



TITLE:

Creating the Annual Review for an Animal Study Proposal – For Investigators

PURPOSE:

The purpose of this SOP is to provide the investigator with information regarding the requirements for the annual review of an Animal Study Proposal (ASP) and to describe how the annual review is prepared in the Internet Animal Study Proposal (IASP) website.

GENERAL INFORMATION:

The Animal Welfare Act Regulations, The Guide to the Care and Use of Laboratory Animals, and the Public Health Service Policy on Humane Care and Use of Laboratory Animals require the ACUC to conduct continuing reviews of activities covered in an approved ASP. An annual review of the ASP is required at the first and second year anniversary of the approval of a three year ASP.

PROCEDURES:

The annual review consists of two documents; the first is a questionnaire that must be completed and the second is a revised disposition form. The last disposition form may not have any changes, but the ACUC would like the form to be reviewed for accuracy (points of contact etc) and the current date put on the form. Both of these documents must be signed by the Principal Investigator (PI). To start an annual review, open the appropriate ASP and click on the “Annual Review” tab in the upper left corner. When this opens, chose “Create an annual review” and the questionnaire will open

A. The Annual Review Questionnaire – answer all questions.

1. Question 3 – if unforeseen complications occurred during the performance of an experiment, check the “yes” box and answer all of the questions in #4.
2. Question 4 – in the event of unforeseen complications, please provide the ACUC with all of the information requested in subsections 4a) through 4e). These answers provide valuable information about the complication, how the problem was addressed and how you plan to avoid these complications in the future.
 - i. If the complications caused an animal to be categorized as Column E and this is not their original pain/distress category, a Column E justification must be added to the ASP. An amendment to cover the animals affected by the complication must be submitted and the approved amendment number should be listed in 4d).
 - ii. The complications will also require an amendment to adjust or change the procedure that was previously approved. Provide the approved amendment number under 4e).
3. Question 5 – please provide a description of any refinement to an approved procedure that resulted in less pain/distress for the animal. Provide the approved amendment number for the refinement in this question.
4. Question 7 – if new co-investigators will be conducting procedures under this ASP, please make sure that an amendment to add the investigator(s) has been approved before allowing the person to perform and work with animals.

5. Question 8 – if a guillotine is approved for use in the approved ASP, please check the date of the last sharpening/servicing of the guillotine. See the NINDS/NIDCD policy on the maintenance and use of guillotines. http://ahcs.ninds.nih.gov/ACUC_pages/pg_014_guillotine.html. If you would like to add the use of a guillotine to the ASP, please make sure that you have an approved amendment before using the guillotine.
- B. The updated Disposition Form – the NINDS/NIDCD ACUC asks that a new disposition form be uploaded as an attachment for each annual review. This ensures that any point of contact, housing location, treatment and criteria for euthanasia are accurate.
1. The form can be downloaded to your computer from the supplements page of the IASP. There is a link to the template forms in the text above the upload boxes.
 2. Complete the form with the current date and current information for your ASP. If more than one species is covered under the ASP, please complete a separate form for each species.
 3. Save the changes made to the form on your computer and upload the saved form into the supplement section of the IASP.
- C. Submitting the annual review and the signed pages.
1. When the questionnaire is completed and the disposition forms have been uploaded into the supplements section, click on the submit button. A text box will open asking if you are sure that you want to submit the form. Click on submit within the text box. The annual review is now locked.
 2. Before leaving the IASP, click on the “Preview” button and a PDF of the questionnaire will open. Print this and have the PI sign the form. Print the disposition form(s) and have the PI sign this/these.
 3. Send the signed questionnaire and disposition forms to the ACUC Coordinators. You can scan/email, fax (301-402-5424), drop the forms by the ACUC office or send the signed documents in the NIH office mail.

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. NINDS/NIDCD ACUC Policy on the Use and Maintenance of Guillotines - http://ahcs.ninds.nih.gov/ACUC_pages/pg_014_guillotine.html
5. Manual 3040-2: [Animal Care and Use in the Intramural Program](#)

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Attachments:

None