IACUC Protocols from a Veterinary Perspective

The completion of a protocol application for the Institutional Animal Care and Use Committee can be noticeably simplified if the objectives of the IACUC are understood and the instructions are followed point-by-point.

The committee’s responsibility for this function derives from the University’s Federal Assurance agreement with the National Institutes of Health, and its obligations under the Animal Welfare Act. Essentially, the agreement is to rely upon the IACUC to oversee the compliance with the Guide for the Care and Use of Laboratory Animals (just newly revised) and other relevant federal policies which determine the conditions under which animal research is conducted. Such an agreement is a condition of eligibility for federal research monies. The new Guide is downloadable in PDF format at:  http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf

When the IACUC is doing its job effectively, investigators understand clearly its functions, the process works efficiently, it is economical of everyone’s time and the University is in a strong position to justify its use of animals in research. It also assures that animal related procedures are judicious and comprehensible to the public and to government compliance groups. And, most fundamentally, animals receiving the care that they require are the most appropriate research models for advancing human health care.

The questions on the form are designed to gather and evaluate the essential information which the committee uses to determine if a proposal complies with the above requirements.

The IACUC protocol form is a public document which is available under open records statutes. If evaluated by outside parties, it should contain sufficient information to assure that:

1. An average member of the public would be able to grasp the significance of the research (Lay Summary).
2. The appropriate animal species and numbers have been selected for the proposed work.
3. Comprehensible plans are in place to manage animal pain and discomfort.
4. The scope of the activities are defined and reasonably limit the project activities.
5. The end points and ultimate disposition of the animal subjects are described.
6. Personnel conducting the work are trained to perform animal procedures competently.
Each section of the form has been designed to elicit the information which addresses the above subjects. The IACUC assigns each protocol to two committee members for detailed review; in addition, the protocol is distributed to all other committee members for review and comment. At a convened meeting of the IACUC, a synopsis of new protocols (and renewals, revisions and amendments) are presented by the primary and secondary reviewers. Discussion then ensues involving the other committee members. Action is then taken on the protocol by committee voting; the principal paths that follow include approval, approval with minor modifications, deferred pending resolution of significant questions or modifications or non-approval.

Most of the reviews of your protocol submissions are done by your faculty peers who serve on the IACUC and volunteer their valuable time to facilitate the research process. A member of the public sits on the IACUC and participates in the dialogue. Their time should be respected and not consumed by submissions which are not focused on the information needed to respond to each question. Being succinct, organized and giving attention to detail, as one would do in a journal publication submission, will be much appreciated and considerate of their time and other obligations.

If significant questions are not adequately responded to when the application is filled out, it results in delay of the approval of the protocol, as well as generating increased administrative time and effort.

The following list describes some of the most common oversights which result in delay of protocol approval:

1. **Title of Protocol** - This should be fairly specific and incorporate the disease or physiologic process being investigated. It should, if possible, complement the Lay Summary (next item). An overly generic title of too a broad scope will not help to distinguish it from other existing or future protocols.

2. **Lay Summary** - This is specifically devoted to distilling the purpose of the work. Keep the language simple, avoid scientific jargon, cryptic acronyms and be sure to explain how this work has the potential to improve human health. A highly technical explanation obscures, rather than elucidates, the importance of your work.

3. **The Use of Acronyms** - As with scientific papers, **always** explain the meaning of an acronym when it is first introduced into the document.

4. **Copying and Pasting** – While it is convenient and tempting to clone blocks of text from existing grant documents, seldom does this serve the purpose of the protocol application. This tends to introduce detail which is not essential and clutters the job for the reviewers. It is not a substitute for a straightforward response to the question at hand. It is, however, a guaranteed method of risking the deferral of your protocol approval.
5. **Statistical Design** – This is not simply explaining how you calculated the number of animals required in the study, but the ‘statistical basis’ for those numbers. One member of the IACUC is a statistician and can be consulted in advance if help is needed to clarify this.

6. **Animal Numbers and Justifications** – Determine how many distinct study groups your work requires, and for each group (including controls) show how you arrive at the numbers (examples are given on the form).

7. **Proposed Research** - This is where the work itself is described and where copy and paste should be curbed. Do not include work that is not in this study. Do not include detailed bench or post mortem procedures which are not relevant to this Committee’s purpose (use of live animals).

8. **Experimental Procedures** – Each type of procedure is listed separately, including anesthesia, surgery, drug dosing regimens, sampling procedures and euthanasia. Be mindful of the pain categories relevant to distinct groups.

9. **Post Procedural Monitoring** – Explain what impairments or complications may be associated with a procedure (or genetic condition) and how you will monitor animals and take appropriate measures in response to their condition. The endpoints of a procedure need to be specifically addressed.

10. **Biohazards or Chemical Hazards** – If your protocol involves questionable agents or compounds, consult early with Safety & Health to obtain the required permissions, since this also could delay the processing or implementation of a project. The IBC (Institutional Biosafety Committee) may need to independently review certain activities. The approval of an IACUC protocol does not guarantee availability of specialized space in DLAR; consult with them to discuss your impending project needs. Space, particularly for specialized usage, is at a premium.

**Other IACUC Protocol Issues**

“**Protocol Creep**” – As the term suggests, continuing to add significant additional aims and procedures to an existing protocol by the amendment process creates real problems.

The IACUC review process becomes increasingly cumbersome if the accumulated modifications begin to outweigh the original scope of the protocol. As such, it also becomes more difficult for the PI’s own staff to accurately comprehend and be up to date on the approved protocol. Since all personnel working on animals in the research program are expected to be knowledgeable of their specific role in the work, the unmanaged growth of a core protocol makes this increasingly difficult. Reassessments should be undertaken periodically to avoid this pitfall. Weed out areas that are no longer needed and remove them via renewal cycles or amendment processes. Group activities logically and into protocols that make sense to everyone.
Deadlines – Log your information for deadlines for expirations and renewals into your Outlook Calendar. IACUC meetings are monthly, and deadlines are to assure that committee members have adequate time for their reviews, while they continue to fulfill their own academic obligations at the university. They are volunteering to perform this service for the research community and need your help. Like most other administrative units at UT, the human resources to manage this process have been shrinking. The protocol form should be filled out in a scholarly manner, with attention to consistency and literacy.

Pain and Discomfort Categories – The current three-tier system (A, B, C) is useful for classifying animal groups in studies. The best strategy for pain management involves “preemptive” intervention. In other words, pain or discomfort is best managed when treatment (analgesics) are provided prior to a surgical or procedural event. Discuss this with veterinary staff and consider this approach when writing a protocol.

Pain management should be recorded in laboratory records, and, if necessary, by the use of Post Procedural monitoring cards which are placed directly on animal cages. Drug acquisition and proper inventory is the responsibility of each PI. If a lab does not possess a stipulated analgesic (in date), e.g., when a specified procedure is carried out, it is presumed that it is not being intended to be used, which could be contrary to the approved IACUC protocol. DLAR does not provide controlled substances to labs.

Surgical Techniques – The protocol form requires a brief outline of specific procedures. Specific mention should be made about aseptic techniques, which are required in survival procedures. Training in preparing materials for aseptic surgery, surgical technique itself and peri-procedural management of veterinary patients is available on request from DLAR.

Protocol Consulting – Individual IACUC members, IACUC staff, DLAR managers and veterinary staff are all available to meet with individual PIs in order to assist them with the development of new or revised animal use protocols. This is encouraged in order to reduce the need to re-process applications which are incomplete.

Guidelines on surgery, blood collection, breeding colonies, and other germane topics are available in the IACUC and DLAR offices. These are all opportunities to update your knowledge of basic procedures as well as to better prepare your post-doctoral, graduate student and technical staffs for their careers in biomedical research.

You don’t have to figure this all out on your own—just ask!

IACUC Office: Ext. # 4252

DLAR Office: Ext. # 4310

Safety & Health Office: Ext. #5069