IRBNet Guidance

IRBNet is a very powerful paperwork management tool. For some users it may not be as intuitive as we would like. Never hesitate to ask the administrator if you have trouble.

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# **How do I create a project?**

The blue strip on the left side of the IRBNet page contains the navigation links (Navigation bar). This is where you can locate templates, upload documents, digitally sign, share, and submit project documents.

Click on the "Create New Project" link. Fill in the dialog box with:

* Title
* Local Principal Investigator (usually UAF faculty, not graduate students)
* Keywords (not required)
* Sponsor (not required)
* Internal Reference Number (not required)

Click "continue" and IRBNet will automatically present the Designer page. Step 1: Select the correct "Library" from the pull-down menu.

* + IACUC reviews vertebrate animal research
  + IRB reviews human subject research
  + IBC reviews the use of recombinant DNA, artificial gene transfer, infectious agents, and biologically derived toxins.

# Next click "Select a Document".

# Highlight the document and click the "download" button. Save to your computer.

# Fill in the template and save to your computer (probably at a later time).

# All documents in a protocol package should be submitted together: protocol, personnel list, other documents (SOPs, permits, etc). To determine which documents you need see " What do I need to submit for a complete protocol package? (below)

If you are reusing documents that you downloaded previously it is a good idea to do a quick comparison to be sure that you have the most current version of that document template.

Packages can be unlocked prior to review if the researcher needs to add another document or make a change. Please don't create a new package for forgotten documents.

# **What do I need to submit for a complete protocol package?**

# **IACUC**

**Initial package:** A complete package for the IACUC includes a protocol document, personnel list (all personnel handling live vertebrates needs to complete IACUC training - including the PI - and submit a Personnel Information Form (PIF)). For many projects there will also be standard operating procedures (capture/transport, surgery, etc), permits, etc. Most new IACUC protocols will be reviewed by the full IACUC committee. An IACUC protocol can be submitted for review prior to all personnel completing their training and PIFs but it cannot be approved without these.

**Modification**: Provide updated documents highlighting all changes in yellow to assist the reviewers.

**Progress Report/Annual Review/Closure Report**: 103 Progress Report template is available in IRBNet. Complete Section 1 for the first and second annual reviews. Complete Sections 1 and 2 for three-year reviews.

### IRB

There are three levels of review for IRB projects.

**Exempt Review:** An exempt protocol includes a 200 Exemption Request and 301 Personnel List (including the PI). If interviews and/or surveys are to be conducted then a list of questions should be included along with the 303 consent. Other documents may be needed depending on the scope of the project; contact the administrator for assistance. All faculty and graduate students must have completed IRB training. An IRB protocol can be submitted for review prior to all personnel completing their training but it cannot be approved without completion of training. Projects often evolve and modifications are common.

**Expedited Review:** An expedited protocol includes a 300 Research Protocol and 301 Personnel List (including the PI). If interviews and/or survey are to be conducted then a list of questions should be included along with the 303 consent. All personnel must have completed IRB training. An IRB protocol can be submitted for review prior to all personnel completing their training but it cannot be approved without completion of training. Projects often evolve and modifications are common.

**Full Board Review:**  A Full Board Review protocol includes a 300 Research Protocol and 301 Personnel List (including the PI). If interviews and/or survey are to be conducted then a list of the questions should be included along with the 303 consent. Other documents may be needed depending on the scope of the project; contact the administrator for assistance. All personnel must have completed IRB training. An IRB protocol can be submitted for review prior to all personnel completing their training but it cannot be approved without completion of training. Projects often evolve and modifications are common.

**Modification**: Provide updated documents highlighting all changes in yellow to assist the reviewers. It is not necessary to include documents that have not been modified.

**Continuing Review/Progress Report/Annual Review/Closure Report**: 302 Continuing Review/Progress Report template is available in IRBNet.

# **IBC**

**Initial package:** A complete package for the IBC includes a registration or protocol document and personnel list (all personnel handling materials need to complete training - including the PI ). There also may be standard operating procedures, etc. Most new IBC protocols will be reviewed by the full committee. An IBC protocol can be submitted for review prior to all personnel completing their training but it cannot be approved without these.

**Modification**: Provide updated documents highlighting all changes in yellow to assist the reviewers.

**Progress Report/Annual Review/Closure Report**: Progress Report template is available in IRBNet.

### How do I check on the status of my project?

Log into IRBNet. From My Projects click on the title of the project you are interested in. IRBNet will take you to the Project Overview. On this page you can see the

* Project Status as of <date>.
* You can see the current package status (definitions of various statuses provided below).
* You can also see the researchers that the project has been shared with and their type of "share" (full, write, or read).

"*Acknowledged*" - Occasionally documents need to be submitted to IRBNet to complete the record but do not need formal review. These are acknowledged. Examples might be letters of support, permits, etc.

"*Approved*" - the review has been completed and the procedures described in the protocol documents are ready to be implemented. If your project evolves and you wish to change your procedures, you must submit a modification and cannot use the new procedures until you have approval for the modification.

"*Approved with Conditions*" - the review has been completed and the procedures described in the protocol documents are ready to be implemented although there have been "conditions" set in the letter. If your project evolves and you wish to change your procedures, you must submit a modification and cannot use the new procedures until you have approval for the modification.

"*Closed*" - when projects have been completed or expired they are closed. New protocol will need to be submitted to reinstate the project.

"*Exempt*" - A project that is exempt is minimal risk and does not require further regulatory review. An annual report is not required. The IRB requests that researchers review their paperwork annually to be sure everything is current.  If  the documents are current then send the administrator an email and she will extend the project for another year.  If there are modifications please submit those in IRBNet (be sure to highlight the changes).  The IRB recommends that  projects remain open until published.

"*Expedited*" - A project that is expedited is minimal risk and is reviewed by a single member representing the IRB. An annual report is required. The IRB requests that researchers review their paperwork annually to be sure everything is current and to submit a 302 Continuing Review/Progress Report (templates in IRBNet).   If there are modifications please submit those in IRBNet (be sure to highlight the changes).  The IRB recommends that  projects remain open until published.

"*Forwarded*" - in most cases the administrator will send an explanation email explaining that a submission has been forwarded to the correct committee. (This is usually because a protocol has been submitted to the incorrect committee).

"*Full*" - A project that is categorized as full is more than minimal risk and is reviewed by the full IRB. An annual report is required. The IRB requests that researchers review their paperwork annually to be sure everything is current and to submit a 302 Continuing Review/Progress Report (templates in IRBNet).   If there are modifications please submit those in IRBNet (be sure to highlight the changes).  The IRB recommends that  projects remain open until published.

"*Information Required*" - the submission has been reviewed and information is requested. A letter is posted in IRBNet under the Reviews button on the left side of the IRBNet page. If you don't see a letter contact the administrator.

"*Locked*" - the submission is locked and the researcher is not able to make changes to that package. Packages can be unlocked prior to review if the researcher needs to add another document. Reviewed packages are not unlocked. This creates the project document record.

"*Modifications Required*" - the submission has been reviewed and modifications are requested. A letter is posted in IRBNet under the Reviews button on the left side of the IRBNet page. If you don't see a letter, contact the administrator.

"*Pending Review*" - a package has been submitted to the committee is pending review.

#### "Research - Not HSR" (not human subjects research) - Not all research involving people requires IRB review. If a project is not HSR then the IRB does not need to review it. The regulations provide the following criteria:

* Research - a systematic investigation, including research development, testing, and evaluations, designed to contribute to generalizable knowledge.
* Human Subject - a living individual about whom an investigator conducting research obtains a) data through intervention or interaction, or b) identifiable private information.

"*Tabled* *without Action*" - either the submission has been reviewed and information/modifications are requested or the committee did not have time to complete the review at the meeting and the time must be added to the next meeting agenda. If information or modifications are required a letter will be posted in IRBNet under the Reviews button on the left side of the IRBNet page. If you don't see a letter, contact the administrator.

"*Withdrawn*" - in most cases the administrator will send an explanation email explaining why a submission has been withdrawn. (This is usually because a duplicate protocol has been unnecessarily submitted).

"*Unlocked*" - a submission can be unlocked prior to review allowing for modification of the submission.

"*Work in progress*" - the package hasn't been submitted it yet. When the "Submit this Project" button has been pushed the package is released to the administrator and an email is sent to the administrator noting the submission. The project is then locked and the researchers cannot make further changes. If changes are needed prior to review please request that the administrator "unlock" the submission rather than creating another package.

### I received a Modifications Required Letter. What do I need to do?

Log into the project in IRBNet and locate the review letter under the Reviews link on the left side of the IRBNet page. The letter will describe the modifications requested by the committee. If you have questions contact the administrator for clarification. Modifications should be made to the documents in IRBNet; be sure to highlight your changes to assist the reviewers. Submit in IRBNet for re-review (see

How do I modify a project or submit new documents? Below)

# **How do I modify a project or submit new documents?**

# Click theDesigner button in the blue Navigation area on the left side of the IRBNet page:

* New templates can be found under Step 1 which is linked to Forms and Templates or you can go directly to the Forms and Templates link. Be sure to choose the correct **library** - IACUC, IBC, IRB.
* Under Step 2 you can find previously submitted documents. Be sure to select the most recent approved version of a particular form. Click on the paper icon on the right and download the form to your computer, make your modifications (be sure to highlight your changes to assist the reviewer), and upload new changes.
* To upload documents (Step 2)
  + - Click "Add New Document" to add a document.
    - Choose "Create New Package" if you are uploading modifications or annual reports (this creates a fresh "package" to insert your new documents into.)
    - Click "Add New Document" to insert the new documents in the new package. (This will look like you have gone back to the same Step 2 screen but IRBNet has created a new "folder" and you will be inserting your revised documents now).
    - Submit your new package when all documents have been uploaded (Submit button on the left side of the IRBNet page).\*

\* Packages can be unlocked prior to review if the researcher needs to add another document or make a change. Please don't create a new package for forgotten documents.

# **How and why do I have to share a project?**

All projects should be shared with all personnel on the Personnel List. Projects should be shared with all personnel so that they can be fully informed about the protocol. Sharing also allows the administrator to contact personnel directly (to discuss training, etc.).

To share a project click on the "Share this Project" button and complete the dialog boxes presented.

Personnel must register in IRBNet before you share with them. If you cannot locate a person perhaps they have not registered in IRBNet. The training website, CITI, is not linked to IRBNet and therefore personnel must register in both places.

There are 3 different levels of sharing:

* Full - recommended for co-investigators and grad students if this is their thesis project so that they can help manage the project paperwork.
* Write - if you wish for the person to contribute documents but not change submissions.
* Read - minimum for all personnel. All personnel need to be able to read the protocol package so that they can be well informed. This also allows the administrator to be able to contact all personnel directly about training, etc.

**Who can make changes to a protocol?**

Anyone with full access to a project (see [How and why do I have to share a project?](#HowShare)) can submit protocol modifications. It is up to the PI or research team to decide how the project will be managed. Graduate students and post-docs are allowed to create and upload documents. PI must sign all submissions indicating that they have reviewed and approve each submission. Management of a project is the PI's responsibility and ultimately the PI is the person held accountable.

# **What are some recommended Data Storage and Handling Guidelines?**

Human subjects research data must be managed in a secure manner. There is a guidance document in the IRB Templates. There may be other ways to securely handle data. This document presents some suggestions. Data security plans should be clearly described in Section O of the IRB protocol.

### My project is completed and I wish to close the protocol. What do I need to do?

When projects have been completed a final closure report should be submitted. Please use the annual Review template available I n IRBNet.

*Questions:* If you have questions please contact the administrator (474-7800 or uaf-ori@alaska.edu).

# **IRBNet Basics**

**All documentation for IRB, IACUC and IBC must be submitted in IRBNet.**

Navigation - The blue strip on the left side of the IRBNet page contains the navigation links (Navigation bar). This is where you can locate templates, upload documents, digitally sign, share, and submit project documents.

Protocol Numbers - IRBNet assigns each new protocol with a six digit number. The number after the dash is the package number (or version number). A brand new protocol is xxxxxx-1. When it is modified the number becomes xxxxxx-2. Most new protocols (with a -1) are reviewed by the Full IACUC Committee for the first review. Subsequently, only major revisions or 3-year reviews are handled by the Full Committee.

Locating projects - If you are unable to locate a protocol this may be because it hasn’t been shared with you. Please contact the PI. Only the PI (or other project researchers with "full" access) can share documents with other researchers.

Document security/access - IRBNet is divided into two parts; researcher side and committee side. Only the researchers with "full" permission can change documents submitted in IRBNet on the researcher's side. The administrator and committee members can review documents but they cannot change what the PI (or researchers with "full" permission) has submitted in the documents. This access and the date stamps (applied to documents when submitted) provide protection to researchers and committees.

Forms and Templates - There are templates in IRBNet for most of the documents that researchers will need. There are also instructions provided in the Forms and Templates folder that may be helpful to researchers when the administrator is unavailable to assist.

Training - UAF uses Collaborative Institutional Training Initiative at the University of Miami (CITI) for our training modules. This is a separate program and website from IRBNet and researchers need to register at their website (www.citiprogram.org) to complete training. At the CITI home page and there will be box towards the middle lower section of the page "My Learner Tools for University of Alaska Fairbanks", select "Add a Course or Update Learner Groups."  There are also instructions on the UAF committee websites.

* IRB personnel training - Under Question 1, researchers should complete the modules called “Social Behavioral Research - Human Subjects - Basic or Refresher.” Or "Biomedical Research Investigators and Key Personnel - Basic or Refresher". Say "Not at this time" for the other questions if they are not relevant.
* IACUC personnel training - Under Question 3, researchers should complete the modules called “Field or Lab Researchers - Basic or Refresher”. Please also complete "Wildlife Research or Working with Fish in Research" or other species modules under Question 3 if these apply to the research being done. Say "Not at this time" for the other questions if they are not relevant to the work.
* IBC personnel training should contact the ORI administrator to be registered for Biosafety Cabinet Training on Blackboard if appropriate.
* Track Training - UAF doesn't use this feature of IRBNet.

**IRBNet Navigation Button Descriptions** (located in the blue strip on the left side of the IRBNet page)

Log into IRBNet and the first IRBNet screen will have:

* My Projects - a list of all of the projects that a researcher has created and/or projects that have been shared with them. Click on the project title to view those documents.
* Create New Project is where new protocols are initiated.
* Forms and Templates is where instructions and templates are located and can be downloaded.

Select a project by clicking the blue title and IRBNet will take you to:

* Project Overview is where you can see the status of the project, the current package and who the project is shared with. (link below "How do I check on status")
* Designer
  + Step 1 is linked to Forms and Templates. Be sure to choose the correct **library** - IACUC, IBC, IRB.
  + Step 2 is where you upload documents.
  + Previous documents can be located and downloaded below Step 2.
  + IRBNet has a training records feature that UAF does not use.
* Share this Project is where you share with other researchers and personnel.
* Sign this Package where researchers digitally sign the submission. PIs must sign to indicate that they have reviewed the submissions created by techs and students.
* Submit this Package is where the package is submitted and released to the administrator for review.
* Delete this Package a package can be deleted any time prior to submission.
* Send Project Mail is where emails can be sent directly to other researchers or the committee and the email record will be linked to this protocol.
* Reviews is where review letters and board documents can be found.
* Project History (list of packages and status).
* Messages & Alerts (list of messages linked to this protocol in IRBNet)
* Forms and Templates - location of most current version of instructions, forms and templates. Be sure to choose the correct **library** - IACUC, IBC, IRB.

**Protocol Definitions** (alphabetical)

Adverse Event Report/Incident Report - Principal investigators are required to promptly report to the Office of Research Integrity all problems/adverse events that are serious and unanticipated and which are possibly, probably or definitely related to the study procedures. Researchers may be required to submit a report outlying the incident details. Templates available in IRBNet.

Annual Review/Progress Report/Continuing Review - Federal regulations require committees to review protocols at least once every 365 days. IRBNet will send out reminders each year 90, 60 and 30 days prior to the expiration date. It is important to submit the annual report with sufficient time for the committee to review the report prior to expiration. IRBNet will send out an expiration notice; activities must cease when a protocol is expired.

Continuing Review/Annual Review/Progress Report - Federal regulations require committees to review protocols at least once every 365 days. IRBNet will send out reminders each year 90, 60 and 30 days prior to the expiration date. It is important to submit the annual report with sufficient time for the committee to review the report prior to expiration. IRBNet will send out an expiration notice; activities must cease when a protocol is expired.

Incident Report/Adverse Event Report - Principal investigators are required to promptly report to the Office of Research Integrity all problems/adverse events that are serious and unanticipated and which are possibly, probably or definitely related to the study procedures. Researchers may be required to submit a report outlying the incident details. Templates available in IRBNet.

Modification - A modification can be initiated by a research team wishing to change their protocol or from the committee asking for changes to a submission. Modifications to protocol procedures must be approved prior to implementation.

Personnel Information Form (PIF **-** IACUC only**)** - A Google form that must be completed by all UAF personnel on an IACUC protocol <https://docs.google.com/a/alaska.edu/spreadsheet/viewform?formkey=dEw2dHlMVEZKZF9sUFBrN21Tck5uVHc6MQ#gid=0>.   This is a Google doc and is similar to a survey when submitted.  It does not create a separate document.  Google will let the administrators know when something is submitted. This will be reviewed by a safety officer from Environmental Health, Safety & Risk Management.

Personnel List (Research or Teaching) - Form that lists all personnel on a project and their qualifications. Templates available in IRBNet.

Principal Investigator (PI) - One person from the research team must be designated as the PI. This is usually a tenure track faculty member or someone with special permission from their department. Graduate students and Postdocs can develop the paperwork that is reviewed/signed/submitted by PI in IRBNet but ultimate responsibility for the project resides with the PI.

Progress Report/Annual Review/Continuing Review - Federal regulations require committees to review protocols at least once every 365 days. IRBNet will send out reminders each year 90, 60 and 30 days prior to the expiration date. It is important to submit the annual report with sufficient time for the committee to review the report prior to expiration. IRBNet will send out an expiration notice; activities must cease when a protocol is expired. Templates available in IRBNet.

Protocol (Research or Teaching) - Form that describes the rationale and procedures for a project. Templates available in IRBNet.

Package/Submission - All of the documents in a submission. A complete initial package would include: protocol form, personnel list, additional documents: permits, interview questions, consents/assents, SOP (capture/transport, surgery, etc). Templates available in IRBNet.

# Satellite Facility Designation - If animals are to be held for more than 12 hours in a location other than a established UAF animal facility, the location must be reviewed, inspected and approved by the IACUC prior to holding animals at the location.

Standard Operating Procedures (SOP) - An SOP describes a procedure that a researcher expects to use over and over in different projects. The advantage of an SOP is that it standardizes a procedure and it saves time because the researcher doesn't have to repeatedly describe the same activity over and over. Some templates are available in IRBNet.