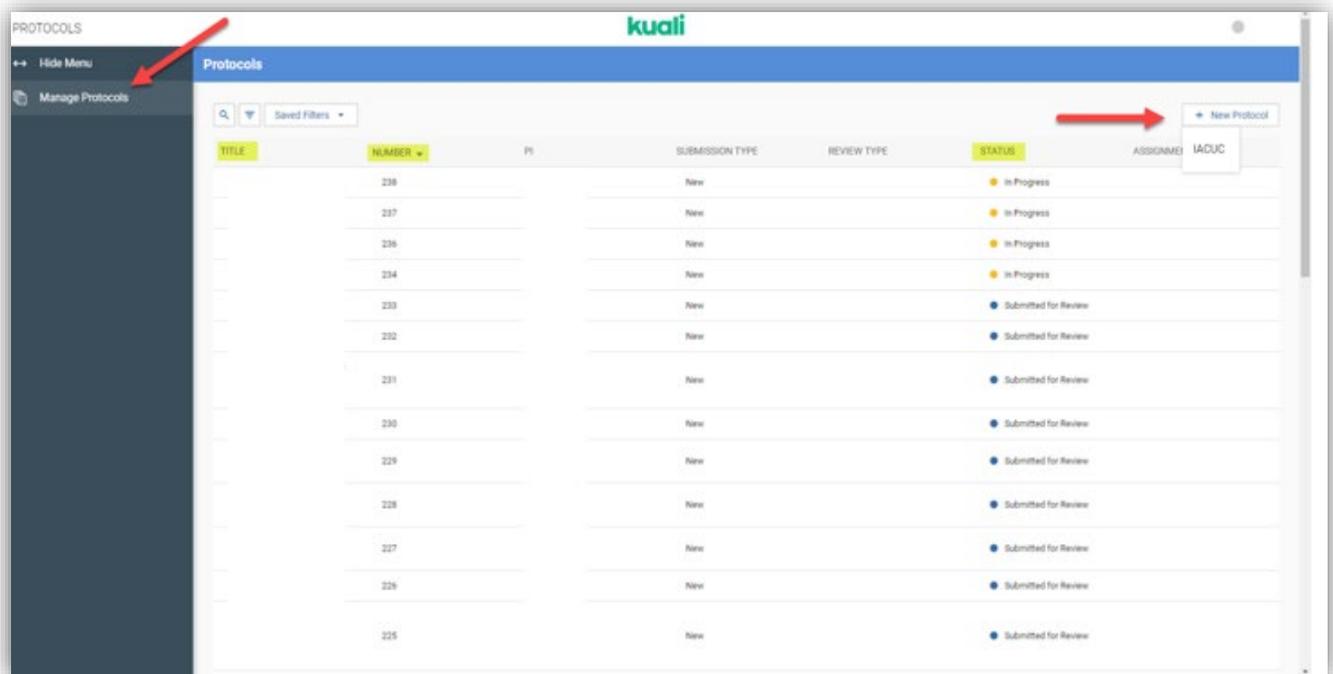


How to Create a New IACUC Protocol

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.

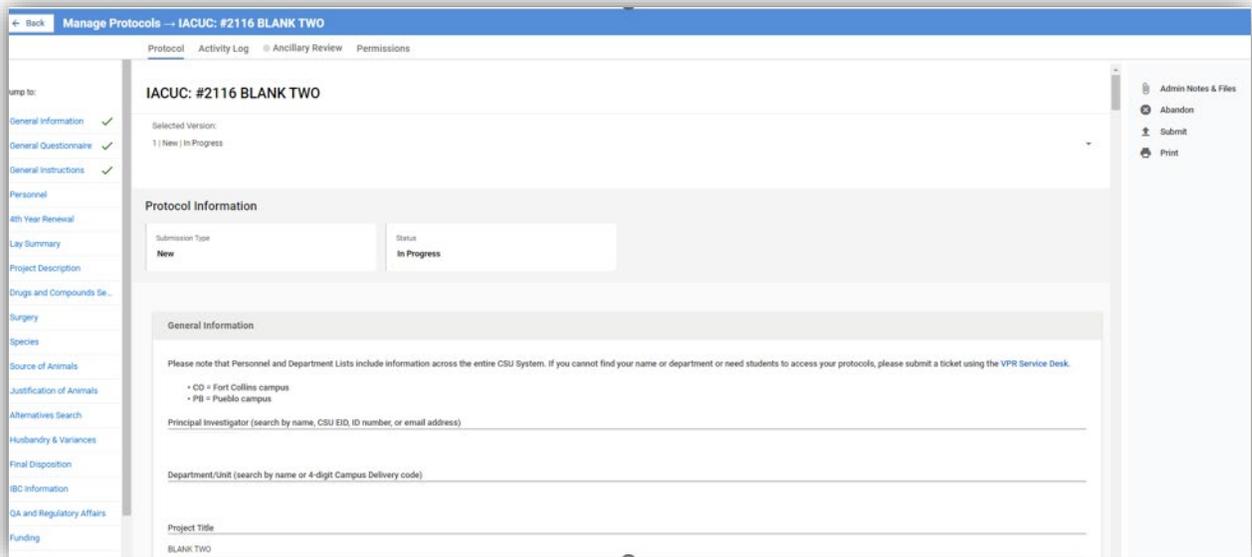
The screenshot shows a web form titled "IACUC - General Information". The form has a blue header bar with the title. Below the header, there is a text area with a note: "Please note that Personnel and Department Lists include information across the entire CSU System. If you cannot find your name or department or need students to access your protocols, please submit a ticket using the [VPR Service Desk](#)." Below this note are two bullet points: "• CO = Fort Collins campus" and "• PB = Pueblo campus". There are three input fields: "Principal Investigator (search by name, CSU EID, ID number, or email address)", "Department/Unit (search by name or 4-digit Campus Delivery code)", and "Project Title" (with a placeholder "Enter response here"). On the right side of the form, there are two buttons: "Cancel" with a close icon and "Next" with a right arrow icon.

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.

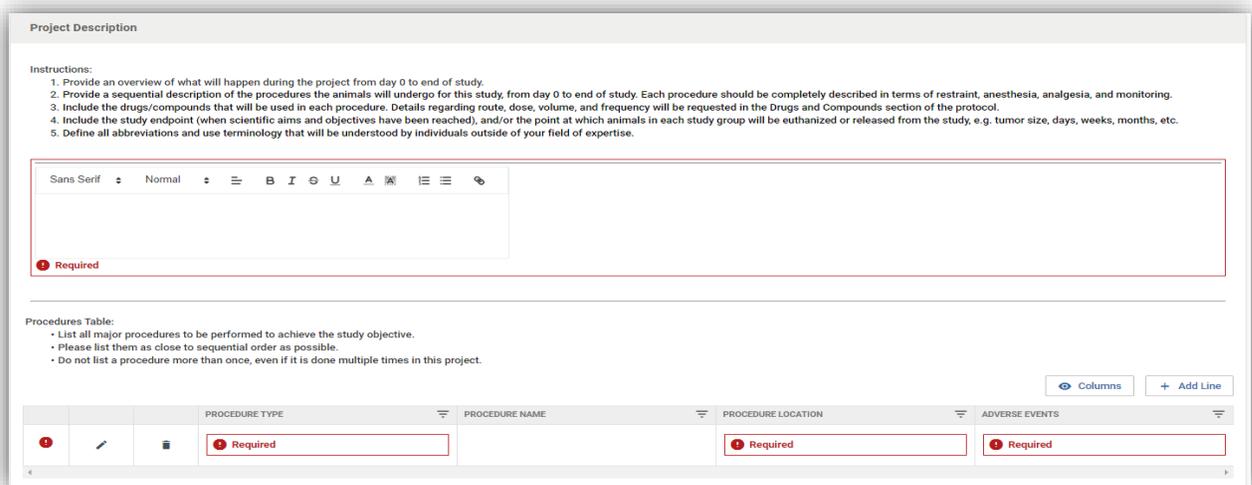
The screenshot shows a web form titled "Manage Protocols" with a sub-header "IACUC: #2139 Test". There is a "Back" button on the left. The main content area contains the text: "Choose the appropriate form(s) for your study." Below this is a note: "VTH Clinical Studies: If you require CRB review of your project/consent form, choose the VTH Clinical Review Board (CRB) Form in addition to either IACUC Waiver or IACUC Protocol." There are three checkboxes with labels: "IACUC Waiver", "IACUC Protocol", and "VTH Clinical Review Board (CRB) Form".

5. IACUC Protocol page **GENERAL LAYOUT:**

- 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.
- Abandoning the protocol at any time will not allow any edits to be done in the future.**
- 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.
- Progressive logic is used throughout the form, so your answer may cause additional question fields to appear -- requiring you to enter additional information.
- Each section includes instructions pertinent to that section with hotlinks to their additional information.



- 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).

Procedures Table:

- List all major procedures to be performed to achieve the study objective.
- Please list them as close to sequential order as possible.
- Do not list a procedure more than once, even if it is done multiple times in this project.

Columns | + Add Line

	PROCEDURE TYPE	PROCEDURE NAME	PROCEDURE LOCATION	ADVERSE EVENTS
+ Add Info				

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).

Drugs and Compounds Section

Will animals be anesthetized/sedated for this project?

Yes 

No

Anesthesia and Analgesia

[Columns](#) [+ Add Line](#)

DRUG NAME	OTHER DRUG NAME	AA FREQUENCY/ROUTE	SAFETY CERTIFICATION	AA NPG QUESTION	NPG CERTIFICATION
-----------	-----------------	--------------------	----------------------	-----------------	-------------------

[+ Add Info](#)

Anesthesia/Sedation Monitoring: 

1. Identify the parameters monitored during the procedure to assess adequacy of anesthesia. Anesthesia monitoring typically includes respiration rate, response to stimuli, e.g. toe pinch, heart rate, muscle tone, etc.
2. Include information as to when additional anesthesia will be administered.
3. If you are using neuromuscular blocking agents, indicate how you will assess adequacy of anesthesia.

Enter response here

Post-Anesthesia/Sedation Monitoring: 

1. Describe the physiological parameters and frequency of monitoring during immediate post-anesthesia and longer term post-surgical recovery period.
2. Animals must be closely monitored and not left unattended or returned to the vivarium until fully awake and/or ambulatory.
3. An anesthetic record must be completed for survival surgery procedures.

Enter response here

Other Compounds, including antimicrobials, experimental substances, hazardous materials, paralytics, etc.

[Columns](#) [+ Add Line](#)

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).
- If Multiple Major Survival Surgery (MMSS) is necessary, a justification is needed.
 - Click **+ Add Info** to add surgery location and select building from drop down menu.

The screenshot shows a form titled "Surgery". It contains several sections:

- Will surgery occur on this protocol?** with radio buttons for "Yes" (selected) and "No".
- For surgical procedures, please describe animal and surgeon aseptic technique in terms of:** with a list of items: "surgical site skin prep", "surgical instrument sterilization", and "surgeon prep and PPE".
- CSU IACUC Guidelines for Rodent Survival Surgery** outlines examples of this and can be adjusted as needed for other species.
- Enter response here** with a text input field.
- Terminal or Survival Surgery?** Please note: rodent survival surgeries must be performed in accordance with the CSU IACUC Guidelines for Rodent Survival Surgery. with radio buttons for "Terminal" and "Survival".
- Multiple Major Survival Surgery (MMSS)?** The definition of a Major Surgery: penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic function. with radio buttons for "Yes" and "No".
- Surgery Location(s)** with a table header "SURGERY LOCATION(S)" and a red arrow pointing to a "+ Add Info" button.

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

The screenshot shows an "Edit" form with the following fields:

- Species/Animal Name** with a dropdown menu.
- Number of Animals: Maximum number of animals for 3 years** with a text input field.
- Pain Category** with a dropdown menu showing "E".
- Pain Category E Justification: Provide justification for procedures involving pain and distress that cannot be ameliorated with drugs or other treatments.** with a text input field.

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

Source of Animals

Choose all that apply:

- Outside vendor (e.g. Taconic, Charles River, Jackson Lab, Charles Carter, etc.)
- Privately-owned (e.g. client, faculty/staff/student, shelter, rescue, food animal facility, etc.)
- Transfer from another approved IACUC protocol(s)
- Free-ranging wildlife
- Other (e.g. collaborator, institution, etc.)

Informed Consent:

As PI of this study, I confirm that informed consent will be obtained for these activities which involve privately owned animals recruited for participation.



- “Other” requires more information.

Source of Animals

Choose all that apply:

- Outside vendor (e.g. Taconic, Charles River, Jackson Lab, Charles Carter, etc.)
- Privately-owned (e.g. client, faculty/staff/student, shelter, rescue, food animal facility, etc.)
- Transfer from another approved IACUC protocol(s)
- Free-ranging wildlife
- Other (e.g. collaborator, institution, etc.)

Other Animal Source:

Enter response here

16. Justification of Proposed Animal Use Numbers: 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. **Alternative Search:** enter information for literature search(es).
- Click **+ Add Info** for searches (**+ Add Line** for any new search(es) needed).
 - If “study is duplicative” is selected for **Alternative Search Question**, a justification is needed.

18. **Husbandry, Social Housing, & Variances:** 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.
- Centralized Unit:** requires justification for non-centralized daily AND/OR veterinary care of these animals.

- b. **Social Housing:** animals housed singly out of necessity must have a justification.

Social Housing

When social species are used on an IACUC protocol, CSU IACUC requires social housing, which includes compatible housing with conspecifics, as well as housing in the same secondary containment with visual, auditory, olfactory, or tactile contact with conspecifics. Reference: [CSU IACUC Policy on Social Management of Animals](#).

Animals will be socially housed

Animals will NOT be socially housed

N/A (non-CSU-owned animals)

Justification for Single Housing: Indicate the experimental constraints that require single housing.

Enter response here



- c. **Variations:** any variations 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).

Husbandry & Variations

Deviation from standard diet-food or fluid (FOOD removal MORE than 12 hours prior to surgery/general anesthesia)

Deviation from standard housing conditions

Deviation from routine sanitation schedule

Deviations from normal space allocation

Deviation from standard environmental enrichment

Restraint of Conscious animals (other than momentary restraints)

Food/Fluid Variance

+ Add Info

+ Add Line

FF JUSTIFICATION

Add

Type of Restriction

Duration of Restriction

Enter response here

Justification for Restriction

Enter response here

Cancel Done



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

The screenshot shows the 'Husbandry & Variances' interface. Under the 'Variances: Choose all that apply' section, the checkbox for 'Restraint of Conscious animals (other than momentary restraint for routine p)' is checked. A modal window titled 'Add' is open, with the following fields:

- Type of Restraint:** A dropdown menu with a search icon.
- Duration of Restraint:** A text input field with the placeholder 'Enter response here'.
- Describe Acclimation to Restraint:** A larger text input field with the placeholder 'Enter response here'.

 At the bottom of the modal are 'Cancel' and 'Done' buttons. In the background, a table header for 'Restraint of Conscious Animals' is visible with columns for 'TYPE OF RESTRAINT', 'DURATION OF RESTRAINT', and 'RESTRAINT ACCLIMATION'. A '+ Add Info' button is located at the bottom left of the table area. Red arrows highlight the 'Add Info' button and the checked checkbox.

19. **Final Disposition:** Describe what happens to animals at end of study (terminal or not).

- a. **Euthanasia** - requires a method(s) to be selected.

The screenshot shows the 'Final Disposition' form. Under the 'Final Disposition' section, the 'Euthanasia' checkbox is checked. Below this is the 'Euthanasia Methods' section, which includes the following text:

- Euthanasia Methods:**
 - Choose all possible euthanasia methods that may be used at end of study and/or in the event of unanticipated injury or illness.
 - Euthanasia methods are outlined in the latest edition of the AVMA Guidelines for Euthanasia, including confirming death.
 - If applicable, please provide secondary euthanasia method.
 - References: [AVMA Euthanasia Guidelines](#) and [CSU IACUC Directions for CO2 Euthanasia of Rodents](#).

 Below the text are several checkboxes for specific methods:

- Carbon Dioxide 30-70%, inhalation (followed by secondary euthanasia Method: Cervical dislocation, thoracotomy, exsanguination, decapitation)
- Pentobarbital (euthanasia solution) 30-88 mg/kg, IV/IP
- MS-222/Tricaine and/or AQUI-S®20E, immersion
- Benzocaine, topical
- Other Euthanasia Method

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

Final Disposition

Choose all options that apply:

- Adoption
- Euthanasia
- Other Disposition
- Released into Home Territory
- Returned to Owner
- Sold at Auction
- Transfer to other approved IACUC protocol(s)

Other Disposition: provide a brief description

Enter response here

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

Final Disposition

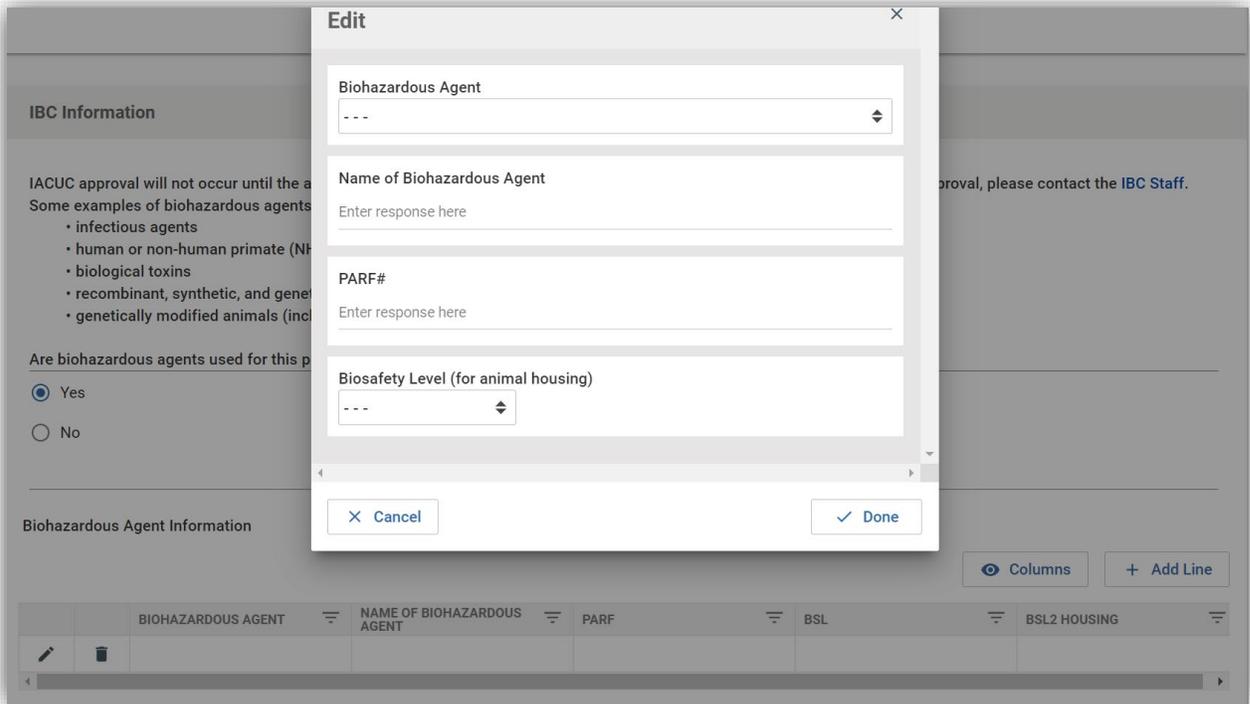
Choose all options that apply:

- Adoption
- Euthanasia
- Other Disposition
- Released into Home Territory
- Returned to Owner
- Sold at Auction
- Transfer to other approved IACUC protocol(s)

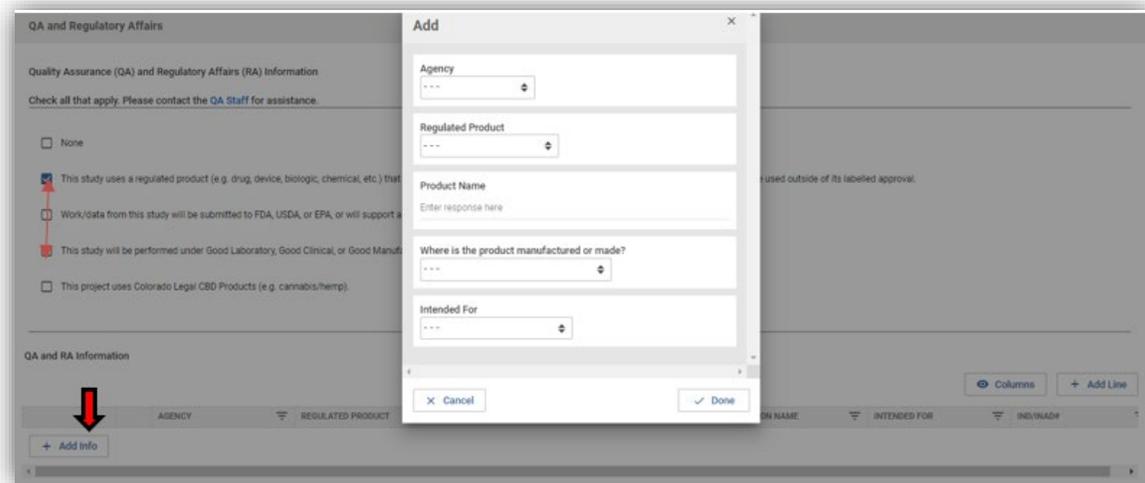
Transfer to CSU IACUC Protocol(s):

Enter response here

20. **IBC Information:** include any biohazardous agent used for the study.
- Click **+ Add Info** to add biohazardous agent (**+ Add Line** for any additional biohazardous agent(s)).
 - 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. **Quality Assurance (QA) and Regulatory Affairs:** include any QA and RA information regarding the work/data from this study.
- 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.

QA and Regulatory Affairs

Quality Assurance (QA) and Regulatory Affairs (RA) Information

Check all that apply. Please contact the QA Staff for assistance.

- None
- This study uses a regulated product (e.g. drug, device, biologic, chem
- Work/data from this study will be submitted to FDA, USDA, or EPA, or
- This study will be performed under Good Laboratory, Good Clinical, or
- This project uses Colorado Legal CBD Products (e.g. cannabis/hemp)

CBD Information

PRODUCT NAME	INTENDED FOR	SPONSOR NAME
+ Add Info		

[Columns](#) [+ Add Line](#)

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

Funding

This project is funded (in whole or in part) by a prime or sub-award/contract from:

- Neither PHS, nor DOD, nor VA
- Public Health Service (PHS): e.g. CDC, FDA, HHS-BARDA, NIH, NSF, NASA
- Department of Defense (DOD): e.g. DTRA, DARPA, SOCOM, ONR -- does NOT include Army Corps of Engineers
- Department of Veterans Affairs (VA)

PHS Funding:

- If this project is funded by a PHS prime or sub-award/contract, then a grant to protocol congruency review must occur. This typically happens during IACUC protocol review where the grant will be compared to the IACUC protocol to ensure they are consistent (NIH Grants Policy Statement).
- Attach the Vertebrate Animal Section (VAS) and Research Strategy Section (RSS) of the grant below.

As the PI of this protocol, I assure that the activities described within this document submitted for IACUC review are consistent with those described in any related PHS grant, contract, or sub-award/contract that has been submitted or awarded.

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

Please attach relevant PHS documentation:

- Vertebrate Animal Section (VAS)
- Research Strategy Section (RSS)

[Download All](#) [Columns](#) [+ Add Info](#)

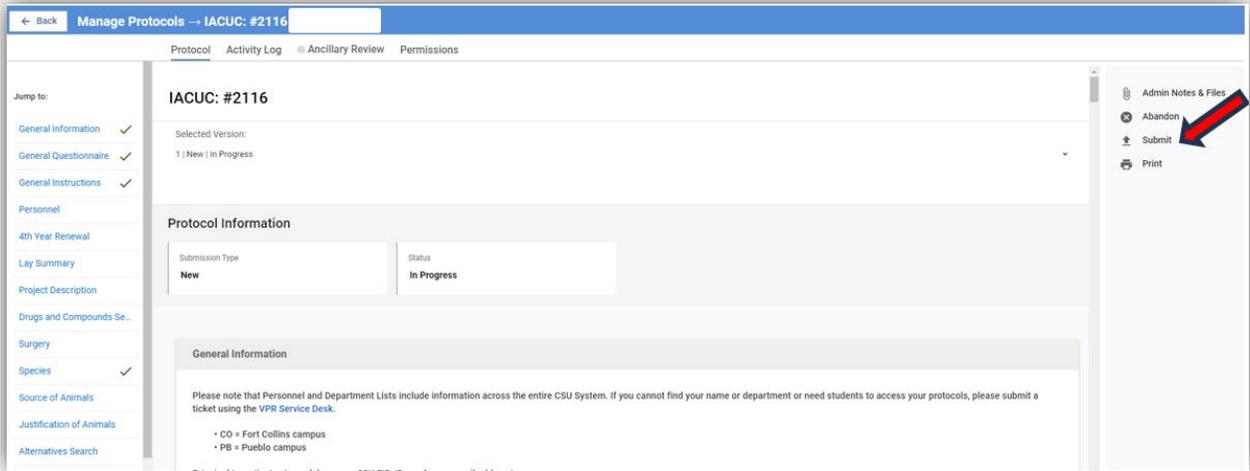
PHS FUNDING ATTACHMENTS

[+ Add Info](#)

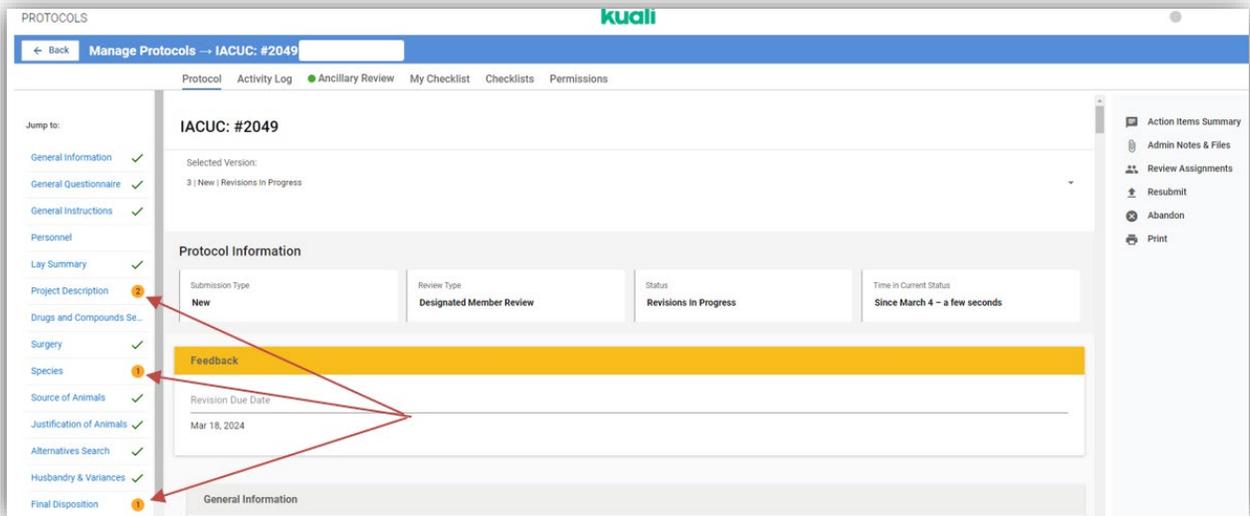
- b. Click **+ Add Info** to add funding information in the table (**+ Add Line** for any additional funding information)
- c. *The **Funding Information Table** subsection is required for any box chosen from the checklist.*

23. **PI Certification:** 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.
- 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.

Project Description

Instructions:

1. Provide an overview of what will happen during the project from day 0 to end of study.
2. Provide a sequential description of the procedures the animals will undergo for this study, from day 0 to end of study. Each procedure should be completely described in terms of restraint, anesthesia, analgesia, and monitoring.
3. Include the drugs/compounds that will be used in each procedure. Details regarding route, dose, volume, and frequency will be requested in the Drugs and Compounds section of the protocol.
4. Include the study endpoint (when scientific aims and objectives have been reached), and/or the point at which animals in each study group will be euthanized or released from the study, e.g. tumor size, days, weeks, months, etc.
5. Define all abbreviations and use terminology that will be understood by individuals outside of your field of expertise.

Action Items: 1

Click here for comments

Sans Serif Normal B I G U A A E E

1. Provide an overview of what will happen during the project from day 0 to end of study.
2. Provide a sequential description of the procedures the animals will undergo for this study, from day 0 to end of study. Each procedure should be completely described in terms of restraint, anesthesia, analgesia, and monitoring.
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5. Define all abbreviations and use terminology that will be understood by individuals outside of your field of expertise.

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.

PROTOCOLS kuali

Manage Protocols → IACUC: #2112

Protocol Reportable Events Activity Log Ancillary Review Permissions

IACUC: #2112

Selected Version: 2 | Amendment | Abandoned

4 | Close Request | In Progress

3 | Renewal | Abandoned

2 | Amendment | Abandoned

1 | Initial | Approved

Review Type: --

Status: Abandoned

Initial Approval Date: Nov 08, 2023

Compare Versions

Action Items Summary

Admin Notes & Files

Review Assignments

Print

- 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, resubmit edited protocol (top right of page) to be reviewed by the CSU IACUC.