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

The Application for Research Activities Involving Recombinant and Synthetic Nucleic Acid Molecules (NIH Non-Exempt), Other Biohazardous Agents and Human Materials is to be completed when a research activity involving recombinant or synthetic nucleic acid molecules is conducted at DePaul University and when the research activity is not limited solely to organisms or molecules meeting the NIH exempt category descriptions and when the research activity involves other biohazardous agents as defined by DePaul policy.

In the NIH Guideline (Section I B.) recombinant and synthetic nucleic acid molecules 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.

Some research activities with recombinant and synthetic nucleic acid molecules are considered to be NIH exempt. If an experiment falls into Sections III A, III B, or III C and one of the other sections, the rules pertaining to Sections III A, III B, or III C shall be followed. If an experiment falls into Section III F and into either Sections III D or III E as well, the experiment is considered exempt from the NIH Guidelines.

Biohazardous materials, agents, or toxins are defined as:
Infectious biological or synthetic agents, biologically derived materials or toxins (including endotoxins such as bacterial lipopolysaccharide or LPS found on 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 lipopolysaccharide (LPS) found 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); 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).

Completing the Form:

At the beginning of the application indicate the date of completion of the application. If revisions were requested by the IBC, include the date the application was most recently revised for re-submission to the IBC. This helps the IBC track which version is the most recent version and ultimately, which version is approved initially and later if there is an amendment.

<u>Section I - Principal Investigator:</u>

Complete the information requested for the Principal Investigator (PI) and the Key Research Personnel.

<u>Section II -Key Research Personnel:</u>

Provide the requested information about the members of your research team, including contact information and training. If you do not know who will be part of the research team at the time of the initial submission, you may indicate NA. If you add key research personnel to the project at a later date, you may add them to the protocol using the Application for an Amendment Changing Personnel (not the PI) for an IBC Approved Protocol form.

Section III - Project Information:

Complete the title of the project and indicate the proposed beginning and end dates of the project. These dates are estimates and do not have to be exact. Complete the chart identifying room numbers where the activities will occur and what activities will occur in each room. Then indicate who will have access to the materials and any security measures that will be in place.

Section IV - Funding:

Indicate whether or not the research is funded. If the research is funded, indicate the type of funding and the source of the funding. Provide the requested information about the funding, such as grant title and grant number. If you have more than one source of funding for the project, provide information on all the sources of funding.

Section V - Conflict of Interest:

Answer the question pertaining to financial conflict of interest. Keep in mind that the PI is responsible for collecting information from all persons listed as key research personnel on the application and certifying whether or not any of these individuals have a conflict related to this project. This section contains links to all DePaul policies on conflict of interest. The PI should read each policy to ensure that he/she understands what a conflict of interest may be in a research context.

Section VI - Protocol Summary:

Complete the check boxes, which provide an overview of what type of agents and activities will be part of the research. Provide a summary of the aims and goals of the research. Then provide a summary of the project and how it will be conducted, including methods and experimental design and focusing on how the agent is used and/or manipulated. Finally, describe any benefits to humans or animals, science, or society that may result from the research.

Section VII - Biohazardous Agent Information:

This section asks about the specific agents to be utilized in the research and general information about the agents such as the risk group, the Biosafety containment level and any specific risks related to the agents. Complete the questions pertaining to any vaccinations that may be needed for personnel working on the projects and whether or not any special permits are required. Then

indicate whether there will be any shipping, transport, and receiving of agents for the research and if so, what the procedures will be for these processes.

Section VIII - Recombinant or Synthetic Nucleic Acid Molecules:

This section asks questions pertaining to recombinant or synthetic nucleic acid molecules so that the IBC can obtain information about the source, the vector, gene expression, etc. for the these types of agents. If the research does not involve these types of agents, skip this section after responding No and go to the next section of the form.

Section IX - Use of Live Animals:

This section gathers information about the use of biohazardous agents with live animals. If live animals are not involved in your research, indicate No and skip to the next section.

Section X - Infectious Agents, Biological Toxins, Select Agents or Toxins, Other Biohazardous Agents:

This section gathers information about the use of infectious agents, biological toxins, select agents or toxins, and any other types of biohazardous agents that might be used in the research. It is important for the IBC to know who or what is at risk due to using the agent, what the risks are if there is an exposure to the agent, how the agent is manipulated and whether work will generate aerosols (requiring the use of a biosafety -cabinet). If the research does not involve these other types of agents, indicate No and skip to the next section.

Section XI - Human Cell or tissue Culture:

This section gathers information about research involving human cell or tissue culture. Identify the cell line or strain and source of the tissue culture material. Indicate whether or not the material has been documented to be free of blood borne pathogens. If so, then the PI must provide a copy of the documentation to the IBC. This can be an entry from a catalog or other source of the cell line. If the cell line has not been documented to be free of blood borne pathogens, then the materials require BSL-2 containment procedures. BSL-2 laboratory inspections of the laboratory facilities must also be completed. If the research does not involve human cell lines or cultures, indicate No and skip to the next section.

Section XII - Human Blood, Blood Components, Human Body Fluids, Tissue and/or Excreta:

This section gathers information about research that involves human blood, blood components, human body fluids, tissue and/or excreta. Please detail how materials will be collected and who will be doing the collecting. If the research does not involve human blood, blood components, human body fluids, tissue and/or excreta, indicate No and skip to the next section.

Section XIII - Plant or animal cell lines:

This section gathers information on plant or animals cells and if they will be utilized in the research. If the research does not involve plant or animal cells, indicate No and skip to the next section.

Section XIV - Training and Safety Measures:

This section gathers information about training and safety measures for the research project. The researcher should describe the training plan for any personnel who will be working with the biohazardous agents, who will provide the training, any special PPE that should be utilized, and how the training will be documented. The researcher should prepare a laboratory manual for research personnel that include safety information as listed in this section. The laboratory manual may be submitted as an attachment to the form versus retyping the information into the form. A template for a possible manual can be found in the *Appendix to the Guidelines for Biosafety in Teaching Laboratories*: http://www.asm.org/images/Education/FINAL_Biosafety_Guidelines_Appendix_Only.pdf The researcher should also indicate whether a biosafety cabinet will be utilized or if any other type of precaution is needed when working with the agents.

Section XV - Sanitation and Disposal:

This section gathers information about the handling, decontamination and disposal of the agents, waste and equipment used.

Section XVI - Assurances for the Research Involving Biohazardous Agents:

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

Submit the completed application via email to orp@depaul.edu . You should hear back from our office within 15 business days or less. If you do not hear from us within 15 business days, contact Diana Alfaro at (312) 362-7592 or dalfaro@depaul.edu . Projects that are not limited solely to the use of NIH exempt recombinant and synthetic nucleic acid molecules require either designated member review (DMR) or full committee review (FCR) by the IBC for initial review.