The Medical Center of Aurora
North Suburban Medical Center
Presbyterian/St. Luke's Medical Center &
Rocky Mountain Hospital for Children
Rose Medical Center
Sky Ridge Medical Center
Spalding Rehabilitation Hospital
Swedish Medical Center
LEADING HOSPITALS. TRUSTED CARE.

# HCA-HealthONE IRB IRBNet User's Guide

HCA-HealthONE IRB

IRBNet

# INTRODUCTION

The HCA-HealthONE IRB is responsible for ensuring that any research study under its jurisdiction is in compliance with federal, state, and institutional regulations. All submissions must be submitted electronically to the HCA-HealthONE IRB through IRBNet. IRBNet is a hosted service that supports electronic, on-line submissions. No hard copies will be accepted. IRBNET can be accessed at the following web address:

The Web Address:

www.irbnet.org

The purpose of this document is to provide guidance for submitting to the HCA-HealthONE IRB via IRBNet. Step-by-step instructions will be given for each type of submission.

# OPTIONS AVAILABLE FOR GUIDANCE

**TRAINING VIDEOS**: For new users, IRBNet has developed Training videos that take you through the steps of using their system. You may access the training videos by going to: www.irbnetresources.org/tresources/training.html and entering in the following:

username: hca-healthone

password: training1

The **New User Registration** Instructions provides instructions for Registering with IRBNet.

The **New Project Submission** video walks through the process of submitting an Initial Submission and the **Post-Submission Advanced Topics** video walks through the process of submitting subsequent materials like Continuing Reviews, Amendments, Study Closures, etc.

**TRAINING ENERGIZERS**: Training Energizers are documents developed by IRBNet that provide step by step visuals of the IRBNet Login Registration Process and the IRBNet electronic submission process that help users understand how to use the system. It is recommended that you print these documents and keep them as a reference to help you navigate in IRBNet.

If you have any questions regarding submitting via IRBNet, please contact the HCA-HealthONE IRB administrative office at 303-584-2300.

Thank You!

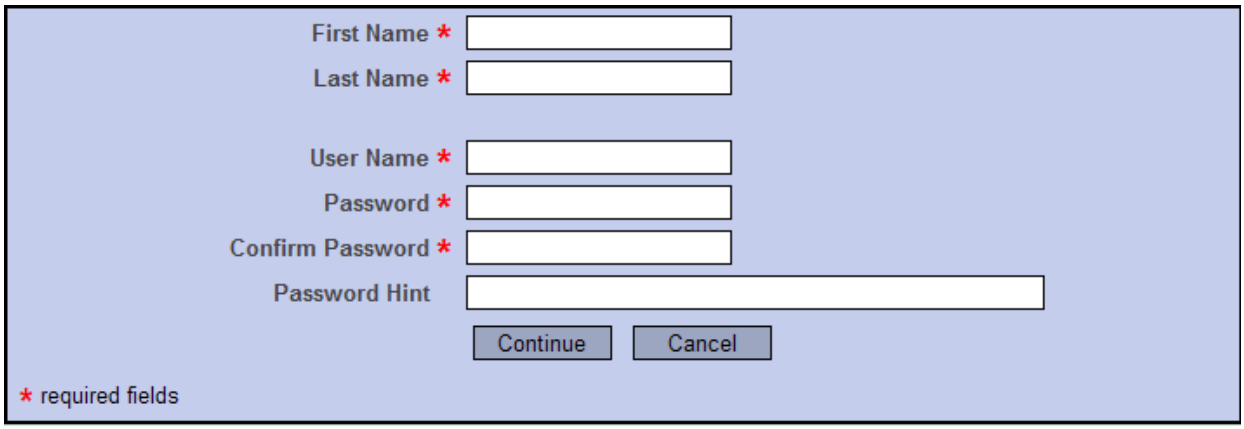
# TABLE OF CONTENTS

# I. INSTRUCTIONS FOR REGISTERING WITH IRBNET

1. Go to http://www.irbnet.org

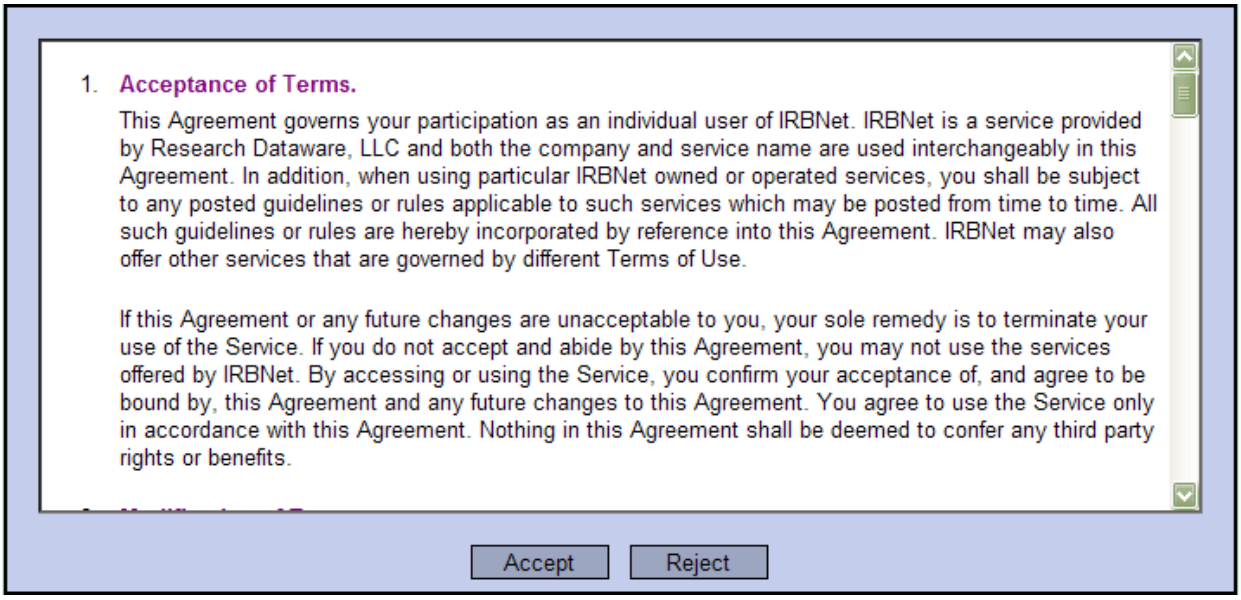
2. Click on the '**New User Registration'** link in the upper right-hand corner of the screen


3. Create your username and password. Fill out the required information. Your password must contain 8 characters. Click '**Continue**'

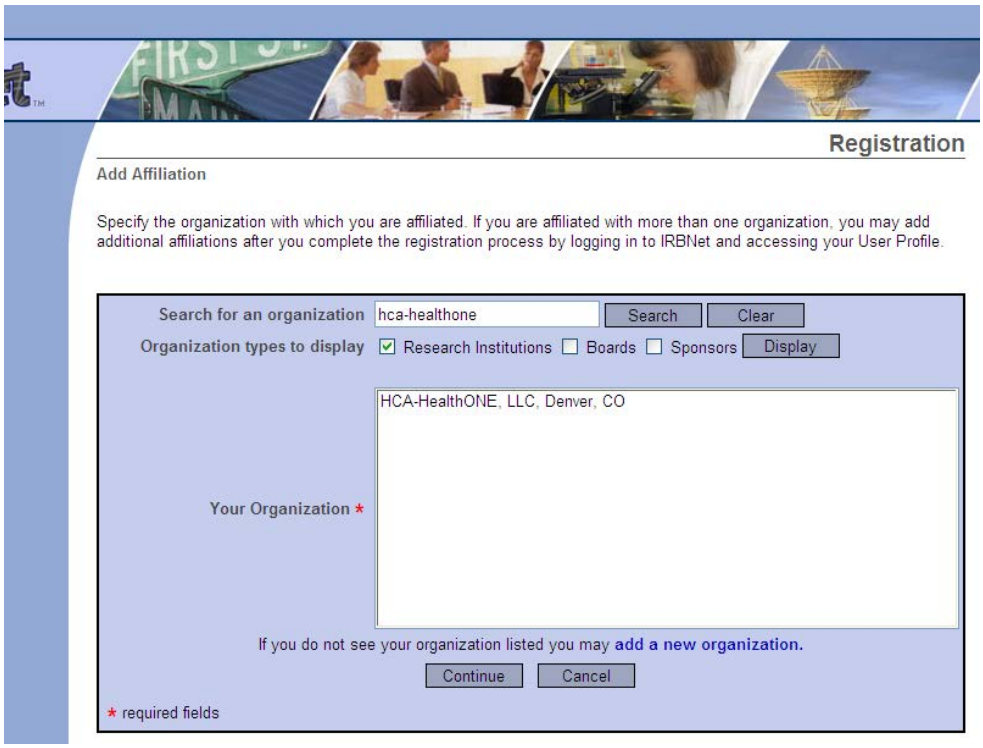



4. Read and **Accept** the Individual User Terms of Use

REGISTER

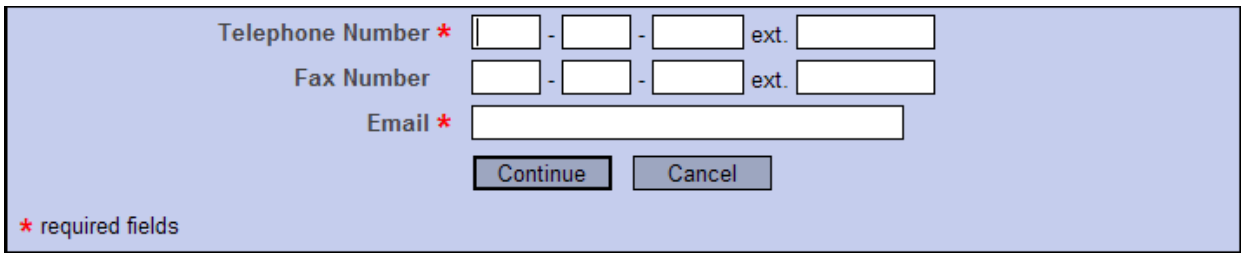



5. To add your affiliation, type the word 'HCA-HealthONE' into the search box. Click '**Display**'. Select 'HCA-HealthONE LLC, Denver, CO' from the organization box. Click '**Continue**'




REGISTER

6. Enter your contact information. Enter the email address you will use to receive communications through the IRBNet system. (e.g. notification of IRB decisions, communications from your research team or administrator). Click '**Continue**'



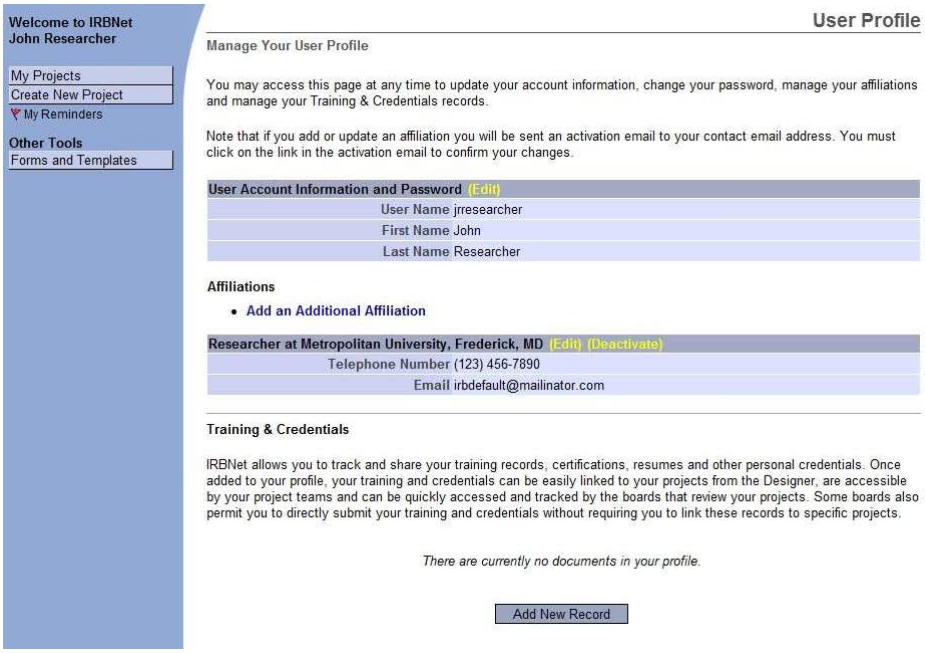

7. Review the information you provided and edit as necessary. When you are satisfied, click '**Register**'

**IMPORTANT**: An email will be sent to the email address you provided in Step 6, with 'IRBNet Activation Required' in the subject line. If you do not receive the confirmation in a short period then check your junk folder to see if it is there. You will need to click on the link provided in this registration email in order to activate your account. Clicking on the link will take you to the IRBNet homepage.

If you have problems activating your account or have forgotten your password, please click on the "**Forgot your Password**?" text in the upper right corner of the IRBNet home page.

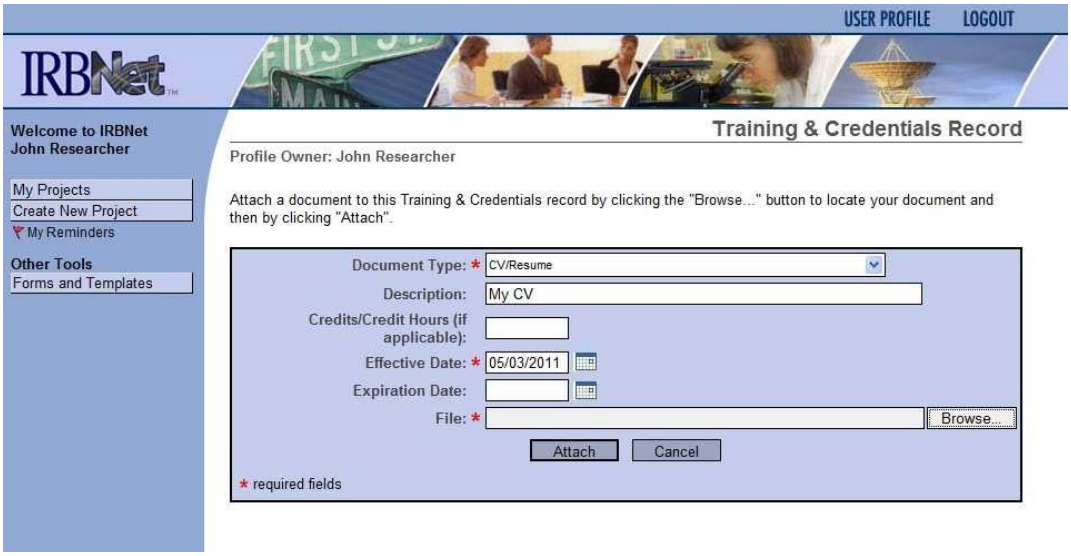
# II. INSTRUCTIONS FOR USING THE TRACK TRAINING TOOL

Step 1: Upload appropriate Training and Credential (T&C) documents to your User Profile (i.e., NIH or CITI Human Subjects Protection Training documents, CV's.)



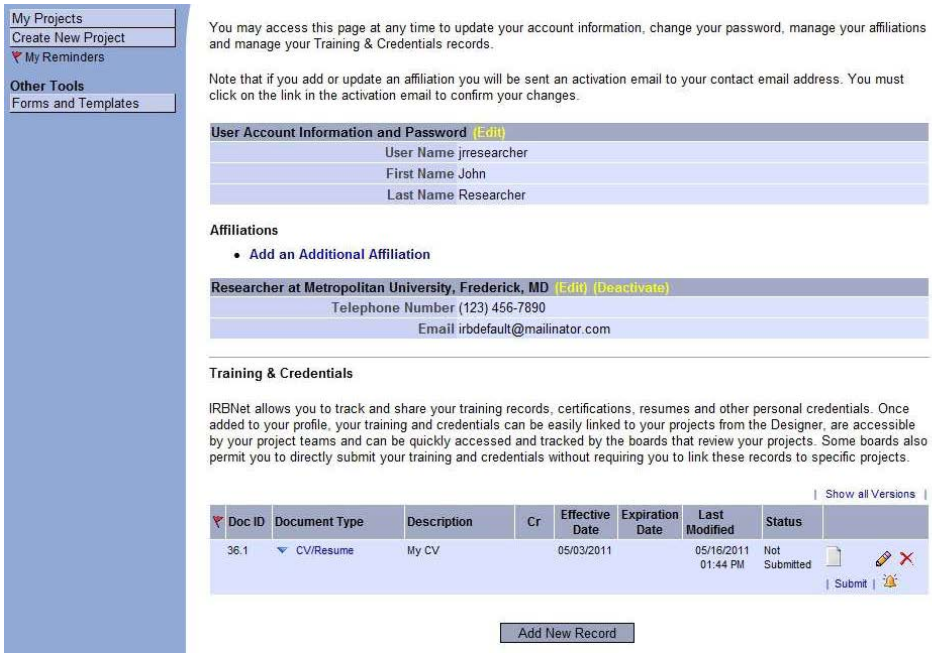

Click on '**Add New Record**

Step 2: Enter the appropriate information and select the correct T&C document. Be sure to enter accurate Credit Hours and Expiration Date if applicable.



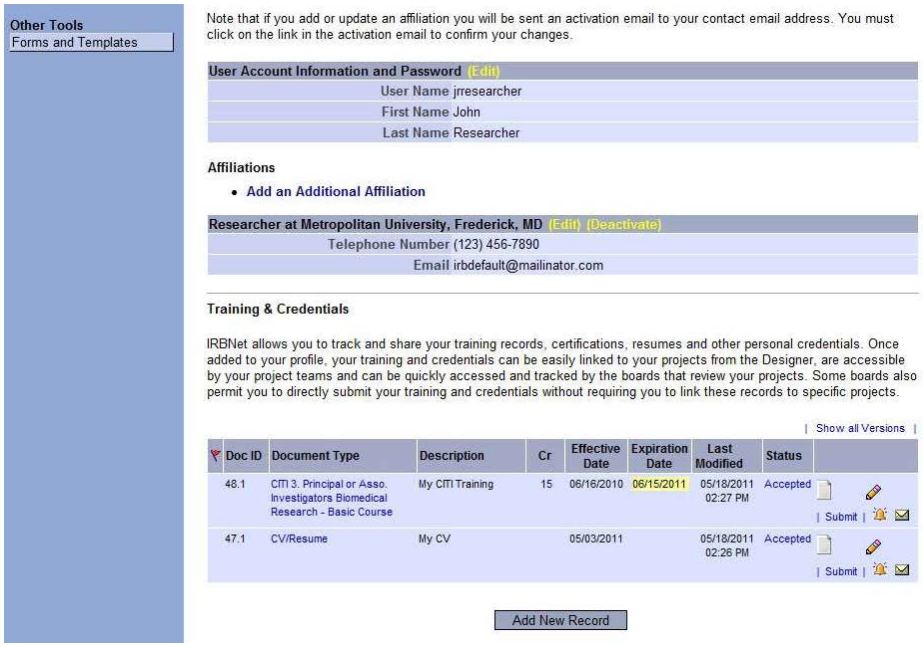

Click '**Attach**' to upload the document. Click '**Browse**' to select the correct T&C document to upload.

Step 3: Submit uploaded T&C documents to the HCA-HealthONE IRB.




Click 'Submit' to submit the document to the HCA-HealthONE IRB

Step 4: Upload additional T&C documents as needed and keep your existing documents up to date as credentials change




The highlighted expiration date indicates the document will expire within the next 60 days.

Manage each T&C document using the icons. To update a document, use the Pencil icon.

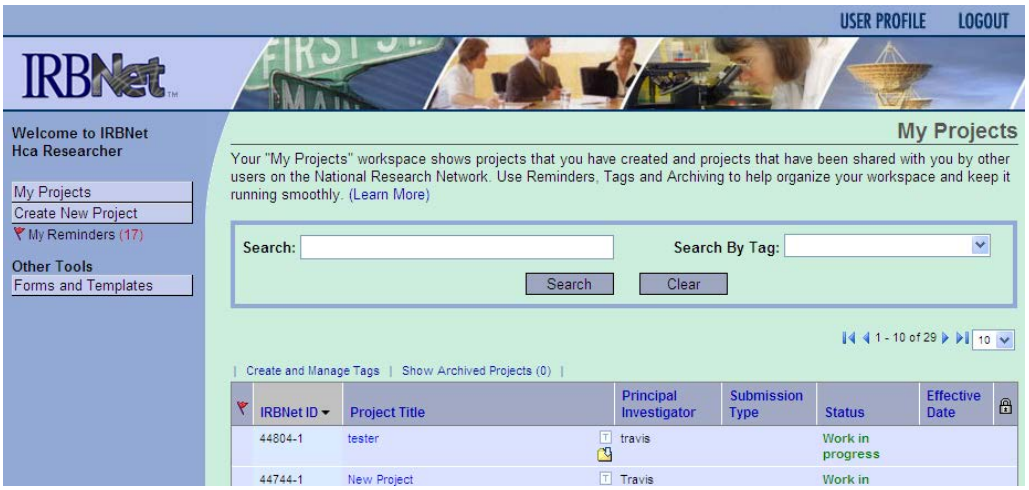
# III. INSTRUCTIONS FOR INITIAL SUBMISSIONS

To submit a study for review, you must first **CREATE A NEW PROJECT** (Study) to hold your documents. Any type of document can be uploaded, but your study MUST include all the required forms for a complete package before any action can be taken on behalf of the board. A good place to start is 'Checklist – New Submissions' which includes a list of the required forms for a New Study. This and other checklists can be found under "**Other Tools**" (**Forms and Templates**) on the left side of your screen.

***Please Note*:** If you are submitting on behalf of the Principal Investigator (PI), the PI must be registered in IRBNet so that he/she can sign your package later in the submission process.

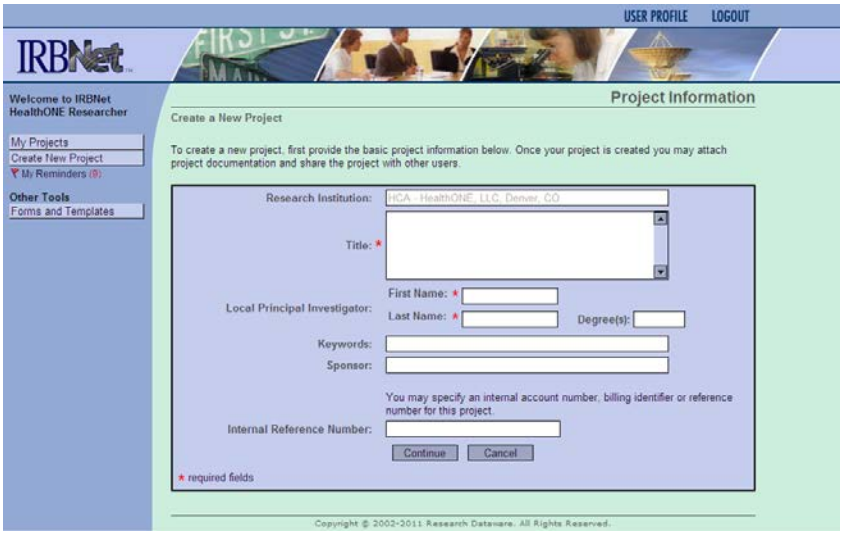
Step 1: Log In to www.irbnet.org using your username and password (for First Time Users, you must Register with IRBNet; please see INSTRUCTIONS FOR REGISTERING WITH IRBNET/ page 3.)

Step 2: The default page will be **MY PROJECTS**, where you will have access to all of your existing studies as well as the ability to create new studies. Click **CREATE NEW PROJECT** (on the left side of your screen).

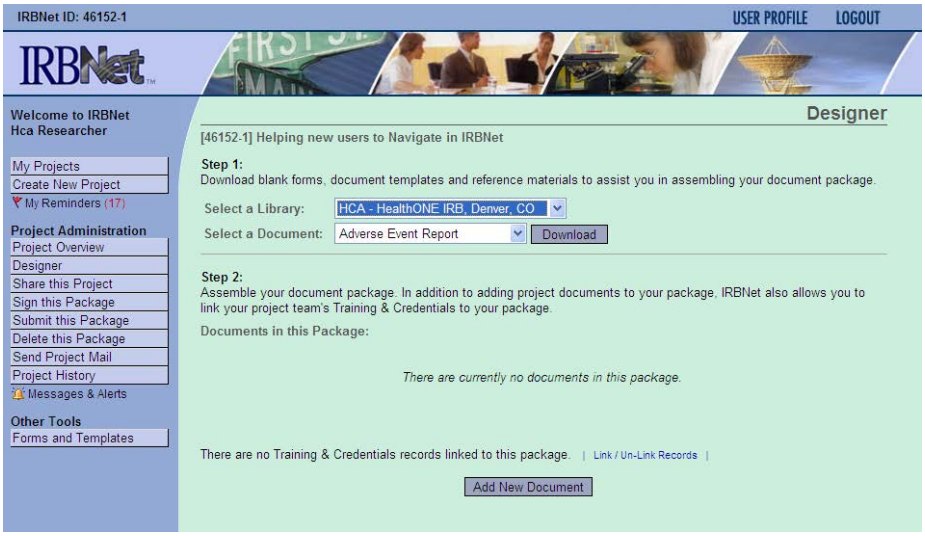



CREATE NEW PROJECT

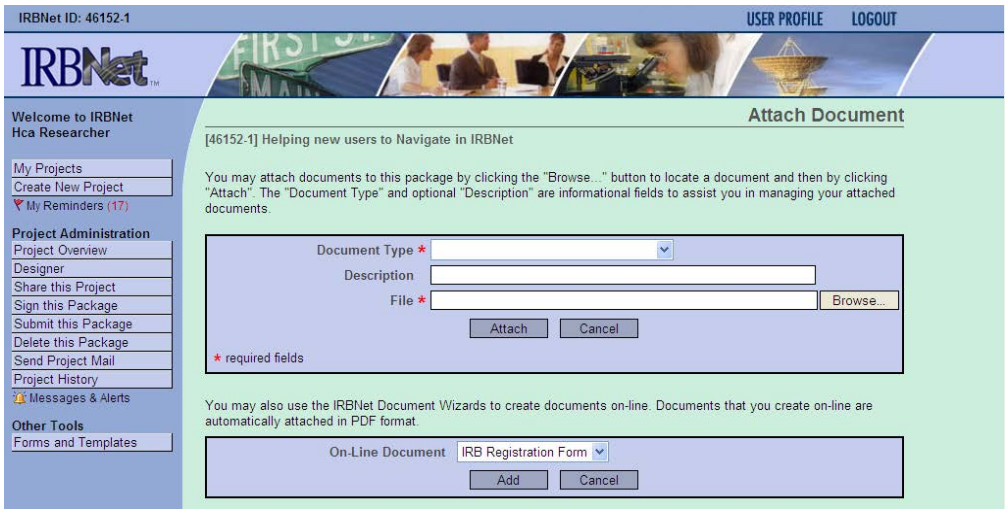
Fill in the relevant information about your project (title, PI name), click '**Continue'**



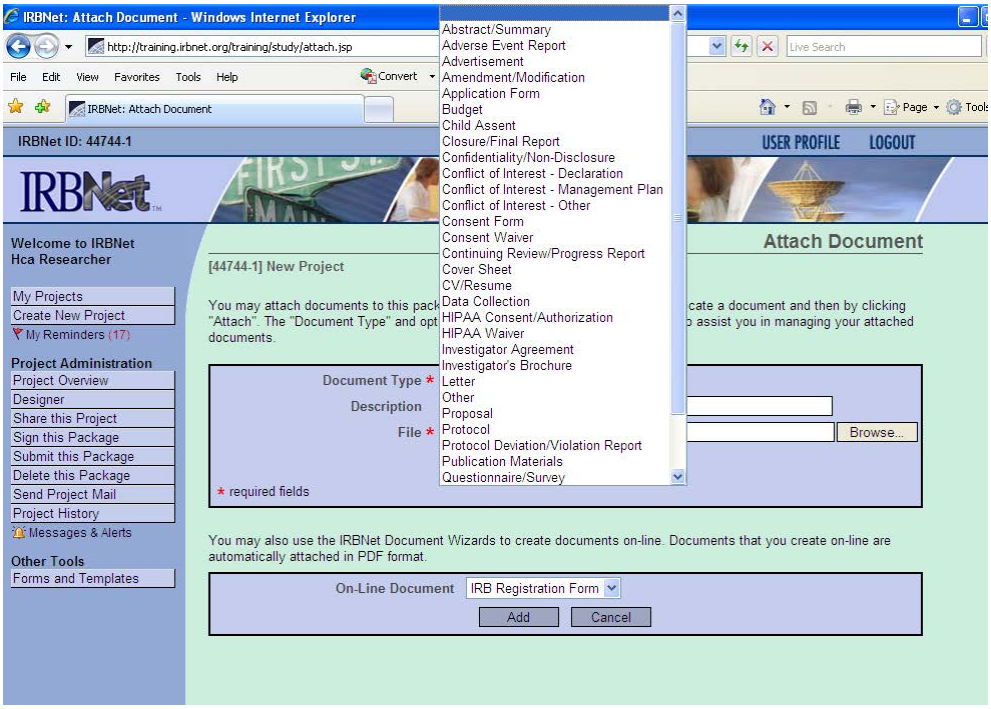

Step 3: You will now be on the **DESIGNER** page where you will download forms, templates, and reference materials to assemble a new study. Select 'HCA-HealthONE, LLC, Denver, CO' from the '**Select a Library'** drop-down menu



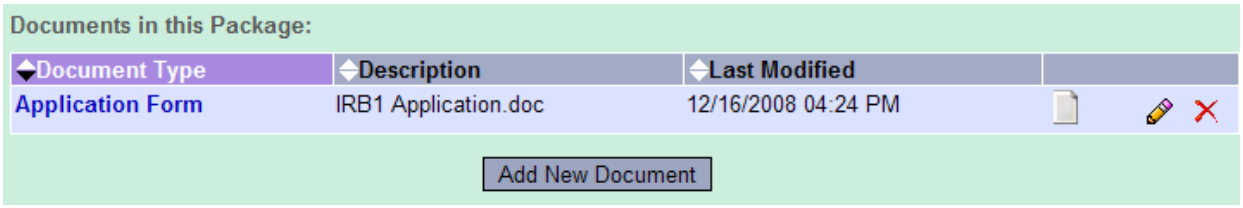

Then Select the necessary forms that pertain to your initial submission from the '**Select a Document'** drop down menu. Save these documents to your computer in a place where you can find them again (i.e., desktop, My Documents, etc.). Click the "**Browse**" button and find the completed document on your hard drive. Once you find the document, click the "**Attach**" button to upload the document. Assemble your document package through clicking on '**Add New Document'** until all documents have been added, and use the checklist as a reference guide.




Label your documents appropriately using the drop down list on the 'Attach Document' screen (i.e., Application Form, Consent Form, Protocol, Letter, etc).




Once you have attached a document to your study package, the Study Designer page will now list your documents.



## On-Line Document

***Please Note**: The On-Line Document provides detailed information about your study that may not be listed in the protocol or the informed consent. The On-Line Document MUST be completed for ALL initial submissions.*

Go to the '**On-Line Document'** (**IRB Registration Form**) at the bottom of the **DESIGNER** page and click '**ADD**'. Complete this form, then click '**SAVE AND EXIT'**.

***User Tip:** You do not need to complete the entire online 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 have completed the IRB Registration Form, click "Preview" to see what the completed form looks like, and confirm that all the information provided is accurate.*

***All other required forms are to be completed, saved and attached to the submission.***

Step 4: **SHARE THIS PROJECT** with your research team. Click the '**Share this Project'** button on the left side of your screen; click the blue '**Share**' link to grant access to this project.

- **Share:** Use this option if you wish to share your study with other Researchers, Committee Members, Administrators or Sponsors at your own institution or any other institution. For example, you may wish to share this study with other members of your research team so that you may collaborate in the design and development of the study, or with a selected Committee Member or Administrator to solicit feedback prior to submitting your study. You may provide any individual with **Full**, **Write** or **Read** access.
- **Multi-site:** Use this option only if your study is a multi-site study and you wish to send a complete and independent copy of this study to a Principal Investigator at another site. The local Principal Investigator will receive their own independent copy of all study documents and may modify their copy of these documents (such as consent forms) to meet the requirements of their local Board. You will be able to monitor the progress of this study at every local site. The other local Principal Investigators will also be able to monitor the progress of this study at every local site (including your own).
- **Transfer:** Transfer your ownership of this study to another user. In doing so you will relinquish all access to this study and the designated user will be granted **Full** access.

Select 'HCA-HealthONE. LLC Denver, CO' from the organization box; click '**Select Organization**' and search for registered users with whom you'd like to share this project (i.e. your Principal Investigator, Co-Investigators, other study staff, etc.) Grant each user a level of **ACCESS:**

**Permissions**

**Full:**

The individual is a project owner and may manage and control all aspects of the project.

**Write:**

The individual may collaborate on project documentation, but may not share the project with others, submit packages for review, or take certain other actions reserved solely for the project owners.

**Read:**

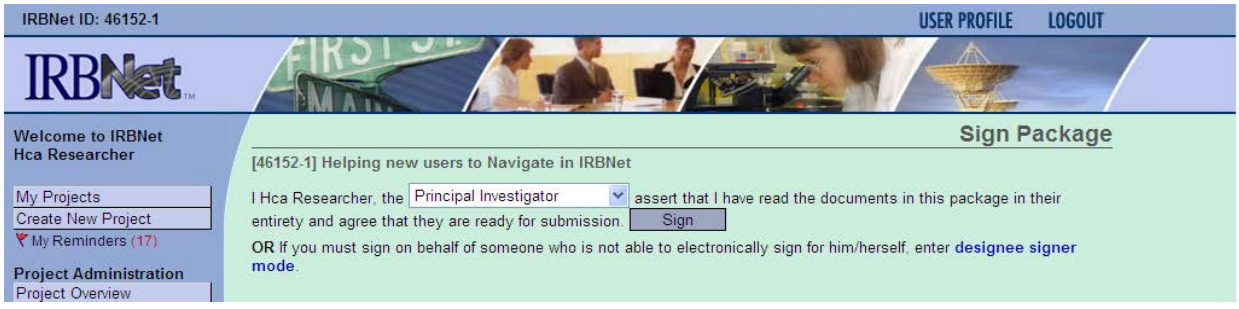
The individual has read-only access to the project. This individual may electronically sign where necessary.

***Please Note:*** *To 'Share' your research with someone, they must be registered with irbnet.org*

Selected users will be notified automatically via email that the project has been shared with them, and you may enter comments to be included within the email.

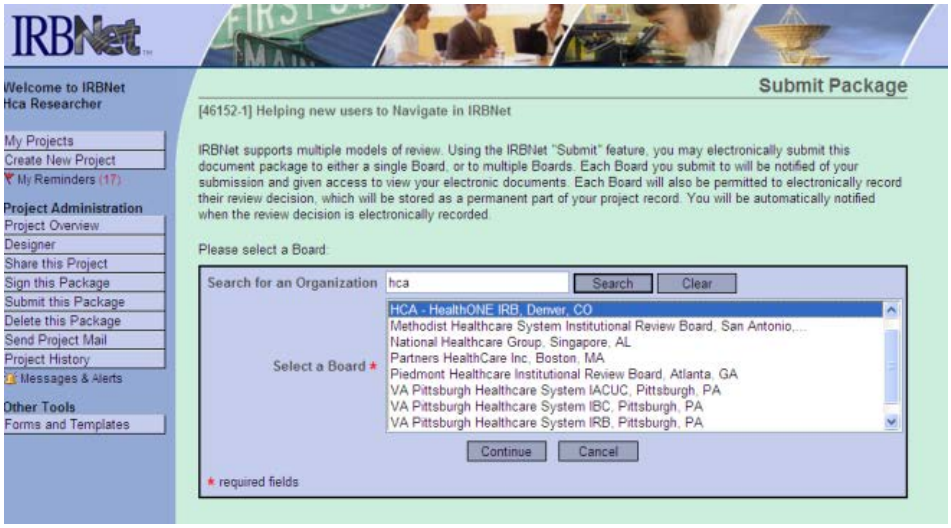
Step 5: When all the necessary documents are uploaded to the package, the Principal Investigator must sign your package electronically. Send an e-mail to the PI using the "**Send Project Mail**" function and request that the PI sign the package.

Step 6: Click on **SIGN THIS PACKAGE**. The Principal Investigator MUST sign the package before it is submitted. Select your appropriate role from the dropdown box and click '**Sign**'.

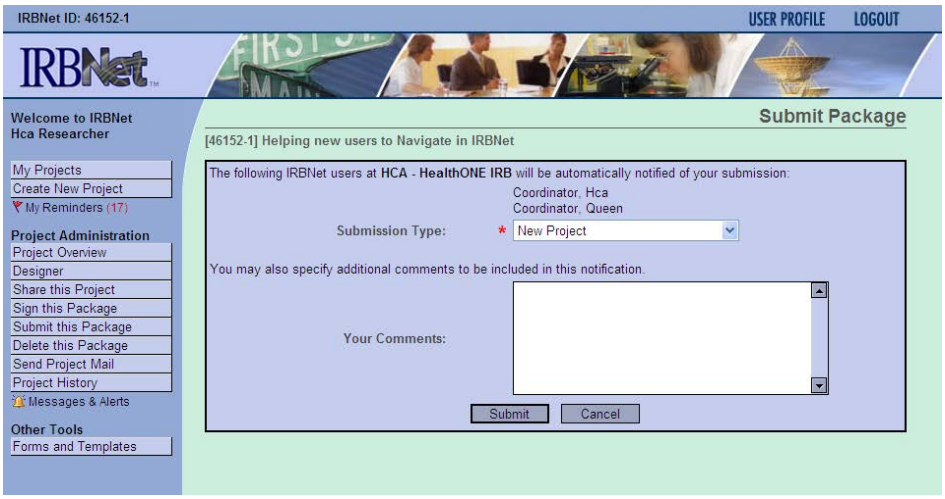



***Note****: If a submission is submitted without the Principal Investigator signature, the submission will not be accepted for review.*

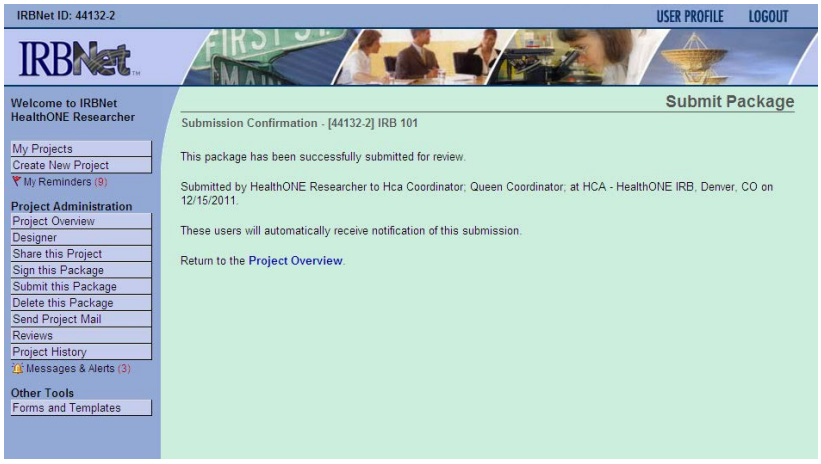
Step 7: Once the PI has signed the package, click **SUBMIT THIS PACKAGE**. Select "HCA-HealthONE IRB, Denver, CO" in the "**Search for Organization**" drop down menu (This will be your default location and should be highlighted already).




Then click the '**Continue**' button. In the Submission Type drop-down menu, select 'New Project' and click '**Submit**'. Once you hit the "**Submit**" button, you will be given a confirmation showing the time your submission occurred.




Once you hit the "**Submit**" button, you will be given a confirmation showing the time your submission occurred.




Step 8: To review what has been sent, click **PROJECT OVERVIEW**. The submission will be under '**Pending Review'** status until a decision by the board has been made. Once a decision letter is formulated, an email will be sent to everyone who has full access and the letter and any supporting documents can be printed.

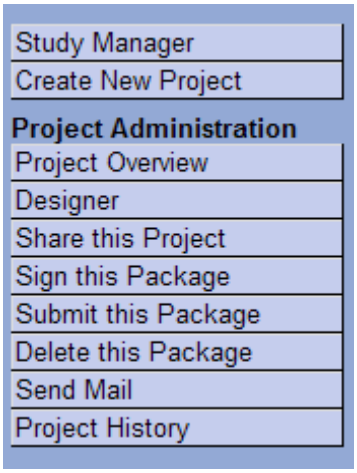
***User Tip:*** *Keep in mind that once you click "Submit" your study is now locked and no other changes can be made to this package. Take the time to be sure all documents are attached and in the final version* ***prior to submitting****. Any incomplete submissions will not be reviewed by the IRB and will be returned for corrections.*

# IV. INSTRUCTIONS FOR SUBMITTING A CONTINUING REVIEW

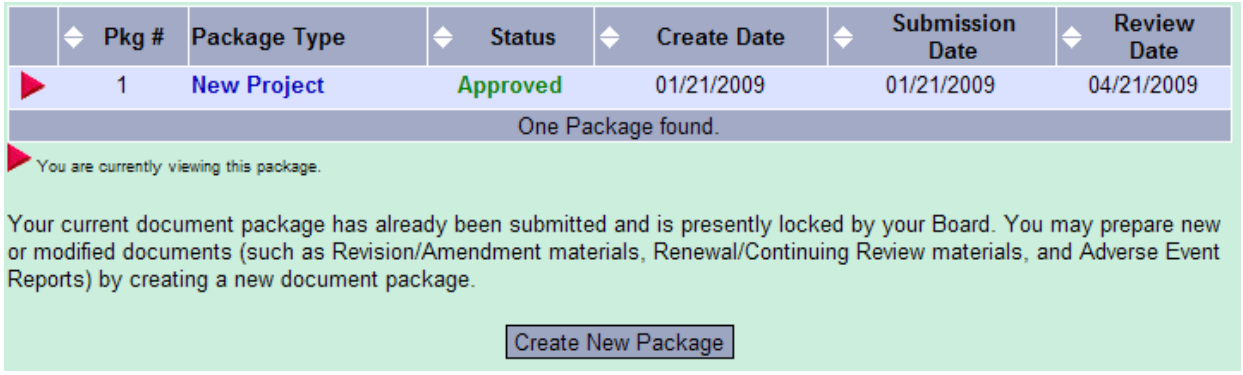
**THE SUBMISSION OF A CONTINUING REVIEW OF AN OPEN STUDY REQUIRES THE CREATION OF A SUBSEQUENT PACKAGE IN A PROJECT.**

Step 1: Login to IRBNet; www.irbnet.org. This will take you to the **MY PROJECTS** page. This is where all of the studies that you have access to will be housed.

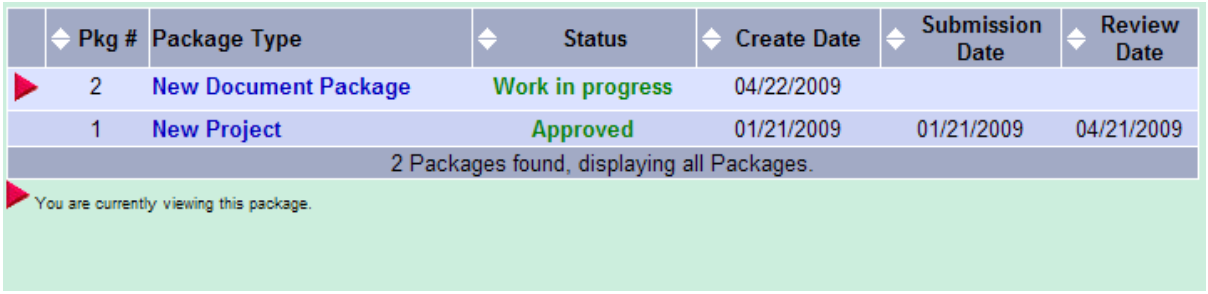
Step 2: Click on the Title of the project that you would like to continue/renew (click on the exact IRBNet project referenced in the e-mail you received reminding you to renew your study). Then click on the **PROJECT HISTORY**




Step 3: Click on **CREATE NEW PACKAGE**



Step 4: A **NEW DOCUMENT PACKAGE** will appear as a "**Work in Progress**". Click on the **New Document Package** title and you will be brought to the **DESIGNER** screen where you can add your documents for this package.



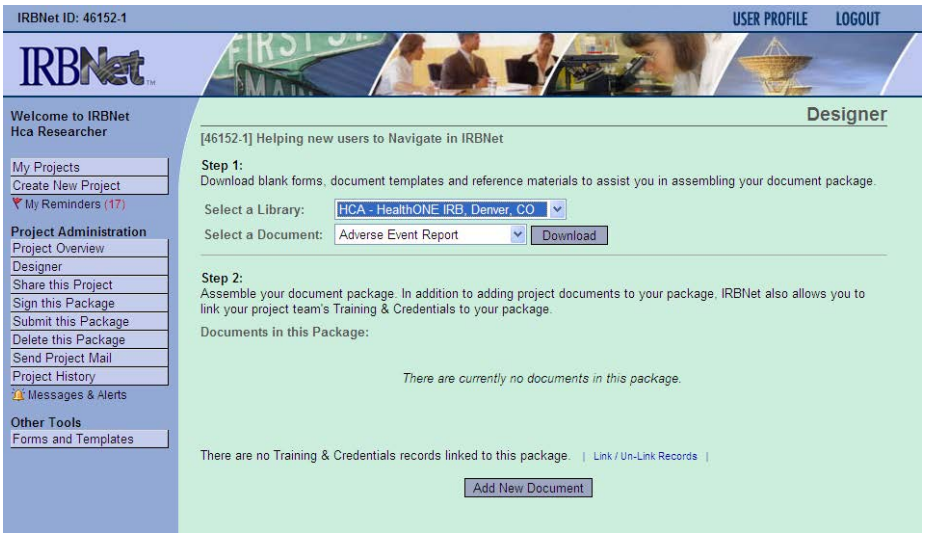
| Pkg # | Package Type | Status | Create Date | Submission Date | Review Date |
|---|---|---|---|---|---|
| 2 | New Document Package | Work in progress | 04/22/2009 | | |
| 1 | New Project | Approved | 01/21/2009 | 01/21/2009 | 04/21/2009 |

2 Packages found, displaying all Packages.

You are currently viewing this package.

Step 5: You will now be on the **DESIGNER** page.

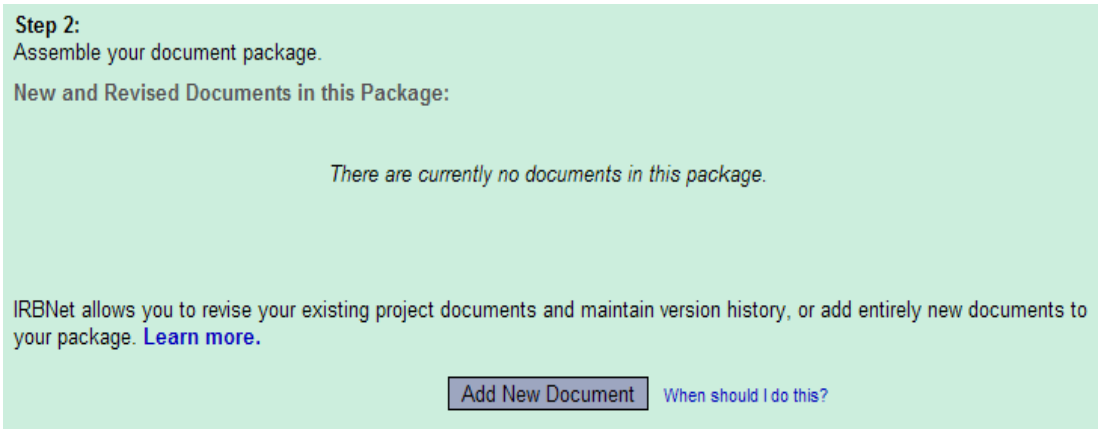
This is where you can access the library of forms as well as any documents from previous packages you have submitted.



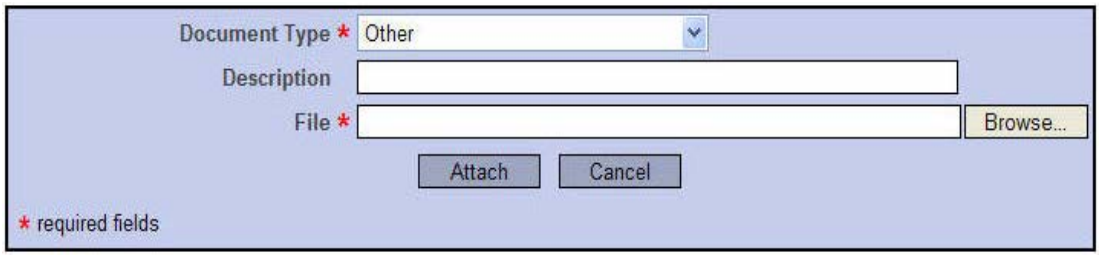

From the HCA-HealthONE IRB Library (**Step 1** – top of screen), Select and download both 'Checklist – Continuing Reviews' and ' Continuing Review Application' from the '**Select A Document**' drop down box.. From here, choose File>Save As to save the document to your computer, complete the *Continuing Review Application* Form, save it to your hard drive, and use the checklist as a reference.

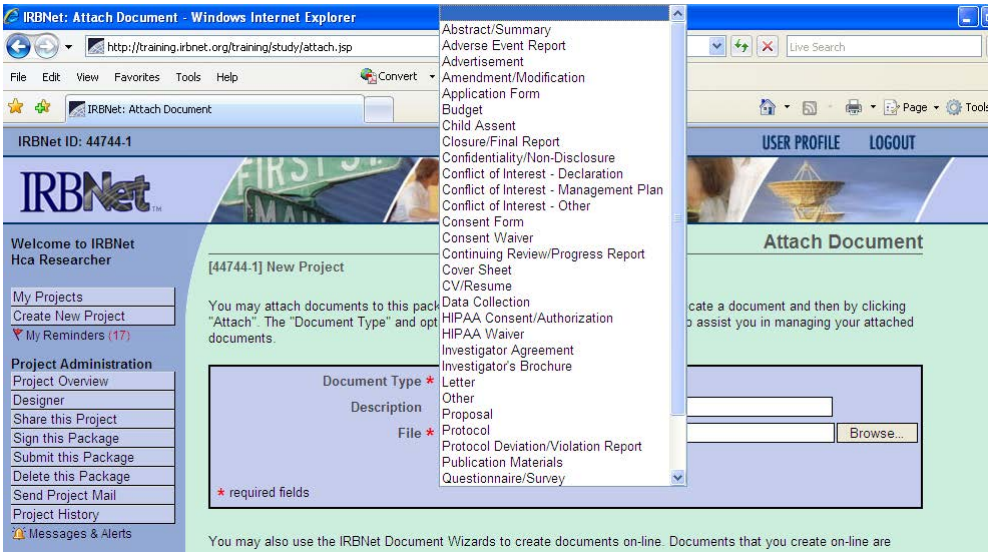
View the On-Line Document (IRB Registration Form) and verify that the data accurately reflects the current status of your study. If changes have occurred to your study that have not previously been reviewed and approved by the IRB, then an amendment/modification will be required (see Section IV).

Attach supporting documents for your continuing review package by clicking on the '**Add New Document'** button and browsing your computer:

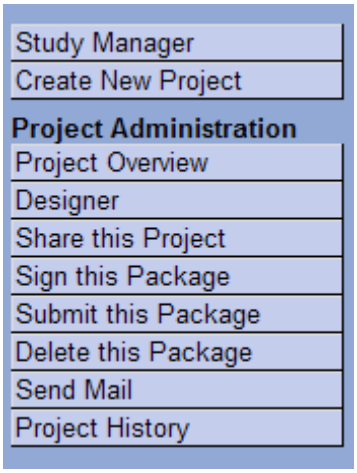



In the **Document Type** drop-down box, pick the best match for the document you are uploading. If it is the application, choose the "Continuing Review/Progress Report" choice. If the type of document you are submitting is not in the list then choose "Other" and enter the type of document in the **Description** field. Click the '**Browse**' button and find the document on your hard drive. Once you find the document click the '**Attach**' button to upload the document.

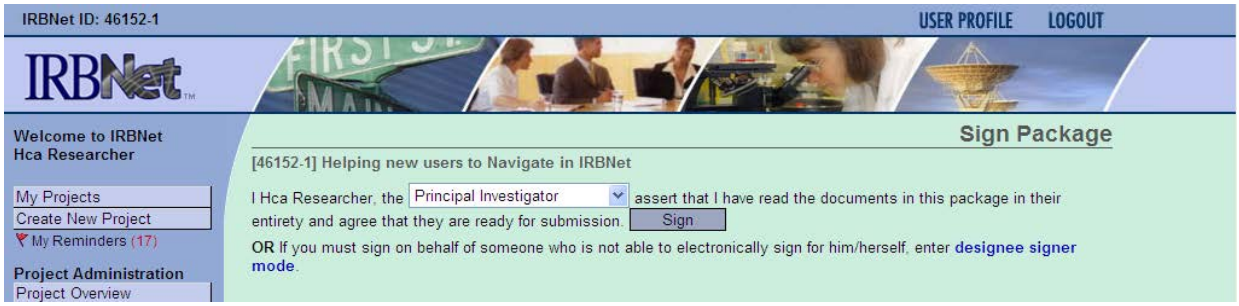



Step 6: When all required continuing review documents are uploaded, the PI needs to sign your package electronically. Send a Project email (**Send Mail**) to the PI for them to sign the package.

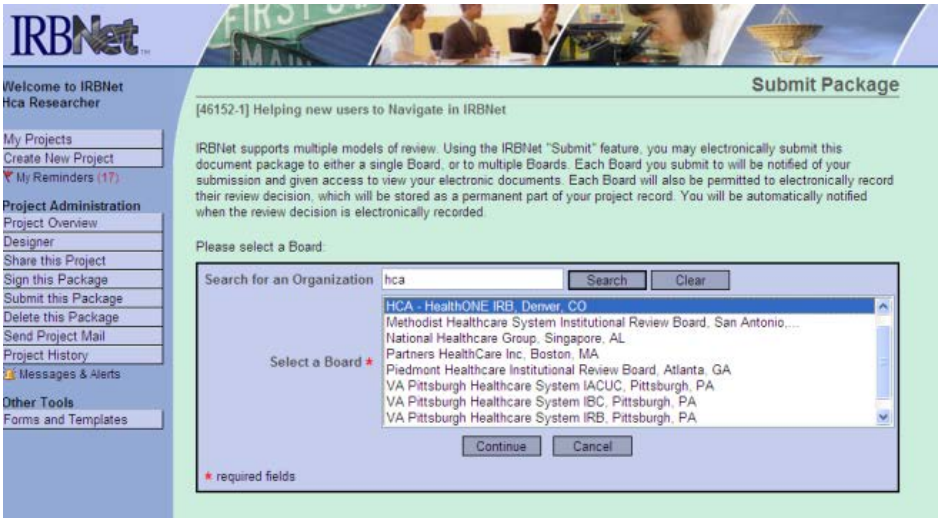



Step 7: To sign a package, click **SIGN THIS PACKAGE**. The Principal Investigator MUST sign the package before it is submitted. Select your appropriate role from the dropdown box and click '**Sign**'.

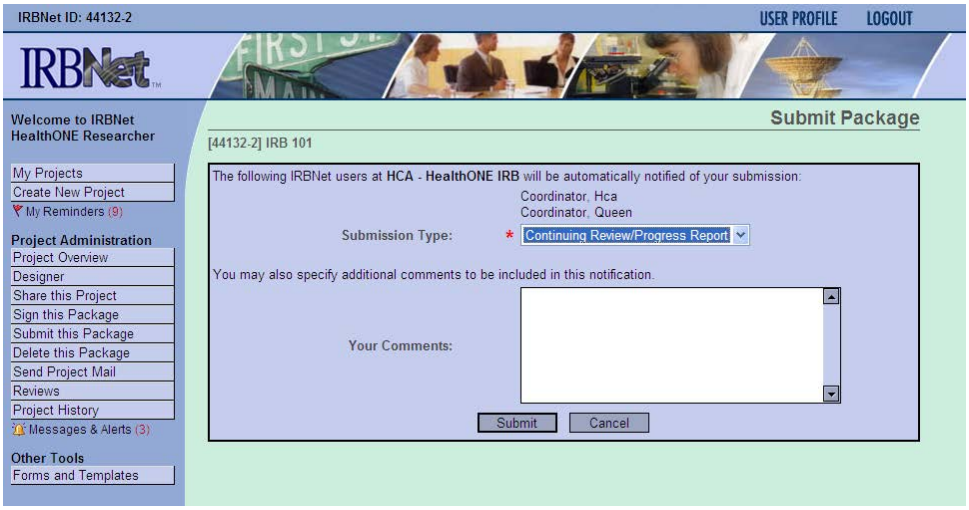



***Note**: If a submission is submitted without the PI signature, the submission will not be accepted for review.*

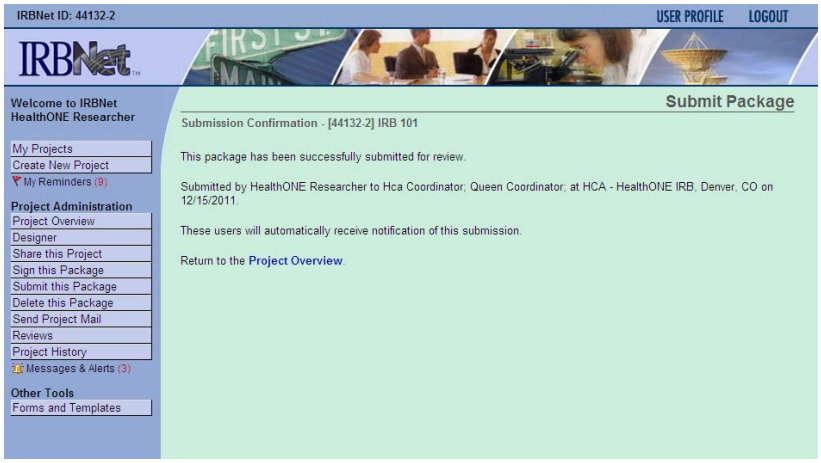
Step 7: Once the PI has signed the package, click **SUBMIT THIS PACKAGE.** Select "HCA-HealthONE IRB, Denver, CO" in the "**Search for Organization**" drop down menu (This will be your default location and should be highlighted already).



Then click the '**Continue**' button. In the **Submission Type** drop-down menu, select 'Continuing Review/Progress Report' and click '**Submit**'.




Once you hit the "**Submit**" button, you will be given a confirmation showing the time your submission occurred.




Step 8: To review what has been sent, click **PROJECT OVERVIEW**. The submission will be under '**Pending Review**' status until a decision by the board has been made. Once a decision letter is formulated, an email will be sent to everyone who has full access and the letter and any supporting documents can be printed.

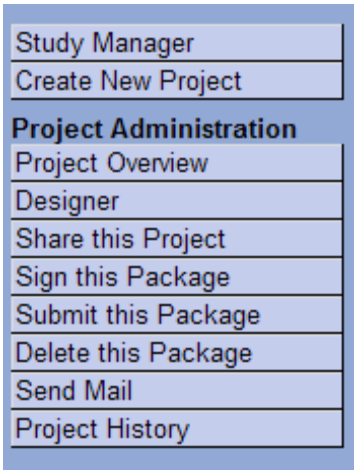
***User Tip:*** *Keep in mind that once you click "Submit" your study is now locked. Take the time to be sure all documents are attached and in the final version* ***prior to submitting****. Any incomplete submissions will not be reviewed by the IRB and will be returned for corrections.*

# V. INSTRUCTIONS FOR SUBMITTING AN AMENDMENT

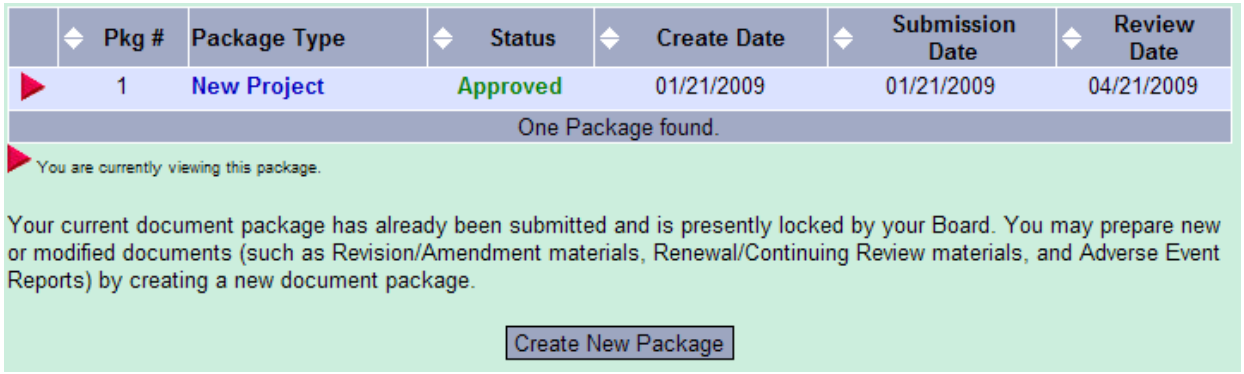
**THE SUBMISSION OF AN AMENDMENT OF AN OPEN STUDY REQUIRES THE CREATION OF A SUBSEQUENT PACKAGE IN A PROJECT.**

Step 1: Login to IRBNet; www.irbnet.org. This will take you to the **MY PROJECTS** page.

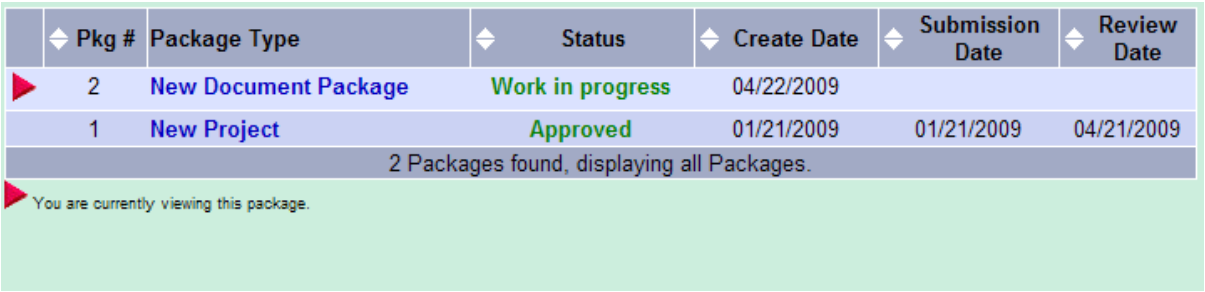
Step 2: Click on the Title of the project that you would like to amend/modify. Then click on the **PROJECT HISTORY**




Step 3: Click on the **CREATE NEW PACKAGE** button and then the **NEW DOCUMENT PACKAGE**



A **NEW DOCUMENT PACKAGE** will appear as a "**Work in Progress**". Click on the **New Document Package** title and you will be brought to the **DESIGNER** screen where you can add your documents for this package.



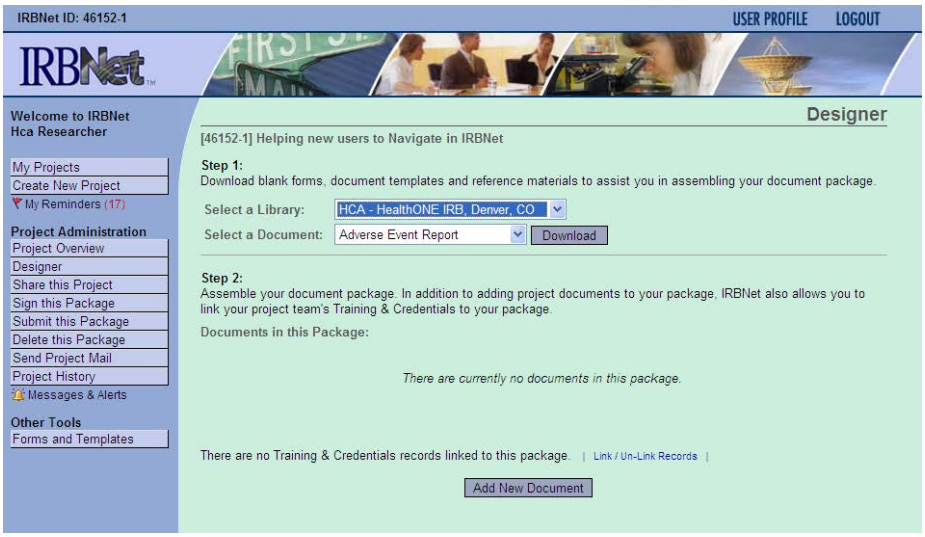
| | Pkg # | Package Type | Status | Create Date | Submission Date | Review Date |
|---|---|---|---|---|---|---|
| ▶ | 2 | New Document Package | Work in progress | 04/22/2009 | | |
| | 1 | New Project | Approved | 01/21/2009 | 01/21/2009 | 04/21/2009 |

2 Packages found, displaying all Packages.

▶ You are currently viewing this package.

Step 4: You will now be on the **DESIGNER** page.

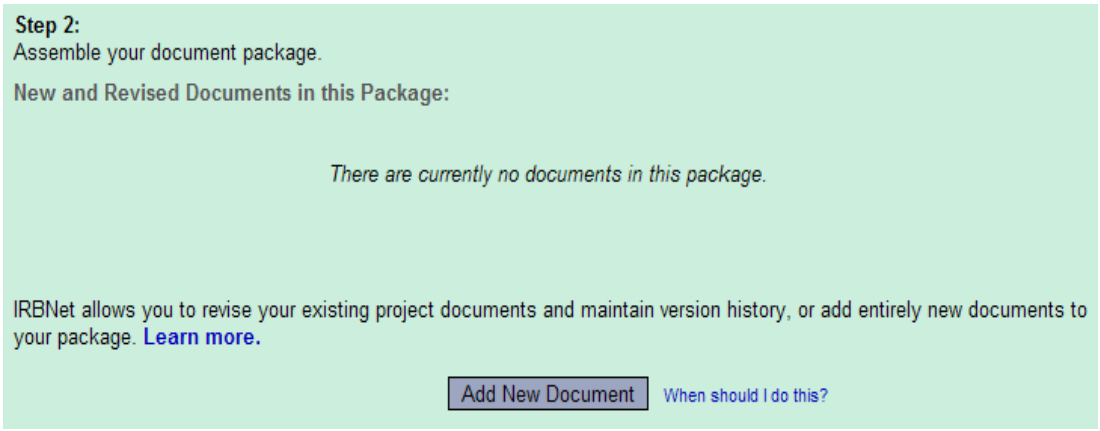
This is where you can access the library of forms as well as any documents from previous packages you have submitted.



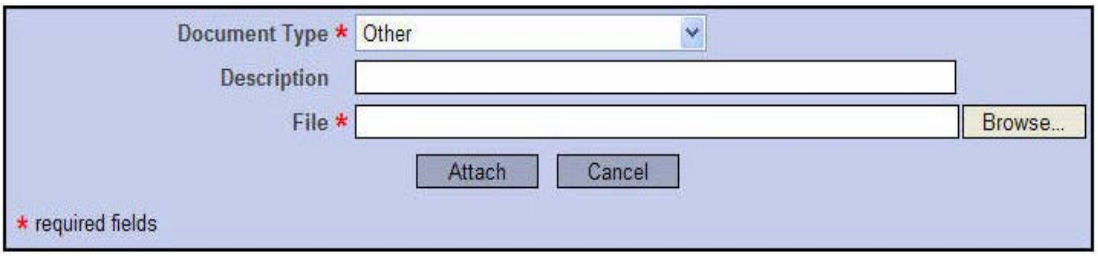

From the HCA-HealthONE IRB Library (Step 1 – top of screen), Select and download both 'Checklist – Amendment/Modifications' and 'Amendment/Modification Application' from the '**Select A Document**' drop down box. From here, choose File>Save As to save the amendment document to your computer, complete the Application Form, save to your hard drive and use the checklist as a reference guide.

If the amendment changes any of the data included in the previously approved **On-Line Document** (IRB Registration Form), i.e., personnel, study locations, contact information, then this form will need to be updated as a part of your amendment submission.

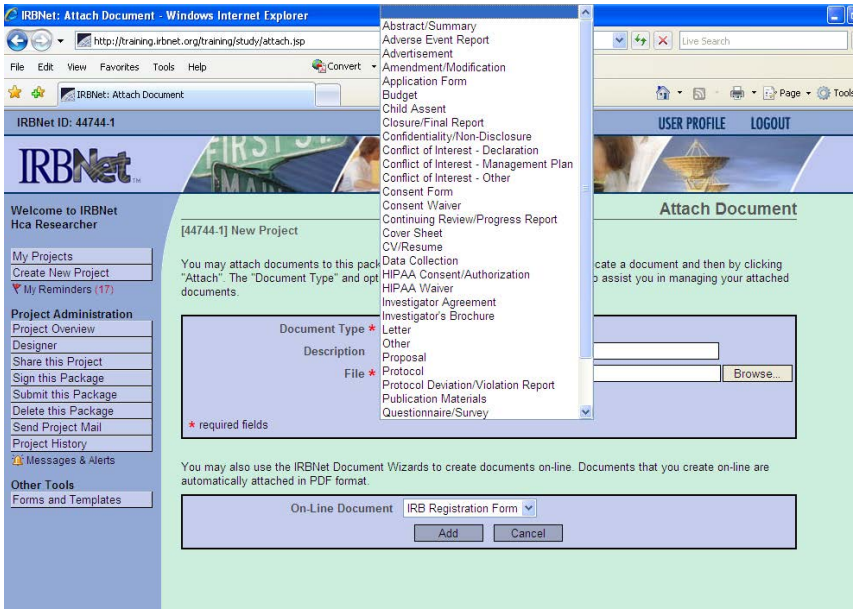
Attach supporting documents for your amendment package by clicking on the '**Add New Document'** button and browsing your computer:




In the **Document Type** drop-down box, pick the best match for the document you are uploading. If it is the application, choose the "Application Form" choice. If the type of document you are submitting is not in the list then choose "Other" and enter the type of document in the **Description** field. Click the '**Browse**' button and find the document on your hard drive. Once you find the document click the '**Attach**' button to upload the document.

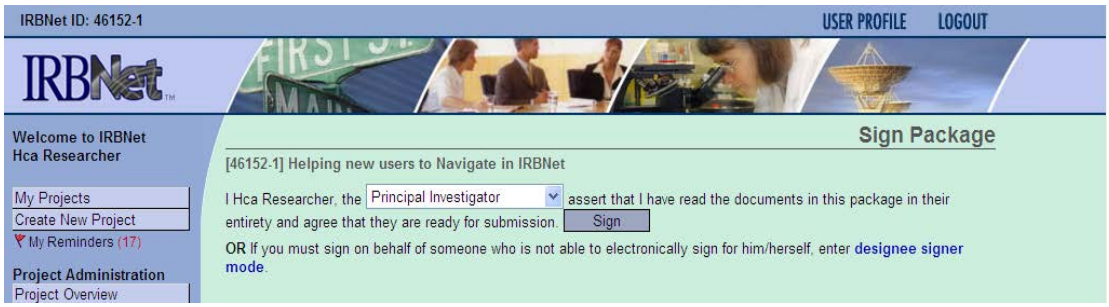



Repeat the steps to upload until all documents have been uploaded to your package.

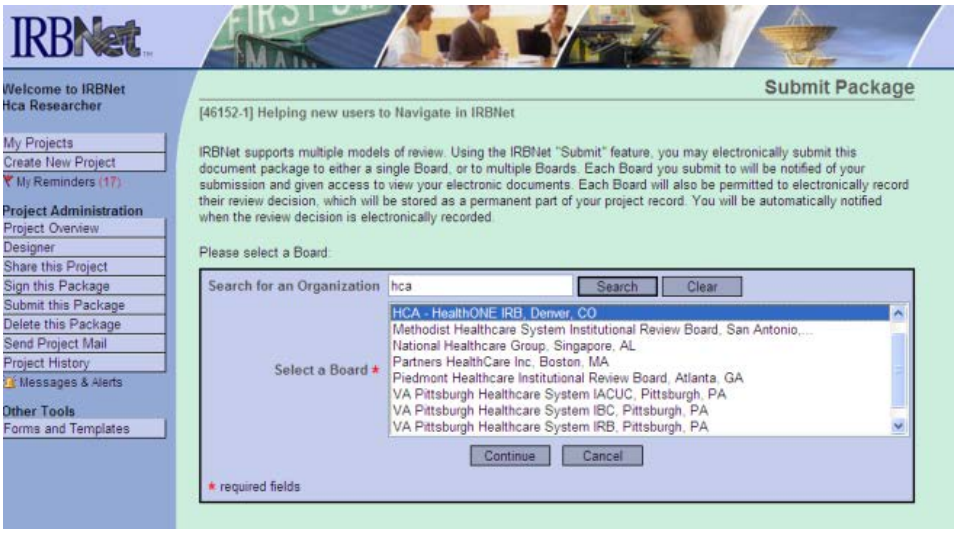


Step 5: When all documents are uploaded the PI needs to sign the package electronically. Send an e-mail (**Send Project Mail**) to the PI and have them **SIGN THIS PACKAGE**.

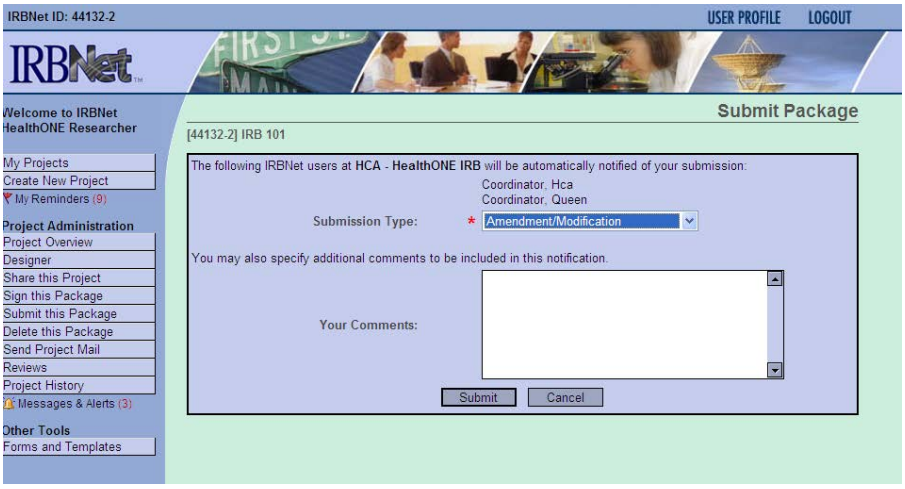
Step 6: To sign a package, click **SIGN THIS PACKAGE**. The Principal Investigator MUST sign the package before it is submitted. Select your appropriate role from the dropdown box and click '**Sign**'.



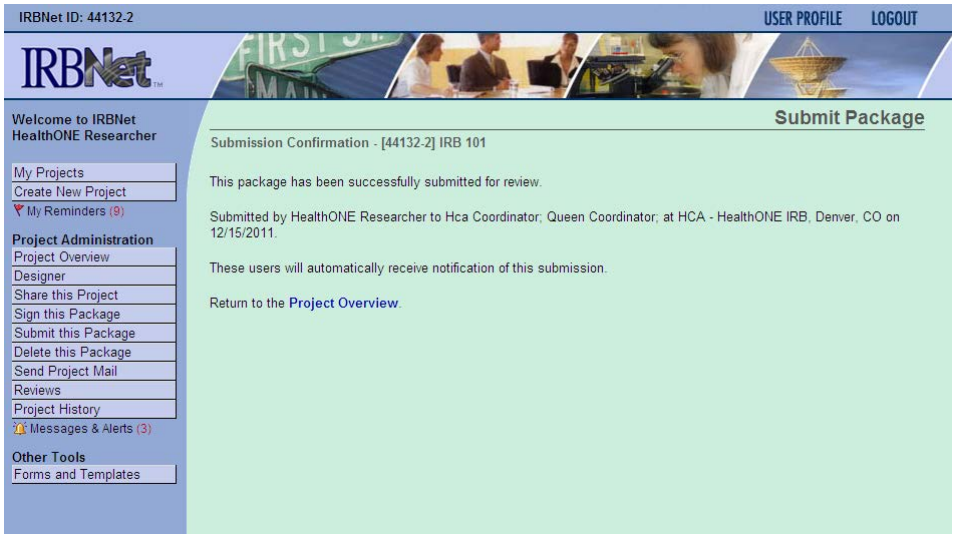

Step 7: Once the PI has signed the package, click **SUBMIT THIS PACKAGE**. Select "HCA-HealthONE IRB, Denver, CO" in the "**Search for Organization**" drop down menu (This will be your default location and should be highlighted already).



Then click the '**Continue**' button. In the Submission Type drop-down menu, select 'Amendment/Modification' and click '**Submit**'.




Once you hit the "**Submit**" button, you will be given a confirmation showing the time your submission occurred.




Step 8: To review what has been sent, click **PROJECT OVERVIEW**. The submission will be under '**Pending Review'** status until a decision has been made. Once a decision letter is formulated, an email will be sent to everyone who has full access and the letter and any supporting documents can be printed.

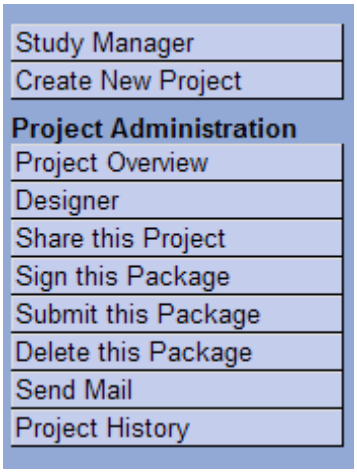
***User Tip:*** *Keep in mind that once you click "**Submit**" your study is now locked and you can no longer make any other changes to this package. Take the time to be sure all documents are attached and in the final version **prior to submitting**. Any incomplete submissions will not be reviewed by the IRB and will be returned for corrections.*

# VI. INSTRUCTIONS FOR SUBMITTING A STUDY CLOSURE

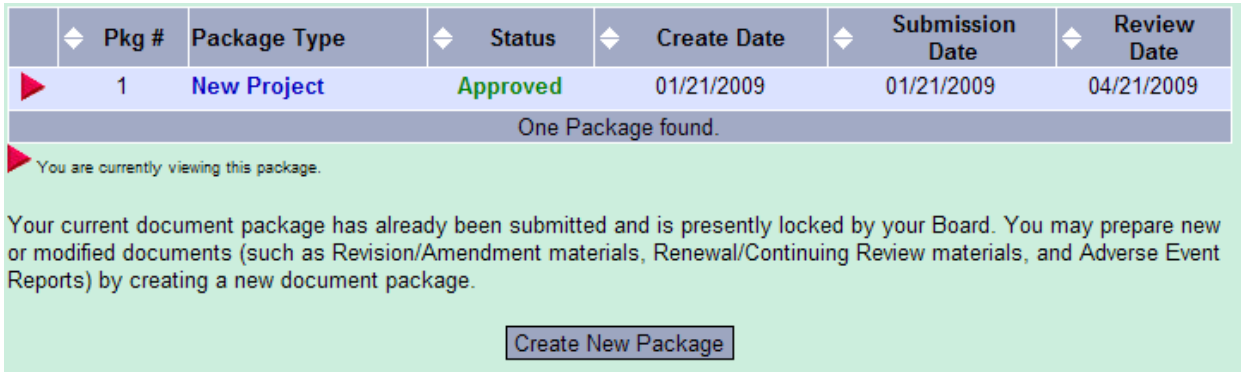
**THE SUBMISSION OF A STUDY CLOSURE OF AN OPEN STUDY REQUIRES THE CREATION OF A SUBSEQUENT PACKAGE IN A PROJECT.**

Step 1: Login to IRBNet; www.irbnet.org. This will take you to the **MY PROJECTS** page.

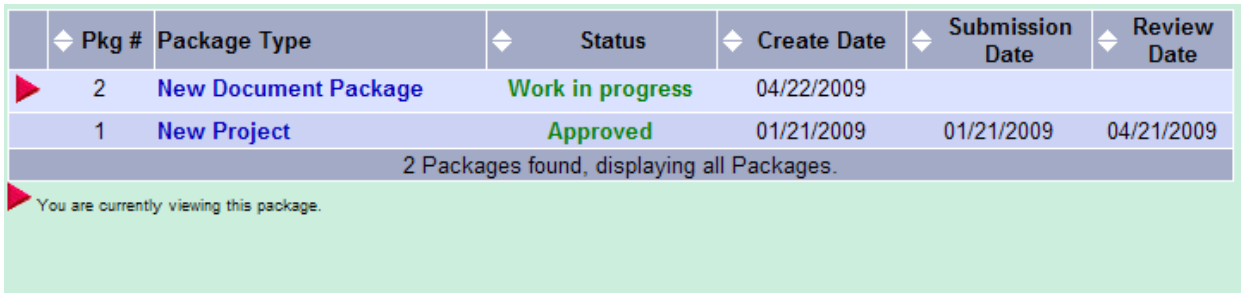
Step 2: Click on the Title of the project that you would like to close. Then click on the **PROJECT HISTORY**




Step 3: Click on the **CREATE NEW PACKAGE** button

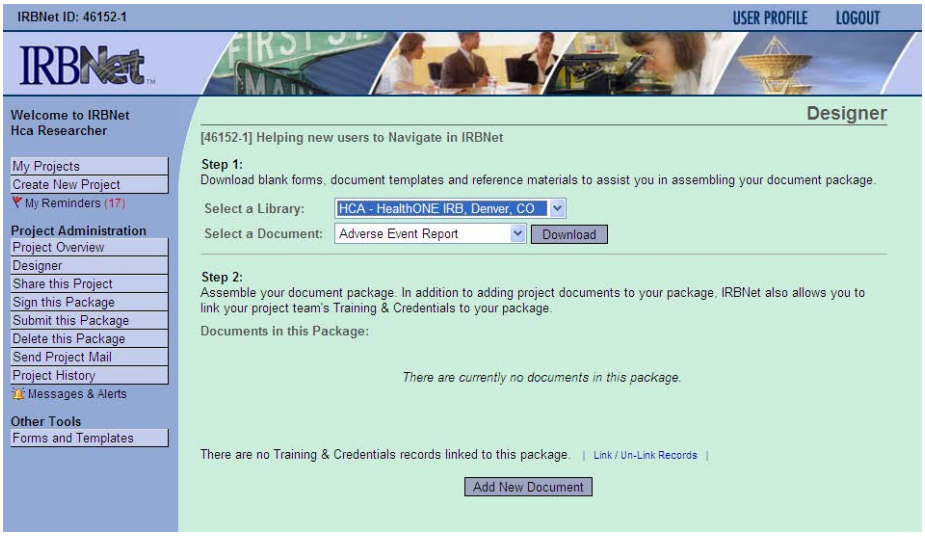


A **NEW DOCUMENT PACKAGE** will appear as a "**Work in Progress**". Click on the **New Document Package** title and you will be brought to the **DESIGNER** screen where you can add your documents for this package.

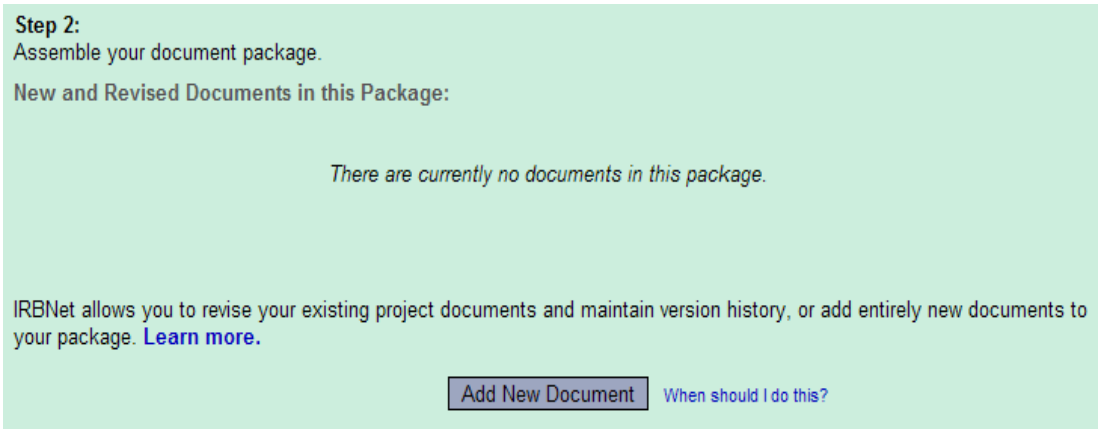



Step 4: You will now be on the **DESIGNER** screen where you can add your documents for this package.

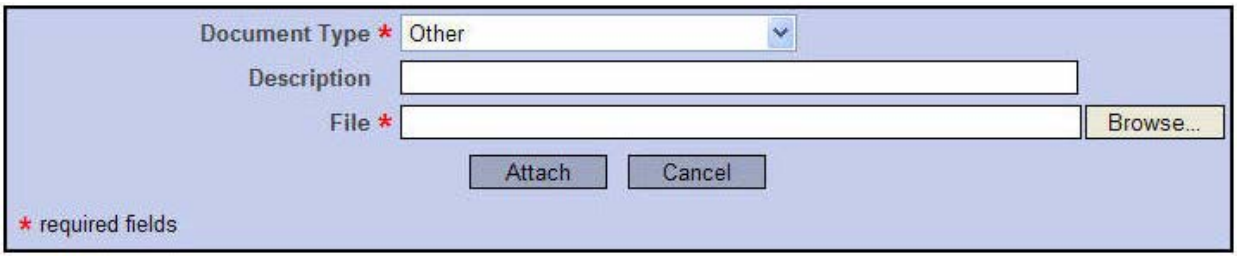
From the HCA-HealthONE IRB Library (Step 1 – top of screen), Select and download 'Final Report Application' from the '**Select A Document**' drop down box. From here, choose File>Save As to save the document to your computer, complete the Application Form and save to your hard drive.



Attach supporting documents for your amendment package by clicking on the '**Add New Document'** button and browsing your computer:

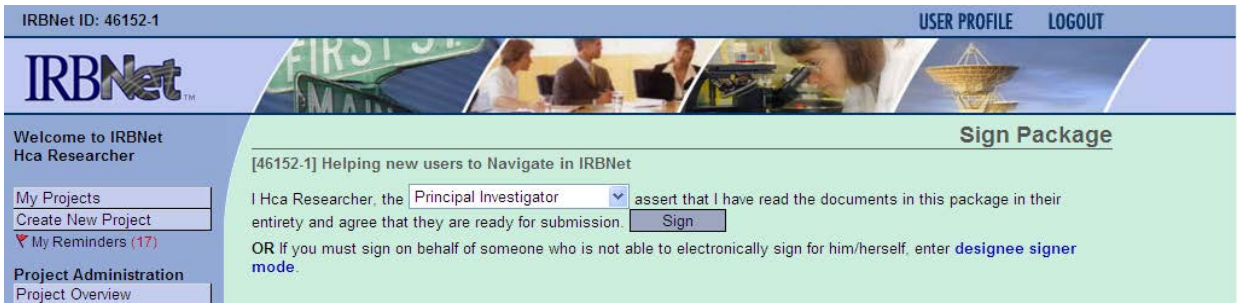



Step 5: Attach supporting documentation for your closure of the study. In the '**Document Type**' box, pick the Closure/Final Report document type in the drop-down box. If the type of document you are submitting is not in the list then choose 'Other' and enter the type of document in the **Description** field. Click the 'Browse' button and find the document on your hard drive. Once you find the document, click the '**Attach**' button to upload the document.



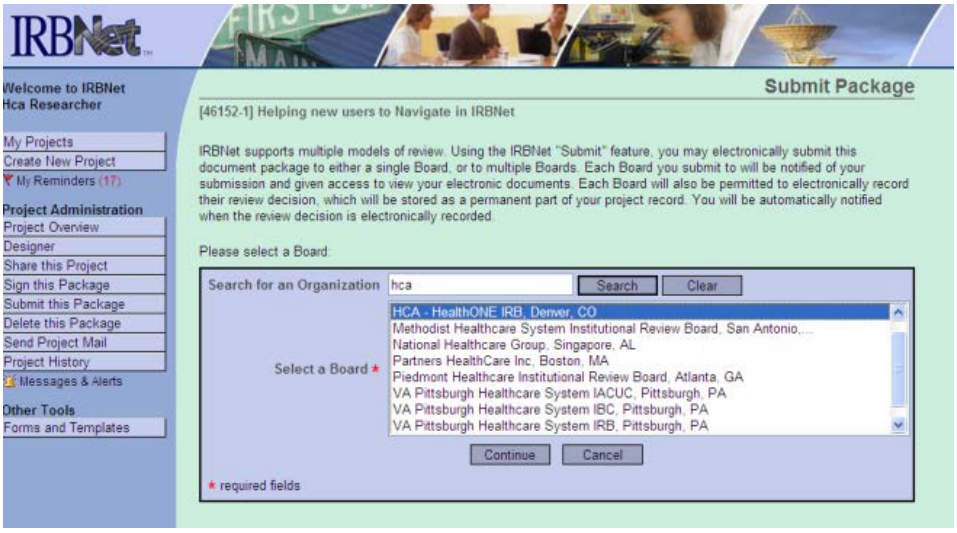

Repeat the steps to upload until all documents have been uploaded to your package.

Step 6: When all required documents are uploaded to the package, the PI needs to **SIGN THIS PACKAGE** electronically. In order to sign a package, select your appropriate role from the dropdown box and click '**Sign**'.

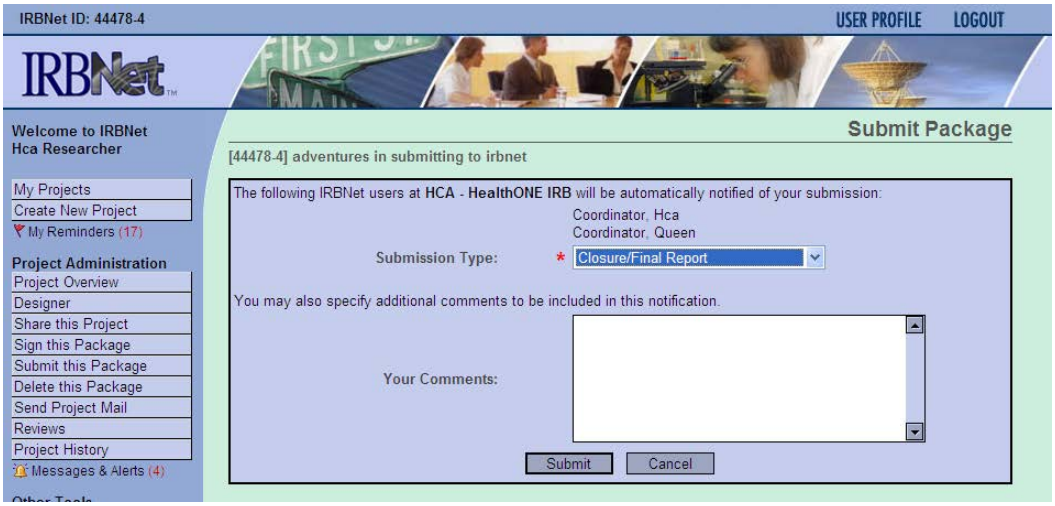


***Note**: If a submission is submitted without the PI signature, the submission will not be accepted for review.*

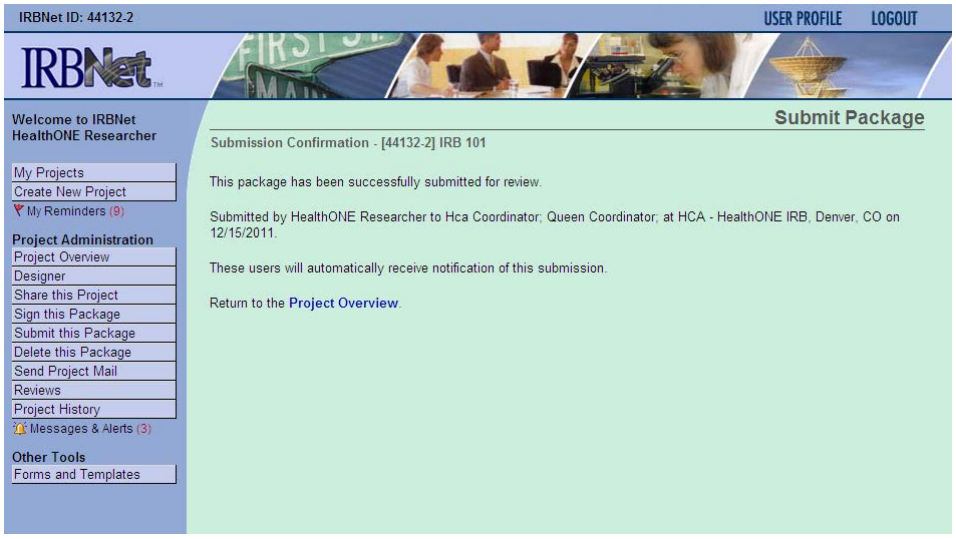
Step 7: Once the PI has signed the package, click **SUBMIT THIS PACKAGE**. Select "HCA-HealthONE IRB, Denver, CO" in the "**Search for Organization**" drop down menu (This will be your default location and should be highlighted already).




Then click the '**Continue**' button. In the Submission Type drop-down menu, select 'Closure/Final Report' and click '**Submit**'.




Once you hit the "**Submit**" button, you will be given a confirmation showing the time your submission occurred.




Step 8: To review what has been sent, click **PROJECT OVERVIEW**. The submission will be under '**Pending Review'** status until an acknowledgement is granted. Once a decision letter is formulated, an email will be sent to everyone who has full access and the letter and any supporting documents can be printed.

***User Tip:*** *Keep in mind that once you click "**Submit**" your study is now locked and no other changes can be made to this package. Take the time to be sure all documents are attached and in the final version **prior to submitting**. Any incomplete submissions will not be reviewed by the IRB and will be returned for corrections.*

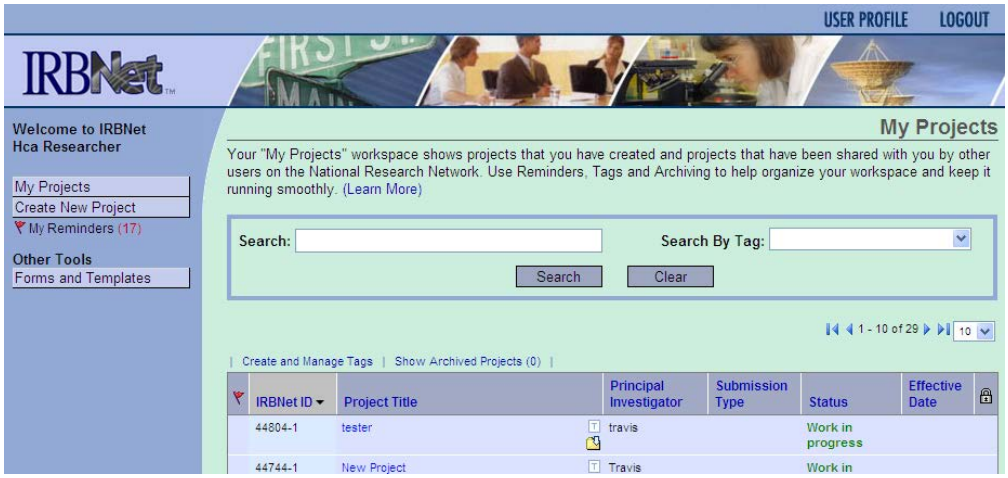
# VII. INSTRUCTIONS FOR SUBMITTING ADVERSE EVENTS or EXTERNAL SAE'S FROM SPONSOR AND REPORTABLE EVENTS

**INCLUDING REPORTABLE EVENTS (Non AE) SUCH AS LOCAL AEs, PROTOCOL DEVIATIONS, UNANTICIPATED PROBLEMS, OR COMPLIANCE CONCERNS**

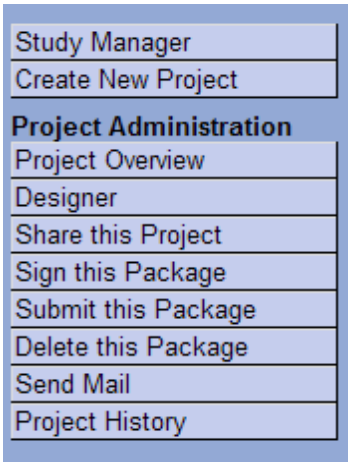
**THE SUBMISSION WILL REQUIRE THE CREATION OF A SUBSEQUENT PACKAGE IN A PROJECT.**

**If you are unsure whether to submit as an Adverse Event or a Reportable Event, consult the HCA-HealthONE IRB website for guidance or call the administrative office at 303-584-2300.**

Step 1: Login to IRBNet; www.irbnet.org. This will take you to the **MY PROJECTS** page




Step 2: Click on the Title of the project of which you are reporting. Then click on **PROJECT HISTORY** button



Step 3: Click on the **CREATE NEW PACKAGE** button

| | Pkg # | Package Type | Status | Create Date | Submission Date | Review Date |
|---|---|---|---|---|---|---|
| ▶ | 1 | New Project | Approved | 01/21/2009 | 01/21/2009 | 04/21/2009 |
| | One Package found. | | | | | |

▶ You are currently viewing this package.

Your current document package has already been submitted and is presently locked by your Board. You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package.

Create New Package

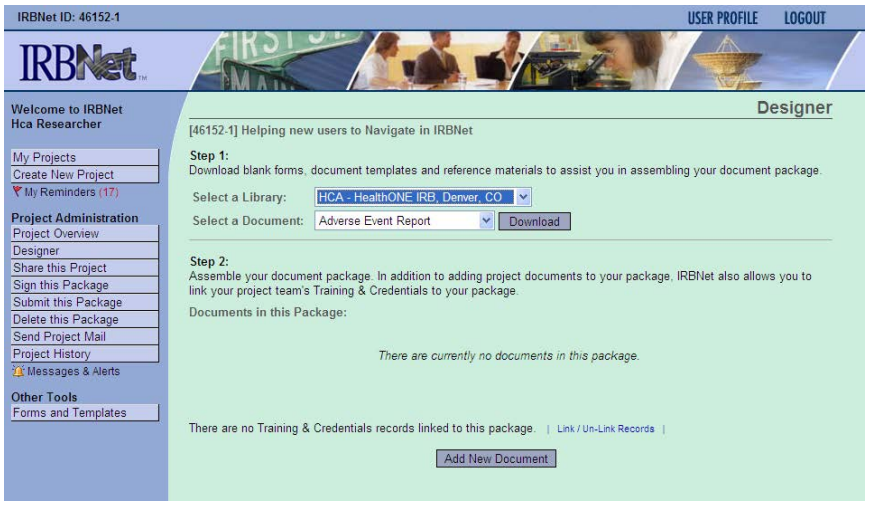
A **NEW DOCUMENT PACKAGE** will appear as a "**Work in Progress**". Click on the **New Document Package** title and you will be brought to the **DESIGNER** screen where you can add your documents for this package.

| | Pkg # | Package Type | Status | Create Date | Submission Date | Review Date |
|---|---|---|---|---|---|---|
| ▶ | 2 | New Document Package | Work in progress | 04/22/2009 | | |
| | 1 | New Project | Approved | 01/21/2009 | 01/21/2009 | 04/21/2009 |
| | 2 Packages found, displaying all Packages. | | | | | |

▶ You are currently viewing this package.

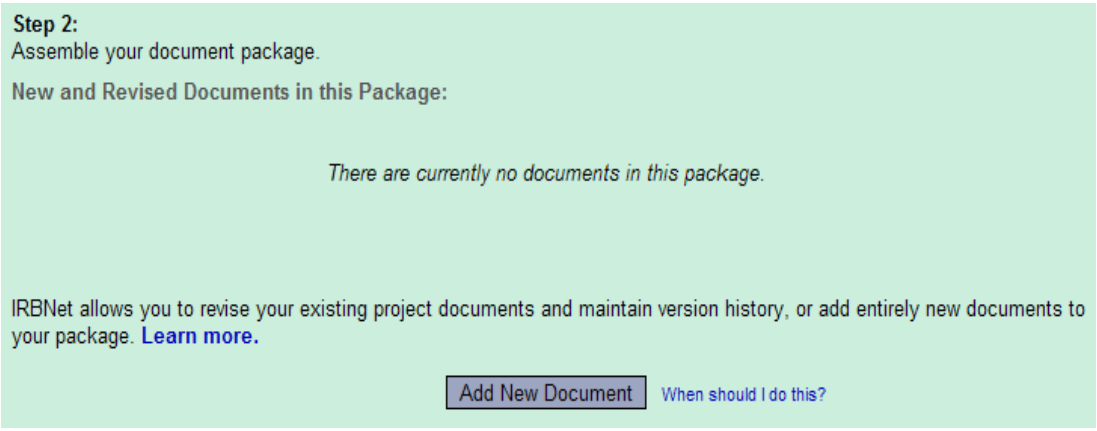
Step 4: You will now be on the **DESIGNER** screen where you can add your documents for this package.

From the HCA-HealthONE IRB Library (Step 1 – top of screen), Select and download the appropriate form for your submission type (i.e., Adverse Event Report Form, Protocol Deviation Report Form, etc.) from the '**Select A Document**' drop down box. From here, choose File>Save As to save the document to your computer, complete the appropriate form(s) and save to your hard drive.

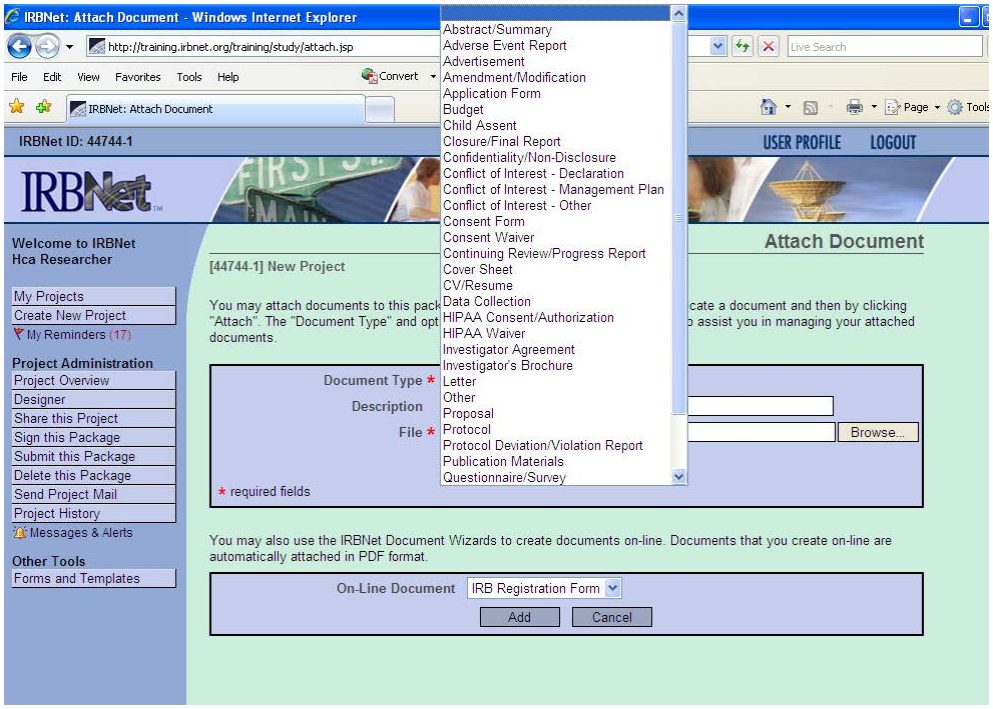


Add supporting documentation to your submission such as sponsor reports, etc.

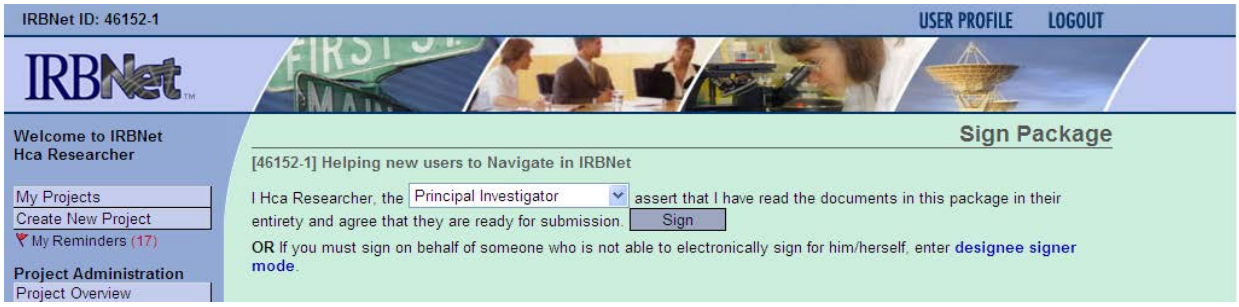
Attach supporting documents for your package by clicking on the '**Add New Document**' button and browsing your computer:




Label your documents appropriately using the drop down list on the 'Attach Document' screen (i.e., Adverse Event Report, Report, Protocol Deviation/Violation Report, Unanticipated Problem Report, Letter, etc).

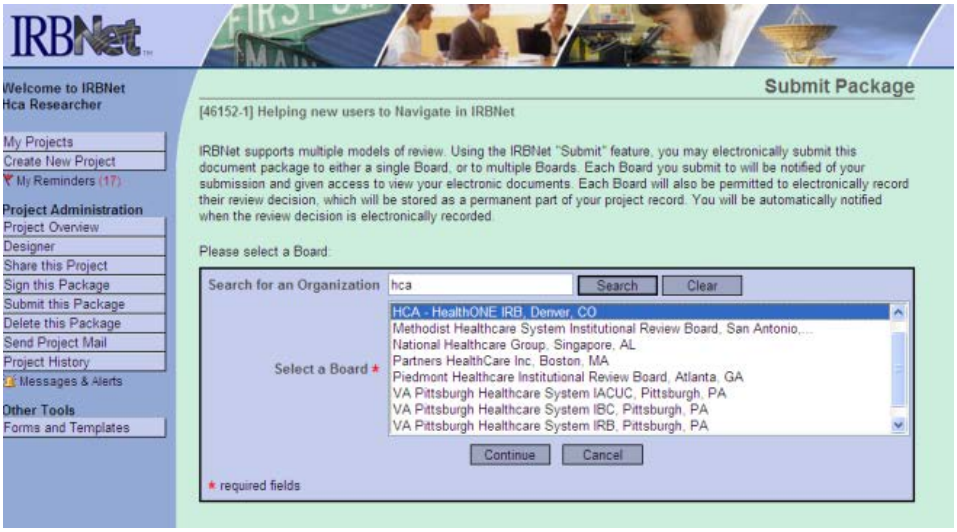


Step 5: When all required documents are uploaded to the package, the PI needs to **SIGN THIS PACKAGE** electronically. In order to sign a package, select your appropriate role from the dropdown box and click '**Sign**'.



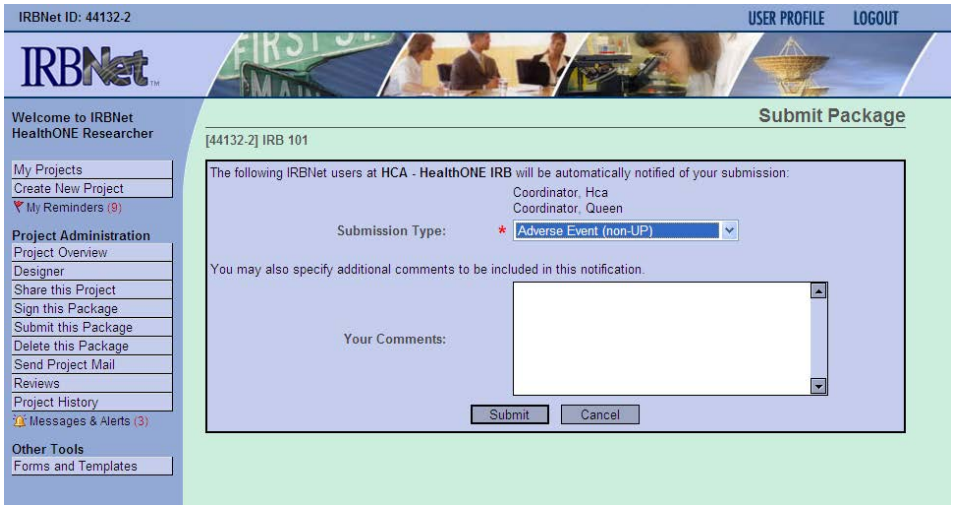

***Note**: If a submission is submitted without the PI signature, the submission will not be accepted for review.*

Step 6: Once the PI has signed the package, click **SUBMIT THIS PACKAGE**. Select "HCA-HealthONE IRB, Denver, CO" in the "**Search for Organization**" drop down menu (This will be your default location and should be highlighted already).

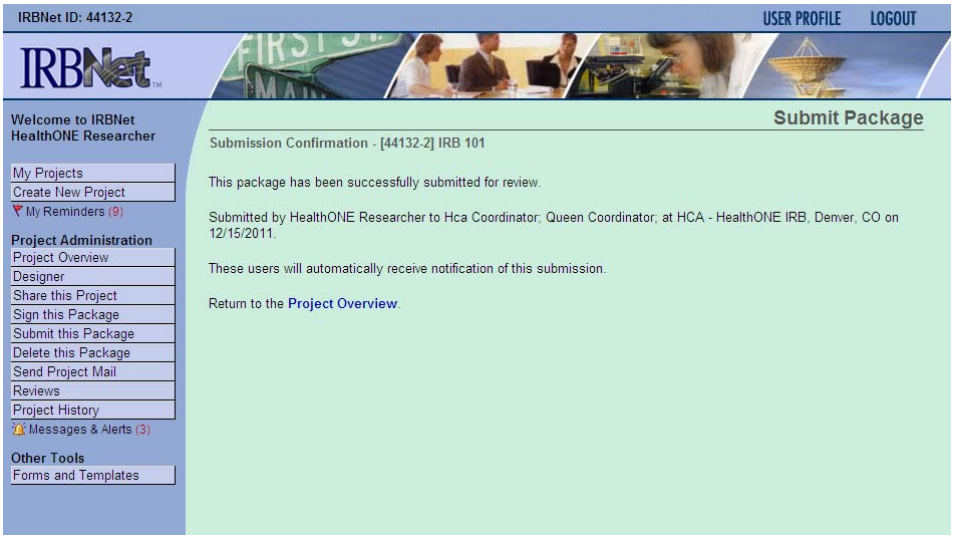



Then click on the '**Continue**' button.

In the Submission Type drop-down menu, select the appropriate submission type, either 'Adverse Event' or 'Reportable Event (Non-AE)' or 'Protocol Deviation' and click 'Submit'.




Once you hit the "**Submit**" button, you will be given a confirmation showing the time your submission occurred.



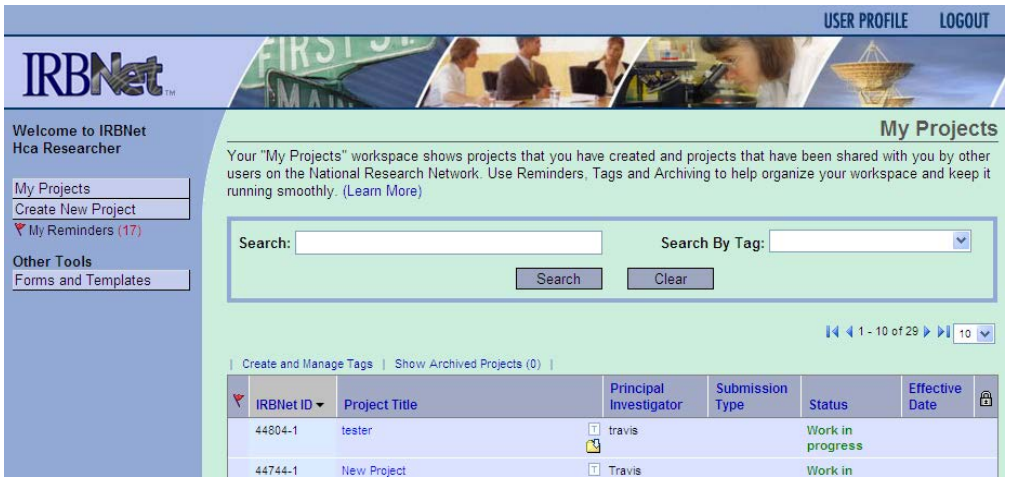

To review what has been sent, click **PROJECT OVERVIEW**. The submission will be under '**Pending Review**' status until an acknowledgement is granted or an action has been taken. Once a decision letter is formulated, an email will be sent to everyone who has full access and the letter and any supporting documents can be printed.

***User Tip:*** *Keep in mind that once you click "**Submit**" your study is now locked and no other changes can be made to this package. Take the time to be sure all documents are attached and in the final version **prior to submitting**. Any incomplete submissions will not be reviewed by the IRB and will be returned for corrections.*

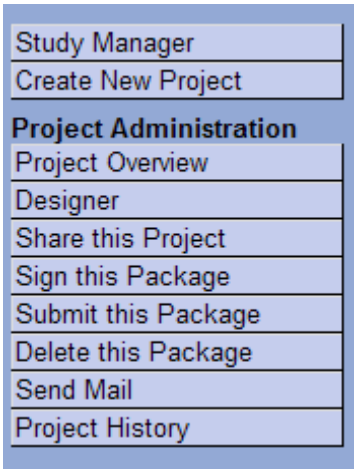
# VIII. INSTRUCTIONS FOR SUBMITTING REVISIONS REQUESTED BY THE BOARD (MODIFICATIONS REQUIRED)

If you have submitted a package and the IRB has determined that **"Modifications are Required",** then you need to submit a **'Revision'.**

Step 1: Login to IRBNet; www.irbnet.org. This will take you to the **MY PROJECTS** page.

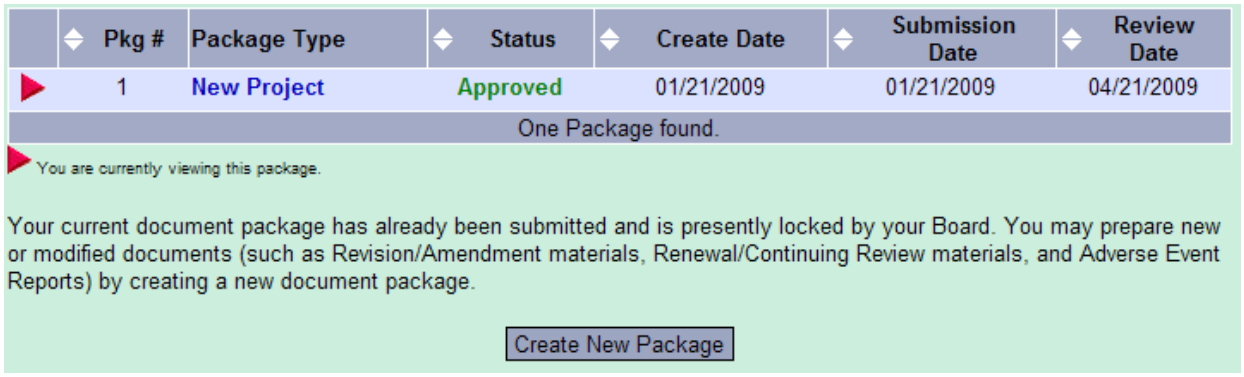



Step 2: Click on the Title of the project of which you submitting revisions. Then click on the **PROJECT HISTORY**

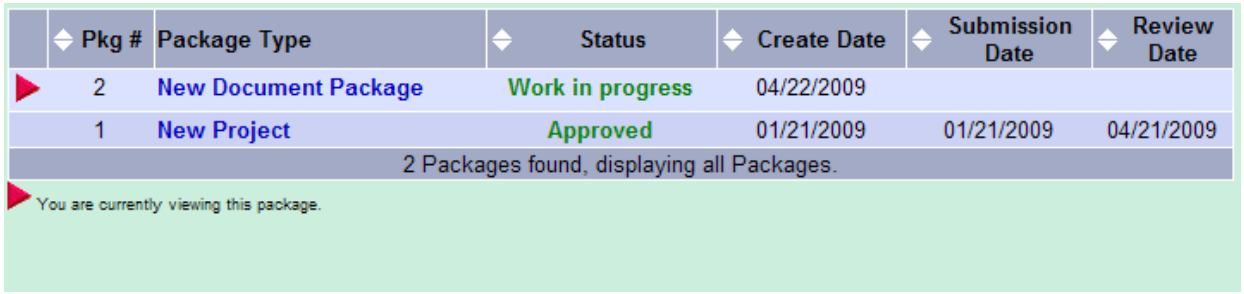



MODIFICATIONS REQUIRED

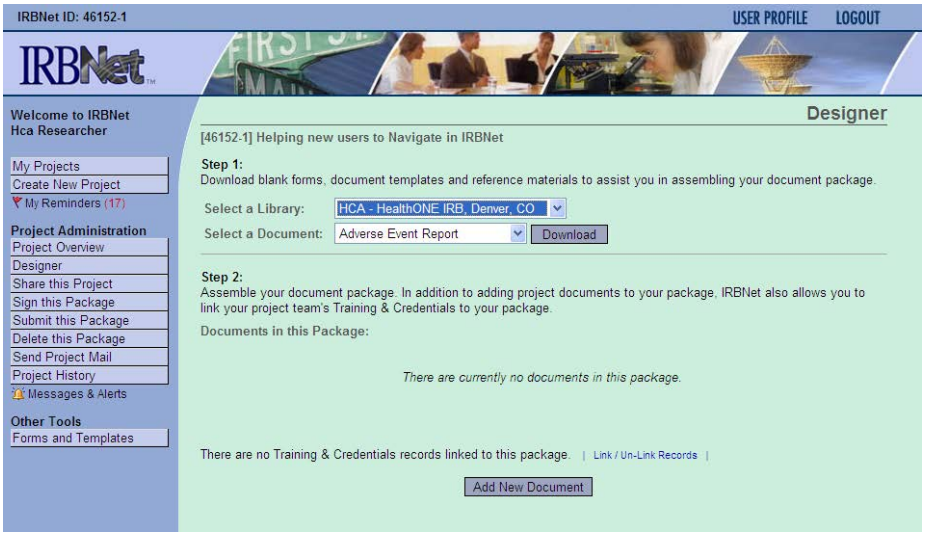
Step 3: Click on the **CREATE NEW PACKAGE** button and then the **NEW DOCUMENT PACKAGE**




A **NEW DOCUMENT PACKAGE** will appear as a "**Work in Progress**". Click on the **New Document Package** title and you will be brought to the **DESIGNER** screen where you can add your documents for this package.



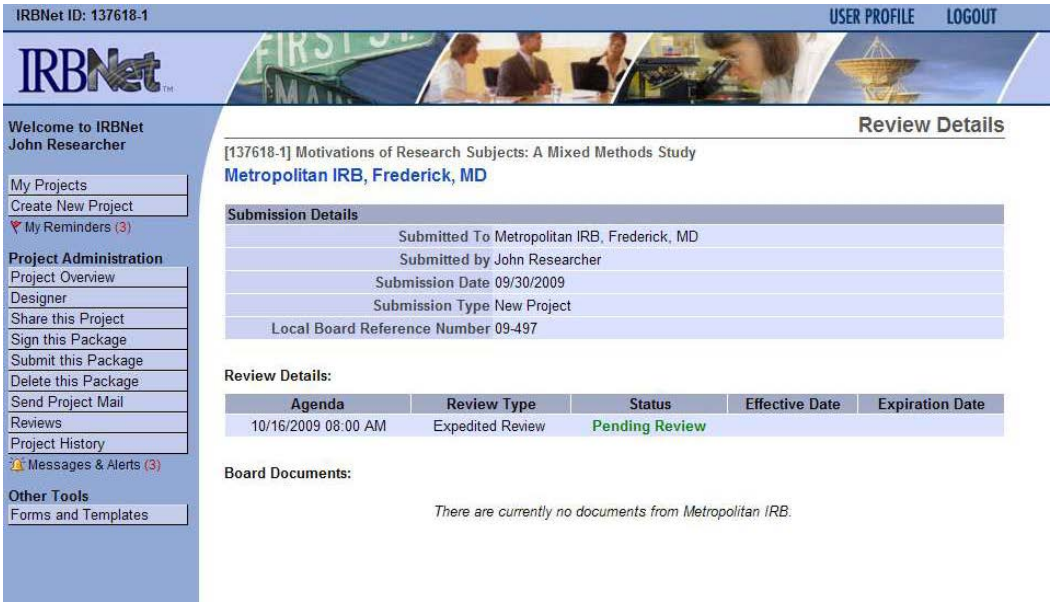

Step 4: You will now be on the **DESIGNER** screen where you can add your documents for this package.




MODIFICATIONS REQUIRED

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. *Note: 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 Section [See Review Details Page]*



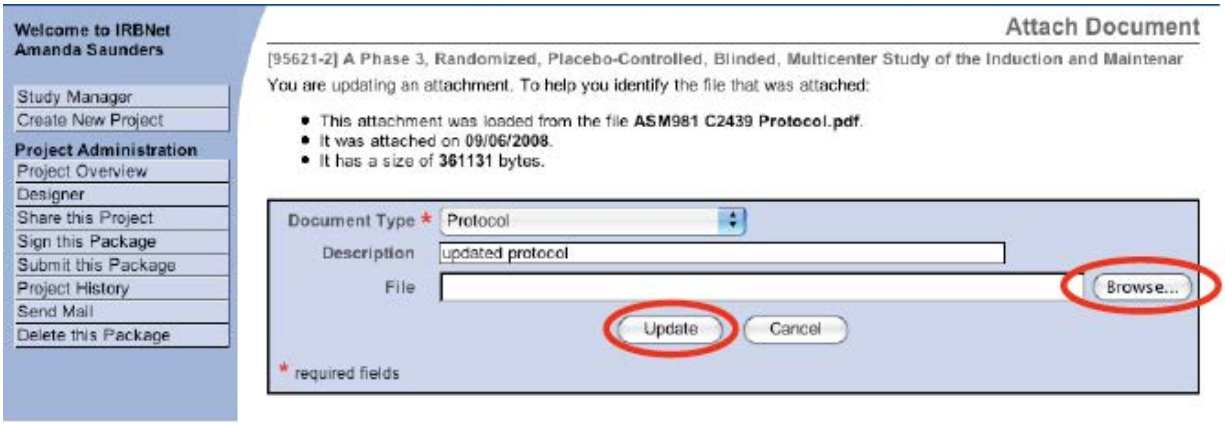

   - Make necessary changes and save the revised document to your computer. Be sure to include both a tracked changes version of your document showing what is changing as well as a clean copy for approval.

     ***Helpful Hint***: *You can find instructions on how to use 'tracked changes' under the Forms and Templates tab under 'Other Tools'. Look for the document entitled 'GUIDANCE – How to Use Track Changes in Documents'.*

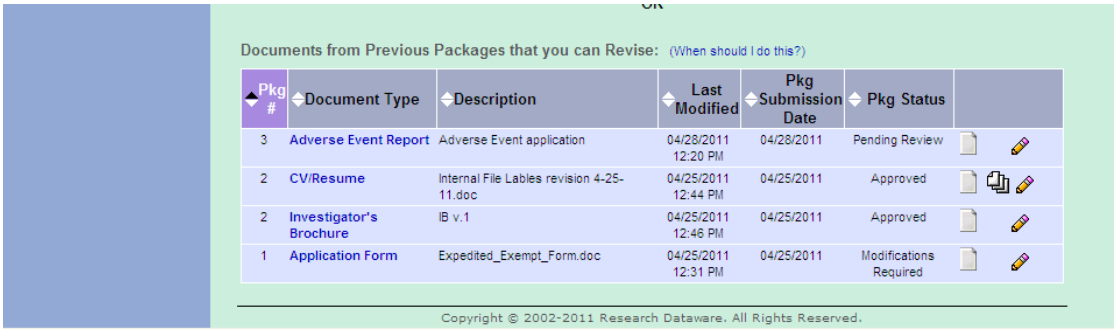
MODIFICATIONS REQUIRED

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


Browse your computer and select your revised version of the document to upload, make changes to the **Document Type** and **Description** as appropriate, and click the **Update** button.

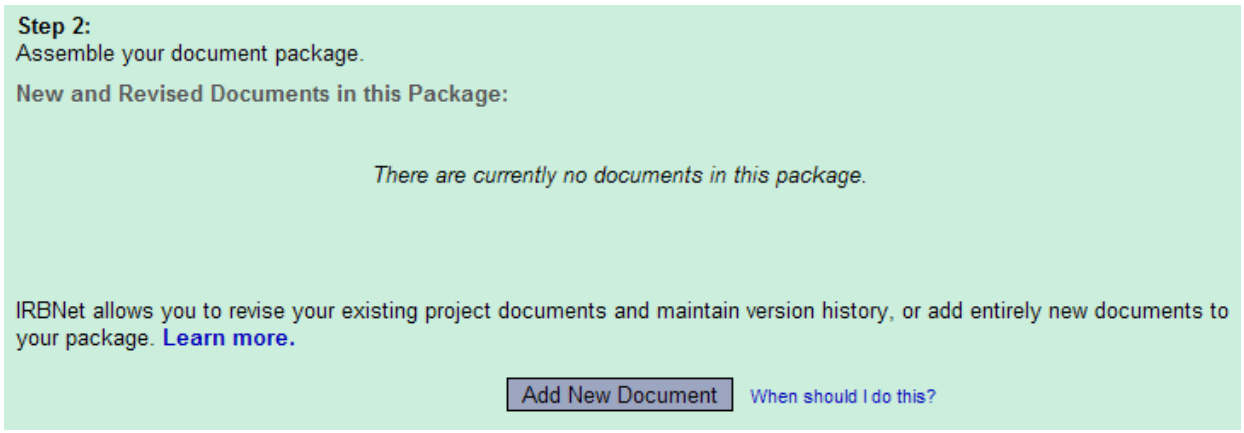



An icon will now show that there are multiple documents to be viewed. This will allow a reviewer (and you) to see the original document and the revised document in one place.



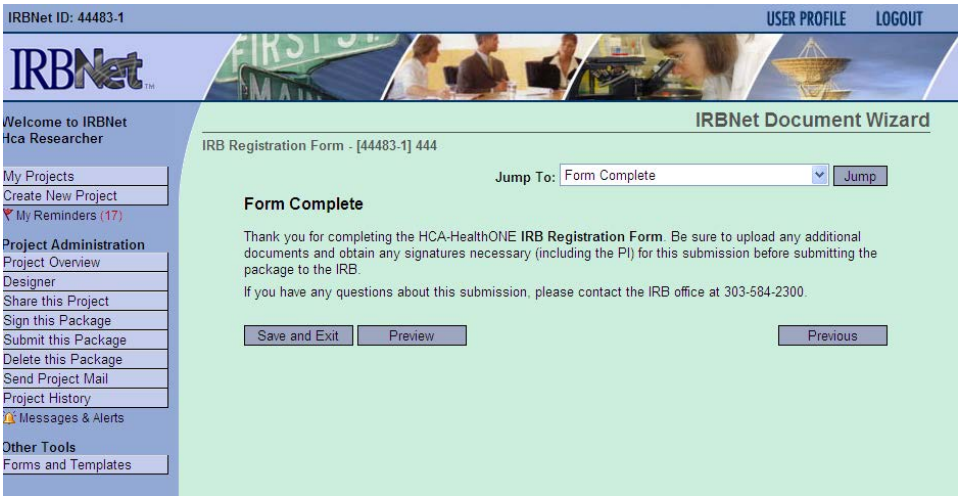

MODIFICATIONS REQUIRED

If you need to add a new document, then click on the '**Add New Document**' button.



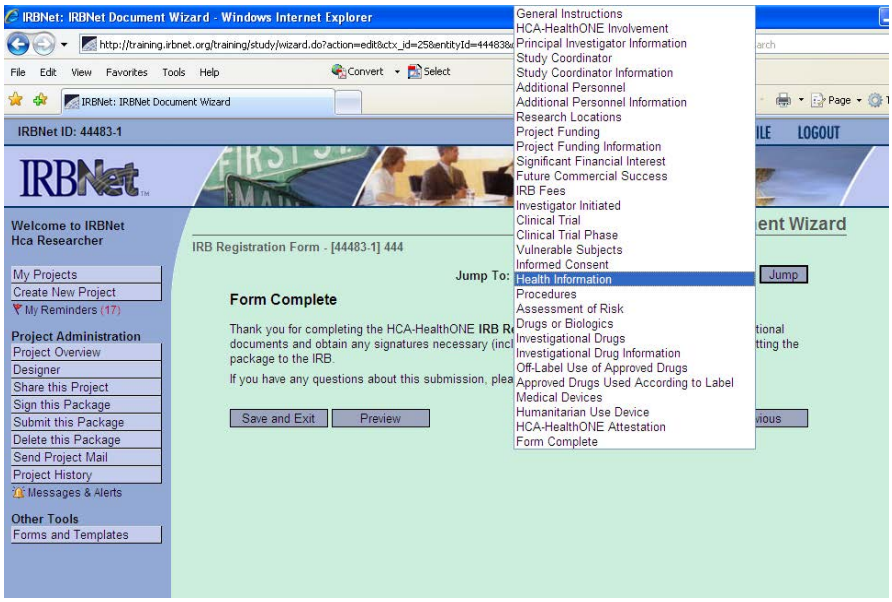

3. To revise **the IRB Registration Form** from a previous package for committee review:
   - Click on the pencil icon for the Registration Form.


   - This will open up the IRB Registration Form (IRBNet Document Wizard screen).



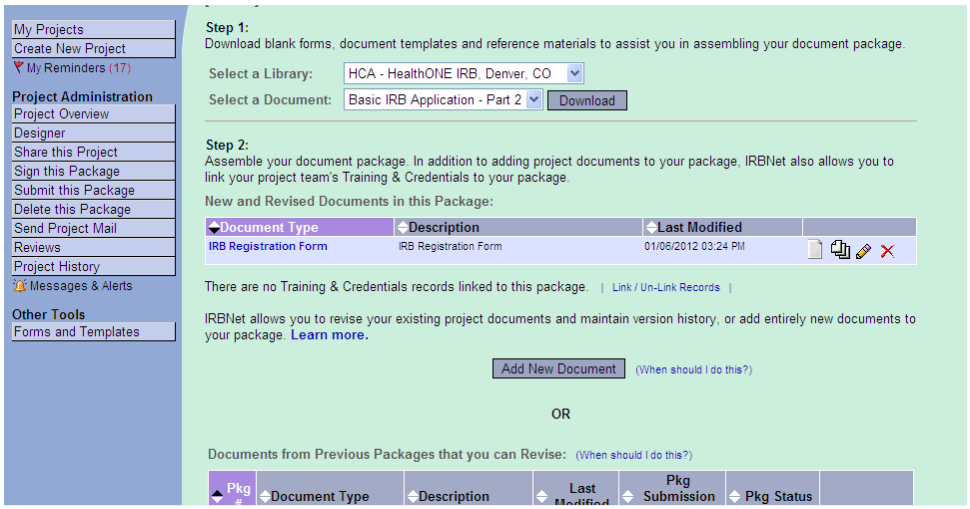

MODIFICATIONS REQUIRED

- Use the **Jump To**: feature in the upper right corner of the IRBNet Document Wizard page to **Jump** to the section that you are revising




- Click on the **Save and Exit** button when you have made all of your changes

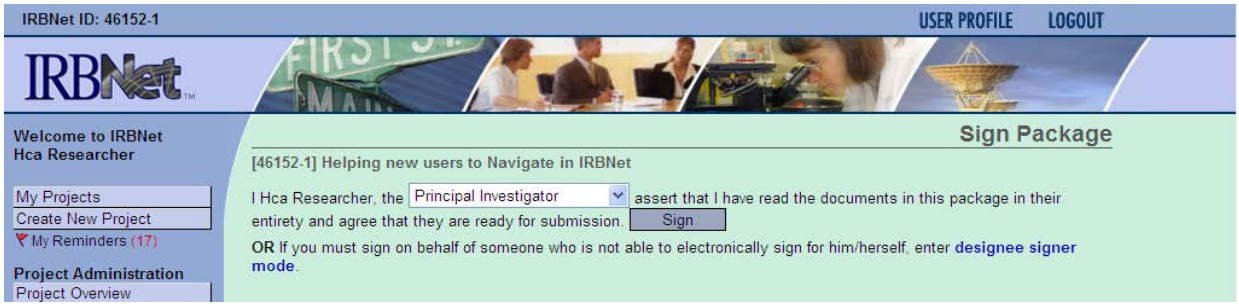
- The document will move to the 'New and Revised Documents in this Package' section on the **DESIGNER** page.



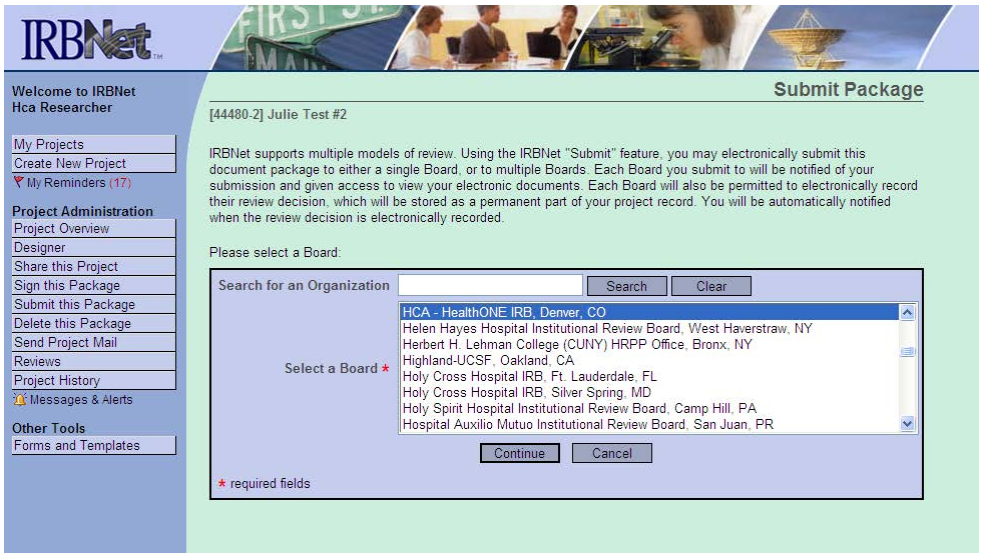

Step 5: Click **SIGN THIS PACKAGE**. The PI signature is required for all submissions

The lead researcher should sign as "Principal Investigator". Studies will not be scheduled for review if the PI has not signed off on the Revisions.

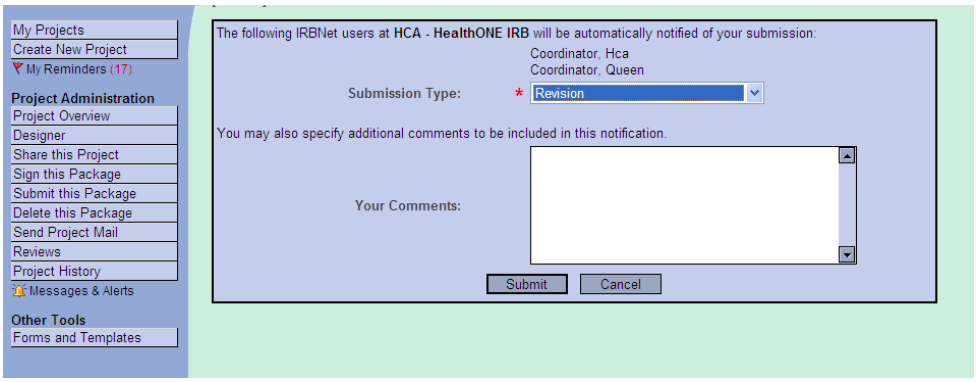
MODIFICATIONS REQUIRED




Step 6: Click on **SUBMIT THIS PACKAGE**; click on "HCA-HealthONE IRB, Denver, CO in the 'Select Organization' box. Then click on 'Continue'



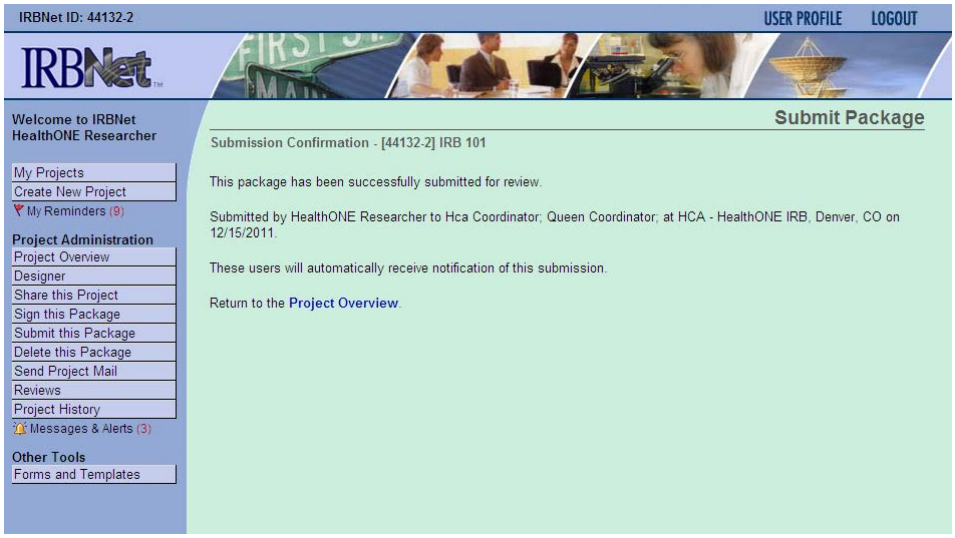

In the Submission Type drop-down menu, select 'Revisions' and click 'Submit'




In the "Your Comments" section, specify what the revision is for - i.e., response to new study submission, amendment submission, continuing review submission, etc. This will assist the board in processing your revision in a timelier manner.

MODIFICATIONS REQUIRED

To review what has been sent, click **PROJECT OVERVIEW**. The submission will be under 'Pending Review' status until a decision has been made.




***Helpful Hints***:

- *Take the time to be sure all documents are attached and in the final version prior to submitting. Any incomplete submissions will be unlocked and will not be reviewed by the IRB. An e-mail will be sent to identify the missing documents or items in the package.*

MODIFICATIONS REQUIRED

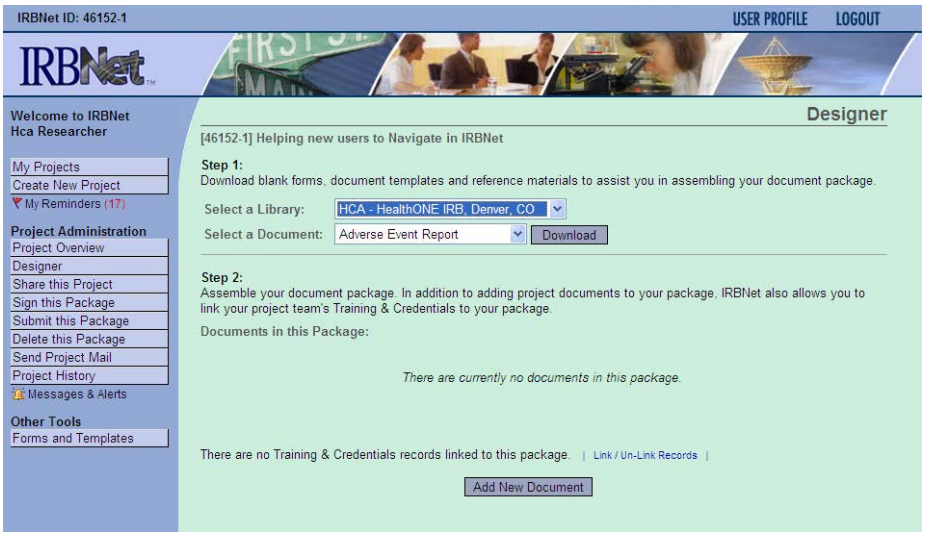
# IX. INSTRUCTIONS FOR SUBMITTING REVISIONS REQUESTED BY THE HCA-HealthONE IRB Administrative Office [Incomplete Submissions]

**You will receive an email that lists what is missing or what changes need to made to your document.**

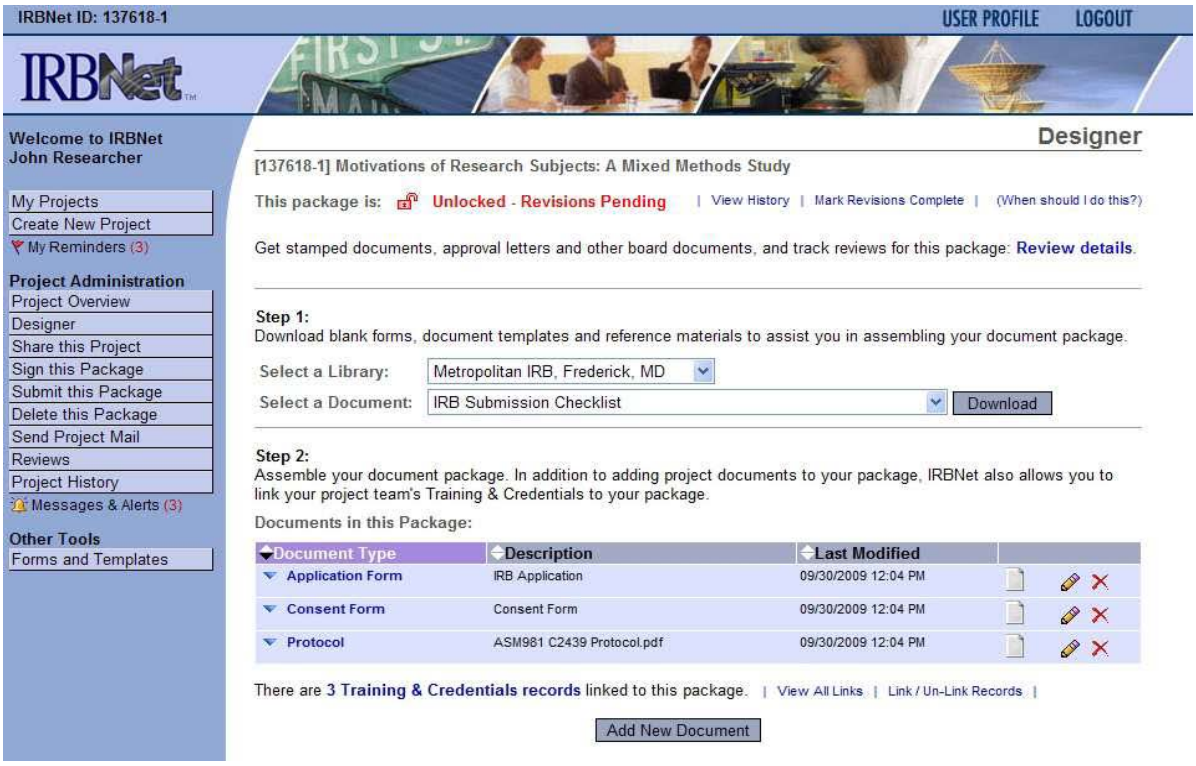
Step 1: Login to IRBNet; www.irbnet.org. This will take you to the **MY PROJECTS** page


Step 2: Click on the Title of the project of which you are submitting missing/corrected documents.

Step 3: Click the **DESIGNER**.



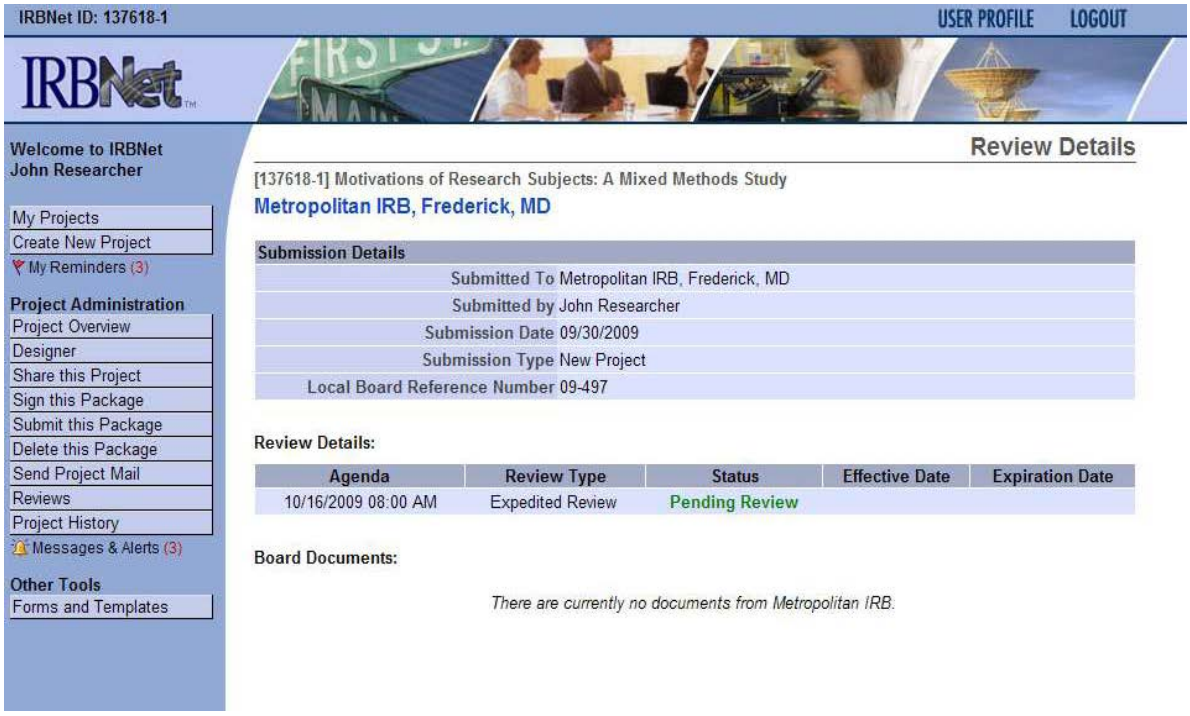

From here, you can upload revised documents for your study by clicking on 'Add New Document'. Browse for your revised documents and any other relevant information from your computer and assign the proper Document Type from the drop down menu. Click 'Attach'.




Step 4: To relock the package, Click on '**Mark Revisions Complete**.'

Step 5: Check the status of your review. Go to **Review Details**


Review Details include Agenda Date, Review Type, Status, Effective and Expiration Dates, and Board Documents



# X. INSTRUCTIONS FOR SUBMITTING OTHER SUBMISSIONS
(such as Other Correspondences or Communications from Study Sponsor)

**An investigator is responsible for reporting any new information as it is obtained during the study.**

Other submissions besides the submission types listed above are submitted using the same methods.

- Log-In to www.irbnet.org
- Click the appropriate title of the study
- Access the Designer
- Click the 'Add New Document' icon
- Attach the Document
- Have the PI Sign the Package
- Submit the package to the appropriate IRB (HCA-HealthONE IRB, Denver, CO) by designating the 'Other' Submission Type.

# *FAQ's:*

## What studies do I have access to?

The **MY PROJECTS** screen can be found by clicking on "My Projects' on the left side of your screen. This will show you the list of studies to which you have access – those you have created and those which have been shared with you. Studies which have not been submitted are labeled "**Work in Progress**" in the Status column. Studies which have been submitted but not reviewed by the IRB are labeled "**Pending Review**."

Clicking on the title of any project will take you to the **PROJECT OVERVIEW** page for the selected project which contains project details.

## What if I submit an incomplete package?

If you have forgotten to add a necessary document or need to make a quick change to a recently submitted project package, contact the HCA-HealthONE IRB administrative office at 303-584-2300.

## My PI says he signed up in IRBNet but I cannot share the project with him?

Anyone can trigger an Activation email by logging into their account on IRBNet and clicking the link provided. If they are not finding the Activation email in their inbox, please have them check their Spam folder. Once they open the Activation email, clicking the link provided will activate his account and allow him/her to log in on IRBNet.

## How do I know if my PI has signed the package?

To know when your PI has signed off on a package, ask them to click the send mail button when they have signed. This will send an automatically generated email from them letting you know they have signed. If they do not do this, you can log-in and review if they have signed by clicking on the **SIGN THIS PACKAGE** tab on the left of your screen. This will bring you to a list of who has signed this study and when it was completed.

## 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 the HCA-HealthONE IRB. Those with full access will receive e-mails when the IRB posts an action or decision.

## How do I "Un-share" a project with someone?

When personnel leave a study, it is very important to complete an amendment to notify the IRB of the change, and also to remove their access to the study. Follow the same steps in **SHARE THIS PROJECT** and click on "No Access".

## What are those little red flags and how do I use them?

The Project Reminders flag lets you know when an important message or alert has arrived. Simply click on the Project Reminders flag to view these messages and alerts. As you review each message and alert, be sure to "Silence" each personal Reminder flag if you no longer need to be reminded. Note that silencing your personal Reminder flags helps you to manage your personal project list and does not affect other users. By making sure to Silence the flags you no longer need, you'll be able to easily see when new messages and alerts arrive because the Project Reminders flag will automatically turn back on.

## What are Project Tags and how do I use them?

Use Tags to organize your projects, track tasks and status, and share important information with other users. When you tag a project you can choose if you want to keep the Tag personal (only you can see it) or if you want to share the Tag so it can also be seen by others (note that you can only share your Tags if you have Full or Write access to the project). For example, you may want to add a personal Tag to remind yourself of items on your individual to-do list, or you may want to add a shared Tag to let everyone on the project team know that they need to update their training credentials before your next submission. Note that shared Tags can be removed by any user that has Write or Full access to your project

## How do I Archive my projects?

You can help keep your workspace clean by Archiving projects that you no longer need to see in your active project list. Note that archiving projects helps you to manage your personal project list and does not affect other users. Archived projects can be viewed at any time by clicking "Show Archived Projects" and can also be Un-Archived at any time if you want them back in your active project list. For example, if you are an advisor or department chair that has to sign-off on large numbers of projects, you'll probably find it useful to Archive projects once you have signed off to help keep your active project list manageable.

You should note that even if you have Archived a project it will still appear in your active projects list if you have Reminders (for example, if you receive a new message or alert). Therefore, to make the most of project Archiving you should be sure to regularly review and silence your Reminders.

## What does my electronic signature mean?

**The HCA-HealthONE IRB requires that the Principal Investigator sign each submission. 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 HCA-HealthONE IRB'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 the HCA-HealthONE IRB
- Promptly report any revisions or amendments to the research activity for review and approval by the HCA-HealthONE IRB 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 HCA-HealthONE IRB-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 HCA-HealthONE IRB 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 HCA-HealthONE IRB
- 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.

## Locked vs. Unlocked Status

Once a study is submitted to the IRB, it will be **LOCKED**.
Packages can only be unlocked by HCA-HealthONE IRB Administrative 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. When you need to respond to a HCA-HealthONE IRB review, or if you want to submit an amendment, or continuing review, you will **CREATE NEW PACKAGE** for the project by adding documents in the designer for that project. See sections I - IX for details.

## 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 #:**

- **The IRBNet # 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.

- The local board reference # is the old number that came over from the previous electronic system, IRB Manager. For example, 2006-111.

## I have submitted a Continuing Review application, why am I still receiving an IRBNet 30-Day Project Expiration Reminder?

- Reminders are automatically generated until the submission has been approved by the IRB. If you can see the Continuing Review submission in PROJECT HISTORY the IRB staff has access to it. PROJECT HISTORY will show the Status as **Pending Review** until it has gone to the Board.

# EXPLANATION OF IRBNet TERMS

| | |
|---|---|
| Project | A Project is an online version of the research protocol being submitted to the HCA-HealthONE IRB |
| Project Package | A package is a submission containing any number of documents that are required by the IRB to conduct their review of a research Project (i.e., Initial project, amendment, continuing review, protocol deviation, etc.) |
| Submission | IRBNet uses the term Submission to denote a Project Package that has been submitted for official review by the IRB |
| Principal Investigator | IRBNet uses the term Principal Investigator (PI) to designate the person with overall responsibility for studies submitted to the HCA-HealthONE IRB. All studies must have a PI, and all submissions must include a PI signature. |
| Amendment/Modification | Amendments/Modifications are changes that the researcher wishes to make **after** a study is approved by the IRB. The researcher must submit an Amendment/Modification package for IRB approval. |
| Revision | A Revision is a change (or changes) required by the Institutional Review Board before a Project or package can be approved. The researcher creates a new Project Package in IRBNet to address any required revisions. |
| My Projects | Lists all projects you have created. You enter the study by selecting it from the list |
| Create New Project | Allows you to enter a New Study for submission. The Initial Project package will include the appropriate applications, the full research protocol, any surveys or instruments, consent forms and any other required documents. |

| | |
|---|---|
| Project Overview | Summarizes the selected project, displays the status and documents. Allows you to submit the package for review, and share with other IRBNet users |
| Designer | This page contains two steps. Step 1 lists the document library where you can find forms to guide you or to fill out (i.e., checklists, applications). Step 2 allows you to upload your documents to a package. This is called "Assemble your document package'. This means you are putting your proposal together |
| Share This Project | Allows you to share your project with other researchers |
| Sign this Package | All packages must include the Principal Investigator signature prior to submission |
| Submit this Package | After the PI signs the package, you will need to submit the package to the HCA-HealthONE IRB. Once you submit a package, it remains in the system permanently. |
| Delete this Package | If you want to remove the package completely, this cannot be undone. |
| Send Project Mail | Allows you to send an e-mail between members of the project team |
| Project History | Lists the Actions related to this project |
| Board Documents | These are decision documents and stamped documents issued by the board in response to your package submission |

# HOW TO LABEL YOUR SUBMISSIONS

When submitting the following items, use the appropriate SUBMISSION TYPE within IRBNet:

| ITEM | SUBMISSION TYPE |
|---|---|
| *Exempt Initial Submission* | *New Project* |
| *Expedited/Convened IRB Initial Submission* | *New Project* |
| *Continuing Review* | *Continuing Review/Progress Report* |
| *Amendment* | *Amendment/Modification* |
| *Consent Revision* | *Amendment/Modification* |
| *Protocol Revision* | *Amendment/Modification* |
| *Information from Sponsor/Notification to the IRB* | *Amendment/Modification* |
| *Study Closure* | *Closure/Final Report* |
| *Response to Approval with Modifications from the IRB* | *Revision* |
| *Response to Additional Materials Request or follow-up from the IRB* | *Revision* |
| *Correspondence* | *Other* |
| *Any Communications from Sponsor that do not require an amendment (i.e., DSMB's, Investigator Brochures, Clarification Memos, Package Inserts)* | *Other* |
| *External SAE's from Sponsor* | *Adverse Event* |
| *Local SAEs* | *Reportable Event/(Non AE)* |
| *Protocol Deviation* | *Reportable Event/(Non AE)* |
| *Unanticipated Problem* | *Reportable Event/(Non AE)* |
| *Compliance Concern* | *Reportable Event/ (Non AE)* |