

Quick Tips for Filling Out an IACUC Protocol

1. When describing **animal numbers** to be used (Item 7.b), try to indicate specific treatment groups, number/group, or some rationale for the number requested. When possible, statistical justification is optimal. The numbers described in 7.b must equal the number in Item 6.a.
2. In Item 8, describe precisely **what will happen to the animals**, with a break-down **by species**. Include dosages (mg/kg), routes (e.g., subcutaneous, intramuscular, intraperitoneal), frequency (e.g., every 6 hours for 5 days), volumes of compounds to be administered; and indicate route, volume, and frequency for tissue/fluid sampling.

For surgical procedures, indicate in Item 8.a the anesthetic to be used, how an acceptable depth of anesthesia will be determined, procedures to maintain asepsis, who will perform the surgery and what his/her qualifications are, analgesic to be used (route, dosage, frequency), and procedures for post-operative care both in the immediate post-op period and through the removal of sutures or wound clips. Remember, that surgical records **must** be maintained and made available to regulatory site visitors.

For studies that involve conditions that might result in animals becoming ill (e.g., infectious disease, cancer models, test compound toxicity) describe exactly what criteria will be used to evaluate the animal, including frequency of evaluation. In addition, state at what point using these criteria the animal will be euthanized (refer to FLSC document, "Humane Endpoints in Animal Experimentation"). If the study requires that the animal not be euthanized, this **must** be justified on a scientific basis, in writing.

If a Freimann Life Science policy or guideline exists for a particular aspect of the work (i.e., anesthesia, polyclonal antibody production), it is often easiest to simply state that that policy/guideline will be followed. A copy of the latest guidelines should be included with the protocol. These can be found at www.nd.edu/~ndflsc/SOPDownloads.html.

3. Item 9 requires a **search for alternatives**. This means that you **must** provide assurance that there are neither non-animal nor less painful/distressful animal models with which to perform the work. The keywords should refer to the **specific** procedure being performed (e.g., "antibody production", "liver biopsy", "*Plasmodium* infection"); the species of animals; and the word, "alternatives". Additional search terms are encouraged. The search should be up to date (within two weeks of protocol submission), and a **narrative** indicating the results of the search provided.
4. Item 10 requires a statement that the **work has not been previously done**. Of course, science should be able to be replicated, but the question really is getting at *unnecessary* duplication.
5. Item 11 should list **everyone using animals or animal tissues/fluids**. These are the people (in addition to the PI) who **MUST** have completed the FLSC animal training module and occupational health program before named persons are allowed to use animals or animal tissues/fluids.
6. Always use the most recent IACUC protocol form, available on the Office of Research Website (<http://www.nd.edu/~research/forms/>).
7. If you have any questions or want someone to pre-review your protocol, contact Mark Suckow (1-6085) or Tracey Poston (1-5386).