**Biological Research Registration Form**

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| --- | --- |
| **Principal Investigator:**  | **Department:**  |
| **Email:**  | **Phone Number:**  |

**Title of Research Project:**

**Instructions:** Biohazards are infectious agents or biologically-derived potentially infectious materials that present a potential risk to the health of humans or animals, either directly through infection or indirectly through environmental contamination. Potentially infectious materials may have the ability to replicate and give rise to potentially large populations when small numbers are released in nature from a controlled environment. Principal investigators should indicate below any of the hazard categories that are stored or in use within laboratories under their supervision. **If boxes are checked, the appropriate section of this registration form must also be completed. In addition, a summary of the research project must be included as described in Section I. The form must be certified by signature, and specific biosafety protocols may also be required as described in Section IV. All forms should be submitted to the Chair of the Longwood University Institutional Biosafety Committee.**

**[ ]  Identified or Potential Pathogens:** human, animal, or plant pathogens, including bacteria, prions, rickettsia, fungi, viruses, and parasites. **Complete Section I: Microbial and Pathogen Registration.**

**[ ]  Human blood and other potentially infectious material:** All human blood, blood products, unfixed clinical tissues, and any body fluids. **Complete Section I: Microbial and Pathogen Registration.**

**[ ]  Cells/Cell lines:** Cultured cells from humans, non-human primates, and other mammalian species and the potentially infectious agents these cells may contain. **Complete Section I: Microbial and Pathogen Registration.**

**[ ]  Clinical specimens: Complete Section I: Microbial and Pathogen Registration.**

**[ ]  Infected animals:** Live animals, animal tissues, animal bedding/waste materials, and other materials derived from known or potentially infectious animals. **Complete Section I: Microbial and Pathogen Registration.**

**[ ]  Toxins or select agents:** (bacterial, fungal, plant, etc.) **Complete Section I: Microbial and Pathogen Registration.**

**[ ]  Recombinant DNA and related products:** Recombinant DNA molecules are defined as either (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) DNA molecules that result from the replication of those described in (i). **Complete Section II: Recombinant DNA Registration.**

* *A summary of section III of the NIH Guidelines is provided in Appendix A.*
* *Definitions of frequently used molecular terminology are provided in Appendix B.*
* *Biosafety levels and risk groups are defined in Appendix C.*

**Section I. Summary of Research Project Involving Biological Hazards**

Provide a summary of the overall objectives and goals of the research project that involves biological hazards. Briefly explain how the agents documented in Sections II and III of this form will be used. Please avoid field-specific terms and phrases to ensure that all members of the committee, who may not be experts in your research field, understand the proposed research. *Please limit your summary to* ***350*** *words and describe a single research project. If you have several distinct research projects, please fill out a separate Biological Hazard Registration Form for each project.*

**Section II. Microbial and Pathogen Registration**

Please describe any potentially infectious material and/or microbial agents used in your research. Please provide a summary statement of your research if it involves any microbial or potentially infectious material as described in Section I. If your research involves potentially infectious material, select agent microbial materials, or microbial materials that require biosafety level 2 or higher, provide standard operating procedures (SOPs) for the materials as described in Section IV.

1. Potentially Infectious Materials: Does the research you conduct or oversee uses human blood or other potentially infectious materials? If yes, please describe the human blood or other potentially infectious materials in the table below.

No [ ]  Yes [ ]

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| --- | --- | --- |
| Type of material (fluid or tissue) | Location (Building/Room) and Status (storage, active research) | Description |
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1. Select Agent Microbial Materials: Does the research you conduct or oversee uses any of the following select agent microbial materials? If yes, please describe the select agent in the table below.

*A list of Health and Human Services (HHS) and US Department of Agriculture (USDA) select agents and toxins is available at* [*https://www.selectagents.gov/selectagentsandtoxinslist.html*](https://www.selectagents.gov/selectagentsandtoxinslist.html)*.*

No [ ]  Yes [ ]

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| --- | --- | --- |
| Type of material (select agent) | Location (Building/Room) and Status (storage, active research) | Description |
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1. Other Microbial Materials: In addition to the select agents listed above, please list any other microorganisms (bacteria, viruses, fungi, or human/animal cell lines) currently under your supervision. Please list the type and species/strain in your possession and their location at Longwood University.

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| --- | --- | --- | --- | --- |
| Type of material (bacterium, virus, fungus, cell line) | Genus and species | Biosafety Level | Location (Building/Room) and Status (storage, active research) | Description |
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**Section III. Recombinant DNA (rDNA) Registration**

This form is designed to categorize rDNA experiment(s) according to definitions provided by the NIH Guidelines. Use the following checklists as a tool in assessing the appropriate NIH category (Exempt or Non-exempt) for all research experiments currently conducted by you, or under your supervision. Each statement listed represents a description of an assigned category of experiments reflected in Section III of the NIH Guidelines. The specific NIH Guidelines section is referenced next to the statement. Please provide a summary statement of your research if it involves any rDNA as described in Section I. If your research involves rDNA that require biosafety level 2 or higher, provide standard operating procedures (SOPs) for the materials as described in Section IV.

1. List all research labs under your control in which rDNA studies or procedure take place:

**Building/Room Number:**

**Building/Room Number:**

1. Please check the appropriate box(es) to indicate the type of recombinant experiments conducted by you or under your control.
	1. Exempt Experiments (Section III-F of NIH Guidelines)

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| --- | --- |
| **Experiments** | **Yes?** |
| Are the experiments performed without the use of living organisms or viruses? (Section III-F-1) | **[ ]**  |
| Do the experiments consist entirely from a single nonchromosomal or viral DNA source? (Section III-F-2) | **[ ]**  |
| Do the experiments consist entirely of DNA from a prokaryotic host including its indigenous viruses? (Section III-F-3) | **[ ]**  |
| Do the experiments consist entirely of DNA from a eukaryotic host excluding its indigenous viruses? (Section III-F-4) | **[ ]**  |
| Do the experiments consist entirely of DNA segments from natural exchangers?(Section III-F-5 and Appendix A) | **[ ]**  |
| Are the experiments considered safe (i.e. **do** **not** pose a significant risk to health or the environment)? (Section III-F-6 and Appendix C) ***Some common examples of these experiments are listed below***. | **[ ]**  |
| * Tissue culture experiments involving recombinant DNA molecules that do not contain one-half or more of any eukaryotic viral genome
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| * Tissue culture experiments that do not involve risk group 3 or 4 organisms or nucleic acid from risk group 3 or 4 organisms
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| * Tissue culture experiments that do not involve introduction of genes coding for molecules toxic for vertebrates
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| * Tissue culture experiments that do not involve infectious viruses
 |
| * Tissue culture experiments that do not involve defective viruses in presence of helper viruses
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| * *E. coli* K-12 , *S. cerevisiae* and *S. uvarum* experiments that do not involve risk group 3 or 4 organisms or nucleic acid from risk group 3 or 4 organisms
 |
| * *E. coli* K-12 , *S. cerevisiae* and *S. uvarum* experiments that do not involve introduction of genes coding for molecules toxic for vertebrates
 |
| * *E. coli* K-12 , *S. cerevisiae* and *S. uvarum* experiments that do not involve any large-scale experiments (more than 10 liters of culture)
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* 1. Non-exempt experiments

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| --- | --- |
| **Experiments** | **Yes?** |
| Transfer of drug resistance trait to organism that does not acquire it naturally (Section III-A-1) | [ ]  |
| Formation of recombinant DNA containing genes coding for the synthesis of molecules toxic for vertebrates (Section III-B-1) | [ ]  |
| Human gene transfer experiments (Section III-C-1) | [ ]  |
| Human or animal pathogen (defined as risk group 2,3 or 4 organism) used as either the host organism or as a vector (Section III-D-1) | [ ]  |
| DNA from risk group 2, 3 or 4 organisms cloned into nonopathogenic prokaryotic or lower eukaryotic host-vector systems (Section III-D-2) | [ ]  |
| Recombinant DNA or RNA experiments involving the use of infectious animal or plant viruses in tissue culture systems (Section III-D-3) | [ ]  |
| Recombinant DNA or RNA experiments involving the use of defective animal or plant viruses in the presence of helper virus in tissue culture systems (Section III-D-3) | [ ]  |
| Recombinant DNA experiments involving whole animal (Section III-D-4) or plants (Section III-D-5) | [ ]  |
| Experiments involving more than 10 liters of culture (Section III-D-6) | [ ]  |
| Catchall section for experiments that are not exempt, but are not covered in other sections (Section III-E) | [ ]  |

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| --- | --- | --- | --- | --- |
| Source DNA (genus, species) | Propagation Host (genus, species, strain) | Target recipient (Cell culture or whole animal) | Target recipient (genus, species) | Exempt? Yes/No |
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1. Please answer the following questions for each recombinant DNA experiment currently conducted by you, or under your supervision. Indicate if the DNA is used for exempt or non-exempt experiments. Indicate N/A (not applicable) where appropriate.

**Section IV. Standard Operating Procedures and Description of Research**

A **Standard Operating Procedure (SOP)** is required for any experiments that utilize potentially infectious material, select agents, pathogens or recombinant DNA experiments that are not exempt according to NIH Guidelines. The SOP must explain handling for the specific agent including: procurement and storage, protective equipment, waste handling, training of individuals that will complete the procedures, equipment use (i.e.: biosafety cabinet, centrifuge, sonication), and sharps handling.

**Training requirement:** The Principle Investigator must complete the “Biosafety Training for the Principle Investigator” CITI training modules PRIOR to receiving IBC approval. If the research involves potentially infectious materials, the “OSHA Bloodborne Pathogens” CITI training modules must also be completed. To document completion of the appropriate CITI training modules, the CITI Completion Certificate(s) needs to be submitted with this form. Failure to comply with CITI training regulations may result in rejection and/or suspension of the research project.

**Certification**

* I have read and answered all applicable questions and assure that all statements made are accurate and account for all experiments being conducted by me, or under my supervision.
* I am familiar with and will comply with the Longwood University Office of Environmental Health and Safety Biosafety Manual for Laboratory and Research Operations and I assume responsibility for compliance by all personnel involved with this protocol.
* All individuals performing experiments described in this application are technically competent and have been (or will be) properly trained in the procedures to ensure that safety protocols are followed as described.
* I understand that any modification made to experiments that may change the answers to the above questions will require formal notification to the Institutional Biosafety Committee prior to implementing the modification.

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Printed Name:**

**Date:**