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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:** | | | |
| |  |  |  | | --- | --- | --- | | **Initial IACUC Approval Obtained?** | **Y** | **N** | | **Initial SRS Approval Obtained?** | **Y** | **N** | | **Initial R&DC Approval Obtained?** | **Y** | **N** | | **ACOS/R Letter Obtained?** | **Y** | **N** | | | | **Date Protocol was first approved by IACUC:**  **Date Protocol was first approved by RDC:** |
|  | | | |
| **Current Audit Date:** | | **Status at Time of Current Audit:[[5]](#endnote-5)  Open  Closed[[6]](#endnote-6)** | |
| **Date of Most Recent Triennial Review:** | | **Auditor(s):** | |

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| **Continuing Reviews** | | | | |
|  | **Y** | **N** | **NA** | *COMMENTS* |
| Has the protocol received the required annual Institutional Animal Care and Use Committee (IACUC) approval(s)?[[7]](#endnote-7) |  |  |  |  |
| Has the protocol received the required triennial de-novo Institutional Animal Care and Use Committee (IACUC) approvals?[[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: |

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|  | **Y** | **N** | **NA** | *COMMENTS* |
| Was the protocol submitted on an Animal Component of Research Protocol (ACORP), which is required for VA-funded protocols?  If “yes”, list the version that was used.[[9]](#endnote-9)  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 study includes a Category E pain and distress level, is a scientific justification provided for not relieving pain or distress?[[11]](#endnote-11) |  |  |  |  |
| Was a veterinarian consulted during the planning stages of the research? (i.e. pre-review of the proposed research?)[[12]](#endnote-12) |  |  |  |  |
| If the study states that animals should be individually housed, is there a scientific justification to explain 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) |  |  |  |  |
| Did the PI conduct a search for alternatives to animal use for procedures involving pain or distress to the animals?[[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 obtained through the VA Pharmacy?[[17]](#endnote-17) |  |  |  |  |
| Are the controlled substances stored in a double-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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| **OCCUPATIONAL SAFETY AND HEALTH PROGRAM** | | | | |
|  | **Y** | **N** | **NA** | *COMMENTS* |
| For the protocol being audited, have all personnel involved in research been offered the opportunity to enroll in an approved Occupational Safety and Health Program?[[19]](#endnote-19)  If not, explain in comments section. |  |  |  |  |

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| **STUDY STAFF QUALIFICATIONS AND TRAINING** | | | | | |
| **Site Personnel[[20]](#endnote-20)** | **All training current Y/N[[21]](#endnote-21)**  **(If Yes, skip next column)** | **initial training completed**  **Y/N** | *WOC*  *Y/N* | *Role in study* | *Comments* |
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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 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].

   Animal studies that are not VA-funded are not required to have an ACORP and can be submitted on an equivalent protocol submission form. The use of the term “ACORP” in this document includes the standard ACORP (Version 3 or Version 4) in addition to any other equivalent forms that may be subsituted. (ACORP version 3 may be used for protocols submitted to the IACUC before 2/1/14).

   Some R&DCs approve research projects or protocols that include more than one ACORP. Each individual ACORP should have a separate audit. Auditors should record the number of approved VA animal research protocols audited, and the number of ACORPs included in each protocol.

   Animal Species covered by an ACORP – The IACUC has flexibility to determine if multiple species can be included in one ACORP. When similar procedures are performed on closely-related species (e.g., the same surgical procedure on mice and rats), it may be appropriate to document both species in a single ACORP. Separate ACORPs are recommended when divergent procedures are performed on very different species (e.g., surgery on mice and behavioral testing of cats). In all cases, the response to each item should clearly differentiate the procedure and species involved.

   The local IACUC Coordinator can provide access to each ACORP and should be contacted prior to starting the audit.

   This audit tool should be used for all protocols overseen by the IACUC. Some protocols involving live animals may also have 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: (1) a list of source documents that are reviewed; (2) roles and responsibilities of the RCO, the PI, and the research staff in scheduling and conducting audits; (3) how progress towards accomplishing all required audits is monitored; (4) reporting of audit results. It is also a good practice to include: (1) record format (electronic and/or hard copies); and (2) the location where records are maintained. [↑](#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 #; PROMIS #.*  [↑](#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. All open animal studies should have a regulatory audit initially within 3 years of IACUC approval and subsequently within 3 years of each IACUC triennial review, even if no animals have been used or are currently on study. [↑](#endnote-ref-5)
6. 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 triennial review. [↑](#endnote-ref-6)
7. Annual reviews are required for all animal studies (including non-regulated species) per VHA and USDA regulations and must be completed within the anniversary month of the IACUC review. [↑](#endnote-ref-7)
8. Triennial “de-novo” reviews are required for all animal studies (including non-regulated species) per PHS policy and must be completed by the third anniversary date of the original IACUC approval or previous de-novo approval. [↑](#endnote-ref-8)
9. Animal Component of Research Protocol (ACORP):

   **Version 3**: May be used for protocols submitted to the IACUC before 2/1/14.

   **Version 4**: Required for any protocol submitted to the IACUC for initial or triennial review after 2/1/14

   For more information, visit http://www.research.va.gov/programs/animal\_research/ [↑](#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 pain/distress 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 pain/distress category that applies.

    The justification for category E pain/distress is found in the ACORP, Section J (2) (Version 3) or 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 parameters that determine when an animal will be removed from a study or euthanized, as a result of complications or disease. 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 stratagies, 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. 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. VHA Handbook 1200.07, Use Of Animals In Research, §7.m(1) and VHA Handbook 1108.01, Controlled Substances (Pharmacy Stock), §20.a(1) specifies that controlled substances used in research conducted at VA medical facilities must be ordered by and received by the local VA pharmacy for disbursement to research personnel. If the study is conducted at the VA and controlled substances are *not* obtained through the VA pharmacy, document the reason why and whether the issue has been brought to the attention of the VMO (VHA Handbook 1180.01, Controlled Substances (Pharmacy Stock), §20.a(2) “Circumstances in which controlled substances are needed for animal research, but cannot be procured locally need to be brought to the attention of the Chief Veterinary Medical Officer immediately by the Associate Chief of Staff for Research and Development, or other local administrator.” [↑](#endnote-ref-17)
18. VHA Handbook 1200.07, Use Of Animals In Research, Appendix D, §1.w(1) specifies that “All drugs used in animals and classified as controlled substances by the Drug Enforcement Agency must be stored in a double-locked cabinet, and must be accessible only to authorized personnel in accordance with VHA policy.” 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. Information on personnel participation in an Occupation Safety and Health Program is found in the ACORP, Section G. [↑](#endnote-ref-19)
20. On this page list all research personnel named on the protocol. (ACORP, Section E) [↑](#endnote-ref-20)
21. RCOs should check that research-related training is current for all staff 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. For research staff identified only by job title in the protocol, the auditor may need to request a list of names of staff from the PI. 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. [↑](#endnote-ref-21)