



**TITLE:**  
**Renewing an Animal Study Proposal – for Investigators**

**PURPOSE:**

The purpose of this SOP is to provide guidance for investigators who are renewing an Animal Study Proposal (ASP).

**GENERAL INFORMATION:**

All ASPs at the NIH must be renewed *de novo* at least every three years. Failure to have an approved ASP in place when the previous iteration expires has serious consequences. Public Health Service (PHS) policy allows no grace period past the expiration date of the ASP. In the event the approval of the renewal does not occur by the expiration date of the previous ASP, any animal activity performed on the animals, (e.g., specimen or data collection, etc.) would become an Office of the Laboratory Animal Welfare (OLAW) reportable event. Any animals held in NIH facilities under the expired ASP will become the property of the ACUC and investigators will not be allowed access to these animals until a completed and approved ASP is available.

Information on working within the Internet Animal Study Proposal (IASP) can be found in SOP 8720. Information on creating a new animal study proposal can be found in SOP 8721. Information in both of these documents may be helpful as you write your renewal. All SOPs regarding Animal Study Proposals will be available in the ACUC section of the Animal Health Care Section web site: <http://ahcs.ninds.nih.gov/>

**PROCEDURES:**

- A. Use the previous ASP and amendments to create the renewal
  1. In the IASP, open the ASP that you will be renewing.
    - i. Click on “Renew Protocol”.
    - ii. A new page will open, do not hit continue yet.
    - iii. Scroll down the page. The ASP will scroll down by section. Check the box to the left for everything that you want transferred to the renewal.
    - iv. For all amendments, the amendment sections will follow the section for the original ASP. If you want to have the amendment information copied into the renewal of the ASP, check the box.
    - v. At the bottom of the page, after you have checked the box of everything you want copied to the renewal ASP, click on the continue button.
- B. The renewal will open. Please note the name of the protocol in the upper right corner has changed to some version of your NIH log-in with a number behind it. This is the name of the renewal until it is fully approved. The status should read pending.
  1. When you have chosen amendment parts to be added to the original, the renewal will just have them pasted below the original text in the appropriate section. To make the reviewing and rewording the renewal easier, it is suggested that you click on the preview button. A PDF copy of the ASP will open. Print the PDF version and read through it marking areas where text will need to be rearranged to make the renewal submission cogent.

2. After reviewing the ASP in its current state, you can start making changes and corrections to the information from the original ASP. Go through each section and tab of the ASP to ensure that the data is correct.
  3. The IASP will time out if you spend too much time working in a section and not connecting to the server. Clicking save frequently communicates with the server and can protect you from getting locked out of the IASP and losing data you have entered.
  4. For sections with text boxes, it is better to work on any changes in a word document. When you have finished word-smithing the text and putting amendment data in the section in a sequential manner, you can paste the information from the word document into the text box in the renewal.
- C. Supplemental documents are not copied into the ASP renewal. You will need to open the supplemental documents from the original ASP, and from amendments to the original ASP, and save them on your computer. Please use SOP 8721 Creating an ASP as a guide when writing the renewal. After three years, there may be components of the requested material that has been forgotten.
1. Using the supplemental documents you have saved on your computer from the original ASP and amendments, you can combine data if needed (e.g., you have multiple intervention and endpoint charts because you have added procedures to the original ASP via amendments). Put the information that will be useful in the renewal in one intervention and endpoint chart and upload the combined chart).
  2. If there are people, procedures or other things which are no longer relevant to the renewal, you can remove these from the appropriate supplemental document or in the case of personnel, in Section A.
- D. Submit the renewal to the ACUC coordinators by clicking on the “submit” button. A box will open asking if you really want to submit the document and you must click the submit” button in the box. The status of the renewal will change to locked and the normal processing of the protocol will begin.

#### 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. PHS Policy on Humane Care and Use of Laboratory Animals: <http://grants.nih.gov/grants/olaw/references/phspol.htm>
4. Manual 3040-2: [Animal Care and Use in the Intramural Program](#)

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Attachments:

None