Guidelines and Template
Submission of modifications to an existing IACUC protocol

Prepared by the Animal Welfare Committee
Department of Biological Sciences, A-State

Note: Our guidelines, comments, and recommendations hereafter will be in blue. Anything in black is what you would see in Cayuse.

If you need to submit a request for modification, follow these steps:

1. Sign in CayuseIRB. If you do not have an account yet, contact CayuseIRB@atate.edu to get an account.
2. From **Dashboard** or **Studies**, look for the study you need to modify and click on the protocol number.

Before you do anything, we'd recommend you download the pdf of your original protocol so you know which sections will need modifications.

3. Click on the blue + **New Submission** button.
4. Select **Modification**
5. Click **Edit**
6. Answer all questions. Below, you will find the questions you will be asked to complete for this request for modification.
7. Once you are done completing these questions, make sure it's all saved (the **Save** option is under the Actions button)
8. Go back by clicking on **SUBMISSION DETAILS** to the left on the title ribbon.
9. Click on **Complete Submission** and **Certify**. If a student is the primary contact, Cayuse will send a request to the Faculty Advisor for certification. If co-PIs are included in the protocol, Cayuse will also send a request to them for certification.

***1. Compliance Committee**

Which committee oversees this research?

- ☐ Institutional Review Board (IRB)
- ▪ Institutional Animal Care and Use Committee (IACUC)
- ☐ Institutional Biosafety Committee (IBC)

By Selecting the above, new questions will appear as follows:

***2. Modification of IACUC Protocol**

Check all areas impacted by this modification:

- ☐ Species, Strain/Stock, Source, Sex
- ☐ Number of Animals (Total used or maximum housed at one time)
- ☐ Procedures
- ☐ Pain or Distress Classification
- ☐ Anesthesia, analgesia, tranquilization, or other agents

- ☐ Research Personnel
- ☐ Other

If you select "Research Personnel", the following additional questions will appear.

Changes in Research Personnel

- **To add or remove a Co-PI:** Please update Section A. Persons added to Section A* will have access to the protocol in Cayuse and must certify submissions.
- **To add or remove other research team members:** Please list them below and explain their role. Then, attach their CITI completion reports below. These individuals will not have access to the protocol in Cayuse nor will they be required to certify submissions.

*You can access Section A in the left margin. The fields you can expect in this section are the same you had when you first submitted your protocol.

***3. Briefly describe the proposed changes.**

***4. Explain why the modification is necessary.**

***5. Legacy Study**

In which protocol management software was the original study submitted?

- ☐ **IRBNet –** This protocol was originally approved via IRBNet. (Legacy Study)
- ☐ **Cayuse IRB –** This protocol was originally submitted and approved via Cayuse IRB.

-IRBNet is the software used previously at A-State. Cayuse has been used since 2018, so if your protocol is older than 2017, you probably used IRBNet; if younger, select Cayuse. Additionally, if originally submitted in IRBNet, the protocol number starts with IRBNet, followed by a number sequence, whereas the label of a protocol submitted in Cayuse starts with FY (as in fiscal year).

-If you select IRBNet, questions 6 and 7 will populate, whether you had to complete the extra questions about research personnel changes in question 2. Please answer anyways.

-If you select Cayuse IRB, skip to NEXT: UPDATE PROTOCOL SECTIONS.

6. Research Personnel Changes

Are you adding or deleting any research team members?

- ☐ Yes (if you select this, it will say, "Please complete 6.a. and/or 6.b., as appropriate.")
- ☐ No

If you select Yes, these sub-questions pop up:

6.a. New Co-PI(s) Requiring Access to the Protocol in Cayuse
Complete this section for Co-PI(s) who require access to this protocol in Cayuse IRB.
These individuals may be required to certify submissions in Cayuse.
(Complete section 6.b. below to add personnel without giving them access to this protocol in Cayuse IRB.)

FIND PEOPLE

☐ **Co-PI(s) not listed**
If you check this box, the following will appear:
To proceed with this submission, we must first add the Co-PI(s) to the system.
Please email a request to add new Cayuse IRB user to CayuseIRB@astate.edu, and provide the following information:

- Name
- Department
- Department Address
- Email address
- Phone Number
- Fax Number

Please allow a minimum of two business days to create new Cayuse users.
Thank you.

6.a.1. **Attach CITI certifications for Co-PI(s)**
All researchers must provide the CITI Responsible Conduct of Research course plus other research/committee-specific CITI courses, as appropriate.

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6.b. Please identify new personnel who do not require access to the protocol in Cayuse IRB, and explain their role in the research. Also identify any previous researchers who will no longer be involved in this protocol.

6.b.1. **Attach CITI certifications for new research team members**
All researchers must provide the CITI Responsible Conduct of Research course plus other research/committee-specific CITI courses, as appropriate.

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7. Attach any new or revised documents for the protocol.

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NEXT: UPDATE PROTOCOL SECTIONS

This only appears if you selected Cayuse IRB in question 5.

Please modify each section of the protocol necessary to reflect these changes.
For example, add new Co-PI(s), updating research plan, or attaching revised documents, etc. This permits side-by-side comparison of modifications to previously approved protocols.

Attachments:

- If the new attachment replaces the existing attachment, please delete the existing attachment before adding the new version.
- If the existing attachment will remain in use, just add the new attachment alongside the previously approved attachment.

For any modification to the protocol, you need to click on **Section B. IACUC Protocol** in the left margin. The details of this section are provided in the Guidelines and template for a new IACUC proposal on our webpage. If you downloaded the pdf of the original submission, you can also use that to determine which subsections will require modifications.

If you need to submit a renewal, follow these steps:
From Dashboard or Studies, look for the study you need to modify and click on the protocol number.
Click on the blue + New Submission button.
Select Renewal
Click Edit
You will be asked to answer several questions presented below. Note that in blue are additional comments from the AWC.
Once you are finished with those questions, go to COMPLETE SUBMISSION and click CONFIRM.

Continuing Review
***Compliance Committee**
Which committee oversees this research?

- ☐ Institutional Review Board (IRB)
- ▪ Institutional Animal Care and Use Committee (IACUC)
- ☐ Institutional Biosafety Committee (IBC)

By Selecting the above, new questions will appear as follows:
IACUC CONTINUING REVIEW

1. **Record of Animal Usage**
   Please indicate the total number approved and total used to date for each species.
   For example:
   SPECIES TOTAL #APPROVED #USED TO DATE

2. **Nature of Protocol/Study**
   Check all applicable items.
   - ☐ Survival (Chronic) Study
   - ☐ Terminal (Acute) Study
   - ☐ Multiple Surgeries
   - ☐ Transgenic Breeding
   - ☐ Prolonged Restraint
   - ☐ Neuromuscular Blockers
   - ☐ Antibody production
   - ☐ Inducement of a Disease State
   - ☐ Inducement of a Behavioral Stress
   - ☐ Blood/Tissue Collection

3. **USDA Project (Pain) Category:**
   As approved in the original protocol
   Category B: Animals being bred, acclimatized, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such proposes. Non-invasive observation only of animals in the wild.
   Category C: Animals that are subject to procedures that cause no pain or distress, or only momentary or slight pain or distress and do not require the use of pain-relieving drugs.

Category D: Animals subjected to potentially painful or stressful procedures for which they receive appropriate anesthetics, analgesics and/or tranquilizer drugs.
Category E: Animals subjected to potentially painful or stressful procedures that are not relieved with anesthetics, analgesics and/or tranquilizer drugs. Withholding anesthesia/analgesia must be scientifically justified in writing and approved by the IACUC.

4. **Protocol Status**
Please indicate the status of this project.
   - ☐ Request Protocol Continuance
   - ☐ Request Protocol Termination

5. **Funding Source**
Please specify the funding source. Please indicate whether funding is internal (e.g., FRAC) or external (e.g., NSF) and include the fund number, if known.

6. **Project Personnel**
Have there been/will there be any changes in PI, Co-PI(s), or other research team members since the last IACUC approval was granted?
   - ☐ Yes
   - ☐ No

If you select Yes, the following question will be added:

6.a. Project Personnel Additions
Please provide the name, role, project responsibility, and personnel qualification statement for each individual to be added to the protocol.

Attach the CITI completion reports for these individuals.
This includes the CITI Responsible Conduct of Research course plus any needed IACUC-specific courses.

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6.b. Project Personnel Deletions
Provide name and effective date for all persons no longer involved in this research.

7. **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?
   - ☐ Yes
   - ☐ No

If you select Yes, the following question will be added:

7.a. Please explain.

8. **Alternatives to Potentially Painful Procedures (for USDA pain categories D and 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?
   - ☐ Yes
   - ☐ No

   If you select Yes, the following question will be added:

   8.a. Please explain.

9. **Duplication**
Activities involving animals must not unnecessarily duplicate previous experiments. Check the box below to indicate your assurance that the activities of this project remain in compliance with the requirement that there must be no unnecessary duplication.
   - ☐ I assure the IACUC that the activities of this project remain in compliance with the requirement that there must be no unnecessary duplication.

10. **Future Plans**
Please select one.
   - ☐ No changes are planned and the project will continue as previously approved by the IACUC.
   - ☐ Changes are planned.
   - ☐ Other

   If you select "Changes are planned", the following question will be added:

   10.a. Planned Changes
   Provide a full description and justification for the proposed changes.
      - Please note that you will be required to submit a modification before implementing changes,
      - If the modifications are significant, you may be required to complete a new application.

   The AWC would recommend submitting request for modifications or new proposal if you plan on making changes to avoid delaying your research.

   If you select "Other", the following question will be added:

   10.a. Please explain.

11. **CERTIFICATION OF THE PRINCIPAL INVESTIGATOR**
   - ☐ By checking this box, the Principal Investigator certifies he or she understands the requirements of the PHS Policy on Humane Care and Use of Laboratory Animals, applicable USDA regulations and the Institution's policies governing the use of

vertebrate animals for research, testing, teaching or demonstration purposes. The PI further certifies that he or she will continue to conduct the project in full compliance with the aforementioned requirements.

CONFLICT OF INTEREST

Is your research externally funded?

- ☐ Yes
- ☐ No

If you select "Yes", the following question will be added:

Has your relationship with the sponsor changed in any way that might require conflict of interest disclosure (e.g., stock purchases, salary, royalty payments, patents, board positions, etc.)?

- ☐ **Yes**
- ☐ **No**

If you select "Yes", the following question will be added:

PLEASE CONTACT THE DIRECTOR OF RESEARCH COMPLIANCE REGARDING THE NECESSARY CONFLICT OF INTEREST FORMS:

(870) 680-8289

jlestes@astate.edu

Please attach any other pertinent documents here.

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