August 8, 2022

ANIMAL FACILITY AND FIELD STUDIES

HANDBOOK

OFFICE FOR RESEARCH

IDAHO STATE UNIVERSITY

HTTPS://WWW.ISU.EDU/RESEARCH/RESEARCH-OUTREACH-AND-COMPLIANCE/ANIMALS-IN-RESEARCH/

I. Introduction to the Procedures Handbook

A. **Background**

To support Idaho State University's (ISU) instructional, research and health education missions, the provision for working with animals in these areas is essential. These animals are a resource that requires management and coordination by a variety of ISU personnel, including the students who benefit from access. Animals are a highly regulated resource. The result: detailed rules calling for a committee to review and approve animal access plans (protocols), animal facilities oversight staff, veterinarian participation, safety plans, and training requirements. Ensuring compliance with these rules is the basis for this Procedures Handbook, published under the authority of the policy ISUPP 7030 General Policy for Animal Use.

B. **Procedures Handbook Explained**

- Primary Reference

This Procedures Handbook, along with Standard Operating Procedures (SOP) posted in the facility, is the ISU references for the Institutional Animal Care and Use Committee (IACUC), Animal Facilities Manager (AFM) and staff, and researchers – faculty and student alike – when preparing for and during research involving animals at ISU. This guidance focuses on providing ISU-specific procedures while referencing the relevant portions of the Guide for the Care and Use of Laboratory Animals, 8th Edition.

- Web-hosted Content

Hyperlinks will not be included in this document in the interest of extending the life of its accuracy and usefulness. Search terms will be provided to direct the reader to the current location of web-hosted forms and documents. With the release of this Procedures Handbook, personnel with responsibilities related to animal studies and care are expected to access the majority of their required reading, training materials, and details of the process through online means. Directions to the related web pages will be included, as search terms, not as URLs or active links.

C. **Applicability**

The guidelines in this Handbook pertain to all animal facility spaces at ISU. This includes the main facility, the fish rooms on the ISU and Meridian campus and any other satellite facilities that are developed. This Procedures Handbook:

- Covers all work with animals by ISU personnel, regardless of location, including wild animal or "field" studies;
- Applies to individuals who include animals in their curriculum or in their research – including faculty, staff, graduate or undergraduate students;
- Describes the ISU oversight roles and authority of positions within the Office for Research (OR) and the Environmental Health and Safety Office to provide direction to other ISU persons seeking to work with animals. These personnel are authorized to acquire and retain sensitive personnel information to achieve compliance with regulations related to research with animals.

- ISU faculty, staff, and students, as well as authorized visitors, are required to comply with the directions provided in this Procedures Handbook to access animals or the facility. Cooperation is expected when dealing with ISU Animal Facilities staff, the attending veterinarian, and the Institutional Animal Care and Use Committee (IACUC).

D. **Relationships**

To ensure a compliant and safe institutional approach to working with animals and caring for them, ISU has defined certain roles in effect within this environment. Each role is listed below, based upon the relevant rules derived from the Guide, 8th Edition, and the AAALAC Program Description.

- Institutional Animal Care and Use Committee (IACUC)

The IACUC operates under the IACUC Chair to ensure that ISU works with and cares for animals by following various rules. The primary IACUC function is to oversee the animal research program at ISU. This includes reviewing protocols, inspecting labs and animal facilities, and semi-annual inspections of the facility and program. This group reviews, requests changes to meet requirements, approves protocols, working within mandated processes. The IACUC function and membership are dictated by OLAW and USDA rules. The IACUC is responsible for follow-up inspections of labs and facilities.

- Research Compliance Coordinator (RCC)

The RCC serves as the receiving point for protocol documents, maintaining the versions of protocols as they proceed to and through IACUC review, compiling the official protocol. Other responsibilities: USDA, OLAW, and other reports; CITI Training system Administrator and monitor for research training compliance; Cayuse point of contact. The RCC serves as the IACUC Administrator.

- Animal Facilities Manager (AFM) and staff

The Animal Facilities Manager is responsible for the safe, compliant operation and use of the Animal Facilities spaces at ISU. The AFM is responsible for the day-to-day management of the facilities. This involves coordinating with researchers, faculty, and their students (pursuing course-related animal facility use), and any visitors to the space. The AFM must ensure persons accessing the Facilities have completed the proper training, have appropriate clothing/personal protective equipment, and have reported any health concerns prior to access to the Facilities or any animals. This oversight requires forms and releases to be collected from all Animal Facilities users and visitors.

- Attending Veterinarian

ISU's compliance with OLAW and AAALAC oversight requires an attending veterinarian to work with the Animal Facilities in an advisory capacity. These services ensure that protocols include plans for appropriate administration of drugs, end-stage processes, and the handling of the animals. The Veterinarian is a resource available to researchers as they plan their animal research projects.

- Institutional Official

The Vice President for Research (VPR) is the Institutional Official designated for ISU. The VPR has

approval authority over certain decisions related to work with animals during research, as well as a decision-making role when any issues may arise. Functionally, the day-to-day oversight of the Animal Care and Use Program at ISU is managed by the Assistant Vice President (AVPR) for Research Outreach and Compliance (ROC). The AVPR for ROC supervises the Animal Facilities Manager and the Research Compliance Coordinator positions.

- Researchers
    - Faculty as Principal Investigators (PI) – A PI is an ISU employee who has the authority to oversee an animal research project.
    - Faculty as Visitors
    - Visitors, non-ISU
    - Student researchers under protocols
    - Students working under course requirements

II. Developing Your Research Project

A. **Selecting a Model for Research**

Choosing an appropriate model must be based on extensive familiarity with the problem or system to be studied (to determine the range of biological responses necessary to the experimental design). This familiarity may be developed by either an extensive review of the literature or from pilot studies. The lead researcher/instructor (hereinafter referred to as "PI;" i.e., the person listed as the PI on the Protocol) can then proceed to select an appropriate model: a whole animal, tissue cultures, or non-animal.

An animal model is a living organism in which normal biological processes can be studied, or in which a spontaneous or induced pathological process can be studied. To be effective, the process being modeled should closely resemble the analogous process in humans or some other species, in one or more ways. Some important criteria of animal models are:

- relevance to the problem being studied;
- the accuracy with which the model reflects all or some important aspects of the problem;
- the model's predictability;
- and the model's availability to researchers/instructors.
- In addition, general species characteristics such as life-history parameters, behavior, and diet can be as important as physiological parameters in species choice. The AV can help as you look at these criteria.

B. **Alternatives to Research Involving Animals**

Alternatives to animal models must be addressed in the protocol and can be divided into four broad categories:

- Modification of existing species of animals. It is sometimes possible to substitute one species of animal for another: e.g., invertebrates may be substituted for vertebrates, or laboratory species (e.g. rats and mice) may be substituted for companion animals (dogs or cats).
- Employ animal-derived material in place of studying whole animals. Although critics of animal research seek alternatives as a way to eliminate animal models in research, many suggested replacements consist of animal-derived material, e.g., cell, tissue, and organ culture. Working with culture specimens avoids potentially painful manipulations of live animals, although these materials must originate from a living animal.
- Replacement of living systems with non-living ones, e.g., using physical or chemical models to study living systems. The study of many biochemical mechanisms, for example, makes use of materials isolated from organs or tissues. Some physical and mechanical models have been developed (mainly for educational uses) and are available commercially. IACUC encourages using such

when feasible.

- Use of mathematical or computer models. Whenever a function or a relationship within a living system can be described mathematically, the possibility exists for developing a mathematical model. Scientists have long employed such models in biological and medical research because they provide the opportunity to vary the parameters involved and to predict what effects different parameters will have on the system. Based on information derived from animal studies, computer models have been developed to analyze relationships within and between living systems.

C. **Project Development**

- PIs anticipating laboratory research involving animals should contact the AFM to ascertain space/housing availability and to discuss needs.
- Consult with the AV for guidance regarding appropriate husbandry, handling, medical treatment, immobilization, sedation, analgesia, and euthanasia of animals. Consultation with the AV is required if USDA animals are used.
- Special requirements for housing, feeding, watering, etc., should be discussed with the AFM prior to submission of the Protocol to the IACUC.
- Please consult with the AFM to determine the lead-time required for your particular animal order, and to ensure your project has both a practical and workable schedule. The interval between ordering and receiving species of animals varies considerably.
- No animals can or will be ordered until the IACUC has approved the associated protocol.

III. Preparing Protocols

ISU requires the completion of a set of documents, called a Protocol, and the completion of their review and approval by the IACUC, before working with animals for a project. Allow plenty of time for the preparation and the review process for these documents. The document set becomes the Protocol under which a project involving animals is permitted; and where the specialized needs of that project – beginning to end – are spelled out. Protocol preparation involves many parties, not only the researcher or instructor wanting to work with animals but also the IACUC, the Animal Facilities Manager (AFM), and the Attending Veterinarian (AV). See Section X. for a flow chart describing this process.

A. **Who submits a Protocol**

The lead researcher or faculty member for the animal project submits the Protocol. Within the protocol documents, this person is identified as the Principal Investigator (PI). Students may not serve as PI on a Protocol.

B. **Timing for Protocol Submission**

Protocols must be submitted by the first of each month and well in advance of the planned research start date. Protocols received after the first will be held until the next meeting.

Submission deadlines and meeting dates are listed on the Research Outreach & Compliance webpages under IACUC. The IACUC does not regularly meet in the summer.

Protocols for summer work should be submitted no later than the April meeting.

Protocols are submitted electronically through Cayuse IACUC. No animals may be purchased, or work with them conducted before an approved protocol is in place.

C. **The Protocol**

Within the Cayuse system you will select the appropriate form for animal husbandry, breeding studies, field studies, or teaching projects.

Additional forms are needed to gain access to the animal facility. These documents must be completed by each person named in the protocol, or added through amendments. These forms are completed on-line through Docusign. Do not include them in the protocol.

*Acknowledgment of working with or around research animals
*Code of Ethics
*Animal Facility Personnel Statement

These forms can be found on the Animal facility website. This must be completed before anyone will be granted access to the Animal Facility.
The Medical Surveillance form must also be completed by each person listed on the protocol. It is submitted via Docusign.

To improve your IACUC review, work with the IACUC Chair, the Attending Veterinarian, the Animal Facility Manager, or the Research Compliance Coordinator before (and while) you prepare your

protocol to ensure proper completion of all sections.

The Protocol document set is first checked by the RCC to ensure it is complete. The set is then posted to the IACUC members for review. Each IACUC member reviews the protocol to ensure that all information and the proposed work with animals meet the standards outlined in The Guide, the Animal Welfare Act, and associated policies and fits within University guidelines and policies, as applicable.

The Committee can:

- fully approve the protocol as written,
- request revisions with subsequent review to be carried out by the full committee or by a designated member of the IACUC with results announced during the next IACUC meeting, or
- disapprove of the protocol.

The Research Compliance Coordinator will contact the PI with requested revisions.

D. **Frequently Asked Protocol Questions**

- What are common problems with first protocol submission?
    - Target animal numbers don't match throughout the documents
    - Project workflow description doesn't clearly explain what happens to each animal (a flow chart helps)
    - Techniques are not written for the layperson to understand
    - All deviations from standard procedures are not justified clearly
    - Lack of online CITI training (see ISU Animal-Related Training Programs)
    - The literature search doesn't address alternatives, pain and stress reduction, and refinements to techniques
- When is my protocol up for renewal?

Approved Protocols will be held on file as "active" for three years or until the project's completion (whichever comes first). Active protocols must be reviewed and updated yearly, through an annual review, which includes a current literature search, current personnel statements, and any changes in procedures and/or reports of adverse events involving animals or personnel. If an annual review is not received before the yearly anniversary the protocol could be suspended and the animals transferred to a holding protocol. It is helpful if the PI (i.e., the researcher or instructor in charge of the project, as specified in the Protocol) sends IACUC a message when their project/protocol is complete.

- Who are the primary Points of Contact?
    - IACUC Chair – Dr. Erin Rasmussen erinrasmussen@isu.edu
    - Attending Veterinarian – Dr. Shelley Knight shelleyknight@isu.edu
    - Animal Facilities Manager – Mia Benkenstein nettmia@isu.edu
    - Research Compliance Coordinator – Tom Bailey tombailey@isu.edu

IV. Gaining Access to the Animal Facilities

To access the Animal Facilities, several steps must be completed in advance of first entry or use of the facilities. These steps vary depending on the role of the person – Principal Investigators have greater responsibilities than do their graduate assistants, or students enrolled in an academic course expecting to work with animals. Questions should be directed to the Animal Facilities Manager, Mia Benkenstein at nettmia@isu.edu.

A. **Training**

Before a PI, student, research assistant, or other parties can gain access to the Facilities three types of training are required.

- CITI Training Modules

PIs, other investigators, and students must complete the Laboratory Animal Welfare module (Question 6 in CITI) with the Species-Specific Modules based on the animals identified for the protocol or course. Detailed information on navigating the CITI module sign-up process to satisfy this requirement appears in Section 11. CITI Training Instructions at the end of this Procedures Handbook.

If you completed CITI training within the past 4 years at another institution, please submit the certificate of completion to the Research Compliance Coordinator. The RCC will confirm that you may be excused from taking the course again. If so, you will be added to the refresher training cycle.

- IACUC-provided Annual Training

All persons planning to work with animals must participate in this training. A session is held at the start of the fall semester (and again at the start of the spring semester, as needed) serving as an orientation to using the ISU Animal Facilities.

- Animal Facilities Manager-led Training

This training session is held with researchers before they are allowed to work in the Facilities. The AFM provides specific information needed to work in the ISU Facilities based on the particular protocol.

B. **Responsible Use of the Animal Facility**

- Appropriate Clothing

The researchers' Bengal ID card must be worn in the Animal Care Facilities. Gowns, bouffant hair covers, and beard covers are also required and are provided at points of entry. These items are disposed of at the facility. No open-toed shoes are allowed.

Cosmetics may not be applied in areas where animals are studied, examined, or housed.

- Restricted Items
    - No outside food or drink is allowed.
    - No unauthorized animals are allowed in the Facilities or associated areas.
    - Nothing that does not pertain to immediate use in the animal rooms or surgical area.
    - No cameras (including cell phone cameras) or photography is allowed unless cleared through the AFM.
    - Cell phones and MP3 players are allowed; however, one ear must be available to hear at all times (e.g., only one earbud may be used).

C. **Miscellaneous**

- All training and paperwork must be completed before working with animals or entering the Facilities.
- Researchers planning to use infectious, hazardous, or toxic material(s) must notify the AFM prior to use, and a Material Safety Data Sheet (MSDS) must be provided for the file with the AFM. A risk assessment must be completed before work can begin. Use of infectious material must have the Institutional Biosafety Committee's approval
- The PI is responsible to provide their research equipment (e.g., gloves, syringes, needles, etc.), and must clean up their work area after each use and at the end of a project.
- Only personnel designated by the AFM may operate equipment such as sterilizers, cage washers, etc.
- Tours and visits are discouraged. When visits are required, contact the AFM well in advance. Visits may be conducted during normal working hours only (8 am – 4 pm M-F), and an Occupational Health and Safety Form must be signed by each visitor and turned in to the AFM prior to access.
- Concerns or complaints may be directed to the AFM, the Chair of IACUC, or any IACUC member. As described in the IACUC SOP all concerns will be reviewed by the entire IACUC.

D. **Occupational Health and Safety**

There are requirements related to occupational health and safety procedures. This information and some related forms are found in the OHS manual through the ISU Environmental Health and Safety website.

E. **Frequently Asked Animal Facilities Access Questions**

- How do I get into the AF?

Complete the steps listed in this section of the Procedures Handbook.

- What are the hours of the AF?

The Animal Facility hours are Monday through Friday 8:00 am to 4:00 pm.

- Can I bring guests into the Facilities?

Guests are welcome only after contacting the AFM, arranging a time during normal working hours, and an Occupational Health and Safety Form is signed and on file. No guests are allowed in the facilities after hours.

- What if my Bengal card does not let me in?

If your card does not let you in, contact the AFM during working hours to reenter your card in the door. After hours call 208-251-5166 so that you may gain access to the facility.

- What if I get a new Bengal card?

If a card is replaced, it will automatically update the system.

- When can I begin working with animals?

You may work with animals after you have completed all of the training and signed forms are on file including CITI modules, Personnel Statement, Acknowledgment form, Code of Ethics, Medical Surveillance, and training with the AFM.

- Why am I required to answer health questions?

The university along with the IACUC has designed an Occupational Health and Safety Program that is required by the federal government for the health of those persons working with animals and in laboratories. A medical doctor will review your health record to recommend what is necessary for your safety to work with animals. Although you may not currently have allergies to animals, there is a possibility while working with them you may have them in the future.

- May I take pictures in the animal facility or satellite rooms?

Pictures and/or recordings of any sort may not be taken in the facility or satellite rooms without the permission of the AFM.

V. Working with Animals at the Animal Facilities

To work with animals, whether as a researcher, an instructor or a student, a variety of requirements and procedures must be learned and consistently practiced. These instructions are role-based, with Principal Investigators bearing responsibility for their students or staff working with their project animals.

A. **Responsibilities**

Prior to purchasing or acquiring animals, arrangements must be made with the Animal Facilities Manager, an approved Protocol must be on file, any required permits obtained, and quarantine (if any) arranged. Unless immediately undergoing terminal procedures, all animals are to be acclimated to their new environment before any use

- Only the AFM can purchase animals. To purchase animals, you must fill out the Animal Order Form and submit it to the AFM. See the website.
- You will be notified by text or email when your animals have arrived. Unless otherwise requested, they will automatically be housed in suitable space within the Facilities. You should then check your animals for compliance with your order. Notify the AFM immediately of any problems.
- Animal Inventory Sheets will be completed daily by Animal Care Facilities personnel or the researcher and abnormalities will be reported to the AFM. It is the duty of the User to monitor and check their animals.

B. **Acquisition and Housing**

All arrangements for acquiring and housing animals from any source must be made through the Animal Facilities Manager. Per Diem charges will be assessed, with rates dependent upon species and number of animals housed – the Animal Facilities Manager should be contacted for the latest information on Per Diem charges. PIs (the lead researcher or instructor listed on the Protocol) are to include such costs in their project budget when applying for external funds.

PIs with animals requiring special care, equipment, or supplies, or any exemptions from standard animal care procedures, must have prior IACUC approval and must inform the Animal Facilities Manager so that appropriate arrangements can be made. PIs must notify the Animal Facilities Manager if their animals will be exposed to materials or procedures which may be hazardous to personnel. A risk assessment conducted by the ISU Environmental Health and Safety department must be in place.

If animals are to be shipped or PI-transported from other than an approved/registered facility, the Attending Veterinarian and Animal Facilities Manager must be consulted beforehand. They will assist the PI in making sure transportation conditions and containers are species-appropriate and conform to pertinent standards, laws, and regulations.

C. **Animal Husbandry and Veterinary Care**

- Husbandry

The Guide has established housing and husbandry standards, and ISU is committed to conforming

to those standards. The Animal Facilities Manager, in consultation with the PI, is to select suitable cages or other housing, in accordance with The Guide. Environmental factors, such as temperature, humidity, ventilation, illumination, feed, bedding, sanitation, waste disposal, and vermin control are all important and necessary to providing optimal housing conditions for the animals. IACUC may approve environmental conditions that differ from the conventional situations only if strong scientific justification is established in the Protocol.

Compiling and maintaining animal health records are the foundation of both husbandry and veterinary care.

- Acclimation and Quarantine

A plan for adequate quarantine and health surveillance/testing will be established prior to animals entering the Facilities. Rooms for such animals have additional restrictions concerning access by personnel; please discuss any concerns in this regard with the Animal Facilities Manager. The extent of any quarantine period is determined by the species and by knowledge of the animal's source and previous history. In quarantine, animals will be separated by species. The isolation, quarantine, and acclimation program for newly arrived animals is necessary to provide time to assess their health status, allow them to recover from the stress of shipment, have an opportunity to adapt to their new environment, and minimize the introduction of disease into the Facilities.

Arriving animals, regardless of source, must be allowed an acclimation period before study. Effects of transport, large temperature fluctuations, as well as changes in feed, water, and housing conditions are physiological stressors that can impact both animal health status and research results. Acclimation times are three days for rodent species, seven days for non-rodent mammals, and are as-needed for non-mammal species.

Animals may be exempt from this policy only if they meet the following criteria:

- Animals undergo immediate terminal procedures
- PI gives scientific justification for why acclimation is not necessary or would have a negative impact on the project. This must be outlined in the protocol and approved by IACUC ahead of time.

Quarantine and surveillance are required for all animals from non-commercial sources. Colonies may be exempt only if they meet the following criteria:

- The colony will only be in existence for six weeks or less
- All the animals will be eliminated and the room completely emptied and sanitized before any new animals are introduced.

- Initial Health Status

Upon arrival, Animal Care Facilities staff will visually inspect each animal, reporting any concerns to the Attending Veterinarian. Rodents from vendors or approved outside sources (e.g., transferred from another university) must have accompanying health records. Fecal samples will be collected for medical testing during this initial inspection. Sentinel animals (if applicable) will be selected and placed in appropriate racks.

(Sentinel animals are periodically euthanized and tested for diseases as a means of monitoring

colony health; PIs need to be aware that if sentinels are required, they must be included in their project budget. Questions concerning sentinel animals should be addressed to the Animal Facilities Manager or IACUC.)

Non-rodents' species will have an Initial Health Plan formulated by the Attending Veterinarian, Animal Facilities Manager, and the PI, based on species, source of animals, and risk to staff and other animals/colonies.

- Surveillance, Diagnosis, Treatment, and Control of Disease

All animals will be checked daily in their rooms, including weekends and holidays. Signs of illness, injury, or abnormal behavior are reported to the Animal Facilities Manager and recorded on the procedure sheet behind the inventory sheet.

Daily monitoring records are kept in the room. As with the Initial Health Plan, the Attending Veterinarian, Animal Facilities Manager, and PI will formulate a plan based on species, source of animals, and risk to staff and existing colonies.

All health concerns are to be recorded and reported to Attending Veterinarian. After initial examination and evaluation, a plan will be formulated by the Attending Veterinarian with the PI and Animal Facilities Manager for diagnosis, treatment, and control. This may include euthanasia and necropsy, blood work or other diagnostic modalities, and removal/quarantine of individuals.

D. **Frequently Asked "Working with Animals" Questions**

- What does it cost to use the Animal Facilities?

Ask the AFM for current per diem rates.

- What is included in my per diem?

Per diems pay for the husbandry of the animal, including food, bedding, water, room care, cage cleaning, PPE for techs and assistant researchers, except gloves as it pertains to research; the cleaning of the facility, and all other things related to the care and access to the animals and their health checks. Expenses and arrangements beyond keeping the animals clean and healthy in the facility are not covered by per diems, that is per diems do not cover an individual researcher's specific project needs: drugs, containers, special caging, equipment used for their research, sutures, health or tissue testing.

- How do I order animals?

Only the AFM can order animals. Use the order form found on the Animal Facilities website or contact the AFM to receive a form.

- Can I transport animals?

Contact the AV and AFM for guidance.

- Available Veterinarian services?

The Attending Veterinarian maintains regular on-campus hours (~5 hours per week) and is available "on-call" to:

- assess animal health
- aid in prevention, control, diagnosis, and treatment of animal disease and injury
- consult with researchers on handling, restraint anesthesia, analgesia, and euthanasia
- train personnel in the appropriate surgical techniques and procedures
- monitor surgical procedures and post-surgical care
- consult with researchers about their protocol. (This is required if using USDA animals.)

- What are the basic animal services provided by the Facilities?

Typically (and as required by pertinent national standards, laws, and regulations) the following describes the most basic level of care for animals in the Facilities:

- all animal care is supervised by the AFM
- all animals have adequate water and are fed food that meets or exceeds standards for good nutrition for laboratory animals (as noted above, any special diets must be handled through the AFM)
- all feeding and watering devices are cleaned as needed (minimum once weekly)
- cages/housing are cleaned as needed; cleaning intervals must be based on individual species' needs
- all animals leaving the facilities for study in other locations will be properly housed in clean cages or other appropriate housing.

- How do I get controlled substances for use in my research with animals?

If you are using a controlled substance as part of your research you will need to secure your own DEA license. See the ROC webpage for details under the Use of Controlled Substances tab.

Controlled substances for euthanasia are provided by the Facilities.

VI. Working with Animals in the Field

A. Responsibilities

- The protocol must be completed, along with the protocol form for field studies. These are submitted for IACUC review.
- PI must have all necessary licenses and permits
- All researchers must take the appropriate CITI training
- Be aware of any requirements for doing research out of the state of Idaho.

B. Frequently Asked Questions about Field Work

- Is it permissible to take a firearm when working in the field?

Use and possession of firearms must comply with ISU policies and Idaho law.

VII. Continued Monitoring

A. **Annual Review**

Yearly you will receive paperwork for an annual review; This is sent to you 3 months before the date of your annual renewal. You must submit the completed annual review to anmlcare@isu.edu at least 1 month before the anniversary date of approval.

B. **Post-approval monitoring (PAM)**

PAM activities are performed to provide assurance to regulatory agencies and the ISU IACUC that animal experiments are performed in accordance with approved IACUC protocols. The post-approval monitoring process confirms the consistency and accuracy of approved protocols and practices.

- Post Approval Monitors

The Post-approval monitors (PM) are typically Animal Care Staff (ACS), the Attending Veterinarian (AV), IACUC members and consultants, and external consultants.

- Types of PAM Methods

PAM methods are described generally in The Guide (pgs. 33-35) and include the following:

- Continuing protocol review;
- Laboratory inspections (conducted either during regular facilities inspections or separately);
- Veterinary or IACUC observation of selected procedures;
- Observation of animals by animal care, veterinary, and IACUC staff and members; and
- External regulatory inspections and assessments.

ISU's IACUC and Animal Care program uses these PAM methods in the following manner:

- Continuing protocol review

A primary PAM takes place at the annual protocol review, which is an opportunity for the investigator to submit proposed amendments for future procedures, to provide a description of any adverse or unanticipated events, and to provide updates on work progress. Field research protocols will be monitored at least once every three years, or more frequently, at the discretion of IACUC or Attending Veterinarian. For the triennial review, a new protocol submission is required and the IACUC may request a progress report on the use of animals during the previous three years.

- Laboratory inspections

Semi-annual facility inspections are performed by IACUC members with the assistance of the ISU Animal Care Staff (ACS) twice a year. While focused primarily on facilities, these inspections also support protocol compliance review in the following ways: a) mechanism to monitor compliance with facility-related issues regarding equipment, supplies, and processes, b) monitoring of drug storage and usage, c) monitoring of surgical and procedure logs, and d) monitoring for potential

animal health and welfare issues. Semiannual reports of visits conducted, including corrective actions, are reviewed at a convened IACUC meeting and submitted to the Institutional Official. Information from these reports can be used during the annual review of a protocol

Importantly, issues of animal care that pose an immediate threat to animal welfare will be referred to the Attending Veterinarian or IACUC member for immediate resolution.

- Informal PAM interactions and observations

Activities involving live vertebrate animals at ISU are subject to routine monitoring and evaluation by the ISU ACS, AV, or IACUC members. These include, but are not limited to: a) daily observations of animal numbers, health, and welfare, b) periodic observations of standard procedures, including surgeries, and c) monitoring of compliance with facility rules, PPE, and standard laboratory practices. Observations, logs of these data, and discussions that arise from them can be used as PAM. In addition, content may include how the study is progressing, whether the PIs and staff are experiencing any difficulties with their procedures or study, any changes to the procedures, adverse effects, etc. Notes of these informal conversations should be identified to the PI as PAM during the conversation with the PI and can be documented by a quick email summary that goes to the PI and the animal care general mailbox. The IACUC Administrator will upload these conversations to Box.

"For cause" monitoring may be conducted at any time by the ACS, AV, or IACUC members, with or without advance notice to the Principal Investigator or research personnel when there are any animal safety or noncompliance concerns. These issues should be reported to the AV and IACUC directly or anonymously.

- External regulatory inspections and assessments

PAM may also be conducted during external inspections, such as those by the USDA, OLAW, or AALAC. In addition, other equipment or vendor visits (e.g., anesthesia machine annual inspections, vendor visits of equipment to PI and facility staff) may document PAM in their reports.

- Formal PAM of Approved Protocols

Formal PAM procedures can be conducted at the discretion of the IACUC or Attending Veterinarian, if, for example, there is a Category D or E designation, or if a non-compliance or other animal concern has occurred under the protocol in the last year, or other issues in which protocols may need extra monitoring.

- Follow-Up Process for Animal Care Concerns

Any major concern that is revealed by PAM will be relayed to the IACUC. The IACUC will discuss the animal care concerns and determine corrective action, if appropriate. The IACUC chair or AV will follow up with the PI on any issues that require corrective action and will attempt to support this action by providing or scheduling required training or assistance with form preparation (e.g., amendment submission). Departures from protocols will be discussed also to determine whether they are reportable to the Office of Laboratory Animal Welfare (OLAW), United States Department of Agriculture.

On occasion, additional monitoring sessions may be part of the follow-up to assist with and ensure

proper corrective actions.

- Appeal Process

PIs who disagree with monitoring results, corrective action plans, or recommendations have 10 business days from receipt of the written report to submit an appeal in writing to the IACUC chair. The appeal should include the specific provisions being challenged, the reason for the appeal, and the justification for a different outcome.

C. **Unscheduled walk-through**

These will occur without advance warning to the PI. Facility staff will conduct daily monitoring of animal health, required documentation, surgical records, and other key data.

VIII. CITI Training Instructions

These are the instructions on how to register and enroll in CITI online training, as noted in IV. Gaining Access to Animal Facilities, Section A. Training. CITI Laboratory Animal Welfare modules are required for both working with animals in laboratory settings and for field research projects.

Students: You will need to know which animal species you will work with or study in order to complete training in the CITI system. You must ask your Principal Investigator or instructor for this information. Page 24 of this document displays the list of choices that are available.

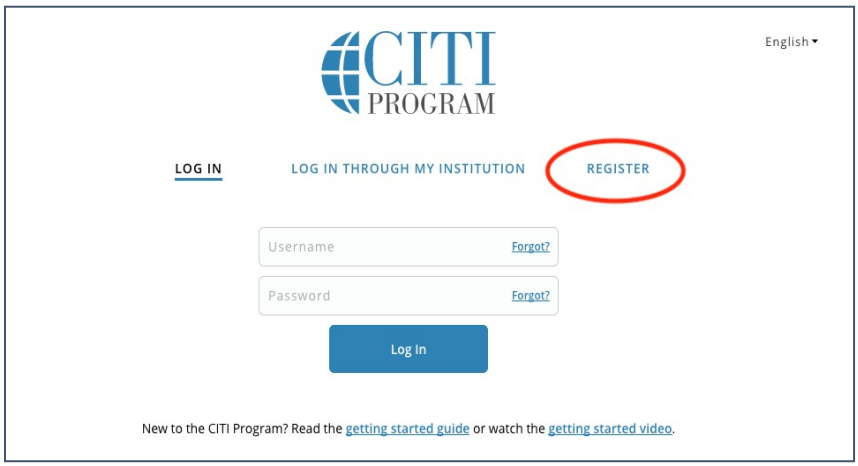
Follow the detailed instructions on the next page to get started with CITI.

Have issues with the software? Contact Tom Bailey at (208) 282-2179, bailthom@isu.edu.

IX. CITI Program Instructions for Animal Users

1. Go to: https://www.citiprogram.org/index.cfm?pageID=14&languagePreference=English&region=1

2. Register: If you have not registered with CITI, click as seen below (if already registered, skip to number 3).



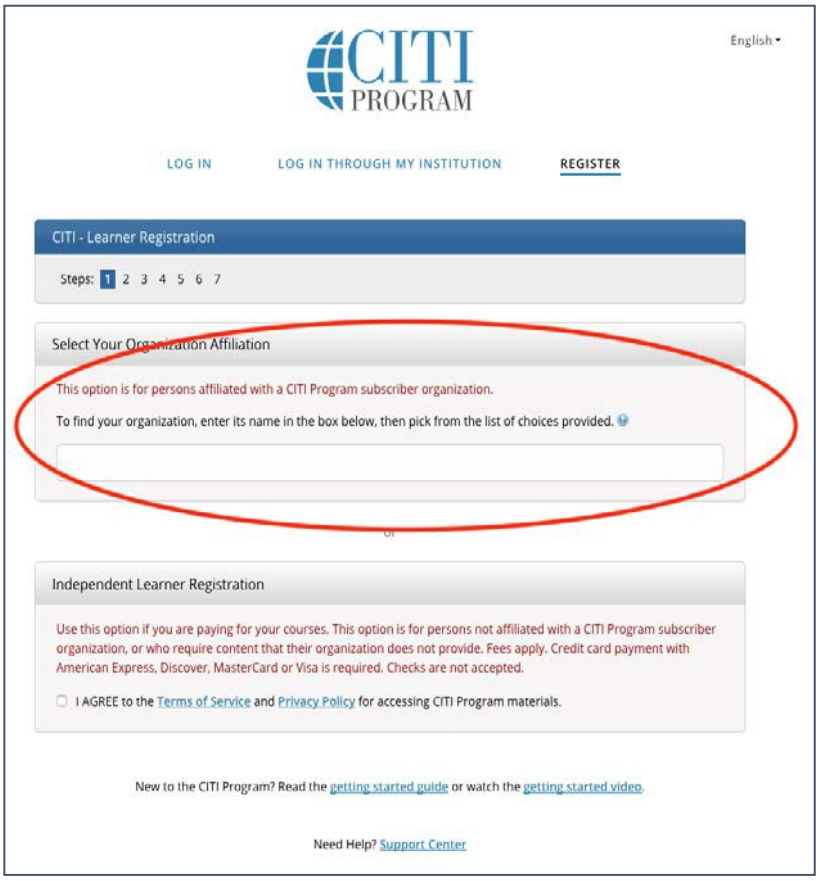
Complete each screen for each of the 7 steps.

Steps: 1 2 3 4 5 6 7

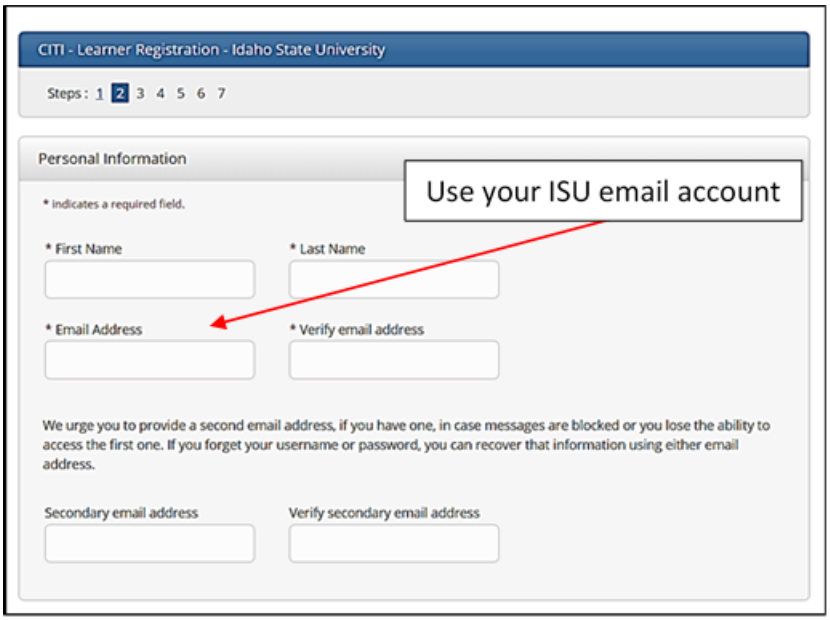
Step 1. You will need to type in "Idaho State University" as your Organization Affiliation, hit enter, then agree to:

- The Terms of Service
- The Privacy Policy
- Affirm that you are affiliated with ISU

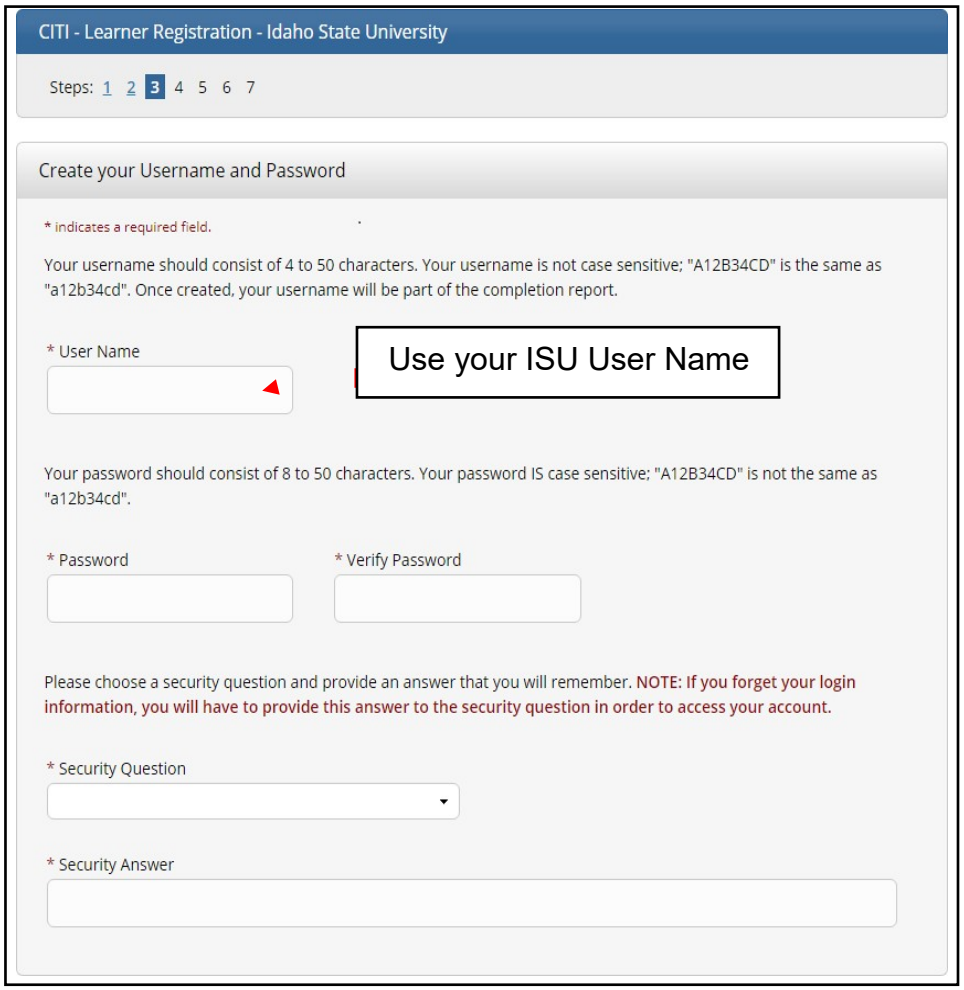
You must respond to each of these fields to continue registration.



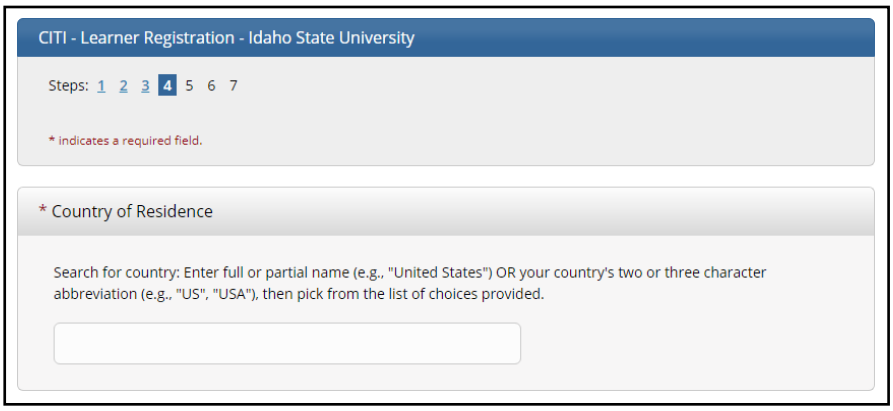
Step 2. Fill in the information requested.



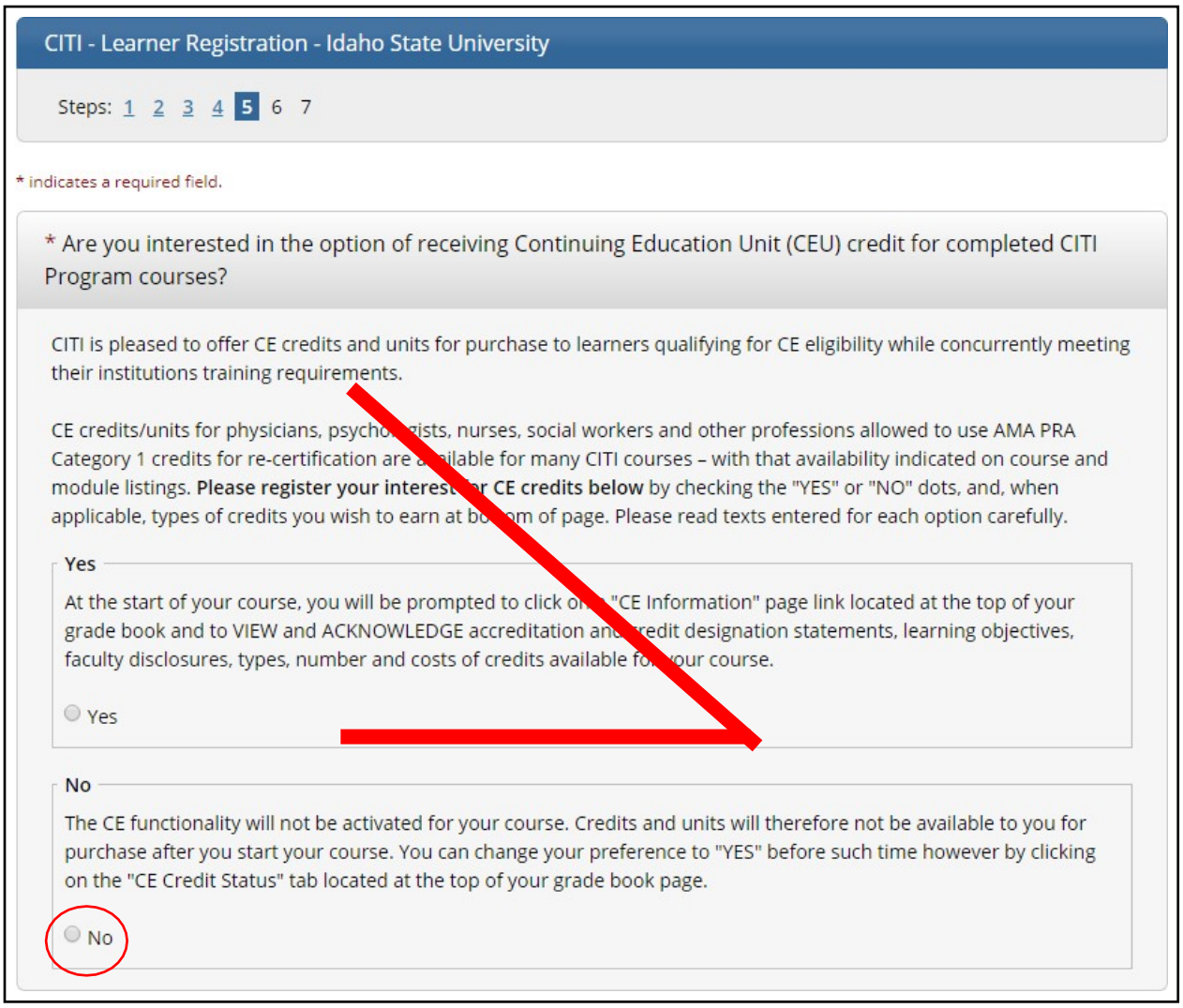
Step 3. Create your Username and Password.



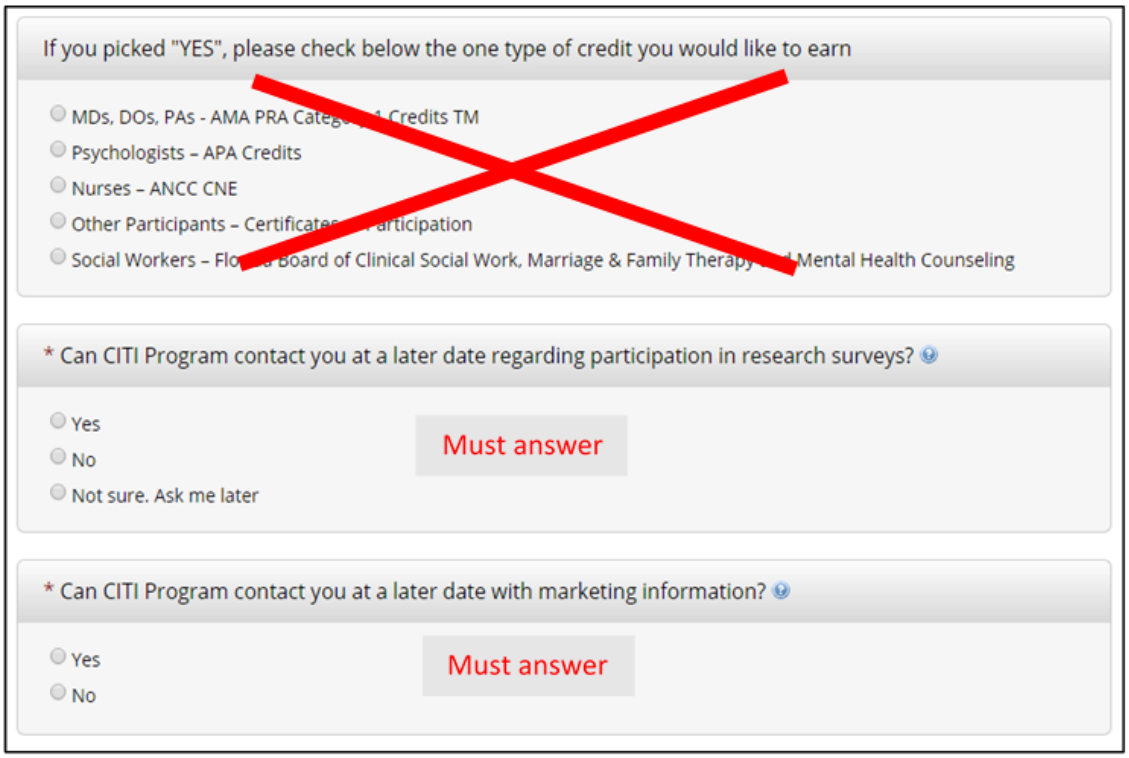
Step 4. Country of Residence.



Step 5. Answer NO to the CA credit question, because **ISU does not support this.**

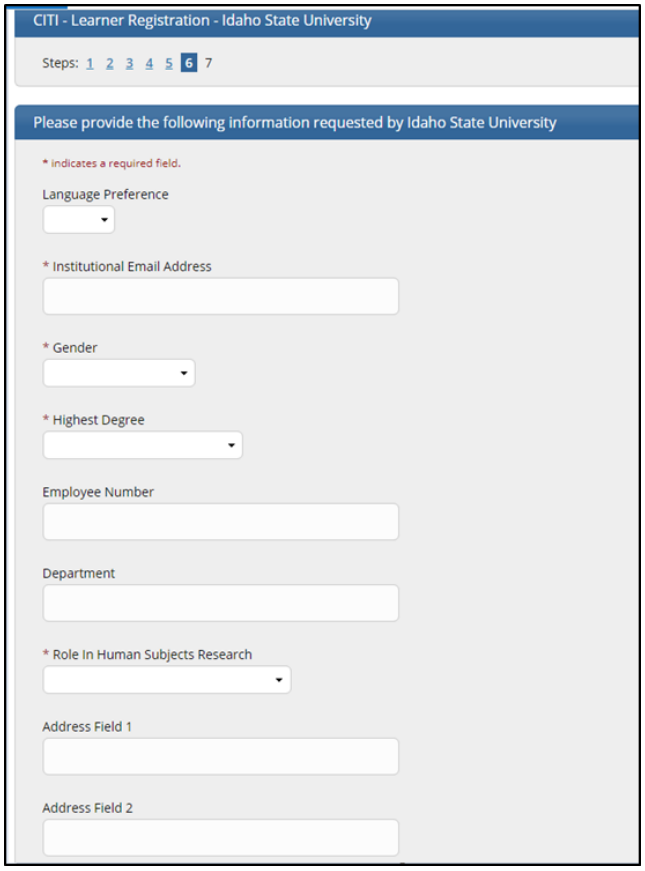


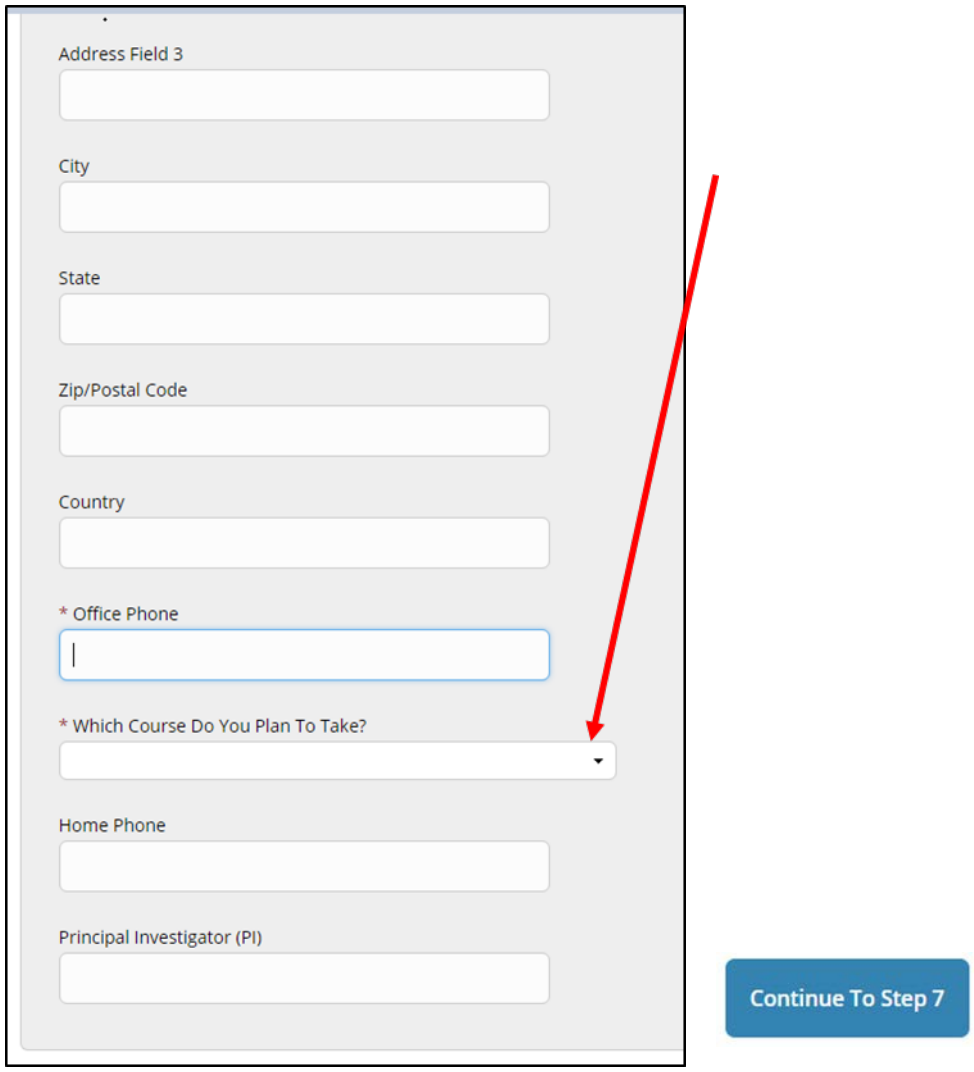
Step 5. Continued – You must also answer the * questions in order to move to Step 6.



Step 6. This is the demographic information. If you do not have an office phone number, you may use a department phone number instead.

Note: These fields in the CITI program display a long continuous screen. These screenshots are split to fit the instruction pages.





Step 6. Continued – Answer the required questions. Select "Laboratory Animal Welfare" from the drop-down menu.

Step 7. Here you will select the Curriculum

There are 8 Curriculum Options, listed as Question 1 thru Question 8.

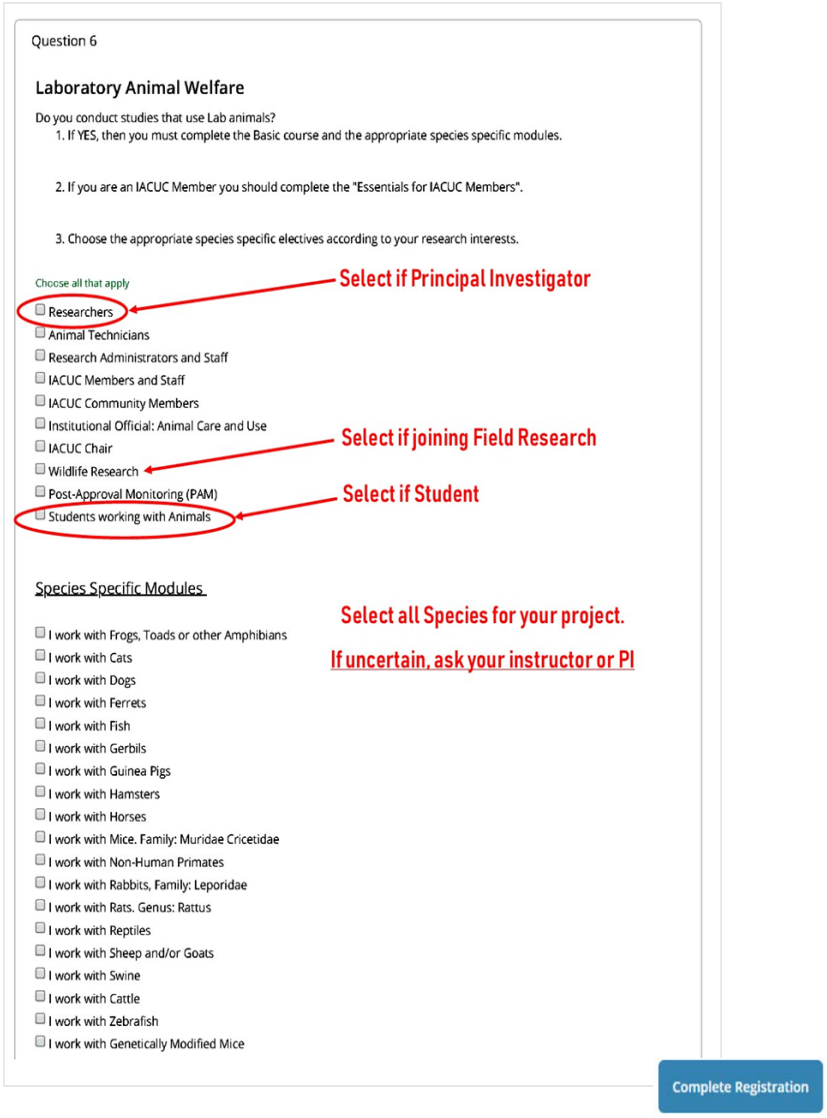
- Skip Questions 1, 2, 3, 4
- Answer Question 5, "Would you like to take the Conflicts of Interest course?", by clicking "No"
- Question 6 "Laboratory Animal Welfare" see following detailed steps.

All animal-related questions are under Question 6.

a) If you are a Principal Investigator you will choose "researchers" from the list below.

b) Students will choose "Students Working with Animals" from the list below (taking one of the species modules is a minimum requirement).

c) If doing Field Research, both Principal Investigators and Students will choose "Wildlife Research" from the list.



Choose any species-specific modules from the list that will pertain to your project.

- Answer Questions 7 "Export Controls" and 8 "Biosafety/Biosecurity", by clicking "Not at this time"

When you have completed the module(s), an email will be sent to ISU's CITI administrator and then will be forwarded to the Animal Care Facility.

CITI Training must be completed to work with animals.

Contact Tom Bailey (208) 282-2179 with CITI software questions. For questions about animal species call Mia Benkenstein Animal Facilities Manager, (208) 282-3895 or nettmia@isu.edu

X. Animal Research Protocol Review Cycle (diagram)

See the following page for this diagram.

Diagram Key:

AFM – Animal Facilities Manager

DMR – Designated Member Review

IACUC – Institutional Animal Care and Use Committee

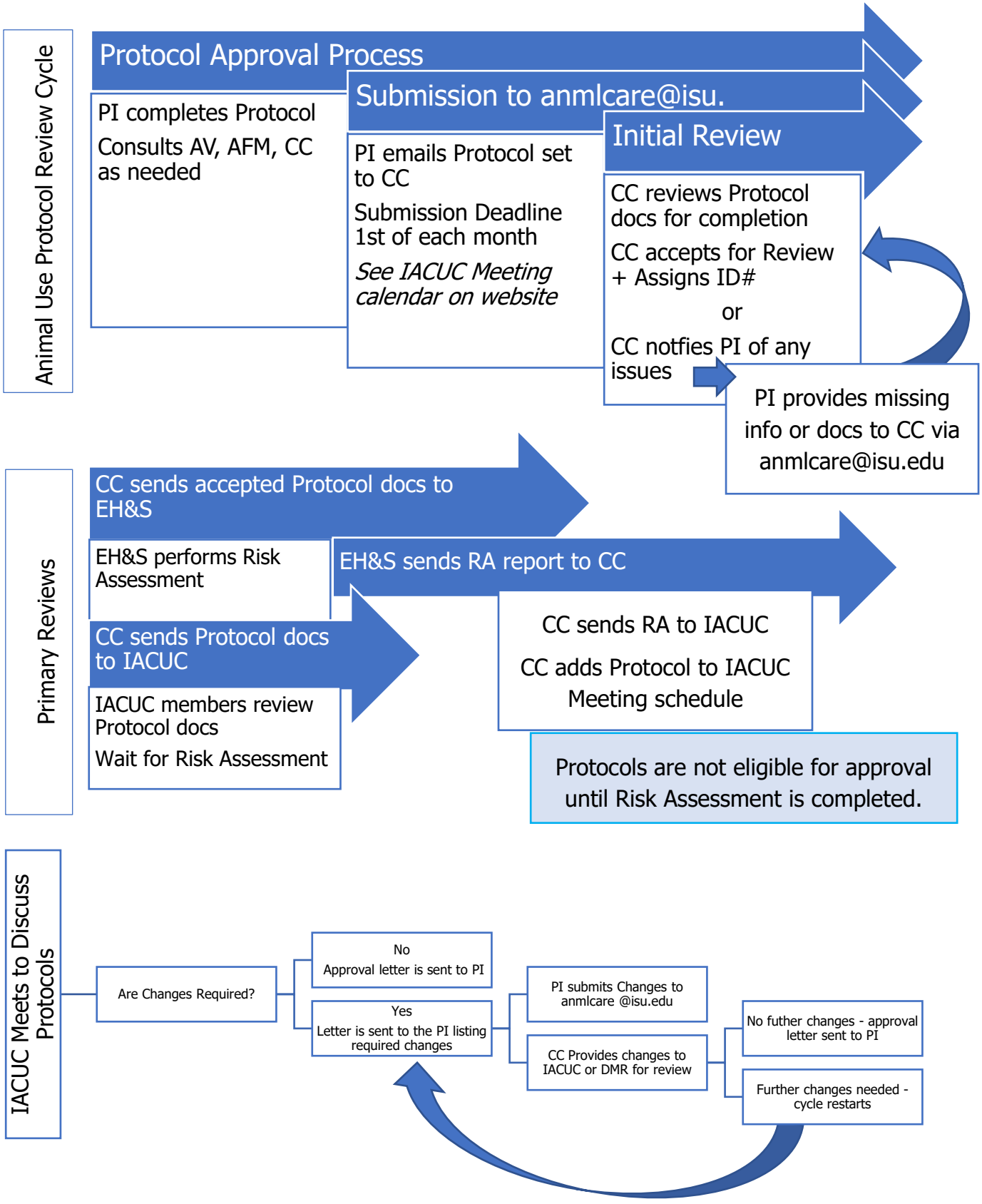
PI – Principal Investigator

AV – Attending Veterinarian

CC – Compliance Coordinator

EH&S – Environmental Health & Safety Office

RA – Risk Assessment


Animal Use Protocol Review Cycle
Protocol Approval Process
PI completes Protocol
Consults AV, AFM, CC as needed
Submission to anmlcare@isu.
PI emails Protocol set to CC
Submission Deadline 1st of each month
See IACUC Meeting calendar on website
Initial Review
CC reviews Protocol docs for completion
CC accepts for Review + Assigns ID#
or
CC notfies PI of any issues
PI provides missing info or docs to CC via anmlcare@isu.edu
Primary Reviews
CC sends accepted Protocol docs to EH&S
EH&S performs Risk Assessment
EH&S sends RA report to CC
CC sends Protocol docs to IACUC
IACUC members review Protocol docs
Wait for Risk Assessment
CC sends RA to IACUC
CC adds Protocol to IACUC Meeting schedule
Protocols are not eligible for approval until Risk Assessment is completed.
IACUC Meets to Discuss Protocols
Are Changes Required?
No
Approval letter is sent to PI
Yes
Letter is sent to the PI listing required changes
PI submits Changes to anmlcare @isu.edu
CC Provides changes to IACUC or DMR for review
No futher changes - approval letter sent to PI
Further changes needed - cycle restarts