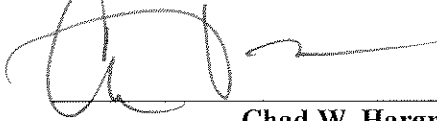
	OFFICE OF RESEARCH AND SPONSORED PROGRAMS <i>Division of Research Compliance</i>	Institutional Animal Care and Use Standard Operating Procedures	
	Title: Post Approval Monitoring of Approved Research in Cayuse Animal Oversight		
Effective Date:	20-Jul-2023	Document Number:	IACUC-SOP-006.01
Approval/Date:  <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="text-align: center;"> Chad W. Hargrave Vice President & Chief Research Officer </div> <div style="text-align: right;"> <i>23 July 2024</i> Date </div> </div>			
REVISION HISTORY			

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):

IACUC		
Alert	Inbox	Total
Protocol Actions	0	24
Draft Protocols	8	8
Protocols in Review	0	3
Continuing Reviews	6	6
Continuations in Review	2	5
De Novo Reviews		
Draft Amendment	1	1
Transfer Ownership	0	0

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

Urso, Philip M	<u>2021-1135</u>	2	Cancellation of dairy steers for use in classroom activities.	05/13/2021	05/13/2023	05/13/2024	1 Approved (w/o Stipulation)
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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:

The screenshot shows a web interface with two tabs: 'Info' and 'Progress Report'. The 'Progress Report' tab is active. On the left, there is a 'Status' dropdown menu with 'Withdrawn' selected. Below it is a text area for the 'Progress Report' with the instruction: 'Progress Report. If the status of this project is Continue As Is, provide a brief update on the progress made in achieving the specific aims of the protocol.*'. To the right of this text area is a rich text editor toolbar with various icons for undo, redo, bold, italic, underline, strikethrough, subscript, superscript, text color, background color, text background color, bulleted list, numbered list, link, unlink, insert link, insert image, and search. Below the text area is an 'Animal Disposition' dropdown menu with 'Transfer to Another Protocol' selected.

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:

<p>Status</p> <p>Progress Report. If the status of this project is Continue As Is, provide a brief update on the progress made in achieving the specific aims of the protocol. *</p>	<p>Continue As Is ▾</p> <p>Continue as Is to proceed getting the doe population under control. Harvest was successful last year; this is a multi-year project.</p>
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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:

Problems/Adverse Events. If the status of this project is active/project ongoing, or project was initiated, but is presently inactive, describe any unanticipated adverse events, morbidity or mortality, the cause(s), if known, and how these problems were resolved. If NONE, this should be indicated. *

No adverse events to report for this approval year.

Alt to Animal Use:

Alternatives to Animal Use. Alternatives to the use of animals should be considered and used when possible. Since the last IACUC approval, have alternatives to the use of animals become available that could be substituted to achieve your specific project aims?

No alternatives to the use of animals have become available to assist the research team in achieving the project's specific aims.

Alt to Painful Procedures:

Alternatives To Potentially Painful Procedures. (Address the following if your project involves USDA Category D or Category E.) Procedures that cause the least amount of pain or distress to the animals should be considered and used when possible. Since the last IACUC approval, have alternatives which are potentially less painful or distressful become available that could be used to achieve your specific project aims?

Not applicable for this study as all animal work was performed under USDA Category C.

Duplication:

Duplication. Activities involving animals must not unnecessarily duplicate previous experiments. Provide written assurance that the activities of this project remain in compliance with the requirement that there must be no unnecessary duplication.

The PI assures that the activities of this project remain in compliance with this requirement. This is always taken into consideration when designing these projects.

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:

Future Plan.

No Changes ▼

Changes are planned:

Future Plan.

Changes are planned ▼

Future Plan Description.

New students will be joining this project. An amendment is forthcoming.

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

Continuing Review

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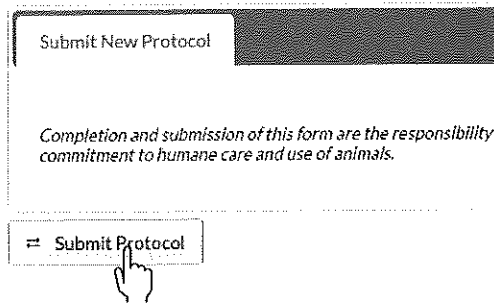
Continuing Review

Submit Continuing Review

Preview Protocol

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

Submit



Submit New Protocol

*Completion and submission of this form are the responsibility
commitment to humane care and use of animals.*

Submit Protocol

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.

REFERENCES

Cayuse Animal Oversight Help Center

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