# SDSU IACUC Guidance

# Types of APF Review

NOTE: Final Review type is determined by the IACUC Office, on a case by case basis.

**Full Committee Review (FCR):**

- New protocol submissions (includes all third year renewal protocol rewrite);
- Addition of a new procedure, process or experiment (with exceptions see VVC below);
- Increase in animal numbers greater than 10%;
- Change from non-survival to survival surgery;
- Addition of procedures or experiments that result in greater pain, distress, or degree of invasiveness;
- Change in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
- Change or addition of species;
- Change in study objectives;
- Change in Principal Investigator (PI); and
- Other additions or changes that may impact personnel safety.

**Designated Member Review (DMR)**

- First or second year annual continuations;
- At the discretion of the IACUC Office and IACUC Chair DMR can be performed if an IACUC meeting will not be held due to lack of quorum, or;
- An emergency or other unforeseen reason **with *justification** as to why submission cannot wait until a scheduled meeting with Full Committee Review (FCR).

* If the justification is approved and the item it routed for DMR, any IACUC member has the authority to call for FCR. Should the IACUC member call for FCR the PI will be notified and he item will be put on the next meeting agenda for discussion.

**DMR subsequent to FCR:**
This type of review is an action the IACUC may take when the committee reviews a proposed animal study at a convened IACUC meeting and determines that the protocol needs further modifications to secure approval. The IACUC can vote DMR subsequent to FCR. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol during the meeting or DMR subsequent to FCR process.

**Administrative Review (AR):**

- Changes in Personnel other than the PI;
- Correction of typographical errors and grammar;
- Addition of funding source (if animal numbers and all animal activities have been previously reviewed and approved);

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- Changes in protocol title (if all animal activities have been previously reviewed and approved);
- updates to contact information;
- addition of a field study location
- Observation only research and teaching – evaluation by the IACUC Chair

- **Veterinarian Verification and Consultation (VVC)**

  The VVC process can be used to make significant changes to animal activities that are part of a protocol that was previously reviewed and approved by FCR or DMR. To utilize VVC the IACUC has an approved policy in place that specifically permits significant changes to previously approved protocols. The VVC process may not be used to add new procedures to a previously approved protocol.

  Some significant changes to previously approved animal activities may be handled administratively by the IACUC office in consultation with the Veterinarian and others, as needed, as authorized by the IACUC, if the changes meet the VVC criteria in accordance with OLAW NOT-OD-14-126 "Guidance on Significant Changes to Animal Activities" and as itemized below. The Veterinarian will not be conducting Designated Member Review (DMR), but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and approved policies is appropriate for the animals in this circumstance.

  - Drugs, Drug Doses and Diet:
    - Change in doses of previously approved drugs to levels known to be safe;
    - Change of clinical medications as prescribed by the veterinarian;
    - Change in method of drug administration to another method of equal or lesser
    - invasiveness (limited to SC, IP, IV, PO);
    - Change in frequency of administration;
    - Change in diet as long as new diet does not create a new change in animal health status.

  - Anesthesia, Analgesia and Euthanasia:
    - Change of anesthesia or analgesia agent; as recommended by the veterinarian
    - Method of euthanasia as long as AVMA-stipulated conditions are met.

  - Blood and Tissue Collection for Genotyping:
    - Change between approved methods of blood collection (route, frequency, volume).
    - Change between tissue types for genotyping;
    - Collection of additional tissue after euthanasia;
    - Non-invasive collection of urine or saliva.

  - Procedures:
    - Change of special husbandry or nursing care as prescribed by veterinarian;

- Change of pre-defined Category C behavioral tests to protocols that already include behavior testing;
- Variations to previously approved surgeries that do not increase the invasiveness or expected outcomes.
- Variations of non-invasive procedures already approved that do not increase the pain or distress level.
- Addition of non-invasive imaging or other procedures that do not cause pain or distress

- Animal Numbers Changes:
  - An increase in previously approved animal numbers by 10% or less.

- Animal Strain or Line Additions:
  - Addition of a laboratory rodent strain or line of the same species. That will be used in same experiments and procedures as outlined in the approved APF and have no expected adverse phenotype.

- Changes in Species - Field Studies ONLY:
  - Addition of species from the same genus and geographical location/habitat as the species of focus on an approved protocol, as long as there are no differences in protection or conservation status and the species is not a USDA covered species, could be reviewed administratively but will be considered on a case by case basis.

**Significant changes NOT eligible for VVC include:**

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 (other than field species, see above);

In study objectives;

In Principal Investigator (PI); and

That impact personnel safety.