



TITLE:

Creating an Amendment to an Animal Study Proposal – for Investigators

PURPOSE:

The purpose of this SOP is to provide guidance on information needed when submitting an amendment to an approved Animal Study Proposal (ASP).

GENERAL INFORMATION:

Amendments to ASPs are handled by the NINDS/NIDCD Animal Care and Use Committee (ACUC) in two different ways. Some amendments are considered minor and the ACUC has written and approved a policy to manage these kinds of amendments by a standing delegated review process. Other amendments are considered major and will have a full review by the veterinarians and the ACUC. The sections below will help describe the information needed for either type of amendment.

For either type of amendment, please refer to the “Creating an ASP” (link at http://ahcs.ninds.nih.gov/ACUC_pages/asp.html) for details on information needed for each section of the amendment.

PROCEDURES:

To create the amendment, open the ASP and click on the amendment tab in the upper left corner. The click on create an amendment. The summary page will open. The summary should briefly list the changes being made to the ASP. The summary page does not fold into the protocol when you are renewing the ASP, so specific details about why and how for the amendment to the ASP should be included in Sections D and/or F.

- A. Minor amendments covered by Standing Delegated Review. See policy below to see what changes can be managed via this review process. http://ahcs.ninds.nih.gov/ACUC_pages/pg_007_standing_delegated_review.html
1. If adding a person, make sure that you add the person in Section A using the pull-down menu at the bottom of the co-investigator page.
 - i. Upload the training form for the individual being added. If you scan and upload a training form signed by both the new investigator and the PI, the amendment will be processed faster.
 - ii. After submitting the amendment, click on the preview button. Print the amendment or the signature page for the amendment. Scan/email or fax the signed signature page to the ACUC coordinators.
 - iii. Requests for exemptions from Aseptic Surgical Techniques training should be made in the comments/duties section for the person being added.
 - iv. If co-investigators have left the section, you can remove them by checking the box “check for removal” to the far right of the row with the person’s name.
 2. The ACUC asks that the investigator adds a statement in Section D explaining how the requested changes are related to the original goals of the ASP. Adding a person would be an exception to this requirement.

- B. Major amendments require veterinarian pre-review and full committee review by the ACUC. Use the “Creating an ASP” SOP as a guide for each section. (http://ahcs.ninds.nih.gov/ACUC_pages/asp.html) For major amendments, each section of the protocol should be reviewed. If the new additions affect the section, you should provide information requested in that Section. Amendments to approved ASPs require the same level of detail for new procedures as would be required in a new ASP. Section D is required for all major amendments.
1. The summary should briefly describe the reason for each addition or change to the new procedures described in the amendment.
 2. If adding animal numbers to a previously approved species, please update the species tab in Section B with all information about the animals being added. Add the name of the strains being added. If you have two years left on the ASP, put the animal numbers in years two and three. If there are phenotypic issues with the animals that affect husbandry or the health of the animal describe this in Section F, put special husbandry information in Section M and update your intervention and input chart to include information for the care of the animals.
 3. If adding a new species to the ASP, you will need to add the species on the “general information” tab of Section B open the species tab and complete all information on the species being added. In addition, please provide information in Section D, describing how the addition of these animals helps achieve the goals of the original ASP. In Section E.2, clarify why the new species is appropriate for the work being done. In Section E.3, justify the animal numbers being requested for the amendment. Please clarify in Section F, which procedures will be used with the new species. Add a new disposition form for the species being added.
 4. If changes to transportation from the animal holding room(s) to procedure areas will change, please indicate these changes in Section C.
 5. In Section D, please provide information on how the new procedures or other changes will help you achieve the original goals of the ASP.
 6. If adding $\geq 10\%$ animals, please expand the information in Section E.3, so that the animal numbers are justified.
 7. Section F: refer to the information in the “Create an ASP” SOP for this section to ensure that all elements of the new procedures are described.
 8. When adding survival surgery, a brief discussion of the surgery and how it fits into the experimental paradigm should lead the reader to Section G for detailed information on the surgery. In Section G, answer each question in the instruction section.
 9. Section H provides the pain/distress category for animals undergoing the new procedures.
 - i. If animals have been added to the ASP, they should be reflected in the correct pain category in Section H. If the animals will have previously approved procedures that place them in Column D or E, a new data base search for alternatives is not required. If the animals will have procedures not previously approved that cause them to be in Column D or E, a new data base search for less painful/distressful procedures using keywords related to the new procedures should be conducted.
 - ii. If animals that have already been approved for the ASP will be used for the new procedures and if the new procedure changes the pain/distress category for the animals, this should also be reflected in this section of the amendment. (E.g. if 50 animals are being moved from Column C to Column D—put a minus 50 [-50] in Column C and then a plus 50 [50] in Column D.) This does not increase the overall number of animals; it just changes the pain/distress category.
 10. Section I should list each analgesic or anesthetic being added in the amendment and provide information on dose, volume, route of administration, and procedures that will use each agent. Please use a separate paragraph for each agent.

11. Section J should describe all methods of euthanasia being added in the amendment. Dose, volume, route of administration should be described. If more than one method of euthanasia is being added, please describe each in a separate paragraph.
12. Section K should list any hazardous agent being added in the amendment. If safety documentation will be required, please contact the DOHS safety representative to begin the process as soon as possible. If documents for a vector, etc have been submitted to DOHS, name the vector and state that it has been submitted for safety review.
13. Section L is to provide information on any cell lines or other biological material being added in the amendment. Cell lines should be tested for microbial contamination.
14. Any special husbandry or handling requirements should be described in Section M.
15. Multiple supplemental documents may be required. See the "Create an ASP" directions for information on these documents.

REFERENCES:

1. U.S. Department of Agriculture. Animal and Plant Health Inspection Service. 9 CFR Part 3: Animal Welfare Standards; Final Rule. Federal Register 56(32):6426-6505 (1991).
2. National Academy of Sciences/Institute for Laboratory Animal Resources. Guide for the Care and Use of Laboratory Animals. National Academy Press, 2011.
3. Manual 3040-2: Animal Care and Use in the Intramural Program
4. NINDS/NIDCD Animal Health and Care Website <http://ahcs.ninds.nih.gov/>
5. AHCS – ACUC Information: http://ahcs.ninds.nih.gov/ACUC_pages/index.html
6. NINDS/NIDCD AHCS - provides information about aspects of animal care after the ASP has been approved: http://ahcs.ninds.nih.gov/AHCS_pages/index.html
7. NINDS/NIDCD ASP information: http://ahcs.ninds.nih.gov/ACUC_pages/asp.html
8. NINDS/NIDCD ACUC training information
http://ahcs.ninds.nih.gov/ACUC_pages/train.html
9. NINDS/NIDCD AHCS animal transfer information is available at :
http://ahcs.ninds.nih.gov/AHCS_pages/imp_nihpolicy.html
10. NINDS/NIDCD ACUC policy and guidelines
http://ahcs.ninds.nih.gov/ACUC_pages/pg.html
11. NINDS/NIDCD ACUC policy on the scheduling of survival surgery:
http://ahcs.ninds.nih.gov/ACUC_pages/pg_015_surv_surg_scheduling.html
12. NINDS/NIDCD ACUC policy on Aseptic Techniques training for survival surgery ASPs:
http://ahcs.ninds.nih.gov/ACUC_pages/train_aseptic.html
13. NINDS/NIDCD ACUC policy on multiple survival surgeries in a single animal:
http://ahcs.ninds.nih.gov/ACUC_pages/pg_001_mmss.html
14. ARAC guideline on the euthanasia of adult rodents:
http://oacu.od.nih.gov/ARAC/documents/Rodent_Euthanasia_Adult.pdf
15. NINDS/NIDCD ACUC policy on the euthanasia of rat or mouse neonates:
http://ahcs.ninds.nih.gov/ACUC_pages/pg_003_euth_neo.html
16. NINDS/NIDCD ACUC policy on euthanasia by cervical dislocation without anesthesia:
http://ahcs.ninds.nih.gov/ACUC_pages/pg_009_cervdis.html
17. NIH Division of Safety documents for the approval of the use of rDNA and other biological agents:
http://www.ors.od.nih.gov/sr/dohs/BioSafety/Pages/bio_chem_safety.aspx

18. NIH Division of Radiation Safety documents for the approval of the use of radionuclides or other radioactive agents: <http://www.ors.od.nih.gov/sr/drs/rsc/Pages/index.aspx>
19. NINDS/NIDCD ACUC policy for testing of tissue, cells, or other biological agents: http://ahcs.ninds.nih.gov/ACUC_pages/pg_002_culture_testing.html
20. NINDS/NIDCD ACUC supplemental documents on the website: http://ahcs.ninds.nih.gov/ACUC_pages/forms.html

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Attachments:

1. None