IACUC Protocol Submission Guidance and Key Information for New and Triennial Reviews

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1 Preamble

The eIACUC protocol submission serves to collect the information necessary to ensure an adequate review of planned animal research. The process is part of the institution’s effort to comply with applicable animal use regulations. Most elements of the eIACUC protocol are straightforward, including a lay-level description of the research, a list of team members and their training history, information about funding, animal housing condition(s), the total number of animals to be used, the justification of their use, and information pertaining to

efforts undertaken to reduce the unnecessary use of animals whenever possible.

The eIACUC protocol submission form is organized around the design of your project(s) into individual **experiments** (often reflecting the specific aims of the project). Each experiment may contain one or more **procedures** which can be conceptualized as the elemental building blocks of the protocol.

Before updating the eIACUC protocol form, plan on making all necessary revisions to the protocol to reflect the next three years of work (Triennial only).

Approval of your IACUC protocol may require additional approvals from other Institutional Committees and/or departments (EHSO and DAR). These approvals will need to be attached to your protocol in eIACUC. See table below:

Use of materials in animals	Committee / Unit approval
Biologicals[Ω]	EHSO- Biosafety/IBC
Chemicals	EHSO- Chemical Safety Committee
Radioactive substances	EHSO- Radiation Safety committee
Laser	EHSO-Laser Committee
Cell line /biologicals screening	School of Medicine DAR -QA & Diagnostics Unit*

[Ω] Biosafety approval must include the names of individuals who have a **procedure assignment** to handle biologicals in the IACUC protocol

* Pathogen Screening Requirements for Cells and Other Biological Materials for Inoculation at Emory University

Creating a Research Team.

The concept of a **Research Team** is unique to the eIACUC software system.

- Generally created under a single PI but can be shared across a group of PIs who work closely together.
- Individuals can belong to more than one **Research Team** and can see all teams in their own dashboard.
- All protocols must be created in and assigned to an individual **Research Team**.
- Protocols created in a **Research Team** cannot be moved to another **Research Team**, even from the same PI.
- Team Procedures created in a **Research Team** can be used in all protocols within that **Research Team**.
- Team Procedures created in different **Research Teams** cannot be shared unless the IACUC Office copies the Team Procedure from one **Research Team** to the other **Research Team,** provided that the PI has approved the copy.
- The **Research Team** acts as the repository for all **Research Team** protocols and data.
- A **Research Team** cannot be deleted.
- Protocol team members should only be added to the **Research Team** if they need to edit the protocol.

See below example for how to add personnel to the **Research Team**

2 Section-specific details

Please note, to enable expeditious review, avoid inconsistencies, and to minimize errors in maintaining a protocol, entries in each section of the form should be unique and not duplicative.

Cutting and pasting large sections from a grant application usually complicates review, potentially leading to delays in approval.
All questions in the eIACUC protocol should be answered.

2.1 Basic Information

Q3: Short Title:

- New protocol: Create a descriptive short title
- Triennials: During the migration from the previous electronic systems to eIACUC, this field was used for the original protocol number from that system (i.e. DAR-40000062-ENTRPR-N). The Short Title needs to be updated when submitting three-year renewals (i.e. Regulation of Interferon by Glucocorticoids).

Q4: Lay Summary

- Use simple terms understandable to high school science students.
- This section should contain a broad overview of the project and be understandable to a general audience.
- It should discuss the following 5 main points:
    - Relevance to health and welfare or advancement of knowledge in the field of study.
    - Overall goals and aims of the proposed research.
    - Note painful procedures and why they are necessary.
    - Describe the need for and use of anesthesia/analgesia in the proposed studies.
    - Describe the disposition of animals at the end of the study. For example, “We will euthanize animals by either CO_2 inhalation, or drug overdose”.

2.2 Breeding

Q1: Will the Protocol Include Breeding?

Indicate if the protocol will include breeding. This answer will affect the remaining questions that appear in this protocol (if yes, see Breeding Notes below in 2.11).

2.3 Protocol Team Members

- 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.
- For all team members, please fill out all the information requested. If you have questions, please contact the IACUC office.
- Note that if you are using veterinary resource groups or other specialized core units to perform duties associated with the protocol, you may add these here (as a group) and then assign it to the procedure that they will be doing. Below is the list of groups available in eIACUC:

    - DAR, Managed Breeding Service
    - EU-DAR, Vet Staff
    - EPC, Behavioral Management
    - EPC, Imaging Personnel
    - EPC, Res Resources
    - EPC, Vet Staff
    - Center for Systems Imaging (CSI), Core Labs
    - AP Core, Core Labs
    - Rodent Behavioral Core
    - CAMS

2.3.1 Notes regarding "Role in Research":

- Identify *at least two* individuals as emergency contacts and provide emergency phone numbers (i.e., cell, home) for at least two people, to be used if DAR needs to make contact off-hours to address a physical plant or animal welfare emergency.
- **Animal Breeding**: Indicate those individuals having direct contact with the animals. Please note, that those individuals require specific training prior to protocol approval (See Education and Training Policy).
  - If breeding is done by the EU-DAR managed breeding service, you need to choose "DAR, Managed Breeding Service" under the "select the protocol team member" question.
- **Euthanasia**: For everyone performing euthanasia, please indicate the type of euthanasia performed by this individual. Please note that the performance of CO_2 euthanasia or of euthanasia by physical methods (without prior anesthesia) requires specific training.
- "New to animal species on protocol": This designation should be used for persons who do not have prior experience working with the animal species in question. These individuals will be supported with additional species-specific training.
- Assigning a Proxy: To be assigned as PI proxy for a submission, you must be a team member on that submission.
  - As a proxy, you can submit a protocol for review or submit a response to requested clarifications.

2.3.2 External team member information section:

This section is for non-Emory collaborators, or for adding visiting scholars who may contribute to the research but will not have a hands-on animal role.

2.4 Funding Sources

Q1. Identify each organization supplying funding for the protocol:

Emory only allows a single funding source for protocols that cover the use of "Act-species" animals (covered by the Animal Welfare Act). The list of Act species includes the following species commonly used at Emory: Nonhuman primates (NHPs), Voles, Pigs, Sheep, Dogs, Guinea Pigs, Hamsters, Spiny mice, Gerbils, 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 update a funding source(s) for the protocol use the +Add icon to open a new pop-up field to add the following data:

1. Select the funding organization: This is a single select field. Note, 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.
   - Example: The Funding Source "NIH Natl Cancer Institute" can be found using one of the following: i. NIH ii. %Cancer iii. % Institute
   - Internal department funding should be listed as "Unassigned Department"
   - 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:
   - NIH Funded Grant: "R01 HL000001-01A1"
   - NIH JIT: "Pending-Just in Time Request"
   - Internal funding: "Not Applicable-internally funded"
3. Internal Billing Code:
   - The provision of accurate information here is critical for generating animal orders and/or per diem charges.

- 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. This number is found in Compass.
- For internally funded projects (for example departmental funding) the speed type number should be used. Note that this number may need to be updated annually.
- 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. The grant title 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, they are not included in subsequent requests for authorized animal numbers per funding source.
6. Attach files: This function can be used to attach either the grant or sections of the grant.
   - If the grant is funded by PHS or other extramural sources of funding, the IACUC will have to perform a grant-to-protocol congruence analysis, as per OLAW guidelines. Attaching the vertebrate animal section of the grant in this section is required.
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.
   - Do not remove inactive funding sources. Instead, change the status to "inactive". These documents may be needed to support an audit.
8. 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.

Q2. Financial Interest in Research Report (COI Report):

- This section is required by federal guidelines to indicate financial interest in the outcome of the research. If the answer to question 2a is "no", then no answer is needed for question 3.
- If the answer is "yes", then the Conflict of Interest and Commitment Office will perform a review and reach out for additional information as necessary.

2.5 Scientific Aims

Q1. Specific Aims.

Provide a broad overview of the scientific goals and objectives of the study. Be brief - do not include the entire research methods section. The descriptions of the Aims should be understandable to a scientifically educated member of the IACUC. A scientific abstract copied from the grant application using highly technical terms is not acceptable.

Q2. Significance and benefits of the research.

Identify the significance of the research as applied to the area of interest and the overall benefit (e.g., in improved patient care, cures or treatments, or advancement of new knowledge and its potential applicability).

Example: The development of new therapeutic agents to treat lung cancer would be expected to cause pain and stress in animals. However, if this research results in improved disease outcomes including tumor regression and remission then it would provide a benefit that would outweigh the potential for harm.

Q3. Describe the potential for pain and/or distress to animals in this study.

- Identify the risk to the welfare of the animals and compare it to the potential benefits of the study.
- If there are possible or likely adverse effects or events, please identify these with a prediction of

incidence and severity, if available. This is where potential adverse events and effects need to be reviewed and updated during the triennial review.

- The protocol should include anticipated deaths, illness or any untoward outcomes. The potential for deleterious effects is a component of animal research. By not noting potential deleterious effects in an IACUC protocol, every time one occurs, no matter how common or predictable, an "Adverse Event" occurs by definition and must be addressed by the IACUC.
- Include measures to be used to prevent or minimize pain, distress, disability, or impairment of the experimental animals.
- Identify the general schedule for monitoring animals to ensure their wellbeing and detect adverse events/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.).
- Include a statement regarding potential sources of pain or discomfort for your experimental animals and how they will be addressed.
- If experimental animals are likely to experience more than momentary discomfort, analgesics will usually be required, unless withholding them is scientifically necessary. 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. Rather, the working standard is that if a similar procedure or state would cause more than momentary pain in humans, the expectation is that the procedure will cause more than momentary pain in the experimental animals.

Q4. Detail all humane endpoints used in this study indicating the criteria utilized and the frequency and timing of observations.

- It is important to provide clear endpoints for your experiments, i.e., specific details about how often animals will be monitored, criteria used to determine endpoints for experimental animals.
- Describe the criteria that will be used to remove subjects from study, require euthanasia, or allow for veterinary medical or nursing care. Disclose the schedule of monitoring of the study subjects for well-being.
- 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"), those can simply be referenced here without mentioning further details.
- If other criteria are used, they should be described in detail. Investigators, as subject matter experts for their model, are encouraged to propose specific measurable or assessable parameters for removal of animals from the study if these deemed to be appropriate and are better suited to the model system than the defaults endorsed above. Be aware that, even with other endpoints in place, the default endpoints still apply, unless a specific exemption has been approved by the IACUC.
- If 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.

2.6 Reviewing Your Experiments

2.6.1 General Points About Experiments

- List only experiments that will be conducted moving forward.
- Review your Team procedures to ensure they reflect current practices. See General Notes on Procedures in Section 2.6.2
- Review the Experiment to confirm that the Standard Procedures have not been archived. If the Standard Procedure has been updated, you will need to replace it with the current version.
- 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 non-Act species (such as mice, rats,

fish, birds, reptiles) if the details of the experiment are logical and can be followed during review. Also consider the requirements from your funding source.

- For each "Experiment" you are required to write an overview of the experiment (i.e., a statement explaining what is to be done to the animal subjects). The regulatory requirement is to provide a clear and concise sequential description of the experimental intervention 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. Do not cut and paste long descriptions of the rationales for experiments from other sources.
- Do NOT describe procedures in the overview section under "Experiment" (Q3 in the Experiment). These details will be captured under "Select Procedures "(Q5) and "Procedure Timing" (Q6).

2.6.2 General Points About Procedures

- If you need to edit any of your approved procedures, you need to create a new version of the Team Procedure.
- Do not copy the procedure to make edits, instead use "*Create New Version*".
  - Creating a new version of a procedure will add ##archived## to the existing procedure wherever it is used.
  - The ##archived## versions of a procedure will need to be updated in other protocols, if that procedure was used.
  - The verbiage of the parent procedure will be carried over to the new version. Note that you are not creating a *de novo* procedure.

2.6.2.1 Standard Procedures:

Standard Procedures are pre-approved by the IACUC. Using Standard Procedures whenever possible provides consistency and efficiency of the review. *Using the Standard Procedures may shorten the review time.*

- Procedures that are not in the Standard Procedures list, will need to be created from scratch, as Team Procedures. The current list of Standard procedures can be found in the eIACUC Wiki Page [https://emory.sharepoint.com/sites/eIACUC/SitePages/Overview.aspx#list-of-standard-procedures-available-in-eiacuc]
- Standard Procedures cannot be edited by the researcher. The research team must be familiar with the standard procedure and follow it without any deviation.
- A Standard Procedure may be copied, it will become a Team Procedure which can be edited. This new Team Procedure must be reviewed and approved by the IACUC.

2.6.2.2 Team Procedures:

- Procedures that either do not exist 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.
- If you need additional assistance in generating or using procedures, please feel free to contact the IACUC office for assistance.

2.6.2.2.1 Generating a Team Procedure:

1. ***De novo creation*** of a procedure. This can be done either by clicking on the "Create Procedure" tab from the Research Team page within eIACUC, or by clicking on the "Create Procedure" tab from inside the protocol submission form.
2. ***Copying & Editing a Standard Procedure***: If a Standard Procedure exists that is similar, but not identical to the procedure used in the lab, it can be edited for use as a Team Procedure.
   - 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.
   - You will be prompted to rename the procedure and assign this procedure to your research team. Rename the procedure (suggested nomenclature: PI lastname-Name of Standard Procedure) and add it to your research team.
   - Creation of the copy will begin and may take several seconds up to a couple minutes. You will have

to hit the refresh button at the 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 the refresh button more than once.

- Once the new Team Procedure is created you can find it under the "**Procedures**" tab within your research team.
- You can then edit the procedure and apply it to a protocol submission.

3. Copying & Editing a Team Procedure from a colleague.

- Note that any preexisting Team Procedures existing within your **Research Team** can be applied equally to any subsequent protocol within your team.
- 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 provide an electronic copy and paste function for you if both **Research Team** PIs approve and provide the relevant information required to perform the transfer. If you wish to do this, please contact the IACUC office for assistance.

NOTE: If you edit a Team Procedure that is used in multiple protocols, you need to submit an amendment to each protocol where that Team Procedure is used after the protocol is approved.

2.6.2.2.2 Editing a Team Procedure

- Creating a **New Version** of the Team Procedure
  a. Go to the procedure and create a new version
  b. Edit the new version
  c. Go back to the experiment where this new Team Procedure will be used:
     1. Add the new Team Procedure to the procedure list.
     2. Remove the archived versions of the same Team Procedure. The existing version of the Team procedure will appear now with the prefix ##ARCHIVED##

2.6.2.2.3 Promoting a Team Procedure to Standard Procedure

- It is possible within eIACUC to promote Team Procedures to become Standard Procedures, which become available for use to all investigators.
- You must have an approved Team Procedure, which will reasonably be expected to have general usage either within a single **Research Team** or across multiple teams. To submit a Team Procedure for promotion to Standard Procedure, please email the request to the IACUC Office (iacuc@emory.edu).

2.6.2.2.4 Substance Administration Procedures (SAP)

- Team Substance Administration Procedures cover the administration of substances and other chemicals to animals.
- All substances administered to animal subjects need to be included in a Substance Administration Procedure.
- Within a given protocol these SAPs can be created either on an experiment-by-experiment basis (thus, potentially leading to multiple SAPs in one protocol), or on a per-protocol basis (thus, leading to a single SAP potentially covering multiple substances). Examples for each of these possibilities are provided at these linked webpages: One SAP per experiment, one SAP per protocol.

2.6.3 Experiment

Define the experiments to be used in this protocol:

- Individual experiments can be created here using the **+Add** icon.
- Once created, 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 or other readers.

2.6.3.1 Specific Questions for Each Defined Experiment

Q1: Experiment name: User defined

Q2: Species: defined by default if identified within the research team page. Species can be changed at the experimental level by using the Select icon

Q3. Describe the experiment

- Describe the experimental design for this specific experiment (see example below)

Goals: Nicotinamide riboside (NR) is an endogenous precursor of NAD+/NADH. It is FDA-approved with NDI status (New Dietary Ingredient). Given systemically as a drug, it has been shown to be protective in rodent models of neurodegeneration, and indeed, in many models of cell, tissue, and whole-body stress. Here we propose to test whether treatment with NR protects against light-induced retinal degeneration (LIRD) in mice.
Type of Data Collected: We will use our "standard" test of a potential neuroprotectant in light-induced retinal degeneration experiment using Balb/C, 129sv, or C57Bl6-tvrm4 mice. NR will be injected i.p. before the light treatment and twice daily thereafter. We will assess mice for retinal function at one and two weeks after treatment. Mice will then be euthanized, and tissues harvested for morphological, biochemical, and molecular analyses. Drug concentrations and dosing regimens are taken from the literature with no harmful effects reported.
Experimental Groups: Number of mice: 10 per group, 5 female, 5 male
1) Vehicle 1 (PBS)
2) Vehicle 2
3) Experimental Drug 1 (500 mg/kg body weight)
4) Experimental Drug 1 (1000 mg/kg body weight)
5) Experimental Drug 2 (500 mg/kg body weight)
6) Experimental Drug 2 (1000 mg/kg body weight)
Repeats: We anticipate the experiment may be run up to three times to ensure the reproducibility of our results.

- Describe how the experiment is 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.
- Indicate if experiments will be repeated and, if so, provide the number of replications for each group.
- Identify the types of data collected (e.g., behavior, phenotypic measurements, survival, images, biological materials such as blood, and/or tissues at euthanasia).
- 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 question 6, below.
- Note that details pertaining to biological, chemical, or radioactive substances (for example: route of administration, dose, concentration, pharmacological grade, etc.) should be included in a Substance Administration Procedure form (see 2.6.2 General Points about Procedures).

Q4. Justify the purpose of this experiment.

- Here you provide the scientific need for the experiment.

Q5. Select Procedures:

- This section is used to list all procedures to be used within this experiment.
- You can search for procedures directly in the form 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. Two of these may be of particular 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 pre-approved by the IACUC and are available for use by all researchers.
- A list of Standard Procedure for quick reference is available in the eIACUC Wiki page at https://emory.sharepoint.com/sites/eIACUC/SitePages/Overview.aspx#list-of-standard-procedures-

available-in-eiacuc.

Q6: Procedure Timing.

- Provide a timeline showing the relationship of the procedures to each other for each experiment. The rich-text field allows the use of tables, flow charts, and other diagrams or pictures. The use of these materials is 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 via cut & paste operations from other programs. Note that these aids will become part of the approved protocol.

Q7: Total Number of animals used in this experiment.

- Add the numbers required for the experiment
- Act-species animals require a breakdown by USDA pain category, while non-Act species (i.e., rats, mice, birds, fish) do not.
- Include experimental animal numbers only. Extra animals beyond strict experimental size (i.e., training animals, expected higher mortality) should be included under the Animal Justification section.
- All animal numbers will need to be justified under the Animal Justification section.

Q8: For Act species:

- Add the number of animals assigned to each USDA pain category

Q8 For non-Act species: Housing Conditions.

- Update 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.).
- If "No Specialized housing-standard care only" is selected no description or justification is needed.
- If a Housing Exception is selected, a description and justification should be added.

2.6.3.2 Experiment Q2: "Will any single animal undergo more than one survival surgery?"

A "yes" answer should be indicated here under the following situations:

- An animal may undergo a second surgery under specific conditions as defined within the protocol if complications arise and this is deemed necessary.
- 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.
- 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.

A "No" answer should be indicated here under the following situations:

- Animal undergoes one survival surgery.
- If a repair surgery might be needed, it should be included in the surgical procedure.
- The following questions also need to be answered if Experiment Q2 is answered YES:
  - Describe the order and time interval between surgical procedures on a single animal: See examples above. This question provides a rich text field; thus, flow charts or diagrams can be used to demonstrate the experimental design.
  - Provide scientific justification for multiple survival surgical procedures on a single animal: The answer to this question can be a simple statement. This question also provides a rich text field, so that flow charts or diagrams can be used.
  - Specify how many animals will undergo multiple surgeries. The answer to this question can be a simple statement. This question also provides a rich text field and so flow charts, tables or diagrams can be used to demonstrate the experimental design.

2.7 Procedure Personnel Assignment

Q1. Select the team members who will be performing each procedure:

- This table will pre-populate with the procedures defined in the last section and will originally default to having all staff listed as performing all procedures.
- To remove the listing of a team member from any given procedure, click on the icon to the right of the row (pencil icon). You can then unselect any given team member by unclicking their name.

- Review the roles assigned to each member at the beginning of the submission (see Protocol Team Members above).
- The roles assigned under the protocol Team Members need to be consistent with the Procedure assignment. For example, if an individual has been assigned the role for CO_2 euthanasia, then the individual's name should be selected in the CO_2 euthanasia procedure.

Q2. Team Member Training:

- This field should auto-populate for all team members.
- Contact the IACUC office for assistance if you have records of personnel having completed a particular training and it is not showing up under this section.
- Training completed in the AALAS free site must be transferred to the Emory group. The individual should send the training record to iacuc@emory.edu to request its update in AALAS.
- Individuals assigned to a surgical procedure and or conduct euthanasia need to have completed an in- person skill assessments. Contact the training group in your DAR unit (EPC-TRN epc-dartrn@emory.edu, or EU-DAR dartrn@emory.edu) to schedule the assessments.
- Review the Education and Training Guidelines Policy to ensure that all personnel have completed the pre-approval training. The PI is responsible for ensuring that the post-approval training/assessment is completed.
- This section also includes the annual Online Health Screening (OHS), as part of the Occupational Health and Safety Program. The OHS clearance is due once per calendar year. Personnel from the Emory Primate Center (EPC) need to complete this screening through the EPC Safety Office. Information related to the IACUC OHS clearance can be found here: https://rcra.emory.edu/iacuc/ohs.html.

2.8 Strains

- This section allows for the identification of animal strains that have phenotypes adversely affecting animal health and welfare. This is a required component of review under the "Special Considerations" section of the "Guide for the Care and Use of Laboratory Animals, 8th edition".

  Examples: Mice with a mutation in a gene which leads to spontaneous tumor growth; platelet deficiency making the animals more susceptible to bleeding; anal prolapse.

- Answer to Q1.
  - Check "**yes**" to this query if there are strains that would expect to have health concerns even without manipulation. Complete the table included in Q2.
  - Check "**no**" if animals are expected to have normal health status prior to experimentation

2.9 Animal Justification

- The Guide 8th Ed. includes the following two points to be considered during IACUC review: availability or appropriateness of the use of less invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation (Alternatives); and unnecessary duplication of experiments.
- This section can be used to modify 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 alterations are requested.
- Researchers should list only animals they need going forward (in the next three years of their work).
- The numbers are populated from the Experiments section (you would have already updated the animal numbers at the Experiment level). Note that there may be reasons why you may need to adjust the numbers, see examples below.

Q1. Adjust the number of animals to be used or produced for this protocol as needed:

- Click Update to complete the adjusted animal count.
- Note that you can add or subtract animals or 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.

Reasons for adjusting animal numbers under the **Adjusted Animal Count**
-Animals for training
-Higher mortality expected
-Using the same control animals for all the experiments

Triennial Review: ensure that the animal number includes the existing census at the time of renewal

Q2. If you adjusted the number of animals for this protocol, explain why:

- Common reasons 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 reasons to reduce animal numbers include originally planned studies are completed, the reuse of control groups across experiments, or the use of experimental animals jointly as more than one experimental group.

Q3. Provide the rationale for using animals in this protocol:

- State the reason(s) why animals are required for the protocol(s) (i.e., why using them at all), not the use of the species. This question does not request a justification for animal numbers. Below is an example for the use of animals "at all":

Animals must be used in this research because alternative approaches such as the use of tissue cultures, organoids, computer-based models, or molecular/genetic techniques will not test the hypotheses proposed in this protocol. Similarly, plants or simple organisms cannot be used because the current study examines the complex interplay between multiple pathways and systems that are not found in simpler systems.

Q4 Justify the number of animals to be involved in this protocol

- This question is aimed at justifying the total number of animals, by species, utilized on the protocol. The response should provide scientific justification for the total number of animals used, not by experiment, or as adjusted.

Q5 Justify why each proposed species was chosen for this protocol.

- This is a required field. The justification is for the **species of animals**, not for the use of animals (Q3).

Q6 Identify each source of animals for this protocol.

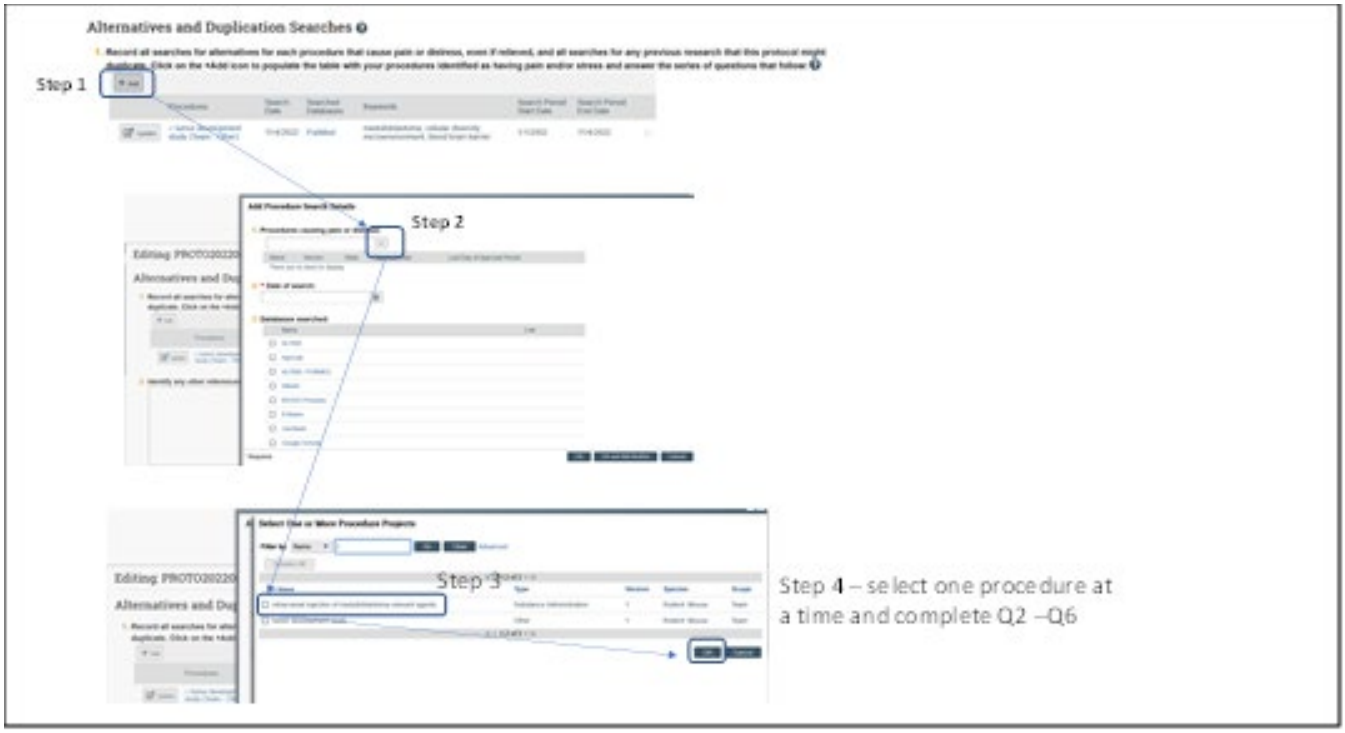
- Provide the source of the animals used in this protocol (i.e., Jackson Labs, Emory Transgenic Mouse Core).

2.10 Alternatives and Duplications Searches

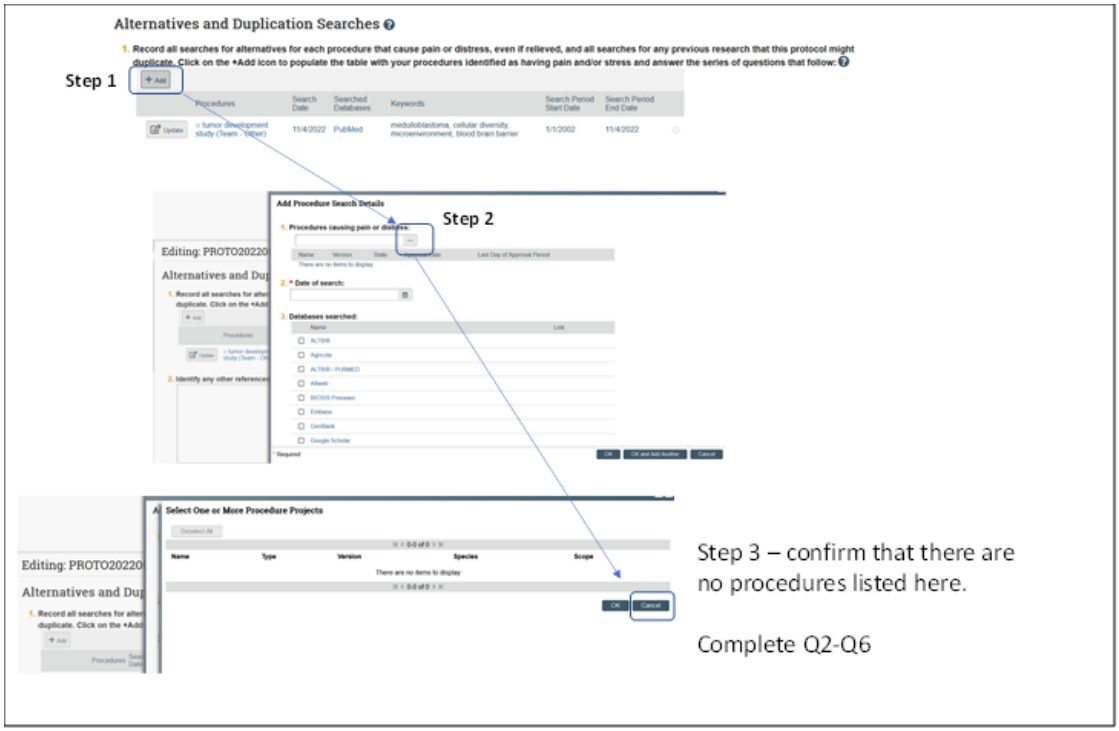
- **Non-Act species**: No Alternatives and duplication searches are required for new submissions or triennials.
- **Act species**: Due to the current regulatory environment, we encourage investigators to complete the alternative and duplications searches for new and triennial submissions.
- PIs are encouraged to contact the Emory Library Services (IACUC Searching and Resources) for guidance and assistance to conduct these searches.
  Website: https://guides.libraries.emory.edu/iacuc
  Contact: Mia S. White
  Email: mia.s.white@emory.edu

Q1. Record all searches for alternatives for each **procedure that cause pain or distress**, even if relieved, and all searches for previous research that this protocol might duplicate.

- If the question in the Standard Procedure or Team Procedures ***"Would administering this procedure in an awake animal cause any more than momentary pain and distress?***" is checked "Yes", then the procedure name is available to be selected by clicking +Add icon to populate the table with your procedures identified as having pain and/or stress. You will also need to fill out Q2-Q6.



If the question, in a Standard Procedure or Team Procedure, ***"Would administering this procedure in an awake animal cause any more than momentary pain and distress?*** is selected "No", leave Q1 blank, then fill out Q2 - Q6



- **Date of search**: Date last search performed. Note it is recommended (but not required) results be saved by the PI team.
- **Database Searched**: Use at least two databases - either ALTBIB or AWIC combined with PubMed Medline or equivalent.
- **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. For example: pig AND craniotomy AND alternatives to animal testing.
Summarize all relevant results. Indicate why there are no alternatives to this research, and why it does not unnecessarily duplicate previous studies

- **Time Period covered by search**: Enter the 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 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.
  Example: Alternatives search was conducted through the Emory Library Services (IACUC Searching and Resources).

Q3. Confirm that you have made every effort to ensure that this protocol is not an unnecessary duplication of previous research. This question is a checkbox.
Q4. Please summarize the findings. If alternatives exist but will not be used, provide scientific justification as to why they will not be used.

The following example is provided only as a suggestion: copy/paste the key words used in Q1 followed by a brief summary of the literature hits.

***Key words used**: behavior AND guinea pig AND alternative AND foot shock*
***Search Results**: No results found on AltBib/PubMed. No studies have evaluated the impact of antibodies in the progression*

Q5. 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.

- **Reduction**: Describe how the number of animals proposed 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 analyses to guide the choice of experimental group sizes and repeats, along with rigorous control of experimental variables.
- **Refinement**: Describe the refinements that have been incorporated into the 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; use of ante mortem endpoints tailored to the specific experimental goals; minimization of doses or exposure to toxic compounds; imaging technique used to assess the progress of the disease without euthanizing the animal; use of fine needle aspirates over biopsies; and other innovations to prevent or minimize pain and/or distress.

2.11 Breeding:

To add breeding to your protocol, follow these steps:

- Check “yes” to the question:” ***Will the protocol include breeding?***”
- Add an Experiment called “Breeding Colony” (See below 2.11.1), ***AND***
- Complete the Breeding section (See below 2.11.2).

2.11.1 Create an experiment called “Breeding Colony”

- Describe the experiment: describe the mouse strains to be used for breeding.
- Justify the purpose of the experiment: usually the justification is because the animals are not commercially available.
- Select procedures: Select all applicable standard procedures for genotyping and euthanasia
- Procedure timing: describe when the animals will be genotyped, for example.
- Total number of animals: type the number of animals requested for breeding.
- Housing condition: there is no need to add information here, unless there is need for an exception due to the type of strain used.

- Supporting documents: do not upload any supporting documents unless related to the breeding process.

2.11.2 Use of the breeding section

Q1: Describe the methods you will use to identify offspring and to collect tissues for genotyping

- list the standard procedures for genotyping listed in the Breeding experiment.

Q2: Describe the breeding scheme to be employed including details of the sex and ages of breeding animals, the criteria for selection, and any other relevant details for breeding colony maintenance

- In the case of rats, mice, fish, or birds, if there is not a breeding procedure description or lab-specific SOP, provide the attributes and necessary production from each genotype maintained to support the studies in a logical and easy-to-follow manner, including:
- The expected number of different genotypes to be maintained.
- The mean and maximum number of breeding cages in the colony.
- The male: female breeder ratio in those breeding cages.
- 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).
- The frequency of replacement of breeders (prior to senescence and at reproductive decline; usually in the 6-9 month of age range).
- 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.
- 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 tabulated amounts.
- Reviewers should be able to easily link the production output here from each colony to each experiment.

Q3 Indicate the age range for weaning animals. Provide justification for delayed weaning and describe any supportive care to be provided.

Q4. Identify any other protocols to which you will supply animals bred from this protocol

2.12 Housing and Use

- Review the table including the sites for housing and experimental use.
- Update the location (building) where your animals will be housed and add any additional spaces outside the DAR facilities that may have been approved for experimental use in the last three years.

Q1: Identify each **vivarium** location where animals will be housed or used:

Q1: In general, the building location is sufficient here for housing. If specific rooms are used 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 location. Some locations appear with the initials of the building. For example: WBRB= Whitehead building; WMRB=Woodruff Building.

Q2: Species as indicated within the protocol.

Please create a separate entry for each species.

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

Please fill this out as appropriate. If a location is used for housing, simply choose “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 for subsequent semi-annual site inspections.

Q5: Describe transport

This section is only applicable if animals are leaving the vivarium. It is not required for animal movement within the vivarium. For example: DAR fleet, covered cart

Q2: Identify each **non-vivarium** location where animals will be housed or used:

Q1: List specific, individual rooms where procedures will be performed. This is critical for protocol approval, and subsequent 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 discuss this with your RPA so they can confirm that the space is approved for animal use.
Q2: Species as indicated within the protocol
Please create a separate entry for each species.
Q3: Indicate the approximate length of time animals will be in this location
Please fill this out as appropriate. If ACT species are held in a location outside of the animal vivarium for greater than 12 hours, or if non-ACT species are held in a location outside of the animal vivarium for greater than 24 hours, this constitutes a "housing" location. The housing location must be added to semi-annual program reviews. Specific justification will be required in 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 for protocol approval and for semi-annual site inspections.
Q5: Describe transport
Update methods for transport of animals. You need to indicate if live animals will be returning to the vivarium or if this will be a terminal transfer.

2.13 Disposition

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

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

This is a text box to allow descriptions of disposition alternatives not shown under Q1.

2.14 Supporting Documents

- Approval of your IACUC protocol may require additional approvals from other Institutional Committees and or departments (EHSO and DAR).
    - Upload/update approval letters in this section. See table below:

Use of materials in animals	Committee / Unit approval
Biologicals[Ω]	EHSO- Biosafety/IBC
Chemicals	EHSO- Chemical Safety Committee
Radioactive substances	EHSO- Radiation Safety committee
Laser	EHSO-Laser Committee
Cell line /biologicals screening	School of Medicine DAR -QA & Diagnostics Unit*

[Ω] Biosafety approval must include the names of individuals who have a **procedure assignment** to handle biologicals in the IACUC protocol

* Pathogen Screening Requirements for Cells and Other Biological Materials for Inoculation at Emory University [https://cores.emory.edu/dar/_includes/documents/BiologicalTestingPolicy_rev012022.pdf] or specific requirements.

Attach a copy of the DAR-issued biologicals approval letter. This approval must be acquired every three (3) years.

- Upload/update lab-specific SOPs for breeding colony management, procedures not included in 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.
- Upload/update Lab-specific SOPs for husbandry (if Research Team is doing the husbandry, for example fish husbandry) need to be attached here.
- Upload/update any applicable wildlife permits.

3 Key information needed for New and Triennial Protocol Submission

General Items

- Assign primary contact. Individual (in addition to the PI) who receives all email notices (Optional).
- Assign proxies. Individual(s) who can act on behalf of the PI (Optional-Highly Recommended).

Protocol Renewal Summary Page (Triennial only)

- Provide a summary of progress from the past three (3) years.
- Summary of Changes to the project for the next three (3) years – these changes need to be reflected in the protocol smartform.
- Explain unanticipated results, examples include:
  The number of animals required was higher than initially anticipated.
  Actual experiment results were different than expected.
  You could also list a summary of amendments submitted during the current review period and reasons for them.

Main Protocol

- 3-Year renewals are updates of the originally approved protocol and complete re-writes are not required.
- Assign to desired Research Team (cannot be reassigned to another team later).
- All Lay Summary Questions addressed.

Team Members:

- All current members are added, and roles/responsibilities are correct
- Members who have left the lab should be removed **(Triennial only).**
- Emergency contact information is current.
- Review training requirements per IACUC Policy Education and Training (PDF) for all members listed.
- All personnel listed must have been cleared by OHS once per calendar year.

Funding Sources:

- Do not remove inactive funding sources. Instead, change the status to “inactive”
- Add any new funding sources as needed and grant documents.
- Review all information and ensure it is accurate.
- Review the conflict-of-interest section if needed.
- The EPEX number should be the same if you are the holder of the external funding.
- If you have an internal subaward or departmental funds, you need to update the speedtype when applicable.

Specific Aims

- Scientific Aims accurately describe goals of the study.
- All potential and expected sources of pain and stress are identified and addressed.
- Humane endpoints are described and fit the potential for pain/stress.

Experiments:

- Replace/update any archived Standard Procedures with the new version.
- Review all procedures (team and standard) to confirm that all are current. For example, procedures are not showing ‘##ARCHIVED##’.
- Check the Standard Procedure list posted on the eIACUC Wiki site to see if a Standard Procedure could replace any of your Team Procedure

[https://emory.sharepoint.com/sites/eIACUC/SitePages/Overview.aspx#list-of-standard-procedures-available-in-eiacuc].

- Ensure that all substances administered to animals are included in a Substance Administration Procedure, if not included as a Standard Procedure.
- Procedure timing indicates what will happen to animals in sequence, including timeline.
- Housing exemption is selected according to the experiment needs (i.e., water exemption, ABSL2, single housing).
- Multiple Survival Surgeries (MSS) on an individual animal. (If Yes, additional questions will populate). (i.e., 5/6 nephrectomy)

Procedure Personnel Assignment:

- Review team member procedural responsibilities. Some of those assignments will trigger completion of training.
- Confirm OHS annual screening questionnaire is current (https://rcra.emory.edu/iacuc/ohs.html)
- Continuing Education (CE) is complete and updated as per IACUC policy: Education and Training (PDF)

Animal Justification

- Update animal numbers within experiments: Note numbers reset at renewal and these can be readjusted as needed.
- Update the Adjusted Animal Count column and provide justification if needed.
- The justification for Animal Numbers need to match the table for animal count.
- Include breeders as part of the adjusted number if a separate Breeding experiment was not created.

Strains

- Some Strains may have adverse baseline phenotypes (If Yes, detailed information is required).

Alternatives and Duplication Searches for procedures involving pain and distress (Q4 in the procedure form)

- Act species: All literature searches must be updated and documented.
- Databases to be used:
  - AltBib: alternatives
  - PubMed: duplications
- Perform any new searches as required if new procedures were added and pain and distress was checked YES.
- If the procedures are not showing in the Alternatives and Duplications table, then you did not check Q4 in a procedure as YES.
- Ensure that key words causing pain and distress are included in the search.

Breeding (Note: This section will only appear if breeding was selected in the earlier sections)

- Breeding schemes are included and contain all required information.
- Methods for identification and genotyping are included.
- Age range for weaning included. Note if delayed weaning is required it must be scientifically justified.

Housing and Use

- Vivarium facility housing and use locations are included (Building name is sufficient).
- Non-vivarium housing and use locations are identified (Requires both room and building location).
- List all spaces (vivarium and non-vivarium) where procedures are done (i.e. imaging, behavioral

studies, surgeries).

- Non-facility usage site: Select from the drop-down menu. Contact the IACUC Office if the space is not on that list.

Disposition

- All dispositions are indicated.
- If euthanasia is checked, at least one euthanasia procedure is included in the experimental section.

Supporting Documents: Current approvals include the materials mentioned in the IACUC protocol

- EHSO: Biological, Chemical, Radioactive materials- remove out of date approvals (Triennial review only)- personnel using biologicals, chemicals, or radioactive materials in animals must be listed in the corresponding EHSO approval.
- DAR QA: Biological testing (every three years) remove out of date approval (Triennial review only)
- Every biological included in the DAR QA approval is included in a Substance Administration Procedure
- Wildlife permits

Responsible Official:	Research Administration
Administering Division/Department	IACUC Working Group for Consistency / Research Compliance and Regulatory Affairs
Effective Date	04/19/2023
Last Revision Date:	04/19/2023

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