Tips for Emory IACUC Review

Position Statements Regarding IACUC Review Expectations

ANIMAL NUMBERS/COLONIES:

- It is understood that IACUC approved animal use numbers for species such as mice and fish are approximations of what will be required to complete the proposed experiments. It is expected that reasonable and appropriate numbers of animals should be included and justified in the protocol for subsequent review.

- As per federal guidance, statistical methods for justification of animal numbers (group sizes/number of repeats) should be included in the justification when feasible. However, it is understood by the committee that this will not always be possible, especially for new studies. Therefore, justification based on literature references and/or PI experience may also be accepted.

- Animals required for breeding colonies should be included in the animal number total and should include a justification for the number of animals needed to produce the offspring required for experimental purposes.

- The IACUC does not require the listing of every strain or strain combination in the protocol. It is sufficient to indicate the relative number of individual strains to be used without the exact listing of each strain (i.e. 4-6 strains, not 5 strains with exact nomenclature).

- It is critical to indicate strains or strain combination groups that are expected to have adverse phenotypes detrimental to animal health and welfare. This detail should be included in the "Strains" section of the protocol form. Guidance for this can also be found within IACUC Policy #308 "Genotypic and Phenotypic Monitoring of Genetically Modified Animals"

SUBSTANCES AND INVESTIGATIONAL AGENTS

- The IACUC does not require the listing of every specific variant of investigational drug and will accept the use of classes or families of drugs having similar properties

- Doses, routes, and volumes of administered substances should be provided as reasonable ranges whenever possible

- Team procedures for substance administration can be streamlined to add more than a single substance to be administered. To aid review substances having more severe potential adverse reactions or outcomes should be separated from those with no/minor expected adverse reactions

- Pharmaceutical grade drugs should be used whenever possible. It is understood that many substances are not available in pharmaceutical grade. However, in this case it is still critical to describe methods used to ensure sterility and stability of the compound, as well as the storage conditions (Substance Administration procedure: Question 4a-c). Guidance for this can also be found within IACUC policy 365 "Non-pharmaceutical Grade Substances". .

STANDARD PROCEDURES

- Researchers cannot alter standard procedures. Reviewers should not ask for changes to standard procedures as part of the review process. If it is felt that modifications are required for an approved Standard Procedure, this should be forwarded to the IACUC office via email and should not delay the ongoing review.

- If it is felt that a Standard Procedure is not appropriate for a given protocol, then that should be expressly stated with the rationale as to why the procedure is not appropriate and what should be used as an alternative.

AMENDMENT REVIEW

- Review of amendments should be limited to questions specific to the submission.

- In some rare cases the reviewer may identify a significant animal welfare or regulatory concern within the approved protocol that is not directly related to the amendment under review. In that circumstance the current review must be completed without requesting revision of the unrelated concern. Once the current amendment is approved, the reviewer can request a re-review of the protocol specific to the identified concern.

OTHER NOTES AND EXPECTATIONS

- Although potentially instructive, it is not required to list post-mortem collection of tissues from non-act species as a procedure.

- Humane endpoints must be included in all protocol submissions, regardless of expectations regarding potential for pain/distress (Specific Aims section Q5). In cases where little/no pain or distress is expected it is generally sufficient to indicate adherence to one or more of the standard IACUC policies for humane endpoints.

- Alternative literature searches are not specifically required for non-act species protocols. The IACUC will accept written verification within the text for the "Alternatives" section (questions 2-4) in lieu of a specific literature search. Alternative searches by procedure are required for all Act species protocols.