Purpose

The purpose of this procedure is to describe the veterinary verification and consultation (VVC) review process for approving significant changes to a previously approved protocol. The Office of Laboratory Animal Welfare (OLAW) (NOT-OD-14-126) “Guidance Significant Changes to Animal Activities” was developed to support the use of performance standards, professional judgment, and campus approved policies to reduce the regulatory burden on the Institutional Animal Care and Use Committee (IACUC).

Process

Significant changes allowable with veterinary verification and consultation

Specific significant changes (amendments) to a protocol may be processed by VVC and approved by the AV, without full committee review (FCR) or designated member review (DMR).

A. A change (i.e., addition or removal) of analgesic, anesthetic, sedative/tranquilizer, or antibiotic or other drugs, consistent with the Great Falls College Montana State University (GFC) IACUC policies or common practice (e.g., stated in a published veterinary formulary).

B. A change (i.e., addition or removal) in route of administration, volume, or formulation of a drug or experimental agent that is consistent with Great Falls College MSU IACUC policies and does not exceed published veterinary resources.

C. Change in blood collection method or method of restraint in accordance with Great Falls College MSU IACUC policies.

D. Refinements of non-surgical or surgical procedure, or other procedure resulting in less potential for pain or distress or decreased invasiveness (e.g., a change from survival surgery to non-survival surgery).

E. Changes in euthanasia to any method approved in the current AVMA Guidelines for the Euthanasia of Animals.

F. Changes in duration, frequency, type, or number of approved procedures performed on an animal, as long as the change does not result in greater pain, distress, or degree of invasiveness. The AV may use discretion and professional judgment to approve minor procedural changes if the changes will not unduly impact animal welfare (i.e., lessens or involves equivalent pain, acute or chronic stress, distress) and are consistent with current standards of veterinary practice or specifically addressed in Great Falls College MSU IACUC policies. Common examples include:

1. Changes related to blood collection (e.g., frequency, volume, vessel access).
2. Revision of sample collection intervals or total samples collected.
3. Altering the duration or interval between procedures (e.g., lengthening an imaging episode or the time between episodes).

Significant changes that may not be handled administratively by VVC and must undergo either FCR or DMR include, but are not limited to:

A. Any change resulting in greater pain, distress or degree of invasiveness
B. A change in housing or use of animals in a location that is not part of the animal program overseen by the IACUC
C. A change in principal investigator
D. A change that impacts the safety of personnel
E. A change in the method of euthanasia not approved by the 2020 AVMA Guidelines for Euthanasia of Animals
F. Addition of a new procedure

Veterinary verification and consultation process

All significant changes to a protocol must be submitted to the IACUC for review. Protocols will be assigned to VVC if the change meets the criteria described above. The AV is authorized by the IACUC to verify the requested changes are in compliance with Great Falls College MSU IACUC policies and appropriate for the specific situation and animal(s). The AV may refer any VVC request to the IACUC for review for any reason.

Reference and Guidance Documents

Diehl et.al DOI: 10.1002/jat.727
AVMA Guidelines for the Euthanasia of Animals
Making Changes: when is VVC appropriate?