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| **ADMINISTRATIVE INFORMATION[[1]](#endnote-1)** |
| **Principal Investigator:**  | **Title of Individual Protocol Audited: [[2]](#endnote-2)** |
| **Individual Protocol Number: [[3]](#endnote-3)** | **Sponsor / Source of Funding: [[4]](#endnote-4)** |
| **Study Site(s):** (check all that apply) [ ]  **VA Facility** [ ]  **Academic Affiliate** [ ]  **Other:**  |
| **First audit? ☐ Y ☐ N If N, Date of last audit: \_\_\_\_\_\_** |  |  |  |
| **Initial approvals reviewed in previous audit?** | [ ]  **Y**  | [ ]  **N** |  |
| **Initial IACUC Approval Obtained Prior to Research?[[5]](#endnote-5)**  | [ ]  **Y**  | [ ]  **N** | **Date Protocol was first approved by IACUC:** |
| **Initial SRS Approval Obtained Prior to Research?** | [ ]  **Y**  | [ ]  **N** | **Date Protocol was first approved by SRS:**  |
| **Initial R&DC Approval Obtained Prior to Research?** | [ ]  **Y**  | [ ]  **N** |  |
| **ACOS/R Letter Obtained Prior to Research?** | [ ]  **Y**  | [ ]  **N** | **Date of ACOS/R Letter:** |
|  |
| **Current Audit Date:** | **Status at Time of Current Audit:[[6]](#endnote-6)** [ ]  **Open** [ ]  **Closed[[7]](#endnote-7)** |
| **Date of Most Recent Triennial Review:**  | **Auditor(s):**  |

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| **Subsequent Reviews** |
|  | **Y** | **N** | **NA** | *COMMENTS* |
| Has the Institutional Animal Care and Use Committee (IACUC) performed a complete review of the protocol and granted renewed approval for work to continue prior to expiration of the initial approval?[[8]](#endnote-8) | [ ]  | [ ]  | [ ]  |  |
| If NO, did any Research occur during the lapse? | [ ]  | [ ]  | [ ]  |       |

**NOTE:** If a protocol is opened and closed without any animal research activities being initiated, completing the audit tool to this point satisfies the requirement for the Animal Welfare audit.

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| **ANIMAL Research PROTOCOL** |
| LIST SPECIES[[9]](#endnote-9):       |

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|  | **Y** | **N** | **NA** | *COMMENTS* |
| Was the protocol submitted on an Animal Component of Research Protocol (ACORP)? If “no”, describe the protocol submission form that was used. | [ ]  | [ ]  | [ ]  |       |
| Does the protocol indicate the maximum number of animals to be used during the 3-year approval period?[[10]](#endnote-10) | [ ]  | [ ]  | [ ]  |       |
| If the protocol involves cats, dogs, or non-human primates, does it have the approval of the VA Secretary? |[ ] [ ] [ ]   |
| If the study includes a Category E pain and distress level, is a scientific justification provided for not relieving pain or distress?[[11]](#endnote-11) | [ ]  | [ ]  | [ ]  |       |
| Is consultation with a veterinarian during the planning stages of the research documented? (i.e., pre-review of the proposed research?)[[12]](#endnote-12) | [ ]  | [ ]  | [ ]  |       |
| If the study states that social animals will be individually housed, is a scientific justification provided for why group housing is not being used?[[13]](#endnote-13) | [ ]  | [ ]  | [ ]  |       |
| Are all animal housing and procedure locations specified (both VA and non-VA)?[[14]](#endnote-14) | [ ]  | [ ]  | [ ]  |       |
| Are endpoint criteria for euthanasia and/or removal of animal(s) from the study described in the protocol?[[15]](#endnote-15) | [ ]  | [ ]  | [ ]  |       |
| Is a search for alternatives to animal use for procedures involving pain or distress to the animals documented in the protocol?[[16]](#endnote-16) | [ ]  | [ ]  | [ ]  |       |

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| **DOES THIS PROTOCOL INVOLVE DRUG ENFORCEMENT ADMINISTRATION (DEA) CONTROLLED SUBSTANCES?** [ ]  **Yes** [ ]  **No**  |
|  | **Y** | **N** | **NA** | *COMMENTS* |
| Is this protocol conducted at the VA? If no, skip the two questions below. | [ ]  | [ ]  | [ ]  |  |
| Are all controlled substances used in research conducted on VA property obtained through the VA Pharmacy?[[17]](#endnote-17) | [ ]  | [ ]  | [ ]  |       |
| Are the controlled substances stored securely (e.g., in a secured locked cabinet or automated dispensing machine such as a Pyxis or Omnicell) and only accessible to authorized personnel?)[[18]](#endnote-18) | [ ]  | [ ]  | [ ]  |  |

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| **STUDY STAFF TRAINING** |
| **Site Personnel[[19]](#endnote-19)** | **All animal welfare training current Y/N[[20]](#endnote-20)****(If Yes, skip next column)** |  **If training not current, initial animal welfare training ever completed** **Y/N** | *WOC Current**Y/N/NA* | *Role in study* | *Comments* |
|         |  |  |  | Principal Investigator |       |
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| **IACUC SUBMISSIONS, APPROVALS, AND OTHER ACTIONS** |
| **Protocol Amendments, Annual Approval etc.** | **IACUC Dates** | **Research & Development Committee Approval****Date or N/A** | **Submission & Approval letters on file?****Y/N/ N/A****Res Svc** | Comments |
| **Approval** | **Expiration** |
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| *DOCUMENT MANAGEMENT SUMMARY* |
| *Documents Reviewed* | *Date/Version* | *Comments* |
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1. **GENERAL INSTRUCTIONS FOR THE ANIMAL WELFARE AUDIT TOOL**

Every protocol approved by the Institutional Animal Care and Use Committee (IACUC) should receive a regulatory audit at least once within 3 years of approval and each subsequent IACUC triennial review using the Animal Welfare audit tool. All actions of the IACUC should be reviewed retrospectively from the date of the audit to the date of the most recent approval [i.e., initial approval or last IACUC triennial (“de novo”) approval, as applicable].

All protocols for projects subject to just-in-time (JIT) processing before release of VA funding, or for work on any project involving sensitive species (cats, dogs, or nonhuman primates) are subject to secondary review by the office of the CVMO, and documentation of that secondary review is to be maintained with the protocol. The office of the CVMO evaluates the adequacy of any forms other than the VA Animal Component of Research Protocol (ACORP) that are received. Animal studies that are not VA-funded, do not describe work with a sensitive species, and are overseen by a collaborating institution as well as by the VA, do not have to be submitted on the VA ACORP and may be submitted on the standard form required by the collaborating institution. The ACORP form is to be used for all other protocols that are not subject to secondary review. The use of the term “ACORP” in this document includes both the standard ACORP (Version 4) and the corresponding forms required by collaborating institutions and acceptable to VA.

Some R&DCs approve research projects that include more than one ACORP. Each individual ACORP should have a separate audit. The local IACUC Coordinator can provide access to each ACORP and should be contacted prior to starting the audit.

This audit tool (or equivalent) should be used for all protocols overseen by the IACUC. All protocols involving live animals have inherent safety concerns, requiring Subcommittee on Research Safety (SRS) oversight for which the Research Safety audit tool should be used. Both tools can be combined, so that data common to both forms is only recorded once.

Every RCO has flexibility to customize tools and develop SOPs that describe the audit plan at their institution. The plan should include: a list of source documents that are reviewed; roles and responsibilities of the RCO, the PI, and the research staff in planning, scheduling and conducting audits; how progress towards accomplishing all required audits is monitored; how the RCO solicits study investigators’ responses to preliminary audit findings; and  reporting of audit results to the relevant review committees, including timelines. It is also a good practice to include: (1) record format (electronic and/or hard copies); and (2) the location where records are maintained.

For more information, visit <http://www.research.va.gov/programs/animal_research/> [↑](#endnote-ref-1)
2. Provide the title of the **individual protocol** that is being audited. If the individual protocol is part of a larger, multi-protocol project, include a cross reference to the larger project. [↑](#endnote-ref-2)
3. Record the identification number or code used by the local protocol tracking system. Example: *NIH Grant R-01-12345; IACUC #; ePROMIS #; VAIRRS #.*  [↑](#endnote-ref-3)
4. Identify sponsoring organization(s) and all funding sources for the protocol being audited, or note if the protocol is unfunded. [↑](#endnote-ref-4)
5. “Initial” refers to the date of the first IACUC approval for the study. RCOs should consult with the IACUC about whether or not the ACORP is considered a “new” protocol after a triennial review. If the IACUC considers the ACORP a “new” protocol after a triennial review, the dates for initial approval and most recent triennial review may be the same. If the IACUC does not consider the ACORP a “new” protocol after a triennial review, the dates for initial approval may be the date the first time the IACUC reviewed and approved the study and may be different from most recent triennial review after the initial audit. Regardless, it is still important to check and see if there are any lapses in approval during which work was done with animals since the last audit. [↑](#endnote-ref-5)
6. All open animal studies should have a regulatory audit initially within 3 years of IACUC approval and subsequently within 3 years of each IACUC complete review, even if no animals have been used or are currently on study. [↑](#endnote-ref-6)
7. Closure audits are not required for studies that have been audited at least once during the three years prior to study closure. This applies even if the previous audit was conducted prior to the most recent IACUC complete review. [↑](#endnote-ref-7)
8. Triennial complete review and approvals are required for any work with animals (including non-USDA regulated species) to continue beyond the third anniversary date of the original IACUC approval or previous renewal of approval. VHA Directive 1200.07, VA Research with Animals (released May 23, 2023), §10.d(5) and (6)) requires only that IACUC approval be renewed according to the requirements of the USDA Animal Welfare Regulations and the PHS policy, which agree that IACUC approval expires no later than three years after it is granted. The requirements for continuing reviews are left to the discretion of the IACUC. [↑](#endnote-ref-8)
9. Animal Species covered by an ACORP – The IACUC has flexibility to determine if multiple species can be included in one ACORP. The RCO should note the species identified in item A.4 of the main body of the ACORP. [↑](#endnote-ref-9)
10. The maximum number of animals approved for use is found in ACORP, Section I. [↑](#endnote-ref-10)
11. Assignment of animals to USDA categories B, C, D or E must be documented. The same animal cannot be assigned to more than one USDA category and reporting should reflect the highest category that applies.

The justification for category E pain/distress is found in the ACORP in Section K (Version 4). [↑](#endnote-ref-11)
12. VA policies require consultation with a veterinarian during the planning stages of research. This information is found in the ACORP, Section L. [↑](#endnote-ref-12)
13. The *Guide for the Use and Care of Laboratory Animals*, 8th Edition, states that social animals are housed in stable pairs or groups, unless a scientific justification is provided to justify individual housing. The justification for housing social animals singly is found in the ACORP, Section M. [↑](#endnote-ref-13)
14. Information on housing sites is found in the ACORP, Section N. [↑](#endnote-ref-14)
15. Endpoint criteria are used to define objective criteria for when an animal will be removed from a study or euthanized. This information is found in the ACORP, Section T. [↑](#endnote-ref-15)
16. Most programs have policies and/or SOPs describing local procedures used to search for alternatives (i.e., number and types of databases to be searched, key words, search strategies, time period for search). Investigators must consider less painful/stressful alternatives to procedures, options to replace the use of animals, and provide assurance that the proposed research does not unnecessarily duplicate previous work. Literature searches should be updated for Triennial protocol submissions to include relevant dates. Information on alternatives is found in the ACORP, Section W. [↑](#endnote-ref-16)
17. Information on procurement of controlled substances is found in the ACORP, Section X and is addressed in VHA Directive 1108.01 (01), Controlled Substances Management, §4.j. This citation specifies that “[a]ll controlled substances for use in research (animal or human) conducted on VA property or facilities are ordered through and received by Pharmacy Service,” and goes on to acknowledge that some “specialized veterinary controlled drugs used in animal research at a VA medical facility will not be available through vendors used by the pharmacy. In such a case, the Chief of Pharmacy should be consulted to ensure that the pharmacy is involved in arranging the purchase of or transfer of such drugs through a non-VA institution for use in the VA program.” If the study is conducted at the VA and controlled substances are *not* obtained through the VA pharmacy (this is documented in ACORP X.1), document the explanation given for the “Other” option of ACORP X.1.b and whether the Chief of Pharmacy has been consulted. RCOs are not expected to validate the explanation. [↑](#endnote-ref-17)
18. VHA Directive 1180.01 (1), Controlled Substances Management, §4.g.9(b) specifies that “controlled substances must be stored in a secured locked cabinet or cart with electronic access or locked commercial automated dispensing system” if stored outside of the pharmacy vault. RCOs may go onsite to confirm that controlled substances are appropriately stored; alternatively, the RCO may check with the controlled substances coordinator for this information. [↑](#endnote-ref-18)
19. On this page list all research personnel named on the protocol. (ACORP, Section E.1 and E.2, which should include all those identified in Section U.3. Appendix 5.3 may include some of the research personnel identified in E.1 and E.2, but may also include veterinary personnel providing support services.) RCOs may also need to check amendment forms or other documentation for personnel added through administrative amendment processes – this will depend on local IACUC processes. [↑](#endnote-ref-19)
20. RCOs should check that training related to animal research is current for all research staff (identified in ACORP E.1 and E.2) participating in the protocol on the date of the audit or date of closure if the study previously closed. No look-back period is expected. Refer to [ORD Guidance on ACUP Training Requirements](http://www.research.va.gov/programs/animal_research/required_training.cfm) for current training requirements. NOTE: RCOs are responsible for monitoring research-specific training records and do not need to monitor VA-mandated training that is not specific to research, such as VA Privacy Awareness, VA Information Security Awareness and Rules of Behavior, No Fear Act, etc. If training required for research with animals is not current as of the time of the audit, check and see if such training was ever completed for this staff member's involvement in this research. If there is no evidence of training ever being completed, this rare circumstance should be noted in the appropriate column. The Research Service is not required to maintain a real-time (up-to-the minute) record of training compliance. If the RCO relies on a list of training compliance maintained by the Research Service, any items that *appear* to indicate a deficiency (lapse in training) must be checked against primary records (e.g., CITI) to verify whether a deficiency in fact exists at the time of the RCO audit. Note that study staff only need to be current on training required for working with animals when they are identified as research personnel on an active protocol for working with the animals. If they are not doing any work with animals, there is no need for the training to be kept “current.” [↑](#endnote-ref-20)