

Guidance for Investigators in completing Appendix G: Research Protocol Safety Survey.

This guidance document is based on safety regulations in Veterans Health Administration Handbook 1200.8 (March, 2009), available in the VA Research Office. The Durham SRS meets monthly to review this form. Deadlines for SRS submission are available from the Durham VA Research Office.

1. Do I need to complete Appendix G?

YES, Appendix G is required for **ALL** research protocols (lab, human, animal, etc.). Please complete the form in its entirety to avoid delay in approval. Please note, the Appendix G is designed to cover research personnel and research space. Laboratory work performed by clinical personnel in clinical laboratories (i.e., clinical pathology, anatomic pathology, and radiological nuclear imaging) should **NOT** be included in Appendix G.

2. How do I fill out the Appendix G?

Complete the top of the form indicating the **PI, project title, date of submission, and research locations**.

Answer **ALL** questions under Question 1 either **YES** or **NO**. Then complete **ONLY** the relevant questions in 2 to 9. The following questions are paired:

<u>If you mark YES to Question:</u>	<u>Then complete Questions:</u>
1a	2. Biological Hazards; perhaps 3. Biological Hazards
1b	4. Cells & Tissue Samples
1c	5. Recombinant DNA
1d (any)	6. Use of Chemicals
1e	7. Controlled Substances
1f (any)	8. Radioactive Materials
1g (any)	9. Physical Hazards

Do NOT complete unnecessary sub-questions. Please leave them blank or mark them "NOT APPLICABLE."

3. Detailed guidance for completing specific sections of Appendix G

Questions 1a and 2 (Biological Hazards):

Question 1a: Note that **ANIMALS** are included in question. If you use animals, you must reply **YES** to question 1a. Most animal users will respond **NO** to question 2a, and will then skip the rest of Questions 2 and 3.

Question 2 (Biological Hazards):

Question 2a (toxin): "Toxin" here includes biological toxins, but NOT toxic chemicals.

Question 2a (biosafety level): BSL1 includes only agents/toxins that can be handled on an open bench with only a sink for hand-washing (e.g. no fume hood or biosafety hood). For additional guidance on BSL2 or 3 agents, see the CDC/ NIH Handbook (http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html).

Question 3 (Biological Hazards):

Complete this Section ONLY if a BSL2 or BSL3 organism, agent, or biological toxin is listed in Question 2.

Prepare a Standard Operating Procedures (SOP)* document for any BSL2 or BSL3 organism or biological toxin. If you have an SOP, you can state "Refer to SOP" for questions 3e and 3f. If you are unsure whether an SOP is required, please contact Laura Ulczynski, ext 6922.

Question 1b and Question 4 (Cells and Tissue Samples):

Question 1b: This question includes both human and animal materials. Animal research normally requires a **YES** answer to questions 1b and 4a.

Question 4a: Specify the tissue or cell line you are using (e.g., "murine blood and tissues," or "human blood" or "established human cell lines").

Question 4b: All human tissues and cell lines are hazardous and should be manipulated at research BSL2. For more information, consult the CDC/NIH Handbook

http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html. The research service has prepared a document entitled "Standard Operating Procedures. Research using human blood, tissue, or cell lines." Investigators who use any human materials should include a signed copy of this SOP. Please also answer 4b.

Questions 4b and 4c are redundant. Complete 4b, then simply state "Refer to 4b" as the answer to question 4c.

Question 1c and Question 5 (Recombinant DNA):

If you are doing any recombinant DNA research, refer to the NIH Guidelines

http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html to properly complete this section. You will check "YES" for Question 1c even if your research is limited to PCR (this is clarified in Question 5b).

Question 5c(1): Describe briefly what you plan to do, then determine the experimental category based on the NIH Guidelines. Exempt experiments must still be described in full detail so that the SRS can confirm their exempt status.

Question 5c(5): If you are using *E. coli*, specify K12 derivative ("lab strain") or wild type.

Question 1d and Question 6 (Use of Chemicals):

Question 6a. Answer YES. Use of chemicals in your laboratory was reviewed when you submitted your bi-annual chemical inventory or prior to submittal of a new protocol for first time investigators.

Question 6b. Answer all 5 questions YES. Anyone working in a lab with hazardous chemicals must have a basic knowledge about all of these special hazards even if they will not be encountered in the specific research project. Training is the responsibility of the principal investigator. Helpful training resources include the Duke University Lab Manual (<http://www.safety.duke.edu/SafetyManuals/lab/default.htm>), and the Durham VA Laboratory Safety Manual and Chemical Hygiene Plan (hard copies in every VA laboratory). The VA Industrial Hygienist (currently Laura Ulczynski, ext 6922) is available to assist with chemical safety training.

****A current chemical inventory must be submitted with this application.**

Question 1e and Question 7 (Controlled Substances): Self-explanatory.

Question 1f and Question 8 (Radioactive Materials):

If you are using radioactive materials, including radiation-generating equipment in your research laboratory (this excludes clinical laboratories such as radiological nuclear imaging), your research protocol use must be approved by the Radiation Safety Committee. If you are working at Duke, indicate your approval date at Duke.

Question 1g and Section 9 (Non-ionizing Radiation and Physical Hazards):

Questions 9a and 9b must be answered YES. The "Occupational Safety and Health Plan" includes the Durham VA laboratory safety manual, and a large body of policies, directives, and other documents. If your research involves a physical hazard that is not addressed by any current facility policy, please contact the VA Safety Officer for clarification (currently Chlorine Chasten, ext 7554). Annual safety training is required for all research workers. If you have not received this training, please correct this before submitting Appendix G.

Sign and date the form (wet signature required).

4. Appendix G attachments:

***Standard Operating Procedures (SOP) for Particularly Hazardous Substances (PHS):**

Prior to purchasing or bringing a new particularly hazardous substance (PHS) (carcinogen, reproductive toxin, or chemical causing acute toxicity) into a VA research laboratory, please complete the **Particularly Hazardous Substance Use Approval Form** and have it approved by the Industrial Hygienist for Research. Definitions of PHS are included in this document and are available here: <http://www.safety.duke.edu/OHS/phs.htm>. Then, prepare a Standard Operating Procedures (SOP) document for any proposed research involving an unusual hazard to laboratory personnel (e.g., neurotoxins, particularly hazardous chemicals, BSL2 or BSL3 organisms, biological toxins, class 4 lasers, etc.). Model SOPs are available in the VA research office. The SOP will save you time in the long run, as you can refer to it when you respond to future paperwork. It will also serve as a key training document for laboratory workers. If you have questions about whether or not a chemical requires an SOP, please contact the industrial hygienist for guidance.

****Chemical inventory**

If you use any hazardous chemicals, then you MUST include a chemical inventory. Key issues to avoid delays in review: **(1)** This inventory must be current and complete, listing every “hazardous” chemical in your laboratory. Due to practical difficulties in defining “hazardous,” it is advisable to simply list all chemicals. Be sure to include every chemical identified in your protocol, including agents used to sedate animals. **(2)** If your protocol proposes the use of chemicals or toxins not in your current inventory, list them in a separate section of the inventory under “proposed use.” **(3)** Mark with an asterisk all chemicals to be used in the current protocol. **(4)** If you are using a chemical that poses unusual hazards to laboratory personnel (i.e., is a PHS), prepare an SOP document and included it with the application. **(5)** MSDS sheets should not be submitted with Appendix G. However, they must be maintained in your laboratory for all hazardous chemicals.

5. Helpful resources:

The NIH and CDC together publish a handbook, entitled Biosafety in Microbiological and Biomedical Laboratories. The current Fifth edition (September, 2009) is available at <http://www.cdc.gov/biosafety/publications/bmbl5/index.htm>. A hard copy is available in the VA Research Office.

The NIH Guidelines for Research involving Recombinant DNA Molecules are available at <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>.