

# **Institutional Animal Care and Use Committee (IACUC)**

# **IRBNet Assistance**

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**Note:** If you have any questions or need any assistance as you read through this document, please contact the Research Integrity & Compliance Office at 907-786-1099. For technical issues or questions regarding your IRBNet account, please contact the IRBNet Support Desk (1-877-261-6461 or <a href="mailto:support@irbnet.org">support@irbnet.org</a>).

#### **GENERAL INSTRUCTIONS AND GUIDANCE**

#### Learn about IRBNet

IRBNet maintains a Resources page with training videos and PDF files that walk you through the registration process, submitting a new project, and post-submission tools. Log-in using the username "anchorage" and the password "training" (do not include quotation marks). The Resources page can be accessed here: http://irbnetresources.org/

#### Locate Forms

Authorized IACUC forms and templates are located on IRBNet. From the Study Designer page, either:

- Select a document from the drop down list of Forms and Templates under University of Alaska Anchorage IACUC, Anchorage, AK (second option in the drop down menu).
  - Select the form or template that you need and save it to your computer to complete. Your work will not be saved and uploaded properly if you fail to save a copy to your computer.
- Click the Add New Document button to:
  - Upload a document from your computer, which may include a completed copy of your research protocol, SOPs, etc.

# Required Signatures

Signatures within IRBNet are compliant with federal regulations on electronic signatures.

- Principle Investigator signature is required for:
  - New studies
  - o SOPs
  - Continuing review
  - Significant changes that require review by the IACUC
  - Serious adverse event reports
- A signature 'on behalf of' the PI should be used only in the rare event when the PI cannot access IRBNet.

Share with other team members, collaborators, or research supervisors

You can share, or give access to, your IRBNet study with any person who has Internet access. This includes:

- UAA animal researchers
- Outside UAA animal researchers
- Sponsors
- Collaborators

Before you share the study, the person must:

- Register with IRBNet (http://www.irbnet.org)
- Complete the User Profile, and
- Affiliate with the University of Alaska Anchorage. It is possible to affiliate your account with more than one site (e.g., University of Alaska Anchorage and University of Alaska Fairbanks) as a researcher.
- Reply to the IRBNet e-mail to complete your registration

**NOTE:** Any personnel in the Research Personnel List must create an IRBNet account and be given "Read" access to the Assurance in IRBNet.

# Assure that an application is complete

The Principle Investigator is responsible for ensuring that submissions to the IACUC are complete. Whether or not the PI or a designated member of the research team submits the package, the application

is not complete until all required elements are received by the IACUC. *Incomplete submissions will not be scheduled for IACUC review.* 

#### Save file versions

- If you are sharing or preparing a draft document, **save it to your computer** (choose save as) before uploading it to IRBNet. Otherwise, you may lose your work.
- If you are replacing a document that has already been uploaded to IRBNet, choose the Update option to replace the current file. Otherwise, you will have multiple versions of that document in your package.

# **NEW STUDY**

Registration/IRBNet application

Step # 1: If you are not already registered as an IRBNet user, go to <a href="http://www.irbnet.org">http://www.irbnet.org</a> to make an account. If you are already registered, please skip to Step #2.

Using the 'New User Registration' link in the upper right hand corner of the page:

- 1. Create a username and password. You will be asked for a password hint. Select Continue.
- 2. Read and 'Accept' the terms and conditions.
  - a. In the search box for affiliated institutions, type "University of Alaska Anchorage" (no quotation marks). Double check that you have selected the UAA IRBNet system.
  - b. If you have already created an IRBNet account previously and you are affiliated with another institution, you will select User Profile in the upper right corner once you are logged in. Select Add an Additional Affiliation and select University of Alaska Anchorage.
- 3. Supply your contact information.
- 4. Confirm your registration information and click Register.
- 5. Wait for an activation e-mail from IRBNet. This may take a minute.
- 6. Confirm your IRBNet account through the activation link in the e-mail.

**NOTE:** If you do not register with IRBNet and affiliate your login with the University of Alaska Anchorage, you will not have access to UAA's specific forms and you will not be able to properly submit your protocol to the IACUC.

**NOTE 2:** Submit a standard operating procedure as a separate protocol package.

# Step # 2: Create a New Study

- 1. Create a new study by clicking "Create New Project" on the left hand side.
- 2. The Designer page should automatically appear after you click "Create New Project." Prepare the documents you will submit. New studies must include the protocol form, personnel list, and OHSP Hazard Evaluation Survey if you are working within UAA animal facilities or working directly with animals in other settings. Standard Operation Procedures (SOPs) are supplemental forms that should be submitted with a new IRBNet study. In other words, SOPs require separate review and approval from your research protocol.
- 3. Verify that the research team has completed required training for animal research.
  - a. The IACUC offers an online training course that fulfills the formal training requirement for UAA faculty, research associates, graduate students, undergraduate students, staff, part-time help, summer interns or externs, anyone working with live vertebrates in a research, teaching, or diagnostic setting. For more information about the the IACUC training, visit: <a href="http://www.uaa.alaska.edu/research/ric/iacuc/training/index.cfm">http://www.uaa.alaska.edu/research/ric/iacuc/training/index.cfm</a>

- 1. In order for your study team to have access to the documents on IRBNet, they must register as an IRBNet user. Click the "Share this Study" tab on the left. Search for users by clicking the "Share" link at the beginning of the first paragraph. Searching for a users' last name is recommended.
- 2. Most IRBNet users at UAA will not use the Multi-site function or Transfer function. Please contact your IACUC Administrator if you have questions regarding these features.
- 3. Specify the access (Read, Write, or Full) you want any shared users to have and click save. **Be** cautious of granting users Full Access to your IRBNet package. This will allow them to perform any function on the study, including submission and deletion.

**NOTE**: If the person you are looking for does not appear, they may not a) be registered in IRBNet and b) you must ask for the affiliation he/she have registered under.

# Step #4: Obtain/Verify Electronic Signatures

Please see the section above on Required Signatures under General Instructions and Guidance.

### Step #5: Submit Your Study

Once all of the required signatures have been obtained, double check your list of documents. Click "Submit this Study" and choose your submission type (e.g., New Project). **Make sure to double check that you've submitted your study to the IACUC for review and NOT the IRB.** Once a study has been submitted, it is automatically locked and you will not be able to make edits.

**NOTE:** Once you submit an IRBNet package to the IACUC for review, this package cannot be deleted by IACUC Chair or IACUC Administrator. Please contact the IACUC Chair or IACUC Administrator as soon as possible if you submit an IRBNet package that should not be reviewed.

# **NEW STANDARD OPERATING PROCEDURE (SOP)**

Registration/IRBNet application

Step # 1: If you are not already registered as an IRBNet user, go to <a href="http://www.irbnet.org">http://www.irbnet.org</a> to make an account. If you are already registered, please skip to Step #2.

Using the 'New User Registration' link in the upper right hand corner of the page:

- 1. Create a username and password. You will be asked for a password hint. Select Continue.
- 2. Read and 'Accept' the terms and conditions.
  - a. In the search box for affiliated institutions, type "University of Alaska Anchorage" (no quotation marks). Double check that you have selected the UAA IRBNet system.
  - b. If you have already created an IRBNet account previously and you are affiliated with another institution, you will select User Profile in the upper right corner once you are logged in. Select Add an Additional Affiliation and select University of Alaska Anchorage.
- 3. Supply your contact information.
- 4. Confirm your registration information and click Register.
- 5. Wait for an activation e-mail from IRBNet. This may take a minute.
- 6. Confirm your IRBNet account through the activation link in the e-mail.

**NOTE:** If you do not register with IRBNet and affiliate your login with the University of Alaska Anchorage, you will not have access to UAA's specific forms and you will not be able to properly submit your protocol to the IACUC.

#### Step # 2: Create a New SOP

There are three SOP Forms available to UAA animal researchers:

Husbandry SOP

- Surgical SOP
- Capture/Transport SOP
- 1. Create a new study by clicking "Create New Project" on the left hand side.
- 2. The Designer page should automatically appear after you click "Create New Project." Download the relevant SOP form, save it to your computer, fill it out, and upload it to IRBNet.

#### Step # 3: Share Your SOP

- 1. In order for your study team to have access to the documents on IRBNet, they must register as an IRBNet user. Click the "Share this Study" tab on the left. Search for users by clicking the "Share" link at the beginning of the first paragraph. Searching for a users' last name is recommended.
- 2. Most IRBNet users at UAA will not use the Multi-site function or Transfer function. Please contact your IACUC Administrator if you have questions regarding these features.
- 3. Specify the access (Read, Write, or Full) you want any shared users to have and click save. **Be** cautious of granting users Full Access to your IRBNet package. This will allow them to perform any function on the study, including submission and deletion.

**NOTE**: If the person you are looking for does not appear, they may not a) be registered in IRBNet and b) you must ask for the affiliation he/she have registered under.

# Step #4: Obtain/Verify Electronic Signatures

Please see the section above on Required Signatures under General Instructions and Guidance.

# Step #5: Submit Your SOP

Once all of the required signatures have been obtained, double check your list of documents. Click "Submit this Study" and choose your submission type (e.g., New Project). Make sure to double check that you've submitted your study to the IACUC for review and NOT the IRB. <u>Once a study has been submitted, it is automatically locked and you will not be able to make edits.</u>

**NOTE:** Once you submit an IRBNet package to the IACUC for review, this package cannot be deleted by IACUC Chair or IACUC Administrator. Please contact the IACUC Chair or IACUC Administrator as soon as possible if you submit an IRBNet package that should not be reviewed.

### PROGRESS REPORT FOR AN APPROVED STUDY

If you are submitting a progress report for an approved research protocol or approved SOP:

- 1. Go to "My Projects" and click on your protocol package.
- 2. Create a new IRBNet document package by clicking the "Create New Package" button under Project History on the left.
- 3. The Designer page should automatically appear after you click "Create New Project." Prepare the documents you will submit.
  - a. Download a copy of the progress report for the research protocol or progress report form for an SOP form to your computer, save it, fill it out, and submit it to IRBNet.
- 4. Share your package (if needed).
- 5. Sign the package.
- 6. Submit your package.

**NOTE:** Once a protocol is reviewed and approved, it must be kept current with respect to any changes, modifications, or new techniques as they evolve. The form must be renewed annually for a maximum of two renewals (3 year time span). If the project is continuing after two renewals, you are required to submit a new protocol. IRBNet sends automatic e-mail reminders 30 days and 60 days before the renewal deadline.

#### PROGRESS REPORT FOR AN APPROVED SOP

SOPs are should be reviewed by the researcher once a year.

- 1. Go to "My Projects" and click on your protocol package.
- 2. Create a new IRBNet document package by clicking the "Create New Package" button under Project History on the left.
- 3. The Designer page should automatically appear after you click "Create New Project." If no updates to the SOP are necessary, please upload a memo indicating that you have reviewed the SOP and that no changes are necessary.
- 4. If updates to the SOP are necessary, please download the original SOP, save it to your computer, make changes highlighted in yellow, and upload it to IRBNet.
  - a. Also, upload a memo indicating that you have reviewed and updated the SOP. Indicate what changes were made and why.
- 5. Share your package (if needed).
- 6. Sign the package.
- 7. Submit your package.

**NOTE:** Once an SOP is reviewed and approved, it must be kept current with respect to any changes, modifications, or new techniques as they evolve. The form must be renewed annually for a maximum of two renewals (3 year time span). If the SOP is continuing after two renewals, you are required to submit a new SOP. IRBNet sends automatic e-mail reminders 30 days and 60 days before the renewal deadline.

#### SIGNIFICANT CHANGE TO AN APPROVED STUDY

If you are submitting a significant change:

- 1. Go to "My Projects" and click on your protocol package.
- 2. Create a new IRBNet document package by clicking the "Create New Package" button under Project History on the left.
- 3. The Designer page should automatically appear after you click "Create New Project." Prepare the documents you will submit. Upload the original protocol and any other pertinent documents with any changes highlighted in yellow.
- 4. Share your package (if needed).
- 5. Sign the package.
- 6. Submit your package.

Once a study is submitted, it is locked against further changes. Unless the IACUC Chair or IACUC Administrator unlocks a study, **any changes will be submitted as a new IRBNet package.** 

To submit revised documents previously submitted (e.g., revised protocol or revised SOP):

- 1. In Study Designer, click Add New Document
- 2. Click: Create New Package. This will bring you to the Study History page.
- 3. Open the new package with the status Work in Progress.
- 4. In Study Designer, you will be able to choose the document(s) you wish to revise/update, or add a new document.
- 5. Delete any document that you do not want to resubmit in your subsequent package. This is important. Otherwise, you are constantly resubmitting documents and your study history will be confusing. <u>Previous package submissions are NOT changed.</u>

#### **ADDING NEW PERSONNEL**

When adding new personnel, upload the ENTIRE personnel list as a new document package. To do this, first download the most recent version of the personnel list:

- 1. Go to "My Projects" and click on your protocol package.
- 2. Click on "Designer" on the left hand side. This will bring you to the document history of your protocol. Download the most recent version of your personnel list. To determine the most recent version, look at the time and date stamped in the "last modified" column.
- 3. Remove the names of personnel that are no longer working on the protocol. Add the names of new personnel. Be sure to save the new version to your computer.

After updating the Research Personnel List, upload it with the associated documents (e.g., OHSP forms) to IRBNet:

- 1. Go to "My Projects" and click on your protocol package.
- 2. Create a new IRBNet document package by clicking the "Create New Package" button under Project History on the left.
- 3. The Designer page should automatically appear after you click "Create New Project." Prepare the documents you will submit. Upload the Research Personnel List and the OHSP Hazard Evaluation Survey for each person.
- 4. Share your package (if needed).
- 5. Sign the package.
- 6. Submit your package. IRBNet will allow you to send a message to the IACUC administrators during this step. Please send a message indicating which personnel have been added or removed.

#### **IACUC REVIEW PROCESS**

#### Review Timeline

If your submission meets the requirements for **administrative** review (e.g., adding new personnel), the package will be reviewed by the IACUC within five business days.

If your proposal is scheduled for full review at the next IACUC meeting, it is strongly advised that you, as principal investigator, attend this meeting to answer any questions. If you are a student, then your faculty supervisor should also attend the IACUC review of the proposed research involving animals. Proposals should be submitted at least 5 days prior to the meeting date. The IACUC meets once a month, typically on the second Friday at 2:00 pm in CPISB 101D.

#### IACUC Decision Letters

To retrieve IACUC documents, such as formal approval letters:

- 1. Login to IRBNet
- 2. Click on your study's title
- 3. Click Review Details
- 4. Under Board Documents, click the document name to view the document

# REPORTING ADVERSE EVENTS

You must report all adverse events directly to the IACUC Chair and/or to the Research Integrity & Compliance Office (907-786-1099).

# **LIST OF IACUC FORMS**

Any application to the IACUC must be done through IRBNet. The IACUC Forms and Templates Library includes:

# **Required Forms**

- · Research Protocol Form or;
- Observational Research Protocol
- Research Personnel List
- OHSP Hazard Evaluation Survey
  - This survey should be submitted if you are working within a UAA animal research facility or working directly with animals in other settings.
- Standard Operation Procedures (SOPs)
  - Husbandry SOP
  - Surgical SOP
  - Capture/Transport SOP

# **Other Forms**

- Progress Report
- Post Mortem Tissue Protocol