

Providence Veterans Administration Medical Center (PVAMC)
Subcommittee on Research Safety (SRS) Submission Guidelines/Transmittal Sheet
Forms for each type of Protocol Submission

Version: 6.15.2016

Deadlines: The SRS Committee generally meets on the first Thursday of each month in which a meeting is held. Please contact the SRS Coordinator, Candace Shuman for dates. After SRS approval, the protocol will be reviewed by the Research and Development (R&D) Committee, which is held on the last Wednesday of every month.

Please note that submissions must receive approval by the SRS chair in order to be reviewed by the R&D Committee, therefore sufficient time must be allowed for this review to occur. If the conditions are not met, the submission to the R&D will not be reviewed until the following month. For new protocols research may not be initiated until the R&D Committee has fully approved the submission.

Forms required: Original documents of all submissions must be accompanied by this form, and a cover letter describing the request that is signed by the Primary Investigator. Please include a WORD copy of the cover letter and abstract (updated for continuing reviews) with the submission. Documents submitted with secure digital signatures are considered as originals and may be submitted via email. Documents with wet ink signatures may be submitted for pre-review via email but cannot be approved until the originals are submitted for the files kept in research administration.

Signatures: In general, signatures of Primary Investigator, Section Chief, ACOS, Service Chief, and the Training Coordinator are required before submission. When required, signature of Research Safety Officer (ACOS) and Radiation Safety Officer are obtained after SRS review and approval.

Subcommittee on Research Safety (SRS)/R&D Coordinator: Candace Shuman X3872 or at Candace.Shuman@va.gov.

The following documents are required for SRS protocol submissions. The links below will take you to each form. If you cannot view the form you need, contact the SRS Coordinator.

Forms can also be located here: [P:\Safety\8 SRS Submission Forms & Deadline Calendar\Updated SRS Forms 2016](#)

Required Forms for NEW PROPOSALS – All studies

- [P:\Safety\8 SRS Submission Forms & Deadline Calendar\Updated SRS Forms 2016\Request to Review Research Proposal-6.15.2016.doc](#)
- [P:\Safety\8 SRS Submission Forms & Deadline Calendar\Updated SRS Forms 2016\Biosafety Survey Form VA 10-0398 v 06152016.docx](#)
- [P:\Safety\8 SRS Submission Forms & Deadline Calendar\Updated SRS Forms 2016\Chief of Service statement 6.15.2016.doc](#)
- [P:\Safety\8 SRS Submission Forms & Deadline Calendar\Updated SRS Forms 2016\FCOI OGE Form.pdf](#) for PI's and Co-PI's only
- [P:\Safety\8 SRS Submission Forms & Deadline Calendar\Updated SRS Forms 2016\Scope of Work for Bench Work Laboratory Personnel ver 6.15.2016.doc](#) for each staff member named on the protocol
- Abstract (in lay persons terms) and please email a **WORD** version to the SRS Coordinator.
- Full Protocol and when applicable, with the budget
- A **dated** copy of the laboratory Chemical Inventory used in this study/protocol with study name on top
- Copy of applicable Laboratory Specific Standard Operating Procedures (SOP)

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IF APPLICABLE

- Copy of IACUC, Appendix 3 Test Substances
- <P:\Safety\8 SRS Submission Forms & Deadline Calendar\Updated SRS Forms 2016\Scope of Work for Animal-Lab Personnel ver 6.15.2016.doc> for each staff member named on the protocol
- Radioisotope Training documentation and a copy of the signed and dated Radiation Permit (for radioisotope users). This requires approval by the Radiation Safety Officer, in addition to the SRS Committee.
- If the research occurs at another facility, a current, signed Institutional Biosafety Committee (IBC or equivalent) approval letter or letter of exemption for the project.

If there is a safety component: SIGNATURES REQUIRED BEFORE SUBMISSION

- Request from the Research Training Coordinator a signature on both the Request to Review Form and the Biosafety Survey Form. Training must be current and must include: Lab Safety for Research personnel (includes: Chemical Hygiene, Hazardous Drug Awareness, Formaldehyde Awareness and Carcinogens Awareness.); Combined Infection Control and Blood borne Pathogens with Exposure Plan; LIVE Hazardous Waste Training and a one-time training in Biosafety/Biosecurity. If animal use is involved: Waste Anesthetic Gases; and if radiation is in use: Radiation Safety Training.

Required Forms for CONTINUING REVIEWS (conducted annually)

- <P:\Safety\8 SRS Submission Forms & Deadline Calendar\Updated SRS Forms 2016\PVAMC Safety Continuing Review Study Closure Ver 6.15.2016.doc> (any modification between old and new Bio-Safety Form should be checked off and explained under the “amendment” blocks on page 2 of form) with abstract in lay persons terms (complete page 4). Email a **WORD** format of the lay term abstract to the SRS Coordinator. Abstract should include narrative of events from the past year (progress section on page 4)
- A **dated** copy of the laboratory Chemical Inventory used in this study/protocol with study name on top
- Copy of **most recently approved** BioSafety Survey Form

IF APPLICABLE (If documents have been changed and/or updated since last submission.)

- New and/or Additional** Laboratory specific Standard Operating Procedures (SOP) that were **not** submitted with the initial submission
- Updated** copy of <P:\Safety\8 SRS Submission Forms & Deadline Calendar\Updated SRS Forms 2016\Scope of Work for Bench Work Laboratory Personnel ver 6.15.2016.doc>
- Updated** copy of IACUC, Appendix 3 Test Substances
- Updated** copy of <P:\Safety\8 SRS Submission Forms & Deadline Calendar\Updated SRS Forms 2016\Scope of Work for Animal-Lab Personnel ver 6.15.2016.doc> for each staff member named on the protocol
- Radioisotope Training documentation and a copy of the Radiation Permit (for radioisotope users). This requires approval by the Radiation Safety Officer.
- If the research occurs at another facility, current and signed Institutional Biosafety Committee (IBC or equivalent) approval letter or letter of exemption for the project.

Required Forms for Lapsed Protocol Reinstatement Request

NOTE: If your protocol expires past the SRS approval period, the protocol is considered lapsed and automatically falls into a suspended category. No activity can occur with the study in this category. For reinstatement, submit cover letter requesting such and all required documents listed under New Protocols above.

If there is a safety component: SIGNATURES REQUIRED BEFORE SUBMISSION

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- Request from the Research Training Coordinator a signature on both the Request to Review Form and the Biosafety Survey Form. Training must have been completed within the last year and must include: Lab Safety for Research personnel (includes: Chemical Hygiene, Hazardous Drug Awareness, Formaldehyde Awareness and Carcinogens Awareness); Infection Control and Blood borne Pathogens with Exposure Plan; LIVE Hazardous Waste Training and a one-time training in Biosafety/Biosecurity. If animal use is involved: Waste Anesthetic Gases; and if radiation is in use: Radiation Safety Training.
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Required Forms for STUDY CLOSURE

- Cover Memo to the SRS or R&D Committee signed by the PI requesting the study be closed.
 Complete items 1-3 on the Continuing Review/Study Closure Form ver. 6.10.2015 with Signature of PI.
 Summary detailing results from the study. (Page 4 of the Continuing Review/Study Closure Form)
 Summary emailed in **WORD** format to SRS Coordinator.
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Required Forms for MODIFICATION/AMENDMENT Request

- Cover memo detailing modification/amendment (specific item (e.g., protocol))
 Provide modified materials (e.g., pertinent training documentation, protocol, Biosafety Survey, CV, resume, Scope, Conflict of Interest Form, etc.)

If there is a safety component: SIGNATURES REQUIRED BEFORE SUBMISSION

- Request the Research Training Coordinators signature on the **updated** Biosafety Survey Form
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Responses to CONDITIONALLY APPROVED Protocol

- Cover memo from PI detailing responses to conditions
 Copy of “Conditionally Approved” memo issued from the Chairperson (either Committee)
 Items/documents outlined in the Conditional Approval letter
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Responses to TABLED/DISAPPROVED Protocol

- Cover memo signed by PI detailing responses to the requests/conditions
 Copy of “Tabled/Disapproved” letter issued from the Chairperson (either Committee)
 Items/documents outlined in the Tabled/Disapproved letter