

NIDA ACUC Policy for Review of Significant Changes to Animal Study Proposals (Amendments)

ACUC approved: January 2019

Introduction:

This policy is in accord with the NIH Animal Research Advisory Committee's (ARAC) Guideline Regarding Significant Changes to Animal Study Proposals, which was revised to address the OLAW Revised Guidance on Significant Changes to Animal Activities:

All amended changes to Animal Study Proposals are to be submitted on a single form which is NIDA IRP Amendment to an Animal Study Proposal form. The amendment is Categorized (1,2.1,2.2, or 3) as determined by the criteria outlined below in this document. The amendment will be reviewed in accordance with the procedures for the respective Category.

I. Significant Changes: Categories 1, 2.1, and 2.2

A. Category 1: Mandatory non-administrative changes

These amendments require **Full Committee Review (FCR)**:

1. Changes from non-survival to survival surgery
2. Changes resulting in greater pain, distress or degree of invasiveness
3. Changes in housing and or use of animals in a location that is not currently part of the animal program overseen by the ACUC
4. Changes in species
5. Changes in study objectives
6. Changes in Principal Investigator (PI)

7. Changes that could impact personnel safety
8. Increase in animal numbers greater than 10% of previously approved amount
9. Change in genotype/strain/stock of animal with adverse phenotype.

Procedure: The ACUC Administrator places the amendment on the agenda for FCR. Following FCR review and approval, changes are updated in the Filemaker system. The ACUC Administrator notifies Animal Care staff via email of changes that require their attention, and also sends an approval letter to the PI.

B. Category 2.1: Conditional Administrative Changes (Veterinary Review with PI consultation)

These changes may be approved by the **NIDA veterinarians (the Animal Program Director or Facility Veterinarian) in consultation with the principal investigator** when changes are within the scope of the following:

1. Changes in anesthesia, analgesia, sedation or experimental substances when consistent with NIDA Guidelines on Anesthetics and Analgesics and Guidelines on Selecting Doses of Investigational Drugs
2. Changes in method of euthanasia when consistent with AVMA, ARAC and NIDA SOP policies.
[AVMA Policy](#)
[ARAC Policy](#)
[NIDA SOP](#)
3. Changes in substances that are the same class of compounds currently approved in the ASP and which are not expected to increase pain or distress, impact the approved endpoint criteria, or impact the approved personnel safety considerations.
4. Change in duration, frequency, type or number of procedures performed on an animal that are not expected to increase pain or distress, impact the approved endpoint criteria, or impact the approved personnel safety considerations. The following

procedures are allowed:

- a. Catheter re-implantation of a separate jugular or femoral vein in rodents using methods consistent with the previously approved protocol and when required for completion of studies. The original catheter must be surgically removed prior to implantation of the new catheter and the removal must be described in the protocol. The use of Equithesin or chloral hydrate for anesthesia must not be repeated in any subsequent surgeries due to the increased risk of developing adynamic ileus. Under this type of approval no rodents can exceed a maximum of two catheter implantations and one removal surgery which includes implantations performed by a vendor.
 - b. Additional compound injections, change in route of administration, and/or dose of the already approved compound, with no expected change in humane endpoint
 - c. Addition of compounds in the same class of compounds as currently listed
 - d. Replacement of osmotic mini-pumps, provided the methods are consistent with the originally approved protocol
 - e. Addition of ear punching for biopsies for genotyping
[NIDA SOP](#)
 - f. Addition of compounds to control gene expression when a new genotype is added
 - g. Change in blood sampling method consistent with ARAC guidelines
[ARAC Rodent Bleeding Guideline](#)
 - h. Change in food/water restriction consistent with ARAC guidelines
[ARAC Diet Control Guideline](#)
[NIDA SOP](#)
 - i. Estrus cycle phase determination in rodents via cytology.
5. For rodents, change in provision of enrichment or type of enrichment.

Procedure: The ACUC Administrator forwards the amendment to the veterinarian for review. The consultation with the veterinarian is documented and this is attached to the final approved Amendment form. Following approval by the veterinarian, the ACUC Administrator then sends an approval notice to the PI. A hard copy of both is placed in

the file and also is filed electronically. Changes are updated in the Filemaker system. A list of approved changes including protocol number, PI, title and description of the change is provided to the ACUC via the agenda and is recorded in the meeting minutes. The ACUC Administrator notifies Animal Care staff via email of changes that require their attention.

Note: The veterinarian has the option to refer the proposed change to FCR.

C. Category 2.2: Conditional Administrative (Veterinary Review)

These changes may be approved by the **NIDA veterinarians (the Animal Program Director or Facility Veterinarian)**

1. Increase of $\leq 10\%$ of previously approved animal numbers, providing that the increase is not due to a change in the objectives of the study.
A rationale for the increase should be provided and the designee will alert the ACUC if the increase is through animal mortality or unexpected events.
2. Change in genotype/strain/stock/source/age/sex of animal provided there is no anticipated adverse phenotype and the addition does not increase the number of previously approved animals by greater than 10%, and does not require DOHS review or registration.
3. Change to single housing for rodents with justification consistent with ARAC social housing guidelines.

Procedure: The ACUC Administrator forwards the amendment to the veterinarian for review. Following approval by the veterinarian, the ACUC Administrator sends an approval notice to the PI along with the approved Amendment form. Hard copies of both are placed on file and also filed electronically. Changes are updated in the Filemaker system. A list of approved changes including protocol number, PI, title and description of the change is provided to the ACUC via the agenda and is recorded in the meeting minutes. The ACUC Administrator notifies Animal Care staff via email of changes that require their attention.

Note: The veterinarian has the option to refer the proposed change to FCR.

II. Minor Changes:

Category 3: Unconditional Administrative (Administrative Review)

The following changes may be approved by the ACUC Administrator.

1. Correction of typographical errors
2. Correction of grammar
3. Contact information updates
4. Change in room location or other area currently overseen by the ACUC
5. Change in personnel other than the PI.

Procedure: For items 1 through 4, the ACUC Administrator makes the changes in the Amendment form. For addition of personnel, the PI submits an amendment using the NIDA IRP Amendment to an Animal Study Proposal form. All in-processing procedures (enrollment in the AEP, attendance at New Hire Orientation Animal User training, completion of the Personnel Qualifications form, online OACU Using Animals in Research training completion, meeting with facility veterinarian and meeting with facility manager) are verified by the ACUC Administrator. The ACUC Administrator sends an approval notice to the PI along with the approved version of the Amendment form. Hard copies of both are placed in the file and filed electronically. Changes are updated in the Filemaker system. A list of approved changes in animal number including protocol number, PI, title and description of the change is provided to the ACUC in the next meeting's agenda.

The NIDA ACUC and Animal Program policies, guidelines and standard operating procedures are reviewed by the ACUC at appropriate intervals of no less than once every three years to ensure they reflect current practices.

ACUC approved 02/26/2015

Revised 04/24/2015 (change wording in Category 2.2)

ACUC approved 05/28/2015

Revised 08/07/2015 (add text requested by OACU)

ACUC approved 08/27/2015

Revised 09/21/2015 (change version tracking, add enrichment changes as Cat. 2.1)

ACUC approved 09/24/2015

Revised 11/17/2015 (add /source/age/sex and change to single housing to Cat. 2.2)

ACUC approved 11/19/2015

Revised 01/20/2016 (Added text in Category 2.1, 4, a and b)

ACUC approved 01/20/2016

Revised 01/2018 (Added text in Category 2.1)

ACUC approved 01/25/2018
Revised 01/05/2019 to incorporate new NIDA Amendment system.
ACUC approved 01/24/2019