|  |
| --- |
| Section D 15  VA Supplemental Documentation – ACORP questions and certifications |

**This section is to be submitted with the SOM IACUC protocol when research is supported by VA funding.**

The use of animals in VA research is a privilege granted to those investigators and programs that commit to meeting the highest ethical and regulatory standards. VA animal care and use programs must follow VA policy on the use of animals found in Handbook 1200.07, "Use of Animals in Research", which incorporates compliance with USDA Animal Welfare Act Regulations and PHS Policy.

|  |  |  |  |
| --- | --- | --- | --- |
| VA Station Name (City) |  | 3-Digit Station Number |  |

|  |  |  |
| --- | --- | --- |
| **Related Documentation for IACUC reference** | | |
| Title of project submitted to the R&D committee |  | |
| If approved by the R&D committee, give the date of approval | |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Triennial Review**  If this protocol is being submitted for triennial *de novo* review, complete the following: | | | | |
| Identify the studies described in the previously approved protocol that have already been completed | | | | |
|  | | | | |
| Indicate the numbers of animals of each breed/strain/genotype that have already been used, and adjust the numbers shown in Item I accordingly | | | | |
|  | | | | |
| 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 | | | | |
|  | | | | |
| List any other relevant previously approved animal use protocols (copy the lines below as needed for each protocol listed | | | | |
| Title of other protocol |  | | IACUC number of the 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 protocol. | |  | | |

|  |  |
| --- | --- |
| **Veterinary Support** | |
| Veterinary consultation is required during planning of a protocol supported by VA funding. Identify the laboratory animal veterinarian who is responsible for ensuring that the animals on this protocol receive appropriate veterinary medical care. | |
| Institution |  |
| Name |  |
| e-mail contact |  |

|  |  |  |
| --- | --- | --- |
| **Veterinary consultation during the planning of this protocol** | | |
| 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). | |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Management of Pain Level D procedures** | | | | |
|  | This protocol does NOT include any Category D procedures. | | | |
|  | This protocol INCLUDES Category D procedures. List each Category D procedure and provide the information requested. | | | |
| Procedure | | Monitoring  (indicate the method(s) to be used, and the frequency and duration of monitoring through post-procedure recovery) | Person(s) responsible for the monitoring | Method(s) by which pain or distress will be alleviated during or after the procedure (include the dose, route, and duration of effect of any agents to be administered) |
|  | |  |  |  |
|  | |  |  |  |
|  | |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Use of Patient Care Equipment and/or Areas for Animal Studies** | | | | | |
|  | Not Applicable | | | | |
|  | This protocol **includes** the use of Patient Care Equipment and/or Areas for Animal Studies. If selected, please answer the following: | | | | |
| Equipment | | | | | |
| Identify the equipment | | | | | |
|  | | | | | |
| Procedure(s) to be performed with this equipment | | | | | |
|  | | | | | |
| 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. | | | | | |
|  | | | | | |
| Human Patient Care Procedural Areas to be Used | | | | | |
| Location | | Animal Species to be studied or treated | Number of Individual animals to be studied or treated | Dates | Time(s) of Day |
|  | |  |  |  |  |
| Procedure(s) to be performed on the animals in these areas | | | | | |
|  | | | | | |
| Protection and cleaning of patient care room surfaces | | | | | |
|  | | | | | |
| Benefits to VA patients**.** Briefly describe how this use of the human patient care areas for research on animal subjects potentially benefits VA patients. | | | | | |
|  | | | | | |
| 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. | | | | | |
|  | | | | | |
| Animal transport.Describe how the animals will be transported back and forth between the animal housing area and the human patient care areas. | | | | | |
|  | | | | | |
| 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. | | | | | |
|  | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Explosive Agents** | | | | | | | | | | | |
|  | Not Applicable | | | | | | | | | | |
|  | This protocol **includes** the use of Explosive Agents. If selected, please answer the following: | | | | | | | | | | |
| Name(s) Used to Refer to the Agent | | | | Name Shown for this Agent on the MSDS on File | | CAS number | | | | Location of the MSDS on File | |
|  | | | |  | |  | | | |  | |
|  | | | |  | |  | | | |  | |
|  | | | |  | |  | | | |  | |
|  | | | |  | |  | | | |  | |
| Location where Agents will be Used | | | | | | | | | | | |
| Building | | | | Room Number | | | | Within the VMU | | | Outside the VMU |
|  | | | |  | | | |  | | |  |
|  | | | |  | | | |  | | |  |
|  | | | |  | | | |  | | |  |
|  | | | |  | | | |  | | |  |
| 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). | | | | | | | | | | | |
|  | | | | | | | | | | | |
| 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.  These precautions generally include, but need not be limited to, the following:   * Use of the agents only within a properly operating, ventilated safety hood. * Locating and powering outside the hood any electrical equipment to be used with such agents. * Storage only in an explosion-proof refrigerator or freezer. * Provisions to ensure that all potentially explosive fumes have dissipated from animal carcasses and other objects before they are placed into storage. * 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. | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Period of Use | | | | | | | | | | | |
| Beginning no earlier than (date) | |  | | | Ending no later than (date) | | | |  | | |
| Animals | | | | | | | | | | | |
| Species | | | Approximate weights of individual animals | | | | | Approximate number of animals | | | |
|  | | |  | | | | |  | | | |
| Personnel  Complete the table below for each individual who will handle any of the explosive agents as part of this protocol. | | | | | | | | | | | |
| Name of Individual(s) | | | | Explosive Agent(s) to be Handled | | | Training and Experience Pertinent to Handling Explosive Agent | | | | |
|  | | | |  | | |  | | | | |
|  | | | |  | | |  | | | | |
|  | | | |  | | |  | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Departures from “Must” and “Should” standards in *the Guide* (8th addition)**  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.): | | | |
|  | Not Applicable | | |
|  | This protocol **includes** the departures from *the Guide* | | |
| 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. |
|  | |  |  |
|  | |  |  |
|  | |  |  |
|  | |  |  |

|  |
| --- |
| **Certifications**  Signatures are required here for any protocol 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 each procedure that apply to this protocol. Do NOT include signatures for procedures that do NOT apply. |

|  |  |  |
| --- | --- | --- |
| **Certification by Principal Investigator(s):**  I certify that, to the best of my knowledge, the information provided in this protocol 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, and that I may be required to complete a newer version of the protocol that requests additional information 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 protocol; * 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 |
|  |  |  |
|  |  |  |
|  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Certification by IACUC Officials**   * We, with the IACUC, have evaluated the care and use of animals described on this protocol, 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 protocol is appropriate and therefore, has 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 copied below or attached. | | |
| Name of Attending Veterinarian (VMO or VMC) | | Signature | Date |
|  | |  |  |
| Name of IACUC Chair | | Signature | Date |
|  | |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Biosafety**  **Certification by PI(s) and IACUC Officials:**  We certify that:   * Before any animal experiments involving hazardous agents identified in this protocol are performed, SOPs 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 this protocol will be informed of possible risks and will be properly trained ahead of time to follow the SOPs to minimize the risks of exposure. | | | |
| Name(s) of Principal Investigator(s) | Signature | Date | |
|  |  |  | |
|  |  |  | |
|  |  |  | |
| Name of Institutional Veterinarian | Signature | Date | |
|  |  |  | |
| Name of IACUC Chair | Signature | Date | |
|  |  |  | |
| **Certification by Biosafety Official**  I certify that:   * Each agent to be administered to animals on this protocol has been properly identified in this protocol 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 this protocol. * The use of each of these agents has been approved by the appropriate committee(s) or official(s). | | | |
| Name of the Biosafety Officer, or of the Chair of the Research Safety or Biosafety Committee | Signature | Date | |
|  |  |  | |
| **Certification by Radiation Safety Official**  I certify that:   * Each agent to be administered to animals on this protocol has been properly identified in this protocol as to whether it is “radioactive”; * The use of each radioactive agent is further documented as required in this protocol; * The use of each radioactive agent has been approved by the appropriate committee(s). | | | |
| Name of the Radiation Safety Officer, or of the Chair of the Radiation Safety or Isotope Committee | Signature | | Date |
|  |  | |  |

|  |  |  |
| --- | --- | --- |
| **Surgery**  **Certification by Principal Investigator(s):**   * To the best of my knowledge, the information provided in the surgery section of this protocol 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 location any survival surgical procedures will be performed 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 postoperative medical records for each animal which include documentation of daily evaluation of overall health, 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 | Date |
|  |  |  |
|  |  |  |
|  |  |  |

|  |  |  |
| --- | --- | --- |
| **Use of Patient Care Equipment or Areas for Animal Studies**  **Certification by Principal Investigator(s):**  I certify that, to the best of my knowledge, the information provided in this protocol 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 | Date |
|  |  |  |
|  |  |  |
| **Use of Patient Care Equipment or Areas for Animal Studies**  **Certification by Principal Investigator(s):**  **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 animal procedural area to be used on animals and then returned to the human patient care area, as described in this protocol. Leave this section blank, if not applicable. | | |
| Name of IACUC Chair | Signature | Date |
|  |  |  |
| Name of the Manager of the Human Patient Care Equipment | Signature | Date |
|  |  |  |

|  |  |  |
| --- | --- | --- |
| **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 this protocol. Leave this section blank, if not applicable. | | |
| Name of IACUC Chair | Signature | Date |
|  |  |  |
| Name of Attending Veterinarian (VMO or VMC) | Signature | Date |
|  |  |  |
| 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 |
|  |  |  |

|  |  |  |
| --- | --- | --- |
| Use of Explosive Agent(s) within the Animal Facility or in Animals.  **Certification by Principal Investigator(s):**  I certify that, to the best of my knowledge, the information provided in this protocol 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 | Date |
|  |  |  |
|  |  |  |
|  |  |  |
| **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 |
|  |  |  |
| Name of Attending Veterinarian (VMO or VMC) | Signature | Date |
|  |  |  |
| Name of Safety/Biosafety Officer for the Facility | Signature | Date |
|  |  |  |
| Name of ACOS for R&D | Signature | Date |
|  |  |  |
| Name of VISN Regional Safety Officer | Signature | Date |
|  |  |  |