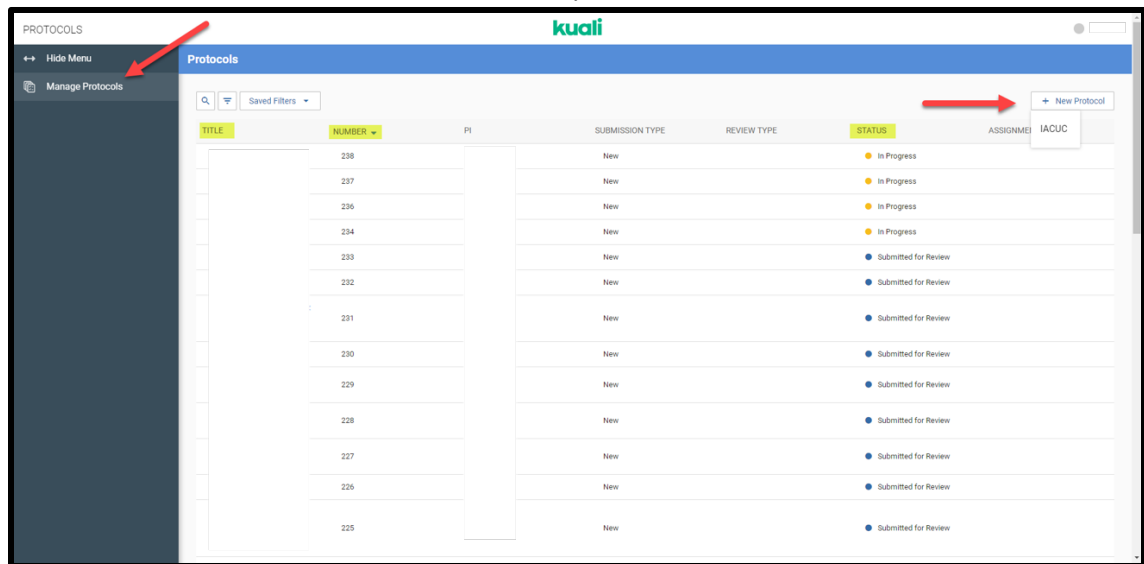


Create a new IACUC Protocol

1. To access Kualu for IACUC protocols go to <https://colostate.kuali.co/protocols> (or access via the IACUC webpage)
 - a. Choose the appropriate CSU campus
 - b. Sign in with your CSU eID name and password
 - c. After signing in, the Principal Investigator will be directed to the “Manage Protocols” screen where all protocols will be stored once submitted (for review or for amendments). The title, number given to the protocol, and the status of each protocol are shown (Hint: You can search and filter protocols).
 - d. Click **+ New Protocol** and choose the IACUC drop-down



2. Accessing the first IACUC- General Information page will ask for PI name, Department, and Project Title

IACUC - General Information

Please note that Personnel and Department Lists include information across the entire CSU System. If you cannot find your name or department, [contact RICRO IACUC Staff](#) for assistance.

- CO = Fort Collins Campus
- PB = Pueblo Campus
- GC = Global Campus (also GR)
- BG = Board of Governors

Examples:

- Clinical Sciences (CO-1678) = CSU, Clinical Sciences
- Biology (PB-P241) = CSU Pueblo, Biology

Principal Investigator (Last, First) **Department**

Last name, First name

Project Title

Enter response here

- a. Select PI name and Department from drop-down menu
- b. All sections must be filled out before proceeding
- c. Click **NEXT** to continue

3. You will select the appropriate form for the project you are submitting: IACUC Waiver, IACUC Protocol, and/or Client Consent

- a. The new IACUC protocol will be given a corresponding number
- b. Click **NEXT** to continue to the IACUC Protocol page

4. 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 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

The screenshot shows a web form titled "Project Overview and Procedures". It contains two main sections of instructions:

- Instructions for IACUC Waivers:**
 1. Provide information on the types of animals that will be used or involved in the project.
 2. Provide a sequential description of the procedures the animals will undergo for this project.
 3. If euthanasia may be performed on the animals at the end of the study, then include the methods used.
- Instructions for IACUC Protocols:**
 1. 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, routes of administration, dose ranges, volumes, frequency, and monitoring.
 2. 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.
 3. For lengthy or complex experiments with many groups and/or procedures, a table or flowchart showing the experimental manipulations by group may be attached in the General Attachments section at the end of the protocol form.
 4. Define all abbreviations and use terminology that will be understood by individuals outside of your field of expertise.

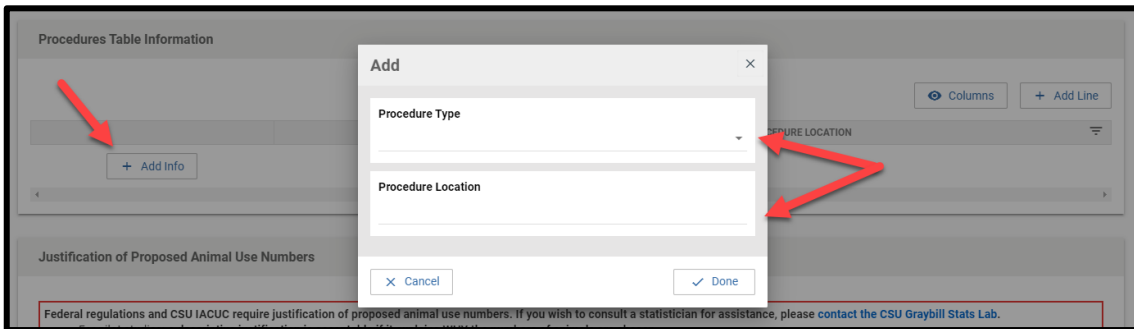
Below the instructions is a text input field with a red border and a "Required" error message. The field contains a single vertical bar character. Below this is another section titled "Early Endpoint Criteria:" with two numbered instructions:

1. What criteria will be used to determine if animals exhibiting adverse effects, clinical or behavioral changes should be given rescue analgesia, other clinical treatments, or euthanasia?
2. Include any scoring system that will be used to determine when humane intervention will be triggered, for example LAR Behavioral Scoring as described in the CSU IACUC Policy on Observation of Animals in Progressive Disease Studies.

Below these instructions is another text input field with a red border and a "Required" error message. The field contains the text "Enter response here".

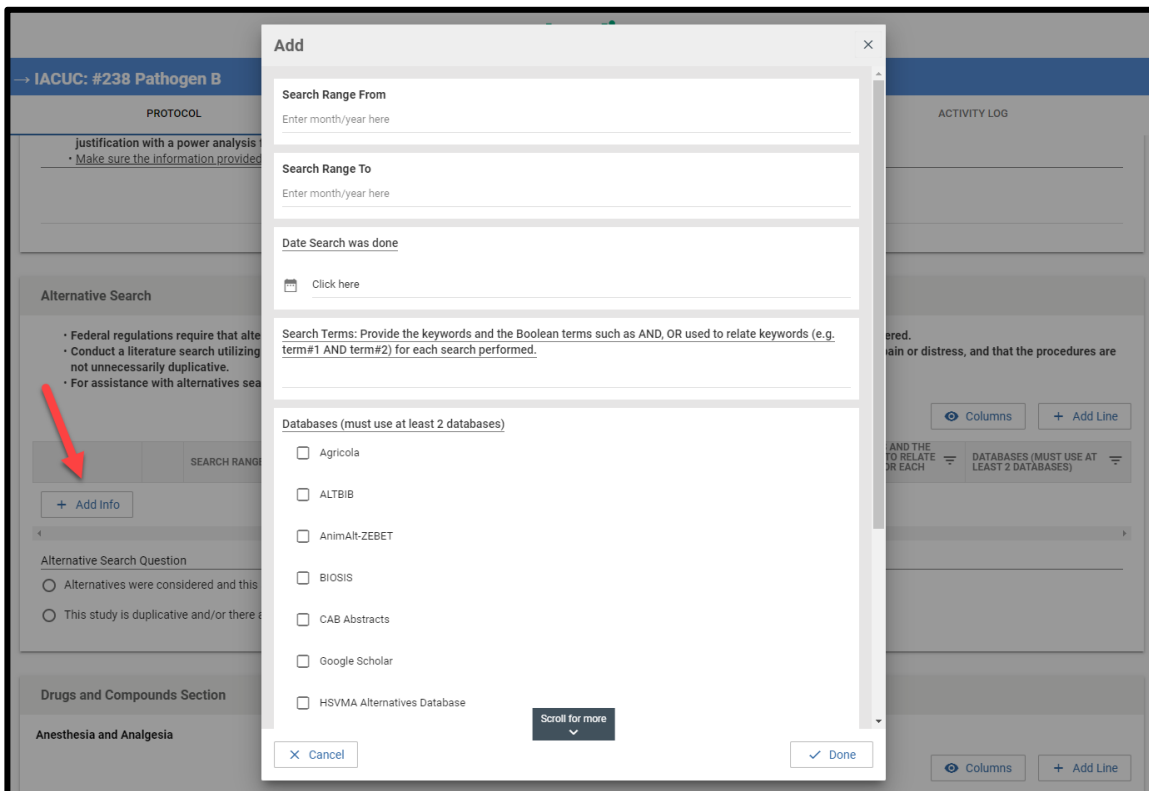
5. **General Instructions:** provides different links for IACUC training, resources, OHSP, etc.
6. **Personnel:** include all researcher and admin roles, group personnel helping with the project, and subsequent training records
 - a. Click **+ Add Line** for each new researcher role *OR* admin role
 - i. At least 1 role (Researcher or Admin) for each person must be selected, but multiple roles may be selected
 - ii. Full Access or Read Only permissions may be designated individually
 - b. Include any training records for all personnel listed in the Researcher role (anyone who will have contact with animals) in **Personnel Attachments** subsection by clicking **+ Add Info**
7. **Legacy ID Number:** **If applicable**, enter ID number used in legacy systems (i.e. eProtocol IACUC protocol number, IACUC Exemption, VCS), if renewing study
8. **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
9. **Project Overview and Procedures:** include types of animals used, description of the procedures performed on the animals, the duration of the study, study endpoint, euthanasia or release information, and disease effects and how to treat or relieve pain

10. **Procedures Table Information:** include type and location of procedures
 - a. Click + **Add Info** for each procedure (+ **Add Line** for any new procedure(s) needed)
 - b.



11. **Justification of Proposed Animal Use Numbers:** enter justification of the number of animals used/needed for the study

12. **Alternative Search:** 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

13. **Drugs and Compounds Section:** include any analgesics, anesthesia, or other compounds used for relief of pain, distress, or other
- 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

The screenshot shows the 'Add' dialog box in the 'Drugs and Compounds Section'. The dialog box contains the following fields and options:

- Drug Name:** A dropdown menu.
- Additional Information: Frequency, Route of Administration, etc.:** A text input field with the placeholder 'Enter response here'.
- This is a Non-Pharmaceutical Grade (NPG) Compound.:** Two radio buttons, 'Yes' (selected) and 'No'.
- NPG Justification:** A text input field with the placeholder 'Enter response here'.

Red arrows point to the 'Yes' radio button and the 'NPG Justification' field. The background shows a table with columns for 'DRUG NAME', 'OTHER CMPDS HAZMAT', and 'Dexamethasone'.

14. **Surgery Section:** surgical procedures requiring a pain category D or E must have Surgeon(s) information, surgical and post-surgical monitoring parameters, and general surgery information

The screenshot shows the 'Surgery Section' form with the following sections and fields:

- Will surgical procedures occur under this project (pain category D or E)?** Radio buttons for 'Yes' (selected) and 'No'.
- Surgeon(s):** A table with a header 'SURGEON NAME(S)' and a '+ Add Info' button.
- Monitoring Information:**
 - Surgical Monitoring:** A list of instructions (1-4) followed by a text input field with the placeholder 'Enter response here'.
 - Post-Surgical Monitoring:** A list of instructions (1-3) followed by a text input field with the placeholder 'Enter response here'.
- Surgery Information:** A table with columns for 'SURGERY LOCATION', 'TERMINAL OR SURVIVAL SURGERY', 'MMSS', and 'MMSS JUSTIFICATION', and a '+ Add Info' button.

Red arrows point to the 'Yes' radio button, the 'Surgical Monitoring' text area, the 'Post-Surgical Monitoring' text area, and the 'Surgery Information' section.

- a. Click + **Add Info** to add surgery information (+ **Add Line** for any additional surgery information)
- b. Under Surgery Information, if **Multiple Major Survival Surgery (MMSS)** is necessary, a justification is needed

The screenshot shows a software interface with a modal dialog box titled "Add". The dialog box has the following sections:

- Surgery Location:** A dropdown menu.
- Terminal or Survival Surgery?** A section with a note: "Please Note: Rodent survival surgeries must be performed in accordance with the CSU IACUC Guidelines for Rodent Survival Surgery." It contains two radio buttons: "Terminal" and "Survival".
- Multiple Major Survival Surgery (MMSS)?** A section with a note: "The definition of a Major Surgery: penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic function." It contains two radio buttons: "Yes" (which is selected) and "No".
- MMSS Justification:** A text input field with the placeholder "Enter response here".

Red arrows in the image point from the "Surgery Information" tab in the background to the "Terminal or Survival Surgery?" and "MMSS Justification" fields in the dialog box.

15. **Species and Protocol Pain Categorization:** include species, location of procedures, number of animals needed, and pain category
 - a. Click + **Add Info** to add surgery information (+ **Add Line** for any additional surgery information)
 - b. *Note: Pain Category E will need a justification*
 - c. If the species being used is on the USDA-covered species list, click the **USDA check box** under Admin Use Only

The screenshot shows a software interface with a modal dialog box titled "Add". The dialog box has the following sections:

- Species/Animal Name:** A dropdown menu.
- Number of Animals: Maximum number of animals for 3 years:** A text input field with the placeholder "Enter response here".
- Pain Category:** A dropdown menu.
- ADMIN USE ONLY:** A section containing a checkbox labeled "USDA".

16. **Source of Animals:** multiple selections are possible: animal vendor, client owned, etc.
a. "Other" requires more information


Source of Animals

Choose all that apply:

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

Other Animal Source

Enter response here



17. **Husbandry & Variances:** include all centralized units providing daily and veterinary care (if necessary), housing requirements for the animals, and any deviations from standard diet, housing environment, or restraint of animals
a. **Centralized Unit:** requires identification of each group needed

Daily and Veterinary Care

A Centralized Unit* will provide daily AND veterinary care for these animals.


*Centralized Units: LAR, AES (ARDEC, ECRC, Rouse Ranch), ETRC, ARBL, ERL, EPAF, VTH Barn Crew.

Yes

No

Check all that apply

- LAR
- AES (ARDEC, ECRC, Rouse Ranch)
- ARBL
- ERL
- EPAF/TMI
- VTH Barn Crew



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

Social Housing

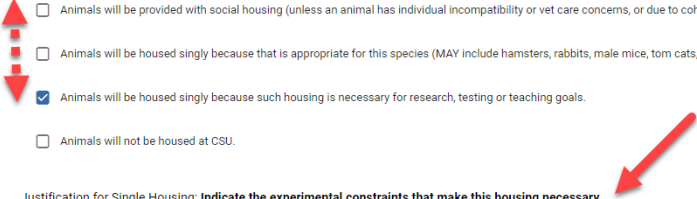
If you are using a social species, there are mandatory housing requirements. CSU considers social housing to include compatible housing with conspecifics, as well as housing in the same secondary containment with visual, auditory, olfactory or tactile contact with conspecifics. [CSU IACUC Policy on Social Management of Animals](#).

Indicate which of the following are true (choose all that apply):

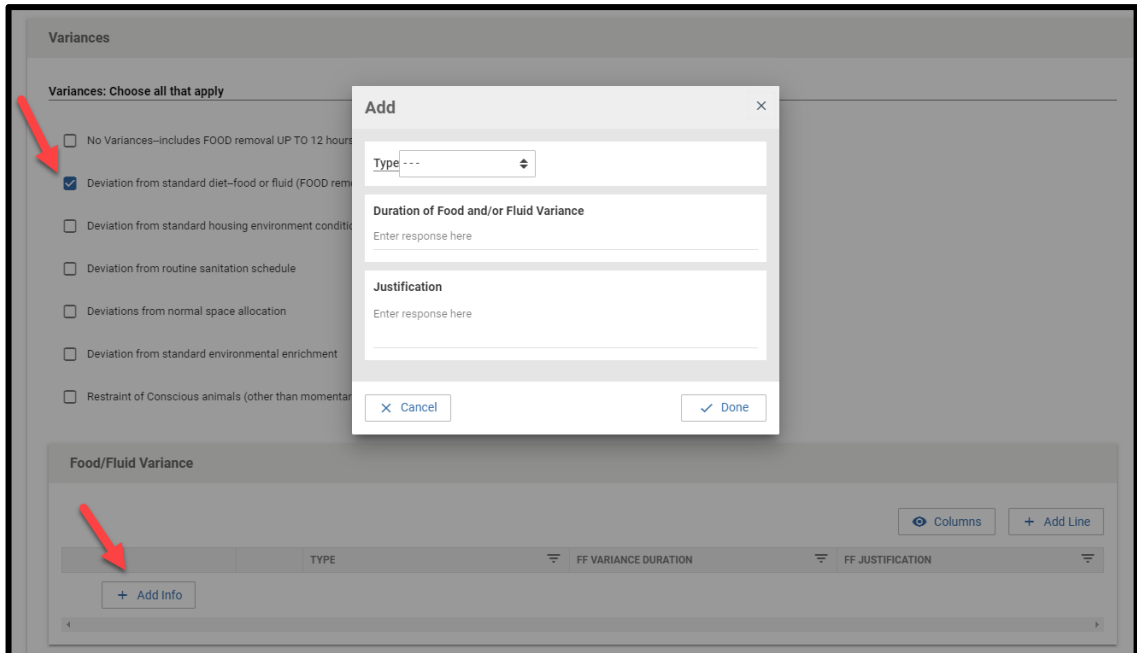
- Animals will be provided with social housing (unless an animal has individual incompatibility or vet care concerns, or due to cohort attrition).
- Animals will be housed singly because that is appropriate for this species (MAY include hamsters, rabbits, male mice, tom cats, livestock in stalls).
- Animals will be housed singly because such housing is necessary for research, testing or teaching goals.
- Animals will not be housed at CSU.

Justification for Single Housing: Indicate the experimental constraints that make this housing necessary

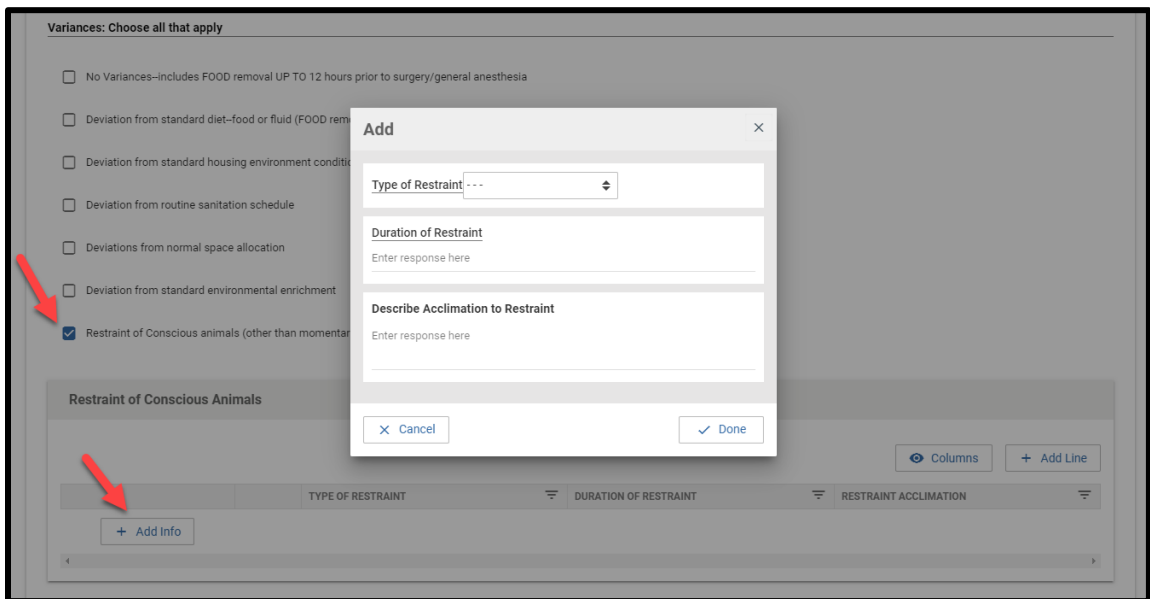
Enter response here



- c. Variations: any variations require justification
- d. **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).



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



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

19. **IBC Information**: include any biohazardous agent used for 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)

The screenshot shows a software interface for adding biohazardous agents. A modal dialog box titled 'Add' is open, containing the following fields:

- Biohazardous agent (dropdown menu)
- Name of biohazardous agent (text input)
- PARF# (text input)
- Biosafety Level (for animal housing) (dropdown menu)

Buttons for 'Cancel' and 'Done' are at the bottom of the dialog. In the background, the 'IBC Information' section is visible, including a table with columns: BIOHAZARDOUS AGENT, NAME OF BIOHAZARDOUS AGENT, PARF#, and BSL. A '+ Add Info' button is located below the table. Red arrows point to the 'Yes' radio button and the '+ Add Info' button.

20. **Quality Assurance (QA):** include any QA 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)

The screenshot shows a software interface for adding Quality Assurance (QA) information. A modal dialog box titled 'Add' is open, containing the following fields:

- Agency (dropdown menu)
- Regulated Product (dropdown menu)
- Product Name (text input)
- Where is the product manufactured or made? (dropdown menu)
- Intended For (dropdown menu)

Buttons for 'Cancel' and 'Done' are at the bottom of the dialog. In the background, the 'Quality Assurance (QA)' section is visible, including a list of checkboxes:

- Work/data from this study will be submitted to FDA, USDA, etc.
- Work/data from this study will support a market/research product.
- This study will be performed under Good Laboratory, Good Clinical Practice, or Good Manufacturing Practices.
- This project uses CBD/hemp products.
- None

A '+ Add Info' button is located below the list. Red arrows point to the first checkbox and the '+ Add Info' button.

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

The screenshot shows a 'Funding' section with a checklist. The first item, 'Public Health Service (PHS): e.g. CDC, FDA, HHS-BARDA, NIH, NSF', is checked. Below it are three unchecked items: 'Department of Defense (DOD): e.g. DTRA, DARPA, ONR – does NOT include Army Corps of Engineers', 'Department of Veterans Affairs (VA)', and 'Neither PHS, nor DOD, nor VA'. A red arrow points to the 'Neither PHS, nor DOD, nor VA' option. Below the checklist is a section titled 'PHS Funding:' with a red arrow pointing to it. The text reads: '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 (Reference: NIH Grants Policy Statement.) Please attach the grant in the General Attachments section in the IACUC protocol. The Vertebrate Animal Section (VAS) and Research Strategy Sections are preferred.' Below this is a radio button option: '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.'

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

The screenshot shows the 'Funding Information Table' section. The 'Neither PHS, nor DOD, nor VA' option is checked. A red arrow points to the '+ Add Info' button. An 'Add' modal is open, showing fields for: 'Funding administered by' (dropdown), 'Sponsor' (text), 'Grant/Contract Title' (text), 'Grant/Contract PI' (text), 'KRPD #' (text), and 'Account #' (text). The modal has 'Cancel' and 'Done' buttons at the bottom.

22. **General Attachments:** attach any necessary supplemental materials

- Click **+ Add Info** to add supplemental materials (**+ Add Line** for additional materials)


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
- Protocol will not be submitted without checking this section*

PI Certification

CSU IACUC Protocols: By submitting this protocol to the CSU IACUC, the Principal Investigator (PI) assures that:

- All protocol personnel working with animals (including myself) are:
 - qualified through education and/or training to conduct procedures involving animals under this proposal
 - have taken the [CSU Online IACUC Training](#), which includes information on the regulatory responsibilities of the institution, the IACUC, and investigators, as well as the concepts of research or testing methods that limit the use of animals or minimize distress, and the methods for reporting animal welfare concerns.
 - and as applicable to their work with animals, all individuals on the protocol have received training in the biology, handling, and care of the species to be used; aseptic surgical methods and techniques; and the proper use of anesthetics, analgesics, and tranquilizers.
- All procedures will be conducted in accordance with all applicable [CSU IACUC Policies and Guidelines](#) as well as [Occupational Health](#) and [Biosafety](#) requirements, including those pertaining to the use of personal protective equipment.
- All protocol personnel working with animals are participating in the [Occupational Health and Safety Program \(OHSP\)](#), including submission of all necessary medical history forms.
- ANY changes in the approved protocol will be submitted in writing to the IACUC as an amendment request, and approved by the IACUC prior to implementation.
- If applicable, I have considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and I have provided a written narrative description of the methods and sources used to determine that alternatives are not available.
- I have provided written assurance that the activities do not unnecessarily duplicate previous experiments.
- The information contained in this application for animal use is accurate to the best of my knowledge.
- The following procedures will be followed if funded in whole or in part by relevant federal agency/agencies.
 - 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, award, contract, or subaward/contract that has been submitted or awarded ([NIH Grants Policy Statement](#)).
 - As the PI of this protocol, I will obtain approval from DOD ACURO for all new protocols, as well as for amendments, and continuing reviews to existing protocols, prior to initiation of the work/change to the protocol ([DOD Animal Care and Use Research Office \(ACURO\)](#)).
 - As the PI of this protocol, I will obtain approval from VA Research and Development Committee for all new protocols, as well as for amendments, and continuing reviews to existing protocols, prior to initiation of the work/change to the protocol ([VA Handbook 1200.07 Use of Animals in Research](#)).
- That as the Principal Investigator for this project, I assume ultimate responsibility for all animal work done by all protocol personnel for this protocol.

CSU Pueblo IACUC Protocols: Same certifications apply under [CSU Pueblo IACUC policies and procedures](#).

I understand that this application and my animal use privileges may be revoked by the IACUC if I violate any of the above statements. 

24. **Once all sections are completed, and accurate 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.

PROTOCOLS kuali

← back Manage Protocols → IACUC: #238

ACTIVITY LOG

General Information ✓

General Questionnaire ✓

General Instructions ✓

Personnel

Legacy ID Number

Lay Summary

Project Overview and P...

Procedures Table Infor...

Justification of Propos...

Alternative Search

Drugs and Compoun... ✓

Surgery Section

Species and Protocol P...

Source of Animals

Husbandry & Variations

Final Disposition

IBC Information

Quality Assurance (QA)

Funding

General Attachments ✓

PI Certification

Version: 1 | New | In Progress

Submission Type	Status
New	In Progress

General Information

Please note that Personnel and Department Lists include information across the entire CSU System. If you cannot find your name or department, contact [RICO IACUC Staff](#) for assistance.

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Principal Investigator (Last, First) Department

Project Title

General Questionnaire

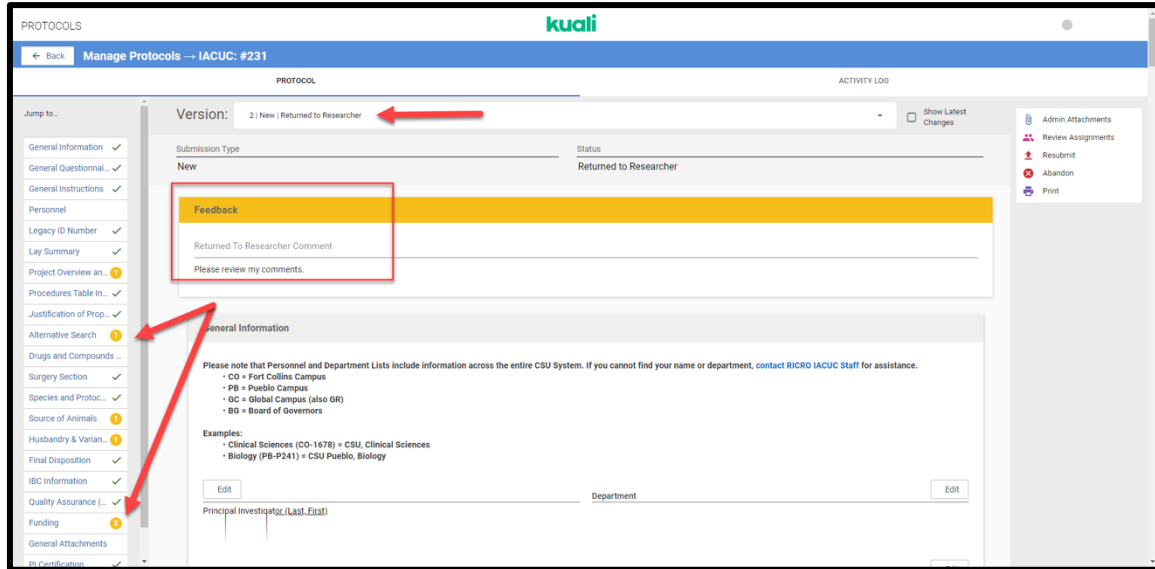
Admin Attachments

Abandon

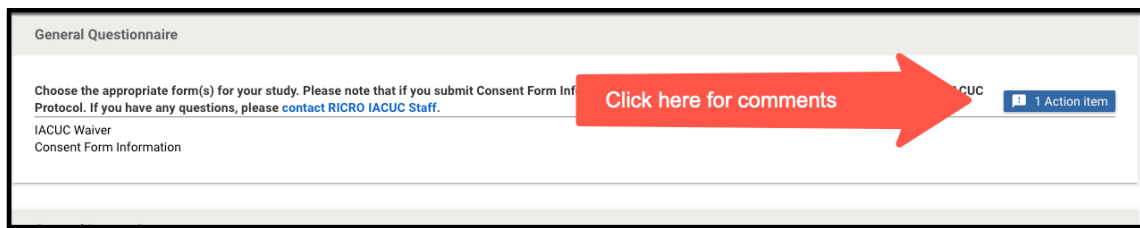
Submit 

Print

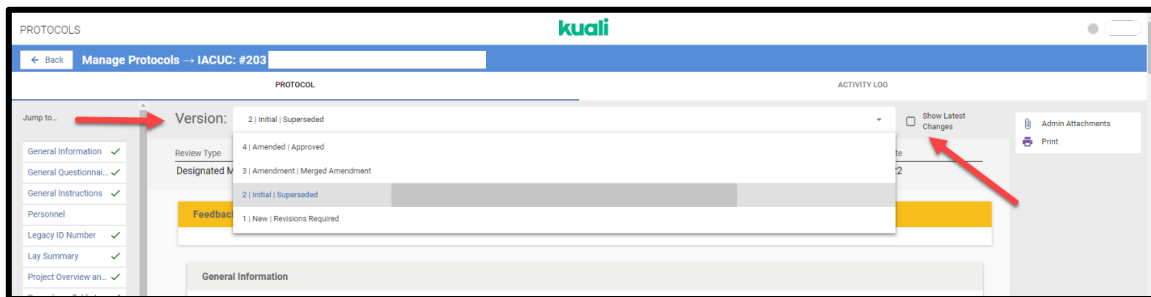
25. After a designated member of the CSU IACUC approval board has reviewed the protocol, the protocol may be returned for edits. Comments will appear throughout the protocol page as “**Action Items**.” The left sidebar menu will show which section has an action item (shown as a yellow circle with a number 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 “**Show Latest Changes**” 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