Create a new IACUC Protocol

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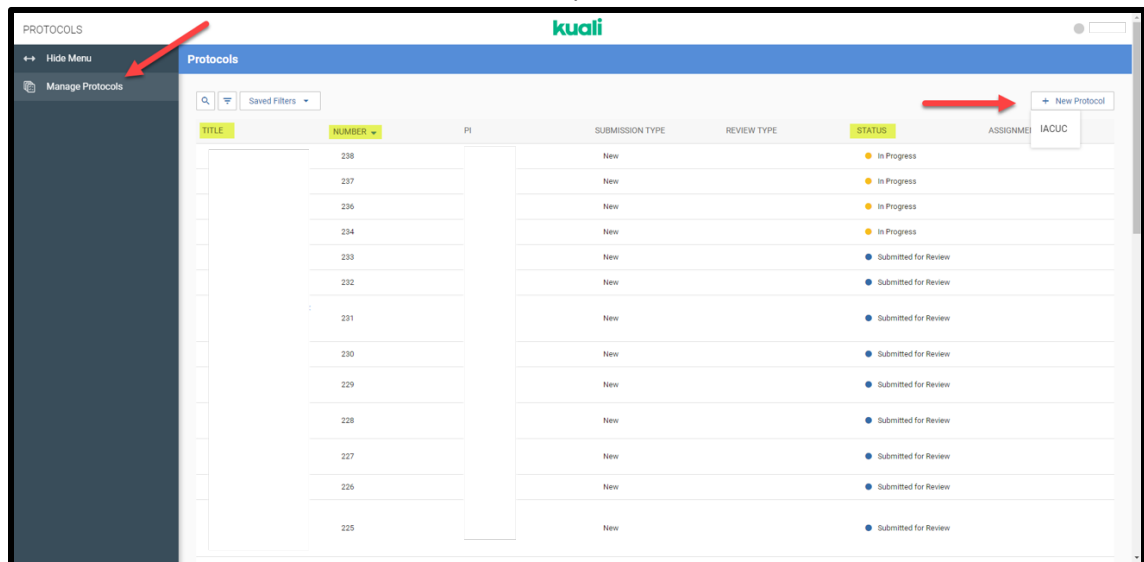
2. Accessing the first IACUC- General Information page will ask for PI name, Department, and Project Title

   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 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

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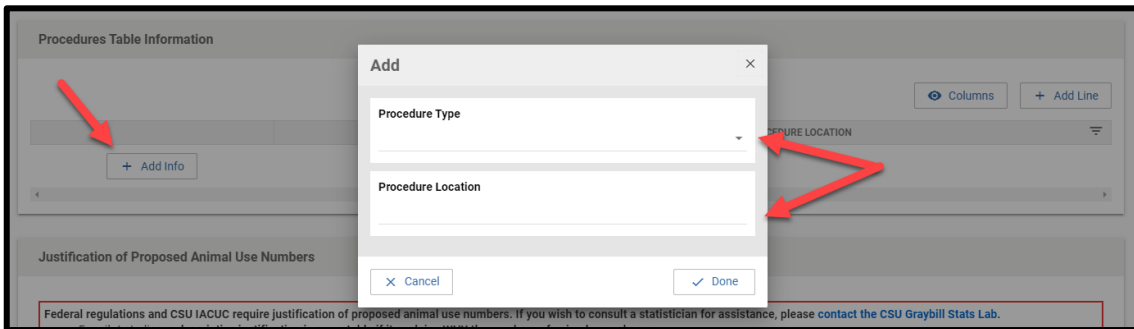
11. **Justification of Proposed Animal Use Numbers:** enter justification of the number of animals used/needed for the study

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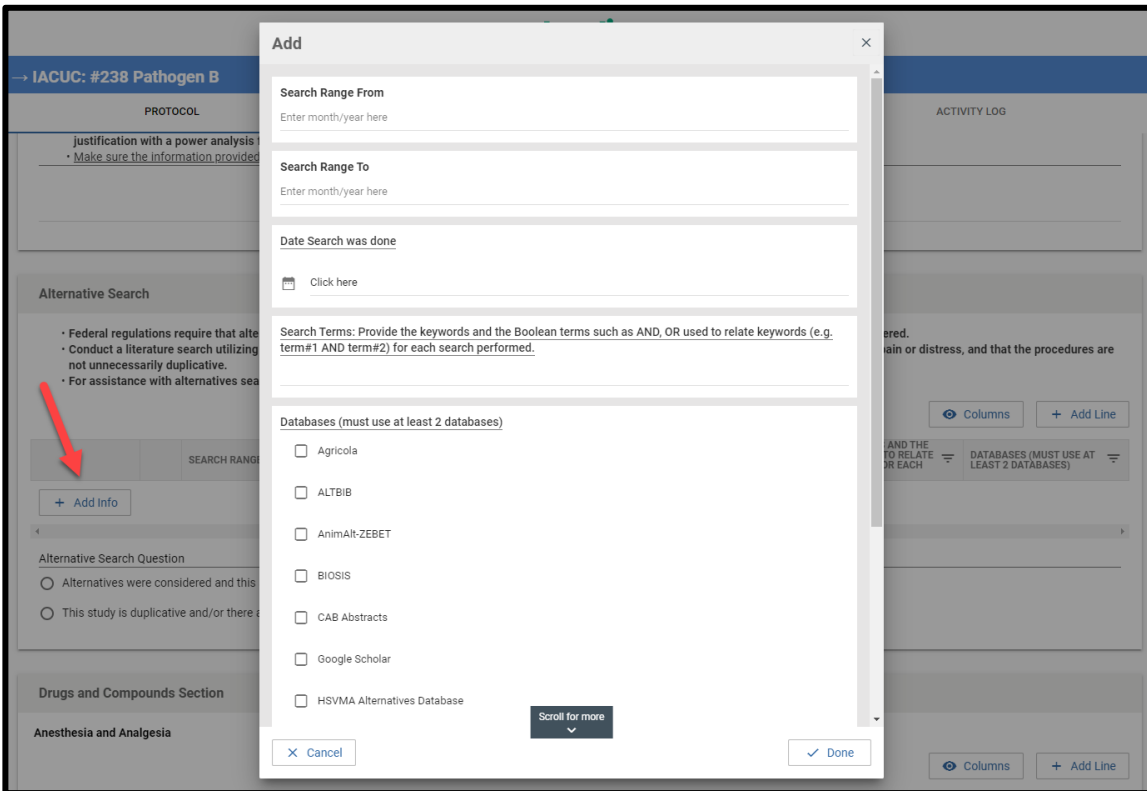
    b. If "study is duplicative" is selected for **Alternative Search Question**, a justification is needed

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

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

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

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 RICRO Use Only

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

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

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

c. <u>Variances</u>: any variances 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).
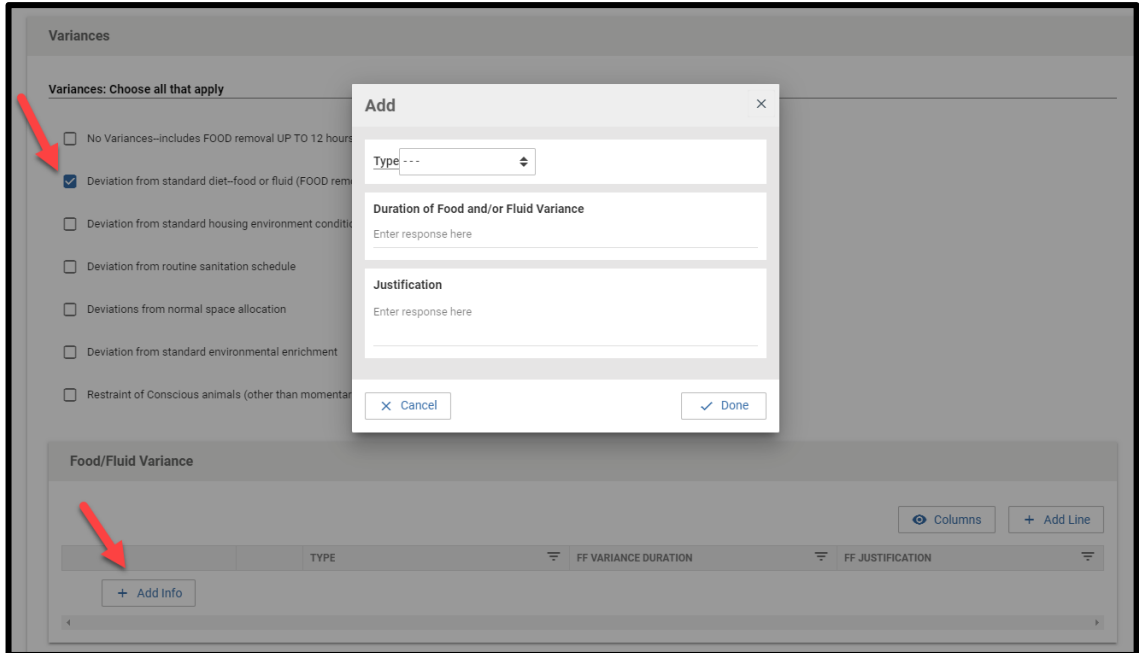
e. **Restraint of conscious animals** requires a more in-depth justification. Click **+ Add Info** to add restraint information (**+ Add Line** for any additional restraint information).
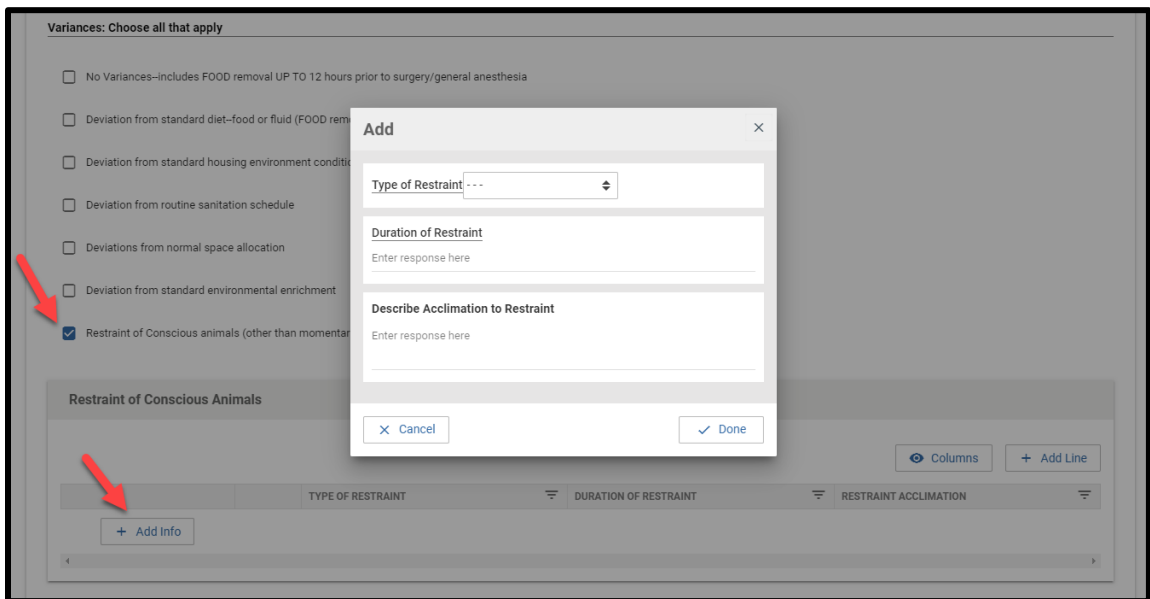
18. **Final Disposition:** Describe what happens to animals at end of study (terminal or not)

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)

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)

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

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

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

22. **General Attachments:** attach any necessary supplemental materials
   a. 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
    a. *Protocol will not be submitted without checking this section*

24. ***Once all sections are completed, and accurate 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 circle with a number for amount of comments in each section).
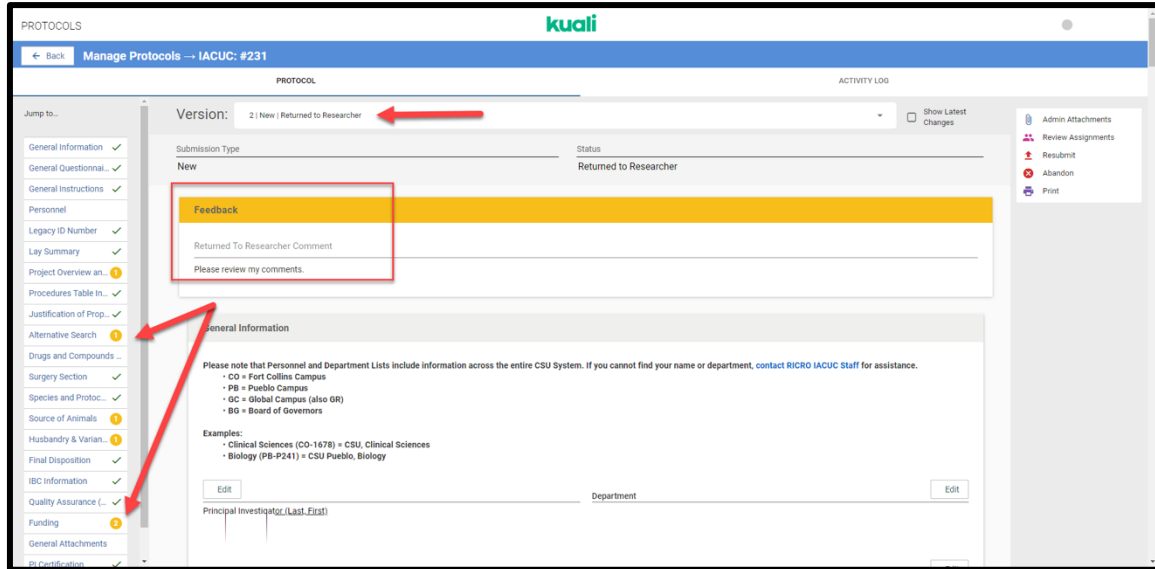
    a.   Click on the "**Action Item**" box to read comments/action items
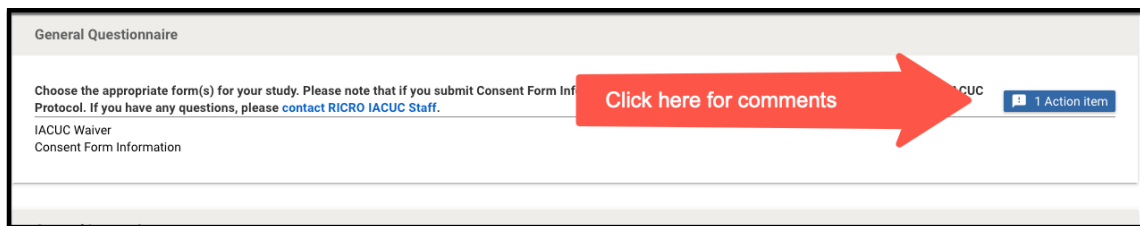
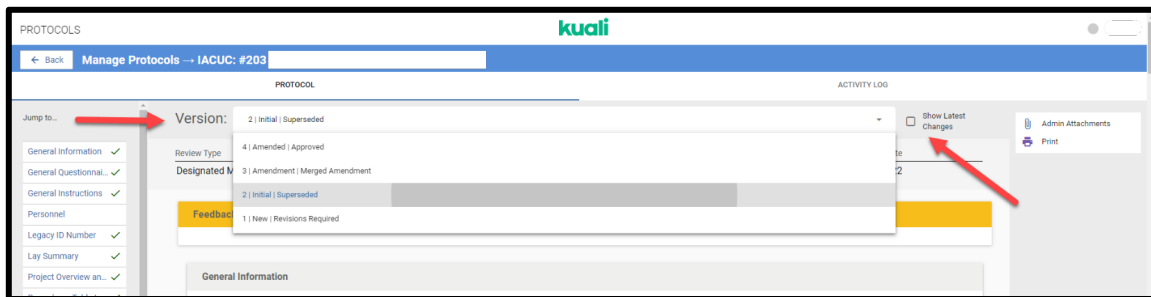26. At the top of the page, ***each version of the protocol can be accessed via the drop-down menu*** next to the **"Version" heading**. This includes the NEW version of the protocol with any revisions required after submission and any amendments.

    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