



The ACC Connection

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WELCOME to the 16th edition of the **ACC Connection**, a bi-monthly newsletter designed to help researchers with questions regarding animal research at the University of Connecticut Health Center. Our 16th issue is designed to familiarize Principal Investigators with the most common errors the ACC encounters when reviewing protocols and how to avoid them.

The *Animal Welfare Act* and *PHS Policy* require that all work done with laboratory animals be reviewed and approved by an Institutional Animal Care and Use Committee (IACUC). In order to facilitate that job, the UCHC ACC has developed an animal care and use protocol form which investigators must fill out and have approved by the ACC prior to using animals.

Adequate review for your protocol depends on the ACC receiving a thorough, well-written document that conforms to USDA and PHS policies as well as recommendations set forth by the Association for the Accreditation and Assessment of Laboratory Animal Care International (AAALAC) and *The Guide for the Care and Use of Laboratory Animals*.

Animal Care and Use Protocol Forms

The UCHC Animal Care and Use Protocol form is located on the ACC website and can be downloaded to your computer desktop (<http://clacc.uchc.edu/ACC/SubmittingProtocols.htm>). It is a Word document which the PI fills out. **The PI must use the most current version of the form; failure to do so will result in the application being returned.**

The UCHC Animal Care and Use Amendment form is located on the above ACC website and can be downloaded to the desktop. It is to be used if the PI has any changes to the approved protocol. This form must be filled out, submitted to, and approved by the ACC **prior** to the implementation of the changes requested. In addition, the form must be returned as a Word document; PDF documents cannot be accepted for submission.

Protocol Form Sections

Section One

The first section requests information related to the personnel involved with the project. Information for both the PI and the main contact person should be completely filled out. This section asks for the training and experience for all project personnel who will be using laboratory animals; if you are unsure of any training dates, there is also a list of animal users with training and OHS enrollment dates on the website (<http://clacc.uchc.edu/Restricted/AnimalUsers.xls>).

Section Two

The next section requests information related to the project being proposed. Information is gathered to grant information, funding agency, and any personnel who will perform parts of the project but not directly work with the animals.

Section Three

The next section requests information related to the scientific merit review of the project (a requirement of both the USDA and PHS).

Section Four

This section requests an overview of the project- in lay terms- regarding the purpose of the study and its potential value to human or animal health, the advancement of knowledge, or the good of society. This helps the ACC to evaluate the ethical merit of the project (a requirement of both the USDA and PHS).

Section Five

The next section requests information on the animals to be used: the species, the total number required for the 3-year period of the protocol, and categorizing animal numbers based on a pain classification system. In addition, it is in this section where alternatives to painful procedures must be described in detail. For more information on how to perform a search for alternatives to painful procedures, please refer to the ACC website (<http://clacc.uhc.edu/ACC/AlternativeSearchHelp.htm>).

Section Six

This section is a check box list- the PI is to check off whatever statements apply to their proposed use of animals. Many of these items, if checked, would constitute the necessity for an exemption to standards and allows the ACC to immediately see if special requirements during review are necessary for the proposal.

Section Seven

This section deals with the hazards of the work being proposed. It is a combination of a check box list and a request for more information if any particular box is checked off by the PI.

Section Eight

The next section is a check box list for the rationale for using animals. It is a federal requirement to have a reason for using animals- the list provides the most common reasons for a requirement to use live laboratory animals in research. If no box is an accurate reason, there is an "other" box which can be checked off and explained. The section also has a check box list for the rationale for the appropriateness of the species being used (also a federal requirement). Again, the list provides the most common reasons for determining the appropriateness of the species being used. It also has an "other" box which can be checked off and explained if none of the choices are accurate.

Section Nine

It is in this section where PIs need to determine how the numbers of animals requested in section 5 were determined. It is requested that, whenever possible, a table be designed to clearly show the numbers of animals requested. In addition, whenever possible, the number of animals requested should be justified statistically.

Section Ten

This is the heart of the application. In this section, the PI must detail all the procedures which will be performed on the animals (excluding surgical procedures). It is important to think about such topics as the approximate time period animals will be on the study, descriptions of any non-standard housing necessary, use of restraint devices, and all animal manipulations. There is a table to be filled out for all experimental drugs to be given during the course of the animal work- this table should be **completely** filled out.

Section Eleven

This section describes all the surgical procedures being performed on the animals. All sections should be filled out- if any one section is deemed to be not applicable to the surgical work being done, this should clearly be stated- **not left blank**.

Section Twelve

This section is a check box list of clinical signs the animals may experience during the course of the experiment. If any sign is applicable to the experiment being proposed, it should be checked off and a **frequency** of monitoring (e.g., once per day, once per week, etc.) should be stated.

Section Thirteen

This section deals with minimizing pain and distress to the animals. It should be detailed here about any procedures being performed that are designed to minimize the discomfort, pain, and injury to the animals. A method for pain management should be included. **It is important that endpoints- objective criteria which would necessitate the removal of the animal from the study- be detailed in this section.** If no pain is anticipated with the study, **this section should not be left blank**- a statement that no pain is anticipated, and the rationale for that statement, must be written by the PI.

Section Fourteen

This section is where PIs should enter the room numbers in which procedures are being performed. It is important for this section to be accurate- it is how the ACC determines what rooms need to be inspected semi-annually in order to comply with federal law.

Section Fifteen

A table to be filled out with all the therapeutic drugs to be given to the animals is in this section. All columns in the table need to be completed. Tables should not be changed from what is presented when the Word document is opened by the PI.

Section Sixteen

This section is where the euthanasia method(s) to be employed during the course of the experiment are described.

Sections Seventeen and Eighteen

These sections are assurance statements if PIs are using dogs or non-human primates in the course of their work. The boxes are to be checked if these species are being used and the PI should be familiar with the laws associated with these animals.

Section Nineteen

This section delineates the assurances the PI agrees to by the submission of the protocol to the ACC. The PI should read these assurances with care.

The Ten Most Common Errors in the Animal Care and Use Protocol Form

- 1. *Training and Experience Table inappropriately filled out in section one.*** This table should not state “3 years experience” for an individual- this does not tell the ACC anything about the training and experience the individual on the protocol has. It should contain information about the training with regards to the procedures the individual will be performing during the course of their work. For example, it may state “3 years experience with handling, IP and IV injections, post-procedural monitoring, and euthanasia of laboratory mice”.
- 2. *List all individuals who will not work with animals.*** If an individual needs to be on a protocol, but will not directly work with laboratory animals, this must be clearly stated. Otherwise, the ACC may delay approval of the protocol or annual reviews waiting for this individual to enroll in the occupational health program in which they may not need to enroll.
- 3. *Project overview being too technical.*** A good, general rule-of-thumb is to write this section as if you were explaining your work to an 8th grader. Avoid acronyms- especially if they are not defined. Be sure to state not only the purpose of the work, but its potential value to the advancement of knowledge, to human or animal health, or to the good of society. For an example of an overview, please refer to the ACC website: <http://clacc.uchc.edu/ACC/Section4.pdf>
- 4. *Inappropriate search for alternatives to painful procedures.*** If any animals are in a “D” or “E” pain category, federal rules state that alternatives to painful procedures be addressed. Many people only perform a search on the use of animals- this is not the federal requirement. Each painful procedure must be listed and a separate search performed for each painful procedure. For more information on how to perform an appropriate search, please refer to the ACC website: <http://clacc.uchc.edu/ACC/AlternativeSearchHelp.htm> and <http://clacc.uchc.edu/ACC/Section5a.pdf>.
- 5. *Death as an Endpoint being checked off in section 6 simply because animals will be euthanized at the end of the study.*** That is not a Death as an Endpoint situation- that is euthanasia of the animals. Death as an Endpoint is the ***natural death of the animal(s) as a direct result of the experimental or testing procedures being performed*** and it must be scientifically justified by the PI and approved by the ACC.
- 6. *Animals used in this protocol will develop acute or chronic illness or disease, but no description provided in section 12.*** It is stated on the protocol form to do this. If you animals will be come sick as a result of your work, you must describe this in the appropriate place in section 12.
- 7. *Inadequate surgical details.*** This typically happens because a PI fails to fill out all sub-sections (a-g) of this section. A good rule-of-thumb to follow is: if the sub-section is not applicable, state that; do not leave any sub-sections blank.
- 8. *Not filling out the Clinical Outcomes section and/or not filling it out with frequency of monitoring.*** After each parameter that is checked off, there should be a short statement detailing ***how often the animals wild be checked*** for that particular outcome.
- 9. *Endpoints not described in the Minimizing Pain and Distress Section. All protocols require endpoints-*** objective criteria that would necessitate the removal of the animal from study. Failure to do this will result in the protocol being returned to the PI for this information.
- 10. *Drug table mix-ups.*** The table in section 10 requires the description of all experimental drugs to be given to the animals. The table in section 15 requires the description of all therapeutic drugs to be given to the animals. Please be careful about where you put the drugs (e.g., β -hCG and calcein are examples of experimental drugs; ketamine, isoflurane, buprenorphine are examples of therapeutic drugs).

Please Note: A PI may always submit a protocol for a pre-review by the ACC office staff. These individuals will be able to tell you what portions of the submitted protocol require changes. Contact the ACC office at ooacc@uchc.edu.

Frequently Asked Questions

I have no changes from my previously approved protocol. Why do I need to fill out a whole new application form?

Federal regulations require a *de novo* review a minimum of every 3 years. Simply stating “no changes to current approved protocol” would not satisfy this requirement. Every 3 years, for the life of the project, a new animal care and use protocol must be submitted to the ACC for review and approval.

My protocol form got sent back to me, stating it was incomplete, but the provisions weren't applicable to my work. Why?

All sections of the form must be filled out (with the exception of section 11- surgical procedures if there are no surgical procedures in the experimental design). If, in the PI's opinion, a section is not applicable, this should be clearly stated. The ACC office has no way of knowing if it is not applicable or was missed by the PI. If an application form is reviewed and sections are found to be incomplete, it will also be sent to the PI. This is to the PI's advantage- it generally means that if the protocol were to be submitted for review by the ACC as written, it has a high probability of being deferred.

Upcoming Training, September 2008 – October 2008

New Animal Users Initial Basic Core Training

Monday, September 22	9:00 am – 12:00 pm	Building 20 conference room
Monday, October 20	9:00 am – 12:00 pm	Building 20 conference room

New Institutional, State, or Federal Regulations

Institutional

None

State

None

Federal

None

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2.710372

Next Issue: Methods to Reduce Animal Numbers

CONTACTS

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