

# Subject: eIACUC Form Preparation Checklist & Detailed Instructions

Version: 4/12/19

## Executive Summary

Provided are instructions for completing the new eIACUC form. As the research community transitions fully to the use of eIACUC, be aware that these instructions are a living document subject to regular revision by the IACUC as greater community experience with eIACUC informs on how to continually improve guidance to users. As such, whenever preparing or amending a protocol, contact your RPA or check the IACUC web site for the most recent version. These instructions are provided in two sections. First is an "Overview" to provide an introduction to the concept of the Procedures and Experiments components and a caution to investigators who have had their Topaz protocol content migrated by the IACUC office into eIACUC. The Procedures and Experiments form the main body of reviewable material in eIACUC. Reliance upon them, however, differs significantly from the Topaz Enterprise and Elements forms. The second section of "Detailed Instructions" provides section-by-section directions for completing the form. Understanding the Procedure and Experiment approach and following the most contemporary version of the instructions will enable greatest efficiency in preparation of protocols or amendments and the speediest IACUC review. Lastly, use these instructions and not those embedded in the eIACUC form except for specific situations identified below. Investigator and protocol form preparer feedback in improving these instructions is encouraged.

## OVERVIEW:

***While a lot of information is required within the eIACUC form (see Detailed Instructions below), the “meat” of the application involves providing a detailed description of the experiments to be performed on the animals in your studies. This is broken down into 2 parts, Procedures and Experiments, which are briefly described below.***

***Procedures:*** The eIACUC protocol submission form is organized around Procedures. As such, the first thing you should do when generating a new/renewal eIACUC protocol is to determine the procedures that will be required for your studies [e.g., intraperitoneal injection of a drug(s), blood collection, CO2 euthanasia, etc.]. The next step should be to determine which, if any, of the required procedures exists in the library of Standard Procedures (these are procedures that have been pre-approved by the IACUC and, if appropriate, can be used by any investigator – streamlining subsequent review of your protocol). Note, however, that if you choose to use a Standard Procedure, you are agreeing to the use of this procedure as written. No alterations are allowed and thus all individuals on the protocol must be familiar with the standard procedure and follow it without edit or deviation. If you do copy and edit a standard procedure it will revert to a team procedure (see below). Procedures that either do not exist as a standard, or that differ from the IACUC approved standard procedure must be written by the lab. These are referred to as “team procedures” and will be subject to review by the IACUC during the protocol review process. Team Procedures can be: (i) *de novo* created; (ii) copied from another PI that has developed the same team procedure; or (iii) generated from an established Standard Procedure that has been edited by you to tailor the procedure to your specific experimental requirements. The method for creating or editing team procedures is described in more detail in other sections of this document. The logical first step in preparing your protocol is to write all the Team procedures that you will need.

Try to streamline your procedures as much as possible. One issue repeatedly encountered is the generation of multiple team procedures which could have been pooled together in a single procedure. For example, if you are planning to intraperitoneally inject a number of drugs, antibodies, etc., these can be written as a single procedure for intraperitoneal injection of a substance – listing the substances that will be introduced via this route (as opposed to writing a different procedure for each substance). In this example you would simply need to identify the range of volumes to be injected and then list the substances along with the concentration and volume to be injected for each (and, in this specific case, you may find the you can create the Team Procedure using the IACUC-approved Standard Procedure for IP injection as a template). This general approach will hopefully decrease the number of Team Procedures that you will need to generate. It should be noted that this approach will not work well for all team procedures created by the lab. If you have specific questions, please contact the IACUC office.

***Experiments:*** The next step will be to determine the “Experiments” to be carried out. Depending on the complexity of your research, it may be easiest to consider developing each “Experiment” as you would a Specific Aim in a research grant. The goal is to describe an experimental plan, not necessarily each single experiment as a separate

entity within that overall plan. You can structure experiments that span multiple funding sources for mice, rats, fish and birds as long as the details of the experiment are logical and can be followed during review. For each “Experiment” you will be required to write an over-view of the experiment (i.e., what is to be done to the animal subjects) in Q3. The regulatory requirement here is for a clear and concise sequential description of the procedures involving the use of animals that is easily understood by all members of the IACUC (Guide for the Care and Use of Laboratory Animals, 8th ed., p 25). In general, 3- 5 sentences (100-150 words) should suffice.

Thing to do and NOT to do:

- (1) Do **NOT** describe procedures in Experiment section 3 – These details will be captured under “select Procedures” (question 5) and “Procedure Timing” (question 6)
- (2) It is critically important that you provide: (i) clear endpoints for your experiments; (ii) the specifics of how often animals will be monitored and what criteria you will use to euthanize experimental animals that are doing poorly; and (iii) what pain the experimental animals may experience and how you will treat this [if experimental animals are likely to experience more than momentary discomfort, then analgesics will usually be required – unless withholding analgesics can be scientifically justified (e.g., their use would interfere with one or more parameters being measured by the proposed experiment)]. With few exceptions, statements such as “analgesics will be administered if the experimental animals appear to be in pain” will **NOT** be accepted since it is often difficult to assess how much pain animals are experiencing (e.g., prey animals frequently mask overt signs of pain). Rather, the working standard is that if a similar procedure would cause more than momentary pain in humans, then the expectation is that the procedure will cause more than momentary pain in the experimental animals.
- (3) Do **NOT** cut and paste long rationales for experiments from either a) your grant or b) the “Complete research description” section from the archival system into the Experiment description – rather, as indicated above, keep this description very focused detailing only the overall goal, numbers of animals required, what procedures will be done on specific groups of animals (

**Other important considerations:** Approval of your IACUC protocol will likely require additional approvals from other university committees, and these approvals will need to be attached to your protocol:

- Biosafety approval (if you are treating animals with any biologics)
- Chemical safety approval (if you are treating animals with any toxic chemicals)
- Radiation safety approval (if you are treating animals with any radioactive substances)
- Laser safety approval, if applicable.
- Cell line testing (if you are injecting cells into experimental animals)

#### **Cautionary Note Regarding Migration Protocols:**

*Please note that migrated protocols present a unique challenge for subsequent review related to both subsequent amendments to the approved protocol or at Three-year renewal. The migration was performed using a cut and paste approach under a “best-fit” methodology. The resultant eIACUC protocol contains all the information previously approved, however it does not conform to the requirements and structure of the new system and is thus an incomplete and possibly inaccurate conversion. There are significant differences between the eIACUC protocol submission form and that utilized in either the Elements or Enterprise version of Topaz. There are many questions in eIACUC that do not have a specific singular correlate in the previous formats, and therefore this detail could not be accurately addressed during the migration process by the IACUC office staff. This presents itself in multiple sections of the form, but is most evident as a complicating factor within the Team Procedures.*

*The IACUC does not require that PI’s revise the migrated protocol prior to three-year renewal, however at renewal all protocols must be fully converted to the new format. It should be noted that in our experience it is often easier to simply start over at three-year renewal rather than try to convert a previously migrated protocol. This is not a requirement, but would be our best advice, especially for large complicated protocols. Regardless, the IACUC does strongly encourage researchers to submit a revision amendment to fully convert the protocol into the eIACUC format prior to submission of subsequent amendments. We strongly believe that this is in everyone’s best interest. In our experience, review of amendments to migrated but unconverted protocols can result in significant delays in approval and multiple rounds of review to answer all questions and concerns. This of course increases burden to all and runs the risk of scientific delays which none of us want. If you have questions or need assistance in this regard, please reach out to the IACUC office for assistance prior to submitting an amendment. They can assist you in determining the best course of action and in*

*modifying the migrated protocol to aid subsequent review. This generally includes replacing team procedures whenever possible with pre-approved standard procedures, which greatly accelerates review and streamlines effort moving forward.*

## **DETAILED INSTRUCTIONS:**

***Please note that to enable expeditious review and minimize complications in maintaining a protocol, such as when amending it, entries in each section of the form should be unique and not repeated in other sections. Cutting large sections from a grant application usually complicates review, potentially leading to delays in approval. This also often leads to inconsistencies, as well as repetition, in the approved IACUC protocol.***

Note that for some sections there are no instructions as input of material is self-explanatory (e.g., instructions are not provided here for what to enter for "Title of Protocol" or "Principal Investigator" or similar simple fields. Please note that this does not mean that those questions should not be answered.

## **BASIC INFORMATION**

Q3: Short Title: for protocols migrated from Topaz, this field was utilized for the original protocol number from that system. This allowed for ease of transition to the new system. For three-year renewals of existing protocols, it would be reasonable to retain this convention. For protocols newly approved in eIACUC, this field is free text, left to the discretion of the researcher.

Q4. Lay Summary.

1. Briefly describe the potentially painful techniques and procedures performed on the animals and why they are necessary.
2. If there are more than momentary painful or stressful procedures, address whether or not anesthetic or analgesic agents are required.
3. A scientific abstract copied from the grant application using highly technical terms is NOT acceptable.
4. Use simple terms understandable to high school science students.
5. Scientific objectives, significance/benefits of the research, and justification for the use of animals and species are addressed in the "Scientific Aims" section and thus do not need to be added here.

## **EXPERIMENTAL RESEARCH PROTOCOL ADDITION**

### **Will the Protocol Include Breeding?**

Indicate if the protocol will include breeding. The answer you specify here will affect the remaining pages that appear for this protocol.

## **PROTOCOL TEAM MEMBERS**

1. Question 1: Identify all team members using the <add> icon. Changes to an individual's record can be made by clicking on that person's name once added and saved. To remove a staff member simply use the "X" button at the far right of each record.
2. Once in a staff member's record please fill out all the information requested. If you have questions, please contact the IACUC office
3. Note that if you are utilizing veterinary resource groups or other specialized core units to perform duties associated with the protocol, you may add these here. Common examples are as follows (listed as last, first in the drop down menu) :
  - a. DAR, Managed Breeding Service
  - b. EU-DAR, Vet Staff
  - c. Yerkes, Behavioral Management
  - d. Yerkes, Imaging Personnel
  - e. Yerkes, Res\_Resources
  - f. Center for Systems Imaging (CSI), Core Labs

4. Notes regarding “Role in Research”:
  - a. Identify at least two individuals as emergency contacts and provide emergency phone numbers (i.e., cell, home) for at least two persons in the event DAR needs to make contact off-hours in the case of a physical plant or animal welfare emergency.
  - b. Animal Breeding: Indicate those individuals having direct contact with the animals. Please note that those individuals require specific training prior to protocol approval. Individuals supervising the breeding but not actually performing the work do not need to be added here. If this activity is performed by the EU-DAR managed breeding service, please choose DAR, Managed Breeding Service” under the “select the protocol team member” question.
  - c. Euthanasia: For each individual performing euthanasia please indicate who would perform each type. Please note that CO2 euthanasia and euthanasia by physical methods (without prior anesthesia) require specific training.
  - d. “New to animal species on protocol” This designation should be used for persons without prior experience in the animal species with which they will work. These individuals will be subject to additional species-specific training.
  - e. “Surgeon in Training”: This indicates individuals who will be trained in surgical techniques, but who have not yet taken the surgical proficiency assessment to be categorized as a “Surgeon”. These individuals must have completed the Surgical training class and must complete the Surgical proficiency assessment within 30 days of being added to the protocol with this role.
  
5. The External team member information section is for addressing students that may rotate through the lab, visiting scientists or scholars from outside Emory who may engage in the research or be provided training.

## FUNDING SOURCES

Q1. Identify each organization supplying funding for the protocol:

Note the following:

- By internal rule Emory only allows one funding source for those protocols covering “Act-species” animals (one funding source-one protocol). Note: ACT- species animals are those covered by the Animal Welfare act and include the following species commonly used at Emory: NHP, Voles, Pigs, Sheep, Dogs, Guinea Pigs, Hamsters, and Rabbits.
- Protocols covering non-Act species are under no such regulation and multiple funding sources are allowed, regardless of funding organization.
- At the end of the protocol form the “Allocating Animal Counts” section will request additional details regarding the number of animals covered under each funding source.

To indicate a funding source(s) for the protocol use the +Add icon to open a new pop-up field to add the following data:

Funding Source Detail Page:

1. Select the funding organization: This is a single select field. Note that this list can be searched using the %text functionality, so that one can search on any part of the word. This can be especially helpful for this list.
  - a. Example: The Funding Source “NIH Natl Cancer Institute” can be found using the following:
    - i. NIH
    - ii. %Cancer
    - iii. % Institute
  - b. NOTE: Internal department funding should be listed as “Unassigned Department”
  - c. If you cannot find the funding source the selection “other-not listed” can be selected. In this case please list the actual name of the funding source under Question 7 on this page.
  
2. Sponsor’s funding ID: This is for externally funded awards and thus may not apply in all instances. Examples could include the following: a. NIH Funded Grant: “R01 HL000001-01A1” b. NIH JIT: “Pending-Just in Time Request” c. Internal funding: “Not Applicable-internally funded”
  
3. Internal Billing Code (EPEX #):

For all sponsored research (external funding) this should be the EPEX number which is associated with the specific funding source at time of grant submission.

For internally funded projects (for example departmental funding) the speedtype should be used.

Please note that provision of accurate information here is critical for generated animal orders and/or per diem charges. If issues with ordering animals or other charges arise after protocol approval please contact the billing office for resolution, not the IACUC. If a billing number simply needs to be updated, this can be done via an administrative amendment.

4. Grant Title: Specific to the funding source. It does not have to match the IACUC protocol title.

5. Will this funding source be used to cover direct animal expenses: Example-Some funding sources require that training grants be associated with an approved IACUC protocol even though they do not fund the actual animal experiments. These can be added to the protocol, but by indicating no in this field are not included in subsequent requests for authorized animal numbers per funding source. (Found in section "Allocating Animal Counts")

6. Attach files: This function can be used to attach either the grant or sections of the grant. Please note that if the grant is funded by PHS or other public dollars, the IACUC will generally have to perform a grant to protocol congruence analysis as per OLAW guidelines. Attaching the grant in this section will help to expedite that process.

7. Funding Status of the award: This is a free-text question which allows you to add relevant information regarding the grant award status. This will assist the IACUC office in performing review and for expediting time sensitive approvals.

Q2. Financial Interest in Research Report (COI Report): Required by federal guidelines to indicate financial interest in the outcome of the research. NOTE: If the answer to question 2a is no, then no answer needs to be provided for question 3.

NOTE: For protocols involving species regulated under the federal animal welfare act (i.e., species other than rats, mice, birds or fish), the IACUC requires a protocol for each grant.

## **SCIENTIFIC AIMS**

### **Q1. Specific Aims.**

1. Provide a description of the scientific goals and objectives of the study as a broad overview.
2. Be brief. Do not include the entire research methods section.
3. A scientific abstract copied from the grant application using highly technical terms is NOT acceptable.

### **Q2. Provide justification for the use of animals and for the species to be used in these studies.**

1. Provide the reason animals are necessary, and why alternatives such as computer modeling, tissue culture, organ preparations or organs on a chip; or invertebrate model systems cannot be used.
2. Explain why the species chosen is necessary and, if multiple species are intended for use, why each is necessary.

### **Q3. Significance and benefits of the research.**

Identify the significance of the research as applied to the area of interest (e.g., quantification of the economic cost or consequences for patients of the disease, condition or lack of knowledge) and the overall benefit (e.g., in improved patient care, cures or treatments, or advancement of new knowledge and its potential applicability) in light of any pain or stress caused to experimental subjects.

### **Q4. Describe the potential for pain and/or distress to animals in this study.**

1. Identify the probability and characteristics of each element of harm or cost to the population in use or under study, including that which is unrelieved and/or may result in death, and balance them against the potential benefit.
2. If there are adverse effects or events possible or likely with the model or model systems please identify these with a prediction of incidence and severity, if possible.

3. Include supportive care to be provided to prevent, minimize or intervene with respect to pain, distress, disability or impairment.
4. Identify the general schedule for monitoring animals for wellbeing and adverse effects, including any measurements to be obtained as baseline and through the course of the study (e.g., periodic body weight, complete blood count, blood urea nitrogen, etc.).

**Q5. Detail all humane endpoints used in this study indicating the criteria utilized and the frequency and timing of observations.**

1. Detail criteria that will be used to remove subjects from study, require euthanasia, or allow for veterinary medical or nursing care.
2. If the protocol will follow the guidelines as specifically outlined under IACUC policy 357 ‘Humane Endpoints’ or specific guidelines for other models as referenced (IACUC Policy 304 ‘Tumor Burden Scoring Guidelines’ or IACUC policy 363 ‘MPTP Guidelines’) then those can simply be referenced here.
3. If other criteria are utilized, they should be described in detail.
4. Investigators, as subject matter experts for their model, are encouraged to propose specific measurable or assessable parameters for removal of animals from study if these deemed to be appropriate and are better suited to the model system than the defaults defined above.
5. Disclose the schedule of monitoring of the study subjects for well-being.
6. Where the research is not expected to cause discernible harm, provide assurance that IACUC endpoints will be used in cases where subjects develop unexpected or spontaneous conditions.

## **EXPERIMENTS**

### **General Note on Breeding Colonies:**

Please note that there is a separate section devoted to breeding of animals near the end of the submission form. This section requests detailed information regarding breeding but does not include a question to indicate the number of animals needed for the breeding activity. There are three acceptable methods to include a breeding colony in the eIACUC form:

- a. Create a separate Breeding experiment in this section, and then refer to the details provided in the breeding section. This allows you to assign specific animals to this activity, as well as to use standard procedures (as applicable) to methods for genotyping and identification.
- b. Inclusion of breeding components into larger experimental designs within the Experiments section. If you use this method, the number of animals devoted to breeding must be clearly defined within the experimental design
- c. Use of the breeding section exclusively to identify and define animals used for and produced by breeding. If you utilize this method, please be aware that animals required for breeding activities must be added under the ‘Animal Justification’ section (described below in that section)

Question 1. Define the experiments to be used in this protocol:

- Individual experiments can be created here by the use of the +Add icon.
- Once created, any individual experiment can be copied by use of the Copy icon if individual experiments are highly similar, but not identical.
- Any given experiment may only utilize a single species of animal and thus for protocols using multiple species/subspecies a minimum of at least one experiment per species is required.
- The definition and scope of an ‘experiment’ is not tightly defined by the IACUC committee. The goal is that the PI can explain what happens to a group of animals in a manner that can be easily explained and followed by reviewers.

Specific Questions for Each Defined Experiment (added using the <Add> icon)

- Q1: Experimental name: User defined
- Q2: Species: defined by default if identified within the research team page. Species can be changed at the experimental level by the select icon
- Q3. Describe the experiment

- i. Provide a concise (e.g., 3-5 sentences) overview of how the experimental design is organized and how individual experimental groups will be performed
  1. Detail the hypothesis or specific aim(s) for the experiment
  2. Describe how experiments are organized and indicate the number of experimental groups, their sizes and differentiating characteristics (including genetic composition, gender(s), age(s), chemical, physical and/or biological agents administered; and surgical induction) up to and including experimental endpoint.
  3. Indicate if experiments will be repeated and, if so, provide the total number of repeats for each group.
  4. Identify the types of data collected (e.g., behavior, phenotypic measurements, survival, images, biological materials such as blood, and/or tissues at euthanasia).
  5. Note that there is no need to define the procedures utilized under this experiment or provide the overall experimental flow. These details will be captured in questions 6,7 below.
- b. Q4. Justify the purpose of this experiment.
  - i. Provide the scientific need for the experiment and provide identification of and justification for any unrelieved pain and/or distress.
  - ii.
  - iii. Note that this question differs from Question 3 in the Scientific Aims section. The focus here should be on the rationale and justification for this particular experiment, not the project as a whole.

c. Q5. Select Procedures:

This section is used to list all procedures to be used within this experiment. You can search for procedures to add to the experiment in one of two ways:

**Using the open text field:** You can use this field to type in a procedure of interest to find it in the procedure list. Using the “%” icon in the front of a search term field will allow you to identify any procedures that contain that term anywhere in the procedure title

**Tapping the “...” icon:** will result in the appearance of a table showing all potential procedures available to you. Note that there is a sortable search field in this view as well. The “%” wildcard works in this field as well. The table has several sortable columns. Note two in particular of specific interest:

**Type:** Identifies the broad area of procedure such as euthanasia or substance administration. This can often be a useful search item to identify specific choices within a broad category.

**Scope:** Indicates the given procedure as either “Standard” or “Team”. Standard procedures are those that have been preapproved by the IACUC and are available for use by all researchers. Note that Standard Procedures will not be subject to review under your protocol submission and are accepted as pre-approved. Team Procedures are those created by individuals on your specific research team and are visible to only your group. These procedures are subject to initial review. Once these have been approved on one or more protocols, IACUC reviewers are instructed not to request revisions unless required by the specific conditions of the protocol in question.

**NOTE: Detailed information regarding the creation and use of Standard and Team procedures are located at the end of this document**

d. Q6: Procedure Timing.

- i. Provide a timeline showing the relationship of the procedures to each other for each experiment.
- ii. The rich-text field allows the use of tables, flow charts, and other diagrams or pictures and these are encouraged. These can be created within the text field by clicking on the triangle symbol at the top of the field. Alternatively, these can be imported using cut and paste from other programs.

d. Q7: Total Number of animals used in this experiment.

- i. Note Act-species animals require a breakdown by USDA pain category, non-Act species (i.e., rats, mice, birds, fish) do not. For these species, select “NA”.

- ii. This table question generates based on the species indicated within the experiment.
- e. Q8: Housing Conditions.
- i. Identify any and all applicable housing requirements needed for the experiment (e.g., ABSL2, ABSL3, single housing, sterile housing, food restriction, water restriction, environmental alteration, chemical containment, lab-provided care, delayed weaning, etc.).
  - ii. In many cases (i.e. “No Specialized housing-standard care only”) very little description or justification would be required, whereas in other situations more details would be required.

## 2. Question 2: “Will any single animal undergo more than one survival surgery”

This question only populates if there is at least one survival surgery indicated in the experiment. Please note that yes should be indicated here under the following situations:

- a) An animal may undergo a second surgery under specific conditions as defined within the protocol if complications arise and this is deemed needed.
- b) The distinct experimental plan is that an animal will undergo multiple survival surgeries within this protocol. Example: an animal will have an osmotic minipump implanted in one surgery, but then will have it removed in a second surgery 3-4 weeks later
- c) An animal will have a single surgery on this protocol, but already had a surgery under a previous protocol or through a vendor. Example: Vasectomized mice are received from the vendor. These animals will then undergo surgery to implant tumors in the prostate

Q3a: Describe the order of and time interval between surgical procedures on a single animal: See examples above. This question is also a rich text field and so flow charts or diagrams can be used to demonstrate the experimental design

Q3b: Provide scientific justification for multiple survival surgical procedures on a single animal: Can be a simple statement. This question is also a rich text field and so flow charts or diagrams can be used Q3c. Specify how many animals will undergo multiple surgeries. Can be a simple statement. This question is also a rich text field and so flow charts, tables or diagrams can be used to demonstrate the experimental design

## PROCEDURE PERSONNEL ASSIGNMENT

Q1. Select the team members who will be performing each procedure: Note that this table will prepopulate with all of the procedures defined in the last section and will originally default to having all staff listed as performing all procedures. To delete a team member from any given procedure simply click on the icon out to the right of the row (pencil icon). You can then unselect any given team member by unclicking their name.

Q2. Team member Training: This field should auto-populate for all team members. Please note all training and if you feel that any is missing please contact the office for assistance in having this updated.

## STRAINS

- 1. Q1. Respond “yes” to this query if there are any genotypes associated with adverse phenotypes. Note: Strains of animals which are NOT expected to have adverse phenotypes prior to specific scientific manipulation do not need to be added here.
- 2. Q2. If you answer yes to question 1, then complete the table.

## ANIMAL JUSTIFICATION

Q1: This section can be used to alter the number of animals requested within the protocol from the default number carried over from the experimental section. Note that the adjusted animal count column must be completed regardless of whether or not alterations are requested.

1. Q1. Click Update to complete the adjusted animal count. Note that you can
  - a) add animals
  - b) subtract animals or
  - c) leave the animal numbers as is.

Simply enter the numerical value of the animals you wish to request on the protocol under the "adjusted animal count" field.

2. Q2. If you update the animal numbers in Q1, identify the reason. Common purposes to increase animal numbers above those necessary for experiments are breeding colonies that generate experimental subjects or to compensate for expected mortality or complications, unforeseen losses, to train new personnel and/or learn new techniques. Common purposes to reduce animal numbers would be the reuse of control groups across experiments, or the use of experimental animals jointly as more than one experimental group.
3. Q3. Justify the number of animals.
  - a. This question is aimed at justifying the total number of animals, by species, utilized on the protocol.
  - b. This response should provide scientific justification for the animal numbers used in total not by experiment, or as adjusted
  - c.
  - d. This

## ALTERNATIVES

**NOTE: Alternative searches are REQUIRED by federal regulations for all ACT species animals (i.e., any vertebrate other than mice, rats, fish and birds) and thus all procedures that cause more than momentary pain or distress (Class D, E) must be included in the search (see below for detailed instructions) Alternative searches are not specifically required for non-ACT species. Note that the IACUC will accept written verification regarding alternatives described under Questions 2 and 4 in this section in lieu of a literature search for these species.**

Q1. Record all searches for alternatives for each procedure that causes pain or distress, even if relieved (such as surgery, lymph node biopsy, etc.).

Click on the +add icon to populate the table with your procedures identified as having pain and/or stress. A text box will appear with a series of questions as follows:

1. Procedure causing pain or distress: use the ... icon to see whether or not any procedures are listed here for your protocol. If any of the procedures you have either written (team) or chosen (standard) has the potential for more than momentary pain or distress, then those procedures will be found under the menu button for question 1 in the "Add Procedures" field. Choose **each** of the procedures that are identified here independently and complete the rest of the questions for each.
2. **Date of search:** Date last search performed. Note it is recommended (but not required) that search results be saved by the PI team.
3. **Database Searched:** Use at least two databases - either ALTBIB or AWIC combined with PubMed, Medline or equivalent.
4. **Keywords used:** Combine procedure key words and the species used related to the experiments with "Animal welfare" and "animal testing alternatives". There should not be any more than 3-4 key words in combination for most procedures.
5. **Time Period:** Enter time period covered by search using the calendar function.

Q2. Identify any other references used to find alternatives (such as periodicals, publications, and consultation)  
Use this section to provide references or other materials including, but is not limited to, the background and

experience of the PI including participation on study section, organization of meetings, conferences and colloquia, or consultation with a bona fide expert.

Q3. Summary of findings: Please summarize all findings and clearly identify what identified alternatives will not be used.

Q4. Provide a narrative of appropriate length detailing how the principles of Reduction of animal use and Refinement of experimental methods have been incorporated into the conduct of the research.

- a. Reduction. Describe how the number of animals to be used has been minimized in this protocol and explain why further reduction would disproportionately compromise the value of the data. Reduction can be achieved, for example, by using statistical methods and power analysis to guide experimental group sizes and repeats along with rigorous control of experimental variables.
- b. Refinement. Describe the refinements that have been incorporated into this work, explain why no further refinements are feasible, and consider how future work might be refined. Refinement is often achieved through the use of state-of-the-art anesthesia, minimally invasive surgical technique, and effective pain management programs; post-op and nursing care interventions where indicated; ante mortem endpoints tailored to the specific experimental goals; dose or exposure minimization; chronological imaging protocols; use of fine needle aspirate over biopsy; and other innovations to prevent or minimize pain and/or distress and avoid death as a routine endpoint.
- c. Note that the third "R" of replacement is addressed at item Q2 of the Scientific Aims section.

## **DUPLICATION**

1. Q1. Record all searches for any previous research that this protocol might duplicate. Click on the +add icon. A text box will appear with a series of questions as follows:
  - a. Date of search:
  - b. Database searched: multiple databases can be utilized here, Pubmed is the most common.
  - c. Keywords used: These should include no more than 4-5 key words for most protocols.
  - d. Time period covered by search: Start and end date using the calendar function.
2. Q2. Identify any other references used to determine that the research is not unnecessarily duplicative. Beyond literature searches, the expertise of the investigator, applicable relevant experience, such as service on study section, and competitive climate for the source of funding are welcomed.

## **BREEDING**

### **NOTES:**

1. If breeding is not a component of this project, this section will be absent.
2. If breeding is covered within the Experiments section as described above, then this section does not need to be completed, and can simply be referred to here.

Q1: Describe methods used for genotyping and identifying offspring if not already described in the experiments section

Q2: Describe the breeding Scheme

3. In the case of rats, mice, fish or birds, if there is not a breeding Procedure description or lab-specific SOP, at Q3 provide the attributes and necessary production from each genotype maintained to support the studies in a logical and easy-to-follow manner, including:
  - a. The expected number of different genotypes to be maintained.
  - b. The mean and maximum number of breeding cages in the colony
  - c. The male: female breeder ratio in those breeding cages.
  - d. The expected production (if not known, use 0.5 pups weaned/breeding female/week for genotypes on inbred background and 1.5 pups weaned/breeding female/week for outbred, non-inbred, crossbred or early back-crossed background).
  - e. The frequency of replacement of breeders (prior to senescence and at reproductive decline; usually in the 6-9 month of age range).
  - f. Segregate progeny into the number of pups anticipated to be by age, genotype, gender and/or other attributes to be useful experimentally and those that will not be useful experimentally and must be culled.
  - g. Please note that un-weaned pups are not tabulated on the census (i.e., only weaned animals are counted) and these should not be included in the tabular amounts.

- h. Reviewers should be able to easily link the production output here from each colony as attributed to each experiment.

## HOUSING AND USE

Complete the table by entering the sites for housing and experimental use. Please note that these locations are broken down to those within the facility and those outside.

### Question 1: Vivarium locations

Q1: In general, the building location is sufficient here for housing. If specific rooms are utilized for experiments or other highly specialized use, then these should be indicated. To identify a building use the search term %vivarium and then pick the appropriate building (example: WMRB-Vivarium)

Q2: Species as indicated within the protocol. A separate entry must be made for each species

Q3: Indicate the approximate length of time animals will be in this location. For housing simply pick greater than 24 hours.

Q4: Describe how this location will be used: Please indicate all experimental procedures that will be performed in this space. This is critical both for protocol approval and also for subsequent semi-annual site inspections. Filling this section out completely will ensure streamlined review, as well as aid in higher level efficiency of site inspections moving forward, reducing burden on research staff

Q5: Describe transport: Only applicable if animals are leaving the vivarium. Not required for movement within the vivarium

### Question 2: non-vivarium locations

Q1: Here specific, individual rooms where procedures will be performed are REQUIRED. This is critical not only for protocol approval, but subsequent monitoring through semi-annual site inspections. Use the search term fields and the “%” wild-card to find the required locations. If a location cannot be found Please indicate it in the provided text field

Q2: Species as indicated within the protocol. A separate entry must be made for each species

Q3: Indicate the approximate length of time animals will be in this location. Please note the following:

**ACT Species:** If animals are held in a location outside the animal vivarium for greater than 12 hours, this constitutes a housing location and this site must be added to semi-annual program reviews. Specific justification will be required in question 5 below

**Non-ACT Species:** If animals are held in a location outside the animal vivarium for greater than 24 hours, this constitutes a housing location and this site must be added to semi-annual program reviews. Specific justification will be required under question 5 below.

Q4: Describe how this location will be used: Please indicate all experimental procedures that will be performed in this space. This is critical both for protocol approval and also for subsequent semi-annual site inspections. Filling this section out completely will ensure streamlined review, as well as aid in higher level efficiency of site inspections moving forward, reducing burden on research staff.

Q5: Justify why animals must be removed from the vivarium.

Q6: Describe transport: Please not methods for transport of animals. NOTE: please indicate if live animals will be returning to the vivarium or if this will be a terminal transfer

## **DISPOSITION**

Q1: Disposition plans for the animals when this research is complete:

This is a multi-select box, so please check all that apply.

NOTE: If euthanasia is selected, then the procedures used for euthanasia must also be described within the experimental section of the protocol.

Q2: If other, provide an animal disposition description:

Text box to describe any alternatives not shown in the menu above.

## **ALLOCATING ANIMAL COUNTS**

Note that the system auto-populates a table showing each source directly funding animal expenses (from the Funding Source table) and a second set of columns indicating all species and adjusted animal counts.

Q1: Identify which animals will be covered by each funding source associated with this protocol.

Use the Update icon to add and update funding sources. For each funding source the following questions are populated:

1) Species:

pull down based on the species listed on the protocol

2) Number of animals covered:

This is a text field to add the number of animals associated with each funding source. An actual number is required, not a percentage such as 50% or text such as "all".

3) Previously assigned Segment ID:

This field refers to any segment used for this funding source under the Topaz system. If there was a previous segment (such as mouse 1, mouse 2) this is needed here so that the DAR's can reconcile both billing and transfer of any animals from the existing protocol to the new eIACUC submission

4) Comments: This is a free text field.

## **SUPPORTING DOCUMENTS**

1. If there are biological hazards used, attach the current letter of approval from the Institutional Biosafety Committee (IBC) for the use of biological hazards signed by Chair G. Marshall Lyon, MD, MMSc with the "Biosafety Protocol Approval Letter - Addendum" defining the conditions of approved use of the biological hazard. This document is normally identified as "Biosafety File # beginning with the prefix "HAD...". The list of biological materials requiring EHSO/IBC review can be found here: <http://www.ehso.emory.edu/research-safety/biosafety-protocol.html>.
2. If hazardous chemicals, radioisotopes, lasers or other hazards are used for animal research purposes, attach the appropriate review and approval documentation.
3. Immortal cell lines in research rodents must be confirmed as fully pathogen-free, particularly of viruses, by the DAR. Please review the material at [http://www.dar.emory.edu/vetcare/Cell\\_and\\_biological\\_testing\\_policy.pdf](http://www.dar.emory.edu/vetcare/Cell_and_biological_testing_policy.pdf) for specific requirements and follow them. Attach a copy of the DAR-issued biologicals approval letter.
4. Lab-specific SOPs for breeding colony management, procedures not logically covered by Team or Standard Procedures, or publications or other documents deemed by the PI to be valuable in association with the protocol can be attached here.

## **Procedures: Creation and use:**

Selection of Procedures for use in an IACUC Protocol

### **STANDARD PROCEDURES:**

Standard procedures are available for view under the "Standard Library" tab by selecting the "IACUC" tab at the very top of selected screens. These procedures have been preapproved by the IACUC and can be utilized by the research community without further review

1. Note that standard procedures are periodically reviewed by the IACUC. If changes are required to the standard, then the current version will be archived, and the new version will take its place in the library.

2. When a version of a standard procedure is edited in this manner, any previous version will be denoted as “archived”
3. If the IACUC deems that a required change to a Standard procedure affects animal welfare or raises a compliance concern, then the lab will be contacted and provided with the new version of the procedure.
4. If this version is acceptable, then a simple amendment can be performed to update the procedure
5. If the IACUC deems that alterations to an approved Standard does not represent a significant concern, then the lab can simply update the procedure at next review.

#### TEAM PROCEDURES:

Team procedures are created or edited by the research team and are not preapproved. These are thus subject to review by the IACUC committee during protocol review. There are three sources for Team Procedures

1. De novo creation of a procedure from scratch. This can be done either by clicking on the “Create Procedure” tab from the Research Team page, or by clicking on the create procedure tab from inside the protocol submission form.
2. Editing a standard procedure: If a standard procedure exists that is similar to, but not identical to the procedure you use in the lab, you may edit that procedure to use as a team procedure.
  - a. To do this you must first select the desired procedure and then make a copy of it. This is done from the main page for the specific standard procedure using the “Copy Procedure” link on the left-hand side of the page
  - b. You will be prompted to rename the procedure and assign this procedure to a new research team. Rename the procedure (suggested nomenclature: PI last name-Name of standard procedure) and add it to the desired research team.
  - c. Creation of the copy will begin. NOTE: you will have to hit the refresh button at the very top of your browser to complete the copy process. The software will not notify you automatically when this process is completed. It may be required to press reset more than once.
  - d. Once the new team procedure is created you can find it under the “procedures” tab within your research team.
  - e. You can then edit the procedure and apply it to a protocol submission.
3. Utilizing a team procedure from a colleague.
  - a. Note that any preexisting team procedures existing within your research team can be applied equally to any subsequent protocol within your team
  - b. To utilize a team procedure from a colleague it would need to be manually copied and pasted from a hard copy provided by the original lab group. Alternatively, the IACUC office can perform an electronic copy and paste function for you if both research team PI’s approve and provide the relevant information required to perform the transfer. If you wish to do this please contact your IACUC office RPA for assistance.

#### PROMOTION OF TEAM PROCEDURES TO STANDARD:

1. It is possible within the eIACUC solution to promote team procedures to standards, which can then be made available for use to all investigators
2. To be eligible for promotion an approved team procedure must exist, which will reasonably be expected to have general usage either within a single research team or across multiple teams
3. To submit a procedure for promotion, please email the request to David Martin ([dwmarti@emory.edu](mailto:dwmarti@emory.edu)) and Walter “Guy” Wiles ([wwiles@emory.edu](mailto:wwiles@emory.edu))

#### EDITING APPROVED TEAM PROCEDURES

We have found that often times procedures are approved on one protocol, but then when added to subsequent protocols reviewers request additional alterations. It is not intuitively obvious to the reviewer when a team procedure has been approved in another protocol, which leads to much of the confusion. If you have this occur, please reach out to you IACUC office RPA for assistance. The RPA can guide you through this and help to resolve the issue. In some cases further revisions may be required, where in others resolution with subsequent further revision can be obtained

**NOTE:**

Detailed instruction to complete the various procedure types are not provided here. The IACUC office would suggest the following:

1. It is always suggested that researchers scan the existing Standard procedures to see if any are available for your desired procedure. Using these whenever possible decreases burden on the entire community and provides consistency and efficiency across the board. New standards are being added on a continuing basis and so be sure to check back often, or contact the IACUC office for newly approved Standards.
2. Reviewing existing Standard Procedures can also be an excellent source for better understanding what the IACUC committee expects from a procedure type and can be used as a reference even if a specific Standard procedure does not exist
3. Feel free to suggest a specific procedure for creation as a standard. To do so please contact David Martin ([dwmarti@emory.edu](mailto:dwmarti@emory.edu)) and Walter "Guy" Wiles ([wwiles@emory.edu](mailto:wwiles@emory.edu)) directly.
4. A number of Standard "template" procedures exist that can be utilized in protocols. These include the word "Template" which can be used to search for these in the standard library
5. If you need additional assistance in generating or utilizing procedures please feel free to contact the IACUC office for assistance