

End of section 1 (General tips)

1. First, consider whether the material you need to cover should be 1 AUP or more than 1 AUP. While there can be convenience with having multiple studies on 1 AUP, there are disadvantages to having multiple experiments on 1 AUP.
 - First, if this AUP were to expire before a replacement AUP is approved, all studies in the lab must stop.
 - Long, complicated AUPs can be difficult to manage, also. For lab members to be able to identify and be familiar with all of the sections that apply to their studies can be challenging.
 - Regarding the review process, the longer and more complicated the AUP, the more difficult it is to follow during review, and the more questions you are likely to receive. Generally, the longer, more complicated AUPs require more rounds of Q&A than shorter, more concise AUPs. Responding to multiple questions for a long, complicated AUP can be challenging, also—people frequently miss answering some questions the first time. So although it may seem like having 2 AUP reviews may seem like it will take longer than 1 review, having 2 easier AUP reviews can actually take less time, and be less challenging.
2. The PI can give writing/editing rights to anyone on the AUP (details in Section 3). So, the PI can have someone else in the lab write the AUP. Only the PI can submit items to the IACUC, however, so the PI does need to click the “Submit” button. We ask that the PI please review the AUP/Amendment before it is submitted, to ensure it describes the project accurately, and that the quality is as desired.
3. The text boxes can be enlarged!! With the Firefox and Chrome browsers, click on the lower right corner of the text box, and drag it downwards, to expand the text box.
4. To review your AUP as a whole, such as when you are getting ready to submit it, or during a revision, it is helpful to create a pdf (print as pdf). The text boxes will automatically enlarge to show all of the text in each pane.

5. Consider writing the response to the longer questions (like Section 8) in a word document, then copy and paste it into the online form. Easier to edit, and if you lose some information if the system times out, it is easier to enter again.
6. Consistency: In order to avoid lack of consistency among sections (and those annoying revision requests to correct them), please only include the information in the section that request it. In other sections, if you want to refer to that information, simply state, for example, “as described in section 5.3”. A great example is humane endpoints. They should only be described in 11.3. In other sections, if you want to clarify that animals are euthanized at the humane endpoints, you would write “animals will be monitored and euthanized at the humane endpoints described in 11.3”.

2.1: Project Title:

This first question should be an easy one! The title is determined by the PI. We recommend that you include enough detail to distinguish it from your other protocols, but to try not to let it get too long.

2.2: Principal Investigator:

- Only 1 person may be a PI on an IACUC protocol. Within the lab, and on grants, you may have co-PIs, and you can note “Co-PI” as part of someone’s role in section 3. However, the IACUC considers the person listed as PI on the protocol to be the person responsible for maintaining regulatory compliance.
- Who may be a PI? Faculty who are tenured, tenure-track, non-tenure track, or temporary may be a PI.
- Adjunct Faculty, Visiting Faculty, Postdoctoral associates, and Non-UGA personnel affiliated with the Innovation Gateway Incubator Center companies may be PIs if certain criteria are met, and with written approval from the IACUC Chair or University Director of Office of Animal Care and Use. Please contact the Office of Animal Care and Use to request PI status for a person in one of these categories.

2.3: Primary Funding Agency:

- For PHS/NIH, NSF, DOD funding, this must be answered.
- For other funding sources, this does not always require a response.
- For private organization funding, you may identify as ‘Private organization’; the agency name is not required, and could be made public if there is a request under the Open Records/Freedom Of Information Act.

2.3.1 Aliases with Funding Agency:

- This does not require a response. HOWEVER, it can be helpful to list known alternate titles, so that if SPA contacts the IACUC to verify a specific grant has a corresponding AUP, we can verify that there is a matching title. Sometimes granting agencies require the IACUC protocol have a matching title.
- Additional grant titles may be added via an amendment at any time. This type of amendment does not require IACUC approval. It can be handled administratively and processed quickly.
- Multiple grants may be covered on 1 AUP and 1 grant may have multiple AUPs.

2.4: Location

- This section is related to the funding and the institution under which the project is performed. If any live animal work is being funded by/via UGA but performed at another institution, this section must be completed.
- Purchasing some biologicals with UGA funding does fall under this category. For example, if antigen is provided to a commercial vendor to create specific (“custom”) antibodies, or a transgenic mouse line is being created specifically for the PI, this needs to be described in a UGA IACUC protocol. This does not apply to “off the shelf” biologicals or the purchase of commercially available transgenic mice.

2.4.1 (a):

- You may not know all of this information, however, it is important to complete as much as you can.
- You can add other details in the text box in 2.4.1(b)

2.4.1(b)

- This section should clearly explain what work is being done at the non-UGA site/s, and why it is not being done at UGA.
- The funding relationship between UGA and the other institution should be clearly explained (e.g., sub-contract).
- Work with non-UGA collaborators in which grant money awarded to UGA/a UGA PI is going to another institution to fund this project (e.g., a subcontract) requires a formal, written understanding (MOU). Usually an MOU is required by the other institution if the grant is going to the other institution and UGA is receiving a sub-grant.
- For PHS funded work, an OLAW Inter-institutional Assurance must be completed. Note that PHS money funded to UGA cannot be used to fund work at an institution that does not have a PHS Animal Welfare Assurance with OLAW/NIH.
- The OACU will help you with this additional paperwork! We have templates and usually contact the other institution and complete the MOU for you.

2.4.1(c)

- If you have any of the documents listed, note that in the text box. The OACU will contact you to acquire any needed documents, such as a copy of an IACUC protocol from the other institution.
- Note that the Artemis system does not allow you to attach documents. Instead, AUP related documents should be emailed to the IACUC office (IACUC@uga.edu), referencing the related AUP number.

2.5: Expiring Protocol

- Please answer this as “Yes” if this AUP is going to replace a previous AUP, even if the previous AUP is not actually expiring, or if the new AUP will have additional projects. This is especially important if you have animals on the previous AUP, so that URAR can transfer them to the correct new AUP.
- Please choose the correct expiring AUP from the drop down list if it is available. Unfortunately, sometimes the expiring AUP number will not be on the drop down

list, for example if it is more than 90 days before the AUP is going to expire, or after it has expired. If you think the AUP should be on the list, but it is not, please contact the IACUC office at iacuc@uga.edu

2.6: Purpose

- Another easy one! Please check at least one box. If both will occur on the AUP, both should be checked. We do use this data—sometimes we need to distinguish research from teaching protocols.
- Note that “Instructional” includes formal courses as well as other educational activities such as extension and personnel training.

3.1: Personnel

This is where you list everyone who will be working with the animals on this project. Including UGA personnel and non-UGA personnel.

- To enter a person’s name, you need to find them in the UGA system. Click on “Add Person” to open the search box connected to the UGA system. If your person does not seem to be in the system, try using only the last or first name.
- For non-UGA personnel, please contact UGA Card Services, so that an “Affiliate” account can be created. You will only be able to find them in the UGA system and add them after they have an Affiliate account. The form needed can be found at the UGACARD VISITORS website:
https://tate.uga.edu/ugacard_content_page/ugacard-visitors
- This is where the PI can give writing/editing rights to others in the lab. Under the person’s name, answer “Yes” to the sentence “Can edit this submission form and draft amendments/renewals for this protocol”. (“No” is the default). Note that this give the person edit rights only for this protocol, not for any other protocols that person is personnel on.
- This section is needed because the IACUC is required to verify that all personnel working with animals are adequately trained for the procedures they may perform. One of the most common mistakes made when completing this section is to not list both the role/responsibilities and the training/experience, or to not provide enough information.

- Role/Responsibilities:
 - For each person on the roster, the role should be clear.
 - Examples: “PI, will not be working with live animals”; “Post-doc, will perform any of the procedures listed on the AUP”; “Undergraduate student summer employee, will handle animals, and may assist others perform procedures, but will not perform any procedures alone”
 - Will the person be working with animals/tissues, and what types of procedures will he/she perform?
 - It is not necessary to list each individual procedure, but you must list at least a general description such as “performing any/all procedures” or “observing behavioral tests”, “assisting with surgeries”, or “managing breeding colony”, for example.
- Relevant training:
 - This is where you need to make it clear whether the person already has experience and/or training for the types of procedures/work with these species that he/she will be performing on this AUP.
 - Examples: “She has 5 years of experience with these procedures in all of the species we are using”; “He has a PhD in Animal Science, and has performed similar work for several years”
 - If personnel do not have experience and/or training, it must be clear that they will receive training before they work independently.
 - If someone needs training, you should note who will do the training. HOWEVER—it is better to not list individuals by name (that may change). Please use a general description, such as, “experienced lab members”, “the PI”, “URAR personnel” “a colleague at another institution”.
 - Note: You do not need to list the UGA required training (IACUC 101, etc), because all of the UGA training the person has completed will automatically appear underneath his/her name when you add a person.

4.1: Objective

- It must be clear what the main goal is.

- If there are multiple goals, please identify them clearly—numbering them is the best method of listing multiple goals because it makes it easier to follow.
Example: “The main goal of this study is to develop effective vaccines for Zika virus. This main goal has 3 objectives: 1) to establish an avian model of Zika virus infection, 2) to test various vaccine candidates for the ability to produce a humoral immune response, and 3) to test the efficacy of the best vaccine candidates by vaccination and challenge with the mouse model.”

4.2: Significance

- This is where you explain the potential benefits of your research. The IACUC needs to know the anticipated benefits in order to consider the cost to benefit balance, as required by the regulations.
Example: “Zika virus continues to be a public health concern, and is known to cause birth defects. The development of an effective vaccine will greatly minimize the number of people who may become infected and greatly reduce the number of babies born with infection induced birth defects.”

4.3: Justification for the Use of Animals

- The response must clearly explain why live animals need to be used, instead of a non-animal alternative.
- Note that this question refers to the use of an animal in general, not the just species to be used (a question about the species comes later, in 5.3).
- Some of the justifications used have included the need for assessing a response in a complex organism, with intact physiological systems (e.g., immune, neurological, metabolic); that a behavior/habitat use/migration is being assessed, which requires live animals capable of performing the behavior/migrating.

5.1: Animal Information

[no tip for 5.1 itself, just the items below]

Species:

- This is usually not a true “species”, but the common name of an animal, (e.g., “mouse”).
- If you are using an animal that is not on the list, let our office know and we can add it for you (iacuc@uga.edu)

Strain:

- The ‘Strain’ is usually not technically a strain, but could be a subset of animals.
- If you are using an animal that is not on the list, let our office know and we can add it for you (iacuc@uga.edu)

Highest Use Category:

- The Highest Use Category must correspond to the activities described on the AUP. See above for the descriptions for A-D.
- For non USDA covered species, you can list all of the animals under the highest category, you do not need to divide them into category groups (e.g., 700 mice under “C”, instead of 200 C mice and 500 B mice).
- For USDA covered species, you do need to list the animals as separate groups if they are in different categories.

Sex:

- Note: “Male” is the default (not our choice!), so “Female” or “Both” need to be chosen from the dropdown.

Quantity (Numerical Only):

- Quantity should make sense compared to the explanations of numbers in 8.2, such as study groups/number of animals per group.
- Note that this includes any animals that are manipulated, captured, or affected by the work, even if you do not use them for data. For example, if you screen a larger group of animals and then only use seronegative ones in your study, you need to count all that you screen. If you are capturing animals, anticipated by-catch animals need to be included, too.
- This number is the total for all 3 years of the AUP’s life.

Housing Location:

- Please read the options on the drop down list carefully. Some buildings include an animal facility (vivarium) as well as lab spaces (Lab), so please choose the correct location for the housing.
- Note that only 1 location may be chosen per section, so if animals will be housed at more than 1 location, the location at which they spend the most time should be chosen here, and the use of more than one housing location will need to be explained in another section (e.g., 6.4, 8.2).
- If the animal work is done at a field location/animals are never housed: “Field Research Site”

Weight Range:

- This is the weight range through the animals’ entire use on the AUP, not solely the weight at acquisition/the start of the study.
- Make this range as wide as needed to cover the species and breed or life stages you are using.
- This information is used to determine the appropriateness of activities that may have a negative impact on an animal, such as how much blood volume can be collected, or what an IM injection limit should be.

Age Range:

- This is the age range through the animals’ entire use on the AUP, not solely the age at acquisition/the start of the study.
- This should be consistent with the weight range.
- For some studies, when animals of multiple ages will be used, you can use terms such as “all ages”.

Preferred Vendor:

- Preferred Vendor may be “Internal” if animals come within UGA, or “External” if they are not from UGA, but not from a commercial vendor on the drop down list.

- If 'Internal' or 'External' are chosen, the specific source, if known, needs to be described in another section (e.g., 8.2).
- For animals captured in the wild, "Wildlife (NA)" is the appropriate choice.

Is the use of this species covered by the USDA Animal Welfare Act?

- Note that some species are always covered (e.g., dogs, NHP), some are never covered (any non-mammal, rats and mice bred for research), and some may or may not be covered, depending on the use (e.g., horses, pigs). If you are not sure, please consult the IACUC office (IACUC@uga.edu)

5.2: Justification of Animal Numbers

- At least one must be checked.
- If "Other" is checked, you need to include an explanation in the text box.
- Note on pilot studies: Pilot studies may be appropriate to determine the technical feasibility of larger studies, determine potential variability, refine procedures, or to make initial assessments of the effect of procedures on animals. If this is a pilot study, be sure to explain why the protocol is being called a pilot study (Section 4.1 is the appropriate location for this explanation).
- Note on pilot studies: At the Annual Renewal of pilot studies, the IACUC will contact you to ask if the study is still a pilot study, or if you have transitioned into the main study.

5.3: Justification for species selection

- At least one must be checked.
- If "Other" is checked, there must be an explanation in the text box.

5.4: Will a breeding colony be maintained?

- A breeding colony refers to continuously keeping animals as breeders to keep a line of animals alive, such as a genetically modified mouse strain. The breeding methods need to be described in 5.4.
- If mating is occurring as part of the research, such as to collect embryos or assess a trait in offspring of treated parents, this is not strictly speaking, a breeding

colony. In that case, 5.4 should be answered “No”, and the breeding methods should be described in 8.1/8.2.

- Most breeding colonies are rodents or zebrafish, so most of the following questions are related to those species. If you are breeding another species, there may be some questions that do not apply—you can use “N/A” as the response.

5.4.1 (a):

- A new strain can be added to the drop down list by contacting the IACUC office (IACUC@uga.edu).
- Rodent strains are not required to be listed here, as long as the gene manipulation/phenotype is clearly described elsewhere (e.g., 8.2).

5.4.1 (b):

[no tip for 5.4.1b itself, just the items below]

Appetite

- It is unusual to check this box for mice! This should not be checked for animals for which individual consumption cannot be assessed (e.g., socially housed rodents, zebrafish).

Excreta

- Please comment on how you will assess excreta for group housed animals (write in the text box under “Laboratory test...”)

Temperature

- This refers to actual measurement of the temperature, not a subjective assessment made by touching the animals. For example, with a thermometer or telemetry device.

Laboratory tests or other evaluation (describe below):

- If this is checked, the test/s must be listed in the text box.

5.4.1 (c):

- It should be clear approximately how many breeders (parents) are being used, and approximately how many offspring are being produced.
- Be sure to explain (either here or in 8.2) how you determine how many offspring are needed for the research projects. It is important that you are creating the number of offspring needed to meet the research goals; you should not be breeding excessive numbers of mice that are culled and not used for research.
- This number may not be identical to the total Quantity in 5.1 (there may be breeding of some animals and purchase of other animals), however, it should make sense (this number should not be MORE than 5.1, for example), and it should make sense in relation to any number explanations in 8.2.

5.4.1 (d):

- For example, a genetically modified mouse strain with a known deleterious phenotype.
- Any deleterious phenotype must be addressed in 6.8 if it is severe enough to cause illness.
- Any deleterious phenotype must be addressed in 11.2 if it requires monitoring.
- Any deleterious phenotype must be addressed in 11.3 if it requires humane endpoints.

5.4.1 (e):

- For example, soft food, or food on the cage floor.

5.4.1 (f):

- This refers to individual identification of the animals/how to tell them apart, not genotyping. For example, ear tags, ear punches, elastomer injections, tattoo.

5.4.1 (g) 1:

- The procedure for collecting the sample must be described here or in 8.1/8.2.

5.4.1 (h):

- This refers to the breeding parents, and should be consistent with the general breeding age of the species.

5.4.1 (i):

- This refers to the female:male ratio of the breeding parents. Breeding pairs (1:1), trios (2:1), or harem (3:1) groups are acceptable. Generally, no more than 3 females are recommended for 1 male. There must never be more than 1 adult male in a rodent breeding cage.

5.4.1 (j):

- Situations to consider/which must be addressed:
 - Breeding with more than 1 female in the cage. Females must be removed and housed singly as soon as they are visibly pregnant.
 - Pair breeding when the weaning age is extended beyond 21 days (typically to 28 days). Mice can become pregnant immediately after giving birth, so a second litter can be born 21 days after the first litter, allowing 1 week of overlap of the 2 litters. If this is a possibility, you need to explain what you would do if a second litter was born. If 2 litters may be maintained in 1 cage, you will need to provide supporting references or experience/data that pups in this situation survive as well as pups in cages with only 1 litter.

5.4.1 (k):

- The justification is usually due to a mouse strain that has small pups that do better if weaned later (e.g., 28 days).
- Generally late weaning is by 28 days, so a length of time beyond 28 days requires a specific explanation about why the late weaning is not by 28 days.

6.1: Will any technique be performed which would result in loss of sensation or paralysis in conscious animals?

- This could be a loss of sensation/paralysis during the procedure during which the animal is awake, or due to a procedure that induces loss of sensation/paralysis that continues after the procedure. Typical examples would be the use of a paralytic (curare) in a conscious animal, or surgical severing of a nerve, or an infectious disease known to cause paralysis.
- It does not apply to a procedure performed under anesthesia when there is no loss of sensation or paralysis after the animal recovers from the anesthesia.

6.1.1 (a):

- What condition, specifically, is caused should also be explained here or elsewhere in the AUP (e.g., 8.2).
- If the animal will experience loss of sensation/paralysis while it is awake, you need to explain why the animal cannot be sedated or anesthetized.
- If the animal will be maintained in this state, any special care needs to be described here.
- Any monitoring needs to be addressed in 11.2 and any humane endpoints addressed in 11.3.

6.2.1 (a): Explain the rationale for use of restraint:

- The response should justify why prolonged physical restraint is necessary for the research, or to protect animal or personnel safety.
- Demonstrate that you have considered alternatives to physical restraint.
- Prolonged restraint cannot be for convenience.

6.2.1 (b): Describe the restraint device, dimensions, etc.:

- It must be clear how the animal is held by the restraint and the extent to which the animal's movement is restricted. For example, can the animal turn around? Stand up fully? Move its head and limbs?
- If a photo or diagram of the device would be helpful to the explanation, please email an image to the IACUC office (IACUC@uga.edu). Unfortunately, we cannot

attach such items in the Artemis system, however, we can add images to the AUP file and share it with IACUC reviewers.

6.2.1 (c): Describe means to acclimate animals to restraint and restraint devices:

- Animals must be given training, with positive reinforcement if possible, to adapt to the restraint, unless acclimation would increase stress to the animal or withholding of acclimation is scientifically justified.
- If acclimation cannot be used, you will need to include the rationale here for not using acclimation.
- Animals that fail to adapt should be removed from the study, or an explanation for why they will not be removed from the study needs to be provided.

6.2.1 (d): Describe the duration and frequency animals will be confined to device:

- This must be the minimum time required to accomplish the goals.
- Be sure to note both the duration (time the animal will be continuously restrained at one time), and the frequency (how often the animal will be restrained). It is a good idea to use ranges or maximums, such as “no more than 15 minutes”; “10-30 minutes”; “at least 1 week between restraint events”.

6.2.1 (e): Describe the observation intervals during confinement:

- Observation intervals must be appropriate—based on species, acclimation, procedure, etc.
- FYI-any lesions/injury/illness/severe behavioral changes associated with the restraint must be reported to a URAR veterinary staff.

6.2.1 (f): List all qualified faculty or staff who will be making observations during confinement:

- Be sure the personnel listed are qualified to observe and assess the animals.

6.3: Will any agents, ...which could cause chronic inflammation and/or pain?

- Complete Freund's is known to cause chronic inflammation.
- Examples of other inflammatory agents: carrageenan, urate crystals.
- Some modern adjuvants do not cause the same degree of inflammation, so may not need to be listed here. For example, adjuvants used in most commercial vaccines should not normally cause chronic swelling/pain. If you are using an adjuvant that is known to not cause swelling, granulomas, etc., be sure to list them in section 8.1 or 8.2, along with an explanation that they should not cause chronic inflammation or pain, so don't need to be listed here in 6.3.
- For the injection schedule, it is best to use a range, such as "every 2-4 weeks", but make sure the range is consistent with other sections of the AUP.
- For volume, it may be best to use a range, or a ml/kg unless you are sure you will always use the same volume.

6.3.1 (a): Describe what will be used, volumes, and the schedule for the injections.

- Note: this section has limited response space; some details may need to be listed in 8.2. In this section, you can write "See 8.2" if your details do not fit here.
- For volume, use a range, e.g., "1-2 ml", "25-40 ul".
- For schedule for injection, use a range, e.g., "at 2-3 week intervals"

6.4: Will animals be subjected to potentially painful procedures for identification, e.g. toe clipping, branding?

[no tip for 6.4]

6.4.1 (a): Describe the identification procedures which will be employed.

- The procedure must be clearly described.
- You will also need to include a description of assessments for pain/complications after the procedure.
- Be sure to explain why a less painful method is not possible/feasible.

6.5: Will it be necessary for live animals to be removed from the animal facility? (This includes any rooms outside the animal facility even if it is in the same building.)

- E.g., animals being taken to a lab, MRI, to another animal facility such as to the AHRC for ABSL3 work.
- This is the only section where we can identify live animals that are removed from an animal facility for any reason, even if it is only to move them to another animal facility. So, even if animals are only being moved from 1 URAR location to another URAR location, please answer this as “Yes”. Your responses to the follow up questions will be minimal if animals are being moved from 1 URAR facility to another, by URAR personnel.

6.5.1 (a):

- If the animal is being transported to a different URAR animal facility, the room number does not need to be specified.
- If the animal is going to a location at UGA other than an animal facility, the room number is very important, so that we can be sure the IACUC is inspecting the location. If you do not see your building, or your room number listed under your building choice, please contact the OACU for assistance. Please do not leave this blank, as we will need to ask you to complete it via a revision.

6.5.1 (b):

- If “Other” is chosen, you need to include an explanation in the text box.
- It must be clear why the animals need to be removed from the animal facility; i.e., why the procedures cannot be performed in the animal facility. Check “Other” to create a text box to use.
- If the animals are only being transported from one animal facility to another, check “Other” and explain that animals are only being transported between animal facilities.

6.5.1 (c):

- If this is answered “Yes” you will need to include a justification for housing animals outside of the animal facility—section 6.5.1(b) is the best location for this, under “Other”.
- Most likely, section 6.9 will need to be answered “Yes” for husbandry provided by PI/PI staff. If that is the case, create a text box in 6.9, choose the title “Husbandry performed by PI staff” and explain the husbandry in the text box.

6.5.1 (c).1:

- Please select the building and room number—this is how we add locations to the IACUC inspection list.
- If you cannot find the correct building or room number on the drop down list, please let us know at IACUC@uga.edu.

6.5.1(d)

- Preferably, URAR/Animal Care should transport animals. If URAR/Animal Care personnel will transport the animals, you only need to explain that URAR will transport them, you don’t need to describe all of the details of the transportation.
- If URAR/Animal Care personnel are not transporting the animals, some details are needed:
 - You must explain why URAR is not moving the animals
 - Animals must be secured, so that they cannot escape/become injured.
 - Animals should not be visible to the public—e.g., cages should be covered or inside an opaque container.
 - If a vehicle is used, it must be climate controlled. Note if it is a UGA owned or personal vehicle. Note that vehicles, including personal vehicles, used to transport animals must be inspected by the IACUC every 6 months.

6.5.1 (e).1:

- Explain that you will consult with facility management personnel to be sure that appropriate procedures are followed. For example, rodent cages that have been outside the animal facility should not be placed directly on a cage rack; rodents

should be moved into clean cages upon return before they are placed back on the cage rack.

6.6: Will animals be subjected to more than one major survival surgical procedure?

- This is only answered “Yes” if both categories are true: be sure that you are going to perform more than 1 surgery, and that they are both 1) major and 2) survival/non-terminal.

6.6.1 (a):

- This should make it clear why both procedures cannot be performed at the same time, and why both surgeries are required for the experiment. This is sometimes related to a need for the procedures to occur when the animal is different ages/sizes, or a time period required for a physiological change, such as hormone decrease.

6.6.1 (c):

- List both/all surgeries, and clarify the time between surgeries. Don’t describe the surgeries in detail in this section; section 9 is the appropriate location for full descriptions of surgeries.
- Example: “Mice will have ovariectomy surgery, followed by a period of 4-5 weeks, and then they will have the kidney injection surgery. “ “Cats will have repeated laparotomy surgery for intestinal serosal biopsies at 6-8 week intervals”

6.7.1 (a):

- There must be an explanation/scientific justification for the procedure.
 - The description needs to be clear enough to understand the procedure and the pain/stress/abnormal behavior outcome.

6.7.1 (b):

- There must be an explanation/scientific justification for the procedure.

- The description should include what the stimulation is, and the characteristics (e.g., intensity, lumens, decibels, duration, frequency)

6.8: Will any adverse effects or overt signs of illness be expected? If YES, explain:

- If you anticipate the animals will probably show signs of illness, this should be answered “Yes”.
- You do not need to list signs of illness that you do not anticipate will occur on this study. Only the signs of illness you anticipate as likely/reasonably possible.
- However, if you do list the general theoretical signs for this condition, be clear about what signs of illness are expected to be seen with this study vs signs that could theoretically be seen, but would not be expected to be seen with this study. For example, if you are using a much lower inoculation dose that would cause severe illness, or you will be euthanizing the animals before they reach the end stage of severe illness, you should make it clear that you do not expect to see severe signs of illness.
- This question does not refer to subclinical illness (e.g. viremia that does not make the animal sick, or a compromised immune system).

6.8.1 (a):

- Note—this is ONLY about the signs of illness you will watch for. Please don’t specify monitoring intervals or humane endpoints here. All of that will be asked for in 11.2 and 11.3. If you list them here, and they are not consistent with 11.2 and 11.3, revisions will be needed. We all want to avoid revisions for inconsistent details.
- This must provide a list or narrative of the signs for which the animals will be monitored. This should be anticipated/relevant signs, not unrelated signs of unrelated conditions (i.e., if you do not anticipate weight loss and will not monitor for weight loss, do not list weight loss).
- You also don’t need to list possible problems not related to the study, for example, incidental injuries.

6.8.1 (b):

- The criteria checked should be consistent with those noted in 6.8.1(a).
- The criteria checked should be related to the potential procedure outcomes, not items that are not relevant. For example, if you are infecting animals with an infectious agent via intranasal inoculation, you should not check “wound site”.
- Items should be species appropriate.
- If some explanation is needed, you will need to check the “Laboratory tests” box, to get the text box to open. Unfortunately, that is the only method for having a text box in this section.

Appetite

- This should not be checked for animals for which individual consumption cannot be assessed –e.g., socially housed rodents, zebrafish.
- If you are going to be assessing the appetite of individuals for this type of species, please be sure to describe specifically how you will assess the appetite.

Guarding

- Refers to protection of a body part/region that may be painful.

Heart Rate

- This may not be appropriate for small animals such as mice.

Licking, biting

- This refers to licking/biting of a specific site of injury/pain.

Temperature

- This may not be appropriate for small animals such as mice unless you are using a rodent specific thermometer or implanted transmitter to monitor the body temperature.
- If you do check this box for rodents, be sure to explain in the text box how you will be measuring the body temperature.

Weight loss

- If this is checked, you will need to describe the method and frequency of monitoring body weight or body condition in 11.2. If body condition will be scored, the scoring system must be named or described (i.e., scale of 1-5 with 3 being ideal/healthy).

Laboratory tests or other evaluation (please specify)

- If this is checked, the test/s should be listed in the text box.

6.9: Exceptions with Scientific Justification / Special Husbandry

Requirements:

- This is for special husbandry requirements that do not require scientific justification (e.g., ABSL2) or exceptions to standards that do require justification (e.g., Husbandry performed by PI staff)
- When you choose an item, a text box will appear. You need to provide a description of the special husbandry requirement, and, for exceptions, a justification/explanation for the exception in the text box.
- Some tips for specific titles:

Single housing of social species

- Social housing of social animals is the default without scientific justification.

Use of animals in more than one project

- This refers to the same animal(s) being used in multiple projects on the same AUP. Use of animals in multiple AUPs should be addressed in Sec. 12.1 as a Transfer.

6.10.1 (a):

- Clarify the scientific rationale for not allowing enrichment.
- Clarify whether an alternative to the standard enrichment is possible, such as a food treat if a structure cannot be used, or vice versa.

6.11: Food/Water Restriction

- This refers to any time food and/or water are withheld such that the standard amount is not provided, or food and/or water are not provided during the times

normally provided. Examples: Removing food from an ad lib fed animal 1 hour before oral gavage; Feeding a measured amount to limit an animal's weight gain, rather than feeding ad lib or the standard amount fed to the species for normal weight gain.

- Note, this does not refer to standard withholding of food/water prior to anesthesia [That belongs in section 9.1.1(c)].
- It also does not refer to the standard feeding schedule for some species that are not fed daily, such as some reptiles. As long as the animals are fed on a standard schedule according to their physiological needs, that is considered normal husbandry for them.

6.11 (a):

Describe the restriction: what is removed, for how long/how often?

- Explain why the food and/or fluid restriction is required for the research.
- You must also describe be a method of monitoring for physiologic and behavioral indexes to assess animal well-being and criteria to remove the animal from restriction, such as weight or hydration.
- Documentation of the assessments, kept in the same location of the restricted animal, is required; e.g., the food/water consumption, hydration status, behavior or clinical parameters, body weight.

6.12: Numbers and Use Category Summary:

- NOTE: This section is automatically filled by Artemis based on the information provided in 5.1.
- If category C is chosen for any species, question 6.12.1(a) will appear and must be answered.

6.12.1 (a):

People frequently do not provide a complete response to this question, however, it is one of the most important questions on the AUP. Also, this is the information required on the USDA Annual Report for USDA covered animals on Category C (USDA Category E) protocols.

- Note that if there is more than 1 procedure or condition that could negatively impact the animal's well-being, for example, infection with an infectious agent and a deleterious phenotype, each procedure/condition must be addressed separately.
- Please be as specific as possible, for example, if you know that analgesia will alter the parameter you are measuring, include that information.

7.1: The Public Health Service Policy and the Animal Welfare Act require ...sound research design.

[no tips for 7.1 itself, only the items that follow]

Source:

- You will need to include the search information from 2 databases.

Date of Search:

- The date must be within 6 months of submission.

Years Searched:

- This must include up through the current year.

Keywords Used or Search Strategy:

- Terms such as 'alternative', 'non-animal', 'alleviation of pain' should be used
- This should relate to the category C procedure/condition/s.
- If there is more than 1 procedure/condition that could negatively impact the animal's well-being, searches for each of the procedures must be completed.
- If "Other Search" is chosen in 7.1, the source needs to be identified elsewhere, such as in 7.2.

7.2: Other Sources of Information on Alternatives to Painful Procedures

- This is optional; only complete if you have another source, such as experts in the field or conferences.

7.3: Narrative on Alternatives to Painful Procedures

- At least one of the 3 options must be checked.
- For any that you check, you need to include the narrative below the check box.
- The narrative must be reasonable/make sense.
- Note that this narrative IS required for all category B and C projects—even if not covered by the USDA AWAR, unlike the database search for alternatives in 7.1.

7.4 Narrative on Duplication:

- You need to provide a statement assuring that the work is not unnecessarily duplicative, with a brief explanation, such as what is unique/novel about this study, or how you know it is not duplicative. Or explain why the duplication is necessary, such as for an instructional AUP.

8.1: Experimental Design and Procedures:

General Tips

- This section is intended to describe the procedures you will use, possibly in multiple experiments. This is so that you do not have to describe the procedures in detail in section 8.2 (which is already long and complicated enough with the experiment descriptions!). For example, if you are collecting blood, in 8.1 you should list and describe all of the methods you may use (saphenous, jugular, wing vein, tail puncture). Then, in 8.2, when you are describing the experiment, you only need to state the method (“once a week we will collect blood via the wing vein”)
- Please do not explain the entire experiment; this is only to identify the individual procedures you will be performing.
- There is a dropdown list of possible titles. Choose the best title for each text box (“Other” is an option if the procedure is not on the list). If you have a procedure that is not covered, and want us to add it to the drop down list, just contact the OACU.
- Do not list multiple different procedures in 1 text box. Create a new text box for each type of procedure.

- Note that it is best if you do not list drug doses or volumes here; this information is required only in section 10. If you do list them here, be sure they match section 10.

The exception is a substance being administered to live animals that does not fit under the categories in 10.1 or 10.2 (e.g., saline/vehicle). For those exceptions, the dose and volume and route need to be described in 8.1 or 8.2.

Procedure specific tips

Anesthesia

- Include the drug/s, but you don't need to include the dose. It is best to only put the dose/s in 10.1.1(a), unless there are multiple variations on a single drug, such as 1 dose for sedation and 1 dose for anesthesia.
- You should note for which procedures you will/may use anesthesia
- If you are not sure what drug/s you may use and what procedures may include anesthesia, you can keep it flexible. In that case, be sure to explain how you would decide which drug/s to use and when you would use anesthesia. And be sure to verify that within any 1 experiment you would use consistent anesthesia to avoid introducing a variable.

Behavioral Modification/testing

- Include training in the description
- Include the purpose of the test—what it is used to test, what data you will collect, and how it relates to your research questions

Blood Collection

- Include the possible methods/sources, and when you would use each
- Include the purpose—what analysis will you do? How does it relate to the research questions?
- Verify that you will not collect more than 10% of the total blood volume within a 14 day period.

Cannulas (done in-house)

- Explain the purpose of the cannula/catheter
- Note the location/s on the body
- If it is a non-surgical implantation (e.g., venous catheter with no cut-down), describe the procedure here.
- If it is a surgical implantation (e.g., cannula through the skull) you do not need to describe the whole implant procedure—that will be described in section 9.1.1.
- Note which animals will have them implanted, and, if they will be removed from a live animal, how long will it be in/when will it be removed?

Food restriction

- Briefly note the purpose of the restriction—all of the details should be in 6.11.

Imaging

- What type?
- What is the goal? What are you learning?
- Approximately how long would a session last?
- What is the maximum number of times/and frequency at which an animal would be imaged if it is imaged more than once?
- Where will the imaging take place? Remember if the animals need to leave the facility to be imaged, you need to answer 6.5 as yes, and add the details of transportation there.

Infectious disease challenge

- Please don't use this title for vaccination/immunization with an infectious agent. "Infectious Disease Challenge" should only be used for challenge—when you are testing to see if an animal will become ill. For vaccination, please choose "Vaccination/Immunization"
- Describe how an animal will be infected with the agent

- You don't need to list the dose and volume here, because it will be in 10.2.1(c).
- For the route, most are listed in 10.2.1(c), however, if yours is not, you can choose "Other" as the route in 10.2.1(c), and note the route here. You can also contact the IACUC office (iacuc@uga.edu) and has us add your route to 10.2.1(c).
- Do not list monitoring of animals after infection, or humane endpoints. Those belong only in 11.2 and 11.3.

Injections

- List all of the routes you may use.
- Provide a brief description of each method...note that the IACUC website has pre-written descriptions for the more common methods for several common species.
- If you are using IM in mice, please include a justification. IM is not recommended in mice due to their small muscle mass and the damage an IM injection can cause.
- You can list the substances that may be injected by each method, if you like. Otherwise, you would include that information in 8.2.
- Please don't use doses or volumes—those should be added to section 10.

Lavage

Monoclonal antibody production

Oral gavage

- Include the instrument you will use
- Include the general method, including if you use anesthesia
- You can list the substances that you will gavage, if you like. Otherwise, you would include that information in 8.2.
- Please don't use doses or volumes—those should be added to section 10.

Other

Pharmacokinetics/Pharmacodynamics

- Outline the general plan—including when the substance is administered, and the time points at which sample collection occurs after administration

Polyclonal antibody production

Prolonged restraint

- Briefly comment on the purpose and method. However, you do not need to include a lot of details here. Instead you will answer 6.2 as “Yes” and put the details in that section.

Surgery

- Note the surgery/surgeries that you will perform, and the main purpose of each one, and how it relates to the research
- You should not include details in this section—those all go into section 9.
- You should not include the anesthesia details here—those should go in section 10.1.1(a).
- Please include terminal surgeries here. If the animal has a surgical procedure under anesthesia, it is considered surgery. Note that euthanasia by perfusion is no longer categorized as a terminal surgery. Perfusion should not be listed under the "Surgery" heading in 8.1 nor in section 9. Perfusion should be described in 8.1 under “Other” and/or in 8.2

Tissue collection (post-mortem)

- Explain what tissues are collected, and what analyses are done with them

Tissue collection (biopsy of live animal)

- Explain what tissues are collected
- Explain the purpose of collecting the tissues—what analyses are done with them?

Vaccination/Immunization

- What substance is being used as the vaccine antigen?
- If adjuvants may be used, list them here, by name if known, or at least, by category.
- What is the schedule for vaccination and boost vaccinations? A range of time is fine, such as “boost at 3-5 weeks after initial vaccine”

Water restriction

- Briefly note the purpose of the restriction—all of the details should be in 6.11.

8.2: Description of Procedures:

General Intro Tips

This is the section in which you explain the actual experiments. Note that there are 3 main sections (A-Hypothesis and data capture, B-Experimental Design, and C-Experimental Procedures) which need to be addressed.

- If you have more than 1 experiment on the AUP, it is usually easiest to separate them, and answer A, B, and C for each experiment, sequentially, instead of answering A for all experiments, then B for all, etc. Of course, if the same hypothesis (A) applies to all experiments, you can simply state that initially, then list B and C for the individual experiments.
- If you find yourself listing multiple experiments and section 8.2 is getting pretty long and complicated, it is best to separate the work into more than 1 AUP. A general rule of thumb is that if you have more than ~ 5 experiments with long descriptions, or ~ 10 experiments with very short descriptions, it may be time to consider how to group them into 2 or more general fields (e.g., inflammatory responses related to cardiovascular system and obesity; cell differentiation in development and in cancer) or species (e.g., rodents and non-rodents; birds and mammals)

Part A:

For Part A, a specific study goal, preferably explained as a hypothesis, is required.

- Note that this goal should be more specific than the general goals that may be stated in section 4.1. For example, 4.1 may state that the goals are to assess new vaccine candidates for an infectious disease. Section 8.2 would then require something more specific, like “Our study is designed to compare our candidate vaccines to each other, and to a non-vaccinated group to assess the difference in colonization and histological pathological changes in tissues.” Or “Our hypothesis is that the candidate vaccines will decrease colonization and histological pathological changes compared to non-vaccinated groups, and that some of the candidates will be more efficacious (have a larger decrease) than others.”
- Regarding data collection/variance capture, you should state what it is, specifically, you will analyze to compare the groups. For example, histological changes, colonization levels, presence or absence by PCR, behavioral test results.

Part B:

For Part B, a general study experimental design is required, with the study groups identified (i.e., treatments and controls), and the number of animals in each group.

- If your study/project does not need an experimental design (e.g., instructional use), you can briefly explain why in this section.
- The number of animals described in the experimental design should correspond with the animals requested in section 5.1. The numbers do not have to be identical, because it is an approximation, and you may want to increase by 10% or so if attrition is expected. However, the numbers should be close enough that it makes sense to a reviewer.

Part C:

For Part C, describe what happens to the animal/s through the entire study, in chronological order as much as possible. The reviewer should be able to understand how the experiments are expected to affect the animals/what happens to the animals.

- If the AUP includes multiple studies and/or multiple procedures, it should be clear if any animals undergo more than one procedure
- Clearly explain when the study ends and animals are removed from the study by euthanasia, transfer, release, etc. (i.e., how long is the study?).

- Specific procedures: The details of procedures should be included in 8.1 so that you do not have to go into detail here in 8.2. However, procedures should be identified adequately so that it is clear which procedure in 8.1 is being referenced. For example, if an injection is administered, only 8.1 needs to include the descriptions of all of the techniques you may use, but in 8.2, you should include the route.
- Note that it is best if you do not list drug doses or volumes here; this information is required only in section 10. If you do list them here, be sure they match section 10.
- Descriptions should be consistent with information in other sections.

8.2.1: Please describe the proposed procedures impact on the animals' well-being.

This questions needs to be answered, even if “none” or “NA” is the appropriate response.

- The stated impact should be consistent with the procedures described.
- This refers to negative impacts that are definitely anticipated/expected, not unexpected but possible complications. For example, inoculating with an infectious agent is anticipated to cause illness and should be described here. Infection of the surgical site after a surgical procedure is not expected, it is only a possible complication, and should not be described here.
- If there is more than 1 procedure/condition that could negatively impact the animals' well-being, the impact of each procedure/outcome must be addressed.

8.3: Will you be using potentially hazardous substances in live animals?

- Consider whether any of these categories apply, or potentially apply.

8.3.1 (a):

- Note that an IBC or Radiation Safety permit number will be required for relevant hazards.

- Note: rDNA includes genetically modified animals (but not natural mutations). Please contact the Office of Biosafety for information on what IBC approval is needed.
- Note: radiation includes radiographs.
- The safety precautions described should focus on work in the animal facility/work with the animals, not in your laboratory.
- What PPE is required for personnel handling the animals or the soiled cages? This includes URAR personnel and lab personnel.
- Are special safety measures needed when handling dosed live animals and carcasses?
- Are there special needs for waste disposal, such as autoclaving or incineration?
- How is soiled animal bedding handled—are precautions needed when dumping soiled cages?
- If autoclaving bedding is required, does this need to be done before cages are dumped or can it be done after dumping?
- Is special containment required?
- Does ESD need to collect water bottles or soiled bedding?

9.1.1 (a):

- If Non Survival is chosen, questions 9.1.1(c)-9.1.1(e) will appear and must be answered.
- If Survival is chosen, questions 9.1.1(b)-9.1.1(g) will appear and must be answered.
- Note that an AUP may include both Non-survival and Survival surgery, in which case, both need to be checked here and described.

9.1.1 (b):

- This is usually related to a need to evaluate the animal for a period of time after the surgical procedure.

9.1.1 (c):

- Some species (not rodents) require fasting before anesthesia. Describe when food will be removed, and the approximate time food will be withheld.
- Note that it is best if you only list the drugs administered here, not the doses or volumes here. Doses and volumes are required only in section 10. If you do list them here, be sure they match section 10!
- This includes anesthetic reversal agents.

9.1.1 (d):

Animal Pre-surgical prep

- How is the skin prepared? Note that for most species (other than aquatics) removal of the fur or feathers, followed by 3 alternating wipes with a disinfectant such as povidine-iodine or chlorhexidine, with alcohol, is the standard and expectation.
- Sterile ophthalmic lubricant must be applied to the eyes.
- Thermal support is required if anesthesia extends beyond a few minutes (~5-10). Please describe the thermal support, keeping in mind that a barrier must be placed between an electric pad and the animal to prevent burns. Microwave or manually activated discs and gel pads are relatively inexpensive options for smaller species. Warm water circulating blankets are ideal for small or larger species.

9.1.1 (d):

Instrument pre-surgical preparation:

- How are they sterilized before first surgery? Note that soaking in alcohol is not considered sterilization. It may be appropriate for some items that cannot be autoclaved, however, there are liquid sterilant options. If alcohol is to be used, you will need to explain why it must be used.
- How are they sterilized between animals? A hot bead sterilizer is a convenient and relatively inexpensive option.

9.1.1 (d):

Surgeon's pre-surgical preparation:

- How does the surgeon scrub?
- What is the surgeon's attire? Note that the policy requires: sterile gloves, a surgical mask, and a clean lab coat, sterile gown, or other attire to replace or cover street clothes.

9.1.1 (d):

Details of surgical procedures:

- There needs to be adequate detail to understand the procedure's impact on the animal: location/approximate size of incisions; extent of tissue resection/damage; closure of any incisions; impact on physiology/mechanical function.
- The PI can verify that the UGA Anesthesia/Surgery Policy will be followed, instead of listing all of the specific details about preparation.

9.1.1(e):

- Be sure these personnel have been or will be trained to perform these activities.

9.1.1 (f): Describe the postoperative care.

Short term

- Animals should be monitored continuously and not left unattended/returned to unattended housing until they are sternal and making purposeful movements.
- Thermal support should be used and described. If electric heating pads are used, a barrier (e.g., hand towel) should be placed between the pad and the animal, to prevent burns. During recovery, any heating pads used should be placed under only approximately half of the cage, so that the animal can move away if it becomes too warm.

- If thermal support will not be used for some reason, you will need to explain why.

Long term

- Generally, “long term recovery” means the time until the animal has healed from the surgical procedure (to the extent that it can). Typically, this is when the incision has healed, however, that may not be the case for surgeries with more significant internal tissue alteration.
- How is the animal assessed until it is healed?
 - The incision should be checked at least once a day for signs of infection (redness, swelling, discharge, heat)
 - The animal’s general health should be assessed via its attitude and behavior.
 - For animals fed individual meals, appetite can be assessed.
- When will any skin sutures or wound clips be removed? This should occur when the skin incision is healed, which is generally ~ 10-14 days after the surgery.

9.1.1 (g): Indicate the names

- Be sure these personnel have been or will be trained to perform these activities.

10.1: Will you be using anesthesia?

[no tip for 10.1 itself, just the items below]

Agent:

- If your agent is not listed here, please contact the IACUC office (iacuc@uga.edu) to have it added

Frequency of Administration:

- This means the number of times over the course of the study the agent is planned to be administered to 1 animal. It does NOT refer to possible re-

dosing during 1 anesthesia event—it is understood that re-dosing may be necessary.

Dose:

- Ranges are strongly recommended instead of exact doses, especially for USDA regulated animals. Even if you only plan to use 1 dose, a range provides flexibility for compliance.

Route:

- If “other” is chosen, the route should be described in 8.1/8.2.

Volume:

- If you listed volumes in section 8.1/8.2, be sure they match! Remember, if the volume is in section 10, it does not need to be listed in section 8!
- This can be a range, listed as a volume/body weight (ml/kg) or stated as a maximum volume; the main concern is that a volume is not too large for a small animal.

10.1.1 (b): Monitoring of Anesthesia.

- How you will determine that the depth of anesthesia is adequate before a painful procedure is performed (e.g., lack of response to a firm toe pinch).
- The method of thermal support that will be provided. Please note that the use of an electric heating pad requires a barrier between the animal and the pad (e.g., a folded towel underneath the recovery cage).
- Monitoring during the immediate recovery from anesthesia. Note that an animal must be monitored continuously until it is able to hold itself in a normal, upright position.
- Items checked should be species appropriate, and the IACUC does not expect all items to be monitored in all cases. Do not mark items that you do not intend to monitor! For most rodent procedures, for example, mucus membrane color, respiration rate, and muscle tone are the only items that would be monitored.

- In the text box, you need to describe the method used to verify the animal is anesthetized deeply enough for a potentially painful procedure. For example, lack of response to a firm toe pinch in a rodent.

Body Temp

- “Body temperature” implies measurement with a thermometer. If you are not measuring body temperature, do not check this box.

10.1.1 (c):

- Note that if you are not providing at least the minimum recommended analgesia, you will need to explain why it will not be provided.
- The recommendation for procedures likely to induce mild to moderate pain is to provide a minimum of 24 hours of post-operative analgesia (e.g., subcutaneous implant), and for procedures likely to induce moderate to significant pain (e.g. abdominal surgery), to provide a minimum of 48 hours of post-operative analgesia.
- In general, multi-modal analgesia (an opioid and a NSAID) is the preferred choice.
- An opioid should be used for any procedure likely to cause more than mild pain, such as abdominal surgery.
- After the routine provision of analgesia, additional analgesia should be provided as needed until the animal does not appear to be experiencing pain.

10.1.1 (d): Describe

- What signs will be monitored?
- How often will animals be monitored? Note that animal should be assessed for the need for additional analgesia at time intervals appropriate to the analgesic being used. I.e., if the analgesic lasts for 6-8 hours, the animals should be reassessed 6-8 hours after the previous dose.

- The assessment should include observation for some specific, objective signs.
- The signs should make sense for the species and its behavior.
- The signs should make sense for the procedure and likely types of pain induced.
- The frequency of observations should be based on the duration of the analgesic used. For example, if the analgesic lasts for 10-12 hours, the animal should be checked 10-12 hours after the previous dose to assess whether additional doses are needed.

10.2.1 (a):

[no tip for 10.2.1(a) itself, just the items below]

Agent:

- If your agent is not listed here, please contact the IACUC office (iacuc@uga.edu) to have it added

Frequency and length of time

- How often will it be administered?
- What is the maximum length of treatment time, or range of treatment time?

Dose:

- Ranges are strongly recommended instead of exact doses, especially for USDA regulated animals.

Route:

- If “other” is chosen, the route should be described in 8.1/8.2.

Volume:

- It is best to state a range, for flexibility.

- Volume can be listed as a volume/body weight (ml/kg) or stated as a maximum volume; the main concern is that a volume is not too large for a small animal.
- Note that volumes are only required here in 10.2, not in section 8. However, if you listed volumes in section 8.1/8.2, be sure they match 10.2!

10.2.1 (b): Cells or Cell Tissue Extracts:

[no tip for 10.2.1(b) itself, just the items below]

Cell(s)/Tissue(s):

- For cells/tissues, the verification to do this testing before use can be explained in 8.1 or 8.2.
- Results of the verification testing must be submitted to the IACUC.

Dose:

- Dose here can be a concentration, or number, such as PFUs or cells.
- Ranges are strongly recommended instead of exact doses, especially for USDA regulated animals.

Route:

- If “other” is chosen, the route should be described in 8.1/8.2.

Volume:

- Volume can be listed as a volume/body weight (ml/kg) or stated as a maximum volume; the main concern is that a volume is not too large for a small animal.
- Note that volumes are only required here in 10.2, not in section 8. However, if you listed volumes in section 8.1/8.2, be sure they match 10.2!

10.2.1 (c): Experimental / Study Agents:

[no tip for 10.2.1(c) itself, just the items below]

Agent:

- Examples: vaccines, chemotherapy, nanoparticle substances, bacteria, viruses, parasites.
- If you are testing multiple individual derivatives of a compound type or group, listing the compound type/group will suffice.

Frequency and length of time:

- How often will it be administered?
- What is the maximum length of treatment time, or range of treatment time?

Dose:

- Ranges are recommended instead of exact doses, especially for USDA regulated animals.

Route:

- If “other” is chosen, the route should be described in 8.1/8.2

Volume:

- Volume can be listed as a volume/body weight (ml/kg) or stated as a maximum volume; the main concern is that a volume is not too large for a small animal.
- Note that volumes are only required here in 10.2, not in section 8. However, if you listed volumes in section 8.1/8.2, be sure they match 10.2!

10.3:

- For a drug with a pharmaceutical option, if you are not using the pharmaceutical option, you need to provide a scientific rationale.
- A couple of common examples:

- Tricaine Methanesulfonate (MS-222): There is no pharmaceutical grade. However, FDA grade is interpreted as pharmaceutical grade. If the MS222 is not FDA grade, answer 10.3 “Yes”. If the MS222 is FDA grade, 10.3 can be answered “No”, however you need to clarify that the MS222 is FDA grade in section 10 or 12, when discussing its use.
 - Finquel® and Tricaine-S® are FDA approved.
- Tribromoethanol: TBE is a non-pharmaceutical grade drug. If TBE is being used, you must answer 10.3 “Yes”.

10.3.1:

- Rationales include a lack of a pharmaceutical grade product, the product being used externally, or the need for consistency with in vitro work or previous studies.
- Explain how the solution is prepared and stored, in terms of maintaining quality and stability and preventing contamination.
- Explain how you will ensure that the substance is sterile, physiological pH, and free of pyrogens if administered parenterally.
- Explain why the potential for inadvertent introduction of quality variability with a non-pharmaceutical grade compound is not a scientific concern for your study.
- Note: cost savings is not an acceptable justification.
- Tricaine Methanesulfonate (MS-222): There is no pharmaceutical grade. However, FDA grade is interpreted as pharmaceutical grade. The AUP should clarify (usually in 8.2 or 12.2) whether MS222 is FDA grade or not. If it is not, then 10.3 should be answered “Yes”.
 - Finquel® and Tricaine-S® are FDA approved.
- Tribromoethanol: TBE is a non-pharmaceutical grade drug. Its use must be justified, including a reason that alternatives cannot be used. If the reason is a lack of a DEA license, the PI must verify that he/she is in the process of obtaining a DEA license or explain why it is not possible to obtain one. In addition, the explanation must verify that you will follow the “UGA IACUC Guidelines for Use of Tribromoethanol in Mice”. Note that the Guidelines

recommend it be used only for 1 survival anesthesia. If you intend to use it for more than 1 survival anesthesia, you need to explain how you have determined that the mice are not affected by peritonitis (hunched posture, lethargy) or abdominal adhesions (after euthanasia). Also, for animals that receive TBE for more than 1 survival procedure, upon euthanasia, you will need to open the abdomen to assess for signs of peritonitis, and notify the URAR veterinarians if any signs are observed.

11.1: Monitoring Interval:

- Your response should not include the daily observations made by University Research Animal Resources/Animal Care staff; this question refers to the lab personnel checking animals for specific clinical signs/humane endpoints.

11.2:

- Monitoring is required for any animal that may show signs of pain, distress, or illness from any research related cause, such as an experimental agent, procedure, including surgery, or genetic predisposition.
- The expectation for monitoring after a surgical procedure is that animals are checked at least once a day until fully recovered (incision/tissue damage healed).
- Your animals may not require monitoring by the lab staff for period of the study. For example, during acclimation, before any procedures are performed, or after animals have fully recovered from 1 procedure, before the next procedure.
- The interval may vary for different groups of animals and/or at different stages of the study. You will need to specify the monitoring plan for each situation.
- The appropriate frequency of monitoring will partially depend on the anticipated rate of health/welfare decline. Slowly progressing, chronic diseases do not require monitoring as frequently as rapidly progressing, acute diseases. Include your previous experience with the model and the rate of progression to explain the appropriateness of your monitoring plan.
- Keep in mind that some monitoring procedures, such as ones that require handling of mice, can be stressful. Hence, more is not always better. Handling

animals should be minimized and done at a rate that makes sense for the situation.

- We recommend that you use ranges of time, to give yourself flexibility.

11.3: Humane Endpoints

- The humane endpoints must be clear.
 - Make it clear what signs or combination of signs are needed for intervention. If you list several signs of illness, make it clear if any individual sign leads to intervention, or if the combination of signs is necessary to lead to intervention.
 - Avoid vague endpoints such as “if the animal appears more sick”, “if the animals’ signs become more severe”
- The humane endpoints should be as objective as possible (specific value cutoffs whenever possible).
 - Avoid subjective endpoints such as “has lost significant weight”, when an objective one can be used, such as “has lost over 15% body weight”
- Some terms may require definitions/descriptions of what you mean. For example, if you will monitor animals with mild lethargy, and euthanize them when they reach severe lethargy, you need to describe what you mean by “mild lethargy” and “severe lethargy” in terms of the animals’ behavior.
- The humane endpoints must be reasonable—animals that are severely ill and/or not likely to recover should be euthanized unless there is a clear reason to not euthanize them --which must be explained in 6.12.1(a).
- The humane endpoints must be consistent with the category. Category B requires that animals are treated/euthanized when more than minor and/or momentary illness/pain/distress is noted. If illness/pain/distress are not alleviated by prompt treatment or euthanasia, it is category C.
- If a scoring system is used, the score assigned to each sign must be reasonable and it must be clear what total/s lead to treatment or euthanasia.
- If treatment is an option (instead of euthanasia), it must be clear what the treatment is, how/at what frequency treatment will be assessed to determine if it is successful, and what will occur if the treatment is not successful.

- Generally, the humane endpoints should address anticipated or likely outcomes. The possibility of unexpected outcomes (e.g., infection after surgery) do not need to be noted here; such events would be handled as medical cases via consultation with the URAR veterinarians.
- Remember that if there are unexpected outcomes that lead to increased pain, distress, or illness, you need to let the IACUC know. If the outcome seems likely to occur again, in future studies, an amendment describing the outcome, and new related humane endpoints, must be approved by the IACUC before you repeat the study.

12.1: Final Disposition

- At least 1 should be chosen.
- The choices must be consistent with the descriptions in the AUP.
- Note that if you check “Euthanasia” here in 12.1, you do not need to, and should not, describe the method. The method needs to be described in 12.2. Describing in both locations leads to...you guessed it(!)...inconsistency and the need for revision.

12.2: Describe the method of euthanasia

- To add details for any section, check the “Other” box to create a text box.
- Even if euthanasia is not planned, a description of euthanasia must be provided, in case of untreatable injury/illness that requires euthanasia for humane reasons.
 - The description can indicate that others will provide euthanasia, such as if the animal is part of a UGA herd, with a standard SOP for euthanasia, or if the lab will contact a URAR or other veterinarian to provide euthanasia.
 - One exception: A category D AUP that involves only observation of a wild animal does not require a method of euthanasia, because the researcher is not responsible for the animal, and may not be able to make safe contact with an animal.

13.1: Do you have any permits?

- Please verify that needed permits are up to date, or pending.

- The IACUC office will contact you to verify the appropriate permits exist or to notify you if the permit you list is expired. Please send copies of all relevant permits via email to IACUC@uga.edu.

SECTION 14: CERTIFICATIONS & SUBMISSION

- All applicable certifications should be checked.