General Tips For IACUC Protocol Submissions

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Getting Started with Animal Research at UCI

- Using animals in research is a privilege
  - expectation that such use will provide new knowledge or lead to improvement in human and/or animal well-being

- The decision to use animals in research requires critical thought, judgment, and analysis and carries with it unique professional, scientific, and moral obligations, and ethical responsibilities

Getting Started with Animal Research at UCI

We have a significant amount of guidance and information available on our website to help researchers understand all that is involved with doing animal research here at UCI.

Topics that would be beneficial for new researchers include:

UCI IACUC Homepage: http://www.research.uci.edu/compliance/animalcare-use/index.html

Training & Education	**Information on setting up UCInetIDs and training requirements for working with animals**
Getting IACUC Approval	Guidance on how to successfully write an IACUC protocol
Submit to the IACUC	Directions on what and how to submit your protocol application
Animal Research Policies & Guidance	Institutional policies and guidance on different types of animal research activities that occur at the university
Conducting Animal Research	Information related to the logistics of conducting animal research: • Protocol continuations, renewals, modifications, and closing reports • Animal purchases/transfers • Breeding colony maintenance

Do you actually need IACUC Review?

- IACUC review is only required if live, vertebrate animals will be used

- Use of invertebrates or receiving tissues from already dead animals do not need to be reviewed by the IACUC
  - Such as, receiving tissues from another lab who already euthanized their animals

- If you are unsure, complete the Determination of Need for IACUC Review form and email it to us

Complete the Required Training

- Everyone, has to complete the required training
  - Completion of this training is required in order to work with live animals
    - This is especially important for the Lead Researcher
- The University is charged with the responsibility to ensure that all personnel who work with live animals are:
  - qualified to do so
  - aware of the risks in working with animals
- Completion of the CITI training and Laboratory Animal Occupational Health Program (LAOHP) questionnaire are ways in which we document this
  - This training is required before someone can be added to a protocol

Submit ASAP – the earlier the better!

- Our agenda capacity is determined on a first-come, first serve basis
  - Submission by the deadline DOES NOT guarantee making it onto the agenda for the next meeting!
  - Submission deadlines and meeting dates: Online Committee Calendar

    Guidance on what documents to submit: Submit to the IACUC
- Three-Year Renewals:
  - Federal regulations require protocols to undergo de novo review every 3 years
    - Email reminders are sent out 90, 60, and 30 days before your protocol's expiration date

Three-Year Renewals Continued

- Start gathering your documents and begin the re-write process when you receive the first reminder
- Aim to submit your renewal between the 90-60 days before your expiration date
  - By submitting early, this provides buffer time to get the protocol approved before it expires
- To determine when you should submit your renewal, ask yourself:
  - When does the protocol expire?
  - What meeting date is before the expiration date?
  - When is the submission deadline for that meeting?
- Aim for an earlier meeting date if:
  - Meeting date is too close to your expiration date, Protocol has a lot of experiments or is complicated, or Protocol has a history of being tabled

Modifications

- Level of review for a modification depends on the nature of the proposed changes
- A general rule of thumb is, the more invasive or more impact a change may have on the animals, the higher the level of review
- Submit early so that if full committee review is needed, you've secured a spot!
  - See our Modification Policy for more information

General Tips

- Check (and read) your UCI email
- Respond to all reviewer comments and questions
  - Even if you disagree with a reviewer's comment, please do still respond to it and try your best to help the reviewer to understand
- Be nice and courteous – You catch more flies with honey
  - Understand that the IACUC is here to work with you! We here in the IACUC strive to help research advance while also ensuring compliance with federal regulations and institutional policies

General Tips Continued

If you wish to learn more about why we do what we do, feel free to get to know the federal regulations and accreditation guidelines:

- Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals

- Animal Welfare Act and Animal Welfare RegulationsGuide for the Care and Use of Laboratory Animals (aka. “The Guide”)

Tips for Writing IACUC Protocols

General Advice:

- Read the application instructions
  - This seems like a no brainer, but a majority of poor submissions are a result of not following directions
- Minimize extraneous information
  - Irrelevant information that does not pertain to the question being asked only adds unnecessary bulk and may create additional problems
- For 3-year renewals, do not include completed experiments in your re-write
  - Any completed experiments and procedures that will no longer be performed or used should not be included in the renewal re-write
- Identifiable information should only be listed in sections that specifically ask for it

Tips for Writing IACUC Protocols Continued

- Animal Numbers:
  - When listing animal numbers, consolidate animals that share similar USDA pain categories. Animals need to be listed as in the highest pain category of the procedures it will undergo
    - For example, if a mouse is being used for breeding but also receives an injection of a drug – this would be considered Pain Category C (not just B for breeding)

Pain Category	Definition	Examples
B	Held only for breeding and not used for any research purposes or experimental manipulations	
C	Momentary or no pain or distress or comfort	Ear punching, needle stick, behavior tests
D	Procedures reasonably considered painful or likely to cause discomfort or distress, but alleviated with analgesics, anesthesia or timely euthanasia.	Surgeries, antibody production, induced infections
***E**	Unrelieved pain, distress or discomfort (requires strong scientific justification)	Pain studies, some tumor studies

Tips for Writing IACUC Protocols Continued

- Project Overview:
  - Use of scientific jargon should be kept at a minimum and if any are used, they need to be defined in layman terms
  - In general, this section needs to be written in a manner that can be easily understood by a non-scientist high school graduate

- Justification:
  - The IACUC needs scientific justification for pretty much everything that is involved with the animals
    - animal numbers, procedures, drugs/experimental agents used, why experiments need to be repeated, etc., etc., etc.

Experimental Design

- There are 5 main topics that reviewers look for in each different experiment that is proposed

- Rationale:
  - Explain the purpose of the experiment or hypothesis

- Groups & Animal Numbers:
  - List the number of different groups and animal numbers per group
  - The most successful way to present this is by using a table
  - Be sure to also designate Pain Category

Experimental Design Continued

- Determination of Animal Numbers:
  - How was the number of animals per group determined?
    - This needs to be explained (i.e. statistical analysis, from previous experience or publications, etc)
- Sequence & Timing of Procedures:
  - Name all procedures that will be performed on the animals, including details about duration, frequency, etc
    - Flow charts and timeline work great here
  - Provide the justification for why these particular procedures and time points were chosen

NOTE: Specific details about how the procedures are performed should not be described here

Experimental Design Continued

- Endpoints:
  - State the procedural endpoints for each group – that is, what determines when the live animal portion of the experiment is complete and animals are euthanized

Sample of Experimental Design

Overall Study Objective:

Obesity is a prevalent health problem that affects a large population. This protocol is looking to evaluate potential therapeutic treatments for obesity, particularly focusing on weight loss.

Experiment #1

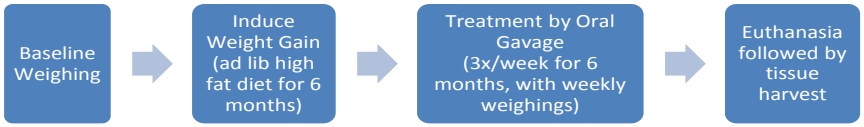
- **Rationale**
  Recently there have been data suggesting that Drug X has the potential to induce significant weight loss. We want to test Drug X to confirm this.

- **Groups & Animal Numbers**

Group	Strain	Treatment	Duration	Animal Numbers	Pain Category
1	Wild Type Mouse	Saline	6 months	10	C
2	Wild Type Mouse	Drug X	6 months	10	C
			TOTAL:	**20**	**C**

- **Determination of Animal Numbers**
  Using power analysis, a minimum of 10 animals per group is needed to maintain statistical significance.

- **Sequence & Timing of Procedures**



  Adult mice will be initially weighed to determine baseline weight, then fed on high fat diet for 6 months to induce weight gain. After 6 months, Group 1 (control) will be given saline and the Group 2 will be given Drug X at dose X – both groups given by oral gavage. While on the treatment, both groups will continue on ad lib high fat diet. Once a week, mice will be weighed.

- **Endpoints**
  Mice will be euthanized at the end of the treatment period by CO_2 inhalation followed by cervical dislocation. Adipose tissue will be harvested for histology.

Got questions? Feel free to email us and we'll be happy to assist!

Get to know the IACUC admin team

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