

Department of Veterans Affairs

MEMORANDUM

Date: September 3, 2008

From: Subcommittee on Research Safety (SRS)

Subj: Research Protocol Safety Survey Instructions for the PIs

1. All protocols that are either VA funded, take place in VA facilities, investigate veterans or samples obtained from veterans, or involve VA collaborators require SRS approval. The Research Protocol Safety Survey requires the following information be submitted to the Subcommittee on Research Safety.
 - The Research Protocol Safety Survey Form - answer all questions in explicit detail; make certain that for every question you correctly check the Yes, No, or N/A box.
 - Before submitting your completed form, please make certain that your answers on the front sheet match the information that you provide in the rest of the form.
 - Please clearly indicate in Section 5 (RECOMBINANT DNA) whether you do new cloning or utilize already available plasmids (e.g. from commercial sources) without transferring inserts into the new constructs. If you do not do new cloning and only confirm validity of your constructs by PCR, answer "yes" to question 5b and write "no new cloning" under 5b(1). Otherwise, fill out section 5 completely.
 - If you use adenoviruses in your studies, they are often classified as BSL-2, in some cases BSL-1 in Section 2 (BIOLOGICAL HAZARDS). The work you are conducting will be in the category in Section 5 (RECOMBINANT DNA) according to the NIH Guidelines. Adenoviruses with animal work most likely will be III-D-4a. Adenoviruses in tissue culture would normally be III-D-1a or III-D-3a.
 - Remember that many anesthetics used in animal work are classified as control substances and must be listed in the corresponding section 7
 - Also on Page #3-Under Cell and Tissue Samples-Please indicate how animal and/or human tissue will be disposed.
 - If bloodborne samples are being transported, a statement must be included indicating that the samples are being transported in a double bagged leak-proof container and marked Biohazard.
 - Helpful terminology and suggestions:
 - Standard precautions not universal precautions
 - Bloodborne pathogens not blood-borne pathogens
 - Class II BSC (biosafety cabinet or biological safety cabinet) not BSC-2
 - Please note that proposal/protocol titles must match on all forms. In the case of VA funded studies the titles on all compliance documents must match the proposal title.
 - The Work Proposed/Methods section of the study that you are going to conduct. Provide a detailed description of the **methods** and **techniques** that are being used in the research protocol with specific emphasis on the hazards. Do NOT attach a complete grant application. Copying the Methods section from a grant application is OK.
 - If your Research involves the use of Radioactive materials in VA facilities the Appendix for Radioactive Material is required.
 - If your research involves Human Subjects please contact Melody Higgins (5-6512). Your protocol will have to be reviewed by the University IRB and the VA Human Subjects Subcommittee. **List the IRB approval number** next to the project title on the front page of the Research Protocol Safety Survey Form.

- If your research involves Animal Subjects please contact Dr. Edwin Kriel, Attending Veterinarian (5-7127). Your protocol will have to be reviewed by the University IACUC. **List the IACUC approval number** next to the project title on the front page of the Research Protocol Safety Survey Form.
 - A complete list of chemicals in your laboratory is required. If your work is conducted entirely in the VA, contact Grazyna Zaidel (grazynazaidel@yahoo.com, 5-6518) for your list of chemicals as of fall 2006, and update the list with recently purchased or discarded chemicals in your laboratory. If at least part of your work is performed outside of the VA, you are solely responsible for the completeness of your chemical list.
2. If you have any questions regarding the Research Protocol Safety Survey please contact Sergei P. Atamas, M.D., Ph.D. Chair, Subcommittee on Research Safety at 410-605-7000 x 6468 (5-6468 if calling from the UMB campus), or email satamas@umaryland.edu.
 3. Submit both an electronic copy and a hard copy of your information to Peggy Wess. Peggy is located in the Research Office and can be reached by phone at 410-605-7000 x 6511 (5-6511 if calling from the UMB campus) or 410-605-7130 (this is the main telephone number for the Research Office), or email peggy.wess@va.gov