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| **Continuing Reviews** |
|  | **Y** | **N** | **NA** | *COMMENTS* |
| Did required Continuing Review(s) occur as scheduled per policy?  | [ ]  | [ ]  | [ ]  |  |
| If NO, did any Research occur during the lapse? | [ ]  | [ ]  | [ ]  |  |

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| **ADMINISTRATIVE INFORMATION[[1]](#endnote-1)** |
| **Principal Investigator:**  | **Title of 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 (or VA-leased space)** [ ]  **Off-site (non-leased) location (specify) \_\_\_\_\_\_\_\_** **ORD Approved Waiver for Off-site research[[5]](#endnote-5):** [ ] **Y** [ ] **N**  |
| **Study Type: Non-animal/Non-human only[[6]](#endnote-6)** [ ] **Y** [ ]  **N****Is this an umbrella protocol that covers multiple projects?** [ ] **Y** [ ]  **N[[7]](#endnote-7)** |
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| **Initial SRS Approval Obtained?**  |  | [ ] **Y**  | [ ]  **N** |
| **Initial R&DC Approval Obtained?** |  | [ ]  **Y**  | [ ]  **N** |
| **ACOS/R Letter Obtained?** **Investigator notified in writing of the outcome of the SRS review?**  |  | [ ]  **Y**[ ]  **Y**  | [ ]  **N**[ ]  **N** |

 | **Date Protocol was first approved by SRS:** **Date Protocol was first approved by RDC:****Date Investigator was notified of SRS review outcome:** |
|  |
| **Current Audit Date:**  | **Status at Time of Current Audit:** [ ] **Open** [ ] **Closed[[8]](#endnote-8)** |
| **Date of Most Recent SRS Review:**  | **Auditor(s):**  |

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

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| **DOES THIS PROTOCOL INVOLVE BIOLOGICAL HAZARDS?[[9]](#endnote-9) 🞏 Yes 🞏 No** |
|  | **Y** | **N** | **NA** | *COMMENTS* |
| Does this protocol involve the use of Biological Hazards? (Microbiological or viral agents, pathogens, toxins, select agents[[10]](#footnote-1), or animals) | [ ]  | [ ]  | [ ]  |  |
| If required, has the protocol been approved by an Institutional Review Board (IRB)? | [ ]  | [ ]  | [ ]  |  |
| If required, has the protocol been approved by the Institutional Animal Care and Use Committee (IACUC)? | [ ]  | [ ]  | [ ]  |  |
| Is there a completed Research Protocol Safety Survey (Form 10-0398)?[[11]](#endnote-10) | [ ]  | [ ]  | [ ]  |  |
| Is the biosafety containment level clearly stated in the protocol?[[12]](#endnote-11) | [ ]  | [ ]  | [ ]  |  |
|  [ ]  **BSL 1** [ ]  **BSL 2** [ ]  **BSL 3**  |  |  |  |  |

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| **DOES THIS PROTOCOL INVOLVE THE USE OF HUMAN OR NON-HUMAN CELL OR TISSUE SAMPLES[[13]](#endnote-12) 🞏 Yes 🞏 No** |
|  | **Y** | **N** | **NA** | *COMMENTS* |
| Does this protocol involve the use of human or non-human cell or tissue samples (including cultures, tissues, blood, other bodily fluids or cell lines)? | [ ]  | [ ]  | [ ]  |  |
| If required, has the protocol been approved by an Institutional Review Board (IRB)? | [ ]  | [ ]  | [ ]  |  |
| If required, has the protocol been approved by the Institutional Animal Care and Use Committee (IACUC)? | [ ]  | [ ]  | [ ]  |  |
| Is there a completed Research Protocol Safety Survey (Form 10-0398)?[[14]](#endnote-13) | [ ]  | [ ]  | [ ]  |  |
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| **DOES THIS PROTOCOL INVOLVE THE USE OF NON-EXEMPT RECOMBINANT DNA (rDNA)[[15]](#endnote-14) 🞏 Yes 🞏 No** |
|  | **Y** | **N** | **NA** | *COMMENTS* |
| If required, has the protocol been approved by an Institutional Biosafety Committee (IBC)?  | [ ]  | [ ]  | [ ]  |  |
| Was the investigator appropriately notified in writing or electronically of the outcome of the IBC’s review?[[16]](#endnote-15) If yes, enter date:  | [ ]  | [ ]  | [ ]  |  |
| Did the protocol receive appropriate annual re-certification? | [ ]  | [ ]  | [ ]  |  |

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| **DOES THIS PROTOCOL INVOLVE CHEMICAL HAZARDS?[[17]](#endnote-16)  🞏 Yes 🞏 No** |
|  | **Y** | **N** | **NA** | *COMMENTS* |
| Was the laboratory chemical inventory reviewed semi-annually as required by VHA policy.  | [ ]  | [ ]  | [ ]  |  |
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| **DOES THIS PROTOCOL INVOLVE RADIOISOTOPES OR A RADIATION SOURCE?[[18]](#endnote-17) 🞏 Yes 🞏 No** |
|  | **Y** | **N** | **NA** | *COMMENTS* |
| Has the protocol been reviewed by the Radiation Safety Officer or the Research Safety Coordinator? | [ ]  | [ ]  | [ ]  |  |

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| **STUDY STAFF QUALIFICATIONS AND TRAINING[[19]](#endnote-18)** |
| Site Personnel[[20]](#endnote-19) | All research safety training current?[[21]](#endnote-20)Y/N(if yes, skip next column) | initial rsearch safety training completedY/N | *WOC**Y/N* | *Role in study* | *Comments* |
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1. All protocols approved by the SRS should receive a safety audit using the Research Safety audit tool at least once every three years. Initial audit should be within 3 years of intial approval by the R&D Committee. Some protocols involving research hazards may be monitored by other research oversight committees (e.g., IACUC and/or the IRB). This audit tool may be combined with other relevant tools, so that data common to both forms is only recorded once. If the study is animal research overseen by the IACUC, then the SRS audit may be combined with the Animal Welfare audit and may occur together on the same cycle;- within 3 years of each IACUC triennial review. [↑](#endnote-ref-1)
2. Provide the title of the **protocol** that is being audited. If the protocol is part of a larger, multi-protocol research 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; SRS #; 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. Off-site research that is also VA-funded must have an Office of Research and Development (ORD) approved waiver. [↑](#endnote-ref-5)
6. Answer Yes if the study does not include animal, or human subject hazards. (Is the research considered; e.g. bench, basic science, wet-lab, safety-science, etc?). [↑](#endnote-ref-6)
7. For umbrella protocols: Audit each umbrella protocol every three years. This basically amounts to auditing the lab or the PI; document the different studies under the umbrella in the “DOCUMENT MANAGEMENT SUMMARY” section; for the FDC report each umbrella protocol as one protocol. [↑](#endnote-ref-7)
8. Closure audits are not required for studies that have been audited at least once during the past three years. [↑](#endnote-ref-8)
9. Information on potential biological hazards associated with the protocol is found in the RPSS, Section 2 and/or Section 4. [↑](#endnote-ref-9)
10. As defined in Title 42 Code of Federal Regulations (CFR) 72.6 [↑](#footnote-ref-1)
11. VA Form 10-0398 [or the the Research Protocol Safety Survey (RPSS)], including any supplemental forms as required by local policies. Facilties locally may opt to add to, but not remove from, information on VA Form 10-0398. Any version of Form 10-0398 acceptable to the SRS per local policies satisfies this audit element. [↑](#endnote-ref-10)
12. Information on biosafety level associated with the protocol is found in the RPSS, Section 2. [↑](#endnote-ref-11)
13. Information on cells and tissue samples used by the laboratory is found in the RPSS, Section 4. [↑](#endnote-ref-12)
14. VA Form 10-0398 [or the the Research Protocol Safety Survey (RPSS)], including any supplemental forms as required by local policies. Facilties locally may opt to add to, but not remove from, information on VA Form 10-0398. Any version of Form 10-0398 acceptable to the SRS per local policies satisfies this audit element. [↑](#endnote-ref-13)
15. Information on recombinant DNA used by the laboratory is found in the RPSS, Section 5 and, for animal research, in ACORP Appendix 3 Section 8. [↑](#endnote-ref-14)
16. Note that all human subjects research needs to have an informed consent audit and all non-exempt research under the pre-2018 Common Rule and all research under the 2018 Common Rule requires a regulatory audit. [↑](#endnote-ref-15)
17. Information on the inventory of chemicals used by the laboratory is found in the RPSS, Section 6. [↑](#endnote-ref-16)
18. Information on the use of radioactive materials by the laboratory is found in the RPSS, Section 8. [↑](#endnote-ref-17)
19. The Research Service at each facility must develop and maintain a system to verify that all research personnel have completed local training requirements commensurate with relevant hazards and duties assigned.  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. Local SOPs should describe the system used to maintain research-specific training records, the location of records, and the individual(s) who are responsible. Safety training requirements will be specific to the activities for each research program. Common safety training courses that may be required for research personnel are chemical hygiene plan, bloodborne pathogens, respiratory protection, formaldehyde awareness training (may be included in the chemical hygiene plan training or a separate course). RCOs should look at RPSS forms to determine potential hazards, staff listing from the PI, scopes of practice (form identifies activities, e.g., blood draws, handling human specimens, and laboratory work/use of chemicals), and chemical inventory to identify formaldehyde/formalin/paraformaldehyde use.
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-18)
20. On this page, list all research personnel named on the protocol. [↑](#endnote-ref-19)
21. Verify safety training is current only at the time of the audit or at the time of closure (for studies that have been closed). No look-back period is expected.
NOTE: Lack of any training records is a serious deficiency, although rare. [↑](#endnote-ref-20)