



POLICY

TITLE:	Changes to Approved Protocols
Policy Number:	2014-048
Responsible Department:	Institutional Animal Care and Use Committee
Policy Contact: Designation: E-Mail:	Donald E. Walters, Ph.D. Chair, Institutional Animal Care and Use Committee dewalters@westernu.edu
Approval Date:	10/8/14
Reviewed:	5/10/17; 6/10/2020
Revised:	10/26/16 (Agreement with formulary); 5/10/17 (Added more changes that can be made in consultation with vet); 9/13/18 (Defined administrative changes and who can make them; eliminated approving increases in animal numbers based on % increase); 6/10/2020 (Added link to OLAW guidance)
Legislation:	Animal Welfare Act (Title 9 CFR Subchapter A, Part 2, Subpart C, § 2.31(d)(1)(i)-(iv))

Purpose of Policy: Describes the process by which requested changes in an Institutional Animal Care and Use Committee (IACUC)-approved protocol will be made.

Policy Information: [Public Health Service \(PHS\) Policy](#) IV.C.1 and the [Animal Welfare Act](#) define the responsibilities of the IACUC regarding review and approval of proposed significant changes to animal activities. Changes to approved research projects must be conducted in accordance with the institution's [Assurance of Compliance](#), the United States Department of Agriculture (USDA) and Animal Welfare Act regulations and must be consistent with the [Guide for the Care and Use of Laboratory Animals](#) unless an acceptable justification for a departure is presented. The IACUC is responsible for assuring that any changes to approved animal activities meet the requirements described in PHS Policy IV.C.1.a-g.

In accordance with [PHS Policy](#) IV.C.1.a-g, the IACUC has some discretion to define what it considers a significant change to a previously approved protocol. It is the responsibility of the IACUC to clearly define and communicate its policy for determining significance to investigators. Significant changes generally include changes that have, or may have a negative impact on animal welfare, although some activities that may not have a direct impact on animal welfare are also considered to be significant. Refer [here](#) for additional guidance from the Office of Laboratory Animal Welfare (OLAW).

Policy:

Changes Requiring Committee Review

The following significant changes in an IACUC-approved protocol must be submitted to the IACUC and approved either by Full Committee Review (FCR) or Designated Member Review (DMR) as described in [PHS Policy IV.C.2](#).

- from non-survival to survival surgery
- resulting in greater pain, distress or degree of invasiveness
- in housing and/or use of animals in a location that is not part of the animal program overseen by the IACUC
- in species
- in study objectives
- in Principal Investigator (PI)
- that impact personnel safety

Administrative Changes^{*} in Consultation with the Veterinarian

The following significant changes may be handled administratively in consultation with the Attending Veterinarian (AV) at either campus; i.e., per Veterinarian Verification and Consultation (VVC). In these instances, the AV is serving as a subject matter expert to verify that compliance with IACUC-approved policies is appropriate for the animals involved. **Consultation with the AV must be documented.** The AV may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC-approved policies.

- Change in diet provided that the new diet does not create a new change in animal health status.
- Blood and tissue collection for genotyping:
 - 1) Change between approved methods of blood collection (route, frequency, volume) as stated within IACUC Policy 2014-004 “Blood Collection”
 - 2) Change between tissue types for genotyping according to IACUC Policy 2014-028 “Genotyping Rodents”.
 - 3) Collection of additional tissue after euthanasia.
 - 4) Non-invasive collection of urine, saliva, feces or other specimens.
- Anesthesia, analgesia, sedation or experimental substances. Changes in anesthetic, analgesia or sedation regimens must be in accordance with the IACUC’s approved Laboratory Animal [Formulary](#) per IACUC Policy 2017-056 or appropriately documented by the AV if the dose, dosing frequency or duration of administration differs from the Formulary.
- Euthanasia to any method approved in the latest version of the [AVMA Guidelines for the Euthanasia of Animals](#)
- Duration, frequency, type or number of procedures performed on an animal
- Procedures:
 - 1) Change to study timelines as long as animal health is not expected to deteriorate.
 - 2) Addition of special husbandry or nursing care as prescribed by a veterinarian.
 - 3) Addition of pre-defined Pain Category C behavioral tests to approved protocols that already include behavior testing provided that there is an IACUC-approved

Standard Operating Procedure (SOP) for the behavioral test to be added and that the request is documented in the protocol.

- 4) Variations to previously approved surgeries that do not increase the invasiveness or expected outcomes.

Administrative Changes* Not Requiring Consultation with the Veterinarian

As stated in the National Institutes of Health notice [NOT-OD-14-126](#), “A significant change that may be handled administratively according to existing IACUC policies without additional consultation or notification is an increase in previously approved animal numbers.” Pursuant to this Notice, it is the policy of WesternU’s IACUC that an increase in animal numbers shall be permitted provided that the following conditions are met:

- The request must be submitted by the Principal Investigator, in writing, to the IACUC Secretary or to the IACUC Chair for approval prior to acquiring additional animals.
- The request must include a detailed explanation of why the additional animals are necessary based on the original study objectives.
- A justification for the numbers of additional animals requested must be provided.
- The study objectives, as described in the approved protocol, must remain the same.

As noted above, a change in the original study objectives, or any change in protocol that impacts animal welfare, will require the request to be submitted to the IACUC for review and approval. Such changes may not be administratively approved.

Once approved, the amendment request, along with the IACUC’s approval, shall be attached to the end of the approved protocol and kept on file in the IACUC Office.

Other changes that may be made administratively without further consultation include:

- correction of typographical errors
- correction of grammar
- contact information updates
- changes in personnel other than the PI (However, there must be an administrative review to ensure that all such personnel are appropriately trained, qualified, enrolled in the occupational health and safety program and meet any other criteria as required by the IACUC.)

Per National Institutes of Health notice [NOT-OD-14-126](#), the USDA Animal and Plant Health Inspection Service concurs with the information presented in this notice.

NOTE: All approved changes must be immediately incorporated into the body of the approved protocol or attached to the end of the protocol along with the IACUC’s note of approval and the date on which the changes were approved.

* For the purpose of this policy, administrative changes are defined as changes made outside of FCR or DMR that have been approved by the Attending Veterinarian AND the IACUC Chair or Vice Chair in the Chair’s absence. Administrative changes should be reported and included in the minutes of the next regularly scheduled IACUC meeting.

Reference: [NOT-OD-14-126](#), *Guidance on Significant Changes to Animal Activities*