ACORP Appendix 3

Biosafety

Version 4 (updated 1/15/21)

See ACORP App. 3 Instructions, for more detailed explanations of the information requested.

1. **Summary of All Materials Administered to Animals on this Protocol.** Complete the table below for all materials to be administered to any animal on this protocol, indicating the nature of the material by marking EVERY box that applies, and indicating the BSL number for any infectious agents:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Material**  (Identify the specific  agent, device, strain, construct, isotope, etc.) | **Source**  (Identify the vendor or colleague, or specify which animals on this protocol will serve as donors) | **Nature of Material** | | | | | | |
| Toxic Agent (Item 4) | Infectious Agent (Item 5) --  Enter the CDC Biosafety Level  (BSL 1, 2, 3, or 4) | Biological Agent (Item 6) | Radioactive Agent (Item 7) | Contains Recombinant Nucleic Acid (Item 8) | Routine Pre- or Post-Procedural Drug | Euthanasia agent |
|  |  | ( ) | ( )BSL\_ | ( ) | ( ) | ( ) | ( ) | ( ) |
|  |  | ( ) | ( )BSL\_ | ( ) | ( ) | ( ) | ( ) | ( ) |
|  |  | ( ) | ( )BSL\_ | ( ) | ( ) | ( ) | ( ) | ( ) |
|  |  | ( ) | ( )BSL\_ | ( ) | ( ) | ( ) | ( ) | ( ) |
|  |  | ( ) | ( )BSL\_ | ( ) | ( ) | ( ) | ( ) | ( ) |
|  |  | ( ) | ( )BSL\_ | ( ) | ( ) | ( ) | ( ) | ( ) |

1. number of cells, mCi protocol will serve as donors) the xpected to be painful or distressing to the animals? inding agents)\_\_**Summary of How Materials will be Administered.** Complete the table below for each of the materials shown in the table in Item 1 above:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Material\*** (Identify the specific agent, device, strain, construct, isotope, etc.) | **Dose** (e.g., mg/kg, CFU, PFU, number of cells, mCi)  and **Volume** (ml) | **Diluent\* or Vehicle\*** | **Route** of admin | **Frequency or duration** of admin | **Reason** for Administration and **Expected Effects** | Location of **Further Details** in this ACORP (specify “Main Body” or “App #”, and identify the Item) | Administration Under **Anesthesia, sedation, or tranquilization** (Y/N) |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

\*Each material, diluent, or vehicle that is listed as FDA approved or is labeled “USP” is pharmaceutical grade. Check on-line for formulations that are FDA approved for administration to humans (<http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm>) or animals ([Section 2.0 -Active Ingredients (fda.gov)](https://animaldrugsatfda.fda.gov/adafda/app/search/public/ingredientsInformationPdf/Section2ActiveIngredients)). Designate with a \* each material and each diluent or vehicle to be used that is not pharmaceutical grade. For each of these, explain here why the use of a non-pharmaceutical grade formulation is necessary, and describe how it will be ensured that the material is suitable for use. (See ACORP App. 3 Instructions, for specifics about the level of detail required.)

►

1. **Anesthesia, Sedation, or Tranquilization.** Complete 3.a. and 3.b. below:
   1. For each material with “Y” entered in the last column of the table in Item 2 above, describe the anesthesia, sedation, or tranquilization to be used, identifying the anesthetic, sedative, or chemical tranquilizer, and detailing the dose, volume, and route of administration (Make sure that these agents are also included in Item 1 of this appendix, as materials to be administered):

►

* 1. For each material with “N” entered in the last column of the table in Item 2 above, explain why no anesthesia, sedation, or tranquilization is necessary, or can be provided, and describe any alternate methods of restraint that will be used.

►

1. **Toxic Agents.** Complete the table below for each of the materials listed as a “toxic agent” in the table in Item 1 above, checking the all of the properties that apply (see ACORP App. 3 Instructions, for details).

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name of Toxic Agent | a. Mutagen | b. Carcinogen | c. Teratogen | d. Select Agent? | | | e. Other – specify toxic properties |
| Not a Select Agent | Select Agent Used in  Sub-threshold Quantities | Select Agent that Requires Registration/Approval |
|  | ( ) | ( ) | ( ) | ( ) | ( ) | ( )\* | ( )► |
|  | ( ) | ( ) | ( ) | ( ) | ( ) | ( )\* | ( )► |
|  | ( ) | ( ) | ( ) | ( ) | ( ) | ( )\* | ( )► |
|  | ( ) | ( ) | ( ) | ( ) | ( ) | ( )\* | ( )► |
|  | ( ) | ( ) | ( ) | ( ) | ( ) | ( )\* | ( )► |
|  | ( ) | ( ) | ( ) | ( ) | ( ) | ( )\* | ( )► |

\*For each “select agent” that requires registration/approval (copy the lines below for each agent):

Name of agent ►

Registered with CDC or USDA ►

Registration Number ►

Registration Date ►

Expiration Date of Registration ►

Name of official who granted approval on behalf of VACO►

Date of approval►

1. **Infectious Agents.** Complete the table below for each of the materials listed as an “infectious agent” in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name and BSL Number of Infectious Agent | a. ABSL Number\* | b. Drug Sensitivity Panel Available? (Describe) | c. Select Agent? | | |
| Not a Select Agent | Select Agent used in Sub-threshold quantities | Select Agent that Requires Registration/Approval |
|  |  | (Yes/No) | ( ) | ( ) | ( )\*\* |
|  |  | (Yes/No) | ( ) | ( ) | ( )\*\* |
|  |  | (Yes/No) | ( ) | ( ) | ( )\*\* |
|  |  | (Yes/No) | ( ) | ( ) | ( )\*\* |
|  |  | (Yes/No) | ( ) | ( ) | ( )\*\* |
|  |  | (Yes/No) | ( ) | ( ) | ( )\*\* |

\*Complete the following for each agent for which the ABSL Number given is less than the BSL Number shown (copy the lines below for each agent):

Name of agent ►

Justification for applying ABSL measures that are less protective than those recommended ►

\*\*For each “select agent” that requires registration/approval (copy the lines below for each agent):

Name of agent ►

Registered with CDC or USDA ►

Registration Number ►

Registration Date ►

Expiration Date of Registration ►

Name of official who granted approval on behalf of VACO►

Date of approval►

1. **Biological Agents.** Complete the table below for each of the materials listed as a “biological agent” in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

|  |  |
| --- | --- |
| Name of Biological Agent | Screening for Infectious Agents |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

1. **Radioactive Agents.** Complete the table below for each of the agents listed as a “radioactive agent” in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

|  |  |  |
| --- | --- | --- |
| Name of Radioactive Agent (specify the isotope) | Authorized Individual | Approving Committee or Official |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

1. **Agents Containing Recombinant Nucleic Acid.** For each of the materials checked in the table in Item 1, above, as “contains recombinant nucleic acid”, indicate which of the conditions applies (see ACORP App. 3 Instructions, for details).

|  |  |  |
| --- | --- | --- |
| Name of Agent  that Contains Recombinant Nucleic Acid | Subject to the *NIH Guidelines for Research Involving Recombinant DNA Molecules* | Exempt |
|  | ( ) | ( ) |
|  | ( ) | ( ) |
|  | ( ) | ( ) |
|  | ( ) | ( ) |
|  | ( ) | ( ) |
|  | ( ) | ( ) |

1. **Potential for Pain or Distress**. Complete the table below for each of the agents listed in Item 1, above, that is expected to have potentially painful or distressing effects on the animals (see ACORP App. 3 Instructions, for details).

|  |  |  |
| --- | --- | --- |
| Name of Agent | Nature of Potential Pain/Distress | Measures to Alleviate Pain/Distress |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

1. **Protection of Animal Facility Staff from Hazardous Materials.** Complete Items 10.a and 10.b, below, for each of the agents listed in the table in Item 1, above, as “toxic”, “infectious”, “biological”, “radioactive”, or “contains recombinant nucleic acid” (detailed in Items 4 – 8). This item specifically addresses members of the animal facility staff; protection of the research staff from each of these agents must be addressed in Item G of the main body of the ACORP. See ACORP App.3 Instructions, for details.
   1. Complete the table below.

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Hazardous Agent | Approving Committee or Official | Institution  (VA or affiliate) | Names of Animal Facility Staff Members at Risk |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

* 1. Detail how the individuals listed in the table above (Item 10.a.) have been (or will be) informed of the possible risks of exposure, and have been (or will be) trained to avoid exposure to these agents.

►

1. **Signatures.** Provide the applicable signatures on the signature pages (Item Z.3) of the main body of this ACORP.