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IRBNet Submission Guidelines

Components of a Basic Submission for a New Project

Registration Form

1. Select Designer on the left hand navigation bar
2. Scroll down slightly to see "Add New Document" in the box in center of your screen - select this
3. 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".
4. Read each screens carefully as they come up and click "next"
5. Fill in the blanks

Committee-specific Application

Grant, if applicable

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

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 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 IBC all be in sync.

Create and Submit a New, First Time Submission

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. 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’ and now you are in the ‘Designer’ where you can build your submission for the committee(s).

2. 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.
- 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

3. Add the specific committee application(s) you need:

- IBC (‘Application for Approval of Activities Involving Recombinant or Synthetic Nucleic Acid Molecules’) 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.)

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

5. 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)

6. 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.

7. 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, so that adequate view of the project can be conducted.
- 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.

8. 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'

How to Add a Document

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

How to Share a Package

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.

What Your Electronic Signature Means on an IRBNet Package

Before you sign an IRBNet package, be sure to refer to the last pages of the IACUC, IBC, and/or SCRO application (as applicable) to understand what you are certifying when you sign the IRBNet package for the activity.

Respond to Committee Concerns, 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.

1. Create a New Package for an Existing Project in IRBNet

- In your 'My projects' view, click on the title of the project in question. This will take you to the Project Overview page.
- Click the Project History button to the left.
- 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)
- 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):

A. 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.

B. 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).

C. 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

2. When all documents are uploaded, obtain PI e-signature.

3. Once all signatures 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'.

Create and Submit a Continuing Review Package – First or Second Renewal

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.

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

1. In the "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.
 - Add the specific continuing review application(s)
 - IBC : 'Application for Continuing Review of Recombinant or synthetic nucleic acid molecules Approval' and/or
 - IACUC: 'Application for Continued Approval for Vertebrate Animals in Research and Educational Activities' and/or
 - SCRO ('Application for Continuing Approval of Stem Cells/Stem Cell Lines in Research')
 - Complete and add a new registration form or edit an existing 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.
 - 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.)
5. 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.

6. 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'

Create and Submit a Continuing Review Package – Full Triennial Review

If you have renewed the study twice (2X) since the last full application to the committee, you are now due for a full, triennial review.

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

1. In "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.
- Add the specific continuing review application(s)
 - IBC : 'Application for Approval of Recombinant or synthetic nucleic acid molecules Activities' 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' and/or
 - SCRO 'Application for Approval of Stem Cells/Stem Cell Lines in Research'
 - Complete and add a new registration form or edit an existing 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.
- 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.
- Review the Designer Library for other forms that may be required.
- Upload active/pending grants that support the activity.
- Upload any other documents you want to submit in support of the continuing review package.

5. 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.

6. 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’

Submit an Amendment to your Approved Study

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

In your “My Projects” view, click on the title of the project. This will take you to the Project Overview page.

1. Click the Project History button to the left.

2. 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)
3. 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 SCRO, upload a cover letter as well to explain the changes.

For IBC, upload the 'Request for an Amendment of Approved Protocol for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (rsNAM)' available in the IBC Designer Library in IRBNet.

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)

4. Submit 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.
5. 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.

Locked vs. Unlocked 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.