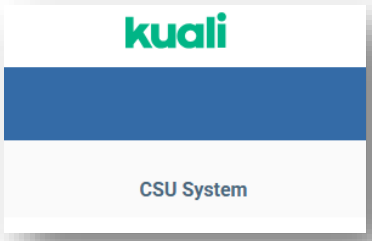
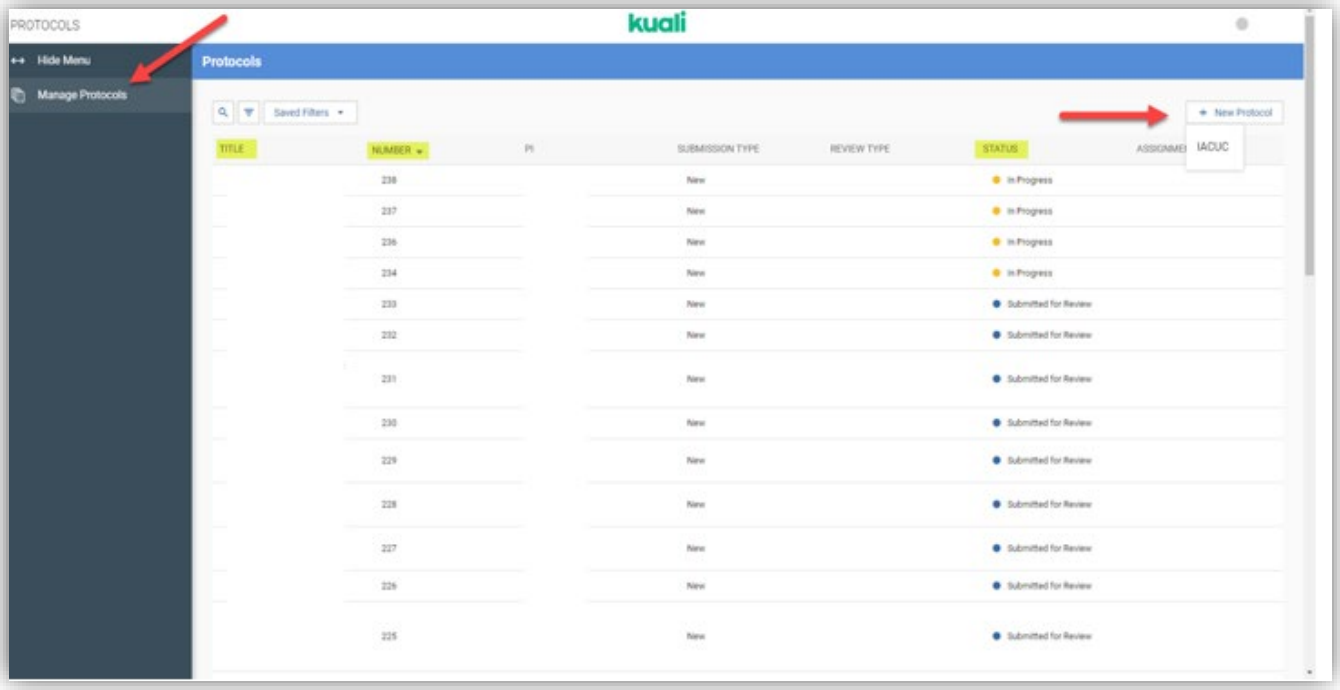
How to Create a New IACUC Protocol

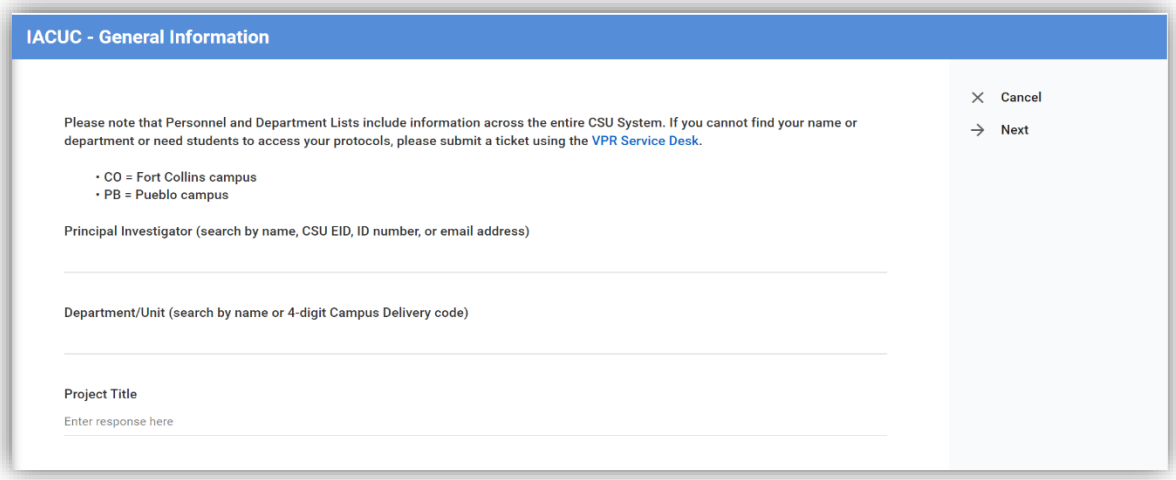
1. Go to https://colostate.kuali.co/protocols/ and select “CSU System” to log in with your CSU NetID and password.



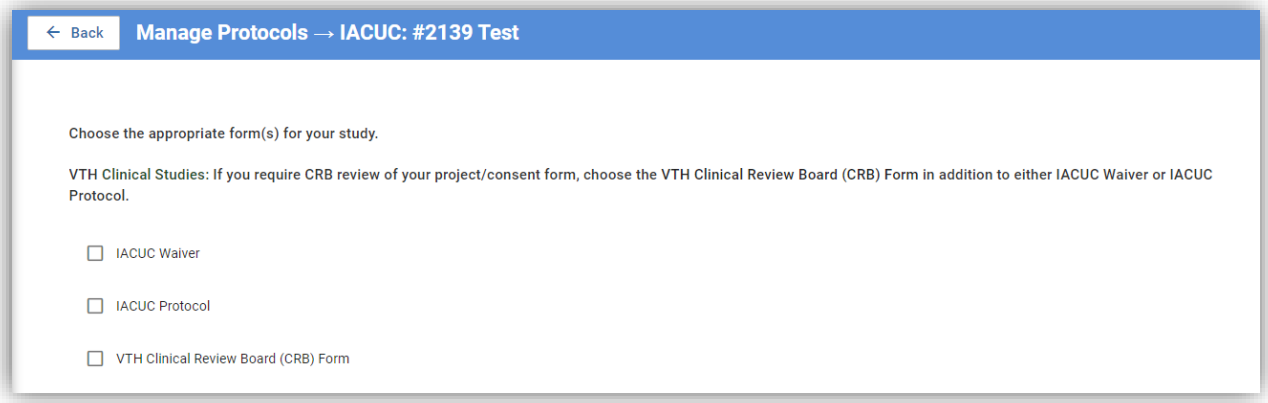
2. After signing in, protocol personnel with full access will be directed to the “Manage Protocols” screen where all protocols will be stored once submitted (for review or actively approved). The title, number given to the protocol, and the status of each protocol are shown (Hint: You can search and filter protocols).
    a. Click **+ New Protocol** and choose the IACUC from the drop-down menu.



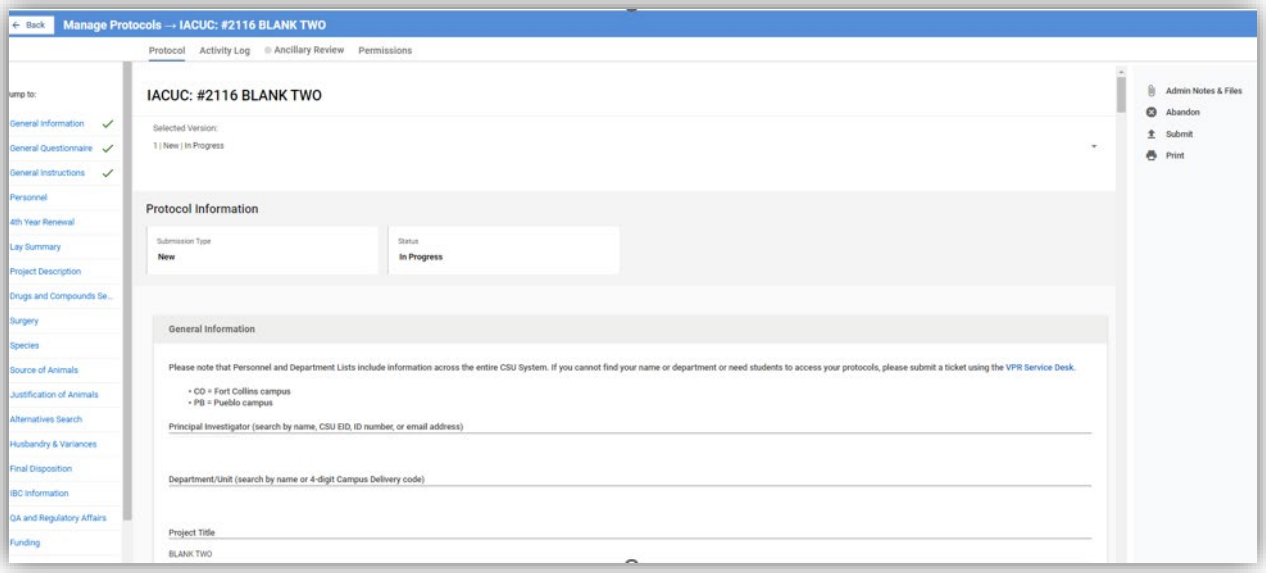
3. Accessing the first IACUC- General Information page will ask for PI name, Department, and Project Title
    a. Select PI name and Department from drop-down menu.
    b. All sections must be filled out before proceeding.
    c. Click **NEXT** to continue.



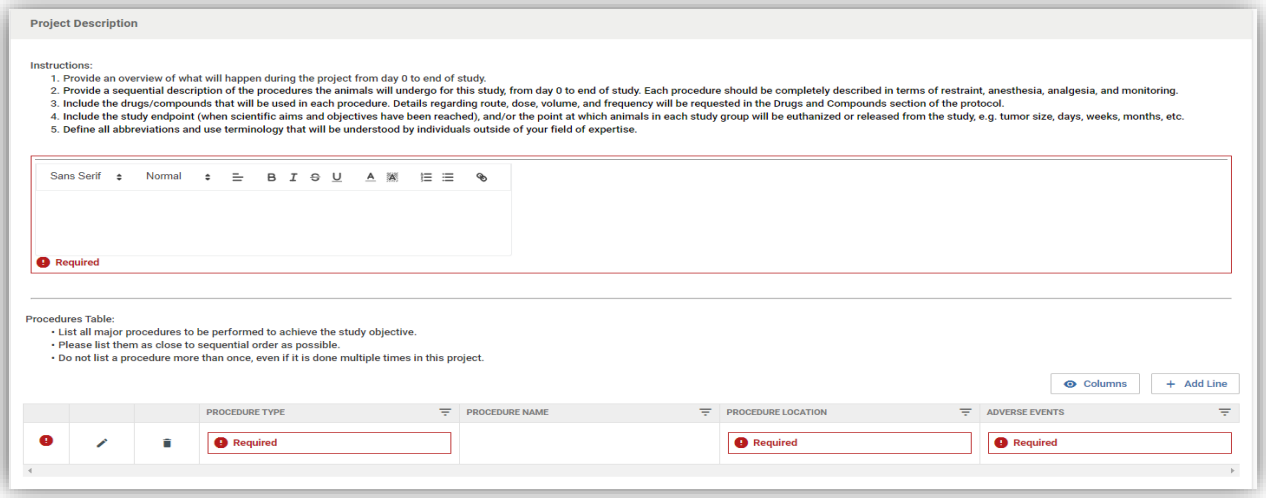
4. You will select the appropriate form for the project you are submitting: IACUC Waiver, IACUC Protocol, and/or VTH Clinical Review Board (CRB) Form
    a. The new IACUC protocol will be given a corresponding number.
    b. Click **NEXT** to continue to the IACUC Protocol page.



5. IACUC Protocol page **GENERAL LAYOUT**:
    a. After entering the IACUC Protocol page, clicking "**BACK"** will save your work and give the protocol an ***"In Progress"*** *status* which can be accessed for further corrections by clicking on the name of the protocol via the "Manage Protocols" home screen.
    b. ***Abandoning the protocol at any time will not allow any edits to be done in the future.***
    c. The left sidebar menu allows for access to each section of the protocol, a ✓ will appear once each section is filled to completion, no ✓ indicates an incomplete section. To jump around to different sections, click on the corresponding section on the left sidebar menu.
    d. Progressive logic is used throughout the form, so your answer *may cause additional question fields to appear* -- requiring you to enter additional information.
    e. Each section includes instructions pertinent to that section with hotlinks to their additional information.



    f. If a required section is not complete, a red box will appear.



6. **General Instructions:** provides different links for IACUC training, resources, OHSP, etc.

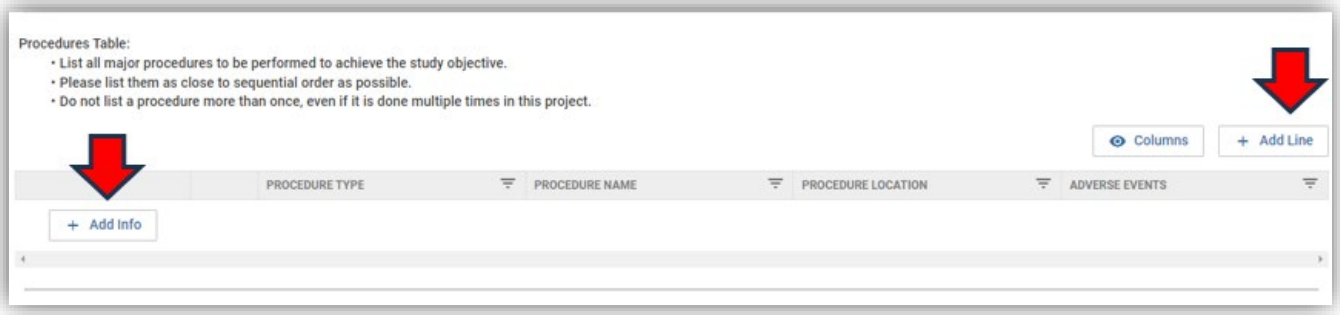
7. **Personnel:** include all researcher and admin roles, group personnel helping with the project, and subsequent training records
    a. Click **+ Add Line** for each new researcher role *OR* admin role.
        i. At least 1 role (Researcher or Admin) for each person must be selected, but multiple roles may be selected.
        ii. Full Access permissions may be designated individually.
    b. Include any IACUC training records for all personnel listed in the Researcher role (anyone who will have contact with animals) in the **All Personnel Attachments** subsection by clicking **+ Add Info.**

8. **4th Year Renewal:** If applicable, please provide a brief summary of work completed thus far and a justification for the continuation of work.

9. **Lay Summary:** include a short summary of why this study is relevant to human or animal health, the advancement of knowledge, or the good of society. Avoid using overly technical terms and be sure to define acronyms.

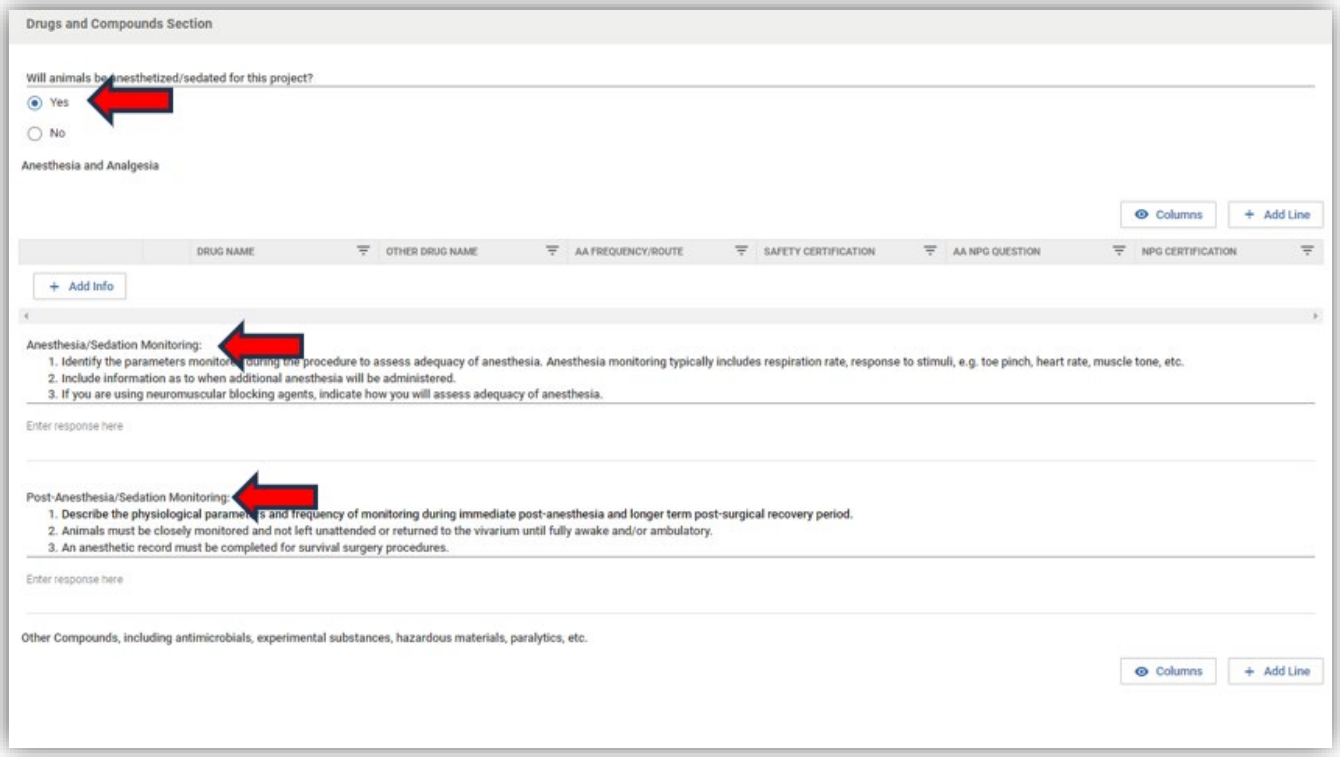
10. **Project Description and Procedures:** include an overview of what will happen during the project from day 0 to end of study, types of animals used, description of the procedures performed on the animals in sequential order, the drugs/compounds used in each procedure, the duration of the study, study endpoint, euthanasia or release information, and disease effects and how to treat or relieve pain.

11. **Procedures Table Information:** include type and location of procedures. Please be sure to list them as close to sequential order as possible.
    a. Click **+ Add Info** for each procedure (**+ Add Line** for any new procedure(s) needed).

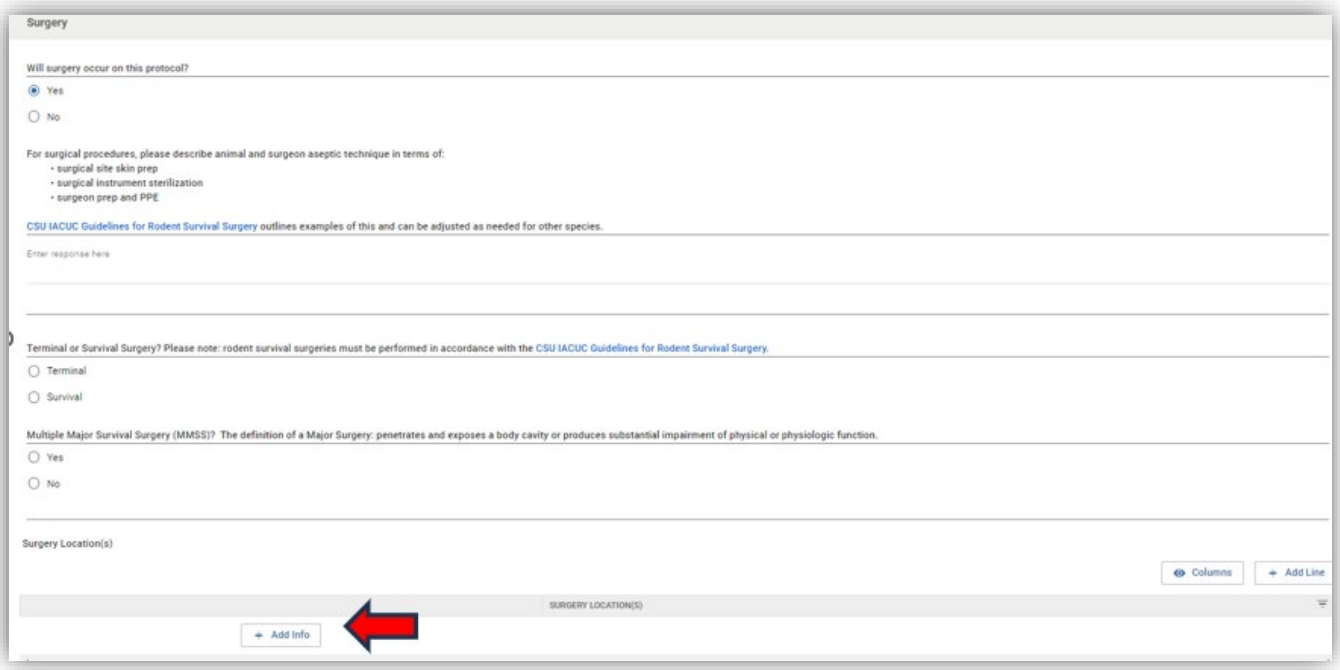


12. **Drugs and Compounds Section:** include any analgesics, anesthesia, or other compounds used for relief of pain or distress.
    a. Click **+ Add Info** to add anesthetic, analgesic, or other compound (**+ Add Line** for any additional anesthetic(s), analgesic(s), or other compound(s))
        i. If the drug or compound is **Non-Pharmaceutical Grade (NPG)**, a justification is needed.

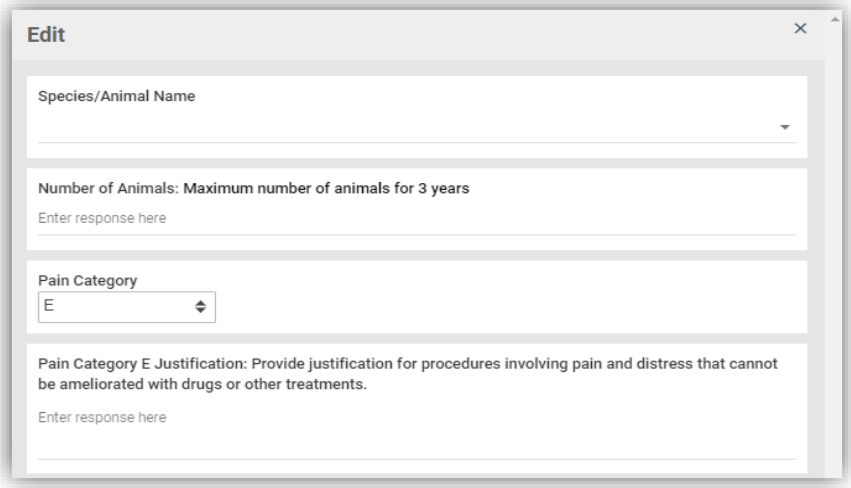
b. If animals are anesthetized/sedated for the study, additional information will be required from you (i.e. Anesthesia/Sedation Monitoring and Post-Anesthesia/Sedation Monitoring).



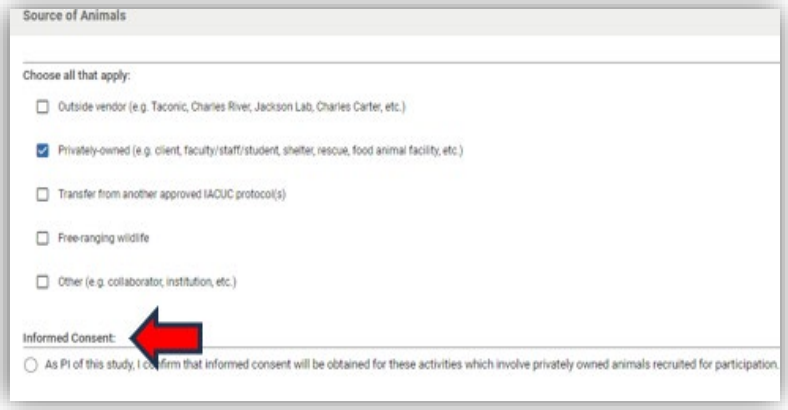
13. **Surgery Section:** surgical procedures requiring a pain category D or E must describe animal and surgeon aseptic technique, select if surgery is terminal or survival and if there is Multiple Major Survival Surgery (MMSS), and provide the surgery location(s).
    a. If Multiple Major Survival Surgery (MMSS) is necessary, a justification is needed.
    b. Click **+ Add Info** to add surgery location and select building from drop down menu.



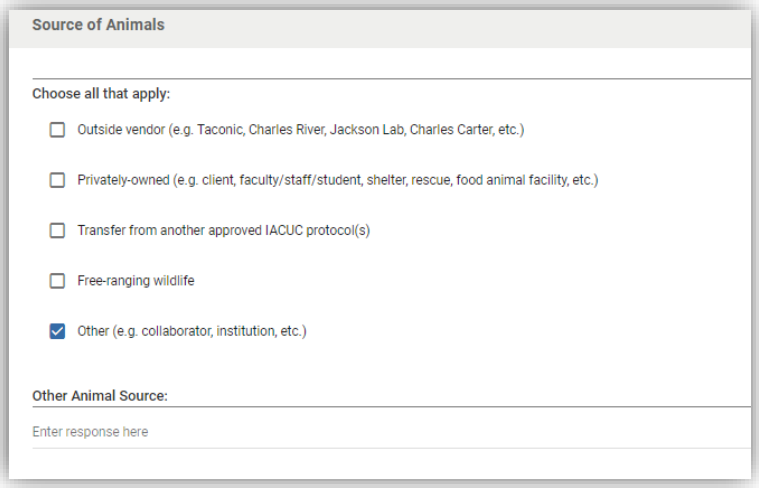
14. **Species and Protocol Pain Categorization:** include species, number of animals needed, and pain category.
    a. Click **+ Add Info** to add species information (**+ Add Line** for any additional species information)
    b. Note: Pain Category E will need a justification



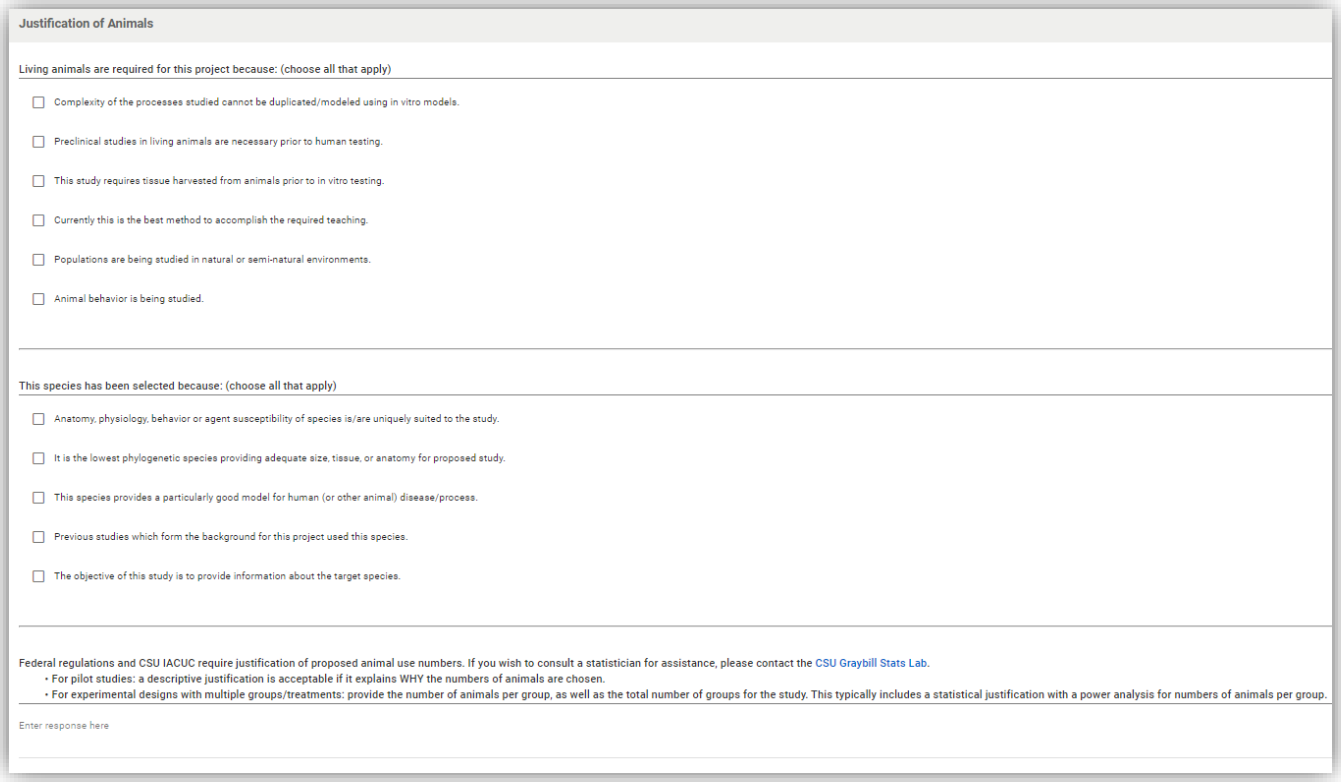
15. **<u>Source of Animals</u>**: multiple selections are possible: Outside vendor, privately-owned, etc.
    a. The PI must confirm that informed consent will be obtained for Privately-owned animals. The study may require review by the Clinical Review Board.



    b. "Other" requires more information.



16. **<u>Justification of Proposed Animal Use Numbers:</u>** select why living animals are required for your project, why the species was selected, and justification of the number of animals used/needed for the study.



Justification of Animals

Living animals are required for this project because: (choose all that apply)

- [ ] Complexity of the processes studied cannot be duplicated/modeled using in vitro models.
- [ ] Preclinical studies in living animals are necessary prior to human testing.
- [ ] This study requires tissue harvested from animals prior to in vitro testing.
- [ ] Currently this is the best method to accomplish the required teaching.
- [ ] Populations are being studied in natural or semi-natural environments.
- [ ] Animal behavior is being studied.

This species has been selected because: (choose all that apply)

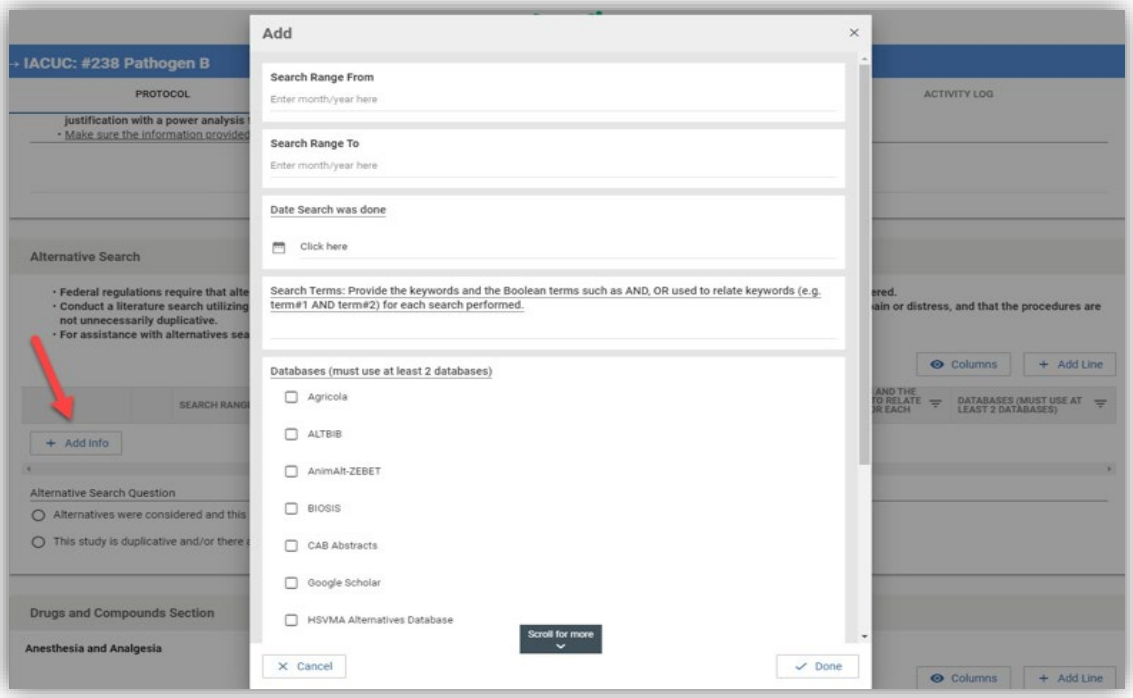
- [ ] Anatomy, physiology, behavior or agent susceptibility of species is/are uniquely suited to the study.
- [ ] It is the lowest phylogenetic species providing adequate size, tissue, or anatomy for proposed study.
- [ ] This species provides a particularly good model for human (or other animal) disease/process.
- [ ] Previous studies which form the background for this project used this species.
- [ ] The objective of this study is to provide information about the target species.

Federal regulations and CSU IACUC require justification of proposed animal use numbers. If you wish to consult a statistician for assistance, please contact the CSU Graybill Stats Lab.

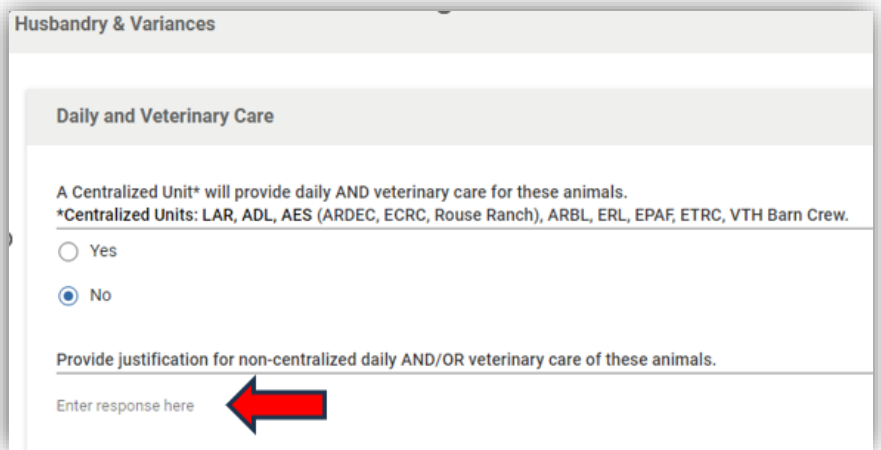
- For pilot studies: a descriptive justification is acceptable if it explains WHY the numbers of animals are chosen.
- For experimental designs with multiple groups/treatments: provide the number of animals per group, as well as the total number of groups for the study. This typically includes a statistical justification with a power analysis for numbers of animals per group.

Enter response here

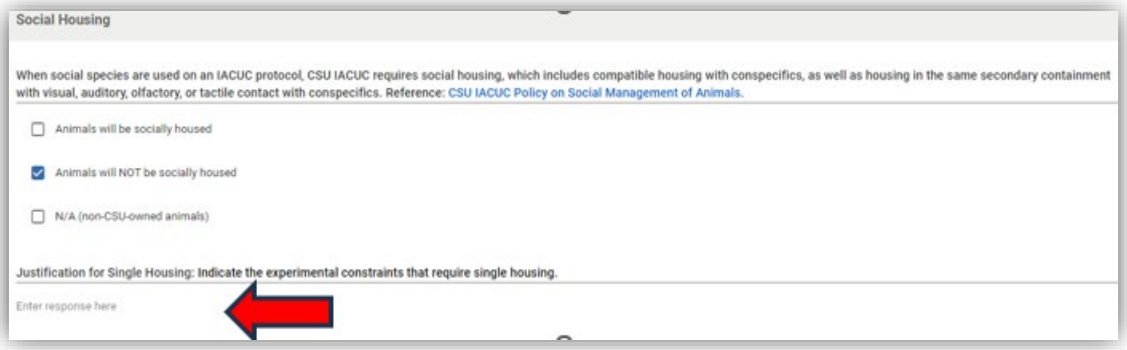
17. **<u>Alternative Search:</u>** enter information for literature search(es).
    a. Click **+ Add Info** for searches **(+ Add Line** for any new search(es) needed).
    b. If "study is duplicative" is selected for **Alternative Search Question**, a justification is needed.



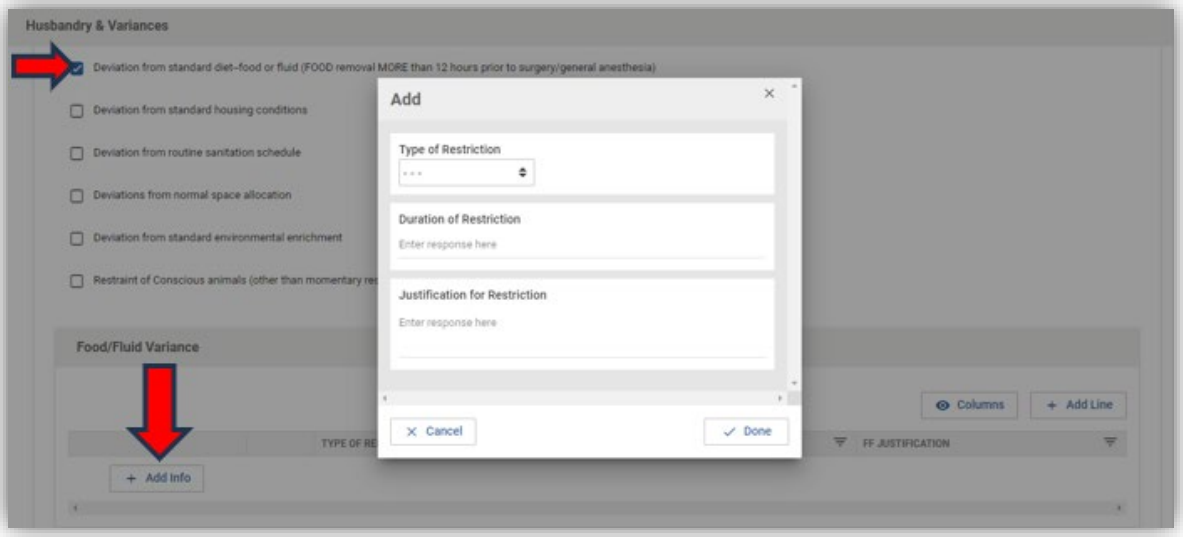
18. **<u>Husbandry, Social Housing, & Variances:</u>** confirm if a centralized unit will be providing daily AND veterinary care, select if animals are socially housed or not, and any deviations from standard diet, housing environment/conditions, restraint of animals, etc.
    a. **<u>Centralized Unit</u>**: requires justification for non-centralized daily AND/OR veterinary care of these animals.



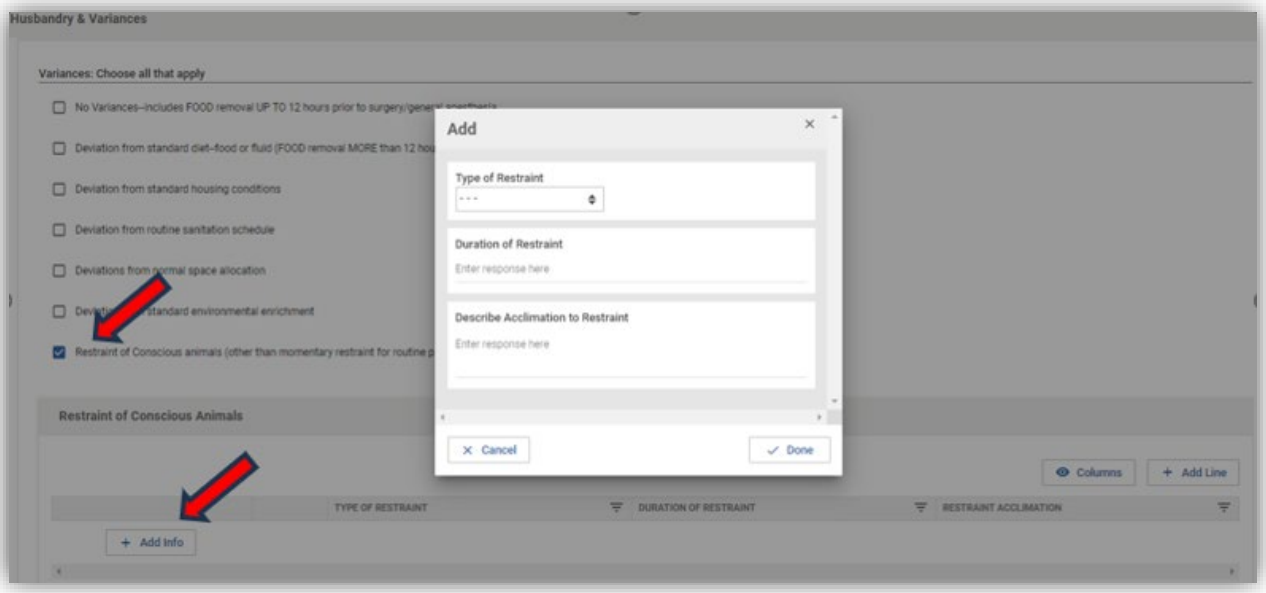
b. **<u>Social Housing</u>**: animals housed singly out of necessity must have a justification.



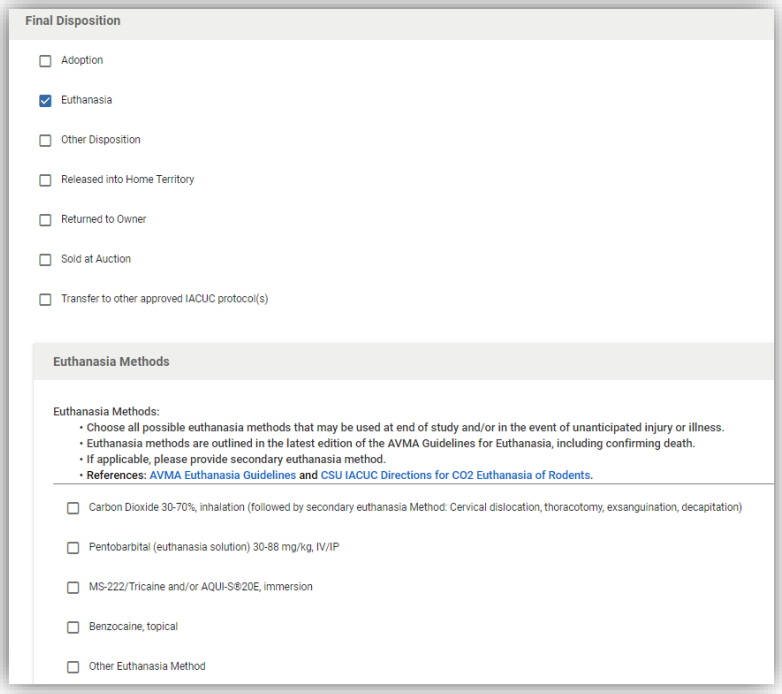
c. **<u>Variances:</u>** any variances require justification
   i. **Deviation from standard diet** – food or fluid requires a more in-depth justification. Click **+ Add Info** to add "food or fluid" information (**+ Add Line** for any additional "food or fluid" information).



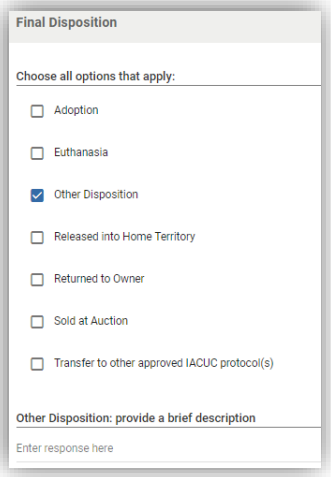
d. **<u>Restraint of conscious animals</u>** - requires a more in-depth justification. Click **+ Add Info** to add restraint information (**+ Add Line** for any additional restraint information).



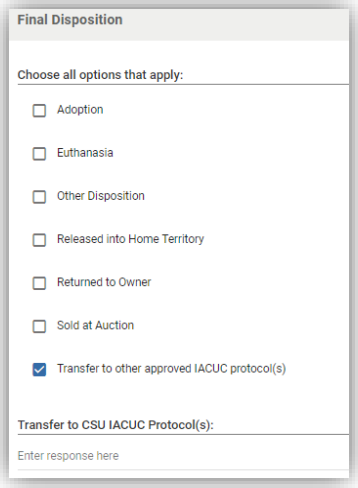
19. **<u>Final Disposition</u>**: Describe what happens to animals at end of study (terminal or not).
    a. **Euthanasia** - requires a method(s) to be selected.



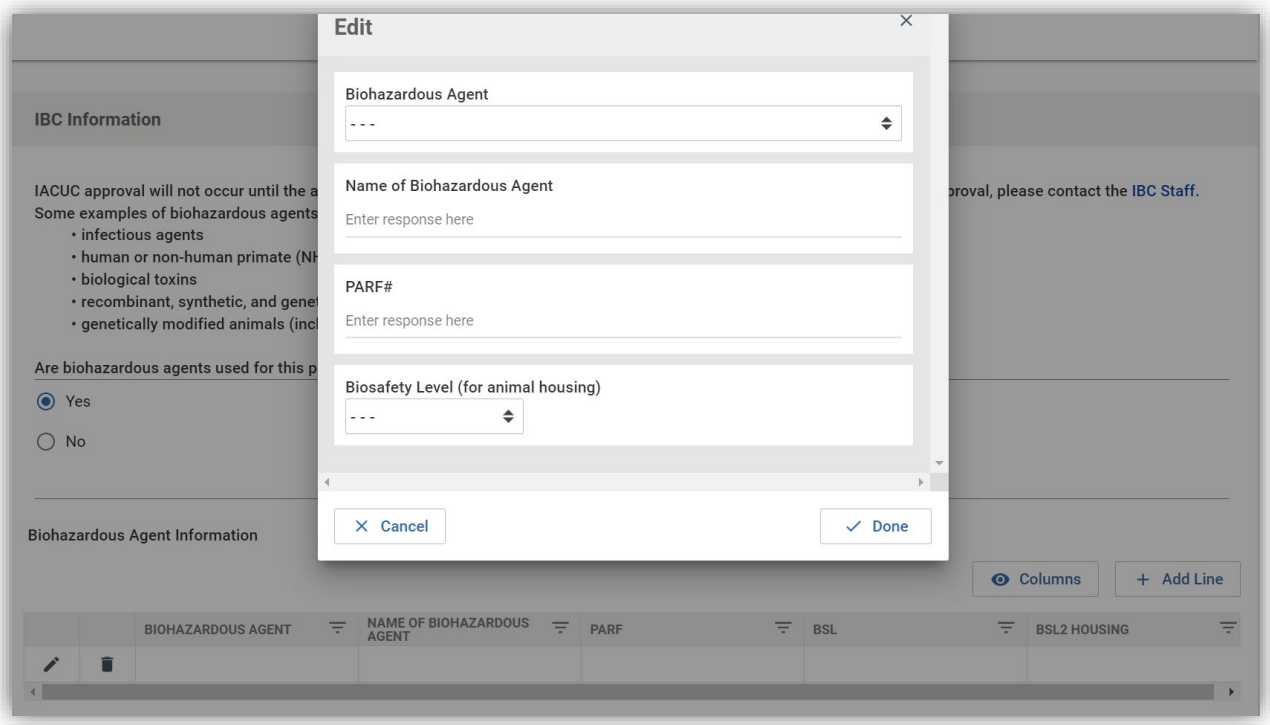
b. **Other Disposition** – requires a brief description.



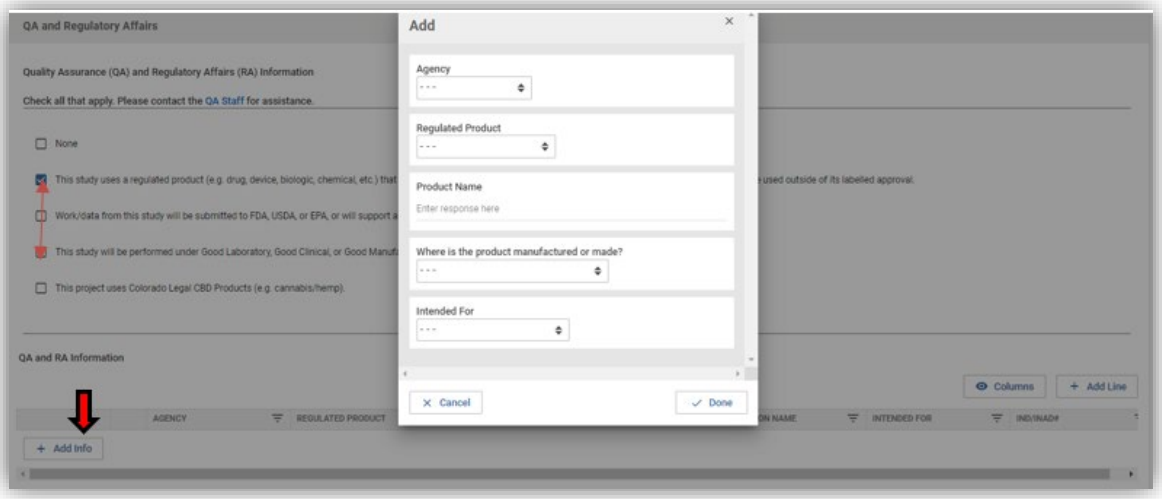
c. **Transfer to other approved IACUC protocol(s)** – requires you to list protocol(s).



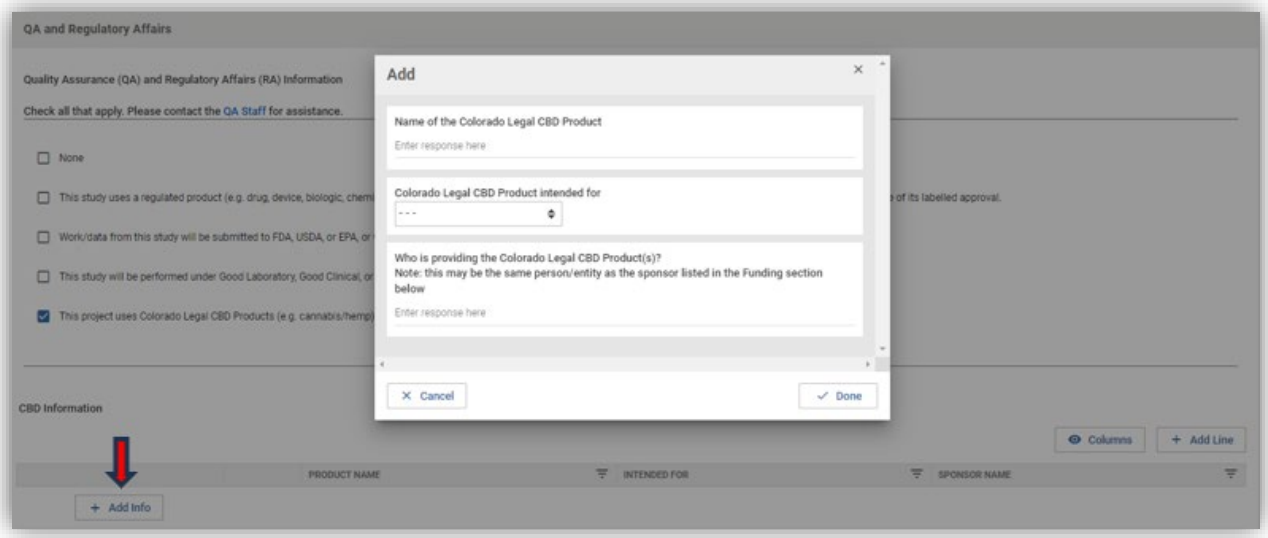
20. **<u>IBC Information</u>**: include any biohazardous agent used for the study.
    a. Click **+ Add Info** to add biohazardous agent (**+ Add Line** for any additional biohazardous agent(s)).
    b. **A PARF# is required for any biohazardous agent(s) used** (radioactive materials, ionizing radiation, human or human tissue research studies, or controlled substances - see the CSU Biosafety Manual for details)



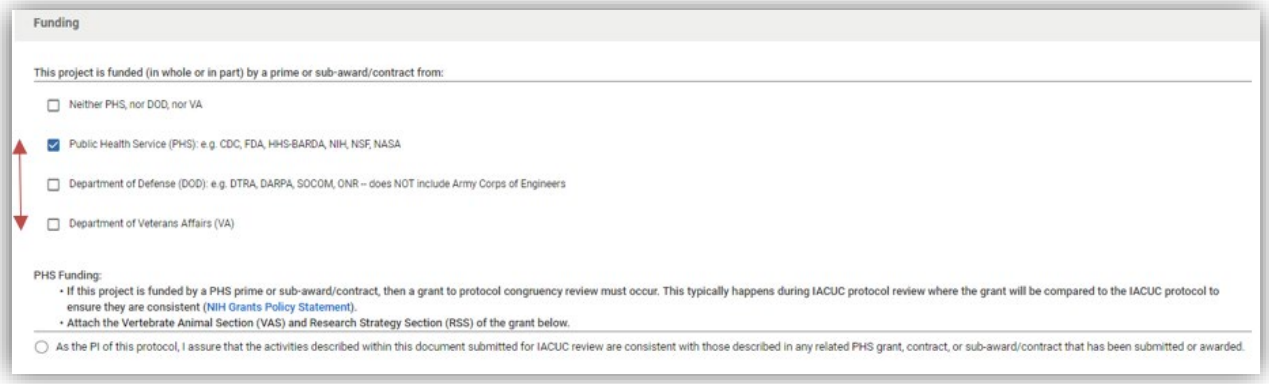
21. **<u>Quality Assurance (QA) and Regulatory Affairs</u>**: include any QA and RA information regarding the work/data from this study.
    a. Click **+ Add Info** to add agency and product information (**+ Add Line** for any additional agency and product information).



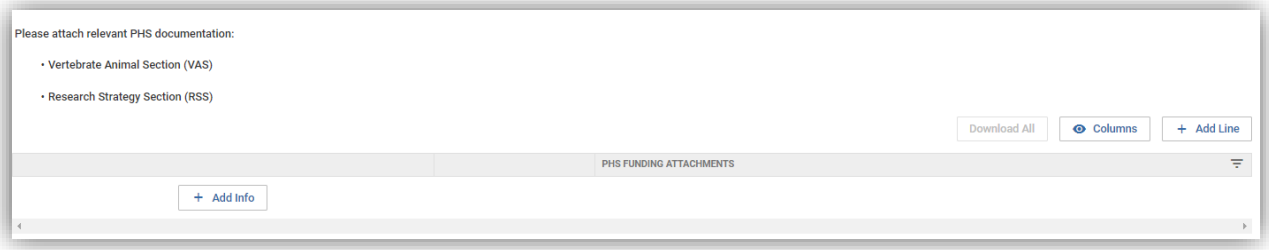
b. If your study uses Colorado Legal CBD products, click **+ Add Info** to add CBD information.



22. **Funding:** describe the source of funding (approval of funding must be issued).

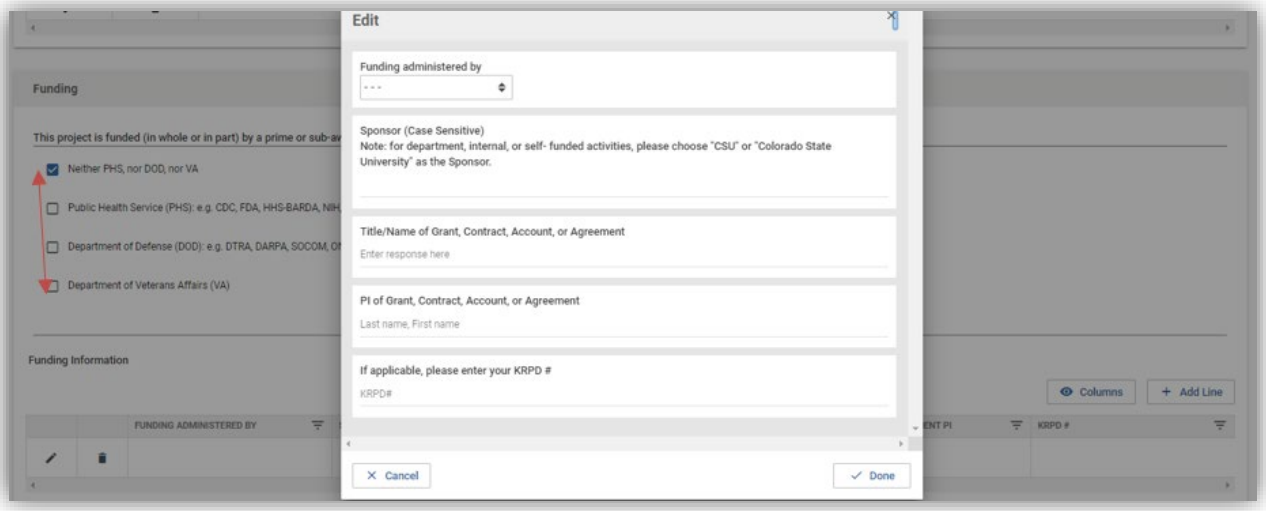


a. For Public Health Service funding, please ensure to attach any relevant PHS documentation.



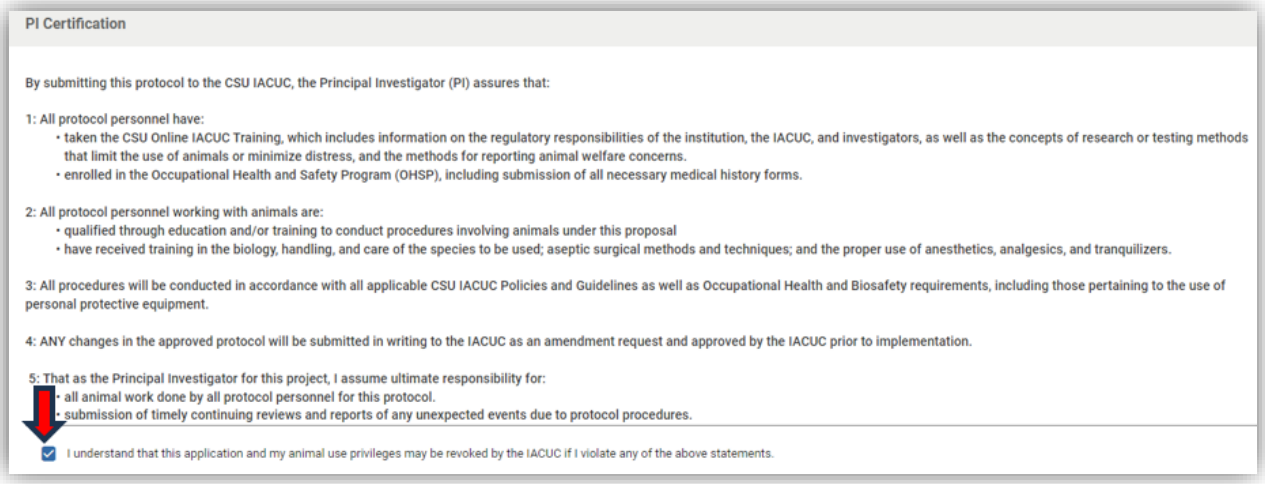
b. Click **+ Add Info** to add funding information in the table (**+ Add Line** for any additional funding information)

*c. The **Funding Information Table** subsection is required for any box chosen from the checklist.*

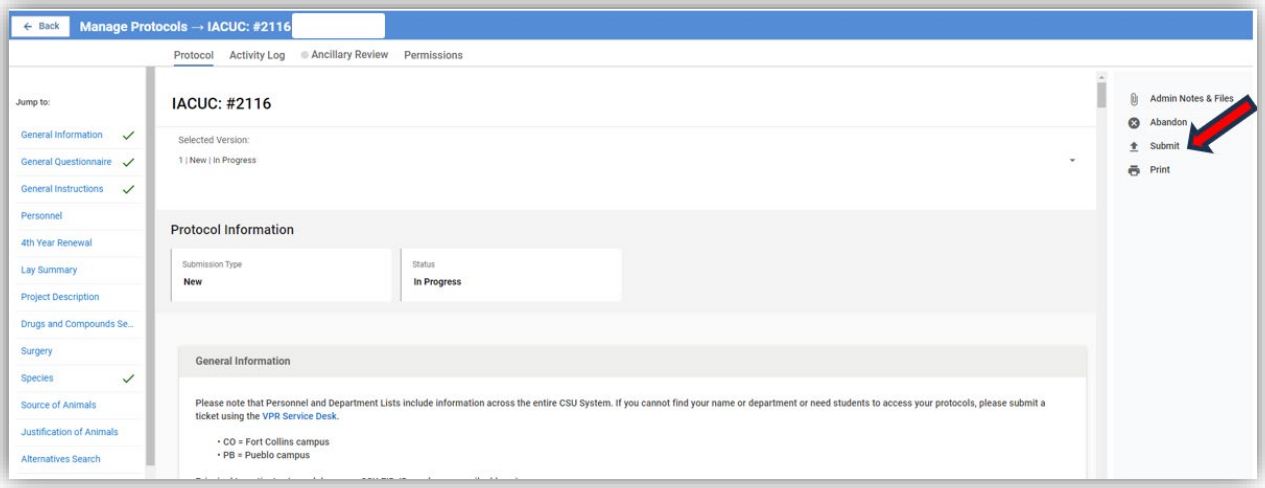


23. **<u>PI Certification</u>**: checking this section ensures CSU IACUC that all personnel are properly certified and trained, all procedures are conducted in accordance with IACUC regulations, all personnel participate in OHSP with submission of medical history, and that the information, procedures, and pain relief alternatives written are accurate to the best of the PI's knowledge.

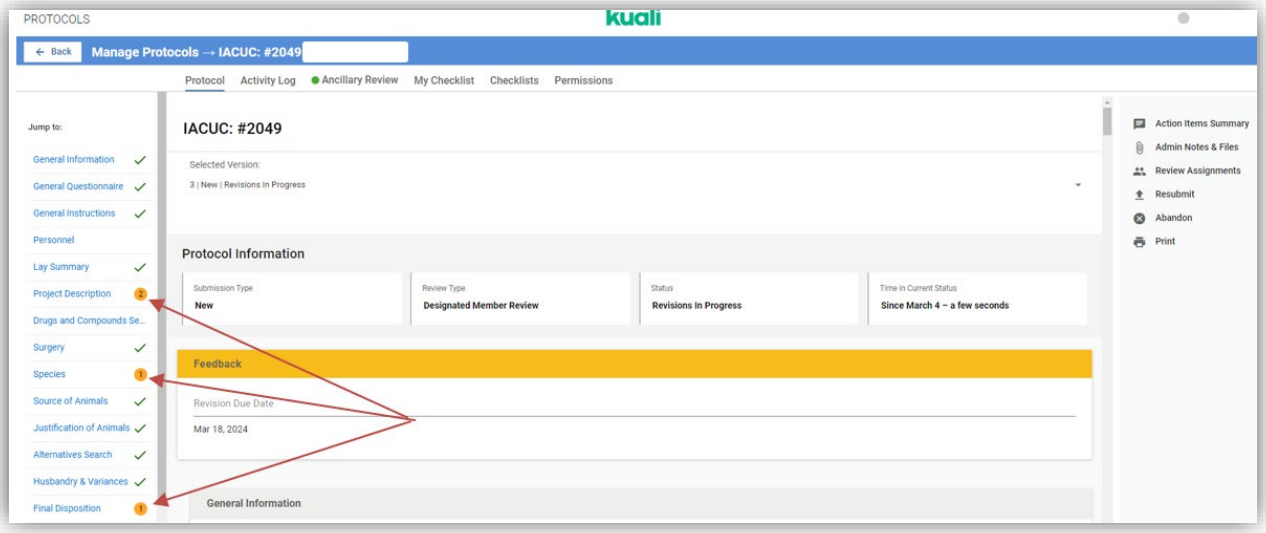
a. Protocol will not be submitted without checking this section.



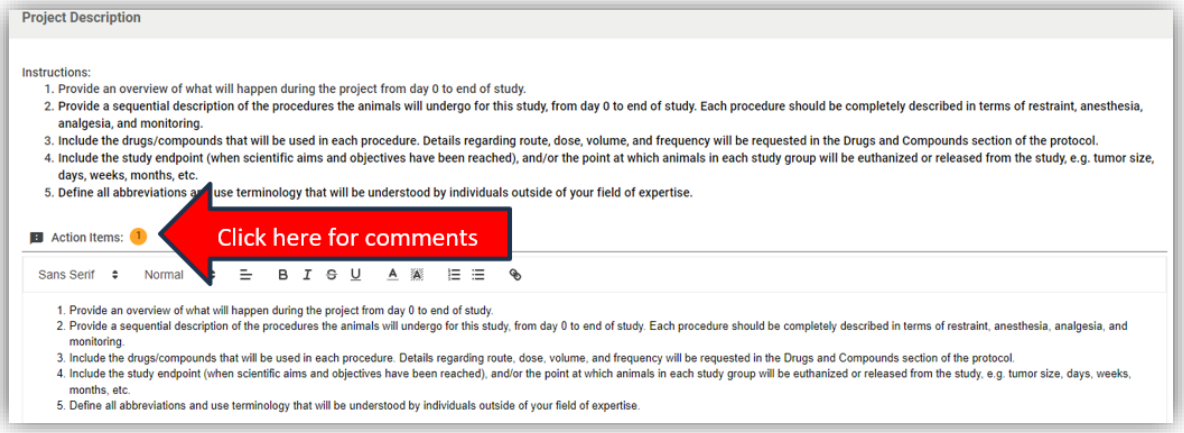
24. Once all sections are completed, and accurate to the best of the PI's knowledge, the protocol may be submitted for review.
    a. Submission **does NOT** mean the protocol is approved. The protocol must be reviewed by a designated member of the CSU IACUC approval board.



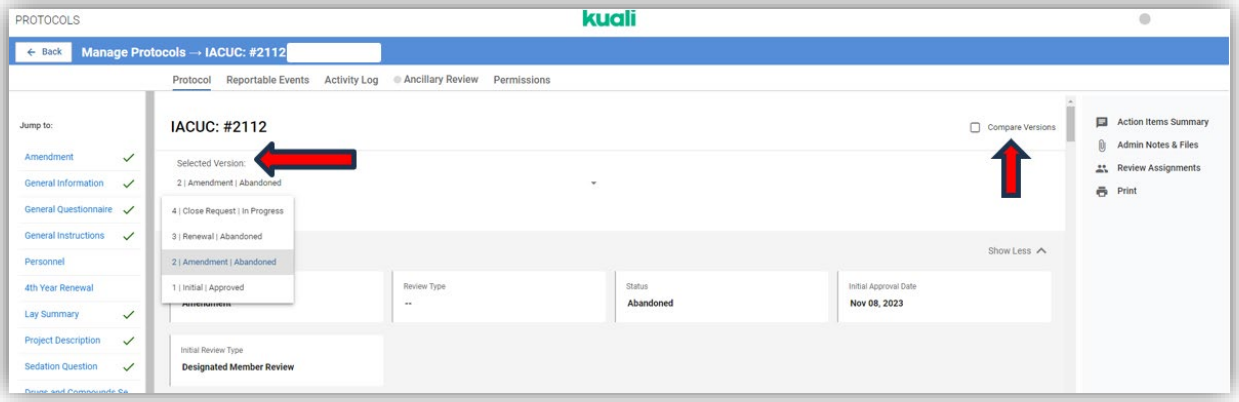
25. After a designated member of the CSU IACUC approval board has reviewed the protocol, the protocol may be returned for edits. Comments will appear throughout the protocol page as "**Action Items**." The left sidebar menu will show which section has an action item (shown as a yellow/orange circle with a number for amount of comments in each section).



a. Click on the "**Action Item**" box to read comments/action items.



26. At the top of the page**, each version of the protocol can be accessed via the drop-down menu** next to the "**Version**" heading. This includes the NEW version of the protocol with any revisions required after submission and any amendments.



a. By checking the "**Compare Versions**" box, the OLD and NEW review request edits and amendments will be shown (in red and green, respectively). The OLD edits will be crossed out throughout the protocol page.

27. When edits are finished, <u>resubmit</u> edited protocol (top right of page) to be reviewed by the CSU IACUC.