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/NCCIH Animal Care and Use Committee (ACUC) in several ways. The ACUC has written and approved a policy to distinguish how amendments will be processed (https://ahcs.ninds.nih.gov/ACUC_pages/pg_007_significant_changes.html). The sections below will help describe the information needed for either minor or significant amendments.

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. Then click on the “Create an Amendment” button. 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 should be included in the Sections of the amendment.

A. Minor amendments covered by the Unconditional Administrative Process. See policy below to see what changes can be managed via this review process. https://ahcs.ninds.nih.gov/ACUC_pages/pg_007_significant_changes.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. If the person is not on the pull-down menu, please contact the ACUC coordinators to have them added to the list of investigators.
   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.

2. 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.

B. Significant amendments fall into two categories, those that qualify for the Conditional Administrative Review Process and those that do not
(https://ahcs.ninds.nih.gov/ACUC_pages/pg_007_significant_changes.html), but all significant amendments require the same level of detail for new procedures as would be required in a new ASP. Section D is required for all significant amendments.

1. The summary should briefly describe the addition or change to the ASP and provide a brief description of each new procedure 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.

3. When adding a new species to the ASP:
   a. On the "general information" tab in Section B, use the pull-down menu to choose the species. Once the name of the species is in the box, click on "Add a new species". Open the species tab for the new animals.
   b. Add all information requested on the page.
   c. Add the name of all of the strains being added.
   d. If you have two years left on the ASP, put the animal numbers in years two and three.
   e. In addition, please provide information in Section D, describing how the addition of these animals helps achieve the goals of the original ASP.
   f. In Section E.2, clarify why the new species is appropriate for the work being done.
   g. In Section E.3, justify the animal numbers being requested for the amendment.
   h. Section F, clearly state which procedures will be used with the new species.
   i. 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 describe 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 animals, please expand the information in Section E.3, so that requested additional 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, complete each part in the instruction section.
   a. Identify and describe the surgical procedure(s) to be performed. Include the aseptic methods to be utilized.
   b. Who will perform the surgery and what are their qualifications and/or experience?
   c. Where will the surgery be performed: Building/Room?
   d. Describe post-operative care required, including considerations of the use of post-operative analgesics, and identify the responsible individual.
   e. Has major survival surgery been performed on any animal prior to being placed on this study? If yes, please justify.
   f. Will more than one major survival surgery be performed on an animal while on this study? If yes, please justify.

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 procedures that cause them to be in Column D or E, a new data base search (2 databases) for alternatives to painful/distressful procedures using keywords related to the procedures should be conducted. If the animals will have previously approved procedures that place them in Column D or E, a new data base search for alternatives is still required.
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 than a plus 50 [50] in Column D.) This does not increase the overall number of animals; it just changes the pain/distress category. A new database search for alternatives is required.

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. All cell lines should be tested for microbial contamination regardless of the source species.

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:

2. NINDS/NIDCD/NCCIH ACUC policy on significant changes: https://ahcs.ninds.nih.gov/ACUC_pages/pg_007_significant_changes.html

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Attachments:

1. None

Updates and/or Changes:
4/13/17:

- Added ACUC policy on significant changes as a reference
- Mentioned the unconditional administrative process
- Section B9i. Added If the animals will have previously approved procedures that place them in Column D or E, a new data base search for alternatives is still required
- Removed irrelevant references