**INSTUTUTIONAL BIOSAFETY COMMITTEE APPLICATION FOR STUDY APPROVAL**

* Protocol approval is valid for 3 years or the length of grant funding period if less than 3 years. At the end of approval period, a new application must be submitted for extension of an approval.
* Protocol involving rDNA in human or animal subjects will be approved for 1 year only. At the end of approval period, a new application must be submitted for extension of an approval.
* Submit the original to the Office of Research Compliance (ORC).
* *Note: An IACUC application must also be submitted if your protocol involves animals.*

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| SECTION 1: PROJECT INFORMATION | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 | | PI Name | | | | | | | | | |  | | | | | | | | | | | | | | | |
| Department | | | | | | | | | |  | | | | | | | | | | | | | | | |
| Office Location | | | | | | | | | |  | | | | | | | | | | | | | | | |
| Phone Number | | | | | | | | | |  | | | | | | | | | Email Address | | | | |  | |
| 2 | | Project Title | | | | | | | | | |  | | | | | | | | | | | | | | | |
| 3 | | Funding Agency | | | | | | | | | |  | | | | | | | | | | | | | | | |
| 4 | | Funding periods | | | | | | | | | |  | | | | | | | | | | | | | | | |
| 5 | | Lay Summary | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6 | | Brief Description Of Project (attach the original grant application) | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |
| 7 | | Personnel | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name | | | | | | | | | | Role in Project | | | | | Phone | | | | | | | | | | |
|  | | | | | | | | | |  | | | | |  | | | | | | | | | | |
|  | | | | | | | | | |  | | | | |  | | | | | | | | | | |
| 8 | | IBC Application Type | | | | | | | | | | New, Renewal, Previous IBC Approved No.\_\_\_\_\_\_ | | | | | | | | | | | | | | | |
| 9 | | Other Approvals | | | | | | | | | | | | | | | | | | | | | | | | | |
| IRB | | | | | | | | | | Not required, Submitted, Approved. | | | | | | | | | | | | | | | |
| IACUC | | | | | | | | | | Not required, Submitted, Approved. | | | | | | | | | | | | | | | |
| Radiation Safety | | | | | | | | | | Not required, Submitted, Approved. | | | | | | | | | | | | | | | |
| Certificate for Environmental Compliance | | | | | | | | | | Not required, Submitted, Approved | | | | | | | | | | | | | | | |
| 10 | | Biological Materials Used | | | | | | | | | | | | | | | | | | | | | | | | | |
| rDNA (Sections 2 and 6)  Infectious Agents (Viruses, Bacteria, Fungi) (Sections 3 and 6)  Biotoxins (Sections 3 and 6)  Human or Non-human Primate Tissues, Cell Culture or Body Fluids (Sections 4 and 6)  Live Animals (Sections 5 and 6) | | | | | | | | | | | | | | | | | | | | | | | | | |
| SECTION 2: USE OF RECOMBINANT DNA | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 11 | | Type of Research (Refer to NIH Guidelines, Section III for details) | | | | | | | | | | | | | | | | | | | | | | | | | |
| Level | | | | Approval/Review | | | | | | | | Requirement | | | | | | | | | | | | | |
|  | III-A | | | NIH/Dir, RAC, IBC | | | | | | | | Transferring a drug-resistant gene into pathogenic microorganisms | | | | | | | | | | | | | |
|  | III-B | | | NIH/OBA, IBC | | | | | | | | Cloning of toxin molecules with LD50 < 100 ng per kg body weight | | | | | | | | | | | | | |
|  | III-C | | | RAC, IRB, IBC | | | | | | | | rDNA transferred into human | | | | | | | | | | | | | |
|  | III-D | | | IBC, (IACUC) | | | | | | | | rDNA transferred to or from: whole animals, whole plant (high risk group), agents listed in Risk Group 2, 3, or 4 or infective eukaryotic viruses in cell culture | | | | | | | | | | | | | |
|  | III-E | | | IBC, (IACUC) | | | | | | | | rDNA involving: eukaryotic viruses (not more than 2/3 genome) in cell culture, whole plant (low risk group), arthropods, or generation of transgenic rodents (BSL1), any work not covered in other categories (most non-pathogenic rDNA work) | | | | | | | | | | | | | |
| 12 | | Description of DNA Vector (List all plasmids/ vectors, use additional paper if needed) | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name | | | | | |  | | | | | | | | | | | | | | | | | | | |
| Origin | | | | | | Virus, Bacterium, Yeast, Fungus,  Animal, Plant, | | | | | | | | | | | | | | | | | | | |
| Source | | | | | | Purified /constructed in PI’s lab.  Purchased. Vender: \_\_\_\_\_\_\_\_\_  Others. Specify\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | | | |
| If it is a viral vector, is it replicative? | | | | | | | | | | | | | | | | Yes. Please complete Section 3.  No. | | | | | | | | | |
| If it is a non-replicative viral vector, is helper virus or cell line packed with replication required genes used in preparation? | | | | | | | | | | | | | | | | Yes. Provide documented evidence for complete removal of the replication required genes.  No | | | | | | | | | |
| 13 | | Description of Gene Insert (List all gene inserts, use additional paper if needed) | | | | | | | | | | | | | | | | | | | | | | | | | |
| Origin | | | | | Virus, Bacterium, yeast Fungus,  Human, Non-human animal, specify\_\_\_\_\_\_ Plant | | | | | | | | | | | | | | | | | | | | |
| Source | | | | | Synthesized/Isolated in PI’s lab.  Purchased. Vender: \_\_\_\_\_\_\_\_\_  Others. Specify \_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | | | | |
| Attach a map of the final construct including the vector and the insert. | | | | | | | | | | | | | | | | | | | | | | | | | |
| Does the insert represent more than 2/3 of the viral genome? | | | | | | | | | | | | | | | | | | | | | | | Yes, No | | |
| Is this a deliberate attempt to express a foreign gene in the cloning vehicle? | | | | | | | | | | | | | | | | | | | | | | | Yes, No | | |
| Can this gene be expressed in mammalian cells or cell lines? | | | | | | | | | | | | | | | | | | | | | | | Yes, No | | |
| Will this expressed gene product be purified? | | | | | | | | | | | | | | | | | | | | | | | Yes No | | |
| Description of the biological activity of expressed gene product or the nature of gene sequence if the gene is not intent to be expressed | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |
| 14 | | List of all plasmid/genetic construct and host(s), such as E. coli, yeast, cell line, or mouse for each construct. (\*The table can be expanded if more than 2 hosts or constructs are used) | | | | | | | | | | | | | | | | | | | | | | | | | |
| Host | | | | | | | Strain | | | | | | | | | | Plasmid/Construct | | | | | | | | |
|  | | | | | | |  | | | | | | | | | |  | | | | | | | | |
|  | | | | | | |  | | | | | | | | | |  | | | | | | | | |
| 15 | | Detail description of the purpose and use of the each plasmid/genetic construct in respective host listed in 14. | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |
| 16 | | What are the potential harms to humans for inadvertent exposure (contact, injection, inhalation, or ingestion) to the genetic construct, expressed gene product, or host harboring this genetic construct and release of these agents to the environment? | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |
| 17 | | How will the laboratory personnel be protected from such exposures? | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |
| SECTION 3: USE OF INFECTIOUS AGENT AND BIOLOGICAL TOXIN | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 18 | | Risk Group of Agent or Toxin Used (Refer to NIH Guidelines, Appendix B for details) | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | 1 | Agent that is not associated with human disease | | | | | | | | | | | | | | | | | | | | | | | |
|  | 2 | Agent that is associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available | | | | | | | | | | | | | | | | | | | | | | | |
|  | 3 | Agent that is associated with serious or lethal disease for which preventive or therapeutic interventions may be available | | | | | | | | | | | | | | | | | | | | | | | |
|  | 4 | Agent that is associated with serious or lethal disease for which preventive or therapeutic interventions are not usually available | | | | | | | | | | | | | | | | | | | | | | | |
| Is it a select agent? | | | | | | | | | | Yes , Category \_\_\_ No | | | | | | | | | | | | | | | |
| Name of Agent | | | | | | | | | |  | | | | | | | | | | | | | | | |
| Source of Agent | | | | | | | | | |  | | | | | | | | | | | | | | | |
| 19 | | What are the diseases or pathologic effects associated with the agent? | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |
| 20 | | Detail Description of the Use of the Agent | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |
| 21 | | What are the preventive and protective measures for the inadvertent exposure (contact, injection, inhalation, or ingestion) or release of agents to the environment? | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |
| SECTION 4: USE OF BLOOD AND OTHER BODY FLUIDS, UNFIXED TISSUES, PRIMARY CELL CULTURE DERIVED FROM HUMAN OR NON-HUMAN PRIMATES | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 22 | | Type of Bio-specimen | | | | | | | | | |  | | | | | | | | | | | | | | | |
| Source | | | | | | | | | |  | | | | | | | | | | | | | | | |
| 23 | | Will this specimen be tested for the possible presence of infectious agents? | | | | | | | | | | | | | | | | | | | | | | | | | |
| Yes, | | | Hepatitis HIV Others, specify\_\_\_\_\_\_, | | | | | | | | | | | | | | | | | | | | | | |
| No, | | | Please provide liability statements and/or evidence for the absence of infectious agent. | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | |
| 24 | | Detail Description of the Use of the Bio-specimen | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |
| 25 | | How will the laboratory personnel be protected from the exposures of the possible presence of infectious agents in the bio-specimen if the evidence for the absence of infectious agent is not provided in Item 23? | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |
| SECTION 5: USE OF LIVE ANIMALS | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 26 | Animal Information | | | | | | | | | | Species\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Gender\_\_\_\_\_\_\_\_\_\_\_\_  Quantity\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | |
| Location of Housing | | | | | | | | | |  | | | | | | | | | | | | | | | | |
| Biosafety Level | | | | | | | | | |  | | | | | | | | | | | | | | | | |
| 27 | Detail description of the procedures that will be conducted on the animals in the Animal Housing Facility. | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| What are the health risks to the animal caretaker? | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| What are preventive measures for such risks? | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 28 | Will animals be removed from the housing area for study? | | | | | | | | | | | | | | | | | | | Yes. Provide Permission from the Director of Veterinary Service.  No. | | | | | | | |
| How animals will be transported? | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| What procedures will be conducted on the animals outside the animal housing facility? | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| How will the laboratory personnel be protected from the health risks that may incur? | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 29 | Method of Decontamination of Equipment Used for the Animal Studies | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Equipment | | | | | | | | | Method of Decontamination | | | | | | | | | | | | | | | | | |
|  | | | | | | | | |  | | | | | | | | | | | | | | | | | |
| SECTION 6: LABORATORY INFORMATION | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 30 | | Sites for Conducting Study | | | | | | | | | | | | | | | | | | | | | | | | | |
| Location | | | | | | | | | |  | | | | | | | | | | | Phone | | | |  |
| Biosafety Level  (submit the laboratory safety level checklist) | | | | | | | | | |  | | | | | | | | | | | Date of Inspection  (for BSL2 or higher) | | | |  |
| Biohazard Signs Posted | | | | | | | | | | Yes No | | | | | | | | | | | | | | | |
| Method of Biohazardous Waste Disposal | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |
| Decontamination Procedure for Working Area | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |
| 31 | | Biosafety Cabinets | | | | | | | | | | | | | | | | | | | | | | | | | |
| Manufacturer | | | | | | | | | | Class/Type | | | | Location | | | | | | | | Certification Date | | | |
|  | | | | | | | | | |  | | | |  | | | | | | | |  | | | |
| Decontamination Procedure | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |
| 32 | | Personal Protective Equipment | | | | | | | | | | | | | | | | | | | | | | | | | |
| Gloves | | | | | | | | | | Type | | |  | | | | | | | | | | | | |
| Eye Protection | | | | | | | | | | Type | | |  | | | | | | | | | | | | |
| Foot Protection | | | | | | | | | | Type | | |  | | | | | | | | | | | | |
| Protective Clothing | | | | | | | | | | Type | | |  | | | | | | | | | | | | |
| Respiratory Protection | | | | | | | | | | Type | | |  | | | | | | | | | | | | |
| Others | | | | | | | | | | List | | |  | | | | | | | | | | | | |
| 33 | | Emergency Plan | | | | | | | | | | | | | | | | | | | | | | | | | |
| What are the courses of actions to manage the accident if inadvertent exposure (contact, injection, ingestion, or inhalation) and release of agents to the environment occur? | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |
| Contact Person(s) | | | | | | | | | |  | | | | | | | | | | | | | | | |
| Contact Phone Number | | | | | | | | | |  | | | | | | | | | | | | | | | |
| 34 | | Personnel’s Safety Training | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name | | | | | | | | | | | Safety Training Date | | | | | | | | | Certificate No. | | | | | |
| (PI) | | | | | | | | | |  | | | | | | | | | |  | | | | | |
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| --- | --- | --- | --- |
| ASSURANCE OF PI  By attaching my name, I agree to the following   1. I have read and agree to comply with the requirement specified by the NIH Guideline involving Recombinant DNA. 2. I have read and am familiar with the standard and special microbiological practices, containment equipment, personal protective equipment, and laboratory facilities recommended for the Biosafety level indicated by CDC/NIH applicable to this project. 3. I accept the responsibility for training and safety of all laboratory workers involved in the project. All research personnel are familiar with and understand the relevant biosafety practice, protective equipment and techniques, potential biohazards, and emergency procedures. 4. I verify that all items described above are accurate. | | | |
| PI | Printed name | Signature | Date |
| Division Chair | Printed name | Signature | Date |

|  |  |
| --- | --- |
| For IBC Use Only | |
| IBC File no. |  |
| Date Received |  |
| IBC Recommendation | Approved, from \_\_\_\_\_\_to \_\_\_\_\_\_  Approved with Provisions  Disapproved |
| Date |  |
| Date of IBC Notification to PI |  |