

## General

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1. I have opened my AUP to begin modifications, but I cannot make changes.
2. What do the different modification icons mean?
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1. What is the difference between an expected outcome and an unexpected outcome?
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### **Annual Review or Closure**

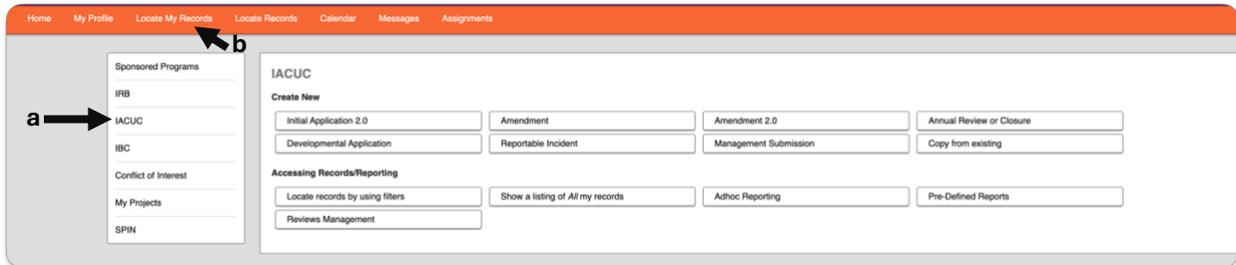
1. How do I submit my Annual Review or Closure?
2. What is the difference between the Annual Review and Closure?
3. When is my annual review due?



## General

### 1. How do I access InfoEd?

- Log in to InfoEd [here](#) using your Clemson credentials.
- Select IACUC (a) to create a new application, amendment, reportable incident, etc.
- Select “Locate My Records” (b) to view your current AUPs.



### 2. How do I contact the IACUC Office with questions?

- a. You can reach us anytime via [email](#) or during our [virtual office hours](#)!



## Initial Application 2.0

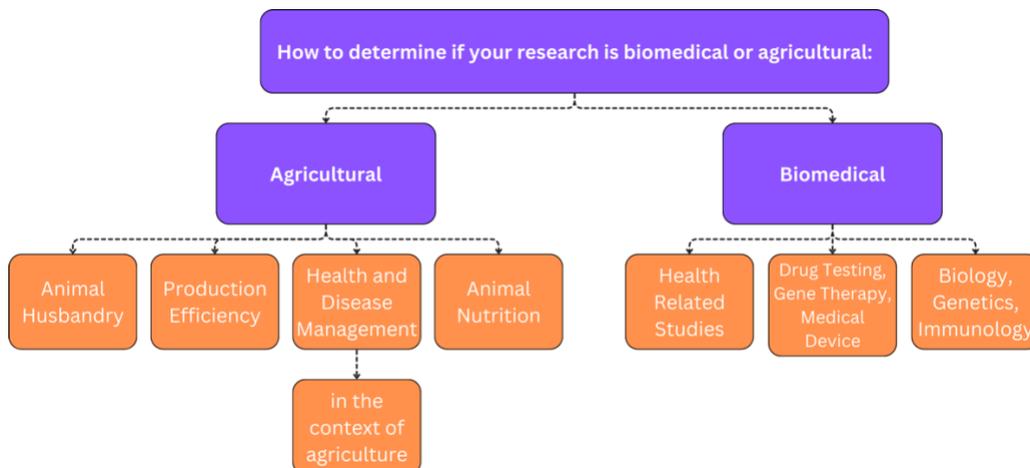
### 1. How do I determine who needs to be listed on the AUP?

- a. Anyone working with live animals must be listed in the AUP. Anyone listed in the Personnel Section will be able to view the protocol in InfoEd and create/submit amendments, annual reviews, and reportable incidents. The graphic below shows how Personnel and Other Personnel are commonly determined. For teaching protocols, students enrolled in a class are not required to be on the AUP but are required to have completed the training protocols; please refer to [2.2 Training Requirements](#) for more information.



### 2. How do I determine if my research and/or teaching is classified as Agricultural or Biomedical?

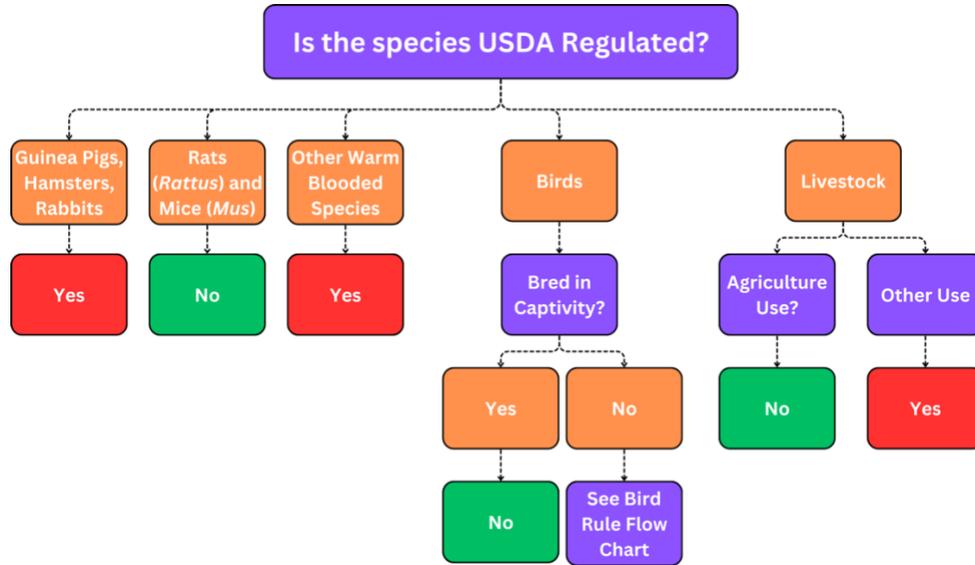
- a. Use the flowchart below or contact the IACUC office with any questions.





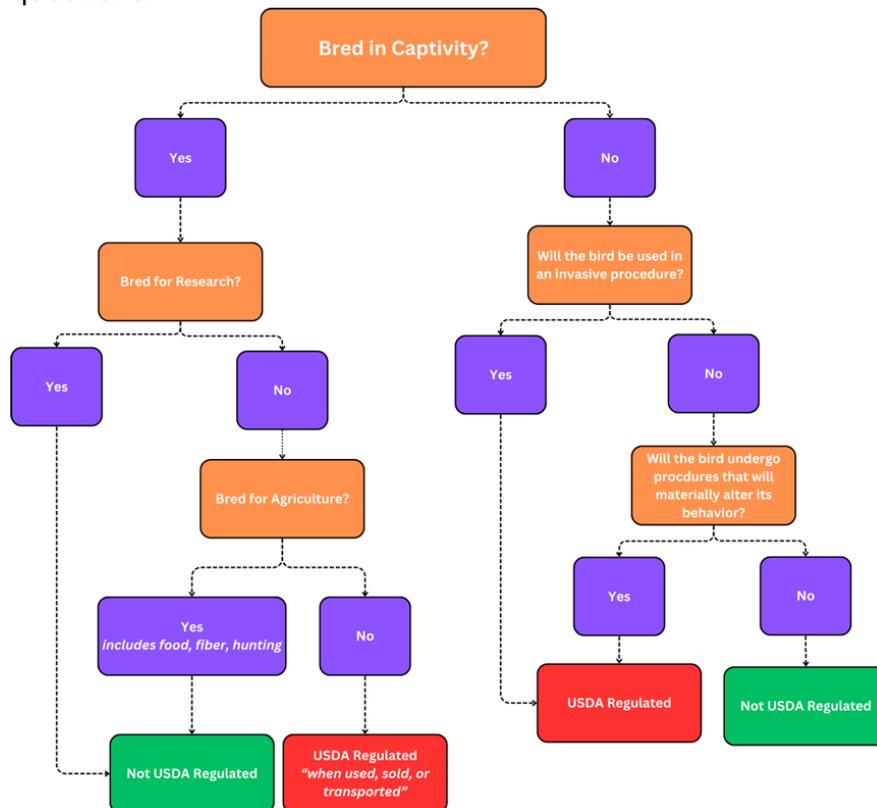
### 3. How do I determine if my research is USDA-regulated?

- a. Use the flowchart below or contact the IACUC office with any questions.



### 4. I am conducting research on birds. How do I determine if my research is USDA-regulated?

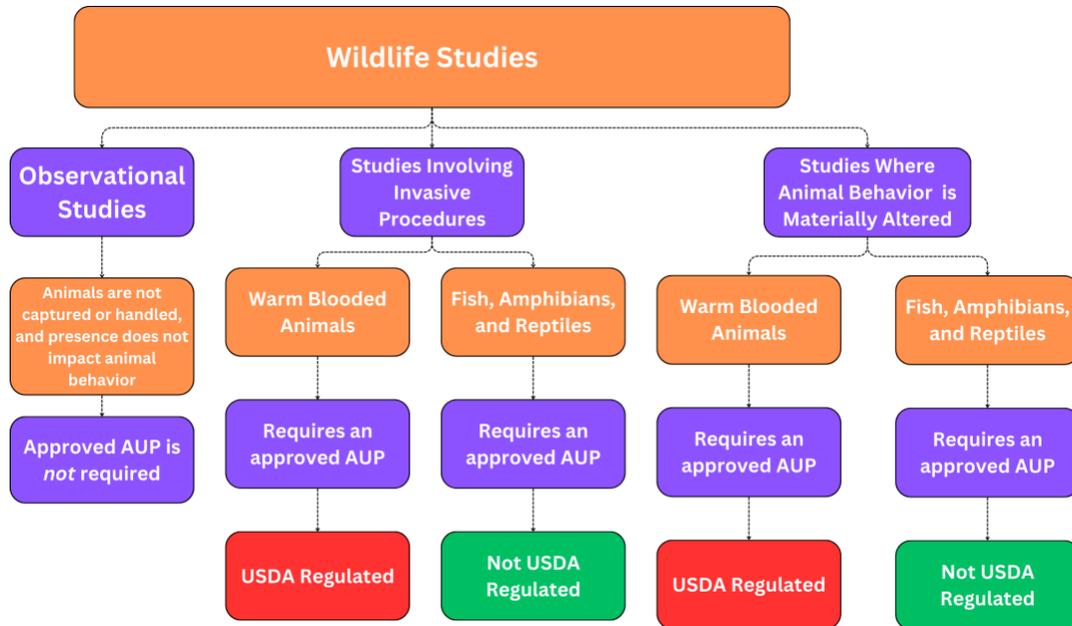
- a. Use the Bird Rule Flowchart below or contact the IACUC office with any questions.





## 5. How do I determine if my wildlife study requires an AUP and how it is regulated?

- a. Use the flowchart below or reference CU-IACUC Policy [2.1 Guidelines on Which Activities Require an Animal Use Protocol](#) and [3.16 Research Involving Wildlife](#).



## 6. Do I need to attach an SOP?

- a. If the SOP you are referencing is in the [SOP Repository](#), you do not need to attach it to your protocol. If you are using an SOP not in the database, you will need to include it in your AUP application.

## 7. When to classify a protocol as “Farm Facility/Colony/Culture Management”

- a. This is primarily used for general farm protocols and breeding protocols. If you are unsure if your protocol requires this, please contact CU-IACUC via [email](#) or during our [virtual office hours](#).

## 8. Where can I find general details and contact information about radioactive, biological, or chemical hazards used in my protocol?

- a. The use of hazardous chemicals in vertebrate animals is regulated through [CU-OES](#).

## 9. When is an IBC protocol required?

- a. Research that includes recombinant DNA, hazardous biological agents, nanomaterials, and select agents may require an [IBC Review](#).

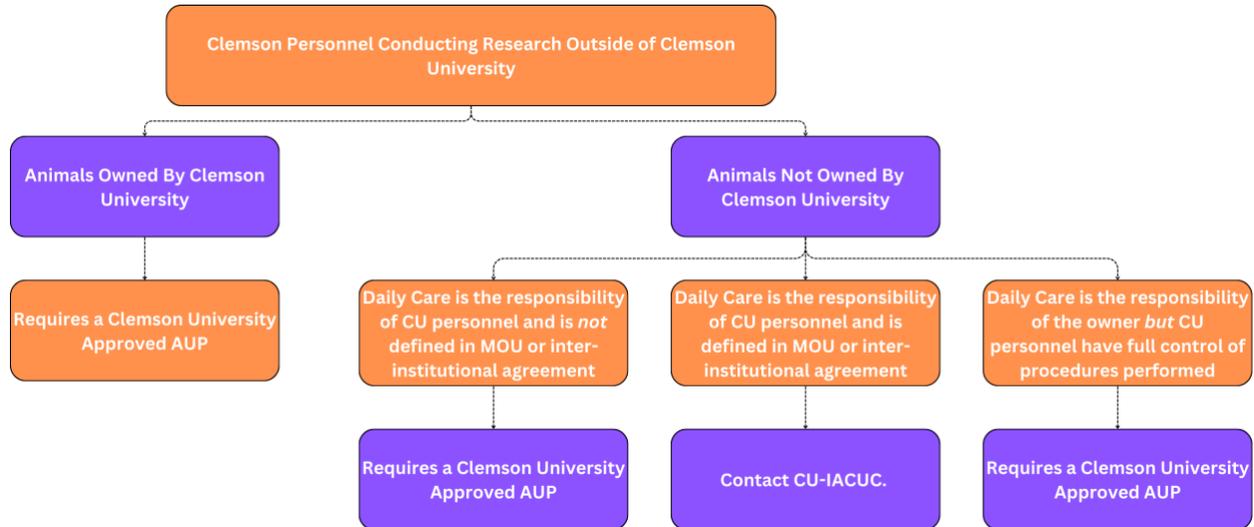
## 10. How do I upload a document?

- a. Click the “Upload” button, and a pop-up window will generate where you can upload a “New Document” and then browse for your file. Click “Add New” if additional documents need to be uploaded.



**11. I am a Clemson researcher conducting animal research at another institution or facility. Do I need a Clemson University AUP?**

- a. Use the flowchart below or reference CU-IACUC [2.1 Guidelines on Which Activities Require an Animal Use Protocol](#).



**12. I have a large number of chemical hazards (11.2) for my protocol. Do I need to enter them individually into Table 11.2.1?**

- a. If you have a larger number of hazards, follow the directions for downloading the “pre-chemical use spreadsheet” and input the hazard information. Upload the spreadsheet using the  icon.

**13. I cannot lock the form. What do I do?**

- a. Make sure to complete all required sections before submitting the form. A pop-up window will be generated with the incomplete mandatory questions to be completed. Click “Dock” to be able to view the incomplete sections while working on the application. If all required sections are complete, your AUP title may be too long to submit.

**14. How can I avoid common mistakes?**

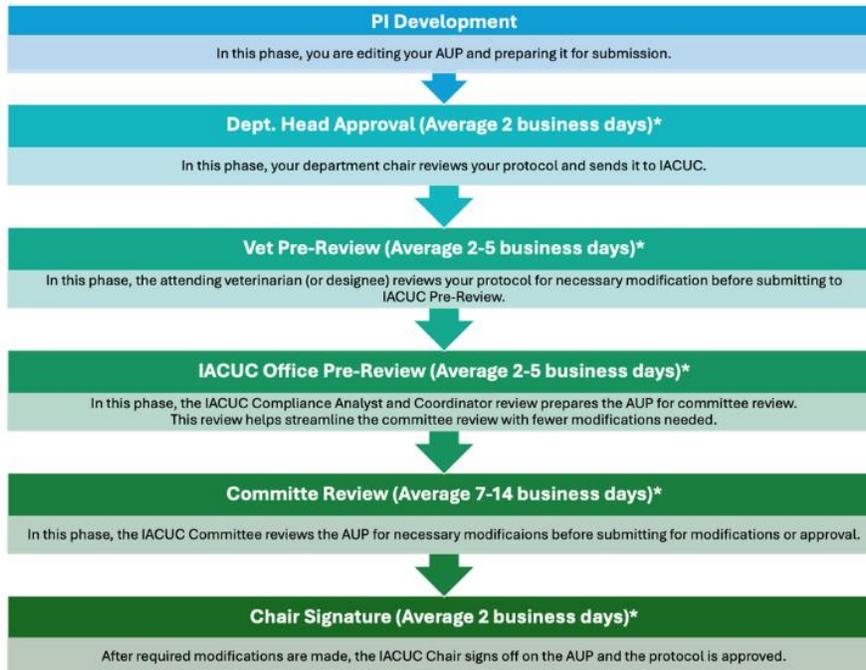
- a. The most common error is inconsistency between sections in the AUP. Make sure that your narrative, flowchart, and all generated sections are correct and consistent, *i.e.*, *number of animals required, dosages, time points, and housing*.



## Approval Process

- 1. In what ways can I ensure a more efficient approval process?**
  - Quickly addressing modification requests can help streamline your approval process. If you have questions about the requested modifications, you can [email](#) the IACUC Office or attend [virtual office hours](#).
- 2. How long does it take an AUP to be approved?**
  - It takes 4-6 weeks for an AUP to be approved. This estimate can vary based on the number of required edits, your responsiveness, and the review process required.
- 3. What is the approval process?**

### The AUP Approval Process



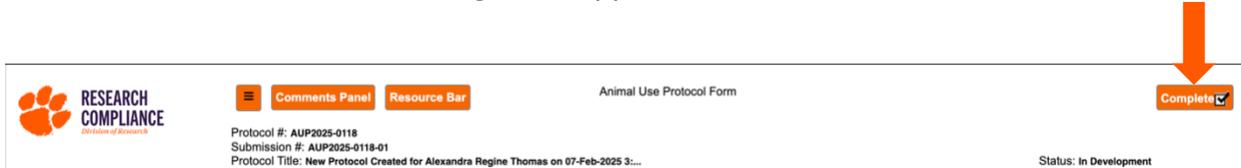
\*Please note that average times reflect protocols without edits. Approval time for protocols with edits will differ based on the PI/facility manager and the time it takes to make modifications.

\*\*If your AUP requires a full committee review it will be reviewed at the next monthly meeting before submitting for approval or requiring edits. Please refer to meeting calendar to estimate your approval timeline.



## Requested Modifications

1. I have opened my AUP to begin modifications, but I cannot make changes.
  - a. Make sure the “Complete” button is unchecked, so the form is unlocked and able to be edited. *If using Initial Application 1.0, look for the “Lock” button.*



## 2. What do the different modification icons mean?



Indicates suggested modifications that do not require a response from the PI to resolve.



Indicates suggested modifications that require a response from the PI to resolve.



Indicates a “response required” comment has been resolved.

## 3. How do I return the form once my modifications are complete?

- a. “Complete” locks the form, but it remains with you.  
The “I am done” button at the top of the eForm returns the form to be reviewed by the AV and IACUC Offices. *If you do not click “I am Done” your edits cannot be reviewed for approval.*

## 4. I cannot lock the form. What do I do?

- a. Check the comments panel for the icon. Directly respond to all comments with the icon, even if you addressed the comment by modifying your AUP. You will be able to lock and submit the form when changes to .

## 5. If modifications are required for attachments, how do I update the attachments?

- a. Click the “Upload” button, and a pop-up window will generate where you can upload a “Version of Existing Document” and then you can browse for your new file and edit it.



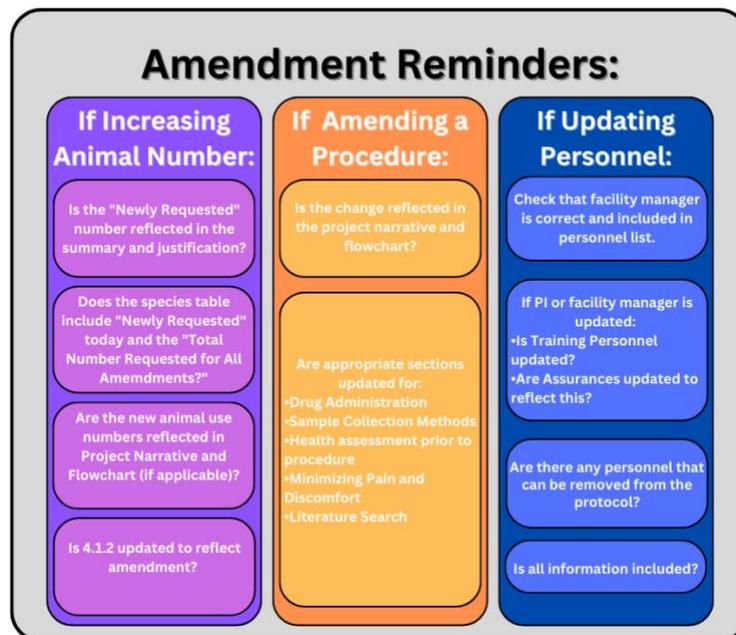
## Amendments

### 1. How do I create an amendment?

- a. Access the [InfoEd](#) IACUC tab and click “Amendment” or “Amendment 2.0,” then search for your AUP. You will need to uncheck “Complete” to make changes.
  - i. Select Amendment if you are amending an Initial Application
  - ii. Select Amendment 2.0 if you are amending an Initial Application 2.0

### 2. What does my amendment need to include?

- a. The amendment form must include the summary and justification for modifications. The narrative, flow chart, and other applicable areas *must* be updated to reflect the amendment before it can be approved.





## Reportable Incidents

- 1. What is the difference between an expected outcome and an unexpected outcome?**
  - a. An expected outcome is something that was anticipated and *is* detailed in the approved AUP. An unexpected outcome is *not* detailed in the approved AUP and must be reported to the AV and the IACUC. For more information, please reference [1.6 Reporting and Investigating Unexpected Outcomes or Adverse Events](#).
  
- 2. What if I am not sure the incident is reportable?**
  - a. If you are unsure, you can contact the AV and/or the IACUC office to discuss the incident.
  
- 3. What is the protocol for reporting an incident?**
  - a. You *must* report any incident to the AV within 72 hours via phone or [email](#) and submit a Reportable Incident on [InfoEd](#). For more information on reporting an incident, please reference [1.6 Reporting and Investigating Unexpected Outcomes or Adverse Events](#).



## Annual Review or Closure

### 1. How do I submit my Annual Review or Closure?

- Log in to InfoEd [here](#) using your Clemson credentials.
- Select IACUC (a).
- Select Annual Review or Closure (b).
- Enter your AUP number (c) and search (d).
- Select the AUP and fill out the eForm.

The screenshot shows the IACUC web interface. On the left, a sidebar menu lists 'Sponsored Programs' with sub-items: IRB, IACUC (labeled 'a'), IBC, Conflict of Interest, My Projects, and SPIN. The main content area is titled 'IACUC' and has a 'Create New' section with buttons for 'Initial Application 2.0', 'Amendment', 'Amendment 2.0', and 'Annual Review or Closure' (labeled 'b'). Below this is a 'Copy from existing' button. The 'Accessing Records/Reporting' section includes buttons for 'Locate records by using filters', 'Show a listing of All my records', 'Adhoc Reporting', and 'Pre-Defined Reports'. Below the main content area, there is a search section with the text 'Add Animal Protocol' and a 'Close' button. The search section includes the text 'Select by Number:' followed by a text input field containing 'Type your AUP# Here' (labeled 'c'), a 'Search' button (labeled 'd'), and a 'Clear All' button.

### 2. What is the difference between the Annual Review and Closure?

- a. Your annual review is submitted each year that your protocol is active. At the end of your experiment or approved protocol time, you will submit it as “Closure” which will inactivate the protocol.

### 3. When is my annual review due?

- a. One year after your approval date, and every year that the protocol is active during the maximum 3-year approval period. Field study reviews are due annually on September 30<sup>th</sup>, as their dates are set to align with the federal fiscal year.