GENERAL UAF IRBNet INSTRUCTIONS

IACUC FORMS

Current versions of the IACUC forms are available in the IRBNet IACUC Forms Library (the library will be available once you click on "Create New Project" and fill out the initial information screen). A list of the current forms including basic instructions on when they should be used is available at the end of this document.

TERMS
- <u>Project</u> – The IRBNet term for what we've traditionally called an "IACUC Assurance"; includes your original submission to the IACUC as well as all subsequent modifications, reports, etc.
- <u>Package</u> – The IRBNet term for each submission you make on a Project. Your initial submission would be Package # 1. The next time you submit something related to the same project it would be considered Package # 2, regardless of whether it is a modification or a progress report
- <u>Protocol</u> – The IRBNet term for what we've traditionally called the "IACUC Assurance application form". The Personnel and Capture & Transport sections of the old application form are now separate forms in IRBNet.
- <u>Progress Report</u> – The IRBNet term for what we've traditionally called a "Continuing Review".

NEW PROJECT SUBMISSION INSTRUCTIONS
- Log-in to IRBNet.
- Select "Create New Project"
- Enter the requested information – both required (indicated by a red asterix) and optional.
  - For sponsored work please put your UAF Proposal (S#) or Grant (G#) number where it asks for an Internal Reference Number.
- Select the IACUC Forms Library
- Select the Document you would like to work on – Typically for new projects you will select the Research Protocol first. You can choose to either open the form and start work on it or save the form to your computer or server so you can work on it later off-line.
- Once you are done with that document save it to your computer or server.
- Repeat the two preceding steps until you have completed all of the documents you need to include for your new project submission.
- Once you've complete work on your document(s) you add it to your submission package by clicking the "Add New Document" button in step #2. (*Note: You do not have to add all of your documents at once, but they do have to be added before you submit your new project for review.*)
  - When you add a new document, please select the correct "Document Type" from the drop down window. Information on document types is provided with the form descriptions below.
  - In the "Description" field, please use the following convention (*Note: Remember, once submitted, these files will be saved as part of your project and can accessed, retrieved, and revised as needed by anyone you choose to share (give read, write or full access to) the project with so there is no need to add a project specific name at this time.*):
    - Personnel Information Forms - use your name as the file name (Ex: Russ Jones).
    - Protocol - use the form name (Ex: Research Protocol) or title of the protocol (Ex: Breeding Behavior of Crested Murrelets).
    - Personnel List - use the form name.

- SOPs - use the form name (Ex: Surgical SOP); if you have multiples of an SOP form you can use the form name plus a descriptor (Ex: Surgical SOP Transmitter Implant).
- Progress Reports - use the form name.
- Satellite Facility Designation - use the form name.
- Select "Browse" and find the correct file.
- Click "Attach"
- This will take you back to the project overview page in the designer.
- Repeat these steps until you have added all of the necessary documents.
- Once you have created your Project you have a few options on what to do next:
  - Share – you can share the project with anyone else who has an IRBNet user account. The IACUC requires that all individuals listed as project personnel be given at least read access to the project in IRBNet. (*Note: The IACUC may make an exception for students in a class or volunteers working in field situations where they will not have internet access. If you would like to request this, please let us know in the comments field when you submit the project.*) For each person you will have to indicate the type of access you wan them to have
    - Full
    - Write
    - Read
  - Sign – The Principal Investigator must sign the package before it is submitted. IRBNet will allow some one to state that they are signing on behalf of another person. PIs should be very clear with their personnel regarding who may and may not submit project documents on behalf of the PI. The IACUC does not require anyone other than the PI to sign off on the submission, but you may choose to have collaborators sign off once they think the project is ready to submit to the IACUC.
  - Submit – this sends the project to the IACUC for review.

NEW PACKAGE SUBMISSION INSTRUCTIONS

The following instructions should be used any time you need to modify or submit an additional document for an IACUC Project already in IRBNet:
- Log-in to IRBNet. You should see all of your current projects (regardless of status) listed. If not click on the "Study Manager" button.
- Select the project you need to work on by clicking on the title. This will open a project overview page.
- To access current form documents or to add new ones click on the "Designer" link in blue font or the "Designer" button on the navigation bar.
  - If you have NOT submitted the project yet:
    - You can now open any of the documents you've already added by clicking on the title.
    - Make any necessary changes, then save the modified document to your computer or server when you're done.
    - Return to the designer screen and click on the pencil icon to upload the new version.
  - If you've already submitted the project for review:
    - You can still open any of the documents by clicking on the title.
    - Make any necessary changes, then save the modified document to your computer or server when you're done.

- Return to the designer screen and click on the pencil icon to upload the new version. You will be asked if you want to "Cancel" or "Create a New Package". Any revision to a previously submitted project (whether or not approved) must be submitted as a new package.
- If you want to add a new document click the "Add New Document" button on the Designer page. You will be asked if you want to "Cancel" or "Create a New Package". Any new document submission to a previously submitted project (whether or not approved) must be submitted as a new package.
  - o Once you've uploaded the revisions and/or new documents you have the same options you have for a new project:
    - Share – when you click this link or button you will see a list of everyone who is currently shared on the project and their level of access. You can share the project with anyone else who has an IRBNet user account, remove someone's access, or change their level of access. Just remember that the IACUC requires that all individuals listed as project personnel be given at least read access to the project in IRBNet. Note: Changing access to the project is not the same as requesting that someone be added to or removed from the list of personnel authorized to work on the project. In order to request a change in approved personnel you must submit a revised Research Personnel List or Teaching Personnel & Class List.
    - Sign – The Principal Investigator must sign the package before it is submitted. IRBNet will allow some one to state that they are signing on behalf of another person. PIs should be very clear with their personnel regarding who may and may not submit project documents on behalf of the PI. The IACUC does not require anyone other than the PI to sign off on the submission, but you may choose to have collaborators sign off once they think the project is ready to submit to the IACUC.
    - Submit – this sends the project to the IACUC for review.

SUBMISSIONS FOR PROJECTS <u>NOT</u> INITIALLY SUBMITTED THROUGH IRBNet

We will be gradually transitioning all pre-IRBNet documents into IRBNet over the next year. As your existing protocols need to be modified or come up for annual review, you will be required to submit the entire protocol through IRBNet on the new forms (follow New Project Submission Instructions, above).

As part of our move to IRBNet we are doing away with the three year re-writes for continuing activities. Protocols will still undergo a complete IACUC review every three years, but since you will now be updating the protocol documents themselves rather than using a modification request form, they should always be up-to-date making the re-write unnecessary.

Please contact Kelly (x7832) or Bridget (x7800) if you have any questions or need assistance transitioning to the new forms.

New IACUC Forms

FORM TYPES - Two types of IACUC Project applications are now available: Research and Teaching. The Research forms should be used for faculty or graduate student initiated research or testing activities. The Teaching forms should be submitted for classes, workshops or other training activities that are not

hypothesis driven. However, small scale student initiated research projects associated with a class should be included under a Teaching Protocol using the Student Project form.

Research Projects – Beginning 7/28/09 the forms below must be used beginning for all submissions to the IACUC. All sections must be completed, although "Not Applicable" may be an acceptable response in some situations. The Protocol is intended to be an independent document; therefore, you may not refer to previous submissions or other documents not included in your IRBNet Project. You may refer to any supplemental forms (Personnel List, Surgery SOP, etc.) submitted as part of the project.

Required Forms

Research Protocol - this form replaces the "Assurance Application" form. The form now gives you the option of describing each planned experiment separately; hopefully, this will make complex research designs easier for the IACUC, Veterinary Services and research staff to follow. Select "Protocol" as the document type in IRBNet.

Research Personnel List - this is a new form that replaces the personnel section of the "Assurance Application". Select "Other" as the document type in IRBNet.

Standard Operating Procedures (SOPs) – these are supplemental forms and should be submitted with a new application or as part of a modification request, as needed.

SOP Surgery - this form is to be used for all surgical procedures (survival and non-survival). Select "Other" as the document type in IRBNet.

SOP Capture & Transport - this form replaces the wildlife capture and transport sections of the "Assurance Application" form's Animal Use Procedures section. We've moved to this format because the IACUC typically has the same questions for every protocol involving the capture and/or transport of wild animals. Select "Other" as the document type in IRBNet.

SOP Husbandry - a Husbandry SOP is required for all animals held for more than 12 hours. The IACUC has approved Husbandry SOPs for species commonly held in UAF animal facilities (arctic ground squirrels, muskoxen, red-backed voles, caribou/reindeer, African clawed frogs, ducks, mice, rats and some freshwater fishes). Contact ORI to request a copy. You can request minor alterations in the Animal Use Procedures section #1 of the Research Protocol. If you need major changes to accommodate your research or testing activities, complete a new Husbandry SOP and submit it as part of your Research Protocol. Select "Other" as the document type in IRBNet.

Other Forms

Progress Report - this form replaces the "Continuing Review" form. Progress Reports are due at least annually. The IRBNet system will send automated emails to everyone granted full access on a protocol 60, 30 and 7 days before the renewal deadline. Failure to submit the Progress Report by the deadline will result in closure of your IACUC protocol. Select "Continuing Review/Progress Report" as the document type in IRBNet.

Satellite Facility Designation - complete this form only if animals will be held outside of a UAF animal facility (AFES, LARS, Irving I Animal Quarters, SFOS fish facility in

AHRB, BiRD or the Biological Reserve) for more than 12 hours. Satellite facility designations are Protocol specific so you must attach this form to all Protocols that will be conducted in that location. Select "Other" as the document type in IRBNet.

Teaching Projects - the forms below must be used for all new submissions and three-year mandatory resubmissions. All sections must be completed, although "Not Applicable" may be an acceptable response in some situations. The Protocol is intended to be an independent document; therefore you may not refer to previous submissions or other documents in your answers. You may refer to any supplemental forms (Personnel List, Surgery SOP, etc.) submitted as part of the protocol packet.

Required Forms

Teaching Protocol - this form replaces the "Assurance Application" form. The form now gives you the option of describing each planned experiment separately; hopefully, this will make the protocol easier for the IACUC, Veterinary Services and teaching staff to follow. Select "Protocol" as the document type in IRBNet.

Teaching Personnel & Class List - this is a new form that replaces the personnel section of the "Assurance Application". Select "Other" as the document type in IRBNet.

Standard Operating Procedures (SOPs) – these are supplemental forms and should be submitted with a new application or as part of a modification request, as needed.

Student Project - this form must be submitted for each individual or small group student research project associated with the class. Observational research projects may be reviewed by the IACUC at any time, but research projects involving animal handling or manipulations must be discussed at a convened meeting so will require additional review time. Select "Study Plan" as the document type in IRBNet.

Surgical SOP - this form is to be used for all surgical procedures (survival and non-survival). It may be submitted with a new Protocol application or as part of a modification request. Select "Other" as the document type in IRBNet.

Husbandry SOP - a Husbandry SOP is required for all animals held for more than 12 hours. The IACUC has approved Husbandry SOPs for species commonly held in UAF animal facilities (arctic ground squirrels, muskoxen, red-backed voles, caribou/reindeer, African clawed frogs, ducks, mice, rats and some freshwater fishes). Contact ORI to request a copy. You can request minor alterations in the Animal Use Procedures section #1 of the Teaching Protocol. If you need major changes to accommodate your research or testing activities, complete a new Husbandry SOP and submit it as part of your Teaching Protocol. Select "Other" as the document type in IRBNet.

Other Forms

Progress Report - this form replaces the "Continuing Review" form. Progress Reports are due at least annually. The IRBNet system will send automated emails to everyone granted full access on a protocol 60, 30 and 7 days before the renewal deadline. Failure to submit the Progress Report by the deadline will result in closure of your IACUC protocol. Select "Continuing Review/Progress Report" as the document type in IRBNet.

Satellite Facility Designation - complete this form only if animals will be held outside of a UAF animal facility (AFES, LARS, Irving I Animal Quarters, SFOS fish facility in AHRB, BiRD or the Biological Reserve) for more than 12 hours. Satellite facility designations are Protocol specific so you must attach this form to all Protocols that will be conducted in that location. Select "Other" as the document type in IRBNet.

Modification Requests - there are no longer "Modification Request" forms. All changes to Research and Teaching Projects, that are on the new forms, should be made directly in the relevant document(s) and submitted through IRBNet as a new package (not a as a new project or study). Please be sure to choose "Amendment/Modification" as the document type.

Personnel Forms

Personnel Information Form - All personnel working on an IACUC Assurance are required to submit this form. Each individual should submit their own PIF through IRBNet as a unique study (do not submit it as part of a Research or Teaching Protocol).

Medical Questionnaire - initially, this form should only be filled out at the direction of the Office of Research Integrity. However, if you have already been assigned to risk category 2 or 3 and have had a significant change in your health status you may fill out this form at any time. Send this form directly to the contract health care provider by fax or regular mail; do NOT send it to the Office of Research Integrity.

Quality Improvement Program (QIP) Forms

QIP Report - this form may be submitted by anyone with concerns about animal care and use, specific IACUC protocols, occupational health & safety or other issues related to the UAF Animal Facilities.

QIP Assessment Checklist - this form will be completed by the Sr. Research Compliance Officer as part of periodic assessments of research programs utilizing live vertebrates.

UAF Animal Facilities

Space Request Form - Use this form to request space within the Irving I or Biological Research & Diagnostics Building animal facilities. Send the completed form to the Animal Quarters Supervisor.