

Stony Brook University
IRBNet Instructions for
IBC, SCRO, IACUC Committees
v. 04.04.12

Introduction: This document will explain, step by step, how to upload the required forms and documents you need to have your project (including continuing reviews, responses to committee concerns, amendments etc) reviewed by the IBC, IACUC, and/or SCRO.

The basic submission for a new project requires that you complete and upload:

1. REGISTRATION FORM

- a. *Select Designer on the left hand navigation bar*
- b. *Scroll down slightly to see "Add New Document" in the box in center of your screen - select this*
- c. *Scroll to bottom to 'add' the online wizard document called 'Registration Form for IBC, IACUC or SCRO' (lower or second blue shaded box). In the 2nd blue box (On-line Document) you will be able to access the Registration form for IBC, IACUC & SCRO from the drop down box. Click on "Add".*
- d. *Read each screens carefully as they come up and click "next"*
- e. *Fill in the blanks*

2. Committee-specific Application

3. Grant, if applicable

4. Long Term (Animal) Housing Form– (if applicable)

5. Genetically Modified Rodent Registration (If applicable)

With IRBNet, one project package can be separately submitted to one, two, or all three committees, if applicable. You can do this for new submissions, and you can also do this if you want to submit continuing review materials to more than one committee, and have your various approval dates for IACUC, SCRO and/or OBC all be in sync.

All these steps are described in the sections below.

What do you want to do?

[1. Do you want to obtain committee approval\(s\) for a new, first time, submission?](#)

2. [ARCHIVED]

[3. Do you want to obtain continuing review approval for a project that is electronic \(resides in IRBNet\)?](#)

[4. Do you want to respond to committee concerns, post-review?](#)

[5. Do you want to submit an amendment, etc. to your approved study?](#)

[6.. Special Topics \(Locked vs. Unlocked Packages, IRBNet #ing system\)](#)

1. Submitting a new (first time) submission

First, register with IRBNet

(skip if you're already registered)

- go to <http://www.irbnet.org>
- at the top right, click 'New User Registration' and fill in the requested fields
- when you have to choose your affiliation, choose Stony Brook University
- To complete the registration process, you will need to authenticate your registration via your e-mail account. Sometimes the authentication e-mail is not recognized by your provider, and may be routed as spam or junk. If you have registered correctly, and you don't receive the authentication e-mail in your inbox, be sure to first check your spam or junk folder before contacting ORC for assistance.

Create your new project

Important note: If your activity requires approval from one, or more of the committees (IBC, IACUC, SCRO), you only need to create one submission 'package', containing the specific applications required for each committee, a single registration form, and the required (awarded or pending) grant information. Follow directions below to submit the one package to all committees you need to. You can use this multiple submission process if you want to get your current IBC, IACUC, and SCRO committee approvals in sync.

1. To begin, log on, choose 'Create New Project' (on the left), and fill out all **required** and non-required initial fields, including **Keywords** (include whatever you like, but be sure to include which committee(s) this study will be reviewed by; IACUC and/or IBC and/or SCRO).

Hit 'continue'

Now you are in the 'Designer' where you can build your submission for the committee(s).

Share your project package

Once you've created your project as above, you will need to share your project with:

- **IBC and SCRO only:** your co-investigators, including non-SBU collaborators (you can allow input, or access to your materials for free)—these individuals can assist you in constructing your submission, and will need to e-sign before the study can be approved.
- The PI's department chair—will need to review and e-sign the submission before it is sent in for review.
- If the project involves a grant or contract, please give read-only access to your Sponsored Programs Administrator and/or Coordinator. If you need help in determining who these individuals are for your department, contact the Office of Sponsored Programs at 632-9949 or 632-4402

Here's how you share your project:

1. When you are in your study package, press the 'Share this Project' button on the left, click on the 'share' option on the resulting page.

2. You will first need to select the name of the **organization** where the individual is affiliated (Stony Brook University-SUNY will be highlighted by default, but you can share the study with collaborators at other organizations, just select the applicable organization from the list. If you don't see the organization, it means that no one from that organization has registered to use IRBNet yet. You should contact the individual and tell him/her to register so you can share the project with him/her.)

3. Hit 'Select organization'.

4. To share the package with individuals, you can search by last name (type it in and hit 'search') or if you don't know the exact spelling, enter a space and then hit 'search', and a listing of all registered users for that organization will pop up. If the individual is not listed, it most likely means that the person has not yet registered on IRBNet. You should contact the individual and tell him/her to do so before you can share the project with him/her.

This screen also provides information regarding the different levels of access you can grant. Consider these levels, as appropriate, for each shared individual. Those with full access will be able to submit the project to the committee(s), and will receive e-mails with actions/decisions have been made on the project.

[Add the specific committee application\(s\) you need](#)

First, you need to download the continuing review application(s) for the committee for which you are seeking continued approval:

IBC ('Application for Approval of Recombinant DNA Activities')

and/or

SCRO ('Application for Approval of Stem Cells/Stem Cell Lines in Research')

and/or

IACUC ('Full Application for Approval for the Use of Vertebrate Animals in Research and Educational Activities'), or ('Application for Use of Animals for Non-Invasive Observational Field Studies')

These applications are located in their respective "Libraries" within the IRBNet Designer (see the dropdown option to 'Select a Library' in Step 1 to choose which committee's documents you need.)

Once downloaded, save the application to your computer. Once you have completed it and saved it to your computer, upload it back into your submission package. This is done by clicking the 'Add New Document' button in the Designer and uploading the file from your computer (via the top, shaded, box). You will now see the completed continuing review application added to your document package.

Review the Designer Library to see if other forms are required for the specific committee

Download and save the form to your computer. Once you have completed it and saved it to your computer, upload it back into your submission package. This is done by clicking the 'Add New Document' button in the Designer and uploading the file from your computer (via the top, shaded, box). You will now see the completed form added to your document package.

Upload active/pending grants that support the activity

This is done by clicking the 'Add New Document' button in the Designer and uploading the file from your computer (via the top, shaded box).

Complete the registration form*

This is done by clicking the 'Add New Document' button in the Designer, and 'add' the online wizard document called 'Registration Form for IBC, IACUC or SCRO' (lower, shaded box). Follow guided directions to complete this, in which you will be asked questions about your proposed use of animals, rDNA, and stem cells, as applicable.

*If you have similar projects, teams or project data already in another existing registration form in IRBNet, You can save time by cloning that registration form (if you have full or write access) . Here's how:

How to Clone a Registration Form

- Click "Add New Document" on the Designer and choose the Smart Form you'd like to add to your package, as you normally would.
- If you have at least one existing wizard that is available to clone, then the system will automatically ask if you would like to (a) create a new wizard from scratch, or (b) clone one of your existing wizards; simply select the option to clone.
- A list of every wizard of this type that you have Write or Full access to will appear. Choose your preferred source file.

The system will copy all information from the selected wizard into a new wizard, and place you at the beginning of the form so you can update any information as needed.

Obtain necessary electronic signatures for your package

IMPORTANT: Before required individuals sign an IRBNet package, it is required that the last section of the committee application be reviewed for details on what their e-signatures certify.

Once you are done uploading all your documents and have given access (shared) your submission with all relevant individuals, be sure to sign your project (click the button 'Sign this Package' on the left side margin of your screen), and make sure your department chair (with whom you shared the project) also electronically signs your project. **The chair should only sign when your documents are finalized for submission, i.e., just before you are ready to submit to to the IBC/IACUC/SCRO, so that adequate view of the project can be conducted.**

For new and continuing studies

- **Before you submit the project to the committee(s)**, you must obtain electronic signatures from the PI and the PI's department chair. Projects that are submitted without these 2 signatures will not be processed until this is done.
- **Before an approval will be issued by the IBC or SCRO committees**, all co-investigator e-signatures will need to be present in IRBNet. Signatures can be added to a project even if the individual in question has 'read-only' access, and even if the project is in 'locked' status.

Submit your project to the applicable committee(s)

When all documents are uploaded, and PI and Chair signatures are obtained, hit the 'Submit this Project' button on the left. You will be able to submit the one package to one or all committees.

- **To send your package to the IBC**, choose Stony Brook University IBC Office as the organization. You will then need to identify the submission type. Choose 'New Project'
- **To send your package to the IACUC**, hit the Submit the Project button again, this time choosing Stony Brook University IACUC Office as the organization. You will then need to identify the submission type. Choose 'New Project'
- **To send your package to the SCRO**, hit the Submit the Project button again, this time choosing Stony Brook University SCRO Office as the organization. You will then need to identify the submission type. Choose 'New Project'

2. [ARCHIVED]

3. Submitting a continuing review submission for a project already electronic, i.e., approved in IRBNet

If this is your first or second renewal of the project since the last full application to the committee, you can submit 'regular continuing review' materials into IRBNet.

If you have renewed the study twice (2X) since the last full application to the committee, you are now due for a full, tri-annual review. **Note the special requirements for tri-annual review below.**

Here's how:

**Create a new package to your existing IRBNet project number. DO NOT
CREATE A NEW PROJECT.**

1. In your "My Projects" view, click on the title of the project. Be sure the IRBNet # is identical to the # contained in the renewal reminder that was e-mailed to you. This will take you to the Project Overview page.
2. Click the Project History button to the left.
3. Click the Create New Package button in the middle of the page (if you don't see the button, you were not granted access to create new packages when the study was shared with you)
4. Click on the 'New Document Package', which will take you into the Designer where you can work on documents for the new package. First,

Add the specific continuing review application(s) you need

First, you need to download the continuing review application(s) for the committee for which you are seeking continued approval:

IBC : 'Application for Continuing Review of Recombinant DNA Approval'

or , for tri-annual review: 'Application for Approval of Recombinant DNA Activities'

and/or

IACUC: 'Application for Continued Approval for Vertebrate Animals in Research and Educational Activities'

or, for tri-annual review: 'Full Application for Approval for the Use of Vertebrate Animals in Research and Educational Activities', or 'Application for Use of Animals for Non-Invasive Observational Field Studies'

and/or

SCRO ('Application for Continuing Approval of Stem Cells/Stem Cell Lines in Research')

or, for tri-annual review: 'Application for Approval of Stem Cells/Stem Cell Lines in Research'

These applications are located in their respective "Libraries" within the IRBNet Designer (see the dropdown option to 'Select a Library' in Step 1 to choose which committee's documents you need.)

Once downloaded, save the application to your computer. Once you have completed it and saved it to your computer, upload it back into your submission package. This is done by clicking the 'Add New Document' button in the Designer and uploading the file from your computer (via the top, shaded, box). You will now see the completed continuing review application added to your document package.

Either

[Complete a new registration form](#)

Complete a New Registration Form

This is done by clicking the 'Add New Document' button in the Designer, and 'add' the online wizard document called 'Registration Form for IBC, IACUC or SCRO' (lower, shaded box). Follow guided directions to complete this, in which you will be asked questions about your proposed use of animals, rDNA, and stem cells, as applicable.

or

[Edit an existing registration form](#)

[Edit an existing Registration Form](#)

Refer to the 'Documents from Previous Packages' section at the bottom of the Designer view.

Click on the pencil icon for the Registration Form. This will open up the Registration Form.

Make any necessary changes to previously entered information and save. The document will move to the 'New and Revised Documents in this Package' section.

[Upload any other documents you want to submit in support of the continuing review package \(e.g., new grants that will support the activity, etc.\)](#)

This is done by clicking the 'Add New Document' button in the Designer and uploading the file from your computer (via the top, shaded box).

(Full Triannual Reviews):

[Review the Designer Library for other forms that may be required](#)

Download and save the form to your computer. Once you have completed it and saved it to your computer, upload it back into your submission package. This is done by clicking the 'Add New Document' button in the Designer and uploading the file from your computer (via the top, shaded, box). You will now see the completed form added to your document package.

(Full Triennial Review)
Upload active/pending grants that support the activity

This is done by clicking the 'Add New Document' button in the Designer and uploading the file from your computer (via the top, shaded box).

. Obtain necessary electronic signatures for your package

IMPORTANT: Before required individuals sign an IRBNet package, it is required that the last section of the committee application be reviewed for details on what their e-signatures certify.

Once you are done uploading all your documents and have given access (shared) your submission with all relevant individuals, be sure to sign your project (click the button 'Sign this Package' on the left side margin of your screen), and make sure your department chair (with whom you shared the project) also electronically signs your project. **The chair should only sign when your documents are finalized for submission, i.e., just before you are ready to submit to the IBC/IACUC/SCRO. For new and continuing studies**

- **Before you submit the project to the committee(s)**, you must obtain electronic signatures from the PI and the PI's department chair. Projects that are submitted without these 2 signatures will not be processed until this is done.
- **Before an approval will be issued by the IBC and SCRO committee(s)**, all co-investigator e-signatures will need to be present in IRBNet. Signatures can be added to a project even if the individual in question has 'read-only' access, and even if the project is in 'locked' status.

Submit your project to the applicable committee(s)

When all documents are uploaded, and PI and Chair signatures are obtained, hit the '**Submit this Project**' button on the left. You will be able to submit the one package to one or all committees.

- **To send your package to the IBC**, choose Stony Brook University IBC Office as the organization. You will then need to identify the submission type. Choose 'Continuing Review/Renewal'
- **To send your package to the IACUC**, hit the Submit the Project button again, this time choosing Stony Brook University IACUC Office as the organization. You will then need to identify the submission type. Choose 'Continuing Review/Renewal'

- **To send your package to the SCRO**, hit the Submit the Project button again, this time choosing Stony Brook University SCRO Office as the organization. You will then need to identify the submission type. Choose 'Continuing Review/Renewal'

4. Responding to committee concerns (modifications required, deferrals etc), post-review

You respond to committee concerns by submitting the requested information in a new package for your project. The following steps will help ensure a smooth submission.

[Create a New Package for an Existing Project in IRBNet](#)

1. In your 'My projects' view, click on the title of the project in question. This will take you to the Project Overview page.
2. Click the Project History button to the left.
3. Click the Create New Package button in the middle of the page (if the button isn't there, you were not granted that type of access by the PI)
4. Click on the 'New Document Package', which will take you into the Designer where you can work on documents for the new package via a few methods (described in detail below):

[You can revise a previously submitted registration form](#)

Refer to the 'Documents from Previous Packages' section at the bottom of the Designer view.

Click on the pencil icon for the Registration Form. This will open up the Registration Form.

Make any necessary changes to previously entered information and save. The document will move to the 'New and Revised Documents in this Package' section.

[You can revise a previously submitted document \(.doc, .xls, .pdf, etc.\)](#)

Refer to the 'Documents from Previous Packages' section at the bottom of the Designer view.

Download the document by clicking on its Document Type or the paper icon.

Make necessary changes and save the revised document to your computer.

Click on the pencil icon for that document in the Designer.

Browse your computer, select your revised document to upload, make necessary changes to Document Type and Description (below), and click the Update button.

When you click Update, the revised document will appear in the current document package ('New and Revised Documents in this Package') with a revision history (the 'stack of paper' icon) that reflects versions from previous packages (see below).

You can attach a new document to the package

Complete applicable forms downloaded from the Library, or create applicable documents on your computer.

Use the Add New Document button to upload the document into the current package. The document will not have a revision history (stack of paper icon) at this time as it is new.

When your response is ready for review

When all documents are uploaded, obtain PI e-signature are obtained, hit the '**Submit this Project**' button on the left. Choose the applicable SBU office (IBC, IACUC, SCRO) as the organization. The appropriate Submission Type for this package is 'Response/Follow-up'.

5. Submitting amendments etc. to your approved study

You will create, and submit **a new package** for the project. The following steps will help ensure a smooth submission.

1. In your "My Projects" view, click on the title of the project. This will take you to the Project Overview page.
2. Click the Project History button to the left.
3. Click the Create New Package button in the middle of the page (if you don't see the button, you were not granted access to create new packages when the study was shared with you)
4. Click on the 'New Document Package', which will take you into the Designer where you can work on documents for the new package via the methods described above in Section #3 to either revise a previously submitted document, registration form, or upload a new document for review (e.g., new grant, etc). For IBC and SCRO, upload a cover letter as well to explain the changes. For IACUC, upload the 'Request for a Minor Amendment to IACUC-Approved Use of Animals in Research and Educational

Activities' available in the IACUC Designer Library in IRBNet (note: major amendments to IACUC require a new, full application to be submitted)

5. Update your registration form:

IF YOU HAVE SIMILAR PROJECTS TEAMS OR PROJECT DATA ALREADY IN ANOTHER EXISTING PROJECT REGISTRATION FORM FROM ANY PROJECT TO WHICH YOU HAVE WRITE OR FULL ACCESS, YOU CAN SAVE TIME BY CLONING THAT REGISTRATION FORM.

How to Clone a Registration Form

- Click "Add New Document" on the Designer and choose the Smart Form you'd like to add to your package, as you normally would.
- If you have at least one existing wizard that is available to clone, then the system will automatically ask if you would like to (a) create a new wizard from scratch, or (b) clone one of your existing wizards; simply select the option to clone.
- A list of every wizard of this type that you have Write or Full access to will appear. Choose your preferred source file.

The system will copy all information from the selected wizard into a new wizard, and place you at the beginning of the form so you can update any information as needed.

When you have attached all the required documents, **submit** the revised package, **complete with required signatures**, to the applicable committee office in IRBNet See section VII. Be sure to indicate the Submission Type as "Modification/Amendment", or another applicable type.

6. Special Topics

Locked vs. Unlocked Status of packages

Once a study is submitted to a committee office, it is **LOCKED** in that office.

VERY IMPORTANT:

You can continue to obtain investigator signatures on a locked package. Under no circumstances should you create a new package just for the purpose of obtaining signatures.

Packages can only be unlocked by ORC Staff. This can be done if you let us know that you've made an error in something that you just submitted, or if we let you know that we see something that is missing or needs to be fixed before review.

The numbering system in IRBNet (What happened to the old #'s?)

You will note 2 different #'s in the IRBNet system, **IRBNet #**, and **Local Board Reference #**:

1. The IRBNet # is will replace your old IACUC# since DLAR now uses the IRBNet # on cage cards, billing and the census. The root # stays the same from creation of a project to termination thereof. The suffix of the IRBNet # (e.g., -1, -2, -3 etc) is the 'package #' with which you are dealing for a single project, i.e., each new package of a project will change the suffix of the IRBNet #.

Example: So if your original submission is given the IRBNet # 123456-1, and the IBC reviews the submission and requires changes, you will submit your response as a new package to the original, and it will be given the IRBNet # 123456-2. If it's then approved, and you want to add an amendment, you will submit it as a new package, it will be given the IRBNet #123456-3. And so on. If you click on 'project history' for IRBNet #1234567-3, you will see all the packages for the study.

2. The local board reference # is the IBC or IACUC or SCRO # for your project. Once a project is assigned that # in IRBNet, that # will remain exactly the same throughout the life of the study.

The numbering system for CORIHS is being changed to comply with recent FDA recommendations, and to ensure that the PI has full knowledge regarding when a 5 year continued approval is due for a given study.

New (first time) applications:

New applications coming into IRBNet will be assigned in sequential order in each committee, starting with 2010-0001. Any committee # beginning with a 2010 # will have to submit another full application (incorporating all amendments since last full application) every three years, so, in 2013 and 2016. It will be your responsibility to track when your 3 year continuing reviews are due in each committee.

Continuing Review Applications:

The last 4 digits of your current IBC or IACUC or SCRO # will stay the same. The first 4 digits (the year 'prefix') will revert back to the year you received approval for a full submission.

So, for e.g.:

If your current IBC# is 2009-0529, and the last time you completed a full application to the IBC was in 2008, then your new IBC# in IRBNet will 'revert' back to 2008-0529 (ORC staff will do the research and issuance of the new #). By doing this, you will now know that your 3 year full review will be due in 2011 and 2014. It will now be your responsibility to track when your full applications are due.