

INSTRUCTIONS FOR COMPLETION OF THE
**ACORP APPENDIX 7 -- USE OF PATIENT CARE EQUIPMENT AND/OR
AREAS
FOR ANIMAL STUDIES
(ACORP APP. 7 INSTRUCTIONS)**

VERSION 4

These instructions provide detailed guidance on completing Appendix 7 of the ACORP, and are referenced to the numbers of the items in Appendix 7. ONLY complete this appendix if it is relevant to the protocol being submitted for review. The PI may use the ACORP Appendix 7 template provided in the RAMS application by using the link available in question 15 of section M.

General Instructions:

Answer each question by completing the table provided or entering the requested information at the ►. Enter "N/A" for any item that does not apply to this protocol. The sections of the form will expand as needed.

To check an item, type "X" inside the () provided.

Define each abbreviation the first time it is used.

Header for Every Page: The header information for this appendix is pre-populated to match header for the Main Body of the ACORP to which it applies, to identify each page of this Appendix with that ACORP:

PI's last name: The PI's name is prepopulated

Protocol No. Assigned by the IACUC – This is a unique identifier for each protocol that is automatically generated by the system to the protocol as a whole

Official Date of Approval – This is the date of final and unequivocal approval by the IACUC, as defined in the PHS Assurance, which determines the due dates of the first annual continuing review and the triennial *de novo* review, as applicable. The IACUC committee will enter this date into the form when a decision is made.

1. **Full Name(s) of Principal Investigator(s).** Give the full name(s) of the Principal Investigator(s), who are responsible for the use of animals on this protocol.
2. **Equipment to be used.**
 - a. Identify the equipment – Describe the human patient care equipment and provide whatever additional identifying information is necessary to make it clear which piece(s) of equipment will be used on this animal protocol.
 - b. Procedures to be performed – Specify the procedures that are to be performed on the animals, using this human patient care equipment.
 - c. Describe the specific protocol to be followed to prevent contamination of the human patient care equipment by animal feces, urine, saliva, blood, or other body fluids, and to clean/sanitize the equipment before its subsequent use for human patients. The procedures used should be at least as thorough as the procedures established by the clinical facility for cleaning and sanitizing the equipment between human patients.
3. **Human Patient Care Procedural Areas to be used.**
 - a. Location(s) -- Identify the location(s) of the human patient care area(s) in which animals will be used, specifying the building(s) and room number(s).

- b. Animal species to be studied or treated – Enter the species covered by this ACORP, so that this Appendix can be reviewed by officials responsible for the human patient care areas, without referring to other portions of the ACORP.
 - c. Number of individual animals to be studied or treated – Enter the total number of animals to be studied or treated in human patient care areas on this protocol.
 - d. 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).
 - e. 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.
 - f. Procedures to be performed in these areas – Specify the procedures that are to be performed on the animals, in these human patient care areas.
 - g. Protection and cleaning of patient care room surfaces – Describe the specific protocol to be followed to prevent contamination of the human patient care room surfaces by animal feces, urine, saliva, blood, or other body fluids, and for any cleaning/sanitizing necessary before subsequent use of the room for human patients. The procedures used should be at least as thorough as the procedures established by the clinical facility for cleaning and sanitizing the room between human patients.
 - h. Benefits to VA patients – Address the potential value of this research to VA patients, which justifies the use of areas dedicated to care of human patients for research on animal subjects.
 - i. Necessity for use of human patient care areas – Explain why the animal facility and research laboratory areas cannot be used for this work on research animal subjects, and the animals must be studied or treated in the human patient care areas.
 - j. Animal transport – 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.
 - k. 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 prevent patients and patient care personnel from becoming aware of the animals because of noises or odors, and the cleaning and disinfection protocols to be followed to protect them from exposure to allergens and transmission of zoonotic pathogens from the animals.
4. **Signatures.** Provide the signatures required on the signature pages (Item Z.7) of the main body of this ACORP. Note that the signatures required for use of human patient care equipment in the VMU or animal research areas are different from the signatures required for treatment or study of research animals in human patient care areas.