

	<p>Guide: 40 Ways to Please the IACUC: Protocol composition tips</p>
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## PROTOCOL INFORMATION

1. When creating a protocol on Granite, always select NEW SUBMISSION.

## TITLE

2. Use one species per protocol, per USDA regulations.
3. Be as brief as possible and include the species in the title, per USDA.

## CATEGORY

4. Each protocol receives a single USDA category based on the one procedure that potentially produces the greatest level of pain and suffering in the experimental design.
5. Select the appropriate category and remain CONSISTENT when entering authorized animal numbers in the Segment.
6. The majority of experimental protocols will be USDA Category D; breeding protocols will be Category C.

## EMERGENCY PHONE

7. fill-in

## PROTOCOL SOURCES

8. Provide a brief history of the research, reference key background papers regarding relevant animal techniques that demonstrate PI's experience, or document feasibility of key techniques in other labs.

## PROTOCOL ASSOCIATES

9. A Principal Investigator (PI) is listed only as PI and not additionally as Protocol Associate (PA). Named personnel must be current and complete in training and OHP.

## PROTOCOL KEYWORDS

10. search keywords (need keywords in any pull-down, contact the IACUC Office)

## DESCRIPTION = Experimental Design

11. The Description is the FIRST printed paragraph, even though Granite lists it last on its tabbed page, so spell out **abbreviations** here and avoid **typos**.
12. Adapt this sentence to your protocol and use it as the first line in the Description:  
*"This is a (survival/non-survival) (surgical/non-surgical) (breeding/organ harvest/field study/teaching...) protocol carried out in (mice/rats/rabbits/amphibians...)."*

Write exactly what happens to the animals, control and treatment group(s), what treatment(s) occur, and under what conditions in the context of the experimental design:

13. Nature of any INJECTION(s): desired effect, pH, composition, toxicity
  - Dosage, administration route (IM, IP, SC etc.), under what conditions, duration
  - Describe potential effects to animal (morbidity, signs of morbidity, expected mortality)
14. Describe ANESTHESIA use in detail.
  - Dose (mg/kg usually), administration route (IP, IM, SC etc.)
  - Criteria to determine plane of anesthesia; maintaining and monitoring anesthesia
  - Need for supplemental heating or other aids like forced ventilation, and how it's provided
  - Are animals revived (survival surgery) or euthanized (non-survival surgery)

15. Detail **SURGERY** techniques.
  - Note pre/post-op care, personnel training, location of surgery, surgical log records.
16. Describe **EUTHANASIA** in detail.
  - Detail primary method of euthanasia (with dosage or physical means)
  - For protocols using asphyxiation by carbon dioxide inhalation, provide confirmatory method of euthanasia to ensure that animals have expired.
  - Be **CONSISTENT**: list same Euthanasia Method(s) under Segment(s) Information.
  - State how observers will recognize any expected and unexpected adverse effects, and what will be done about it. When will veterinary advice be sought and followed?
17. Describe any special **EQUIPMENT, APPARATUS or PROCEDURE** to be used, including its location, special training required or key operator (if needed).
18. Veterinary consults prior to protocol submission can illuminate unique details regarding **INJECTIONS, ANESTHESIA, SURGICAL TECHNIQUES** and methods of **EUTHANASIA**. These consults have been known to expedite a protocol's passage through the IACUC. In the case of PIs new to the University, using techniques that are new to the PI, or just seeking knowledgeable advice, the IACUC recommends use of this invaluable resource. The USDA Animal Welfare Act also advocates veterinary consultation prior to IACUC review.
19. If animal groups or treatments number five or more, consider itemizing groups or treatments at the left-hand margin or in tables, rather than in paragraph form.
20. Be **CONSISTENT**: the total number of animals mentioned in the Description must add up to the same number of animals that are requested in the Segment(s) and calculated in the Justification of Animal Number (see Protocol Questionnaire Q5 below).
21. Many granting periods are **FIVE** years. IACUC protocols are approved for **THREE** years. Adjust requested animal numbers accordingly.

Many PIs write their Description with too little detail or cut and paste large passages from grants. Such narratives address only superficially the details sought by the IACUC. Therefore, write specifically for the IACUC: questions on the Protocol Detail Report and the issues listed above answer regulatory requirements that have to be addressed for the IACUC to approve your research.

**Be brief, but DON'T BE VAGUE**

The clearer you present your case, the less the IACUC struggles with questions, the fewer clarifications are returned to you, the faster your protocol is approved.

**OBJECTIVE**

22. State the research goal in terms understood by any non-expert outside your field.

**RATIONALE**

23. Succinctly state why this protocol needs to be done and relate its potential benefits to human and/or animal welfare. Clarifications here usually result from insufficient or unclear information that does not encompass the scientific scope of the experimentation to be conducted.

**HAZARDOUS AGENTS** (Need keywords in any pull-down? Contact the IACUC Office)

24. To use a particular radioactive agent, a PI must have permission for that use filed with Radiation Safety, 460-7063.
25. To use a particular biohazard, a PI must have current (not expired) approval from the Biosafety Committee, 460-6625.
26. To use a particular chemical compound, the compound must be part of the PI's lab formulary and registered with Safety and Environmental Compliance, 460-7070.

## PROTOCOL QUESTIONNAIRE

All questions must be answered; the following are most problematic:

27. Q2 List only one funding source and give grant name and number; send a copy of grant to the IACUC Office. If there is no external grant support, a source to pay for animal charges must still be specified, i.e. departmental funds or a private 3-account.
28. Q5 Justification of animal number *See Appendix Two*  
In all but rare cases, this requires statistical validation of animal number and study group size. The preferred approach for determining group size is to conduct a power analysis.
29. Q6 Alternatives to the use of animals  
This is often confused with Q7, but the question here is actually whether the scientific question to be answered by this protocol can be done successfully without the use of animals.
30. Q7 Alternatives to painful procedures  
In response, most PIs can state that "Animals will not be exposed to painful procedures."
31. Q9 Database searches  
Searches must be recent with a specific date from an acceptable source like PubMed or other search library in your specialty (for those in Life Sciences). Avoid vague phrases like "every day at work".
32. Q10-13 Protocols will not be approved without completion of training and OHP enrollment.

## SEGMENT

Segment(s) are the business end of Granite and keep animal care functioning. Thus, the Segment Description, Species, Stock/Strain/Breed and all Questions on the Segment Questionnaire must be filled in. Questions about ordering and husbandry requirements (particularly breeding, transgenics, knockouts, or nudes) are best answered by DCM staff.

33. Strain/Stock/Breed: must be filled-in for PI to order animals  
If a desired S/S/B is missing from the pull-down, contact the IACUC Office.
34. Euthanasia Method(s)  
Be CONSISTENT: select method(s) identical to those in Description; never select all methods.
35. Authorized Number of Animals  
CONSISTENCY counts: animal number in Segment(s) must yield the same total as those totaled in Description and Protocol Questionnaire Q5; insert across from proper USDA category.
36. Request enough animals to last for the entire three year approval period so that this protocol will not have to be re-submitted prematurely, YET do not significantly exceed the animal number approved by the supporting granting agency.

## COMMENTS:

37. IACUC submission deadlines are first Fridays of each month at close of business. Submissions that are written and submitted in a hurry show it. Take your time and submit your best effort.
38. Why is a protocol that is submitted to replace an expired protocol not approved quickly, especially when "it is the exact same protocol that was approved three years ago"?
  - New committee members are in place three years later and may pose different questions relative to new and changing regulations.
39. Each protocol is reviewed on the basis of its own merit. Even if procedures in this protocol are identical to those in another protocol, describe the procedures in detail in this protocol, but do not reference another protocol or its protocol number, and do not state "see other protocol".  
Only exception to this rule: transfer of offspring from a breeding protocol to an experimental protocol requires listing the protocol number for transfer in Breeding Segment Questionnaire Q11.
40. Past performance of a PI or departmental affiliation has no influence on the discussion or outcome of a protocol. Each protocol stands alone; the IACUC reviews the protocol at hand only.

This document outlines only the most common clarifications requested by the USA IACUC committee.