



GUIDELINES ON WHEN APPLICATION FOR MAKING SIGNIFICANT CHANGES TO APPROVED PROTOCOLS IS REQUIRED

Any significant change to an approved animal protocol must be reviewed and approved by the IACUC **before** it is implemented. The IACUC uses standard review process for this: Designated Member Review (DMR) or Full Committee review (FCR). A notice of guidance to PHS awardee institutions and IACUCs on what constitutes a significant change to animal activities previously approved by the IACUC is outlined in NOT-OD-14-126.

Briefly: Significant changes include changes that have, or have the potential to have, a negative impact on animal welfare. In addition, some activities that may not have a direct impact on animal welfare are also considered to be significant. The IACUC has some discretion to use IACUC reviewed and approved policies to define what it considers a significant change, or to establish a mechanism for determining significance on a case-by-case basis in accordance with the PHS Policy IV.C.1.a-g.

The following describes the IACUC policy at RFUMS:

Significant changes include changes:

- in study objectives;
- from non-survival to survival surgery;
- resulting in greater pain, distress, or degree of invasiveness;
- in species or strain
- an increase in any number of animals used (even one animal)
- in Principal Investigator (PI);
- in anesthesia, analgesia, sedation, or experimental substances;
- in euthanasia method
- in duration, frequency, type, or number of procedures performed on an animal.

Other changes may be considered significant as determined on a case-by case basis by the IACUC. Examples include changes:

- in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
- that impact personnel safety.

If significant changes to an animal care protocol are considered, the PI must submit a Significant Change application form to the IACUC, complete the review process and receive a formal approval from IACUC **prior to implementing** the change/s.