

Annual Review Tutorial

Section 1: Designee(s)

- This section allows the PI to designate any active personnel on their protocol to complete the annual review on their behalf.
- Multiple designees may be assigned for each protocol.
- Designee assignments are only valid for the current annual review.
- All e-mail notifications and correspondences will be sent to the PI and assigned designee(s).

NOTE: The PI maintains accountability for information provided on their behalf.

Section 2: Protocol Status

- Inactive: No animal use or holding has occurred during this reporting period. No further reporting necessary for this annual review.
- Active: Animal use or holding has occurred during this reporting period and is documented in this annual review.
- Close Request: Close the protocol as of the day the annual review is submitted. Animal use and reportable events occurring during this reporting period are documented in this annual review.

Note: If you chose to close the protocol you must terminate (by approved methods on the protocol) or transfer all remaining animals (to approved protocols). If you need to transfer animals to the Office of the University Veterinarian's holding protocol please contact them directly.

Section 3: Protocol Changes/Problem

Please review the approved protocol and provide a detailed description of any instances of protocol updates, deviations and/or problems that occurred within each of the following categories:

3.1 Procedural changes initiated not previously IACUC approved:

Examples:

- Procedures performed that are not described in the protocol
- Procedures that were not performed exactly as approved in the protocol
- Procedure frequency not as defined in the protocol
- Administering and/or withholding a substance:
 - At a dosage/amount that does not match the approved doses (higher or lower)
 - Not listed on the protocol
 - Via a route and/or location that is not approved in the protocol
- Change of location where procedures are being performed

3.2 Personnel or Funding changes not previously IACUC approved:

Examples:

- Update personnel
 - Change in the PI
 - Addition of personnel working on the protocol not currently listed
 - Deletion of personnel currently listed that have left the university and/or the project
- Recently awarded funding not updated on the protocol

3.3 Animal Number or Species changes not previously IACUC approved:

- The use of more animals than currently approved in the protocol
- The use of strains, breeds or species not previously approved in the protocol

3.4 Pain or Distress levels higher than previously IACUC approved or reported:

- Provide a detailed explanation of the incident(s) of increased pain and/or distress and then document the actual number of individuals that experienced the increase in Section 4 (below)
- Animals experiencing unrelieved pain or distress must be recorded under Pain Category E in Section 4 (below)

3.5 Unanticipated deaths not previously reported to the IACUC:

- Any animals that experienced spontaneous death or were euthanized due to health status and was not described as an anticipated endpoint in the study.
 - Provide a detailed explanation of each incident of spontaneous death and/or euthanasia
 - Animals that spontaneously die must be recorded under Pain Category E in Section 4 (below)

Section 4: Pain Category and Animal Use Numbers

1. Pain categories are determined by the highest level of pain the INDIVIDUAL animal experiences:

Example 1: If an animal started as natural breeding only (Pain Category B), was then used for embryo transfer on the breeding protocol (Pain Category D), but died unrelieved (Pain Category E), that individual would be counted once under the E pain category ONLY.

Example 2: Three animals were in the same treatment group on a protocol with an expected pain category of C. During the project one animals spontaneously died elevating the pain category for that individual to an E. One animal had a complication that required pain

relieving drugs elevating the pain category for that individual to a D. The remaining animal completed the experiment with no complications at the originally designated C pain category.

On the annual review the animals were recorded as follows: 1 in pain category C, 1 in pain category D and 1 in pain category E as this represented each individual's highest level of pain category experienced during the protocol.

2. An individual animal should only be counted as used ONCE on any given protocol.

Examples below:

Example 1:

Individual animals recorded during their first annual review (AR) should NOT be counted in subsequent years. Only new individual animals used should be included in the remaining AR.

Scenario: Protocol request 15 animals.

First year only 5 are used = AR year 1 = 5 animals reported

Second year same five animals used again plus 3 new animals = AR year 2 = 3 animals reported

Third year same 8 used again from year 1 and 2, plus 7 new animals = AR year 3 reports 7 animals used

The total animals used during the three annual reviews (5+3+7) on the protocol = 15.

Example 2:

An expiring protocol transfers 10 animals to its continuation protocol. The continuation protocol has approval for a total of 20 animals.

AR year 1 would count the 10 animals transferred initially from the expiring protocol (leaving 10 new animals to be added over the lifetime of the protocol.)

Example 3:

An approved protocol transfers 55 animals from another approved protocol. The protocol has approval for a total of 250 animals.

AR year 1 would count the 55 animals transferred from the other approved protocol (leaving 195 animals to be added over the lifetime of the protocol.)

3. Animals to be counted as used include:

- a. Any animal purchased or transferred onto a protocol
- b. Mice and Rats born on a protocol at first live manipulation or no later than at time of weaning
- c. Xenopus tadpoles at first manipulation if >4 dpf and no later than 58 dpf
- d. All other animals born on a protocol at first live observation