UCSF Office of Research
Institutional Animal
Care and Use Program

Administrative Approval of Significant Changes using Veterinary Verification and Consultation (VVC)

IACUP Policy
Effective Date: 05/19/2020

I. Purpose

This policy outlines situations and circumstances where significant changes to an IACUC protocol may be handled administratively, without Full Committee or Designated Member review, in compliance with NIH and USDA guidance.

II. Regulatory or Accreditation Authority

The PHS Policy on Humane Care and Use of Laboratory Animals (Policy) (IV.C.1.) and Animal Welfare Regulations (9 CFR 2.31 (d) (1) (i)-(iv)) 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, the United States Department of Agriculture (USDA) Animal Welfare Act and Animal Welfare Regulations and must be consistent with the Guide unless an acceptable justification for a departure is presented. Additionally, IACUCs are responsible for assuring that the changes to approved animal activities meet the requirements described in the PHS Policy IV.C.1.a-g

III. Scope

This policy applies to the review of IACUC protocols with significant changes using Veterinary Verification and Consultation (VVC).

IV. Policy

Some significant changes to an IACUC protocol may be handled administratively by IACUC staff in consultation with a LARC or IACUP veterinarian. These changes must be made in accordance with an existing IACUC or LARC approved guideline, procedure, or policy, and meet the criteria listed in B. and C. below, as determined by a LARC or IACUP veterinarian.

A. Veterinarian Authority

The LARC or IACUP veterinarian has the authority to request IACUC review of proposed changes for any reason, and must request IACUC review for any changes which do not meet

the parameters of this policy. The veterinarian is the subject matter expert who determines that the change meets IACUC policies and does not require committee review.

B. Significant Changes

Regulators at NIH and USDA define Significant Changes in animal protocols as those that have, or have the potential to have, a negative impact on animal welfare; on human health and safety; or some other matters, such as changes that may actually increase animal welfare, or changes in Principal Investigator.

Significant changes may be approved without Full Committee or Designated Member review in the following areas:

1.) Changes to compounds or dosage of Anesthesia, Analgesia, Sedation, or Experimental Substances. Examples of changes which may be approved under this category are:
    a. A change in dosage, route, frequency or duration within acceptable and known veterinary parameters; using agents listed in the Reference below.
    b. Switching from one analgesic, anesthetic, or sedative agent to another; or
    c. Changing the dosage, timing or route of an experimental substance if that will not increase the potential for animal pain or distress.
2.) Changing euthanasia method to any method approved in the AVMA guidelines.
3.) Changes in duration, frequency, number, and type of procedures performed. Typical examples under this category may include:
    a. Changing an already approved procedure on the protocol in terms of its duration, frequency, number, or type, consistent with IACUC and LARC policies, guidelines, and standard procedures
    b. Changes in experimental timeline (e.g., resulting from unanticipated delays) that do not negatively impact animal welfare and health. Approved monitoring, humane endpoints and associated documentation are required, when applicable, during periods of delay.
    c. Changing a surgery from survival to non-survival
4.) Increasing the number of non-USDA regulated animals approved for study by up to 10%.

C. Changes Requiring IACUC Approval

Changes which would otherwise fit under the categories listed above in accordance with IACUC policies, procedures, or guidelines may still require IACUC committee review. A proposed change requires IACUC review if it:

1.) Is expected to result in greater pain, distress, degree of invasiveness, or mortality;
2.) Changes the study objectives;

3.) Impacts personnel safety;
4.) Changes housing to a location that is not currently overseen for animal use;
5.) Changes a surgery from non-survival to survival surgery; or.
6.) Changes study species.

D. IACUC Notification of administrative approval of significant changes

Principal Investigators receive a standard Approval letter. The RIO software contains a report function that lists all protocols by their method of approval, including protocols approved administratively with veterinary consultation.

V. References

a. NIH Guidance on Significant Changes to Animal Activities, NOT-OD-14-126 http://grants.nih.gov/grants/olaw/140821_seminar_transcript.pdf
b. LARC Veterinarians' Anesthesia and Analgesia Recommendations for UCSF Laboratory Animals (Jan 2018)
c. Paul Flecknell. *Laboratory Animal Anaesthesia*. Elsevier/Academic Press, 2016.
d. Richard E. Fish, Peggy J. Danneman, Marilyn Brown, and Alicia Z. Karas, eds. *Anesthesia and Analgesia in Laboratory Animals* (Second Edition), Academic Press, 2008.
e. "Primate Formulary", University of California, Davis , https://safetyservices.ucdavis.edu/article/list-formularies#primate
f. Donald C. Plumb. *Plumb's Veterinary Drug Handbook (Ninth Edition),* Wiley-Blackwell , 2018.
g. James W. Carpenter and Christopher J. Marion, eds.: *Exotic Animal Formulary (Fifth Edition),*W.B. Saunders, 2018.
h. "Nonhuman Primate Formulary", Association of Primate Veterinarians, https://www.primatevets.org/education--resources
i. C. Terrance Hawk, Steven Leary, Timothy Morris, eds. *Formulary for Laboratory Animals (3rd Edition)*, Wiley-Blackwell, 2005.