**Animal Component of Research Protocol** **(ACORP)**

**Main Body**

**Version 4 – 03/13/14**

See Instructions for Completion of the Animal Component of Research Protocol (ACORP Instructions), for help in completing specific items.

1. **ACORP Status.**
   1. Full Name of Principal Investigator(s)►
   2. VA Station Name (City) and 3-Digit Station Number► Ann Arbor, 506
   3. Protocol Title►
   4. Animal Species covered by this ACORP (A separate ACORP must be completed for each species being studied.)►
   5. Funding Source(s). Indicate each of the source(s) of funds that will be used to perform these animal procedures once application is approved by the VA IACUC:

►( ) Department of Veterans Affairs.

►( ) US Public Health Service (e.g. NIH).

►( ) Private or Charitable Foundation -- Identify the Foundation:

►( ) University Intramural Funds – Identify the University and Funding Component (Department, Center or Office):

►( ) Private Company – Identify the Company:

►( ) Other – Identify Other Source(s):

* 1. Related Documentation for IACUC reference.
     1. If this protocol applies to a project that has already been submitted to the R&D Committee for review, identify the project:
        1. Title of project►
        2. If approved by the R&D Committee, give the date of approval►
     2. Triennial review. If this protocol is being submitted for triennial *de novo* review, complete the following:
        1. Identify and summarize the studies described in the previously approved ACORP that have already been completed.

►

* + - 1. Indicate the numbers of animals that have already been used, and adjust the numbers shown in Item I accordingly.

►

* + - 1. Describe any study results that have prompted changes to the protocol, and briefly summarize those changes, to guide the reviewers to the details documented in other Items below.

►

* + 1. List any other relevant previously approved animal use protocols (copy the lines below as needed for each protocol listed).
       1. Title of other protocol ►
       2. IACUC approval number of other protocol ►

Give the name of the VA station or other institution that approved it, if it was not approved by the IACUC that will review this ACORP ►

* 1. Indicate the type(s) of animal use covered by this protocol (check all that apply):

►( ) Research

►( ) Teaching or Training

►( ) Testing

►( ) Breeding and colony management only; not for any specific research project

►( ) Holding protocol (Local policy may specify the use of holding protocols for animals transferred from expired or suspended protocols. There are no VA, PHS, or USDA regulatory requirements for such protocols.)

►( ) Other. Please specify►

## Proposal Overview

1. **Description of Relevance and Harm/Benefit Analysis.** Using non-technical (lay) language that a senior high school student would understand, briefly describe how this research project is intended to improve the health of people and/or other animals, or otherwise to serve the good of society, and explain how these benefits outweigh the pain or distress that may be caused in the animals that are to be used for this protocol.

►

1. **Experimental Design.**
   1. **Lay Summary**. Using non-technical (lay) language that a senior high school student would understand, summarize the conceptual design of the experiment in no more than one or two paragraphs.

►

2. **Complete description of the proposed use of animals.**  Use the following outline to detail the proposed use of animals. Describe the proposed use of animals as it relates to the experimental design, providing sufficient detail and using language suitable for scientific colleagues who may not be experts in your discipline.

* + 1. **Summarize** the design of the experiment in terms of the specific groups of animals to be studied.

Provide a ***timeline for each group*** of animals showing the **sequence of procedures**. Give the rationale why each procedure or manipulation is necessary. Specific details of each procedure are requested in C.2.c. and should not be described here. For complicated experimental designs, a flow chart, diagram, or table is strongly recommended.

►

* + 1. **Justify the group sizes and the total numbers of animals requested.** Provide the number and type of experimental and control groups in each experiment. Describe how the estimated number of animals needed for the experiments were determined. A power analysis is strongly encouraged to justify group sizes.

►

1. **Describe each procedure** to be performed on any animal on this protocol. Use Appendix 9 to document any of these procedures that involve “departures” as defined by OLAW relative to PHS policy, including the “must” and “should” provisions in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any “departures” are involved.

***List each procedure individually.*** ***Describe specifically*** what will be done, what the animals will be expected to experience, what measures are planned to address any potential pain or distress, rational if no special measures are taken to address potential pain or distress. Although full descriptions of most procedures are requested in later appendices, you should provide enough detail for the IACUC to determine the potential impact of the procedure on the animal.

►

1. **Species.** Justify the choice of species for this protocol. Consider such characteristics as body size, availability of specific strains, breeds, or mutants, data from previous studies, and unique anatomic or physiologic features. Explain why these are important to the work proposed.

►

**Personnel**

1. **Current qualifications and training.** (For personnel who require further training, plans for additional training will be requested in Item F.)

1. PI

Name►

Animal research experience ►

Qualifications to perform specific procedures

|  |  |
| --- | --- |
| Specific **procedure(s)** that the PI will perform personally | **Experience** with each procedure in the species described in this ACORP |
|  |  |
|  |  |

2. Other research personnel: include any research staff or laboratory staff (students, post docs, etc.) who will be involved in the work with the animals in this protocol. (Copy the lines below for each individual.)

Name►

Animal research experience ►

Qualifications to perform specific procedures

|  |  |
| --- | --- |
| Specific **procedure(s)** that this individual will perform | **Experience** with each procedure in the species described in this ACORP |
|  |  |
|  |  |

3. VMU animal care and veterinary support staff personnel

Name► Maurice Anderson

|  |  |
| --- | --- |
| Specific support **procedure(s)** assigned to this individual | **Qualifications** for performing each support procedure in the species described in this ACORP (e.g., AALAS certification, experience, or completion of special training) |
| Post-Operative Care Monitoring | 7 years animal husbandry experience including post-op care monitoring of various species |
| Sexing/Weaning | 7 years animal husbandry experience including sexing/weaning of various species |
| Euthanasia | 7 years animal husbandry experience including various methods of euthanasia |
| Animal Treatments as needed | 7 years animal husbandry experience including various types of animal treatments that may be required |
| Administering Special Dietary Requirements | 7 years animal husbandry experience including diet manipulations |

Name► Alphanzo Fuller

|  |  |
| --- | --- |
| Specific support **procedure(s)** assigned to this individual | **Qualifications** for performing each support procedure in the species described in this ACORP (e.g., AALAS certification, experience, or completion of special training) |
| Post-Operative Care Monitoring | 13 years animal husbandry experience including post-op care monitoring of various species |
| Sexing/Weaning | 13 years animal husbandry experience including sexing/weaning of various species |
| Euthanasia | 13 years animal husbandry experience including various methods of euthanasia |
| Animal Treatments as needed | 13 years animal husbandry experience including various types of animal treatments that may be required |
| Administering Special Dietary Requirements | 13 years animal husbandry experience including diet manipulations |

Name► Rosemary Knudson

|  |  |
| --- | --- |
| Specific support **procedure(s)** assigned to this individual | **Qualifications** for performing each support procedure in the species described in this ACORP (e.g., AALAS certification, experience, or completion of special training) |
| Post-Operative Care Monitoring | 3 years animal husbandry experience including post-op care monitoring of various species |
| Sexing/Weaning | 3 years animal husbandry experience including sexing/weaning of various species |
| Euthanasia | 3 years animal husbandry experience including various methods of euthanasia |
| Animal Treatments as needed | 3 years animal husbandry experience including various types of animal treatments that may be required |
| Administering Special Dietary Requirements | 3 years animal husbandry experience including diet manipulations |

Name► Joseph Scott

|  |  |
| --- | --- |
| Specific support **procedure(s)** assigned to this individual | **Qualifications** for performing each support procedure in the species described in this ACORP (e.g., AALAS certification, experience, or completion of special training) |
| Post-Operative Care Monitoring | 4 years animal husbandry experience including post-op care monitoring of various species |
| Sexing/Weaning | 4 years animal husbandry experience including sexing/weaning of various species |
| Euthanasia | 4 years animal husbandry experience including various methods of euthanasia |
| Animal Treatments as needed | 4 years animal husbandry experience including various types of animal treatments that may be required |
| Administering Special Dietary Requirements | 4 years animal husbandry experience including diet manipulations |

4. For each of the research personnel listed in items 1 and 2 above, enter the most recent completion date

for each course.

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Individual | Working with the VA IACUC | ORD web-based species specific course (Identify the species) | Any other training required locally (Identify the training) |
|  |  |  |  |
|  |  |  |  |

1. **Training to be provided.** List here each procedure in Item E for which anyone is shown as “to be trained”, and describe the training. For each procedure, describe the type of training to be provided, and give the name(s), qualifications, and training experience of the person(s) who will provide it. If no further training is required for anyone listed in Item E, enter “N/A”

►

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name | Procedure | Training Type | Trainer Name | Trainer Qualifications | Trainer’s  Experience |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. **Occupational Health and Safety.**

Each individual included in Item E must be enrolled in an Occupational Health and Safety Program (OHSP) either through the VA or an equivalent program with the affiliated institution. An enrolled individual has the opportunity to participate fully in the Preventative Medicine Program (PMP) provided by the institution, but may elect to sign a waiver to decline these optional services.

1. Complete one line in the table below for each of the personnel identified in Item E:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name | Enrollment in OHSP | | | | Declined optional services | Current on Interactions with OHSP?  (yes/no) | |
| VA Program | | Equivalent Alternate Program - if yes, check and identify the program | |
| Yes | No |
| Yes | No | Yes | Identify the Program |
|  | ( ) | ( ) | ( ) |  | ( ) | ( ) | ( ) |
|  | ( ) | ( ) | ( ) |  | ( ) | ( ) | ( ) |
|  | ( ) | ( ) | ( ) |  | ( ) | ( ) | ( ) |
|  | ( ) | ( ) | ( ) |  | ( ) | ( ) | ( ) |
|  | ( ) | ( ) | ( ) |  | ( ) | ( ) | ( ) |

1. Are there any non-routine OHSP measures that would potentially benefit, or are otherwise required for, personnel participating in or supporting this protocol?

**Non-routine** OHSP measures include special vaccines, prophylactic measures (e.g., selegiline for

MPTP or stable iodine for radioactive iodine), education, or additional health screening techniques.

**Routine** measures already included in the Occupational Health and Safety Program (e.g., vaccination

for tetanus, rabies, hepatitis B, and TB screening) need not be mentioned here.

► ( ) No. (Proceed to H.)

► ( ) Yes. Describe them. ►

**Animals Requested**

1. **Animals to be Used.** Complete the following table, listing the animals on separate lines according to any specific features that are required for the study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Description** (include the species, strain, stock, genotype, breed, surgical alteration by vendor) | **Gender** | **Age/Size** on Receipt | **Source**  (e.g., Name of Vendor, Collaborator, or PI of local breeding colony) | **Health Status**  (SPF or Conventional) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1. **Numbers of animals requested.** Animals are to be categorized according to the pain and/or distress associated with the procedures to be performed. The same animal cannot be assigned to more than one USDA category. If several procedures are planned, animal should be placed in the category appropriate for the most painful/distressful procedure. If you have difficulty determining the appropriate category, contact the attending veterinarian or IACUC Chair for assistance.

Notes:

* **For each category**, **list the procedures** that account for the assignment of animals to that category.
* Be sure to include all of the animals that will be used in connection with this protocol, including not only the actual study subjects, but also all additional individuals such as (but not exclusive to) breeders, tissue donors, and those generated in breeding colonies and culled because of unusable gender, genotype, or date of birth.

**USDA Category B**

List by year the number of animals that will be bred or purchased for breeding but not used in the experiments. This includes breeders and any young that may be culled because of unusable gender, genotype, or date of birth. (Note: if tail snips are necessary for genotyping, this category is not appropriate.)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Procedures► | | | | | | |
| Experimental Group / Procedures(s) | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | **Category B TOTAL** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **CATEGORY B GRAND TOTAL** | | | | | |  |

**USDA Category C**

List by year all animals that will only undergo procedures that involve no more than very brief or minor pain or distress, for which no pain relieving drugs are needed. Examples include observational studies, most intravenous and parenteral injections of non-irritating agents, most blood collections from peripheral vessels, tail snips for genotyping if done before 21 days old, and euthanasia for postmortem collection of cells and/or tissues.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Procedures► | | | | | | |
| Experimental Group / Procedure(s) | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | **Category C TOTAL** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **CATEGORY C GRAND TOTAL** | | | | | |  |

**USDA Category D**

List by year all animals that will only undergo no more than procedures that are potentially painful or distressing, but for which the pain or distress is prevented or relieved by appropriate anesthetics, sedatives, analgesics, or other means (e.g., acupuncture). Examples include surgery performed under anesthesia (major or minor, survival or non-survival), tissue or organ collections or other painful procedures performed on living animals under anesthesia (such as retro-orbital blood collection in rodents), prolonged restraint accompanied by tranquilizers or sedatives, and experiments with provisions for immediate euthanasia to effectively prevent pain and/or suffering in animals that are becoming sick. If an endpoint is defined such that the animals are likely to experience significant pain or distress, Category E is more appropriate.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Procedures► | | | | | | |
| Experimental Group / Procedure(s) | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | **Category D TOTAL** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **CATEGORY D GRAND TOTAL** | | | | | |  |

**USDA Category E**

List by year all animals that will undergo procedures in which pain or distress CANNOT be relieved. An important rule of thumb for deciding whether an animal should be assigned to Category E is to consider whether a human experiencing a comparable condition would be expected to seek relief. Examples include studies in which animals must be allowed to die without intervention (e.g. LD50, mortality as an end-point), studies that require endpoints that may be painful or stressful, studies that require withdrawal from addictive drugs (without palliative treatment), pain research, and studies that involve noxious stimuli that are not immediately escapable, food or water deprivation beyond that necessary for standard pre-surgical preparation, or paralysis or immobility in conscious animals.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Procedures► | | | | | | |
| Experimental Group / Procedure(s) | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | **Category E TOTAL** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **CATEGORY E GRAND TOTAL** | | | | | |  |

**TOTALS over all Categories**

Bring down totals for each category, over all groups and/or procedures in all categories, for each year (if using the yearly columns) and for the protocol as a whole.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Category | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Grand Total |
| B |  |  |  |  |  |  |
| C |  |  |  |  |  |  |
| D |  |  |  |  |  |  |
| E |  |  |  |  |  |  |
| Total All Category Procedures |  |  |  |  |  |  |

1. **Management of USDA Category D procedures**. Indicate which statement below applies, and provide the information requested.

► ( ) This protocol does **NOT** include any Category D procedures. Proceed to K.

* + 1. ► ( ) This protocol **INCLUDES** Category D procedures. List each Category D procedure and provide the information requested. (For **surgical procedures** described in Appendix 5, only identify the procedure(s) and enter “**See Appendix 5 for details**”.) (**Copy the lines below for each Category D procedure.**)

Name of Procedure►

Monitoring

Method►

Frequency►

Duration►

Person responsible for monitoring►

Pain and/or distress alleviation

Method►

Dose►

Route►

Duration of effect►

1. **Justification of Category E procedures.** Indicate which statement below applies, and provide the information requested.

Identify each Category E procedure included and justify scientifically why the pain and/or distress cannot be relieved. For example, give the evidence that drugs available for relieving the anticipated pain or distress would make the results uninterpretable. If animals must be observed until natural death (e.g. in some studies of infectious disease or oncology), or if the endpoint that must be used otherwise allows the animals to experience more than very brief or slight pain or distress, you must explain why an alternate endpoint (such as moderate weight loss, clinical signs, tumor size, etc.) prior to death or the onset of pain or distress cannot be used. ***(If animals will undergo category D procedures as well as Category E procedures, give the details about the Category D procedures in Item J.)***

► ( ) This protocol does **NOT** include any Category E procedures. Proceed to L.

► ( ) This protocol **INCLUDES** Category E procedures. Identify each Category E procedure included in this ACORP and justify scientifically why the pain or distress cannot be relieved.

|  |  |
| --- | --- |
| Category E Procedure | Scientific justification why the pain or distress cannot be relieved |
|  |  |
|  |  |
|  |  |

**Veterinary Care and Husbandry**

1. **Veterinary Support**.
   1. Identify the laboratory animal veterinarian who is responsible for ensuring that the animals on this protocol receive appropriate veterinary medical care.

Name►

Institutional affiliation►

E-mail contact►

Phone contact►

* 1. Veterinary consultation during the planning of this protocol. ***NOTE: This ACORP will NOT be reviewed without a completed veterinary review prior to its submission to the IACUC.***

VA Policy (*1200.7*, par. 8.f(2)(b)) requires that a laboratory animal veterinarian be consulted during the planning stages of every protocol, so that the veterinarian’s recommendations can be incorporated into the ACORP before the protocol is submitted for IACUC review. To be valid, the most recent consultation must have occurred no more than 1 year before the protocol was submitted for IACUC review. As an alternative to a face-to-face meeting, the veterinarian may perform a prereview of a draft of the ACORP and provide comments to the PI so that the ACORP can be revised prior to IACUC review.

Name of the laboratory animal veterinarian consulted►

Date of the veterinary consultation (meeting date, or date of written comments provided by the veterinarian to the PI) ►

1. **Husbandry.** As a reference for the animal husbandry staff, summarize here the husbandry requirements of the animals on this protocol. (Use Appendix 6 to justify the use of any special husbandry and to detail its effects on the animals. Use Appendix 9 to document any aspects of the husbandry that involve “departures” from the standards in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any “departures” are involved.)
   1. Caging needs. Complete the table below to describe the housing that will have to be accommodated by the housing sites for this protocol:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Species | Type of housing\* | Number of individuals per housing unit\*\*  (note single housing on separate line) | Is this housing consistent with the *Guide* and USDA regulations?  (yes/no\*\*\*)  Contact VMU Supervisor if unsure | |
| Yes | No |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

\*Type of housing. Enter any special features required. These may include features such as (but not limited to):

Standard -- If no special features are required, enter “Standard (see SOP)”for housing according to

any local SOP and enter the requested information about the SOP into the table in Item Y.

Gnotobiotic (germ-free or defined flora) isolation

Biohazard or other special hazard containment

Sterile microisolator caging, with filtered cage top

Non-sterile microisolator caging, with filtered cage top

Wire-bottom

Quarantine

\*\* The *Guide* states that social animals should generally be housed in stable pairs or groups. Provide a justification if any animals will be housed singly (if species is not considered “social”, then so note).

►

\*\*\*Use Appendix 9 to document “departures” from the standards in the *Guide*.

* 1. **Enrichment.** Complete the table below to indicate whether “standard” exercise and environmental enrichment will be provided to the animals on this protocol, or whether any special supplements or restrictions will be required (See ACORP Instructions, for more information on enrichment requirements. Use Appendix 9 to document any enrichments requirements that represent “departures” from the standards in the *Guide*.):

|  |  |  |
| --- | --- | --- |
| Species | Description of Enrichment\* | Frequency |
|  |  |  |
|  |  |  |

\*If enrichment will be provided according to a local SOP, enter “standard (see SOP)” and enter the SOP into the table in Item Y.

* 1. **Customized routine husbandry**. Check all of the statements below that apply to the animals on this protocol, and provide instructions to the animal husbandry staff with regard to any customized routine husbandry needed.

► ( ) This ACORP INCLUDES **genetically modified animals**. List each group of genetically modified animals (e.g., special in-bred strains, transgenic, knock-in or knock-out strains, etc.), and describe for each any **expected characteristic** clinical signs or **abnormal behavior** related to the genotype and any **customized routine husbandry** required to address these. For genetic modifications that will be newly generated on or for this protocol, describe any **special attention** needed during routine husbandry to monitor for unexpected clinical signs or abnormal behavior that may require customized routine husbandry.

►

► ( ) **Devices** (e.g., cannulae, acrylic implants, catheters, etc.) that extend chronically through the skin WILL be implanted into some or all animals on this protocol. Describe any customized routine husbandry to be provided by animal husbandry staff to minimize the chances of chronic infection where the device(s) penetrate the skin.

►

► ( ) Some or all of the animals on this protocol WILL require other customized routine husbandry by the animal husbandry staff, beyond what has been described above. Describe the **special husbandry** **needed.** Customized routine husbandry may include such features as special bedding material, alternate watering devices, or a modified schedule of bedding changes.

►

► ( ) This ACORP does NOT include use of any animals that will require customized routine

husbandry. Proceed to N.

1. **Housing Sites**. Document in the tables below each location where animals on this protocol may be housed.

► **Housing on VA Property**. Identify each location on VA property where animals on this protocol will be housed, and indicate whether or not each location is inside the VMU. (Enter N/A if animals will NOT be housed on VA property.)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Building | Room #  (Contact VMU Supervisor) | Standard Housing | | Biohazard Housing | | Inside the VMU? | |
| Yes | No | Yes | No | Yes | No |
|  |  | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) |
|  |  | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) |
|  |  | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) |

► **Housing in Non-VA Facilities**. Identify each location not on VA property where animals on this protocol will be housed, and provide the information requested in the table. (Enter N/A if animals WILL be housed on VA property.)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name of Non-VA Facility | Is this facility accredited by AAALAC? | | | Building | Room Number |
| Yes | Status\* | No\*\* |  |  |
|  | ( ) |  | ( )\*\* |  |  |
|  | ( ) |  | ( )\*\* |  |  |
|  | ( ) |  | ( )\*\* |  |  |

\*For the status of AAALAC accreditation, enter one of the following (Consult your Attending Veterinarian or IACUC for the status of the non-VA facility.): “CFA” (Continued Full Accreditation), “DCA” (Deferred Accreditation), “PROB” (Probation), “RFA” (Restored Full Accreditation), or “Other” – please explain.

\*\*For any facility listed above that is not accredited by AAALAC, attach documentation that a waiver has been granted by the CRADO.

**Special Features**

1. **Antibody Production.** Will any of animals on this protocol be used for the production of antibodies?

► ( ) **NO** animals on this protocol will be used in the production and harvesting of antibodies. Proceed to P.

► ( ) **Some or all** of the animals on this protocol **WILL** be used in the production and harvesting of antibodies. Check “Appendix 2” in Item Y, below, and complete and attach Appendix 2, “Antibody Production”.

1. **Biosafety.** Will any substances be administered or applied to the animals on this protocol?

► ( ) This protocol does **NOT** involve administration of any substances to the animals~~.~~ Proceed to Q.

► ( ) This protocol **INVOLVES** administration or application of substances to the animals~~.~~ Check “Appendix 3” in Item Y and complete and attach Appendix 3, “Biosafety”.

1. **Locations of procedures.** Complete the table below, listing the location(s), inside or outside of the animal facility, for **each of the procedures** to be performed on animals on this protocol.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Procedure | Surgical? | | Bldg | Room | Requires transport through non-research areas? | |
|  | Yes | No |  |  | Yes – describe method of discreet transport | No |
|  | **( )** | **( )** |  |  | **( ) --** | **( )** |
|  | **( )** | **( )** |  |  | **( ) --** | **( )** |
|  | **( )** | **( )** |  |  | **( ) --** | **( )** |
|  | **( )** | **( )** |  |  | **( ) --** | **( )** |

1. **Body Fluid, Tissue, and Device Collection.** List each body fluid, tissue, or device to be collected, and complete the table below to indicate the nature of the collection. Check the relevant Appendices in Item Y, below, and complete and attach them, as shown in the column headings.

Tail clipping performed for genotyping may be a surgical procedure (detailed in Appendix 5) or a non-surgical antemortem tissue collection (detailed in Appendix 4), depending on the age of the animal and the amount of tissue removed. Do not include tissue that is removed and discarded (e.g., ovaries removed in ovariectomy).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Body Fluid, Tissue, or Device to be Collected | Collected AFTER Euthanasia | Collected BEFORE Euthanasia | | |
| Blood Collection Associated with Antibody Production  (Appendix 2, “Antibody Production”) | Collected as Part of a Surgical Procedure  (Appendix 5, “Surgery”) | Other Collection from Live Animals (Appendix 4, “Antemortem Specimen Collection”) |
|  | **( )** | **( )** | **( )** | **( )** |
|  | **( )** | **( )** | **( )** | **( )** |
|  | **( )** | **( )** | **( )** | **( )** |

1. **Surgery.** Does this protocol include any surgical procedure(s)?

“Surgery” includes any major or minor, survival or non-survival surgical procedure. The Ann Arbor VA considers any procedure that requires anesthesia followed by a monitored recovery period to be “surgery” that must be included in Appendix 5.

► ( ) **NO** animals on this protocol will undergo surgery. Proceed to T.

► ( ) Surgery **WILL BE PERFORMED** on some or all animals on this protocol. Check “Appendix 5” in Item Y, below, and complete and attach Appendix 5, “Surgery”.

1. **Endpoint criteria.** Describe the criteria that will be used to determine when animals will be removed from the protocol or euthanized to prevent suffering. Consult the IACUC or the Attending Veterinarian for help in determining whether any “departures” are involved.

Examples of appropriate criteria that should be considered include weight loss to less than a specified percentage of initial or expected body weight, anorexia for longer than a specified allowable duration, tumor size greater than a specified size or total tumor burden greater than a specified percentage of body weight, the presence of health problems refractory to medical intervention, and severe psychological disturbances. For genetically modified animals to be newly generated on or for this protocol, the possibility of unexpected phenotypic changes should be addressed in the endpoint criteria.

►

1. **Termination or removal from the protocol**. Complete each of the following that applies:

► ( ) Some or all animals will **NOT** be euthanatized on this protocol. Describe the disposition of these animals. (Use Appendix 9 to document any “departures” from the standards in the *Guide* represented by these methods of disposition. Consult the IACUC or the Attending Veterinarian for help in determining whether any “departures” are involved.)

►

► ( ) Some or all animals MAY be euthanatized as part of the planned studies. Complete the table below to describe the exact method(s) of euthanasia to be used. (Use Appendix 9 to document any departures from the standards in the *Guide* represented by these methods. Consult the IACUC or the Attending Veterinarian for help in determining whether any “departures” are involved.)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Check each method that may be used in this protocol | Method of Euthanasia | Species | AVMA Classification | | |
| Acceptable | Conditionally Acceptable | Unacceptable |
| ( ) | CO2 from a compressed air gas tank  Duration of exposure after apparent clinical death►  Criteria for confirming death►  Secondary physical method► |  | ( ) | ( ) | ( ) |
| ( ) | Anesthetic overdose  Agent►  Dose►  Route of administration►  Criteria for confirming death►  Secondary physical method► |  | ( ) | ( ) | ( ) |
| ( ) | Decapitation under anesthesia  Agent►  Dose►  Route of administration►  Criteria for confirming death► |  | ( ) | ( ) | ( ) |
| ( ) | Decapitation without anesthesia►  Criteria for confirming death► |  | ( ) | ( ) | ( ) |
| ( ) | Exsanguination under anesthesia  Agent►  Dose►  Route of administration►  Criteria for confirming death►  Secondary physical method► |  | ( ) | ( ) | ( ) |
| ( ) | Other (Describe) ►  Criteria for confirming death► |  | ( ) | ( ) | ( ) |

* 1. For each of the methods above that is designated as “Conditionally Acceptable” by the AVMA, describe how the conditions for acceptability will be met:

►

* 1. For each of the methods above that is designated as “Unacceptable” by the AVMA, give the scientific reason(s) that justify this deviation from the AVMA Guidelines:

►

* 1. Identify all research personnel who will perform euthanasia on animals on this protocol and describe their training and experience with the methods of euthanasia they are to use in the species indicated.

|  |  |  |
| --- | --- | --- |
| Name | Method of Euthanasia | Qualifications |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

* 1. Instructions for the animal care staff in case an animal is found dead.
     1. Describe the disposition of the carcass, including any special safety instructions for animals treated with hazardous materials. If disposition is to be handled according to a local SOP, enter “according to local SOP” and enter the information requested about the SOP into the table in Item Y.

►

* + 1. Describe how the PI’s staff should be contacted.

► ( ) Please contact a member of the PI’s staff immediately. (Copy the lines below for each individual who may be contacted.)

Name►

Contact Information►

► ( ) There is no need to contact the PI’s staff immediately. Describe the routine notification procedures that will be followed. If the routine notification procedures are described in a local SOP, enter “according to local SOP” and enter the information requested about the SOP into the table in Item Y.

►

1. **Special Procedures.** List each special procedure (including special husbandry and other special procedures) that is a part of this protocol, and specify where the details of the procedure are documented.

Special procedures include both special husbandry and other non-husbandry procedures that are required by the experimental design. Examples include non-standard methods for monitoring animal health, special diets, caging, environmental conditions such as lighting cycles or temperatures, enrichment, means of identification, restraint practices, application of noxious stimuli, forced exercise, behavioral conditioning, total body irradiation, radiography or other imaging procedures, etc.

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Special Procedure | Identify Where the Details of the Procedure are Documented | | |
| SOP (title or ID number)\* | Other Items in this ACORP -- specify the Item letter(s) | Appendix 6 |
|  |  | Items: | ( )\*\* |
|  |  | Items: | ( )\*\* |
|  |  | Items: | ( )\*\* |
|  |  | Items: | ( )\*\* |

\*If any special procedure is detailed in a SOP, identify the SOP and enter the information requested about the SOP in the table in Item Y.

\*\*If any special procedure is detailed in Appendix 6, check “Appendix 6” in Item Y, below, and complete and attach Appendix 6.

Use Appendix 9 to document any “departures” from the standards in the *Guide* represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any “departures” are involved.

1. **Consideration of Alternatives and Prevention of Unnecessary Duplication.** These are important to minimizing the harm/benefit to be derived from the work. Keep copies of computer database search results in your files to demonstrate your compliance with the regulatory requirements.
   1. Document the database searches conducted.

List each of the potentially painful or distressing procedures included in this protocol.

►

Then complete the table below to document how the database search(es) you conduct to answer Items W.2 through W.5 below address(es) each of the potentially painful or distressing procedures.

Both ALTBIB and Google Scholar should be used in your search.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Name of the database | Date of search | Period of years covered by the search | Potentially painful or distressing procedures addressed | Key words and/or search strategy used | Indicate which mandate each search addressed | | | |
| Replacement of animals (item W.2) | Reduction in numbers of animals used (item W.3) | Refinement to minimize  pain or distress (item W.4) | Lack of unnecessary duplication (item W.5) |
|  |  |  |  |  | ( ) | ( ) | ( ) | ( ) |
|  |  |  |  |  | ( ) | ( ) | ( ) | ( ) |
|  |  |  |  |  | ( ) | ( ) | ( ) | ( ) |
|  |  |  |  |  | ( ) | ( ) | ( ) | ( ) |

* 1. Replacement. Describe the replacements that have been incorporated into this work, the replacements that have been considered but cannot be used, and the reason(s) that further replacements are not acceptable. Replacement refers to the use of non-animal systems (for example, computer, mechanical, or chemical models) or *in vitro* techniques instead of animals, use of non-mammalian species instead of mammalian species, and use of less-sentient mammals for more-sentient mammals.

►

* 1. Reduction. Describe how the number of animals to be used has been minimized in this protocol and explain why further reduction would disproportionately compromise the value of the data.

►

* 1. Refinement. Describe the refinements that have been incorporated into this work and explain why no further refinements are feasible. Refinement refers to use of approaches that lessen or eliminate pain or distress in the animals that are used. This includes (1) choosing procedures that prevent or relieve pain or distress likely to be associated with the experimental design, (2) setting the earliest possible endpoints for the experiments, (3) appropriate use of analgesics, anesthetics, and tranquilizers, including selection of better agents (more effective, with fewer or less severe potential side effects) as they become available, (4) improving post-surgical care with new technology as it becomes available, and (5) special husbandry such as providing softened food after procedures likely to cause discomfort with swallowing, soft bedding, easier access to food, or environmental enrichment, as appropriate.

►

* 1. Describe how it was determined that the proposed work does not unnecessarily duplicate work already documented in the literature.

►

1. **Other Regulatory Considerations**.
   1. **Controlled drugs**. Will controlled drugs be used in this study?

►No ( ). Proceed to Item X2.

►Yes ( ). Complete all of Item X1. Include in Appendix 3 all controlled substances listed here.

* + 1. Complete the table below for each drug that is used in animals on this protocol and that is classified as a controlled substance by the DEA. See ACORP Instructions, for explanations about the information requested.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Controlled substance(s) | Storage | | Personnel Authorized to Access | Location for Use | | Procurement | |
| Double-locked | Not Double-locked\* | VA Property | Not on VA Property | VA  Pharmacy | Non- VA |
|  | ( ) | ( )\* |  | ( ) | ( ) | ( ) | ( ) |
|  | ( ) | ( )\* |  | ( ) | ( ) | ( ) | ( ) |
|  | ( ) | ( )\* |  | ( ) | ( ) | ( ) | ( ) |

\*For any controlled substance that will NOT be stored under double lock, with limited access, describe how it will be stored, and explain why this is necessary.

►

* + 1. Check each statement below that applies, to confirm that all controlled substances used on this protocol will be procured according to VA pharmacy policies:

► ( ) Some controlled substances **WILL** be used on VA property, and **ALL** of these will be obtained through the local VA pharmacy. VA policy does not permit any controlled substances obtained through an affiliate institution to be brought onto VA property to be administered to animals in the VMU.

► ( ) Some controlled substances **WILL NOT** be obtained through the local VA pharmacy, but **NONE** of these will be used on VA property. If the controlled substances will only be used at non-VA locations, *1108.01* states that, “the local Chief of Pharmacy Services must be consulted to determine whether controlled substances are to be obtained through the VA pharmacy.”

► ( ) Other. If any controlled substances that are to be used on VA property will NOT be procured through the local VA pharmacy, please explain how they will be procured and why this is necessary.

Explain►

* 1. **Human patient care equipment or procedural areas**. Does this protocol involve use of any human patient care equipment or procedural areas?

► ( ) No human patient care equipment or procedural areas will be used for the animal studies on this protocol. Proceed to X. 3.

► ( ) Yes, some human patient care equipment or procedural area(s) will be used for the animal studies on this protocol. Check “Appendix 7” in Item Y, below, and complete and attach Appendix 7, “Use of Patient Procedural Areas for Animal Studies”.

* 1. **Explosive agents**. Does this protocol involve use of any explosive agent?

► ( ) No explosive agent(s) will be used as part of this protocol. Proceed to Y.

► ( ) Yes, some explosive agent(s) will be used on this protocol. Check “Appendix 3” and “Appendix 8” in Item Y, below, and complete and attach Appendix 3, “Biosafety”, as well as Appendix 8, “Use of Explosive Agent(s) within the Animal Facility or in Animals”.

1. **Summary of Attachments.** To assist the reviewers, summarize here which of the following apply to this ACORP.

**Appendices.** Indicate which of the Appendices are required and have been completed and attached to this protocol. Do not check off or attach any appendices that are not applicable to this ACORP.

► ( ) Appendix 1, “Additional Local Information”

► ( ) Appendix 2, “Antibody Production”

► ( ) Appendix 3, “Biosafety”

► ( ) Appendix 4, “Ante-mortem Specimen Collection”

► ( ) Appendix 5, “Surgery”

► ( ) Appendix 6, “Special Husbandry and Procedures”

► ( ) Appendix 7, “Use of Patient Care Equipment or Areas for Animal Studies”

► ( ) Appendix 8, “Use of Explosive Agent(s) within the VMU or in Animals”

► ( ) Appendix 9, “Departures from “Must” and “Should” Standards in the *Guide*”

► ( ) Appendix 10, “Biohazard Containment Caging”

► ( ) Appendix 11, “Laboratory Safety Hazard Assessment Form”

**Standard Operating Procedures (SOP’s).** List in the table below, each of the SOP’s referred to in this protocol, providing the information requested for each one. The approved SOP’s must be included when the approved ACORP and Appendices are submitted for Just-in-Time processing before release of VA funding support.

|  |  |  |  |
| --- | --- | --- | --- |
| Item | SOP | | Approval Date |
| Title | ID |
| C.2.c |  |  |  |
| M.1 |  |  |  |
| M.2 |  |  |  |
| U.4.a |  |  |  |
| U.4.b |  |  |  |
| V |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. **Certifications.** Signatures are required here for any ACORP that is to be submitted to VA Central Office in support of an application for VA funding. Include the typed names and dated signatures as shown below for the Main Body of the ACORP and for each of the Appendices that apply to this protocol. Do NOT include signatures for, or attach, any appendices that do NOT apply.
   1. **Main Body of the ACORP.**
      1. **Certification by Principal Investigator(s):** I certify that:

* To the best of my knowledge, the information provided in this ACORP is complete and accurate, and the work will be performed as described here and approved by the IACUC.
* I understand that IACUC approval must be renewed at least annually, and that the IACUC must perform a complete *de novo* review of the protocol at least every three years, if work is to continue without interruption.
* I understand further that I am responsible for providing the information required by the IACUC for these annual and triennial reviews, allowing sufficient time for the IACUC to perform the reviews before the renewal dates.
* I will be required to complete a newer version of the ACORP that requests additional information, if such a newer version is in use at the time of each triennial review.

I understand that further IACUC approval must be secured before any of the following may be implemented:

* Use of additional animal species, numbers of animals, or numbers of procedures performed on individual animals;
* Changing any procedure in any way that has the potential to increase the pain/distress category to which the animals should be assigned, or that might otherwise be considered a significant change from the approved protocol;
* Performing any additional procedures not already described in this ACORP;
* Use of any of these animals on other protocols, or by other investigators.

I further certify that:

* No personnel will perform any animal procedures on this protocol until the IACUC has confirmed that they are adequately trained and qualified, enrolled in an acceptable Occupational Health and Safety Program, and meet all other criteria required by the IACUC. When new or additional personnel are to work with the animals on this protocol, I will provide this information to the IACUC for confirmation before they begin work;
* I will provide my after-hours contact information to the animal care staff for use in case of emergency.

|  |  |  |
| --- | --- | --- |
| Name(s) of Principal Investigator(s) | Signature | Date |
|  |  |  |
|  |  |  |

* + 1. **Certification by IACUC Officials.**

We certify that:

* We, with the IACUC, have evaluated the care and use of animals described on this ACORP, in accordance with the provisions of the USDA Animal Welfare Act Regulations and Standards, PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, and VA Policy;
* The IACUC has determined that the care and use of animals described in this ACORP is appropriate, and has therefore approved the protocol;
* The full text of any minority opinions is documented here as indicated below:

► ( ) No minority opinions were submitted by any IACUC participant for inclusion.

► ( ) Minority opinions submitted by IACUC participants are attached on separate pages labeled “IACUC Minority Opinion” (indicate the number of pages► )

|  |  |  |
| --- | --- | --- |
| Name of Attending Veterinarian (VMO or VMC) | Signature | Date |
| **Melissa Dyson, DVM** |  |  |
| Name of IACUC Chair | Signature | Date |
| **Michal Olszewski, DVM** |  |  |

* 1. **Appendix 2. Antibody Production.** No signatures required.
  2. **Appendix 3. Biosafety.**
     1. **Certification by PI(s) and IACUC Officials:**

We certify that:

* The use of each of the hazardous agents described in this protocol will not begin until it has been approved by the appropriate committee(s) or official(s), as shown in Item 10.a of Appendix 3.
* Before any animal experiments involving hazardous agents (identified in Item 10.a of Appendix 3) are performed, SOP’s designed to protect all research and animal facility staff as well as non-study animals will be developed and approved by the appropriate VA or affiliated university safety committee and by the IACUC;
* All personnel who might be exposed to the hazardous agents (identified in Item 10.a of Appendix 3) will be informed of possible risks and will be properly trained ahead of time to follow the SOP’s to minimize the risks of exposure.

|  |  |  |
| --- | --- | --- |
| Name(s) of Principal Investigator(s) | Signature(s) | Date |
|  |  |  |
|  |  |  |
| Name of Institutional Veterinarian | Signature | Date |
| **Melissa Dyson, DVM** |  |  |
| Name of IACUC Chair | Signature | Date |
| **Michal Olszewski, DVM** |  |  |

* + 1. **Certification by Biosafety Official.** I certify that:
* Each agent to be administered to animals on this protocol has been properly identified in Item 1 of Appendix 3 as to whether it is “toxic”, “infectious”, “biological”, or “contains recombinant nucleic acid”;
* The use of each of the agents thus identified as “toxic”, “infectious”, or “biological”, or “contains recombinant nucleic acid” is further documented as required in Items 4, 5, 6, and/or 8, as applicable, and in Item 10.a of Appendix 3;
* The use of each of these agents has been approved by the appropriate committee(s) or official(s), as shown in Item 10.a of Appendix 3.

|  |  |  |
| --- | --- | --- |
| Name of the Biosafety Officer, or of the Chair of the Research Safety or Biosafety Committee | Signature | Date |
|  |  |  |
|  |  |  |

* + 1. **Certification by Radiation Safety Official.** I certify that:
* Each agent to be administered to animals on this protocol has been properly identified in Item 1 of Appendix 3 as to whether it is “radioactive”;
* The use of each radioactive agent is further documented as required in Items 7 and 10.a of Appendix 3;
* The use of each radioactive agent has been approved by the appropriate committee(s), as shown in Item 10.a of Appendix 3.

|  |  |  |
| --- | --- | --- |
| Name of the Radiation Safety Officer, or of the Chair of the Radiation Safety or Isotope Committee | Signature | Date |
| **Melonie Wissing, RSO** |  |  |
|  |  |  |

* 1. **Appendix 4. Ante-mortem Specimen Collection.** No signatures required.
  2. **Appendix 5. Surgery. Certification by the PI(s).** I certify that:
  + To the best of my knowledge, the information provided in Appendix 5 of this ACORP is complete and accurate;
  + The surgical procedures will be performed and the post-operative care (including administration of post-operative analgesics) will be provided as described;
  + The spaces where any survival surgical procedures will be performed (listed in Item 4 of Appendix 5) are suitable for sterile/aseptic surgery;
  + The names and contact information for research personnel to notify or consult in case of emergencies will be provided to the VMU supervisor and veterinary staff;
  + Post-operative medical records will be maintained and readily available for the veterinary staff and the IACUC to refer to, and will include the following:
* Identification of each animal such that care for individual animals can be documented.
* Daily post-operative medical records for each animal, that include documentation of daily evaluation of overall health and descriptions of any complications noted, treatments provided, and removal of devices such as sutures, staples, or wound clips;
* Documentation of the administration of all medications and treatments given to the animals, including those given to reduce pain or stress.
* Daily records covering at least the period defined as “post-operative” by local policy.
* The signature or initials of the person making each entry.

.

|  |  |  |
| --- | --- | --- |
| Name(s)  of Principal Investigator(s) | Signature(s) | Date |
|  |  |  |
|  |  |  |

* 1. Appendix 6. Special Husbandry and Procedures. No signatures required.

* 1. Appendix 7. Use of Patient Care Equipment or Areas for Animal Studies.
     1. **Certification by the Principal Investigator(s).** I certify that, to the best of my knowledge, the information provided in Appendix 7 of this ACORP is complete and accurate, and the use of patient care equipment or areas for these animal studies will be as described.

|  |  |  |
| --- | --- | --- |
| Name(s)  of Principal Investigator(s) | Signature(s) | Date |
|  |  |  |
|  |  |  |

* + 1. **Certification by the officials responsible for the use of any human patient care equipment in animal procedural areas.** Each of the following must sign to indicate that they have granted approval for the human patient care equipment to be moved to the VMU or other animal procedural area to be used on animals and then returned to the human patient care area, as described in Appendix 7. Leave this section blank, if not applicable.

|  |  |  |
| --- | --- | --- |
| Name of IACUC Chair | Signature | Date |
| **Michal Olszewski, DVM** |  |  |
| Name of the Manager of the Human Patient Care Equipment | Signature | Date |
|  |  |  |

* + 1. **Certification by the officials responsible for the use of the equipment in human patient care areas for these animal studies.** Each of the following must sign to indicate that they have granted approval for animals to be transported into human patient care areas for study or treatment, as described in Appendix 7. Leave this section blank, if not applicable.

|  |  |  |
| --- | --- | --- |
| Name of IACUC Chair | Signature | Date |
| **Michal Olszewski, DVM** |  |  |
| Name of Attending Veterinarian (VMO or VMC) | Signature | Date |
| **Melissa Dyson, DVM** |  |  |
| Name of the Chair of the Clinical Executive Board, or the Service Chief responsible for the Patient Care Area and Equipment | Signature | Date |
|  |  |  |
| Name of ACOS for R&D | Signature | Date |
|  |  |  |
| Name of Chief of Staff | Signature | Date |
|  |  |  |
| Name of Director or CEO of the Facility (Hospital or Clinic) | Signature | Date |
|  |  |  |

* 1. Appendix 8. Use of Explosive Agent(s) within the Animal Facility or in Animals.
     1. **Certification by the Principal Investigator(s).** I certify that:

To the best of my knowledge, the information provided in Appendix 8 of this Animal Component of Research Protocol (ACORP) is complete and accurate, and the use of explosive agents in these animal studies will be as described.

I further certify that:

* + - * Procedures involving explosive agent(s) will be performed within a properly operating, ventilated safety hood;
      * All electrical equipment operating when explosive agent(s) are in use will be positioned and powered outside of the hood;
      * Once the seal is broken on any containers of explosive agents, they will be kept in a safety hood throughout use, stored in an explosion-proof refrigerator or other approved storage area, and discarded properly once completely emptied;
      * Proper procedures will be used for safe and appropriate disposal of items (including animal carcasses) that may contain residual traces of the explosive agent(s).

|  |  |  |
| --- | --- | --- |
| Name(s)  of Principal Investigator(s) | Signature(s) | Date |
|  |  |  |
|  |  |  |

* + 1. **Certification by the officials responsible for overseeing the use of explosive agent(s) in this protocol.** Each of the following must sign to verify that they or the committee they represent have granted approval.

|  |  |  |
| --- | --- | --- |
| Name of IACUC Chair | Signature | Date |
| **Michal Olszewski, DVM** |  |  |
| Name of Attending Veterinarian (VMO or VMC) | Signature | Date |
| **Melissa Dyson, DVM** |  |  |
| Name of Safety/Biosafety Officer for the Facility | Signature | Date |
| **Joseph Jurasek, M.S., CHSP, CHCM** |  |  |
| Name of ACOS for R&D | Signature | Date |
|  |  |  |
| Name of VISN Regional Safety Officer | Signature | Date |
|  |  |  |

* 1. **Departures from “Must” and “Should” Standards in the *Guide*.** No signatures required.
  2. Appendix 10. Biohazard Containment Caging. No signatures required as they are covered by signatures used for Appendix 3.
  3. Appendix 11. Laboratory Safety Hazard Assessment Form. No signatures required as they are covered by signatures used for Appendix 3.

**ACORP Appendix 1**

**Additional Local Information**

**Version 4**

This appendix may be used to collect additional information required by the local IACUC. See ACORP App. 1 Instructions, for more detailed explanations of the information requested.)

List, in order of priority, the staff members (including the principal investigator) who should be contacted regarding any issue arising from the procedures described in this ACORP.

|  |  |  |
| --- | --- | --- |
| Name of Individual | Contact Information  ***During*** business hours | Contact Information  ***After*** hours |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**ACORP Appendix 2**

**Antibody Production**

**Version 4**

See ACORP App. 2 Instructions, for more detailed explanations of the information requested.

1. **Immunization.** Provide the information requested below for any animals to be used for raising antibodies specifically for use in this protocol.
   1. Describe the immunization protocol in the table below, using a separate row for each day on which any agent (including primer, antigen, and/or adjuvant) will be administered. (Make sure that each primer, antigen, and adjuvant is also included in Appendix 3.)

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Immunization day(e.g. day -7, 0, 7, 30, etc.) | Antigen | | | | | Primer or Adjuvant | | | Total injection volume (ml) per animal (antigen plus adjuvant) | Divided among how many injection sites? |
| Name | Total amount (mg) and volume (ml) | | Injection route and location of injection site(s) on body | | Name, concentration (conc), and volume (ml) | | |
| mg | ml | Route | Site | Name | conc | ml |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

* 1. Describe how each antigen will be screened to make sure that it does not harbor infectious agents that could infect other laboratory animals or people after injection.

►

* 1. List possible adverse effects that might be observed in animals receiving the proposed primer, antigen, and/or adjuvant injections, and describe the measures that will be taken if these adverse effects occur.

►

* 1. Give the justification for using any primer or adjuvant that is expected to cause pain or distress in the animals.

►

1. **Survival Blood Collection.** Will blood be collected as a survival procedure for the production and harvesting of antibodies on this protocol?

► ( ) **No**, the production and harvest of antibodies on this protocol does not involve survival collection of blood. Proceed to 3.

► ( ) **Yes**, this protocol requires the collection of blood in a survival procedure, before (as a “pre-bleed”) and/or after immunization. Make sure this is included in Item R of the ACORP, and complete items 2.a, 2.b, and 2.c, below.

* 1. Describe each survival collection of blood in the table below, including any “pre-bleeds” prior to immunizations:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Site of Blood Collection | Amount of Blood Collected at any one time,  expressed as volume (ml) and as % of body weight (assume 1 ml = 1 gram) | | Number of Blood Collections | Time Interval(s) Between Successive Collections | Volume Replace-ment?  (yes/no) | |
| Volume (ml) | % of body weight | Yes | No |
|  |  |  |  |  | **( )** | **( )** |
|  |  |  |  |  | **( )** | **( )** |
|  |  |  |  |  | **( )** | **( )** |
|  |  |  |  |  | **( )** | **( )** |

* 1. Will anesthetics, tranquilizers, or analgesics be administered for blood collection?

► ( ) **No** anesthetics, tranquilizers, or analgesics will be administered for blood collection. Explain why it is appropriate or necessary NOT to administer pain-relieving agents:

►

► ( ) **Yes.** Describe the administration of pain-relieving agents, including the name of each agent, and its dose (mg/kg), volume (ml), and route and frequency/duration of administration (Make sure this information is also included in Appendix 3):

►

* 1. Will volume replacement be provided for blood that is collected?

► ( ) Volume will **NOT** be replaced for some of the blood collection listed. For each collection listed in Item 2.a, above, for which volume will NOT be replaced, explain why not.

►

|  |  |
| --- | --- |
| Site of Blood Collection | Why it will not be followed by volume replacement |
|  |  |
|  |  |
|  |  |

► ( ) Volume **WILL** be replaced for some of the blood collection listed. For each collection listed in Item 2.a, above, for which volume WILL be replaced, describe the replacement(s) that will be provided (including the composition of the replacement(s), volume, and route of administration).

|  |  |  |  |
| --- | --- | --- | --- |
| Site of Blood Collection | Composition of volume replacement | Volume (ml) | Route of Administration |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. **Terminal Blood Collection.** Will animals be euthanatized by exsanguination, for harvest of antibodies?

► ( ) **No**, this protocol does NOT involve terminal blood collection for harvest of antibodies. Proceed to 4.

► ( ) **Yes**, this protocol DOES require terminal blood collection for the harvest of antibodies. Make sure this is included in Item R of the ACORP, and complete Items 3.a., 3. b., and 3.c., below:

* 1. Describe the method(s) to be used for euthanasia and exsanguination:

►

* 1. Will anesthetics, tranquilizers, or analgesics be administered for exsanguination?

► ( ) **No** anesthetics, tranquilizers, or analgesics will be administered for the exsanguination(s).

Explain why it is appropriate or necessary NOT to administer pain-relieving agents:

►

► ( ) **Yes.** Describe the administration of pain-relieving agents including the name of each agent, and its dose (mg/kg), volume (ml), and route and frequency/duration of administration (Make sure this information is also included in Appendix 3):

►

* 1. Describe how you will make sure that the animals are dead after collection of the blood:

►

1. **Harvesting Feeder Cells.** Will animals be used in this protocol for the harvesting of feeder cells?

► ( ) **No** animals will be used on this protocol for the harvesting of feeder cells. (Proceed to 5.)

► ( ) **Yes**, this protocol requires use of some animals for *harvesting feeder cells*. Describe the exact procedures (including administration of pain-relieving agents) that will be used on any donor animals from which feeder cells will be collected for this protocol, and estimate the number of animals needed for this purpose. Make sure that these animals are included in Item I of the ACORP, and that the harvesting of feeder cells is included in Item R of the ACORP.

1. **Expansion of Hybridoma Cell Line(s) *in vivo***. Will any animals be used to expand hybridoma cell lines so that antibody can be harvested from ascites fluid?

► ( ) **No** animals will be used on this protocol for *in vivo* expansion of hybridoma cell lines.

► ( ) **Yes**, this protocol requires use of some animals for *in vivo* expansion of hybridoma cell lines. Make sure that the animals used for this are included in Item I of the ACORP, the priming agent and the hybridoma cells are documented in Appendix 3, and the collection of ascites fluid is included in Item R of the ACORP. Complete items 5.a, 5.b, and 5.c, below.

* 1. Explain why alternate research methods that do not require the use of additional animals (e.g., *in vitro* cell culture systems for harvesting monoclonal antibodies) are not adequate to meet the research objectives of this project.

►

* 1. Complete the following table to summarize the procedures to be performed in expanding the hybridoma cell lines and collecting ascites fluid:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Hybridoma cell line designation | Number of animals to be used for ascites production | Priming agent and volume (ml) | | Number and timing of priming injections | | Volume of injected hybridoma cells | Number of abdominal taps before euthanasia |
| Agent | Volume (ml) | # | Timing |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

* 1. Describe the exact procedures (including administration of pain-relieving agents) that will be used for the abdominal taps to be performed on this protocol

►

* 1. List the criteria for euthanasia of animals prior to the last planned abdominal tap.

►

Use Appendix 9 to document any “departures” from the standards in the *Guide* represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any “departures” are involved.

ACORP Appendix 3

Biosafety For Animals

Version 4

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 information below for each of the materials shown in the table in Item 1 above:
   1. Complete information below for each of the materials shown in the table in Item 1 above. (**Copy the lines below for each material.)**

**Name of Material** ►

**Dose** (e.g., mg/kg, CFU, PFU, number of cells, mCi) ►

**Volume** (ml) ►

**Diluent\* or Vehicle\***►

**Route** of administration ►

**Frequency or duration** of administration ►

**Reason** for Administration ►

**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) ► ( )Yes ( )No

\*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 (<http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/UCM042847>).

Designate with an \* 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 how it will be ensured that the grade, purity, sterility, pH, pyrogenicity, osmolality, stability, formulation, and pharmacokinetics of the material will be suitable for use in the animals, and describe how it will be ensured that the material is suitable for use.

►

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):

|  |  |  |  |
| --- | --- | --- | --- |
| Anesthetic, Sedative or Tranquilizer to be Used | Dose | Volume | Route |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

* 1. For each material with “N” entered in the last column 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.

|  |  |  |
| --- | --- | --- |
| Material | Explanation | Alternate method of restraint |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

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 | Mutagen | Carcinogen | Teratogen | Select Agent? | | | 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** (e.g., bacteria, viruses, fungi, protozoa, and prions). 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 | | ABSL Number\* | Drug Sensitivity Panel Available? (Describe) | | | Select Agent? | | |
| Not a Select Agent | Select Agent used in Sub-threshold quantities | Select Agent that Requires Registration/Approval |
| Name | BSL # | Yes | No | Describe |
|  |  |  | ( ) | ( ) |  | ( ) | ( ) | ( )\*\* |
|  |  |  | ( ) | ( ) |  | ( ) | ( ) | ( )\*\* |
|  |  |  | ( ) | ( ) |  | ( ) | ( ) | ( )\*\* |
|  |  |  | ( ) | ( ) |  | ( ) | ( ) | ( )\*\* |
|  |  |  | ( ) | ( ) |  | ( ) | ( ) | ( )\*\* |

\*Specify the ABSL level of the minimum measures that will be applied in handling each agent. The practices, safety equipment, and facilities that correspond to each ABSL level are described in Biosafety in Microbiological and Biomedical Laboratories, 5th edition (December 2009), available at www.cdc.gov/biosafety/publications/bmbl5/.

ABSL1 is the recommended minimum for BSL1 agents.

ABSL2 is the recommended minimum for BSL2 agents.

ABSL3 is the recommended minimum for BSL3 agents.

ABSL4 is the recommended minimum for BSL4 agents.

**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** (e.g., antigens, serum, cell lines, tissue, and nucleic acid).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** (including both isolated recombinant nucleic acid and recombinant infectious agents).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 even if measures will be taken to prevent animals on this protocol from actually experiencing the pain or distress. Focus on the effects of the agents, and not on the potential pain or distress associated with the procedures involved in administering them, which are addressed elsewhere in the protocol.

Describe ALL measures that will be taken to alleviate this potential pain and/or distress (may include not only administration of pharmacological anesthetics, analgesics, tranquilizers, or sedatives, but also appropriate special husbandry procedures (describe in Appendix 6).

|  |  |  |
| --- | --- | --- |
| 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 |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

\*Include each agent listed in Item 4, 5, 6, 7, and 8 of this Appendix.

* 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.

Include what information will be posted, and where, and summarize any specific training to be provided.

►

Use Appendix 9 to document any “departures” from the standards in the *Guide* represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any “departures” are involved.

ACORP Appendix 4

**Antemortem Specimen Collection**

**Version 4**

See ACORP App. 4 Instructions, for more detailed explanations of the information requested.

1. **Summary.** Complete the table below for each specimen, including tail snips, to be collected from a live animal on this protocol (see ACORP App. 4 Instructions, for details).

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Specimen Collected | Site and Method of Collection | | Anesthesia (Yes/No) | | Amount Collected Each Time | Volume Replacement (Yes/No/NA) | | | Total Number of Collections per Animal | Time Intervals Between Successive Collections |
| Site | Method | Yes | No | Yes | No | N/A |
|  |  |  | **( )** | **( )** |  | **( )** | **( )** | **( )** |  |  |
|  |  |  | **( )** | **( )** |  | **( )** | **( )** | **( )** |  |  |
|  |  |  | **( )** | **( )** |  | **( )** | **( )** | **( )** |  |  |

1. **Use of Anesthetics, Tranquilizers, or Analgesics**.
   1. For each specimen described in Item 1, above, as being collected **WITHOUT** anesthesia, complete Items 2.a(1) and 2.a(2), below:
      1. Explain why no measures will be taken to prevent pain (e.g., because of scientific requirements described here, or because the collection method involves no more than minor or momentary pain).

►

* + 1. Completely describe any method of physical restraint that may be used.

►

* 1. For each specimen described in Item 1, above, as being collected **WITH** anesthesia, complete the following table:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Anesthetic, tranquilizer, or analgesic agent | Dose (mg/kg) and volume (ml) | | Route of administration | Frequency of administration |
| Dose | Volume (ml) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1. **Volume Replacement for Fluid Collections.** 
   1. For each fluid specimen described in Item 1, above, for which **NO** volume replacement will be provided, explain why not.

►

* 1. For each fluid specimen described in Item 1, above, for which volume replacement **WILL** be provided, describe the replacement fluids that will be administered (including their composition, volume, and route of administration).

►

1. **Monitoring the animals.** Detail how the animals will be monitored after collection of specimens to ensure that they recover appropriately (see ACORP App. 4 Instructions, for details).

Include the methods of monitoring to be used, and how long the animals will be monitored specifically for recovery from specimen collection. Describe the criteria that will be considered indicators of the need for intervention, and describe the corresponding interventions to be made (e.g., administration of analgesics, application of pressure, euthanasia, etc.).

►

|  |  |  |  |
| --- | --- | --- | --- |
| Monitoring Methods | Length Monitoring Time till Recovery | Indicators for Intervention | Corresponding Intervention |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Use Appendix 9 to document any “departures” from PHS policy, including the standards in the *Guide*, represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any “departures” are involved.

ACORP Appendix 5

**Surgery**

**Version 4**

See ACORP App. 5 Instructions, for more detailed explanations of the information requested.

1. **Surgery Classification.** Complete the table below for each surgery included in this protocol, and indicate how it is classified (terminal, minor survival, major survival, one of multiple survival). See ACORP App. 5 Instructions, for details.

Terminal surgery is any surgery during which the animal is euthanatized without being allowed to recover from anesthesia.

Survival surgery is any surgery after which the animal will be allowed to regain consciousness. This requires that provisions be made for recovery from anesthesia, and for post-operative care.

Minor survival surgery/procedure is defined as any non-major procedure requiring anesthesia of the animal followed by a recovery period.

Major survival surgery is defined as a surgical procedure in which a major body cavity is penetrated and exposed, produces substantial impairment of physical or physiological functions, or involves extensive tissue dissection or transection. Examples of major surgeries include thoracotomy, craniotomy, joint replacement, and limb amputation.

One of multiple surgeries is each survival surgery (including any minor surgical procedures that may induce substantial post-procedural pain or impairment, as well as any major surgeries) that will be performed as part of this protocol, in addition to any other such surgery (on this or another protocol) on the same individual animal.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Surgery | Classification | | | |
| Terminal | Survival | | |
| Minor | Major | One of Multiple\* |
|  | ( ) | ( ) | ( ) | ( )\* |
|  | ( ) | ( ) | ( ) | ( )\* |
|  | ( ) | ( ) | ( ) | ( )\* |
|  | ( ) | ( ) | ( ) | ( )\* |

\*If survival surgery (including major surgeries and any minor surgeries that may induce substantial post-procedural pain or impairment) will be performed as part of this protocol in addition to any other such surgery (on this or another protocol) on the same individual animal, complete items 1.a and 1.b, below:

* 1. Provide a complete scientific justification for performing the multiple survival surgeries on an individual animal:

►

* 1. Give the interval(s) between successive surgeries, and the rationale for choosing the interval(s):

►

1. **Description of Surgeries.** Describe each surgery listed in Item 1, providing enough detail to make it clear what the effects on the animal will be. (Details of pre-operative preparation, anesthesia, and post-operative recovery will be covered in items 5, 6, and 7, below so it is sufficient to provide only summaries of these here.)

**Example:** Name of Surgery (taken from Item 1) followed by the description of events – administration of pre-op analgesics, anesthetic induction, animal prep – surgical site, eye lube, checking anesthetic depth prior to beginning procedure, positioning of animal, details of procedure, details of closure, administration of post-op analgesics, recovery, removal of sutures, staples, etc. (**Copy the lines below for each surgery**):

**Name of Surgery** ►

Description ►

1. **Personnel.** Complete the table below for each individual who will be involved in any of the surgeries on this protocol.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name of Surgery  (see Item 1) | Individual | Role in Surgery | | | |
| Surgeon | Assistant | Manage Anesthesia | Other (describe) |
|  |  | ( ) | ( ) | ( ) | ( ) |
|  |  | ( ) | ( ) | ( ) | ( ) |
|  |  | ( ) | ( ) | ( ) | ( ) |
|  |  | ( ) | ( ) | ( ) | ( ) |
|  |  | ( ) | ( ) | ( ) | ( ) |

1. **Location of surgery.** Complete the table below for each location where surgery on this protocol will be performed.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name of Surgery  (see Item 1) | Building | Room Number | Type of Space | | |
| Dedicated Surgical Facility | Other Dedicated Surgical Space | Other Space not Dedicated to Surgery |
|  |  |  | ( ) | ( )\* | ( )\* |
|  |  |  | ( ) | ( )\* | ( )\* |
|  |  |  | ( ) | ( )\* | ( )\* |
|  |  |  | ( ) | ( )\* | ( )\* |

\*For each space that is not in a dedicated surgical facility, provide the justification for using this space for surgery in this protocol.

►

1. **Pre-operative protocol.**
   1. **Pre-operative procedures.** Complete the table below for each pre-operative procedure that will be performed to prepare the animal(s) for surgery.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Surgery  (see Item 1) | Fast  (Specify Duration) | Withhold Water (Specify Duration) | Place Intravenous Catheter(s)  (Specify Site(s)) | Other – Describe |
|  | ( ) -- | ( ) -- | ( ) -- | ( ) -- |
|  | ( ) -- | ( ) -- | ( ) -- | ( ) -- |
|  | ( ) -- | ( ) -- | ( ) -- | ( ) -- |
|  | ( ) -- | ( ) -- | ( ) -- | ( ) -- |

* 1. **Pre-operative medications.**  Complete the table below. Include agent(s) for induction of anesthesia, as well as any other pre-treatments that will be administered prior to preparation of the surgical site on the animal. Include eye lubrication, all sedatives, tranquilizers, and other agent(s) to be used for induction of anesthesia, as well as any antibiotics or other pre-treatments to be administered in preparation for surgery. Each of these agents should also be included in Item 1 of Appendix 3.

1)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name of Surgery (see Item 1) | Agent | Dose (mg/kg) & Volume (ml) | | Route of Admini-stration | Frequency of Administration  (e.g., times/day) | Pre-operative Period of Treatment  (e.g., immediate, or # of days) |
| Dose | Volume (ml) |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

2) How will depth of anesthesia be assessed prior to beginning the procedure?

►

* 1. **Pre-operative preparation of the surgical site.** For each surgery, identify each surgical site on the animals, and describe how it will be prepared prior to surgery. Include details about hair removal (such as whether clippers or chemical hair removal products will be used and how the clipped hair or chemicals will be cleaned away), skin disinfection, and the use of surgical drapes. (**Copy the lines below for each surgery**):

**Name of Surgery** (see Item 1)►

Surgical Site►

Description ►

1. **Intra-operative management.**
   1. **Intra-operative medications.** Complete the table below for each agent that will be administered to the animal during surgery. Include all maintenance anesthetic agents, paralyzing agents, fluids, and other pharmaceuticals that will be administered to the animal during surgery. Also include any experimental pharmaceuticals that will be administered during surgery. Each of these should also be included in Item 1 of Appendix 3.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name of Surgery  (see Item 1) | Agent | Paralytic\* | Dose (mg/kg) & volume (ml) | | Route of Admini-stration | Frequency of Administration |
| Dose | Volume (ml) |
|  |  | ( )\* |  |  |  |  |
|  |  | ( )\* |  |  |  |  |
|  |  | ( )\* |  |  |  |  |
|  |  | ( )\* |  |  |  |  |

\* For each agent shown above as a paralytic, explain why its use is necessary, and describe how the animals will be monitored to ensure that the depth of anesthesia is sufficient to prevent pain.

►

* 1. **Intra-operative physical support.** For each surgery, describe any physical support that will be provided for the animals during surgery (e.g., warming, cushioning, etc.). (**Copy the lines below for each surgery**):

Name of Surgery (see item 1)►

Intra-operative physical support►

* 1. **Intra-operative monitoring.** Describe the methods that will be used to monitor and respond to changes in the state of anesthesia and the general well-being of the animal during surgery. Include the variables that will be monitored (e.g., mucous membrane color, heart rate, blood pressure, motor responses), the criteria for adjusting the level of anesthesia or other support, and the additional measures that may be taken, as appropriate. (**Copy the lines below for each surgery**):

Name of Surgery (see item 1)►

Intra-operative monitoring►

1. **Survival surgery considerations.** For each survival surgical procedure indicated in Item 1 and described in Item 2, complete Items 7.a. – 7.g.
   1. Complete the table below for each survival surgery listed in Item 1, above.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Name of Surgery  (see Item 1) | Survival Period\* | Measures for Maintaining Sterility | | | | | | | |
| Sterile Instruments | Surgical Cap | Sterile Gloves | Surgical Scrub | Sterile Drapes | Sterile Gown | Face Mask | Other\*\* |
|  |  | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( )\* |
|  |  | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( )\* |
|  |  | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( )\* |
|  |  | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( )\* |

\*Survival Period – Enter how long the animal(s) are expected to survive after surgery (number of hours, days, weeks, etc.). For animals that will undergo multiple repetitions of any one survival surgery, enter the length of time after the last repetition before euthanasia.

\*\* Describe any “other” measures to be taken to maintain sterility during surgery.

►

* 1. For each surgery, describe the immediate post-operative support to be provided to the animals.

(This commonly includes the use of circulating warm water heating pads and blankets, administration of fluids, etc.) (**Copy the lines below for each surgery**):

**Name of Surgery** (see Item 1)►

Description of immediate post-op support►

* 1. Post-operative analgesia. Complete the table below for each surgery listed in item 1, above.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name of Surgery (see Item 1) | Agent\* | Dose (mg/kg) & Volume (ml) | | Route of Admini-  stration | Frequency of  Administration  (e.g., times/day) | Post-operative Period of Treatment  (e.g. days) |
|  |  | Dose | Volume (ml) |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

\*For each surgery for which **NO** post-operative analgesic will be provided, enter “none” in the “Agent” column, and explain here why this is justified. (**Copy the lines below for each surgery**):

**Name of Surgery** (see Item 1)►

Justification for NOT giving post-operative analgesics►

* 1. Other post-operative medications. Complete the following table to describe all other medications that will be administered as part of post-operative care. This may also include hydrating fluids.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name of Surgery  (see Item 1) | Medication | Dose (mg/kg) & Volume (ml) | | Route of Admini-  stration | Frequency of  Administration (e.g. times/day) | Post-operative Period of Treatment  (e.g. days) |
| Dose | Volume (ml) |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

* 1. Post-operative monitoring.After-hours contact information for the personnel listed must be provided to the veterinary staff for use in case of an emergency.
     1. Immediate post-operative monitoring (until the animal recovers sufficiently from anesthesia to ambulate without danger to itself.)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Surgery (see Item 1) | Frequency of Monitoring | Duration at this Frequency | Name(s) of Responsible Individual(s) | Contact Information |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

* + 1. Post-operative monitoring after the immediate post-operative period (until animal fully recovers from surgery).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Surgery (see Item 1) | Frequency of Monitoring | Duration at this Frequency | Name(s) of Responsible Individual(s) | Contact Information |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

* 1. Post-operative consequences and complications.
     1. For each surgery, describe any common or expected post-operative consequences as well as potential complications that may arise and what will be done to address them. (**Copy the lines below for each surgery**):

**Name of Surgery** (see Item 1)►

Possible consequences or complications►

* + 1. List the criteria for euthanasia related specifically to post-operative complications. (**Copy the lines below for each surgery**):

**Name of Surgery** (see Item 1)►

Euthanasia criteria►

* + 1. In case an emergency medical situation arises and none of the research personnel on the ACORP can be reached, identify any drugs or classes of drugs that should be avoided because of the scientific requirements of the project. (If the condition of the animal requires one of these drugs, the animal will be euthanatized instead.)

►

* 1. Maintenance of post-surgical medical records. Complete the table below for each surgery, specifying where the records will be held, and identifying at least one individual who will be assigned to maintain accurate, daily, written post-surgical medical records. Indicate whether the named individuals are research personnel involved in this project, or members of the veterinary staff.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name of Surgery  (see Item 1) | Location of Records | | Name(s) of Individual(s) Responsible for Maintaining Written Records | Research Personnel | Veterinary Staff |
| Room | Bldg. |
|  |  |  |  | ( ) | ( ) |
|  |  |  |  | ( ) | ( ) |
|  |  |  |  | ( ) | ( ) |
|  |  |  |  | ( ) | ( ) |

Use Appendix 9 to document any “departures” from PHS policy, including the standards in the *Guide*, represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any “departures” are involved.

ACORP Appendix 6

**Special Husbandry and Procedures**

**Version 4**

See ACORP App. 6 Instructions, for more detailed explanations of the information requested.

1. **Description of Procedures.** Complete the table below for each procedure listed in Item V of the main body of the ACORP that is not detailed in an SOP or in another item or Appendix of the ACORP. For each special procedure, check **ALL** features that apply.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Special Procedure | | Features | | | | | | | |
| Name | Brief Description | Husbandry\* | Restraint | Noxious Stimuli | Exercise | Behavioral Conditioning | Irradiation | Imaging | Other\*\* |
|  |  | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) |
|  |  | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) |
|  |  | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) |
|  |  | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) |

\*Husbandry refers to all aspects of care related to the maintenance of the animals, including (but not limited to) provision of an appropriate diet, access to water, control of environmental conditions, and the selection of primary and secondary enclosures.

\*\*Describe any “Other” features that are involved.

►

* + 1. Provide a complete description of each special procedure listed above, including all of the following (**copy the lines below for each procedure**):

Name of Procedure (see Item 1) ►

What will be done during the procedure►

Duration of procedure►

How frequently it is to be repeated in each animal►

Potential effects that are expected►

How these effects will be addressed►

* + 1. Explain why each of these special procedures is necessary. (**Copy the lines below for each procedure**.)
  1. Name of Procedure (see Item 1) ►

Why is this procedure necessary►

1. **Personnel.** Complete the table below for each special procedure listed in Item 1, above. Identify the individual(s) who will be responsible for carrying out the procedures, and those who will be responsible for monitoring the condition of the animals during and after the procedures. After hours contact information for the personnel listed must be provided to the veterinary staff for use in case of an emergency.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Procedure Name  (see Item 1) | Responsible Individual(s) | | | | |
| Carrying Out Procedure | After Hours Contact Information |  | Monitoring the Animals | After Hours Contact Information |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. **Potential Pain or Distress.** Complete the table below for each special procedure identified in Item 1, above, indicating for each procedure, whether potential pain and/or distress is expected, and if so, describing the potential pain and/or distress and indicating whether any measures are to be taken to prevent or alleviate it.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Procedure Name  (see Item 1) | Expected Potential Pain and/or Distress | | | |
| No | Yes | | |
| Description | To Be Relieved | Not to Be Relieved |
|  | ( ) |  | ( )a | ( )b |
|  | ( ) |  | ( )a | ( )b |
|  | ( ) |  | ( )a | ( )b |
|  | ( ) |  | ( )a | ( )b |

* 1. For each procedure for which potential pain and/or distress is expected, but WILL be prevented or alleviated by administration of the analgesic(s) or stress-relieving agents, complete the table below:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Procedure Name  (see Item 1) | Agent | Dose (mg/kg) & Volume (ml) | | Route of Administration | Frequency of Administration  (e.g. times/day) | Duration of Administration  (days post-procedure) |
| Dose | Volume (ml) |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

Describe any non-pharmacological measures to be taken to address the potential pain and/or distress (e.g., acupuncture, humane handling, trained staff so procedures will be done proficiently and expeditiously as possible, etc.). (**Copy the lines below for each procedure**.)

Name of Procedure (see Item 1) ►

Describe non-pharmacological measures►

* 1. For each procedure for which potential pain and/or distress is expected and will NOT be prevented or alleviated, provide the scientific justification for this (e.g., studies on pain or inflammatory processes that would be affected by certain analgesics). (**Copy the lines below for each procedure**.)

Name of Procedure (see Item 1) ►

Justification for not preventing potential pain and/or distress►

1. **Monitoring.** Describe how the condition of the animals will be monitored during and after each of the special procedures, and list the criteria that will be used to determine when individual animals will be removed from groups undergoing these procedures, because of pain or distress (see ACORP App. 6 Instructions, for details):

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Procedure Name (see Item 1) | Monitoring Methods  (Variables being monitored and methods used) | Frequency of Monitoring | Intra-Procedure | Post-Procedure | Endpoint Criteria |
|  |  |  | ( ) | ( ) |  |
|  |  |  | ( ) | ( ) |  |
|  |  |  | ( ) | ( ) |  |
|  |  |  | ( ) | ( ) |  |

* 1. Describe how written records are maintained for each animal monitored.

►

Use Appendix 9 to document any “departures” from PHS policy, including the standards in the *Guide*, represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any “departures” are involved.

**ACORP Appendix 7**

**Use of Patient Care Equipment and/or Areas**

**for Animal Studies**

**Version 4**

See ACORP App. 7 Instructions, for more detailed explanations of the information requested.

1. **Full Name(s) of Principal Investigator(s)** ►
2. **Equipment to be Used.**
   1. Identify the equipment ►
   2. Procedure(s) to be performed with this equipment ►
   3. Describe how contamination of the human patient care equipment will be prevented and how the equipment will be cleaned/sanitized before its subsequent use for human patients.

►

1. **Human Patient Care Procedural Areas to be Used.**
   1. Location(s) Specify the building(s) and room number(s). ►
   2. Animal species to be studied or treated ►
   3. Number of individual animals to be studied or treated ►
   4. Date(s) Enter specific dates, or indicate the days of the week and the period of weeks over which animals will be studied or treated in the human patient care area(s). ►
   5. Time(s) of day Specify the time(s) of day at which the animals will be studied or treated in the human patient care area(s), and address how these relate to the times of day at which human patients receive care in these areas. ►
   6. Procedure(s) to be performed on the animals in these areas ►
   7. Protection and cleaning of patient care room surfaces The procedures used for cleaning these areas should be at least as thorough as the procedures established by the clinical facility for cleaning and sanitizing the room between human patients.►
   8. Benefits to VA patients**.** Briefly describe how this use of the human patient care areas for research on animal subjects potentially benefits VA patients.

►

* 1. Necessity for use of human patient care areas.Explain why this work on animal subjects cannot be performed within the animal facility or a research laboratory area.

►

* 1. Animal transport.Describe how the animals will be transported back and forth between the animal housing area and the human patient care areas. Transportation of animals through human clinical care areas must be discrete and secure. Corridors and elevators used by human patients must be avoided. Include descriptions of the transport enclosures (cages, carriers, etc.) and how they will be secured to prevent escape, any vehicles to be used, the planned route(s) for the transport, and any other precautions to be taken to minimize the likelihood that patients, visitors, or other non-research personnel will become aware of the animals.

►

* 1. Preventing human patients and patient care personnel from being affected by the presence of the animals. Provide detailed descriptions of the measures to be taken to address noises and odors, allergens, and zoonotic pathogens associated with the animals.

►

Use Appendix 9 to document any “departures” from PHS policy, including the standards in the *Guide*, represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any “departures” are involved.

**ACORP Appendix 8**

**Use of Explosive Agent(s) within the VMU or in Animals**

**Version 4**

See ACORP App. 8 Instructions, for more detailed explanations of the information requested.

1. **Full name(s) of Principal Investigator(s)** ►
2. **Explosive agents to be used.**
   1. Identify the explosive agents. Complete the table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name(s) Used to Refer to the Agent in This ACORP | Name Shown for this Agent on the MSDS on File | CAS number | Location of the MSDS on File | |
| Bldg | Room |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

* 1. Locations where the explosive agents will be used. Complete the table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Agent Name | Location Where Agent Will Be Used | | | |
| Building | Room Number | Within the VMU | Outside of VMU |
|  |  |  | ( ) | ( ) |
|  |  |  | ( ) | ( ) |
|  |  |  | ( ) | ( ) |
|  |  |  | ( ) | ( ) |

* 1. Procedure(s) to be performed. Briefly describe the use of each of the explosive agents on this protocol and explain why it is necessary to use these agents (why non-explosive replacements cannot be used instead).

►

* 1. Precautions to be taken to prevent explosions. Describe the measures to be taken to store, use, and dispose of safely each explosive agent and any materials contaminated with it, and to prevent the generation of sparks in its presence. Commonly used precautions include, but are not limited to:

(1) Use of the agents only within a properly operating, ventilated safety hood.

(2) Locating and powering outside the hood any electrical equipment to be used with such agents.

(3) Storage only in an explosion-proof refrigerator or freezer.

(4) Provisions to ensure that all potentially explosive fumes have dissipated from animal carcasses

and other objects before they are placed into storage.

(5) No disposal of empty containers or other items containing traces of any explosive agent by

incineration or in receptacles for waste that is ordinarily incinerated.

►

* 1. Period of use.

Beginning no earlier than (date) ►

Ending no later than (date) ►

* 1. Animals that will be administered explosive agents:

Note that any explosive agents to be administered to animals on this protocol must also be documented in Appendix 3.

Species ►

Approximate weights of individual animals ►

Approximate number of animals ►

1. **Personnel.** Complete the table below for each individual who will handle any of the explosive agents as part of this protocol.

|  |  |  |
| --- | --- | --- |
| Name of Individual | Explosive Agent(s) to be Handled | Training and Experience Pertinent to Handling Explosive Agents |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

Use Appendix 9 to document any “departures” from PHS policy, including the standards in the *Guide*, represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any “departures” are involved.

**ACORP Appendix 9**

**Departures from “Must” and “Should” Standards in the *Guide (2011)***

**Version 4**

See ACORP App. 9 Instructions, for more detailed explanations of the information requested.



For each IACUC-approved “departure” of this protocol from a “Must” or “Should” standard in the *Guide*, provide the following information. (Consult the IACUC or the Attending Veterinarian for help in determining whether any “departures” are involved.):

Copy the lines below for each departure.

Briefly summarize the “Must” or “Should” standard, and provide the number(s) of the page(s) on which it appears in the *Guide:*

►

Describe the specific alternate standard(s) that will be met on this protocol, and how they will be monitored.

►

Provide the scientific, veterinary medical, or animal welfare considerations that justify this departure.

►

**VA LABORATORY SAFETY HAZARD ASSESSMENT FORM**

**Research Safety Subcommittee**

**VA Ann Arbor Healthcare System (506)**

##### **2215 Fuller Rd., Ann Arbor, MI 48105**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Principal Investigator:** | | **Email Address:** | | |
| **Lab Personnel List:** | | **Email Address:** | | |
| **Project Title:** | | | **Submission Date:** | |
| **Building:** | **Room #:** | | **Mail Code:**  151 | **Lab Phone:** |

Will the project use any of the following? (Please check all that apply.)

**[ ] A**. **Human tissue, including blood, other body fluids and cell lines**

**[ ] B**. **Ionizing Radiation (radioactive materials or radiation producing equipment)**If this item is checked, applicant must have one of the following approvals:

(1) For work performed at the VA, the applicant must have an approved Ann Arbor VA Application to Use Radioisotopes in Research form which is available in the Radiation Safety Office, or

(2) For work using radiation producing devices performed at the VA, the applicant must be approved by the Radiation Safety Committee, or

(3) For work performed in University space, appropriate, current University approval(s) must be attached to this form.

**[ ] C**. **Biological Agents** (including microbiological, viral or plant agents, pathogens, toxins, poisons, allergens, or venoms)

**[ ] D**. **Chemicals (If you are using any chemicals in these studies, this must be checked)**

**[ ] E**. **Recombinant DNA** (appropriate UM approval(s) must be attached to this form.)

**[ ] F Non-Human Cell lines and Tissue Culture** (This must be checked if the research involves work with blood, body fluids, organs, tissues, cell lines or cell clones from non-human primates or animal sources)

**[ ] G. Physical agents (UV light, lasers, radio-frequency or microwaves, electricity, trauma)**

**[ ] H. Animals - If this item is checked, you must submit an approved or new Animal Component of Research Protocol (ACORP) form.**

**[ ] I. Controlled Substances (**If your research involve the use of any substance regulated by the Drug Enforcement Agency)

**[X] J**. **Staff Training** (This section must be completed)

**A.** **Human tissue, including blood, other body fluids and cell lines**(Applicants must submit a VA Human Studies Application for any use of research subject samples.)

1. Will human tissue, blood or body fluids be collected? **[ ]** Yes **[ ]** No   
If Yes, then answer these questions:

a) Describe the samples to be collected \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

b) Where will the samples be collected: Building # Room # \_\_\_\_\_

c) Who will be collecting? **[ ]** Clinical Staff **[ ]** VA Research Staff

**[ ]** Other (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

d) Where will the samples be analyzed? Building # Room # \_\_\_\_\_\_\_\_\_\_

e) Will the samples be transported/shipped offsite? **[ ]** Yes **[ ]** No

f) How will the samples be transported/shipped? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

g) Have personnel completed Department of Transportation – Shipping of Hazardous Materials training? **[ ]** Yes **[ ]** No If No, contact Joe Jurasek, Industrial Hygienist (x55417)

If yes, please list names: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

h) Who will be analyzing? **[ ]** VA Clinical Staff **[ ]** VA Research Staff

**[ ]** Other (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

i) How are the samples inactivated and disposed? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. Will personnel work with human cell lines? **[ ]** Yes **[ ]** No

If Yes, please complete table below:

|  |  |  |  |
| --- | --- | --- | --- |
| **Cell line** | **Biosafety Level** | **How Inactivated** | **How Disposed** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

If any cell lines are **BSL2**, you must answer questions 3-11 under Section C, Biological Agents.

3. Are all laboratory personnel familiar with OSHA's "Bloodborne Pathogen Regulations" and have all personnel completed Bloodborne Pathogen Training? **[ ]** Yes **[ ]** No

*(All VA employees must attend the VA-based Bloodborne Pathogen Training when working with human specimens)*

**-----------------------------------------------------------------------------------------------------------------------------------------------**

**B. Ionizing Radiation**

**1) Radioactive Materials:**

Where will this work be performed? Building # \_\_\_\_\_ Room # \_\_\_\_\_

a) List all Isotopes to be used:

|  |  |
| --- | --- |
| Isotope Name | Maximum Amount in Laboratory at any Time |
|  |  |
|  |  |
|  |  |

b)If iodine is used, will compounds be radio-iodinating?

**[ ]** Yes **[ ]** No If yes, what location? :Building # \_\_\_\_\_ Room # \_\_\_\_\_

c)Will radioisotopes be used in humans? **[ ]** Yes **[ ]** No

RADIATION SAFETY LICENSE VERIFICATION (check all that apply)

**[ ]** VA NRC License # 03-23853-01 VA (VHA Permit # 21-00159-04)  
*For work performed at the VA, the applicant must have an approved Ann Arbor VA Application   
to Use Radioisotopes in Research (the form is available in the VA Radiation Safety Office)*

**[ ]** UM License # 21-00215-04   
*For work performed in University space, you must attach the appropriate, current University approval(s)*

**[ ]** Not currently licensed. Name of licensed user who will supervise your work involving the use of radioisotopes: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**[ ]** Not currently licensed. Do you have an application in progress? **[ ]** Yes **[ ]** No

**2) Radiation Producing Devices: [ ]** Yes **[ ]** No

If Yes, then:

a) What equipment will be used?

b) Where is the location of the equipment?

c) Who will be using the equipment ?

d) Will this equipment be used on: **[ ]** Humans, **[ ]** Animals,

**[ ]** other (please describe) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*For work using radiation producing devices performed at the VA, the applicant must be approved by the VA Radiation Safety Committee*

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**C. Biological Agents** (including Microbiological, Viral or Plant agents, Pathogens, Toxins, Poisons, Allergens, or Venoms)

1. Where will this work be performed? Building # \_\_\_\_\_ Room # \_\_\_\_\_

It is the responsibility of each PI to:

a) Consult the NIH-CDC publication entitled "Biosafety in Microbiological and Biomedical Laboratories" <http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm> **and**

b) Identify the Biosafety Level for each organism, agent or toxin below

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Organism/Agent/Toxin** | **Biosafety Level** | **How Inactivated/**  **Disposed?** | **Infectious To Humans?**  **(Yes/No)** | **\* Select Agent?**  **(Yes/No)** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

\* The CDC select agent list [DHHS 42 CFR 72, Appendix A] is included at [the](http://www.cdc.gov/od/ohs/lrsat/42cfr72.htm) end of this application)

2. If you are requesting to use a Select Agent, give the required registration number for the transfer of the agent. #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**For each Organism/Agent/Toxin greater than Biosafety Level 1, you must answer questions 3-11.   
For more than one agent, you must submit a separate set of answers.**

**C. Biological Agents: Select Agents or Biosafety Level 2 Agents**

**PLEASE LIST EACH AGENT ON A SEPARATE FORM**

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Additional Questions for Select Agents or Biosafety Level 2 Agents

3. Name of organism/agent/toxin \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4. Is antibiotic resistance expressed? **[ ]** Yes **[ ]** No

5. Largest volume of organism used is: \_\_\_\_\_ Liter(s) Concentration: \_\_\_\_\_

6. Is organism inactivated prior to other lab manipulations? **[ ]** Yes **[ ]** No

7. Does this agent harbor any recombinant genes? **[ ]** Yes **[ ]** No

If Yes, please describe \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If Yes, have you submitted this protocol to the UM IBC **[ ]** Yes **[ ]** No

Applications can be submitted on-line at:

<http://www.research.umich.edu/policies/um/committees/BRRC/BRRC.html>

8. Specify methods of agent concentration (if applicable)

**[ ]** Centrifugation: **[ ]** Precipitation:

**[ ]** Filtration: **[ ]** Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

9. Specify methods of agent inactivation:

**[ ]** Heat **[ ]** Chemical **[ ]** Radiation

**[ ]** Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

10. How is inactivated material disposed? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

11. What containment equipment is available? (Check all that apply.)

**[ ]** Biological Safety Cabinet: **[ ]** Class I **[ ]** Class II **[ ]** Class III  
 Date of Last Certification: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**[ ]** Chemical Fume Hood

**[ ]** Containment Centrifuge **[ ]** Centrifuge

**[ ]** Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

12. What methods will be employed to monitor the health and safety of personnel involved in this research?

13 If there is evidence of exposure, what course of action will be taken?

------------------------------------------------------------------------------------------------------------------------------------------------------------

**-----------------------------------------------------------------------------------------------------------------------------------------------**

**D. Chemicals** (Please answer all questions below with information **pertaining to this study only**.  
 and **ATTACH THE CHEMICAL INVENTORY FOR YOUR LABORATORY**)

**1**. Toxic chemicals (including heavy metals) No **[ ]**  Yes **[ ]**

Name of item(s): \_\_\_\_\_ Bldg # \_\_\_\_\_ Rm # \_\_\_\_\_

**2**. Flammable/explosive/corrosive chemicals No **[ ]**  Yes **[ ]**

Name of item(s): \_\_\_\_\_ Bldg # \_\_\_\_\_ Rm # \_\_\_\_\_

**3**. Carcinogenic/mutgenic/teratogenic chemicals No **[ ]**  Yes **[ ]**

Name of item(s): \_\_\_\_\_ Bldg # \_\_\_\_\_ Rm # \_\_\_\_\_

**4**. Toxic compressed gases No **[ ]**  Yes **[ ]**

Name of item(s): \_\_\_\_\_ Bldg # \_\_\_\_\_ Rm # \_\_\_\_\_

**5**. Acetylcholinesterase inhibitors/neurotoxins No **[ ]**  Yes **[ ]**

Name of item(s): \_\_\_\_\_ Bldg # \_\_\_\_\_ Rm # \_\_\_\_\_

**Chemical Inventory:**

If you are using chemicals, you must attach a complete Chemical Inventory list for your laboratory. Please include these headings:

Chemical Name, Bldg, Floor, Room, Room Function, End Point (use, disposal), Qty on Hand, Units, Yearly Use Est., Units, MSDS (Yes/No), Manufacturer.

**-----------------------------------------------------------------------------------------------------------------------------------------------**

**E. Recombinant DNA**

You must submit an approval letter from the University of Michigan Institutional Biosafety Committee (IBC). Applications can be submitted on-line at:

<http://www.research.umich.edu/policies/um/committees/BRRC/BRRC.html>

1. Where will this work be performed? Building # \_\_\_\_\_ Room # \_\_\_\_\_

2. DNA source(s): \_\_\_\_\_

3. Nature of insert/protein expressed: \_\_\_\_\_

4. Vector(s): \_\_\_\_\_

5. Host: \_\_\_\_\_

6. Cell/animal/plant recipient(s): \_\_\_\_\_

7. Assessment of levels of physical and biological containment \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
(check relevant sections of NIH Guidelines, April 1998  
<http://www.niehs.nih.gov/odhsb/biosafe/nih/rdna-apr98.pdf>

**-----------------------------------------------------------------------------------------------------------------------------------------------**

**F. Non-Human Cell Lines and Tissue Culture** (including work with blood, body fluids, organs, tissues,   
cell lines or cell clones from non-human primate or animal sources)

1. Where will this work be performed? Building # \_\_\_\_\_ Room # \_\_\_\_\_

It is the responsibility of each PI to:

a) Consult either the NIH-CDC publication entitled "Biosafety in Microbiological and Biomedical Laboratories": <http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm> **or** search the catalog at  
the American Type Culture Collection web-site: <http://www.atcc.org/>

b) Identify the Biosafety Level for each specimen.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Specimen** | **Species** | **Biosafety Level** | **How Inactivated** | **How Disposed** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

2. If your research involves the use of non-human primate blood, body fluids, organs or tissues, are all laboratory personnel familiar with OHSA's "Bloodborne Pathogen Regulations" and have all personnel completed Bloodborne Pathogen Training?

**[ ]** Yes **[ ]** No **[ ]** NA

**For all specimens greater than Biosafety Level 1**, please answer questions 3-10

3. Name of specimen(s) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4. Largest volume of specimen used is: \_\_\_\_\_\_\_Liter(s)

Concentration: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

5. Specify methods of specimen concentration (if applicable)

**[ ]** Centrifugation: **[ ]** Precipitation:

**[ ]** Filtration: **[ ]** Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

6. Specify methods of specimen inactivation:

**[ ]** Heat **[ ]** Chemical **[ ]** Radiation

**[ ]** Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

7. How is inactivated material disposed?

8. What containment equipment is available? (Check all that apply.)

**[ ]** Biological Safety Cabinet: **[ ]** Class I **[ ]** Class II **[ ]** Class III  
 Date of Last Certification: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**[ ]** Chemical Fume Hood **[ ]** Containment Centrifuge

**[ ]** Centrifuge **[ ]** Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

9) What methods will be employed to monitor the health and safety of personnel involved in this research?

10) If there is evidence of exposure, what course of action will be taken?

**-----------------------------------------------------------------------------------------------------------------------------------------------**

**G.** **Physical agents** (UV light, lasers, radio-frequency or microwaves, electricity, trauma)(attach brochure if appropriate)

Describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**-----------------------------------------------------------------------------------------------------------------------------------------------**

**H.** **Animals** - If this item is checked, you must have a new or approved Animal Component of Research Protocol (ACORP) form. Please attach your ACORP application form:

Species: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1) Will animals be exposed to Hazardous Agents (radiation, biological, chemical, recombinant DNA, etc) and returned to VMU housing?

[ ] Yes [ ] No,  **If Yes, please answer the following:**

a) Identify the agent:

->

b) How will the animal be exposed?  
->

c) Is special housing required once the animal is exposed?  
->

d) How is the agent excreted from the animal?  
->

e) Will the animal be infective to other animals or humans?  
->

f) If the animal is infective, how many days before it will be non-infective? \_\_\_\_\_\_\_\_\_\_\_\_

**-----------------------------------------------------------------------------------------------------------------------------------------------**

**I. Controlled Substances\***

1. List the controlled substance(s) that will be used in your research   
(Refer to the Schedule of Controlled Substances web site.)

<http://www.deadiversion.usdoj.gov/schedules/schedules.htm>

|  |  |
| --- | --- |
| **Controlled Drug Name** | **Are Scheduled drugs stored in a double-locked vault? (Yes/No)** |
|  |  |
|  |  |
|  |  |
|  |  |

\*\*You will be added to the monthly narcotics inspection list.

2. All rules and regulations governing the use of controlled substances in Research Areas found in **VHA HANDBOOK 1108.1 - CONTROLLED SUBSTANCES (PHARMACY STOCK)** must be followed. They are listed below:

**CONTROLLED SUBSTANCES IN RESEARCH AREAS**

a. **Procurement.** All controlled substances for use in research (animal or human) must be ordered on VA Form 2237 through Pharmacy. All controlled substances must be ordered separately from non-controlled substances. The drugs are to be charged to the appropriate research cost control point.

b. **Issue**

(1) On receipt, Pharmacy Service must issue the drug to the appropriate research area. The drugs are to be charged to the appropriate research cost control point. (2) Issuance of controlled substances to research areas must be in accordance with the general provisions for dispensing controlled substances outlined in paragraph 8. Persons authorized to receive controlled substances must be designated by the medical center Director, on the advice of the Associate Chief of Staff for Research, or the Chief of Staff.

c. **Control**

(1) One VA Form 10-2638 must accompany each container of drugs issued. **NOTE:** Research staff must always use a printed copy of VA Form 10-2638.

(2) Authorized employee(s) in the research area(s) must maintain appropriate records in accordance with the provisions of this Handbook.

(3) VA Form 10-2638 must indicate the experiment number, date, and any other identifying information available to provide satisfactory proof-of-use record for each dose of drug administered. **NOTE:** VA Form 10-2638, when completed, must be returned to the pharmacy.

d. **Inspection.** The authorized research staff must make VA Form 10-2638 and the corresponding drug available for monthly inspection.

e. **Storage**

(1) All controlled substances must be secured according to VA Handbook 0730.

(2) Access must be limited to employees specifically authorized in writing to have access to the controlled substances

**J. Staff Training:** With regard to any of the potential hazard categories identified on page 1, describe the training that will be provided for each safety hazard to laboratory staff in:

Building # \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Room # \_\_\_\_\_\_\_\_\_

**(1) Coordination with facility safety officials:**

**(2) The practices and techniques required to ensure safety:**

**(3) The procedures for dealing with accidents:**

***-----------------DELETE THIS HINT SECTION IN FINAL APPLICATION------------------------------------------***

**Helpful Hints for Answering Section J, Staff Training**

These are some suggestions for addressing the Laboratory Staff Training portion of the Subcommittee on Research Safety Form. These are only guidelines. You must appropriately address safety as related to procedures conducted in conjunction with your research program.

**(1) Coordination with facility safety officials:**

You must address training (new employee, annual safety training update, new employee and annual radiation safety training, infection control training, veterinary medical unit training, lab specific training). If your lab is located at the University, address coordination and safety training which takes place at the University.

**(2) The practices and techniques required to ensure safety:**

Make sure to address each of the components you checked off on page 1, for example, human tissue/sample, animals, radioisotopes, microbial agents, chemicals, recombinant DNA, etc.

Sample:

General lab safety procedures are practiced at all times.

Hazardous chemicals are used in a properly vented hood, safety glasses & gloves are worn when necessary.

MSDS sheets are available for all chemicals.

Radiation monitoring is carried out as directed by Radiation Safety Officer. (if appropriate)

Cell culture work is carried out in certified laminar flow hoods.

Standard precautions are followed.

Be aware of the policies and procedures outlined in the Safety Policies Handbook Binder which must be in each VA lab.

**(3) The procedures for dealing with accidents:**

Describe how you will follow the procedures for dealing with accidents and you will follow instructions as outlined in the Safety Policy Handbook: You must cite the appropriate policies listed here.

MSDS sheets for hazardous chemicals

Radiation Safety Program Handbook (if appropriate)

S-1, Radiation Safety Committee and the ALARA Program (if appropriate)

S-2, Hazardous Materials Management S-3, Safety Management Program

S-4, Exposure Control Plan S-5, Emergency Preparedness Program

S-22, Safe Use of Fluoroscopy (if appropriate)

Blood Spill Clean-Up In The Research Facility (8-17-06)

119-6, Hazardous Drug Safety & Health Plan: Preparation, Administration and Disposal of Cytotoxic Agents (If using chemotherapeutic agents only)

VHA Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories (10-21-05) (If using select agents only)

(Please cite other appropriate policies and procedures)

***-----------------DELETE THIS HINT SECTION IN FINAL APPLICATION------------------------------------------***

**PRINCIPAL INVESTIGATOR ACKNOWLEDGEMENT OF RESPONSIBILITY**

I certify that my research studies will be conducted in compliance with and full knowledge of Federal, State, and local policies, regulations, and CDC-NIH Guidelines governing the use of, biohazardous materials, chemicals, radioisotopes, and physical hazards. I further certify that all technical and incidental workers involved with my research studies will be aware of potential hazards, the degree of personal risk (if any), and will receive instructions and training on the proper handling and use of biohazardous materials, chemicals, radioisotopes, and physical hazards. A chemical inventory of all Occupational Safety and Health Administration (OHSA) and Environmental Protection Agency (EPA)-related hazardous chemicals is attached to this survey.

Principal Investigator\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**CERTIFICATION OF SAFETY OFFICER’S APPROVAL**

A complete list of chemicals to be used in the proposal has been reviewed. Appropriate occupational safety and health, environmental, and emergency response programs will be implemented on the basis of the list provided.

**CERTIFICATION OF PROPOSAL APPROVAL**

The safety information for this application has been reviewed and is in compliance with Federal, State, and local policies, regulations, and CDC/NIH Guidelines governing the use of biohazardous materials, chemicals, radioisotopes, and physical hazards. Copies of any additional surveys used locally are available from the Research Office.

Chair,

R&D Committee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Chair, Subcommittee

on Research Safety: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Radiation

Safety Officer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(If applicable)

Facility Safety Officer/

Industrial Hygienist: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical Center Director\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(If using Controlled Substances)**October 21, 2005 VHA HANDBOOK 1200.06**

**APPENDIX A**

**HAZARDOUS BIOLOGICAL AND CHEMICAL AGENTS**

1.The Centers for Disease Control and Prevention (CDC)has identified certain biological, chemical and radioactive materials or agents as having potential for use as weapons by terrorists. Improper use and/or containment of these materials or agents pose a risk to national security because of their:

a. Ease of dissemination or transmittal between individuals;

b. Potential for high mortality rates and major public health impact;

c. Potential for causing public panic and social disruption; and

d. Risk for public health preparedness.

**2. Storage and/or use of these materials or agents in any quantity in a Department of Veterans Affairs (VA) research laboratory requires special consideration for physical security, personnel access, inventory control, and emergency preparedness. These include:**

a. Select Agents and Toxins. A current list of select agents and toxins may be found at [http://www.CDC.gov/od/sap.](http://www.CDC.gov/od/sap) This site also includes agents and toxins that are included on the United States Department of Agriculture (USDA) list of biological agents and toxins that overlap with the CDC list. This website contains:

(1) A list of toxin amounts (exempt quantities) permissible for an investigator to store or use without requiring compliance with Title 42 Code of Federal Regulations (CFR) 73; and

(2) A list of agents and toxins that have been excluded from the list of select biological agents and toxins.

b. List of USDA Biologic Agents and Toxins. A list of USDA biologic agents and toxins may be found at: <http://www.aphis.usda.gov/>.

c. Chemical Agents Considered to be Hazardous Agents. The following chemicals are considered hazardous agents. *NOTE: This list may be updated in the future and updates will be found on the Office of Research and Developments website:* [*http://vaww1.va.gov/resdev/*](http://vaww1.va.gov/resdev/)*.*

**HHS AND USDA SELECT AGENTS AND TOXINS  
7 CFR Part 331, 9 CFR Part 121 and 42 CFR Part 73**

**HHS SELECT AGENTS AND TOXINS**

Abrin

Cercopithecine herpesvirus 1 (Herpes B virus)

*Cocciciioides posadasif*

Conotoxins

Crimean-Congo haemorrhagic fever virus

Diacetoxyscirpenol

Ebola virus

Lassa fever virus

Marburg virus

Monkeypox virus

Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments

Ricin

*Rickettsia* prowazekll

*Rickettsia* rickettsii

Saxitoxin

Shiga-like ribosome inactivating proteins

South American Haemorrhagic Fever viruses

Flexal Guanarito

Junin Machupo

Sabia

Tetrodotoxin

Tick-borne encephalitis complex (flavi) viruses

Central European Tick-borne encephalitis

Far Eastern Tick-borne encephalitis

Kyasanur Forest disease

Omsk Hemorrhagic Fever

Russian Spring and Summer encephalitis

Variola major virus (Smallpox virus)

Variola minor virus (Alastrim)

Yersinia pestis

**OVERLAP SELECT AGENTS AND TOXINS**

*Bacillus anthracis*

Botulinum neurotoxins

Botulinum neurotoxin producing species of *Ciostrid/um*

*Brucella abortus*

*Brucella melitensis*

*Brucella suis*

*Burkholderia* mai!ei (formerly *Pseudomonas mallei)*

*Burkholderia pseudornallei* (formerly Pseudomonas *pseudoma f/el)*

*Clostridium perfringens* epsilon toxin

Coccidio/des *immitis*

Coxieifa *burnetii*

Eastern Equine Encephalitis virus

*Francisella tularensis*

Hendra virus

Nipah virus

Rift Valley fever virus

Shigatoxin

Staphylococcal enterotoxins

T-2 toxin

Venezuelan Equine Encephalitis virus

**USDA SELECT AGENTS AND TOXINS**

African horse sickness virus

African swine fever virus

Akabane virus

Avian influenza virus (highly pathogenic)

Bluetongue virus (Exotic)

Bovine spongiform encephalopathy agent

Camel pox virus

Classical swine fever virus

*Cowdria ruminantium* (Heartwater)

Foot-and-mouth disease virus

Goat pox virus

Japanese encephalitis virus

Lumpy skin disease virus

Malignant catarrhal fever virus

(Alcelaphine herpesvirus type 1)

Menangle virus

*Mycopiasma capricolumi MF381M. mycoides Capri* (contagious caprine pleuropneumonia)

Mycoplasrna mycoides rnycoides

(contagious bovine pleuropneumonia)

Newcastle disease virus (velogenic)

Peste des petits ruminants virus

Rinderpest virus

Sheep pox virus

Swine vesicular disease virus

Vesicular slornatitis virus (Exotic)

**USDA PLANT PROTECTION AND QUARANTINE (PPQ)**

**SELECT AGENTS AND TOXINS**

*Candidatus Liberobacter africanus*

*Cand/datus Liberobacter asiaticus*

*Peronosclerospora philippinensis*

*Ralstonia solanacearum race 3, biovar 2*

*Schlerophthora rayssiae var zeae*

*Synchytrium endobioticum*

*Xanthornonas oryzae.pv. oryzicola*

*Xylella fastidiosa* (citrus variegated chlorosis strain)

**Chemical Agents Considered to be**

**Hazardous Agents by VA ORD *10/21/05***

(1) 3-quinuclidinyl benzilate (BZ);

(2) Chlorine gas;

(3) Cyanogen chloride (OK);

(4) Cyclosarin (GF);

(5) Diphosgene (OP);

*(6)* Hydrogen cyanide (AC);

*(7)* Lewisite (L); *L-1, L-2, and L-3*

(8) Lysergic acid diethylamide (LSD);

(9) Nitrogen mustard (HN-1, HN-2, or HN-3);

(10) Phosgene (CG), also known as carbonyl chloride;

(11) Phosgene oxime (CX);

(12) Sarin (GB);

(13) Soman (GD);

(14) Sulfur mustard (H, HD, or hIT), also called mustard gas or mustard agents;

(15) Tabun (GA); and VX (name and symbol).

Table 1. Summary of Recommended Biosafety Levels for Infectious Agents

Click this link for the full CDC Guidebook: <http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm>

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **BSL** | **Agents** | **Practices** | **Safety Equipment**  **(Primary Barriers)** | **Facilities**  **(Secondary Barriers)** |
| **1** | Not known to consistently cause disease in healthy adults | Standard Microbiological Practices | None required | Open bench top sink requireda |
| **2** | Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure | BSL-1 practice plus:  Limited access  Biohazard warning signs  "Sharps" precautions  Biosafety manual defining any needed waste decontamination or medical surveillance policies | Primary barriers = Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPEs: laboratory coats; gloves; face protection as needed | BSL-1 plus:  Autoclave available |
| **3** | Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences | BSL-2 practice plus:  Controlled access  Decontamination of all waste  Decontamination of lab clothing before laundering  Baseline serum | Primary barriers = Class I or II BCSs or other physical containment devices used for all open manipulations of agents; PPEs: protective lab clothing; gloves; respiratory protection as needed | BSL-2 plus:  Physical separation from access corridors  Self-closing, double-door access  Exhausted air not recirculated  Negative airflow into laboratory |
| **4** | Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission | BSL-3 practices plus:  Clothing change before entering  Shower on exit  All material decontaminated on exit from facility | Primary barriers = All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure personnel suit | BSL-3 plus:   1. Separate building or isolated zone   Dedicated supply and exhaust, vacuum, and decon systems  Other requirements outlined in the text |