

Guidelines and Template Submission of a new IACUC protocol or SOP

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 new protocol, follow these steps:

1. Sign in [CayuseIRB](#). If you do not have an account yet, contact CayuseIRB@atate.edu to get an account.
2. Click on **New Study**
3. Under **Study details**, type a title for your study
4. Click on the check mark to validate
5. A blue button + **New Submission** should appear (or become active) toward the top-right corner. Click on this button
6. Select **Initial**.
7. Now your protocol has been assigned a number and you're ready to enter the information needed.
8. Click on **Edit**.
9. Answer all questions. Below, you will find the questions you will be asked to complete for a protocol or SOP.
10. Once you are done completing these questions, make sure it's all saved (the **Save** option is under the Actions button)
11. Go back by clicking on **SUBMISSION DETAILS** to the left on the title ribbon.
12. 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.

A. PI Contact Information

***A.1. Primary Contact**

Browse to select the primary contact for this study.

Typically, this is the PI. This field is required by the CayuseIRB software.

This will automatically populate in a table. To the far right, you'll see a View link. If you click on it, it will show your CITI trainings with their expiration dates.

***A.2. Principal Investigator (PI)**

Browse to select the PI for this study.

This field is required by the CayuseIRB software.

FIND PEOPLE

Even if you are listed as primary contact, you would still need to populate your information here, unless, of course, someone else is the primary investigator. Click on the **Find People** button to generate this information.

***A.3. Attach PI's CITI Certificates**

- At a minimum, these parties must complete the most relevant Responsible Conduct of Research course. Other courses may apply, e.g., Human Subjects Research course for IRB protocols, Working With the IACUC course for IACUC protocols, or Biosafety/Biosecurity course for IBC protocols.
- To complete these courses, please create an account at www.CitiProgram.org. You must affiliate with Arkansas State University when you register.
- To obtain a PDF of the completion report, log in to CITI, select Arkansas State University Courses, select View Previously Completed Coursework, select View under the Completion Report column for the course, right-click on the report, and save as a PDF file.

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The PI may be the primary contact but even if their training can be seen from the View button, the PI still needs to attach the completion report (or certificate of completion) of their CITI training.

***A.4. PI's relationship to Arkansas State University**

- Arkansas State University – Jonesboro**
 - Faculty**
 - Staff – If you are conducting this research as a student, please select your student status.**
 - Post Doc**
 - Graduate Student**
 - Undergraduate Student**

- Other (e.g., ASU-MH, NYIT, or Catalyst entities)**
Please provide your organization, position, and contact information.

***A.4.a. Faculty Advisor or A-State Contact**

This will appear if post-doc, graduate, or undergraduate student selected. Use the **Find People** button to populate advisor.

FIND PEOPLE

***A.5. Co-Principal Investigator(s)**

Does this project involve Co-PI(s)?

- Yes
- No

***A.5.a. Co-Principal Investigator(s)**

Browse to select the Co-PI(s).

FIND PEOPLE

This will appear if you selected Yes in question A.5. Use the **Find People** button to populate the appropriate information. Then, attach their CITI training.

Attach CITI Certificates for Co-PI(s)

ATTACH

***A.6. SPONSOR**

Is this project funded by a grant, internal or external?

- Yes
- No

A.6.a. Please list internal grant and FOAP, if known.

Example: FRAC grant.

This question and the next will appear if you selected Yes in question A.6.

A.6.b. Please list external funding source and FOAP, if known.

If A-State is the subrecipient, list both the funding agency and the prime recipient.

Example: NSF grant awarded to University of California-Irvine, subawarded to A-State.

A.7. COMPLIANCE COMMITTEE SELECTION

Select the appropriate committee for this protocol.

- Institutional Review Board (IRB) -- for research involving human subjects
- Institutional Animal Care and Use Committee (IACUC) -- for research involving animals
- Institutional Biosafety Committee (IBC) -- for research involving recombinant DNA or other potentially hazardous biological materials

Obviously, if you opened this document, you'd select IACUC here. When you do, a new section (B. IACUC Protocol) will appear in the left table of content of the Cayuse page. You can either click on the forward arrow or on the section link in the table of content to access this section. See below for questions you'll be expected to address under this section B.

B. IACUC Protocol

PLEASE NOTE: THE FIRST USE OF EACH ABBREVIATION OR ACRONYM MUST INCLUDE THE DEFINITION.

Example: APHIS (Animal and Plant Health Inspection Service)

RESEARCH OR SOP

Are you submitting a research protocol or a standard operating procedure (SOP)?

- Research Protocol
- Standard Operating Procedure (SOP) – *Typically submitted by the Animal Facility Manager*

--If you select [SOP](#), you will be prompted to attach a PDF of your SOP. Unfortunately, the A-State IACUC does not provide an SOP template, so we encourage you to look at the example available on our AWC [webpage](#). Once you have attached your SOP, you are pretty much done; just make sure to save before you complete the submission.

--If you select [Research Protocol](#), more subsections appear, as shown below.

B.1. EFFECTIVE DATES

Expected Start Date

Expected End Date

Because an IACUC protocol is valid for three years, we recommend indicating a three-year window. If your project is longer than 3 years, you will need to submit a renewal.

*B.2. SPECIES

*B.3. STRAIN/STOCK

*B.4. SOURCE

B.4.a. In-house breeding colony?

- Yes
- No

*B.5. SEX

- Male
- Female

*B.6. TOTAL NUMBER OF ANIMALS TO BE USED.

*B.7. MAXIMUM NUMBER OF ANIMALS TO BE HOUSED AT ONE TIME

***B.8. RATIONALE FOR RESEARCH USING ANIMALS**

Please justify this research, briefly explaining whether it is new research, why the research is important, and why it is necessary to use animals.

Only a brief description is necessary. Do not cut and paste your grant proposal here.

***B.9. RATIONALE FOR USING SELECTED SPECIES**

***B.10. EXPERIMENTAL/INSTRUCTIONAL PROCEDURES**

Please describe the experimental/instructional procedures. In cases where offspring are used in experiments, what are the plans for the mothers within the study?

Please provide a general description of the experiments and the experimental design. Do not cut and paste your grant proposal here.

Click below to add attachments, such as PDF files containing diagrams, etc.

Please identify each attachment as it relates to the description above, e.g., "Figures 1 - 4."

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B.11. ANIMAL PROCEDURES

Please provide a description of all animal procedures, surgical and non-surgical.

- To justify the number of animals that will be used, provide a statistical analysis, such as power analysis, and include the result of that analysis in the description.
- With the description, please include a table that includes group, treatment, number of animals, pain category, and whether the animal will be euthanized at the end of the experiment. (A sample is attached below.)

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If you click on their [Sample Animal Procedure](#) link, it will download an Excel spreadsheet with just the headings of the table below, which we filled out with a hypothetical example. You may also find an example of such attachment on our webpage.

Group	Treatment	No of animals	Pain category	Euthanized at the end of Expt
Control	No drug	8	C	Yes
Expt 1	Drug 1	8	D	Yes
Expt 2	Drug 2	8	E	Yes

B.12. USDA PAIN AND DISTRESS CATEGORIES AND CONSIDERATION OF ALTERNATIVES

***B.12.a. USDA CATEGORIES FOR PAIN AND DISTRESS**

Check all that apply

Category B: No pain or distress

Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.

Examples include:

- breeding colonies
- wild animals held for observation

***Number of animals subject to Category B: _____**

Category C: Slight or momentary pain or distress or no pain or distress

Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs.

Examples include procedures performed by correctly trained personnel, such as:

- blood collection from a common peripheral vein per standard veterinary practice
- parenteral injections of non-irritating substances
- euthanasia by IACUC approved methods
- short-term manual restraint

***Number of animals subject to Category C: _____**

Category D: Pain or distress appropriately relieved by analgesia, tranquilization, or anesthesia.

Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals AND for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.

Examples include:

- surgical procedures
- blood collection by more invasive routes
- administration of drugs, chemicals, or toxins that would be expected to produce pain unless alleviated by analgesics

***Number of animals subject to Category D: _____**

If you select Category D, you will also need to answer the following questions:

Anesthesia, Analgesia, Tranquilization, and Other Agents

Drugs to be used

--

Dosage

--

Administration route

--

Category E: Unrelieved pain or distress

Animals upon which teaching, experiments, research, surgery, or tests involving accompanying pain or distress to the animals will be conducted AND for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

Examples include:

- toxicity studies
 - microbial virulence testing
 - research on stress, shock, or pain
 - negative conditioning via electric shocks that would cause pain in humans
- *Number of animals subject to Category E: _____**

If you select Category E, you will also need to answer the following questions:

Provide an explanation of the procedures producing pain or distress in these animals and the justification for not using appropriate anesthetic, analgesic, or tranquilizing drugs.

CONSIDERATION OF ALTERNATIVES

Please complete this section for any procedures which fall into USDA Categories D or E, causing more than momentary or slight pain or distress to the animals.

Describe your consideration of alternatives instead of using animals (e.g., cell culture); your determination that alternatives are not available and, thus, there is no other choice except to use animals for this research; and delineate the methods and sources used in the search.

You are expected to perform a research publication database search using appropriate key words related to your research. From these search results, determine if all publications or the majority of publications in your area of research have used only animals, then describe those results to support your use of animals.

Sample databases include:

- PubMed.gov
- [Biological & Agricultural Index Plus](#)
- [Biological Abstracts](#)
- [BioMed Central](#)

Alternatives include methods that refine existing tests by:

- Minimizing animal distress
- Reducing the number of animals necessary for an experiment
- Replacing whole-animal use with in vitro or other tests

Information on alternatives may be obtained at the following sites:

- [AltWeb](#)
- [USDA Animal Welfare Information Center](#)
- [University of California Center for Animal Alternatives](#)

Databases searched

Date of search

Period covered

Keywords searched

Describe your consideration of alternatives instead of using animals (e.g., cell culture). Describe your determination that alternatives are not available and, thus, there is no other choice except to use animals for this research. Delineate the methods and sources used in the search.

- By checking this box, you certify that, based on your search and knowledge, no valid alternative was identified to any of the described procedures which may cause more than momentary pain or distress, whether relieved or not.**

***B.13. EUTHANISIA**

Are animals to be euthanized at the end of the investigation?

- Yes
- No

B.14. Which approved animal facility euthanasia protocol(s) will be used?

Include the protocol number and title, if possible.

If there is only one approved animal facility protocol available, you are expected to use that. (Please check with the animal facility manager at 870-680-4855.)

The parenthetical note is referring to the ABI Animal Facility. If you are using another facility, the manager is either you or a colleague in the department. Contact the AWC and we will help identify the right individual.

***B.15. HAZARDOUS AGENTS**

Will animals be exposed to hazardous agents?

- Yes
- No

If you select Yes, a few additional questions will appear as follows:

Pathogenic:

Chemical:

Carcinogenic:

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You may attach additional hazardous agents and SOP sheets here:

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How will you dispose of these hazardous agents?

B.16. ANIMAL DISPOSAL

Recommended disposal route

Incineration

Other

Please specify: _____

Please attach any other pertinent documents here.

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

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.

Click on the blue + New Submission button.

Select Modification

Click Edit

You will be asked to answer several questions presented below. Note that in blue are additional comments from the AWC.

***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. Another trick is to look at the protocol number. If originally submitted in IRBNet, the protocol number will look be named 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 new 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.

Once you are finished, go the [Submission Details](#) of your protocol and click on [Complete Submission](#). You will have to certify before it's routed to your co-PIs for certification and before it is ready for IACUC to process.

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

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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.

ATTACH