

Instructions for completing a Research Protocol Safety Survey (RPSS Form 10-0398) for VA Projects seeking R&DC Approval

The Subcommittee on Research Safety (SRS) must review each RPSS. The Subcommittee will check that the information in the RPSS agrees with that in your grant, pertinent approved protocols and other Project related documentation. It will take 1-2 weeks to review the RPSS. Any delay in submitting the completed RPSS can delay your grant funds being sent from VACO or released for non-VA projects. In addition, exercise the same care in completing the RPSS as for your grant application. For example, please type all information requested in the survey. Handwritten surveys will be returned for remediation. Scanned surveys are additionally not recommended.

All information contained in your grant (or Project packet, if unfunded) regarding safety issues must be comprehensively covered in the RPSS and by various approved protocols that apply to your planned research:

- I. Biological Use Authorization (BUA) Protocol
 - II. Animal Component of Research Protocol (ACORP)
 - III. Human Studies Protocol, i.e., Institutional Review Board (IRB) approval
 - IV. Radiation Safety Protocol or Radioactive Use Authorization (RUA)
 - V. Standard Operating Procedure/s (SOP/s) for hazardous chemicals
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- I. If the research involves biological hazards and/or recombinant DNA, you should have an approved or pending-approval Biological Use Authorization (BUA) Protocol. If not, please complete one as soon as possible and send to Michael Kim, Biosafety Officer (ext. 22229, Michael.Kim2@va.gov).
 - II. If the research involves animals, you should have an approved or pending-approval Animal Component of Research Protocol (ACORP). If not, please complete one as soon as possible and send to Kim Hutchison, Institutional Animal Care and Use Committee (IACUC) Coordinator (ext. 23233, Kimberly.Hutchison2@va.gov). Make sure that the YES box is checked for Item 1.a. on Page 1 of the RPSS.
 - III. If the research involves human subjects, human tissues, fluids etc., or other human-based research, you should have an approved or pending-approval Institutional Review Board (IRB) Protocol. If not, please complete one as soon as possible via the UCSF iRIS online submission system and communicate with HRPP Coordinators, Gregory Green (ext. 22996, Gregory.Green@va.gov) and Jennifer Ransom (ext. 26340, Jennifer.Ransom@va.gov). A human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) **data through intervention or interaction with the individual** OR (2) **identifiable private information**. If the research DOES NOT include human subjects as defined above, then an IRB protocol is not required. Consult Gregory Green for any questions about this.
 - IV. If the use of radioisotopes and/or x-ray is involved in human and non-human research, you should have an approved or pending-approval Radiation Safety Protocol. If not, please complete one as soon as possible and send to Victor Goretsky, Radiation Safety Officer (ext. 24944, Victor.Goretsky@va.gov).
 - V. If the research involves use of hazardous chemicals, you must have signed copies of Standard Operating Procedures (SOPs) in your lab. If the research involves use of permissible amounts of select agents, submit an SOP to Yuichiro Tanaka, Ph.D., Chair of SRS (ext. 22031, Yuichiro.Tanaka@ucsf.edu)

All blank protocols can be downloaded from the VAHCS, San Francisco Research website/Research Subcommittees: <https://dvagov.sharepoint.com/sites/SFC/research/SitePages/Home.aspx>

Make sure that you have a current chemical inventory in the RIO system: <http://vhasfcapprio.v21.med.va.gov/RIO/>
Contact Rakita Singh, Research & Development Safety Officer (RDSO) for help in accessing the RIO program (ext. 24122, Rakita.Singh@va.gov). Make sure that all personnel in your lab know how to access and use the RIO system; i.e., entering and deleting items from the system. Also, ensure that all lab personnel know how to fill out the chemical waste collection form and how to label each waste container. The form and labels are located here:

<https://dvagov.sharepoint.com/sites/SFC/research/srs/SitePages/Home.aspx>

RPSS

Answer all questions on the RPSS. Type-in useful information such as what is done at VA versus UCSF whenever relevant. For Question No. 4 of the RPSS Coversheet, list all linked protocols and make sure that you put “N/A” for protocols that are not applicable to your project. If a protocol is pending, please write, “pending”.

Page 1:

Section 1 (Does the research involve the use of any of the following?)

Make sure that all the information requested in the RPSS Main Form under the “List VA and Non-VA Locations in which PI conducts Research” at the top of Page 1 has been provided, indicating VA Building & Room numbers and off-site locations such as UCSF and all other locations. The date should be the day the form was submitted for review, not the Grant submission deadline date.

From the information provided in the pertinent grant, make sure that all of boxes in Part 1 of Page 1 are checked appropriately. All information provided in the RPSS will be checked against your Grant and various Protocols. If you are using animals, check the YES box for item 1.a.

Pages 2-4:

Sections 2, 3, 4 and 5 (Biological Hazards; Biological Hazards – Description of Use; Cells and Tissue Samples; Recombinant DNA)

Please check that all aspects of research with biological agents and recombinant DNA methodologies presented in your grant are dealt with adequately in these sections. In addition, make sure that the approved BUA covers all aspects of the research described in the grant. Within these sections, you should also provide information on the use of human tissues, cells, fluid, etc., and if the research involves the use of animals, if these are components of the proposed research.

Working with any animal cell line that carries a BSL1 or higher rating mandates the need for a BUA to cover the work. There are, for example, mouse tumor cell lines that are BSL1. Work with most types of mouse and rat primary cultures does not require a BUA. Tumor tissue and CNS tissue are exceptions.

In section 5.c (1), where it asks for the NIH classification (i.e., Risk Group), please refer to the “Guidelines for Research Involving Recombinant DNA Molecules” found at the website: <http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines>

Section 6 (Use of Chemicals)

If the research involves the use of chemical agents, make sure that all the appropriate boxes are checked correctly. If you will not be using a particular agent listed in Part b in the planned research, check the N/A box. If you check the YES box, you must provide proof of training of lab personnel in the use and disposal of these agents. Checking NO may imply you are using but not aware of the hazard.

Page 5:

Section 7 (Controlled Substances)

If the research involves the use of Controlled Substances, make sure that the requested information is provided. If you are not sure that a chemical is a Controlled Substance, check the pdf document that can be found on the Internet site <https://www.deadiversion.usdoj.gov/schedules/orangebook/orangebook.pdf>

Section 8 (Radioactive Materials)

If the research involves the use of radioactive substances, make sure that the requested information is provided.

Section 9 (Physical Hazards)

If the research involves the use of physical hazards, make sure that the requested information is provided.

If these requirements are not met, the RPSS will be returned to the PI for remediation and revision. If you have any questions about completing the RPSS, please contact:

- Yuichiro Tanaka, Ph.D., Chair, Subcommittee on Research Safety (Yuichiro.Tanaka@ucsf.edu) or
- Leslie Cape, R&D Project Compliance Coordinator (Leslie.Cape@va.gov)

When you have completed the RPSS, send it to:

- Rebecca Yu (Rebecca.Yu@va.gov) for a VA-administered grants.
- Natalie Viola (Natalie.Viola@ncire.org) for NCIRE-administered grants.
- Leslie Cape (Leslie.Cape@va.gov) for UCSF-administered grants and Unfunded Projects.