|  |
| --- |
| **ADMINISTRATIVE INFORMATION[[1]](#endnote-2)** |
| **Principal Investigator:**  | **Title of Protocol Audited:[[2]](#endnote-3)** |
| **Individual Protocol Number:[[3]](#endnote-4)** | **Sponsor / Source of Funding:[[4]](#endnote-5)** |
| **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-6):** [ ]  **Y** [ ]  **N** [ ]  **NA**  |
| **Study Type(s) check all that apply: Animal** [ ]  **Human** [ ]  **Bench only[[6]](#endnote-7)** [ ]  **Is this an umbrella protocol that covers multiple projects?** [ ]  **Y** [ ]  **N[[7]](#endnote-8)**  |
| **First audit?** [ ]  **Y** [ ]  **N If N, Date of last audit:** **Initial approvals reviewed in previous audit?** | [ ]  **Y** | [ ]  **N** |  |  |
| **Initial SRS Approval Prior to Research?**  | [ ]  **Y**  | [ ]  **N** |  | **Date protocol first approved by SRS:** |
| **Investigator notified in writing of the outcome of the SRS review?**  | [ ]  **Y** | [ ]  **N** |  | **Date Investigator was notified of SRS review outcome:** |
| **Initial R&DC Approval Prior to Research?** | [ ]  **Y** | [ ]  **N** |  | **Date Protocol was first approved by RDC:** |
| **ACOS/R Letter Prior to Research?**  | [ ]  **Y** | [ ]  **N** |  | **Date of ACOS/R Letter:** |
| **IRB Approval (if required)?**  | [ ]  **Y** | [ ]  **N** | [ ]  **NA** | **Completed Research Protocol Safety Survey (Form 10-0398)?[[8]](#endnote-9)** [ ]  **Y** [ ]  **N** |
| **IACUC Approval (if required)?****IBC Approval (if required)?[[9]](#endnote-10)**  | [ ]  **Y**[ ]  **Y** | [ ]  **N**[ ]  **N** | [ ]  **NA** [ ]  **NA** |  **If “N” above, what form was used?****Date of IBC Approval (if required)** |
|  |
| **Current Audit Date:**  | **Status at Time of Current Audit:** [ ]  **Open** [ ]  **Closed[[10]](#endnote-11)** |
| **Date of Most Recent SRS Review:**  | **Auditor(s):**  |

|  |
| --- |
| **Continuing Reviews** |
|  | **Y** | **N** | **NA** | *COMMENTS* |
| Did review of the PI’s VA laboratory program by the SRS occur annually?[[11]](#endnote-12)  | [ ]  | [ ]  | [ ]  | **Date:** |

**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.

|  |
| --- |
| **DOES THIS PROTOCOL INVOLVE BIOLOGICAL HAZARDS?[[12]](#endnote-13)** [ ]  **Yes** [ ]  **No** |
|  | **Y** | **N** | **NA** | *COMMENTS* |
| Does this protocol involve the use of Biological Hazards? (Microbiological or viral agents, pathogens, toxins, select agents[[13]](#endnote-14) or animals) | [ ]  | [ ]  | [ ]  |  |
| Is the biosafety containment level clearly stated in the protocol?[[14]](#endnote-15) | [ ]  | [ ]  | [ ]  |  |
|  [ ]  **BSL 1** [ ]  **BSL 2** [ ]  **BSL 3**  |  |  |  |  |
| Has the investigator specified precautions to be taken for specific hazards (e.g., personal protective equipment to be used, work in a biological safety cabinet)?[[15]](#endnote-16) |[ ] [ ] [ ]   |

|  |
| --- |
| **DOES THIS PROTOCOL INVOLVE THE USE OF HUMAN OR NON-HUMAN CELL OR TISSUE SAMPLES[[16]](#endnote-17)** [ ]  **Yes** [ ]  **No** |
|  | **Y** | **N** | **NA** | *COMMENTS* |
| Will this use represent a potential biohazard for lab personnel? | [ ]  | [ ]  | [ ]  |  |
| If yes, has the investigator specified the hazard and precautions to be taken? |[ ] [ ] [ ]   |
| If protocol involves handling human blood or other potential infectious materials, did all personnel take annual blood-borne pathogens training?[[17]](#endnote-18) |[ ] [ ] [ ]   |

|  |
| --- |
| **DOES THIS PROTOCOL INVOLVE THE USE OF NON-EXEMPT RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES?[[18]](#endnote-19)** [ ] **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?[[19]](#endnote-20) If yes, enter date:  | [ ]  | [ ]  | [ ]  |  |
| Did the protocol receive appropriate periodic review (as determined by the IBC or other local policy)? | [ ]  | [ ]  | [ ]  |  |

|  |
| --- |
| **DOES THIS PROTOCOL INVOLVE CHEMICAL HAZARDS?[[20]](#endnote-21)** [ ]  **Yes** [ ]  **No** |
|  | **Y** | **N** | **NA** | *COMMENTS* |
| Was the laboratory chemical inventory reviewed semi-annually as required by VHA policy?  | [ ]  | [ ]  | [ ]  |  |

|  |
| --- |
| **DOES THIS PROTOCOL INVOLVE RADIOISOTOPES OR A RADIATION SOURCE?[[21]](#endnote-22)** [ ]  **Yes** [ ]  **No** |
|  | **Y** | **N** | **NA** | *COMMENTS* |
| Has the protocol been reviewed by the Radiation Safety Officer? | [ ]  | [ ]  | [ ]  |  |

|  |
| --- |
| **STUDY STAFF TRAINING[[22]](#endnote-23)** |
| **Site Personnel[[23]](#endnote-24)** | **All research safety training current?[[24]](#endnote-25)****Y/N****(if yes, skip next column)** | **If training not current, Research safety training ever completed?****Y/N** | *WOC Current**Y/N/NA* | *Role in study* | *Comments* |
|   |  |  |       | Principal Investigator |       |
|  |  |  |       |       |       |
|  |  |  |       |       |       |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

|  |
| --- |
| **SRS SUBMISSIONS, APPROVALS, AND OTHER ACTIONS**  |
| **Initial, Modifications, Continuing Approvals etc.** | **SRS Dates** | **Research & Development Committee Approval****Date or N/A** | **Submission & Approval letters on file?****Y/N/ N/A****RESEARCH SERVICE** | Comments |
| **Approval** | **Expiration** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

|  |
| --- |
| **IBC SUBMISSIONS, APPROVALS, AND OTHER ACTIONS**  |
| **Initial, Modifications, etc.** | **IBC Dates** | **Research & Development Committee Approval****Date or N/A** | **Submission & Approval letters on file****Y/N/ N/A** | Comments |
| **Approval** | **Expiration** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

|  |
| --- |
| *DOCUMENT MANAGEMENT SUMMARY* |
| *Documents Reviewed* | *Date/Version* | *Comments*  |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |

1. All protocols approved by the Subcommittee on Research Safety (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 Research Safety 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-2)
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-3)
3. Record the identification number or code used by the local protocol tracking system. Example: *NIH Grant R-01-12345; SRS #; ePROMIS #; VAIRRS #.* [↑](#endnote-ref-4)
4. Identify sponsoring organization(s) and all funding sources for the protocol being audited, or note if the protocol is unfunded. [↑](#endnote-ref-5)
5. Off-site research that is also VA-funded must have an Office of Research and Development (ORD)-approved waiver. If the PI or Research Service has any questions related to whether or not a full or partial off-site waiver is applicable they should contact the applicable ORD funding service. [↑](#endnote-ref-6)
6. Check “Bench Only” if the study does not include animal or human subject hazards. (Is the research considered bench, basic science, wet-lab, safety-science, etc) [↑](#endnote-ref-7)
7. For umbrella protocols, audit each umbrella protocol every three years – which 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, document each umbrella protocol as one protocol. [↑](#endnote-ref-8)
8. If answer “No” to this question, skip to the next section. VA Form 10-0398 [or the the 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-9)
9. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) require the Institutional Biosafety Committee (IBC) review recombinant or synthetic nucleic acid molecule research. Your facility may have additional requirements for research requiring IBC review.

 [↑](#endnote-ref-10)
10. Closure audits are not required for studies that have been audited at least once during the past three years. [↑](#endnote-ref-11)
11. VHA Directive 1200.08(1) §6.f(1). Each PI’s VA laboratory program must be reviewed by the SRS at a convened meeting on an annual basis. The review must include: (a) A list of projects that utilize SRS approved protocols; (b) An evaluation of all SRS approved protocols (individual or umbrella) to ensure that the hazards, BSL, risk assessments, training of personnel and status of the project are up to date; (c) Laboratory inspection report including findings and plans to address any deficiencies; (d) Summary of all changes or amendments to the safety components of the protocol approved since the last review; (e) Changes in space allocation; and (f) Reports of any issues related to employee safety and security. [↑](#endnote-ref-12)
12. If answer “No” to this question, skip to the next section. Information on potential biological hazards associated with the protocol is found in the Research Protocol Safety Survey (RPSS), Section 2 and/or Section 4. [↑](#endnote-ref-13)
13. As defined in Title 42 Code of Federal Regulations (CFR) § 72.6. [↑](#endnote-ref-14)
14. Information on biosafety level associated with the protocol is found in the RPSS, Section 2. [↑](#endnote-ref-15)
15. This can be found the RPSS, Section 3. [↑](#endnote-ref-16)
16. This includes cultures, tissues, blood, other bodily fluids or cell lines. If answer “No” to this question, skip to the next section. Information on cells and tissue samples used by the laboratory is found in the RPSS, Section 4. [↑](#endnote-ref-17)
17. Human blood includes: human blood components and products made from human blood. Other Potentially Infectious Materials means: (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV. Definitions per 29 CFR 1910.1030. [↑](#endnote-ref-18)
18. If answer “No” to this question, skip to the next section. 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-19)
19. VHA Directive 1200.08 §5.o.(4). [↑](#endnote-ref-20)
20. If answer “No” to this question, skip to the next section. Information on the inventory of chemicals used by the laboratory is found in the RPSS, Section 6. [↑](#endnote-ref-21)
21. If answer “No” to this question, skip to the next section. Information on the use of radioactive materials by the laboratory is found in the RPSS, Section 8. [↑](#endnote-ref-22)
22. 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-23)
23. On this page, list all research personnel named on the protocol. [↑](#endnote-ref-24)
24. 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. If safety training 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., TMS) to verify whether a deficiency in fact exists at the time of the RCO audit. NOTE: Lack of any training records is a serious deficiency, although rare. [↑](#endnote-ref-25)