IRBNet Instructions for SBU and BNL Investigators

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Stony Brook University uses IRBNet for the electronic administration and management of its IRB's, the Committees on Research Involving Human Subjects (CORIHS). Below is a 'How to' tutorial on IRBNet. Chairs and Departmental Review Committee Chairs should also review SBU's Instructions for Chairs (Departmental or Departmental Review Committee)

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I. How do you register with IRBNet?

Go to www.irbnet.org and register with IRBNet.
Follow the directions for New User Registration.

Note:

- When you choose your affiliation, choose either Stony Brook University or Brookhaven National Laboratory, depending upon your primary appointment.

- 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.

- You will be sharing your study with co-investigators (i.e., allowing them to electronically review your submission), as well as other individuals (see section IV). Make sure they are aware of the need to register as well, or else you will not be able to share with them.

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II. How do you create and submit a new (first time) project submission in IRBNet?

Note:

- *Depending on an individual's access level, the PI can delegate (through sharing) to a co-investigator, or a study coordinator, the task of helping to create the study.* ***Higher levels of sharing (ability to submit a study, as an example) should be granted to as few individuals as possible (e.g., PI and study coordinator).***
- *In addition to the documents addressed below, BNL investigators should obtain additional* BNL-specific forms for completion at http://www.bnl.gov/ora/ORA.asp
- Note that consent forms **should** be submitted in Microsoft word, and **should not** be submitted on letterhead.

- To begin, log on, choose 'Create New Project' (on the left), and fill out all initial required fields (and non-required fields as you wish for your own 'search' requirements).

- Complete the **Registration Form for Expedited or Full CORIHS Review**:
  - Go to your project's Designer
  - Select 'Add New Document'
  - In the lower shaded 'On-Line Document' box, select 'Registration Form for Expedited or Full Committee Review', then hit the 'Add' button
  - Begin completing the Registration Form. You do not need to complete the whole form in one sitting; you can 'save and exit', and then go back and update the document by clicking the pencil icon next to the document listed in the designer.
  - When you are done completing the registration form, click **"Preview"** to see what the completed form looks like, and confirm that all the information provided is accurate. Once you are satisfied in this regard,

Click "Save and Exit", and then continue constructing your project package to completion:

- Download and complete the "Application for Expedited or Full CORIHS Review", a downloadable document located in the project's in the Document Library (found on Designer page, step one) that will capture more detail about the answers you provided in the Registration Form.
- Download and complete other required, downloadable forms (found on Designer page, step one), in accordance with the requirements outlined in the **CORIHS Submission Requirements for New, First Time Submissions**, which is available in the project's Library. Examples of such forms are the consent templates for customization to your study, 'Application for Approval to Conduct Research at University Hospital', and Supplemental forms (if your project is proposing use of questionably viable or nonviable neonates, international sites, prisoners, or must comply with ICH-GCP). Once completed, you will upload the completed forms from your computer. You will need to supply a 'document type': select the descriptor that best describes what you are uploading. If unsure, select 'other' and provide the description you want in the field called 'description'. Then browse and find the document for uploading from your computer by clicking on 'Add New Document' in the Designer, and using the top shaded area on the next screen.

- Upload other documents from your computer to complete the submission, such as sponsor protocol, investigator brochures, advertisements etc, by clicking on 'Add New Document', and using the top shaded area.
- Share with your project team members (see section IV).
- Obtain appropriate signatures (see section V, VI).
- Submit the package to the **Stony Brook University Human Subjects Committee (IRB)** by clicking the 'Submit this Project ' button on the left. You will be submitting to the Stony Brook University Human Research Committee (IRB). The first time you submit a brand new project, you will choose the submission type **'New Project'**.

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III. How do you create and submit a regular or 5 year continuing review package?

NOTE:

- *If you are unsure as to whether you need to submit a 'Regular' or 'Five Year' continuing review application, go to section XI.2 for a discussion of how your CORIHS# reveals the answer.*
- *Consent documents **should** be submitted in Microsoft word, and **should not** be submitted on letterhead.*
- *For instructions on **how to terminate a study**, see section XII*
- *You can also take a document from a previous package of the project in IRBNet, revise it, and submit with the current continuing review package. See Section IX for instructions.*

a. If you need to submit a 'Regular' (Years 1-4) Continuing Review package:

- Create a new package to your previously approved project:
  - Go into your 'My Projects'.
  - Click on the exact IRBNet project (including same suffix) referenced in the e-mail you received reminding you to renew your study
  - Go into Designer, and select 'Add New Document' at the bottom of the page, then select **'**Create New Package'

- Download and complete the "Application for Continuing Expedited or Full CORIHS Review", a downloadable document located in the project's Library (found on Designer page, step one) .
- Download and complete other required, downloadable forms (found on Designer page, step one), in accordance with the requirements outlined in the **CORIHS Submission Requirements for Continuing Reviews (Regular and Five-Year)** which is also available in the project's Library. Once completed, you will upload the completed forms from your computer. You will need to supply a 'document type': select the descriptor that best describes what you are uploading. If unsure, select 'other' and provide the description you want in the field called 'description'. Then browse and find the document for uploading from your computer by clicking on 'Add New Document' in the Designer, and using the top shaded area on the next screen.
- Upload other documents from your computer to complete the submission, such as sponsor protocol, investigator brochures, advertisements etc, by clicking on 'Add New Document', and using the top shaded area on the next screen.
- Share with your project team members (see section IV).
- Obtain appropriate signatures (see section V, VI).

- Submit the package to the **Stony Brook University Human Subjects Committee (IRB)** by clicking the 'Submit this Project ' button on the left. You will be submitting to the Stony Brook University Human Research Committee (IRB). You will choose the submission type **'Continuing Review/Renewal'**.

b. If you need to submit a Five Year Continuing Review package:

- Create a new package to your previously approved project:
    - Go into your 'My Projects'.
    - Click on the exact IRBNet project (including same suffix) referenced in the e-mail you received reminding you to renew your study
    - Go into Designer, and select 'Add New Document' at the bottom of the page, then select **'**Create New Package'

- Complete the **Registration Form for Expedited or Full CORIHS Review**:
    - Go to your project's Designer
    - Select 'Add New Document'
    - In the lower shaded 'On-Line Document' box, select 'Registration Form for Expedited or Full Committee Review', then hit the 'Add' button
    - Begin completing the Registration Form. You do not need to complete the whole form in one sitting; you can 'save and exit', and then go back and update the document by clicking the pencil icon next to the document listed in the designer.
    - When you are done completing the registration form, click **"Preview"** to see what the completed form looks like, and confirm that all the information provided is accurate. Once you are satisfied in this regard,

Click "Save and Exit", and then continue constructing your project package to completion:

- Download and complete the "Application for Five Year Continuing Expedited or Full CORIHS Review", a downloadable document located in the project's Library (found on Designer page, step one) that will capture more detail about the answers you provided in the Registration Form.
- Download and complete other required, downloadable forms (found on Designer page, step one), in accordance with the requirements outlined in the **CORIHS Submission Requirements for Continuing Reviews (Regular and Five-Year)** which is also available in the project's Library. Examples of such forms are the consent templates for customization to your study, 'Application for Approval to Conduct Research at University Hospital', and Supplemental forms (if your project is proposing use of questionably viable or nonviable neonates, international sites, prisoners, or must comply with ICH-GCP). Once completed, you will upload the completed forms from your computer. You will need to supply a 'document type': select the descriptor that best describes what you are uploading. If unsure, select 'other' and provide the description you want in the field called 'description'. Then browse and find the document for uploading from your computer by clicking on 'Add New Document' in the Designer, and using the top shaded area on the next screen.
- When, during uploading your forms, you are asked for 'document type', select the descriptor that best describes what you are uploading. If unsure, select 'other' and provide the description you want in the field called 'description'. Then browse and find the document for uploading from your computer.
- Upload other documents from your computer to complete the submission, such as sponsor protocol, investigator brochures, advertisements etc, by clicking on 'Add New Document', and using the top shaded area on the next screen.
- Share with your project team members (see section IV).
- Obtain appropriate signatures (see section V, VI).

- Submit the package to the **Stony Brook University Human Subjects Committee (IRB)** by clicking the 'Submit this Project ' button on the left. You will be submitting to the Stony Brook University Human Research Committee (IRB). You will choose the submission type **'Continuing Review/Renewal'**.

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IV. Sharing your submission package:

- **How do you share your submission with SBU or other researchers?**
- **What level of access should the members of your study team have?**
- **With whom must you share your submission?**

How do you share your submission with SBU or other researchers?

- Press the 'Share this Project' button on the left.
- You will first need to select the name of the organization where the individual is affiliated (Stony Brook will be highlighted by default, but you can share the study with individuals who are registered with *other* organizations', 'Brookhaven National Laboratory', etc. Just select the organization from the list)
- Click 'select organization'.
- On this next screen, 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 means that the person has not yet registered on IRBNet.** You must contact the individual and tell him/her to do so before you can share the project with him/her.
- Only the principal investigator and maybe one other (a study coordinator) should have full access to edit and submit the project to the IRB. **Those with full access will receive e-mails when the ORC or IRB posts an action or decision.**

What level of access should the members of your study team have?

It is up to you to decide what kind of access shared individuals should have. It bears repeating: only the principal investigator and maybe one other (a study coordinator) should have full access to edit and submit the project to CORIHS. Those with full access will receive e-mails when the ORC or IRB post an action or decision. Note in the following list other special circumstances under which full access must be provided.

With whom must you share your submission?

- all **co-investigators, including non-SBU collaborators** (you need to tell them to register with IRBNet)…you can allow input, or access to your materials for free.
- your **study coordinator**
- **your department chair/dep't review committee chair**
- **If your research activity involves the facilities, patients, and/or services of any of University Hospital's inpatient or outpatient locations,** (with the exception of the outpatient clinics located at Riverhead, Southold, Plainview, or Medford), **you must additionally:**
  - share your study on IRBNet, and obtain the electronic signature endorsements of Dr. Joseph Laver and Rhona Vainder (Chernoff) or Regina Rigoroso, in her absence, and
  - also share and obtain endorsement, as applicable, from:
    - Jay Bock, if your study involves Pathology/Laboratory Services,
    - 'Research Pharmacy' (if your study involves the Pharmacy),
    - Mark Schweitzer (if your study requires Radiology services), or
    - Stephanie Musso (if identifiable subject health information will be electronically transmitted outside of SBU).
- **If the project comes from BNL, Darcy Mallon** must be given full access

- **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.
- **Non-SBU collaborators**

When you share your project, the individuals you select will get an e-mail notification that you have done so.

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V. Obtaining necessary electronic signatures for your package

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 . **Chair should only sign when your documents are finalized for submission, i.e., just before you are ready to submit to CORIHS.**

For new and continuing studies

- You will need to provide electronic signatures from the PI, chair, and BNL (i.e., Darcy Mallon, for applications from BNL) before you submit the project to CORIHS.
- All co-investigator e-signatures will need to be present before the project will be approved by CORIHS. 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.

For any interim submissions (amendments, UPs, SAEs)

- The PI must provide electronic signature before the project is submitted to CORIHS.

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VI. What does your electronic signature mean?

Good question.

If you are the Principal Investigator, your electronic signature that is associated with a given project means that the research described in the application and supporting materials will be conducted in full compliance with Stony Brook University's Policies and Federal regulations governing human subject research. Furthermore, you will:

- Ensure that all aspects of the project will be conducted by the study team as approved by CORIHS,
- Promptly report any revisions or amendments to the research activity for review and approval by CORIHS prior to commencement of the revised protocols, with the only exception to this policy being those situations where changes in protocol are required to eliminate apparent, immediate hazards to the subject,
- Promptly report any unanticipated problems or serious adverse events affecting risk to subjects or others,
- Assume full responsibility for selecting subjects in strict accordance with the inclusion/exclusion criteria outlined in the application materials,
- Use only CORIHS-approved, stamped consent forms for studies in which consent form(s) have been approved for the research activity, and
- Ensure that all personnel involved with human subjects, or human data and/or biological specimens during the course of this research activity are trained in the Protection of Human Subjects and HIPAA in Research, in full accordance with SBU policy on this matter.

If you are a co-investigator, your electronic signature that is associated with a given project means that:

- You are fully cognizant of the details of the protocol, and will conduct all aspects of the project as approved by CORIHS
- You will promptly report to the Principal Investigator any unanticipated problems or serious adverse events affecting risk to subjects or others
- You will not be involved in any aspect of the project for which you have not been trained, or conduct any procedure in which you are not certified/licensed.

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VII. What is the administrative routing once you submit a package to the CORIHS Office? What's with all the e-mails?

You (and anyone else to whom you have granted full access on the study) will receive e-mails at various steps of the review process for your package. They are meant to be informative, and to make the IRB process more transparent.

The 'front office' of the IRB does a preliminary review of your submission to confirm that all obvious components are present, critical individuals have been granted access where applicable (e.g., BNL, GCRC, Dr. Griffin for UH studies, etc.) and PI and dep't chair e-signatures have been provided. If any such components are missing, the PI, study coordinator, and anyone else having full access will be notified by e-mail to address the issue.

Once a complete submission is received by the CORIHS Office, it will take one of two routes.

Exemption Submissions: If you are applying for exemption, the study will remain in the 'virtual' CORIHS office and be assigned a CORIHS# (see section XI for more on the various #'s in IRBNet). ORC administrators will then review the submission on behalf of the institution. You will receive an e-mail notifying you when the review is completed, and a decision is rendered. You will then log on to IRBNet, click on the study title, go into your project designer and review the decision letter from the office.

Non-Exempt Submissions (expedited or full committee reviews of new studies, continuing reviews, amendments, UP's etc): If you have submitted something that requires review by one of our IRB's, the submission will be assigned a CORIHS# (see section XI for more on the various #'s in IRBNet) and will then be forwarded from the CORIHS Office to IRB administrators for either CORIHSa or CORIHSb (depending on variables, e.g., deadlines, prior history of review etc.). Any investigator with full access on the study will receive an e-mail notifying them that the study has been forwarded to an IRB for either immediate review assignment (expedited review materials) or to be placed in queue for full committee review (full review materials). This e-mail does not require action from you. It is just an 'FYI'.

- If your package is expeditable, the IRB administrators will 'share' the submission with 1 or more IRB members of the relevant committee for their review. When all reviews are in, the IRB administrators will change the status on the study from 'pending review' to either approved, modifications required, or deferred to full committee. Any investigator will full access on the study will receive an e-mail notifying them of the change in status, with instructions to log on to IRBNet and see the review details in your 'My Documents', under Board Documents.

- If your package requires full review, you will receive an e-mail, usually immediately following the 'forwarded' e-mail indicating that the project has been 'Referred to Full Board', along with the date of the meeting at which it will be reviewed. This e-mail does not require action from you. It is just an 'FYI'. The IRB Administrators will prepare the meeting agenda approximately one week prior to the particular IRB meeting. Once the meeting has occurred, any investigator will full access on the study will receive an **e-mail** notifying them of the IRB's decision regarding their submission.

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VIII. How do you respond to CORIHS, post-review (i.e., for modifications required, deferrals etc)?

Answer: You respond by submitting to CORIHS a revised project package with updated information.

The following steps will help ensure a smooth submission.

Create a New Package for an Existing Project in IRBNet

1. In your 'My Projects', click on the title of the project to go 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.
4. Click the Designer button to work on documents for the new package via two methods (described in detail below):

- **METHOD #1:** Revise a previously submitted document;
  or
- **METHOD #2:** Attach a new document to the package.

METHOD #1: Revise or Submit a Previously Submitted Document for Review (Designer page)

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

1. To revise **the Registration Form** from a previous package for committee review:
   - 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.

2. To revise an **uploaded document** (.doc, .xls, .pdf, etc.) from a previous package:

   - First 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).

METHOD #2: Attach a New Document to the Package (Designer)

1. Complete applicable forms downloaded from the Library, or create applicable documents on your computer.
2. 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.

ONCE YOU HAVE COMPLETED CONSTRUCTION OF THE PACKAGE USING EITHER METHOD

- Obtain appropriate signatures (see section V, VI).
- Submit the package to the **Stony Brook University Human Subjects Committee (IRB)** by clicking the 'Submit this Project ' button on the left. You will be submitting to the Stony Brook University Human Research Committee (IRB). You will choose the submission type **' Response/Follow-up'**.

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IX. OK. Your project is approved. Now what? How do you submit amendments, Unanticipated Problems (including SAE's) etc.?

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

Create a New Package for an Existing Project in IRBNet

1. In your Study Manager click on the title of the project to go 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.
4. Click the Designer button to work on documents for the new package via two methods (described in detail below):

- **METHOD #1:** Revise a previously submitted document **(e.g. for amendments etc.)**
  or
- **METHOD #2:** Attach a new document to the package **(e.g., continuing review application, Unanticipated Problem Form, etc).**

METHOD #1: Revise or Submit a Previously Submitted Document for Review (Designer page)

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

1. To revise **the Registration Form** from a previous package for committee review:
   - 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.

2. To revise an **uploaded document** (.doc, .xls, .pdf, etc.) from a previous package:

- First download the document by clicking on its Document Type or the paper icon. **If you will be revising a consent document, be careful to ensure that the document in your designer that you will be downloading and revising is identical to the most current, stamped, IRB-approved version that sits in the Board Documents.**
- 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).

METHOD #2: Attach a New Document to the Package (Designer)

1. Complete applicable forms downloaded from the Library, or create applicable documents on your computer.
2. 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.

ONCE YOU HAVE COMPLETED CONSTRUCTION OF THE PACKAGE USING EITHER METHOD

- Obtain appropriate signatures (see section V, VI).
- Submit the package to the **Stony Brook University Human Subjects Committee (IRB)** by clicking the 'Submit this Project ' button on the left. You will be submitting to the Stony Brook University Human Research Committee (IRB). You will choose the most appropriate submission type (e.g., 'Modification/Amendment' , 'Reportable Event' etc.).

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X. Locked vs. Unlocked Status

Once a study is submitted to the IRB, it will be **LOCKED**.

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 forwarding to CORIHS.

When you need to respond to a CORIHS review, or if you want to submit an amendment, or continuing review, you will **create a new package** for the project by adding documents in the designer for that project. See sections VIII and IX for details.

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

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

1. The IRBNet # is not your CORIHS #, but is an important 'internal tracker' provided through IRBNet which is assigned to all studies that you create (new and continuing). 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 will change the suffix of the IRBNet #.

Example: So if your original submission is given the IRBNet # 123456-1, and the IRB 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.

NOW:

2. The local board reference # is the CORIHS # for your project. Once a project is assigned a CORIHS# 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, starting with 2008-0001. Any CORIHS # beginning with a 2008 # will have its 5 year continuing reviews due in 2013 and 2018. It will now be your responsibility to track when your 5 year continuing reviews are due.

Continuing Review Applications:
The last 4 digits of your current CORIHS # will stay the same. The first 4 digits (the year 'prefix') will revert back to the year you received approval for a full submission (either as a new or as a 5-year continued application, whichever is later).

HUH?
If your current CORIHS# is 2007-3529, and the last time you made a full submission to CORIHS was 2005, then your new CORIHS# in IRBNet will 'revert' back to 2005-3529 (ORC staff will do the research and issuance of the new #). By doing this, you will now know that your 5 year continuing reviews will be due in 2010 and 2015. It will now be your responsibility to track when your 5 year continuing reviews are due.

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XII. Continuing Reviews /Termination Reports (Non-exempt Studies)

Once your project is approved by CORIHS, IRBNet will send those with full project access an e-mail notification 90 and 60 days prior to the expiration of the approval period. You should respond to the first notice as soon as possible, to ensure that there is no lapse in your study approval. If your approval **does** lapse before you have been re-approved (even if you submitted the continuing review materials), the research activity (including data analysis) must be halted immediately.

Once you receive your e-mailed notice to renew your study:

A. If you do not want to continue the study (including data analysis) past the study expiration date:

- Go into your 'My Projects'.
- Click on the exact IRBNet package (including same suffix) referenced in the e-mail you received
- Go into project designer, and select 'add new documents'. **You will be creating a new package for this study.**
- Go into the Library, and download the 'Application for Continuing Expedited or Full CORIHS Review'.
- Complete the document as a Termination Report, and upload it back into IRBNet.
- Obtain e-signatures of PI and Department Chair.
- Submit the package as a 'Closed/Final' report.
- You will receive acknowledgement of the closure by ORC.

B. If you do want to continue the study (including data analysis) past the study expiration date, you first need to determine if you must undergo 'regular' continuing review, or 'Five year' continuing review:

If the first part of the CORIHS # referenced in the e-mail notification (the 'year' part) is 5 years or older than the current year, you must complete a 'Five Year' continuing review, unless:

a) the human subject aspects of your study are now limited to data analysis,

b) enrollment has ended, subjects have completed all research-related intervention AND the study is now limited to long-term follow-up of subjects, OR

c) there has been no enrollment to date AND there has been no increased risk identified (via amendments, SAE's etc) for your study during the time it has been active with CORIHS.

If your study falls into a, b, or c above, or the CORIHS# above shows a year that is not 5 years or older than the current year, you will be able to undergo 'regular' continuing review.

Directions for submitting 'regular' and 'five year' continuing reviews are available in Section III above.

XIII. Continuing Reviews /Termination Reports (Exempt Studies)

Once your project receives exemption status from the Office of Research Compliance, IRBNet will send those individuals with full project access an e-mail notification 90 and 60 days prior to the expiration of the exemption period. You should respond to the first notice as soon as possible, to ensure that there is no lapse in your study approval.

Once you receive your e-mailed notice to renew your exemption:

- Go into your 'My Projects'.
- Click on the exact IRBNet package (including same suffix) referenced in the e-mail you received
- Go into project designer, and select 'add new documents'. **You will be creating a new package for this study.**
- Go into the Library, and download the 'Exemption Status Report'
- Complete the document and upload it back into IRBNet.
- Obtain e-signatures of PI and Department Chair.
- Submit the package as a 'Continuing Review' or 'Closed/Final' report, depending on whether or not you are continuing or ending the project (respectively).

- You will receive renewal of exemption status (or acknowledgement of the closure) by ORC.