OFFICE OF RESEARCH AND SPONSORED PROGRAMS *Division of Research Compliance*		**Institutional Animal Care and Use Standard Operating Procedures**	
Title: Post Approval Monitoring of Approved Research in Cayuse Animal Oversight			
Effective Date:	20-Jul-2023	**Document Number:**	IACUC-SOP-006.01

Approval/Date:

9 Aug 2024

Chad W. Hargrave — **Date**
Vice President & Chief Research Officer

REVISION HISTORY		
27-JUL-2024		

PURPOSE

The goal of post-approval monitoring is working with researchers to confirm accurate and consistent protocol performance in a collegial and unobtrusive manner. As such, post-approval monitoring for researchers at SHSU will involve completing a short continuing review protocol in Cayuse Animal Oversight (AO, hereafter). The purpose of continuing review is to provide the IACUC with a progress report for the previous year's activities.

SCOPE

Continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies (*The Guide*, p. 33). This SOP provides step-by-step instructions for completing Continuing Review in Cayuse AO.

DEFINITIONS AND ABBREVIATIONS

AO—Animal Oversight, Cayuse's IACUC electronic solution product

DMR—Designated Member Review, the IACUC's version of expedited review

IACUC—Institutional Animal Care and Use Committee

PI—Principal Investigator

PAM—Post Approval Monitoring, protocol monitoring after the IACUC's initial protocol approval

SHSU—Sam Houston State University

SOP/SOP's—Standard Operating Procedure(s)

USDA Categories—United States Department of Agriculture Pain Scale Classification of Procedures

RESPONSIBILITIES

It is the responsibility of the SHSU IACUC to assure that all animal use activity meets federal regulations, policies, and recommendations. As part of PAM, it is the responsibility of the PI to submit continuing reviews for all IACUC-approved work at SHSU, regardless of USDA species use or pain categorizations and regardless of funding. It is the responsibility of the PI to submit continuing reviews

for their protocols in a timely manner in order to update the IACUC on their progress and to assure the IACUC office of the following:

(1) which IACUC studies need to close before the end of the 3-year approval period

(2) which studies require personnel to be removed

(3) which studies need to add personnel

(4) which studies have adverse events to report (if not reported during the year), and

(5) if any changes to the study need to be made.

PROCEDURE

In Cayuse AO, the left-hand menu contains different sections for alerts regarding a PI's protocols. These alerts tell the PI where a protocol is within the routing process. For example, each year that a protocol is active, it will appear in the **Continuing Review** alert—this section shows protocols that have come up for the first-year review.

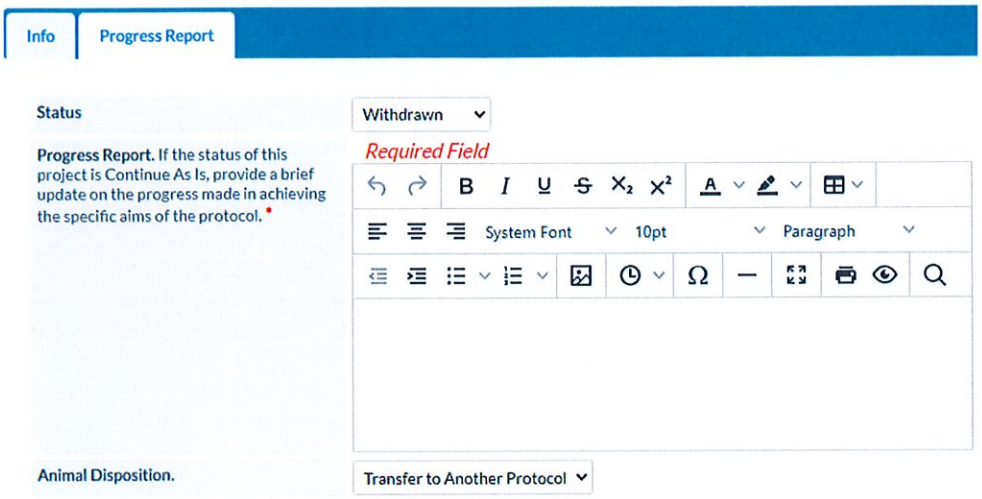
When you are in Cayuse AO, click on this alert as shown below to see which protocol needs continuing review (see p.2):

Click on the protocol number to open the submission as shown below:

Two Options for Continuing Review

Withdrawing a Protocol Approval

This option can be used to close a protocol if the PI is leaving the University or if the PI completes the animal work before the 3-year approval period ends. To complete this step, select Withdrawn from the Status pull-down menu, as shown below:



As you can see above, the progress report field must be completed even for a project that is complete. In this field, provide a brief statement to inform the IACUC office that the aims of the protocol were or were not met, and include a request for the IACUC office to close this protocol.

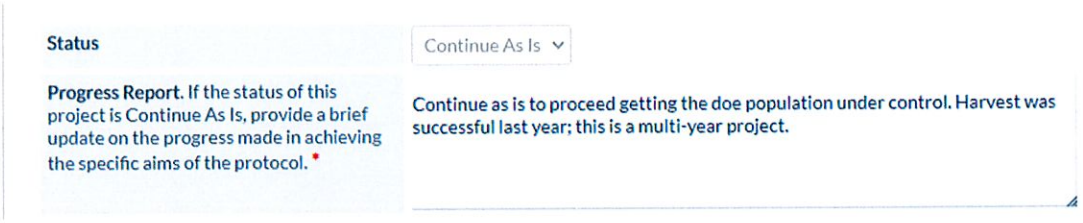
Continuing a Protocol Approval

This option should be selected if the PI wishes to keep the IACUC approval active for an additional year or until the approval lapse date. In this case, continuing review becomes an annual update to the IACUC. CR should include the following content, which aligns with the AO CR form:

a) A description of progress made over the previous year
b) Deletion of personnel who have or will be leaving the project [**Note:** if the PI wishes to add personnel, this must be reported through AO's amendment procedure]
c) A description of any adverse events that occurred during the previous year
d) A confirmation that since last IACUC approval that no alternatives to the use of animals in research have become available
e) A confirmation that since last IACUC approval that no alternatives which are less painful or distressful have become available
f) An assurance that the activities of the project remain in compliance with the requirement that there must be no unnecessary duplication
g) Documentation of future plans for the project if any are planned

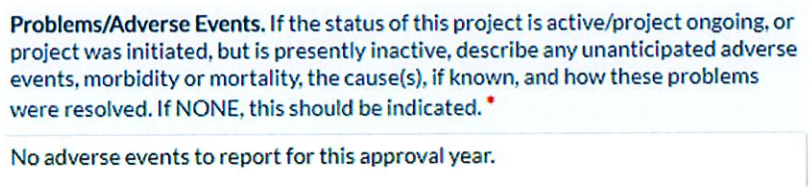
The following screenshots are an example of a recent continuing review submission that was approved by the IACUC Chair:

Progress Report tab:

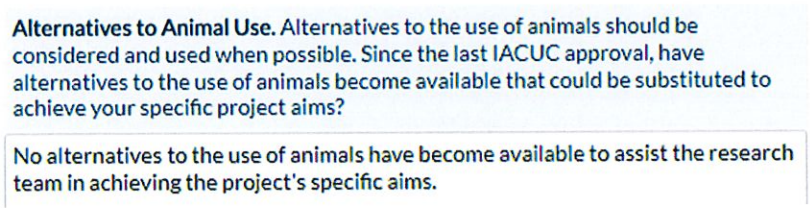


Project Personnel: This tab lists all personnel that were initially approved to work on the project. During Continuing Review, the only change that can be made is removing personnel from the project. If you plan on adding personnel, you would be required to submit an **Amendment** (see the SOP on Revising your Protocol).

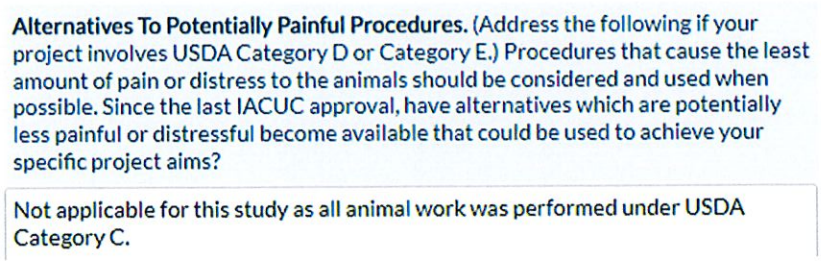
Adverse Events:



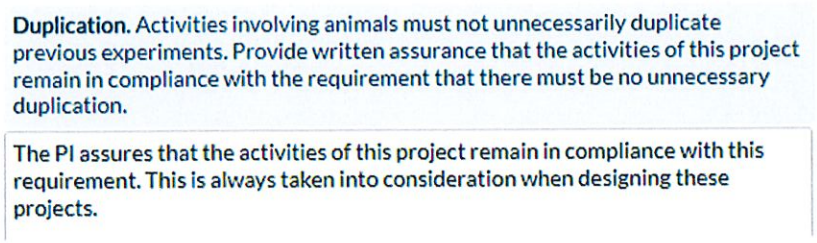
Alt to Animal Use:



Alt to Painful Procedures:



Duplication:

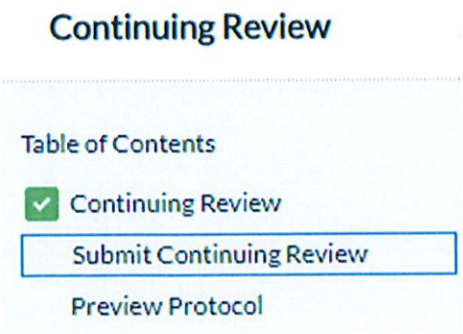


Future Plans: For this tab, you actually have 3 options: No Changes, Changes are Planned, and Other. For the latter two options, a details box will open to allow the PI to provide additional information. Below are two screenshots shown as examples of the first two options:

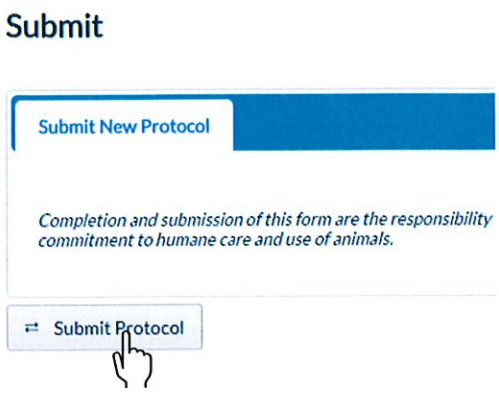
No Changes:

Changes are planned:

When each tab of the Continuing Review protocol is complete, the **Continuing Review** section will achieve a check mark as shown below:



The **Submit Continuing Review** tab will open to allow the PI to submit the protocol to the IACUC office:



Method of IACUC Continuing Review

1. All IACUC members would be provided a copy of the completed Continuing Review Form and would have access to the corresponding IACUC protocol file on request.
2. Any IACUC member could ask for a full committee review of the Continuing Review Form and the protocol.
3. Utilizing the DMR process, if none of the IACUC members requests full committee review after 48 hours, the IACUC Chair would then designate at least one qualified member (i.e., designated reviewer) to conduct an in-depth review of the current protocol in conjunction review of the CR Form.
4. Once the IACUC DMR provide approval in Cayuse AO, the IACUC Office will release the CR approval to the PI via email.

Violations of this SOP

If a Principal Investigator (PI) violates the terms of this Standard Operating Procedure (SOP), the Institutional Animal Care and Use Committee (IACUC) may take corrective actions, which could include the suspension of the PI's protocols. This decision is made after evaluating the severity and frequency of the violations. For instance, an IACUC member may recommend protocol suspension if repeated attempts to adhere to the SOP have failed. The suspension aims to ensure compliance with federal regulations and to maintain ethical standards in animal research.

REFERENCES

Cayuse Animal Oversight Help Center

The Guide for the Care and Use of Laboratory Animals, 8th edition