Acid Molecules (NIH Non-Exempt), Other Biohazardous Agents, and Human Materials
- Application for Teaching Activities Involving Biohazardous Agents (NIH Recombinant and Synthetic Nucleic Acid Molecules [Exempt and Non-Exempt], Other Biohazardous Agents, and Human Materials)
- Application for Research Activities That Involve Only Recombinant or Synthetic Nucleic Acid Molecules That Are NIH Exempt
- Institutional Biosafety Committee (IBC) Adverse Biosafety Event Report Form
- Institutional Biosafety Committee (IBC) Final Closure Report Form
- Institutional Biosafety Committee (IBC) Annual Renewal Report Form
- Application for Amendments to Research and Teaching Activities That Require IBC Review and Approval
- Application for an Amendment Changing Personnel for an IBC Approved Protocol
- Hepatitis B Vaccination Acceptance/Declination Statement Form

The completed forms and any supporting materials should be sent via Email to the general Email box for the Office of Research Services, Research Protections section at orp@depaul.edu . Upon receipt of the submission materials, the Office of Research Services staff will complete the protocol log-in process, which consists of creating the hard-copy protocol file, assigning a protocol number, creating an electronic file, and pre-review of the materials for completeness and the appropriate review process.

Once the IBC reviews the submission, the PI will be notified via Email of the IBC's review determination. Notices are usually sent to PIs within 5 business days of the IBC review.

5.6 Continuing Review/Annual Renewal

In accordance with federal regulations, the IBC is required to periodically review research involving recombinant or synthetic nucleic acid molecules (including NIH exempt activities) conducted at DePaul University to ensure compliance with the *NIH Guidelines*. Approved projects involving recombinant or synthetic nucleic acid molecules, any biohazardous agent, or select agent or toxin as defined in this policy must be renewed annually.

In addition to the triennial approval period and expiration date, the approval letter for each protocol indicates a date (expiration date) by which annual continuing

review/ annual renewal must be obtained. Renewal applications should be submitted at least 30 days prior to the annual renewal date to allow sufficient time for the IBC to conduct the annual review. Research and teaching activities cannot continue if the protocol renewal is not approved prior to the annual anniversary date. In the event the renewal process is not completed before the end of the annual anniversary date, the annual approval period may be adjusted as to approval date, but the anniversary expiration date remains the same.

Investigators must complete the Institutional Biosafety Committee (IBC) Annual Renewal Report Form and submit it to the Office of Research Services at orp@depaul.edu . The annual renewal process involves a review of the status of the protocol and what has occurred in the past year; including whether there have been any safety concerns. In general, the annual renewal review is less in-depth than the initial review process.

As a courtesy, the PI will receive a reminder from the Office of Research Services via Email 90 days, 60 days and 30 days prior to the expiration of the annual review period. However, the responsibility remains with the PI to ensure the submission of the renewal application with sufficient time to allow for IBC review and approval.

If the annual report is not submitted to the Office of Research Services before a lapse in annual approval occurs, the Office of Research Services on behalf of the IBC will send a final reminder notice indicating that approval has lapsed, all activities conducted under the approval must stop, and that if the PI wishes to continue the activity a renewal application must be submitted within 15 business days or the activity will be terminated. Failure to provide an adequate and timely response to the final notice will result in an automatic termination of the protocol. In such cases, the IBC will send a "Notice of Termination," and the investigator will be required to submit a new protocol for review and approval prior to continuing the activity.

When reviewing revised or resubmitted protocols for projects previously approved, the IBC reserves the right to request additional information or revisions that were not requested during previous reviews that may be the result of changes to the regulations or guidelines or DePaul policy and procedure since the last in-depth review.

5.7 Triennial (*de novo*) review

Each approved protocol is provided with a triennial approval period, which cannot be extended. In the event the annual renewal does not occur by the annual anniversary date, the date of the triennial review approval period is not adjusted.

At the end of the three-year approval period, the protocol must be re-submitted as a new protocol. Triennial (*de novo*) review is as in-depth as the initial review process.

Triennial reviews are conducted using the procedures outlined for initial review and approvals.

5.8 Amendments/Changes to Approved Protocols

During the course of the conduct of the protocol, any changes or amendments to an approved protocol (i.e., removal or addition of research personnel, room changes, new procedures, new agents, or a new funding source) must be reviewed and approved by the IBC prior to initiating the change. A new protocol document may be requested if the changes are extensive and impact the information in the initial IBC application (the protocol) or there is a change in the scope of the research.

To submit amendments or changes to the IBC for review, the PI should complete and submit the Application for Amendments to Research and Teaching Activities That Require IBC Review and Approval to orp@depaul.edu. If the change is limited to the addition or deletion of personnel, not involving the PI, the Application for an Amendment Changing Personnel (not the PI) for an IBC Approved Protocol form may be submitted without the separate protocol amendment form. If the changes impact the information originally submitted to the IBC in the initial protocol application, the protocol application should be revised to ensure that the IBC has complete information about the changes and that the PI has a consolidated protocol document that reflects the current status of the research plan.

Amendment changes may not be initiated until final written approval has been obtained from the IBC.

Changes in personnel, other than the PI, may be reviewed via AR. Minor changes to the protocol may be reviewed via DMR. Substantive changes must be reviewed by the convened IBC. For all review processes and actions, the PI will receive written notice of the review decisions from the Office of Research Services on the behalf of the IBC usually within 5 business days of review.

5.9 Closing a Protocol

Investigators should close the protocol once biohazardous materials are no longer being used and/or the protocol objectives have been completed. Investigators should notify the IBC of their desire to close a protocol by submitting a completed Final Closure Report. Alternatively, investigators may notify the IBC of study

closure at the time of annual renewal/continuing review. If the protocol is being closed at the time of annual renewal, the PI should still complete and submit the Institutional Biosafety Committee (IBC) Final Closure Report Form.

When investigators leave DePaul, they must close all IBC protocol(s) by notifying the IBC in writing. If a protocol will continue and be conducted by a new investigator, then a new protocol submission or an amendment clearly outlining the change in personnel, room number changes, and other applicable changes will be required to be submitted to the IBC by the new PI before activities can continue under the new PI. Submitting changes of this nature related to teaching protocols is especially important.

5.10 Administrative Closure of Protocols

The Office of Research Services on behalf of the IBC will administratively close protocols or withdraws protocol submissions from review if an investigator does not respond to the multiple reminders (30-day, and 60-day) to submit modification requests. The investigator will be notified in writing that the protocol has been withdrawn and closed.

5.11 Notifications to Principal Investigators

5.11.1 Approval memos

When the IBC provides final approval for a protocol, the PI will be sent an approval memo signed by the IBC Chair, or designee via Email. The approval memo will include the following:

- The Name of the PI
- The protocol number assigned by the IBC
- The protocol title
- The approval date, the triennial approval period, and the date by which annual renewal must occur.
- If applicable, the name of the funding source, the grant or contract number, grant title, and PI of the grant
- The assessed Risk Group for the agent(s) being utilized
- The IBC's decision regarding the Biocontainment/biosafety level to be used for the proposed activity
- Other pertinent information pertaining to the review of the protocol and reminders regarding policy

5.11.2 Requests for Modifications

When reviewing submissions, the IBC may request modifications or changes or additional information to clarify information provided in the IBC application. The

PI will receive written notification via Email of the IBC's determination and the items that need to be addressed before approval can be obtained. When the IBC requests revisions to a protocol or additional information during the review process for a submission (initial review, renewal, amendment) the PI is expected to reply to the revisions request via Email within 30 days. If the IBC does not receive a response within 30 days, the ORS will send a reminder Email to the PI indicating that a response is expected within an additional 30 days. If after sending the second reminder to the PI, a response is still not received, the protocol submission will be withdrawn administratively from review.

5.11.3 Continuing Review/renewal reminders

The PI of the protocol is ultimately responsible for submitting the annual renewal application and the triennial resubmission for each protocol. The Office of Research Services will send 90-day, 60-day, and 30-day reminder letters via Email to the PI indicating the need to submit the renewal or triennial resubmission application for a protocol. If the project is completed, the PI should submit a Final Closure Report Form for the protocol.

5.11.4 Failure to Submit Renewal/Resubmission Application

If the IBC approval lapses all activities involving recombinant or synthetic nucleic acid molecule, biohazardous agents, or select agents and toxins must stop and re-approval must be obtained as soon as possible. ORS will send a notice to the PI via Email and within a week of the lapse date indicating that the approval has lapsed and that in order to continue the activity re-approval must be obtained immediately. The PI will be requested to respond within 14 days. If the PI does not respond within 14 days, the ORS will send an additional reminder indicating that if a response is not received within 7 days, the protocol may be terminated by the IBC. If a response from the PI is not received after the second notice, the protocol will be added to the next IBC meeting agenda and the IBC must determine whether or not to terminate the protocol. Termination of the IBC protocol may also require termination of any related IACUC or IRB protocols and notification to any external funding agencies, and possibly funding mechanisms internal to DePaul, of the termination.

5.11.5 Protocol Termination

The IBC may terminate a protocol for failure to respond to the IBC's requests, lapses in approval without a response from the PI, non-compliance, or for safety concerns related to an adverse event report. The decision to terminate a protocol must be made by the IBC at a convened meeting. The reasons for terminating the protocol will be documented in the minutes. The PI will be notified in writing via Email of the termination and the reasons for termination. When applicable, external funding agencies will be notified of the protocol termination.

5.12 Research Requiring Review by Other DePaul Committees (IRB, IACUC)

IBC protocols involving the use of live vertebrate animals will require IACUC review and approval prior to initiating any activities with animals. The IBC and IACUC applications may be submitted simultaneously and the Office of Research Services staff will coordinate communications between the two committees to ensure that dual approval is received prior to initiation of the protocol activities. The IACUC may request information about the risks to the animals related to the use of the biohazardous agents from the IBC before providing IACUC approval.

IBC protocols involving the administration of recombinant or synthetic nucleic acid molecules or other biohazardous agents to humans, or that involves the collection of tissues or fluids directly from humans, requires IRB review and approval prior to initiating research activities involving human subjects. The IBC and IRB applications may be submitted simultaneously, however, the IRB must have feedback from the IBC as to potential risks to the human subjects in order to adequately conduct a protocol review. The Office of Research Services staff will coordinate communications between the two committees to ensure that dual approval is received prior to initiation of the protocol activities.

Section 6: Reporting Requirements

6.0 Reportable Incidents (Unanticipated Problems and Adverse Events)

This section of the manual only applies to activities conducted at DePaul University. If work is being conducted solely at other locations (such as Rosalind Franklin University Medical School), investigators should refer to the policies and procedures of the institution at which the activity with biohazardous agents will occur.

As framed by the *NIH Guidelines*, the requirements for reporting events are as follows:

- **IBC requirements:** Section IV-B-2-b-(7) The IBC shall report any significant problems with violations of the *NIH Guidelines* and any significant research-related accidents and illnesses to the appropriate institutional official and NIH/OBA within thirty days or immediately (depending upon the nature of the incident), unless the institution determines that a report has already been filed by the Principal Investigator.
- **Researcher requirements:** Section IV-B-7-a-(3) The researcher shall report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the Biological Safety Officer (where applicable), Greenhouse/RSF Director (where applicable),

Institutional Biosafety Committee, NIH/OBA, and other appropriate authorities (if applicable) within 30 days. DePaul policy requires immediate reporting to campus offices to allow for appropriate actions to take place and within 72 hours to ORS/IBC to ensure the reporting to NIH/OBA can occur within the required 30-day time period.

At DePaul, any reportable event or safety issue that involves spills or personnel exposure to chemicals or biohazardous agents, which occurs related to an IBC Protocol, must first be reported immediately to Public Safety at 773-325-7777 by the PI or designee. The investigator is also responsible for reporting the event or safety issue to DePaul Environmental Health and Safety, the Office of Research Services, and the IBC Chair. The Chair will discuss the report with the IBC at a convened meeting and the IBC will determine if the event is sufficiently significant to necessitate reporting to the institutional official or NIH/OBA and who will assist with any additional reporting responsibilities of the investigator. The main focus of the reporting mechanism is to ensure that personnel exposed to biohazardous agents are medically treated, when necessary, and that any spills or loss of containment are appropriately dealt with in order to prevent further hazards or exposure to personnel.

Any non-compliance with these procedures may result in the suspension of the IBC approved protocol at DePaul.

Any problems, incidents, accidents, illnesses, or adverse events (clinical trial – related) involving recombinant or synthetic nucleic acid molecules, biohazardous agents, or select agents and toxins must be reported immediately to Public Safety Environmental Health and Safety and to the IBC within 72 hours using the event reporting form. The report process to Environmental Health and Safety should follow the procedures outlined in the Chemical Hygiene Plan (http://ehs.depaul.edu/ManualsandProcedures/index.html) and the DePaul University Emergency Operations Plan (http://emergencyplan.depaul.edu/Documents/University%20Emergency%20Response%20Plan.pdf).

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) state that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH OBA within 30 days. Certain types of incidents must be reported on a more expedited basis. For example, Appendix G of the *NIH Guidelines* specifies certain types of accidents that must be reported on a more expedited basis. Specifically, Appendix G-II-B-2-k requires that spills and accidents in BL2 laboratories resulting in an overt exposure must be immediately reported to the OBA (as well as the IBC). In addition, Appendices G-II-C-2-q

and G-II-D-2-k require that spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to OBA (as well as the IBC and BSO).

Under the *NIH Guidelines,* incident reporting is articulated as a responsibility of the Institution, IBC, Biological Safety Officer, and Principal Investigator. Institutions have the discretion to determine which party should make these reports, and one report for each incident or set of information is generally sufficient. At DePaul, the PI and the ORS staff, on behalf of the IBC, should work together to submit this report to OBA. A form for reporting to OBA can be found at: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/institutional-biosafety-committees

Incident reports should include sufficient information to allow for an understanding of the nature and consequences of the incident, as well as its cause. A detailed report should also include the measures that the institution took in response to mitigate the problem and to preclude its reoccurrence.

The kinds of events that must be reported to NIH OBA might include skin punctures with needles containing recombinant DNA, the escape or improper disposition of a transgenic animal, or spills of high-risk recombinant materials occurring outside of a biosafety cabinet. Failure to adhere to the containment and biosafety practices articulated in the *NIH Guidelines* must also be reported to OBA. Minor spills of low-risk agents not involving a breach of containment that were properly cleaned and decontaminated generally do not need to be reported.

Reportable events or incidents that should be reported to the IBC may be a result of overt exposure, such as needle stick, splash, and contamination due to equipment failure, or a containment breach, which may subsequently be determined to have posed or potentially pose a risk of exposure to individuals. It should be noted that waste from recombinant or synthetic nucleic acid, biohazardous agent, or select agents or toxins is considered biohazardous and incidents involving improper disposal for these materials would also indicate a reportable event.

Examples of reportable events or safety issues include: work-related exposures, injuries, illnesses, laboratory accidents, any event of non-compliance, such as research or other activities conducted outside the scope of the approved protocol. If the protocol in question involves animals, the IACUC will also evaluate the adverse event or handle the non-compliance jointly with the IBC. If the protocol involves human subjects, the IRB may also need to evaluate the event or non-compliance issue.

When human subjects are involved in the research, adverse event reporting in compliance with the federal regulations for human subjects under 45 CFR 46 and 21 CFR 50, 56, 312 is required. Under FDA clinical trial regulations an adverse event is defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. A *Serious adverse event* or *serious suspected adverse reaction* is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes:

1. death,
2. a life-threatening adverse event,
3. inpatient hospitalization or prolongation of existing hospitalization,
4. a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions,
5. a congenital anomaly/birth defect
6. an important medical event that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed above.

An unexpected adverse event or *unexpected suspected adverse reaction* is considered "unexpected" if it is not listed in the investigator brochure for the drug or is not listed at the specificity or severity that has been observed; or, if an investigator brochure is not required or available, is not consistent with the risk information described in the general investigational plan or elsewhere in the current application or IRB approved consent document.

Under the *NIH Guidelines* the definition of serious adverse event is an event occurring at any dose that results in any of the following outcomes:

1. death
2. life-threatening event
3. in-patient hospitalization or prolongation of existing hospitalization
4. a persistent or significant disability/incapacity
5. a congenital anomaly/birth defect
6. An important medical event that may not result in death, be life-threatening, or require hospitalization also may be considered a serious adverse event when, upon the basis of appropriate medical judgment, they may jeopardize the human gene transfer research subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition

Gene transfer studies covered under the *NIH Guidelines* indicate an adverse event is associated with the use of a gene transfer product when there is a reasonable possibility that the event may have been caused by the use of that product.

6.1 Principal Investigator Reporting

Principal Investigators and other personnel listed on the protocols must report any significant incident, violation of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the DePaul Public Safety immediately, and the IBC and DePaul Environmental Health and Safety within 72 hours of the event so that the IBC can fulfill the requirement of reporting to NIH/OBA within 30 days of the incident. Examples of reportable incidents or violations include:

- Overt exposures are defined as exposures that result in direct exposure of personnel to biohazardous materials such as injection, spills, splashes, or aerosol inhalation.
- Potential exposures are defined as exposures that have high risk of exposing personnel to biohazardous materials such as spills, containment failures while working with the agent or equipment failure that may produce aerosols.
- Any overt exposure that occurs in a BSL 1 or BSL 2 laboratory
- Any exposure (overt or potential) in a BSL 3 laboratory. **Note DePaul does not currently allow BSL 3 level work to be conducted at DePaul.**
- Any illnesses that may have been caused by the agents used in the laboratory or incidents involving improper disposal of biohazardous materials.

6.2 Office of Research Services Reporting

The Office of Research Services is required under the *NIH Guidelines* to report to the IBC:

- Any allegations of non-compliance or violations of the *NIH Guidelines*
- Any reports of significant incidents, adverse events, or unanticipated problems
- Any reports of significant research-related accidents or illnesses.

ORS will assist the IBC in the review of the report and in the preparation of any reports that subsequently need to be sent to the IO, federal or state agencies, or the funding agency.

6.3 IBC Reporting

The IBC through the Office of Research Services must file an annual report to the NIH/OBA that includes:

- A roster of all the IBC members and that also clearly indicates the Chair, contact person, BSO, plant expert, and animal expert.
- Biographical sketches or resumes/CVs of all IBC members.

The IBC is required by the *NIH Guidelines* to report to the DePaul IO and the NIH/OBA within 30 days any significant incidents, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses. The IBC is responsible for determining what actions, if any, are necessary in the event these types of incidents occur. The IBC may choose to change the frequency of the lab inspections or change the Biosafety containment level of the protocol, based upon the results of the review of an incident. The IBC must document in the minutes their discussion and any determination made regarding reported incidents.

Other IBC reporting requirements (to the IO, NIH/OBA and other agencies) include, but are not limited to:

- When research involving recombinant or synthetic nucleic acid molecules, biohazardous agents, or select agent or toxins is conducted without prior IBC approval.
- When incidents of lax security, unsafe practices or procedures in the laboratory, or improper disposal of biohazardous waste are found.
- When there are changes to a protocol that involve significant changes to the risks and the changes are initiated without prior notification and approval of the IBC.

Certain types of incidents must be reported to NIH/OBA on an expedited basis. Spills or accidents involving recombinant or synthetic nucleic acid molecules requiring BSL 2 containment procedures and that resulted in an overt exposure of personnel must be reported immediately to NIH/OBA. Spills or accidents involving recombinant or synthetic nucleic acid molecules and occurring in BSL 3 or BSL 4 containment laboratories and that result in an overt or potential exposure must be reported immediately to NIH/OBA. The Office of Research Services will aid the IO in completing a report to NIH/OBA when a report is required. **Please note, DePaul does not currently allow research requiring BSL 3 or BSL4 containment procedures.**

Incidents, problems, or concerns that may be reported to a College Dean or Department Head include, but are not limited to:

- Failure of a PI to comply with institutional and federal regulations, guidelines, and policies
- Non-compliance of a serious or continuing nature by a PI

- Violations of safety practices that could have an impact on other persons working near the laboratory or facility of the non-compliant PI.
- Suspension of approval for safety or non-compliance concerns.

The IBC, through the IO, will forward any public comments made regarding IBC actions and the IBC's response to the public comments to the NIH/OBA as required in the *NIH Guidelines*.

6.4 Institutional Official (IO) Reporting

6.4.1 Reports to the Institutional Official

Copies of the IBC minutes and reports of laboratory incidents, accidents, spills potential or actual exposure to infectious or biohazardous materials, and incidents of non-compliance, protocol suspensions or terminations will be provided to the IO for review. The IO will be consulted before any required reports are filed with the Office of Biotechnology Activities or other agencies. The IO will be copied on any reports sent.

In addition, the IBC will conduct at least annually a self-assessment of the program and adherence to the *NIH Guidelines*. An annual report will be made to the IO regarding changes and improvements to the IBC, as well as the results of the self-assessment. The assessment and reporting process provides a mechanism for the Institutional Official to assess the performance of the IBC and to relay this information to other senior institutional officials.

6.4.2 Institutional Official Reporting Responsibilities

The IO must report the following upon being notified by the IBC:

- Any problems with or violations (non-compliance) of the *NIH Guidelines*, any significant incident, accidents, or illnesses related to recombinant or synthetic nucleic acid molecules to the NIH/OBA within 30 days or immediately for overt exposure to agents requiring BSL 2 containment procedures or potential or overt exposure to agents requiring BSL 3 or higher containment procedures. These reports will be made in writing.
- Incidents involving Select agents or toxins will be reported to the CDC or USDA/APHIS, as applicable.
- Any significant research-related illness or accident that may be hazardous to the public health. The IO will cooperate with any state or local public health departments, as needed.

6.5 Reporting of Public Comments or Questions

If the IBC receives any comments or questions from the general public about its activities or actions, the IBC must respond in writing to the comments and questions. When the comments or questions are related to activities covered under the *NIH Guidelines*, the institution must forward both the public comments and the IBC's response to NIH OBA.

Section 7: Non-Compliance

7.0 Noncompliance Introduction

Noncompliance with the *NIH Guidelines* or other federal regulations or guidelines can have serious consequences for an institution. Non-Compliance may result in: 1) suspension, limitation, or termination of financial assistance (NIH funding) for the noncompliant research project or other projects involving recombinant or synthetic nucleic acid molecule research at DePaul, or 2) a requirement for prior NIH approval of any or all recombinant or synthetic nucleic acid molecule projects at DePaul. Other penalties or restrictions may be implemented, depending upon the nature of the noncompliance.

Noncompliance may also result in harm or injury to personnel when procedures have not been properly designed to protect the personnel working with the biohazardous agents or personnel have not completed appropriate training regarding Biosafety hazards and procedures.

7.1 Allegations of Non-Compliance

Failure by research personnel to follow federal regulations and guidelines and institutional policies and procedures may require reporting to the appropriate institutional official, local or federal agencies, or the funding agency, if applicable. Non-compliance includes, but is not limited to conduct of new or ongoing research or teaching activities without proper federal or institutional registration, review, approval or oversight.

The IBC investigates all concerns brought to its attention. Investigators are asked to self-report any non-compliance using the appropriate form on the IBC forms and templates page. Persons who are not the PI should report any allegations of non-compliance or unsafe working conditions to the IBC Chair, to a member of the IBC, the Office of Research Services staff working with the IBC, or the IO. If the allegation is not made directly to the IBC Chair, the allegation will be forwarded to the Chair immediately. Anonymous reports may also be submitted to the Office of Research Services through the online web-based form available on

the IBC web-site. All reports submitted through this channel will be sent to the IBC Chair and included on the next available agenda. Any report or allegation of noncompliance should include as much information as possible, such as the time, dates, location, the persons involved and procedures of concern. The IBC, in cooperation with the Office of Research Services and Environmental Health and Safety, is responsible for investigation and resolution of all allegations of non-compliance. The allegations and the resulting investigation will remain confidential to the extent possible.

7.2 Investigation and Review Process

After receiving a report of non-compliance, the IBC Chair will appoint a subcommittee of IBC members to investigate the allegation. The subcommittee will inform all persons involved in the investigation of the allegations of the purpose of the investigation and the manner in which the investigation will be conducted. The subcommittee will examine all documents and procedures relating to the allegation of non-compliance. Then the subcommittee will interview individuals named in the allegation and others who may have knowledge of the circumstances surrounding the allegation and determine if there is a basis in fact to the support the allegation. The IBC may also observe or inspect the environment and review pertinent records related to the allegation. The subcommittee will report its findings to the convened IBC to make the final determinations regarding the allegations. The subcommittee report will summarize the concern(s) reported to the IBC, the results of the interviews, the results of inspections or observations, the results of record or document reviews, any supporting materials such as correspondence, report, or animal records, any conclusions drawn from review of the *NIH Guidelines*, the *BMBL*, or institutional policies and procedures, and any recommended corrective actions or suggested deadlines for action.

The IBC will discuss the subcommittee report at a convened meeting, and based upon the information provided, will make a determination as to whether the allegation of non-compliance is substantiated and the seriousness of the incident. All persons involved in the allegation of non-compliance will be given the opportunity to respond to the allegations and the subcommittee's findings. The report and the recommendations from the subcommittee will be discussed further and voted upon after everyone involved has had an opportunity to respond. The persons named in the allegations will not be allowed to be in the meeting room during the final discussion and determinations of the IBC. Once a final determination has been made, the IBC will inform all parties involved in writing, including the submitter of the allegation (if possible), of the IBC's determination.

The IO, NIH/OBA, USDA/APHIS and when applicable, the funding agency may be notified of the IBC's determination, when reporting is required.

7.3 Possible Outcomes

The IBC has the authority to review and take action on allegations of non-compliance with the *NIH Guidelines*, the *BMBL*, and DePaul University policies and procedures related to biohazardous agents, and any other legal requirements. The IBC's determinations related to the review of noncompliance may include, but are not limited to one or more of the following determinations and/or actions:

- The investigation did not reveal an issue of non-compliance.
- The investigation revealed non-compliance, which requires further actions such as:
    - Suspension of approval to use recombinant or synthetic nucleic acid molecules, biohazardous agents, or select agents and toxins for a specific research or teaching protocol, pending acceptance and completion of a written corrective action plan from the PI to correct the problem and to prevent the reoccurrence of the problem in the future.
    - Termination of approval to use recombinant or synthetic nucleic acid molecules, biohazardous agents, or select agents and toxins.
    - Initiation of an IBC-mandated corrective action plan and independent audit of an individual protocol or multiple protocols conducted by one PI.
    - Confiscation of recombinant or synthetic nucleic acid molecules, biohazardous agents, or select agents and toxins for a specific research or teaching protocol.
    - Destruction of recombinant or synthetic nucleic acid molecules, biohazardous agents, or select agents and toxins.
- Related aspects of the program require review and possible revision.
- Other related institutional policy or programs may require review or revisions.
- Any other action that is necessary to protect DePaul faculty, staff, and students and the public, including restricting access to the laboratory in order to suspend activities.

Section 8: Record Retention and Record Keeping

8.0 IBC and Office of Research Services

The Office of Research Services retains the following records on behalf of the IBC:

- IBC administrative records, which include rosters, biosketches or resumes/CVs, reports sent to NIH/OBA, other federal agencies, or funding agencies, reports made to the IO or other institutional officials, and the meeting agenda and approved meeting minutes.
- Educational records for personnel working on IBC protocols, IBC members, and Office of Research Services staff who support the IBC
- Protocol files for each investigator protocol submitted to the IBC
- IBC policies, procedures, and guidance

All materials, except for policy procedures, and guidance are retained for ten years. Protocol files are retained for ten years after closure of the protocol. Policies, procedures, and guidance are retained permanently.

8.1 Principal Investigator

Principal Investigators are required to comply with the following record retention schedules:

- For research records related to human subjects activities, the IRB protocol related records must be obtained for a minimum of three years after the closure of the protocol
- For research records related to animal care and use activities, the IACUC protocol related records must be obtained for seven years after the closure of the protocol.
- For activities reviewed and approved by the IBC, protocol records must be retained for 10 years following the closure of the protocol. The protocol records include protocol applications, training records for personnel, copies of laboratory Biosafety Plans or SOPs, Blood Borne Pathogen Plans, and communications to and from the IBC.

Records should be retained in a manner such that they are accessible for inspection and copying by the Office of Research Services, the IBC, and other authorized representatives, such as federal and state authorities.

Section 9: Monitoring, Emergency Planning, and Responses to Emergencies

9.0 Monitoring Program (Including BSL-2 Laboratory Inspections)

The IBC utilizes several methods to monitor the conduct and progress of approved protocols and the safety of DePaul faculty, staff, and students working with biohazardous materials at DePaul.

- Annual renewal reports confirm the staff members who are working on the project, the location of the work, the progress on the work, and whether there have been any adverse events or other problems during the conduct of the work.
- Lab inspections of facilities utilizing BSL 2 agents occur annually, as conducted by the BSO utilizing a checklist. The BSO provides inspection information, particularly any significant problems noted, to ORS and subsequently the IBC to ensure that all laboratory space linked to IBC protocols utilizing BSL 2 agents meet the necessary standards set forth in the *NIH Guidelines* and the *BMBL*.
    - Any issues found during the annual inspections and the actions taken to resolve the issues will be reported to the IBC at a convened meeting. The IBC may aid the BSO in resolving the issues, if needed.
    - During the lab inspections the certification status of each Biological Safety Cabinet is checked and verified.
- Confirming biosafety cabinets are inspected and certified annually utilizing information provided in the IBC applications and communications with departmental personnel responsible for certification procedures.
- Review of allegations of non-compliance.

9.1 Health Surveillance Programs for Workers

9.1.1 Recombinant or Synthetic Nucleic Acid Molecules

The *NIH Guidelines* require that a detailed occupational health plan be developed for personnel working with large-scale research or activities involving viable organisms containing recombinant or synthetic nucleic acid molecules which require BSL 3 or higher containment. The plan should be specific for the agents being utilized and should be developed in advance of working with the agents. In addition, a mock drill of the plan should be undertaken periodically. The plan should include a description of the incident reporting system in place, which includes any loss of containment, spills, accidents, or potential exposures. The plan must specify that all such incidents must be reported immediately to the appropriate institutional authorities and no later than 72 hours to the appropriate public health authorities, when necessary.

DePaul specific policy related to spills, accidents, etc., and occupational health and safety concerns can be found in the DePaul University Emergency Operations Plan (http://emergencyplan.depaul.edu/Documents/University%20Emergency%20Resp

onse%20Plan.pdf) and the Environmental Health and Safety Office Chemical Hygiene Plan (http://ehs.depaul.edu/ManualsandProcedures/index.html)

DePaul does not currently conduct work with agents that require BSL 3 or 4 containment procedures. However, in the interest of safety of all DePaul faculty, staff, and students and all personnel working with biohazardous agents should be aware of the policies in place for dealing with spills, injuries, or exposure to biohazardous agents, including seeking immediate medical attention (when needed) and the campus and Federal reporting requirements.

9.1.2 Animal Research and Teaching Activities

Health surveillance and Occupational Health and Safety programs for individuals working with live animals at DePaul are detailed in the Research Support Facility Policy and Procedure Manual and the Institution Animal Care and Use Committee Policy and Procedure Manual. Copies of these manuals are available on the ORS website or through ORS staff. When the health issue is solely related to the use of recombinant or synthetic nucleic acid molecules or other biohazardous agents, select agents or toxins, health surveillance policies noted in this manual prevail.

9.2 Emergency Planning and Responses

DePaul specific policy related to emergency planning and the expected responses or actions that must be taken for specific emergencies can be found in the DePaul University Emergency Operations Plan (http://emergencyplan.depaul.edu/Documents/University%20Emergency%20Response%20Plan.pdf) and the Environmental Health and Safety Office Chemical Hygiene Plan (http://ehs.depaul.edu/ManualsandProcedures/index.html)

DePaul faculty, staff and students should report any personnel contamination, research-related injuries or illnesses, accidental spills, loss of containment, or any violations of this policy immediately to the IBC, ORS, and appropriate institutional offices as outlined in the DePaul University Emergency Operations Plan. Spills should be dealt with according to the IBC approved SOPs for each protocol. Immediate medical attention should be sought, when necessary.

Revision History

Description	Location	Version	Date
