ROAMWyo

Research Organization Administration and Management

Animal Oversight (IACUC)

Researcher SOP

Title: ROAMWyo Animals Oversight: Animal Use Protocol (AUP) Submission and Management	Process Owner: Office of Research & Economic Development	Approved By: Carolyn Brandt
Date Approved: 01/11/2022	Effective Date: 11/1/2022	Date of next review: TBD

Purpose: To provide guidance and instructions to the University of Wyoming's investigators, who are conducting animal research, on how to best utilize and manage the animal use protocol lifecycle within ROAMWyo.

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Scope: This guidance document applies to all relevant University of Wyoming investigators/researchers utilizing ROAMWyo Animal Oversight for new protocol submission and post-submission protocol management.

Responsibility: University of Wyoming's investigators and researchers are responsible for adhering to this document to utilize ROAMWyo for various processes surrounding their Animal Use Protocols (AUPs).

Principal Investigators (PI)/Investigators/Researchers – utilize ROAMWyo's Animal Oversight module to submit new Animal Use Protocols, continuing reviews (annual reviews), 3-year renewals (De Novo), and amendments. This user group will also use the module to respond to IACUC office/committee reviews comments and questions.

IACUC Office – are staff of the University of Wyoming's Research and Economic Development Division, Animal Oversight, and are responsible for the administrative management of animal oversight regulatory compliance and coordination of related work between the IACUC and the researchers.

IACUC – is a group of experts from various backgrounds who are responsible for the review of Animal Use Protocols (AUPs), amendment submissions, continuing reviews ("annual review"), or de novo reviews. The committee is ultimately responsible for determining the approval or withholding status of an AUP.

Definitions:

Terms	Definitions
AUP	Acronym for "Animal Use Protocol", which details the animal research project proposed by a UW PI and reviewed by the IACUC. Approved AUPs require an annual review (Continuing Review) and a total lifespan of 3 years. Projects that continue beyond 3 years must be resubmitted as a De Novo review prior to the 3-year deadline.
Continuing Review (Annual Review)	The required annual update for an ongoing AUP. A Continuing Review must be submitted and approved prior to the AUP deadline or the research must end. The terms "Continuing Review" and "Annual Review" are used interchangeably.
De Novo Review	A protocol must be reviewed as if it were a new submission after three years of the protocol being active and is referred to as a "de novo" review or submission.
Full Committee Review (FCR)	Full Committee Review of protocols requires a convened meeting of a quorum of the IACUC members. The U.S. Public Health Services (PHS) Policy and U.S. Animal Welfare Regulations (AWR) are explicit that proposals reviewed by the full committee must receive the approval vote of a majority of the quorum present in order receive approval.
Icons	Various icons are used to illustrate actions that have been made or need to be taken; or indicators of page completion. See Image 1.
Researcher Staff Member	An individual within the UW system with an active role in preparing or revising proposals, amendments, or reviews. Researcher Staff Members are assigned to the PI Group that they work under. By UW Policy, only a faculty member can submit an AUP, though other individuals can prepare documents for PI review and formal submission. Individuals with additional roles (e.g., IACUC members with research programs) must select the Researcher Staff Member role in order to submit their own AUPs.

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Principal Investigator (PI)	A faculty member at UW involved in animal research. This individual is ultimately responsible for the welfare of all research animals involved in their projects, and is responsible for the final review and submission of all AUPs and other documents within ROAMWyo. Proposals written by their research team (e.g., a postdoc) are automatically routed to the PI upon submission and the PI must review and authorize the proposal in order to complete the submission or revision process and begin the IACUC review.
Trigger Question	Questions within the module that when answered consequently trigger additional questions that appear in the form.
Type of Animal Use: Agricultural Research	When selected on the 'Use Type(s)' tab, populates questions specific to an agricultural-based study protocol. Further, species-specific questions will populate based on the selection(s) made in the Protocol Species Grid under the 'Options' tab. These choices will typically be made when a research endeavor includes production, biological, or behavioral research involving agriculture animals.
Type of Animal Use: Vivarium Research	When selected on the 'Use Type(s)' tab, populates questions specific to a vivarium-based study protocol. Further, species-specific questions will populate based on the selection(s) made in the Protocol Species Grid under the 'Options' tab.
Type of Animal Use: Wildlife Research	When selected on the 'Use Type(s)' tab, populates questions specific to a wildlife field study protocol. Researcher Staff Members may also need to select 'Wildlife' in the Protocol Species Grid under the 'Options' tab to fully expose all relevant questions.
Type of Animal Use: Breeding	When selected on the 'Use Type(s)' tab, populates questions specific to breeding and maintaining an animal colony. Live animals being bred or held for use in teaching, testing, experiments, research, or surgery, but not yet used for these purposes. Maintaining a breeding colony is subject to IACUC review. Replaces the "Breeding Colony Approval Form" in the previous submission process. NOTE: a single ROAMWyo AUP can be for either research OR as a breeding colony form. AUPs proposing breeding as well as research endeavors will likely be returned without review.
Type of Animal Use: Holding	Currently this Animal Use Type is not supported by ROAMWyo's Animal Oversight module. Researchers that require an Animal Holding Protocol can do so by completing IACUC Form 09-01.
Type of Animal Use: Teaching	When selected on the 'Use Type(s)' tab, populates questions specific to a teaching protocol, which utilizes live animals only being used for observational and/or non-invasive teaching. The use of animals in educational research settings is subject to IACUC review. Examples include using animals to teach agricultural techniques, animal husbandry, and medical or veterinary procedures in a research setting.
Preview Function	A tool that displays both the original protocol version and the modified/edited version in a comparison mode to clearly show the changes made. See Image 3.
Quick Tips	An icon that appears throughout the protocol form as a purple circle with a checkmark inside of it. When hovering above it, information will be provided such as keys/legends for other icons throughout the form, and additional information and tips to complete the AUP form and understand it better.

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Reduce, Refine, Replace Section	A new section of the AUP that requires the researcher to consider all possible alternatives to their proposed research model, with efforts to minimize animal pain and distress. Reduce – reduction of animal use (i.e., modifying the experimental paradigm or performing statistical analysis to allow the use of fewer animals to obtain the needed information). Refine – Refinement of animal use such as modifying manipulations or measurement techniques to reduce the pain and/or distress experienced by the animals as compared to prior techniques, or using fewer sentient species (e.g., frog instead of mouse, mouse instead of dog). Replace – Replacement of animals with non-animal techniques (e.g., using tissue culture, computer simulations, etc.).
Review Note Tool Window	A window that appears during the review and respond process. It is the "notepad" of where the reviewer will add comments/questions pertaining to the form section. The receiver of the comments will utilize this window to view the comments, provide rebuttals to the comments/questions, and view changes and revisions made. See **Image 2.**
TOC (Table of Contents)	Table of Contents of the AUP form, located on the left side of the screen.

Icons Legend – The system relies heavily on the icons below to indicate that an action has been taken, or needs to be taken, or an action has been completed, or indicates an error. These symbols will be seen during the AUP form completion process and during the review and response process between the submitter and reviewer(s).

**Image 1.** Table of Contents Legend

PI
Page has not been completed yet
Child Page(s) have not been completed yet
Page completed
Page marked with Reviewer comments
Page revised during review process or Amendment
Page marked for review is completed
New record added by PI during review

Committee
Page reviewed by me
Page reviewed by other committee members
Reviewer(s) comments merged into one comment
PI revised a page not marked for review
PI completed a page marked for review
New record added by PI during review

Related Policies:
- The University of Wyoming Policy Statement on Animal Research
- IACUC Policies and Procedures Manual 2015
- University of Wyoming Program of Veterinary Care
- Guidelines related to Euthanasia of Wild Ungulates
- Needle Gauge Guideline Table
- Standard Operating Procedure for Rodent Genotyping
- Documents above and other detailed information is located at http://www.uwyo.edu/research/compliance/animal-care/index.html

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OVERVIEW OF USING ROAMWYO ANIMALS OVERSIGHT FOR AUP SUBMISSIONS

Use "quick tips" 🔵 for additional tips/explanations

Trigger Questions – Certain questions when answered will trigger additional branching questions to appear. The trigger questions listed below are in the first protocol section *Options* and will create a form specific to your protocol elements. Other pages of the AUP may trigger additional sections of the form.

Example Section – Options
The trigger questions are associated with the animal species, collaboration with outside groups, use of animal/human tissues, procedures/surgeries, etc.

1. Will you be using tissues from animals from another UW protocol or collaborating institution? **Animals Tissues** and **Collaboration** sections will appear (if using tissue from a deceased animal, you will be able to answer that in the **Animals Tissue** section and no further action will be needed).
2. **Antibodies Source** will appear upon answer to: *Will antibodies be specifically generated for this study?*
3. **Outside Collaboration** will appear upon answer to: *Will you be collaborating with an outside institution?*
4. *Will you dispose of any carcasses or drugs? Disposal* section will appear if 'Yes' is selected
5. *Will animals be moved through public access areas? Transportation* section will appear if 'Yes' is selected
6. *Will human clinical areas be used? Human Clinical Info* section will appear if 'Yes' is selected
7. *Will any of the following field studies be performed? Field Study* section will appear if 'Yes' is selected
8. Regarding Funding:
   a. *Federal/Foundation funded?* **Federal/Foundation Funding** will appear in the TOC and within the protocol if the box is checked by the Researcher Staff Member
   b. *Internally funded?* **Internal Funding** will appear in the TOC and within the protocol if the box is checked by the Researcher Staff Member
   c. *Private/Commercially funded?* **Private Funding** will appear in the TOC and within the protocol if the box is checked by the Researcher Staff Member
   d. *Other funding source?* **Other Funding** will appear in the TOC and within the protocol if the box is checked by the Researcher Staff Member

   Note: Multiple funding types will appear as separate sections in the TOC

Protocol Species Grid
Next, the Researcher Staff Member must select all species covered under this proposal and select what categories each species will be subjected to. The species categories of work (selected in *Options* section will trigger certain form questions to appear under the *Species Information* section of the protocol.

- **Euthanize** will trigger the *Euthanasia* section to appear
- **Restraint** will trigger the *Restraint* section to appear
- **Drugs** will trigger the *Drugs* section to appear
- **Procedures** will trigger the *Non-Surgical Procedures* section to appear
- **Surgery** will trigger the *Surgery* and *Multiple Survival Surgeries* to appear

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- **Hazardous** Agents will trigger the *Hazardous Agents* to appear

How questions are answered in the first section *Options* will dictate which questions and sections will appear throughout the protocol form sections. For questions not related to your research, leave the response blank.
Note: Enter N/A into sections of the form that do not apply to the protocol but are required queries to be completed to continue. They are denoted by a red asterisk (*)

PROTOCOL DEVELOPMENT AND SUBMISSION

For initiating an Animal Use Protocol (AUP), which has replaced UW's previous "Protocol Approval Form", "Wildlife Protocol Form", and the "Breeding Colony Form".

Note: Breeding colonies must still be approved by the IACUC and researchers must submit a separate AUP for their breeding needs. Do NOT combine a Breeding Colony request and an experimental study into one AUP.

1. **Log in** to ROAMWyo using SSO
    a. Select **Animal Oversight** from **Products** dropdown menu (top right of the screen).
    b. Select the appropriate role for creating a new AUP: **Researcher Staff Member** from the role dropdown on the toolbar
2. Select **+ Start a New Protocol Application**
3. Complete **Will your research involve the use of LIVE vertebrate animal?**
    a. If no, process ends – a protocol submission is not required
4. Select **+ Start New Application**
5. Complete **Protocol Introduction (Options)** section
    This section includes trigger questions that will dictate how the AUP form will appear depending on how questions are answered.
    a. Select funding type: 1) Federal/Foundation Funding; (2) Internally funded; (3) Private/Commercially funded; (4) Other funding. *Note: Multiple funding sources may be selected*
    b. Identify breeding protocol type and protocol attributes. *Note: Researchers who plan to breed animals for experimentation or to establish/maintain a colony will need to submit the breeding portion as a separate protocol.*
    c. Identify species to be used in the **Protocol Species Grid**
        i. The completion of the grid is not required if it's not applicable to an AUP
6. Complete **Protocol Overview** section
    a. All tabs require a response, if not applicable, indicate with **N/A**
7. Complete **Funding** section
    a. Funding Section(s) are dependent on how the funding trigger question was answered in *Options* section
8. Complete **Use Type** section
    a. A syllabus upload is required if the protocol is for teaching purpose
9. Complete **Species Information** section

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a. Species Information section does not appear if species was not selected in the *Options* section. If there is more than one species in the protocol, the form will automatically advance to the next species listed.

b. Complete category of work subsection for each species type (number of subsections is dependent upon which categories of work were selected in the *Options* section).

10. Complete **all other relevant study-related sections**.
11. **Key Personnel** section
    a. Upload CITI training documentation as indicated in the form
12. Complete **Databases Searched** Section
    a. Includes links to databases for the researcher's convenience
13. Complete **Endpoints** section
14. Review **Preview Protocol** section
    a. Preview the protocol for accuracy prior to submission
15. Upload relevant attachments in the **Attachments** section
16. **Submit Protocol** once the AUP has been reviewed and confirmed for accuracy

Note: You cannot retract your submission once it has been submitted. A submitted protocol will be illustrated in your ROAMWyo AO inbox as gray and italicized font.

17. Select **Cancel Draft Protocol** to cancel the draft protocol

Note: If you cancel a draft protocol there will be no record of the protocol.

Next Steps

The AUP is electronically routed to the IACUC Office for review.

OVERVIEW OF HOW TO USE THE REVIEW AND RESPONSE FUNCTIONALITY

Review Note Tool is a pop-up window with three tabs: history, view changes, review notes. Information within the review note tool changes depending on what TOC section is being viewed and if comments have been made.

- Tab1: **History** – displays the review and comment history
- Tab 2: **View Changes** – displays the modifications and changes made
- Tab 3: **Review Notes** – the review notes are created by reviewers here and a **rebuttal** is the response made by the investigator submitter.

Image 2. Review Note Tool (in a reviewed protocol mode, seen by the investigator/submitter)

RECEIVING AND RESPONDING TO IACUC OFFICE COMMENTS

1. Receive an email notification from ROAMWyo
2. Select the link in the email or sign into ROAMWyo using SSO
3. Select **Animals Oversight** from the **Products** dropdown menu
4. Select the protocol
5. Locate this icon in the **TOC** section, which indicates that a Reviewer Comment has been made to that section and requires a revision:
   a. Alterations to the AUP can be made in the Animal Oversight form. When the Researcher addresses a critique from the IACUC and/or IACUC Office, the green checkmark icon will appear
   b. Changes made to sections not flagged for review will also indicate a change with the pencil icon
   c. A **Rebuttal** allows for the Researcher to comment on a decision or rationale *outside* of the official AUP. While not required for resubmission, this may be an appropriate place to justify a decision, though there is no guarantee that a Rebuttal alone will satisfy the IACUC's request for revision.
6. Select **Review Notes** tab to review the note
7. Address the Reviewer comment(s) in the AUP.
8. Check **Review Rebuttal** box if you wish to enter a comment to the IACUC that will not be included in the AUP
9. Enter a rebuttal or response to the reviewer's comment
10. Select **Save changes**

    a. A checkmark icon will appear, signifying a completed revision
11. Repeat steps 5-8 for each section with a note
12. Select **Submit Protocol** from the lower section of the TOC
13. AUP is routed to the IACUC Office and Committee
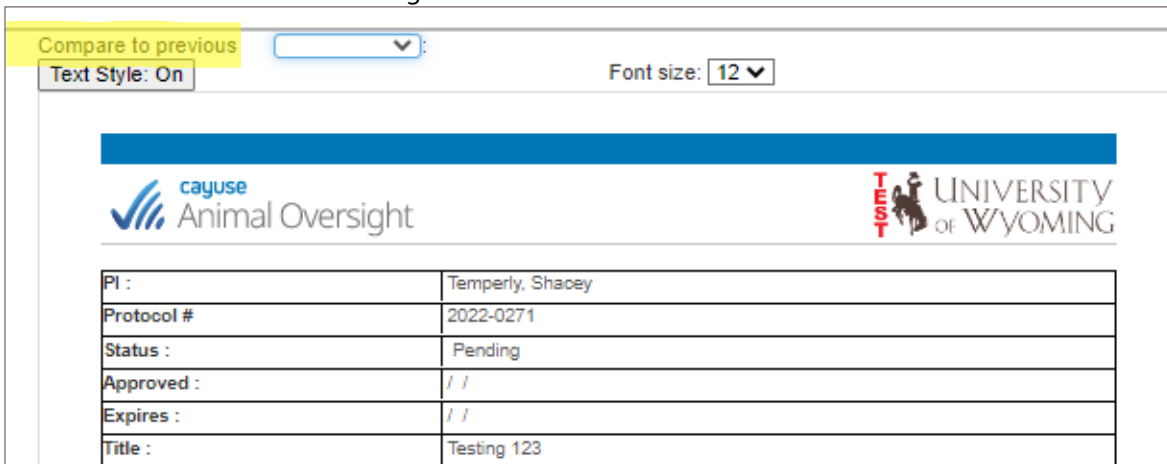
Next Steps
The AUP is routed back to the IACUC Office and IACUC for review.

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OVERVIEW OF HOW TO VIEW PROTOCOL VERSIONING

- **In form review** - select section, select review note tool
- Preview protocol function – this view will display the original version next to the modified version for easy identification of changes made.
  - Select **Protocol Preview** from the TOC
  - Select **Preview**
  - Select **Revisions** from the dropdown **Compare to Previous** (see below)

Image 3. Preview Protocol view to see original and revised version in one screen

SUBMITTING A CONTINUING REVIEW (ANNUAL REVIEW)

1. Receive email notification that a continuing review/annual review of the AUP is approaching

   Note: notification emails are sent 30-60 days prior to the annual due date).

   Note: you cannot create an Amendment during this 60-day period until the Continuing Review is approved

2. Select the link in the email or sign into ROAMWyo using SSO
3. Select **Animals Oversight** from the **Products** dropdown menu
4. Select **Continuing Reviews** in the Inbox
5. Select the protocol
6. Review **Info** tab
7. Click on the **Progress Report** tab
8. Select protocol status
9. Select **Withdrawn** – if your research project has concluded
10. If **Withdrawn** is selected, provide the **Animal Disposition** by selecting one of the following options: (1)**Euthanize**; (2)**Leaving with PI**; (3)**Transfer to Another Protocol**

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IMPORTANT NOTE: This animal disposition plan <u>must</u> agree with your AUP's approved method of disposition. Any desire to alter the animal disposition plan <u>must</u> be approved via Amendment <u>prior</u> to any protocol deadlines.

11. Select **Continue As Is** – if your research project continues
12. Review first tab **Info** to ensure accuracy
13. Complete the tabs (1)**Progress Report**; (2)**Project Personnel**; (3)**Adverse Events**; (4)**Alt To Animal Use**; (5)**Alt to Painful Procedures**; (6)**Duplication**; (7)**Future Plans**

Next Steps

The AUP is routed back to the IACUC Office and Committee for further review and the following actions could result:

- Return to PI for corrections or for additional information
- Approval
- Withheld

DE NOVO SUBMISSION

1. Receive an email notification that de novo deadline is approaching

   Note: automated notification emails are sent periodically 30-60 days prior to a de novo due date. It is encouraged to submit in advance of the de novo due date (expiration date) to allow for enough time to process the review. Research work is required to stop once the protocol expires.

2. Select the link in the email or sign into ROAMWyo using SSO
3. Select **Animals Oversight** from the **Products** dropdown menu
4. Select **De Novo Reviews** in the Inbox
5. Select the protocol
6. Select the dropdown option for **Please Choose De Novo Review Action**
   a. Select **Protocol will be renewed** – if the research is ongoing and current; move to step 7.
   b. Select **Lapse Upon Expiration** – if the PI does not intend to renew the AUP
      i. Provide the **Animal Disposition** by selecting one of the following options: (1)**Euthanize**; (2)**Leaving with PI**; (3)**Transfer to Another Protocol**

   IMPORTANT NOTE: This animal disposition plan <u>must</u> agree with your AUP's approved method of disposition. Any desire to alter the animal disposition plan <u>must</u> be approved via Amendment <u>prior</u> to any protocol deadlines.

   No further action is required.
7. Provide an Animal Use protocol **Progress Report**
   a. You may include images, tables, charts, etc.
8. Complete: **Number of animals used in the project during the last year**
9. Review the **Protocol Species Grid** and confirm that the information is correct or make updates as needed

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10. Review the **Fund Source Table** and confirm that the information is correct or make updates as needed
11. Select **Save Changes**
12. Select **Start De Novo Review**
13. **Review, verify,** or **make updates** to each form section

   Note: A checkmark [   ] icon next to each form section will appear to verify that the section has been reviewed or updated. A De Novo Review submission cannot be submitted until all checkmarks have appeared.

14. Click **Submit Protocol**

Next Steps

The AUP is returned to the IACUC Office and Committee for further review and the following actions could result

- Returned to PI with questions/comments
- Approval
- Withheld

OVERVIEW OF AMENDMENTS/IMPORTANT MENTIONS

- Changes to the project may not be implemented until the amendment is approved.
- The IACUC Office and Committee will determine if the amendment is significant. If significant, the amendment may warrant further review and discussion by the Full Committee.

Examples of significant changes:
- Changes in animal species
- Changes in housing
- Changes in experimental agents or procedures
- Changes in clinical signs and morbidity criteria
- Changes in pain or distress
- Changes in principal investigator
- Changes in study procedures
- Changes that impact personnel safety

The following changes may be handled administratively by the Office of Research:
- Change in personnel, other than the PI. (Note: An administrative review will still be conducted to ensure all personnel are adequately trained/qualified and enrolled in the Animal Occupational Health and Safety Program (and cleared to work with animals), and meet other criteria as required by the IACUC.)

INITIATING AN AUP AMENDMENT

1. Login to ROAMWyo using SSO
2. Select **Animals Oversight** from the **Products** dropdown menu
3. Select the protocol you wish to amend from the **Protocol Actions** menu on the lefthand side

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4. Select **Start an Amendment**
5. Enter the reason for the amendment in the text box Reason for Change
6. Click Amend Protocol
7. Modify/update the relevant form section(s) that pertain to the amendment
    a. Any section that has been modified will be illustrated in the TOC with a pencil icon and the initial entry will be illustrated with a strikethrough in the page itself. Using the **preview protocol** option will not show the original entry, only the modification/amendment. The plus icon indicates that an addition was made.
8. Click **Submit Protocol** from the TOC

Next Steps
The AUP is routed back to the IACUC Office and Committee for review.

OVERVIEW OF SHELL PROTOCOLS

All AUPs that were **approved** prior to the launch of ROAMWyo have been placed into the Animal Oversight module as "Shell Protocols". This has created a foothold in the new platform for your study, but you as the researcher will be responsible for "converting" your Shell Protocol into ROAMWyo to fully integrate the AUP into the new platform. A Shell Protocol will only contain the following information:

- PI Name
- Protocol # (this is a new number specifically generated by ROAMWyo, and will likely be '2022-0XXX)
- Protocol Title (your previously approved title, plus the original UW protocol #, and may also denote USDA-covered species)
- Approve Date (original approval date)
- Review Date (the deadline of the **next** Continuing Review)
- Expiration Date (3 years from the Approve Date and deadline for any De Novo Review)

The PI will need to convert this Shell Protocol by inserting all necessary components of their previously-approved Animal Approval Form. This will be done by creating an Amendment (detailed below) and simply cutting and pasting in all of the information from the previous form into the correct location of the new AUP form.

Note: Converting a Shell Protocol into the full long-form AUP is NOT an opportunity for any changes, updates, revisions, or any deviations from your currently approved protocol. Do NOT change or add ANYTHING from the approved document. Any deviations will be considered a serious non-compliance issue and may result in significant penalties from the IACUC and Compliance Office. It is strongly recommended that all researchers convert their Shell Protocols ASAP so that they can make any Amendments in a subsequent future change.

A researcher can convert their Shell Protocol at any time but must do so prior to making any experimental changes (Amendment), updates (Continuing Review or De Novo Review), or within one calendar year of the

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official hard launch date for AO. Personnel changes may be possible without conversion but only with approval by IACUC@uwyo.edu.

CONVERTING A SHELL PROTOCOL DURING AN AUP AMENDMENT

1. Login to ROAMWyo using SSO
    a. Select **Animal Oversight** from **Products** dropdown menu (top right of the screen)
    b. Select the role **Researcher Staff Member** from the dropdown on the toolbar
2. Select **Protocol Actions** from the TOC

    Note: Protocol Actions have the categories of Continuing Reviews, De Novo, and Amendment

3. Highlight the relevant protocol by selecting the row
4. Select **Start an Amendment**
5. Enter the reason for the amendment in the text box **Reason for Change**
6. Select **Amend Protocol**
7. Complete the relevant form section(s) that pertain to the amendment

    Note: information included in the shell protocol is the PI's full name, protocol number, protocol title, and original approval date. Everything else must be updated. The form will be customized based on how questions are answered in the first section Options. See "Overview of Using ROAMWyo Animals Oversight for AUP Submissions" for general guidance and background of using ROAMWyo.

    a. Update all TOC sections pertinent to the protocol to transition it to a full protocol: **Options, Funding, Use Types, Animal(s) Information, Personnel, Databases Searched, Endpoints, Attachments, and the Amendment Reason**
8. Click **Submit Protocol** from the TOC

CONVERTING A SHELL PROTOCOL DURING AN AUP DE NOVO REVIEW

1. See the section above called *De Novo Submission*, as it follows the same steps for transitioning a shell protocol to a full protocol during the De Novo submission.

    Note: information included in the shell protocol is the PI's full name, protocol number, protocol title, and original approval date. Everything else must be updated. The form will be customized based on how questions are answered in the first section Options. See "Overview of Using ROAMWyo Animals Oversight for AUP Submissions" for general guidance and background of using ROAMWyo.

    a. Update all TOC sections pertinent to the protocol to transition it to a full protocol: **Options, Funding, Use Types, Animal(s) Information, Personnel, Databases Searched, Endpoints, Attachments, and the Amendment Reason**

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CANCEL A DRAFT PROTOCOL

1. **Login** to ROAMWyo using SSO
2. Select **Animals Oversight** from the **Products** dropdown menu
3. Select the protocol
4. Select **Cancel Draft Proposal** from the TOC

COPY A PROTOCOL

1. **Login** to ROAMWyo
2. Select **Animals Oversight** from the **Products** dropdown menu
3. Select the protocol
4. Select **Copy Protocol to New Document**
5. Complete a new AUP Submission Form
   a. Refer to *Overview of Using ROAMWyo Animals Oversight for AUP Submissions* and *Protocol Development and Submission* at the beginning of this document for details and steps

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