|  |  |
| --- | --- |
|  | **DREXEL UNIVERSITY’S INSTITUTIONAL BIOSAFETY COMMITTEE****BIOSAFETY PROTOCOL APPLICATION*****Animal Use Addendum (Form D)*** |
| ***Instructions**** *Complete this form for all research activities involving the use of animals in conjunction with recombinant DNA (rDNA), toxins, chemical carcinogens, or cytotoxic drugs (collectively referred to hereafter as “hazardous substances.”*
* *This form must be accompanied by the* ***General Biohazard Form (Form A)****.*
* *If your animal experiments involve the use of more than one hazardous substance, fill out one form for each hazardous substance used in your experiments.*
* *Changes to an approved biosafety protocol must be made by filing a* ***Protocol Amendment Form (Form E)*** *for Institutional Biosafety Committee review.*
* *If you have questions about this form or the application process, please contact us by e-mail (**biosafety@drexel.edu**).*
 |

|  |
| --- |
| 1. PROJECT AND INVESTIGATOR INFORMATION |
| Project Title (Must exactly match the grant title if externally funded)      |
| Principal Investigator’s Name      |

|  |
| --- |
| 2. RESEARCH DESCRIPTION |
| a. Provide a brief description of experimental procedures that involve animal use. |
|       |
| b. Indicate the species of the animals to be used. **Note**: Use one form for each species (unless details for all species are identical). |
|       |

|  |
| --- |
| 3. BIOHAZARDS ASSOCIATED WITH ANIMAL USE (check all that apply): |
| [ ]  | Pathogenic organisms or human/primate samples (as described on **Form A**) |
| [ ]  | Generation or use (in vitro or in vivo) of rDNA (also complete **Form B**) |
| [ ]  | Use of chemical carcinogens or cytotoxic agents (also complete **Form C**) |

|  |
| --- |
| 4. BIOHAZARDS AND RISKS |
| a. List the hazardous substance associated with experiments involving animals. **Note**: Use one form for each hazardous substance (unless details for all hazards are identical). |
|       |
| b. Indicate the Animal Biosafety Level (ABSL) required for this work. For more information about ABSL categories, refer to Biosafety in Microbiological and Biomedical Laboratories ( https://www.cdc.gov/labs/pdf/SF\_\_19\_308133-A\_BMBL6\_00-BOOK-WEB-final-3.pdf |
| ABSL 1 [ ]  ABSL 2 [ ]  ABSL 3 [ ]  ABSL 4 [ ]  |
| c. Where will the hazardous substance be encountered during experiments involving animals? |
| *Location of work with animals* | *Building* | *Room Number* |
|  |       |       |
|  |       |       |
|  |       |       |
| d. Complete the following table to indicate how the hazardous substance will be administered to animals. Routes of administration include (but are not limited to) intravenous, intraperitoneal, intracerebral, gavage, application to skin, ingestion, and inhalation. If only one administration is required, enter “Once” for the frequency. If multiple administrations are required, indicate the frequency of administration (e.g., daily, every 3 hours). Duration of hazardous conditions after administration typically include 72hrs after last treatment with chemical and viral vector and duration of the experiment with human cells and infectious agents.  |
| *Location ofadministration* | *Route ofadministration* | *Frequency of Administration* | *Duration of the hazardous condition after administration* |
|  |       |       | Other:       |
|  |       |       | Other:       |
|  |       |       | Other:       |
| e. Describe the potential modes of exposure (e.g. inhalation, ingestion, skin contact, injection) for personnel working with the hazardous substance and handling animals after administration of the hazard.. |
|       |

|  |
| --- |
| 5. RISK MANAGEMENT |
| a. As a consequence of working with this hazardous substance, do people working with animals require any prophylactic vaccinations, health surveillance, or protective outerwear beyond that required for normal entry into the animal facility or animal facility room (e.g., respirator, safety glasses)? If your answer is **Yes**, provide the information below. **Note**: It is the responsibility of the **Principal Investigator** to make arrangements for special protective outerwear (other than gloves, gowns, and shoe covers), vaccinations, health surveillance, or training in these areas. | [ ]  Yes [ ]  No |
| *Location whereprotection is needed* | *Description ofrequired protection* | *Required durationof protection* |
|  |       |       |
|  |       |       |
|  |       |       |
|  Are there any requirements for decontamination and disposal of protective outerwear, other than disposal in red bags in animal rooms? If so, describe the procedure. |
|       |
|  Describe, if required, the vaccination or health surveillance. Include in your description the source of the vaccination or the provider of the health surveillance service. |
|       |
| b. When working with animals, is it necessary to have mechanical protection from the hazardous substance (e.g., use of a biosafety cabinet or change station for injections or changing cages, microisolator cages)? If your answer is **Yes**, provide the following information. Duration of protection typically include 72hrs after last treatment with chemical and viral vector and duration of the experiment with human cells and infectious agents. | [ ]  Yes [ ]  No |
| *Location whereprotection is needed* | *Description of necessarymechanical protection*  | *Required durationof protection* |
| Animal Facility |  | Other:       |
|  |       | Other:       |
|  |       | Other:       |
|  Describe the procedures necessary to decontaminate the mechanical protection if different than cleaning and disinfection materials provided by ULAR. |
|       |
| c. Do individuals who interact with the animals need to be informed of appropriate safety procedures that need to be followed? If your answer is **Yes**, indicate how these individuals will be trained in or informed of these procedures. **Note**: Personnel affected by the use of hazardous substances in animals include: (i) individuals who administer the hazard, (ii) individuals who perform animal surgeries, (iii) animal facility personnel who care for the animals, clean cages, and otherwise regularly interact with the animals. Responses should include: door signage; cage signage; discussion with ULAR staff prior to experiments; and/or a final copy of this form in the animal room. | [ ]  Yes [ ]  No |
| *Individual needing training* | *Description of training* |
| Animal Facility |       |
|  |       |
|  |       |
| d. Are there any additional precautions needed during cage changing to protect against dust formation or the production of aerosols? If your answer is **Yes**, select the necessary precaution (\*investigator-initiated cage change). | [ ]  Yes [ ]  No |
| Perform cage change . |
| e. Should bedding be decontaminated by autoclaving prior to dumping the bedding into plastic bags? | [ ]  Yes [ ]  No |
| f. Are there any additional precautions that are necessary for working with these animals? If your answer is **Yes**, describe the necessary precautions. | [ ]  Yes [ ]  No |
|       |
| g. Describe the storage and disposal of animal carcasses if other than routine carcass disposal. *Routine disposal includes placing carcasses in red bags and bags into the ULAR coolers.* |
|       |

|  |
| --- |
| 6. EMERGENCY PROCEDURES |
| a. As a consequence of working with this hazardous substance in animals, are there procedures to be followed in the event of accidental **direct** human exposure (e.g., needle stick, inhalation, animal bite)? If your answer is **Yes**, describe the necessary actions. **Note**: Refer to the following specific guidance regarding needle sticks or injuries by contaminated sharps. | [ ]  Yes [ ]  No |
|       |
| **Note**: In the event of a needle stick or any other injury resulting from exposure to contaminated sharps, employees should, in accordance with the Drexel University Bloodborne Pathogens Compliance Plan, take the following actions:* Immediately cleanse the affected area with soap and water. Be sure to use plenty of soap and a strong stream of water. If the eyes, nose, or mouth are exposed, rinse heavily with water only (no soap).
* After cleansing, notify your supervisor immediately and seek medical care at Concentra Occupational Health (located 219 N. Broad Street 1st Floor Suite 101) for post exposure evaluation. This facility is open Monday through Friday from 8 am until 5pm. If Concentra is not available or if exposure occurs after hours or on the weekend, please proceed to the nearest emergency room.
* Complete and fax an Employee Injury Report to Risk Management and the Department of Environmental Health and Radiation Safety (EHRS) within 24 hours. EHRS will conduct an accident investigation after any exposure incident.
 |
| b. As a consequence of working with this hazardous substance in animals, are there procedures to be followed in the event of accidental **indirect** human exposure (e.g., a spill on the floor)? If your answer is **Yes**, describe the necessary actions. **Note**: If a response to **indirect** exposure requires materials other than those commonly available (e.g., paper towels), it is the responsibility of the **Principal Investigator** to provide the necessary supplies. | [ ]  Yes [ ]  No |
|       |
| c. If medical attention is necessary, does a physician require special training or information? If your answer is **Yes**, describe the training or information, and indicate how the physician will receive that training or knowledge. **Note**: It is the responsibility of the **Principal Investigator** to arrange for such training and provide the necessary information. | [ ]  Yes [ ]  No |
|       |

|  |
| --- |
| 7. ADDITIONAL INFORMATION |
| Use this text field to provide any additional information pertinent to your work and this biosafety protocol form. |
|       |

|  |
| --- |
| CERTIFICATION BY THE PRINCIPAL INVESTIGATOR |
| I affirm that, to the best of my knowledge, the information I have provided is complete and accurate. I understand my responsibilities as noted in this form. No changes will be made without prior approval of the Institutional Biosafety Committee. |
| Signature of Principal Investigator | Date      |
| Name of preparer (if prepared by someone other than the PI)      | Position      |

*SUBMISSION INSTRUCTIONS:*

*Once you have completed this form, convert the completed form directly to an Adobe PDF file and electronically sign the form using the E-signature feature of Adobe Acrobat. Alternatively, print the completed form, add your signature, and scan it to create an Adobe PDF file. Send the completed form by e-mail as an attachment to* *biosafety@drexel.edu**.*