Wake Forest University
User's Guide to eIRB

edition 073007

Logging in

Objective

Log in to the eIRB system

How do I log in?

✓ Before beginning the application process, please take time to review the eIRB FAQs available on the Reynolda campus IRB website.

1 Go to www.wfu.edu/rsp/irb/forms.html

2 Click on the link to *eIRB*.

3 Enter your *User name*: and *Password*:

4 Click *Log In* to enter the site.

The eIRB Sandbox

➢ The eIRB Sandbox is a special eIRB web site, created for the sole purpose of providing an area where you can experiment with the eIRB and its functionality.

➢ The eIRB Sandbox is identical to the main eIRB as far as its functionality is concerned.

💣 Do not create any actual studies, as the Sandbox is cleaned frequently and any studies you create in the Sandbox will be lost.

💣 Do not put any confidential information in this site since these are shared accounts used for training.

How do I access the eIRB Sandbox?

1 Users on the Wake Forest University network can access the eIRB Sandbox by going to http://eirbdev.wfubmc.edu/sandbox.

2 Click Login at the top right of your screen.

3 Use any of the following usernames:

Role	Username
PI	g_hall
Study Coordinator	e_terrace
Co-Investigator	h_hill
Student	m_park
IRB member	sp

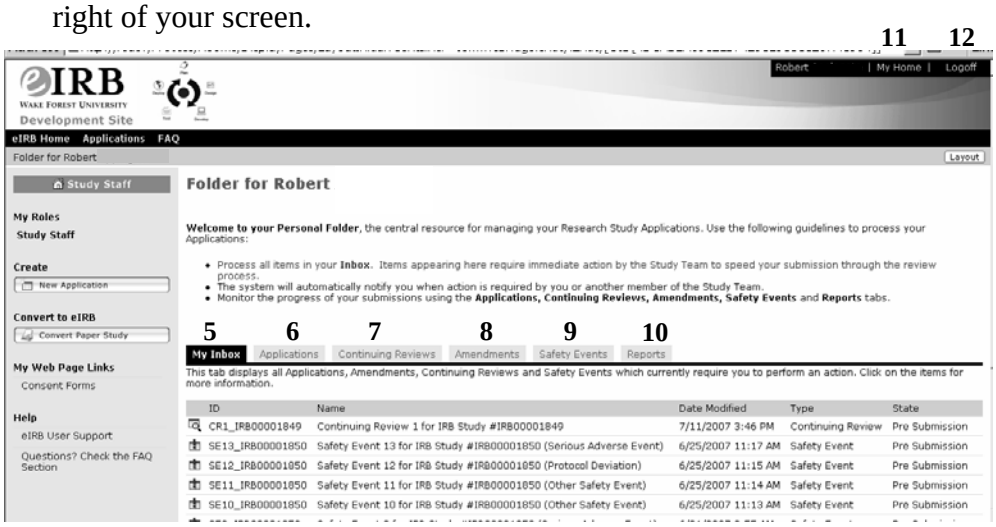
4 All passwords for these accounts are *wakeeirb*.

Your Personal Workspace

Objective Become familiar with your Personal Workspace

Your Personal Workspace

- Your Personal Workspace, otherwise known as My Home, displays all the eIRB study submissions associated to you.
  - ✓ If you are not already at your home page, click *My Home* at the top right of your screen.



Key workspace areas

#	Name	Description
1	My Roles	Select your eIRB role, if you have more than one.
2	New Application	Initiates a new IRB application.
3	My Web Page Links	Links to additional documentation, e.g. Consent forms.
4	Help	Links to FAQ and User Support. *See note below.*
5	My Inbox	Any study which requires an action on your part. Click the *Name* of the submission to view more detail.
6	Applications	Any study which you can view or edit that has not been submitted or is in review.
7	Continuing Reviews	Requests for renewal of approval that must be made by the 358th day from the date of the previous approval.
8	Amendments	Requests to approve proposed changes to an approved study.
9	Safety Events	Reports of adverse events, unanticipated problems and protocol deviations to the IRB.
10	Reports	Administrative function for IRB staff only.
11	My Home	Returns you to your Personal Workspace from any other workspace.
12	Logoff	Exits the eIRB.

FAQs

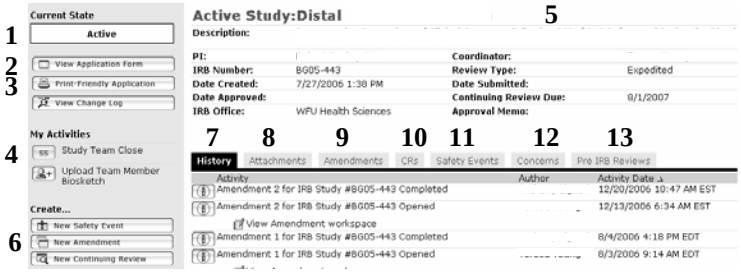
- ✓ The FAQ Section on your homepage will direct you to the Medical School FAQs.
- To view the Reynolda campus eIRB FAQs, go to www.wfu.edu/rsp/irb/forms.html.

The Study Workspace

Objective Become familiar with the Study Workspace

What is the Study Workspace?

- When you open an existing application, amendment, or continuing review from your Personal Workspace, you will be taken to the Study Workspace.
- The Study Workspace is the area where all activities associated with the study will be performed.
- Below is a snapshot of the Study Workspace after an application has been approved.



Key Study Workspace areas

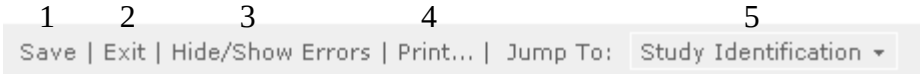
#	Name	Description
1	Current State	Indicates where the study is in the IRB review/approval process.
2	Edit/View Application Form	Opens the study for editing or viewing. A study can not be edited while it is under review.
3	Print-Friendly Application	Opens a new window where you can print the entire study.
4	My Activities	Common activities related to the study, e.g. submitting an application.
5	Study Summary	Details on the selected study.
6	Create…	Options for creating new items related to the study, e.g. an amendment.
7	History	A list of events, most recent on top, which charts the movement of the study through the review process.
8	Attachments	Lists any attachments associated with the study.
9	Amendments	Lists any amendments associated with the study and their status.
10	CRs	Lists any continuing reviews associated with the study and their status.
11	Safety Events	Lists any safety events associated with the study and their status.
12	Concerns	Lists any concerns identified during the review process and the study team's response.
13	Pre-IRB Reviews	Allows study team to see who has agreed to participate.

Navigating in a Study

Objective

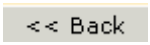
Navigate in an application or study

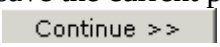
Navigation features



#	Name	Description
1	Save	Saves the current page.
2	Exit	Exits the study.
3	Hide/Show Errors	Opens a separate window at the bottom of the screen to show any errors on the page.
4	Print	Prints the current page only.
5	Jump To:	Navigates to a specific page in the application or study. Select the page from the drop-down.

Navigation tips

- The *Back* button does not save. ⇒ 

- The *Continue* button will save the current page and advance to the next page of the application. ⇒ 

- At any point, you may click *Save* to save the data entered without moving to a different page.
  - ✓ Be sure to always save your work.
- The *Exit* button will prompt you to save your work, if you have not already done so.
- You may Save and Exit a study at any time. The study will remain in your Inbox so that you can easily access it.

Creating a new application

Objective Create a new application

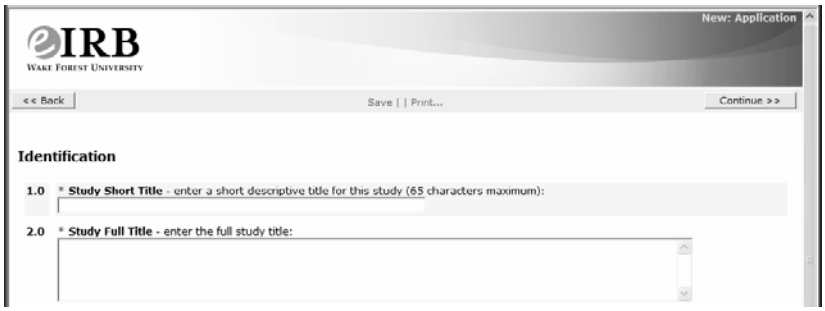
How do I create a new application?

✓ Applications for new research studies must be submitted by the Principal Investigator (PI). Student co-Investigators (co-Is) may complete, but not submit applications.

1 Click the 

button to initiate a new IRB Application.

2 Begin by filling out the first page of an application.



- Required fields are denoted with a red asterisk.
  - ✓ You may not advance through the application without completing the required fields on the current page.
  - ✓ A message at the top of an incomplete page will alert you to any errors.
- ✓ The *Study Full Title* you enter in the application will appear on the approval letter. Be careful how you name your study.

3 Click *Continue* to advance to the next page of the application.

- ✓ Once you click *Save* or *Continue*, the study will be created in the system; do this only if you are sure that you want to create a new study.

4 When you are finished, click Save to save your changes and then Exit to exit the application form and return to the Study Workspace.

➢ Your new study is now visible in your Inbox and the Inbox of the designated PI, study coordinator, co-Investigators, and other team members.

- ✓ Before the study is submitted, it may be edited by any study team member.

Adding Study Team members

Objective Add study team members to your study

Adding Study Team members to your study

- Student researchers will have the role of student co-Investigators (co-Is) on a study. The faculty advisor will assume the role of Principal Investigator (PI).
- You must add study coordinators, co-Investigators, and other study team members to your study in order for them to be able to view your study.
- An IRB application cannot be approved until all study team members have current Human Subjects Protection Education (CITI) certification dates in the eIRB system. See page 8 for more information.

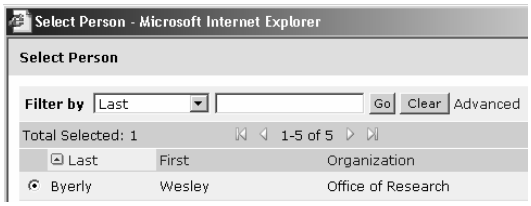
How do I add study team members?

1 Start a new application or create an amendment for an already approved study. See *Amendments,* page 17.

2 Click the *Select (*or *Add)* button beside the study team member to be added - Principal Investigators, Study Coordinators, co-Investigators, other team members.

3 Filter the list to find the team member you want to add.

   ✓ Type the first three letters of the last name and click *Go*.



4 Select the team member to be added by clicking the radio button beside their name.

5 Click *OK*.

Adding study team members not in the pick list

- If a study team member does not appear in the pick list for a particular role (PI, Coordinator, co-I), then they have not been assigned this role in eIRB.
- You may request a role by contacting the IRB Administrator at 758-5888, or irb@wfu.edu.
  - ✓ Requesting a user role for a study team member will not place the person on any particular study. Rather, it makes the person eligible for these roles on any given study.
- If the study is not yet active, you may request that the application be returned to you for editing and then add/delete the team member.
- If the study has been approved (i.e., is active), you must submit an *Amendment Request* (see page 17) to add or remove study team members.
- Study Team members who are changing their role should add themselves to the new role before changing their original role to avoid locking themselves out of the application.

CITI certification

Objective Understand CITI certification requirements

CITI certification and application approval

- An IRB application cannot be approved until all study team members have current Human Subjects Protection Education (CITI) certification dates in the eIRB system.
  - ✓ If a study team member has completed CITI, but does not have a certification date listed in the *IRB Cert Date* field, contact the IRB Administrator at 758-5888 or irb@wfu.edu.
- CITI will notify the IRB office once certification has been completed and the IRB Administrator will add the study team member to the list of those completing CITI.

Uploading documents

Objective Upload documents to your application

What types of documents will I need to upload?

- Examples of documentation that will need to be uploaded to eIRB include: protocol documents, biosketches, informed consent/assent forms, advertisements/recruiting material, and debriefing scripts.

How do I attach/upload a document?

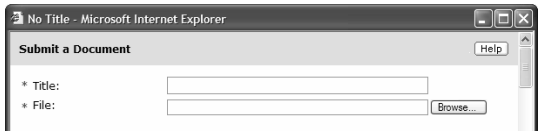
- Throughout the application forms, you will be asked to *Add* various documents to the Application.

1 Click the *Add* button and a new window will appear.

✓ You may be prompted with a message asking whether you want to accept the certificate. If so, choose *Yes* or *Grant Always*.

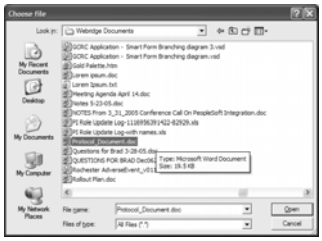
2 Enter a *title* for the document you are uploading or leave it blank.

✓ Entering a title is optional. If you do not enter a title, the filename becomes the title of the document.



3 Click *Browse…* and select the file you want to attach.

✓ Document file names can not contain spaces or special characters.



4 Click *Open.*

5 Click *OK*.

✓ A link to your document is now visible on the application.

Biosketches

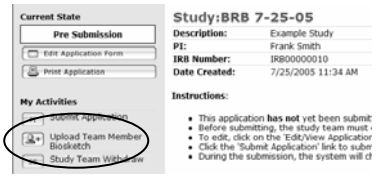
Objective Attach a biosketch to an application

How do I attach a biosketch?

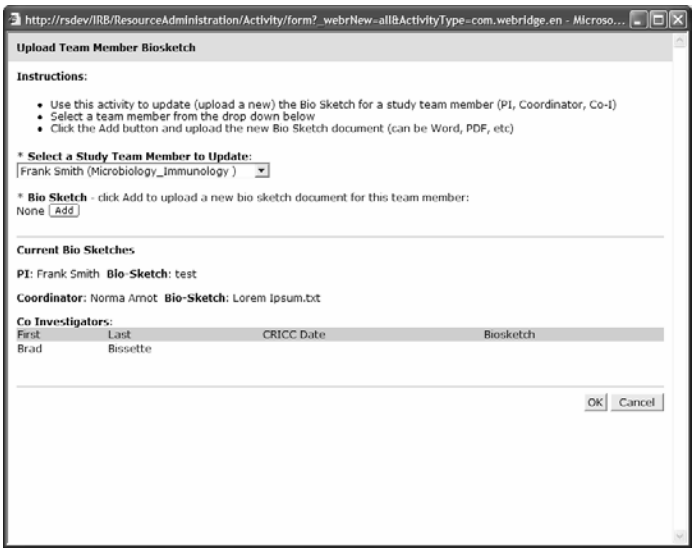
- Any person designated as PI, study coordinator or co-I must have a biosketch or CV in eIRB.
  - ✓ A study coordinator may substitute a CV for a biosketch.
  - ✓ Student co-Is may follow the Investigator Addendum from the IRB website, www.wfu.edu/rsp/irb/forms.html to prepare an abbreviated biosketch.
- Once a biosketch has been added, eIRB will store it for future use with other studies.

1 If you are prompted at any point to attach a biosketch, *Save* and *Exit* the application in order to return to the Application workspace.

2 Click the *Upload Team Member Biosketch* button on the left side of the Study Workspace screen.



3 Select the Study Team Member for whom you want to upload a biosketch from the dropdown.



4 Click the *Add* button to upload a new biosketch document for this team member.

Informed Consent documents

Objective

Create or modify informed consent documents for electronic submission

Informed Consent documents

✓ Assent documents should be modified following the same procedures used for informed consent documents.

Uploading original informed consents

➢ Informed Consent templates, and sample consent/assent forms (in English and Spanish) can be found at www.wfu.edu/rsp/irb/forms.html.

1 Save the Informed Consent template to your computer or network drive.

2 Open the Informed Consent template and modify the body of the template as required for your study.

💣 Do not change or modify the text box stamp located in the template footer.

3 *Save* the document.

4 Back in the eIRB application, use the *Add* button to attach the original Informed Consent in the *Consent Forms* section.

Editing informed consent documents

➢ An application can not be edited while it is under review.

✓ An application can only be edited when it has been returned to the study team. This ensures that all changes are accurately tracked.

1 Re-open the original Informed Consent document on your computer or network drive.

2 Turn on change tracking and modify the body of the document as needed.

💣 Do not change or modify the text box stamp located in the template footer.

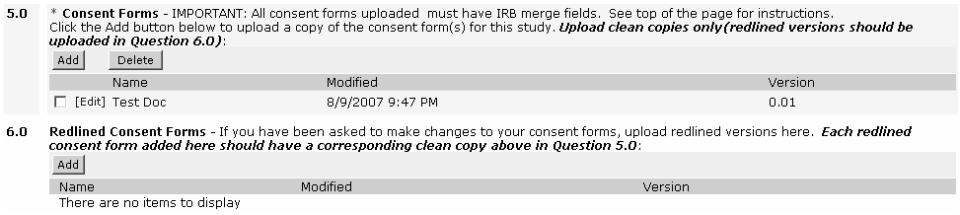
3 Save the redlined copy.

4 Turn off change tracking, accept all changes, and save a clean copy of the document.

5 Once back in the eIRB application, use the *[Edit]* link to attach the revised clean copy in the *Consent Forms* section.

✓ The edited version of the document is uploaded with the current version number displayed.

6 Use the *Add* button to attach the redline copy in the *Redline Consent Forms* section.



Editing and deleting study documents

Objective

Edit or delete study documents that have previously been uploaded

Editing documents

- An application can not be edited while it is under review.
  - ✓ An application can only be edited when it has been returned to the study team. This ensures that all changes are accurately tracked.
- To edit informed consent/assent documents, see page 11.
- You can edit and upload a revised version of any documents that you have previously uploaded.

1. Open the document on your computer or network drive.
2. Make the necessary changes.
3. Save the document.
4. Back in the eIRB application, select the checkbox beside the name of the currently uploaded document.
5. Use the *[Edit]* button to upload the revised copy.
   - ✓ The edited version of the document is uploaded with the current version number displayed.

Deleting a document

- You can delete a previously uploaded document from the eIRB.

1. Select the check box in front of the name of the document to be deleted.
2. Click the *Delete* button.

Agreement to participate

Objective Agree to participate in a study for which you have been named a study team member

How do I agree to participate?

- Once the PI submits the study application, an email will automatically be sent to the study team members with a link to log into the application, review the protocol and agree to participate.
- Before the PI can submit the application, study team members must access the application and accept their assigned role.
  - ✓ If all study team members do not agree to participate, an application can not move forward.

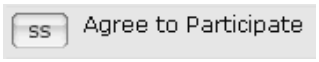
1 From your Inbox, in the *Agree to Participate* section, click the *Study Title* to access the Study Workspace.


Agree to Participate
This list shows any studies waiting on you to agree to participate in as a study team member. If there are any items in the list, please click on the link and then click the "Agree to Participate" button.

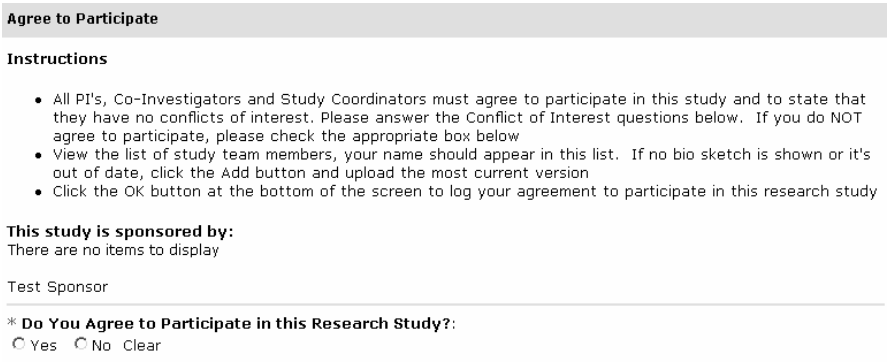
IRB #	Study Title	Principal Investigator
IRB00000004	Stress Management	Gray Hall

OR

Click the link in the email to take you directly to the Study Workspace.

2 Click the *Agree to Participate* button. ⇒ 

3 Complete the information on the Agree to Participate activity page.


Agree to Participate

Instructions

- All PI's, Co-Investigators and Study Coordinators must agree to participate in this study and to state that they have no conflicts of interest. Please answer the Conflict of Interest questions below. If you do NOT agree to participate, please check the appropriate box below
- View the list of study team members, your name should appear in this list. If no bio sketch is shown or it's out of date, click the Add button and upload the most current version
- Click the OK button at the bottom of the screen to log your agreement to participate in this research study

This study is sponsored by:
There are no items to display

Test Sponsor

* **Do You Agree to Participate in this Research Study?**:
Yes No Clear

- Click the radio button indicating acceptance of your role.
- Upload or update your biosketch (see page 9).
- Complete the *Conflict of Interest Disclosure* section.

4 Click *OK*.

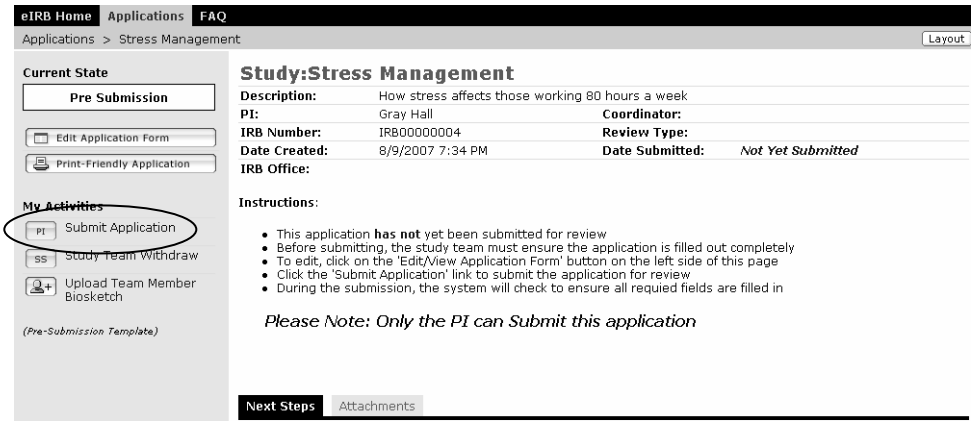
- Study team members who have accepted their roles are indicated in the Study Workspace.

Submitting an application

Objective Submit an application

Submitting an application

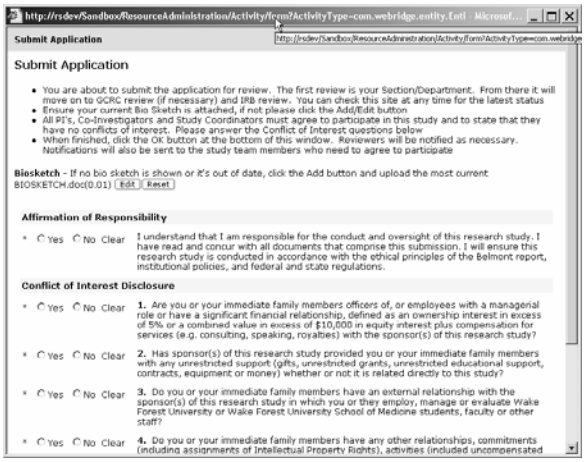
- When an application is complete, it may be submitted for review.
- Once the submit action has been completed, the study will enter the review process.
- The *Submit Application* activity can only be performed by the PI.
  - ✓ This ensures a digital signature on the application before it begins the review process.
- After submission, the study team will not have access to edit the application unless it is returned with changes requested by eIRB.
- The *Submit Application* activity is performed from the Study Workspace shown below.



How do I submit an application?

1 From the Study Workspace, click the *Submit Application* button.

2 Complete all questions on the Submit Application screen.



3 Click *OK* at the bottom of the Submit Application window.

- ✓ You will be returned to the Study Workspace and your study will now be listed in the History log.

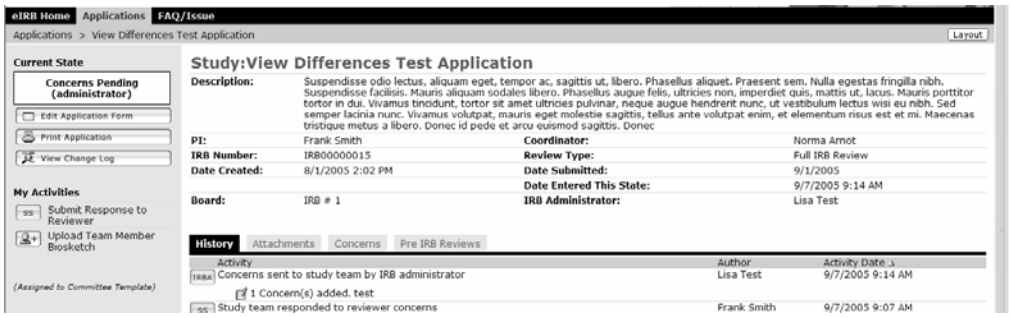
Viewing reviewer concerns

Objective View the concerns of reviewers

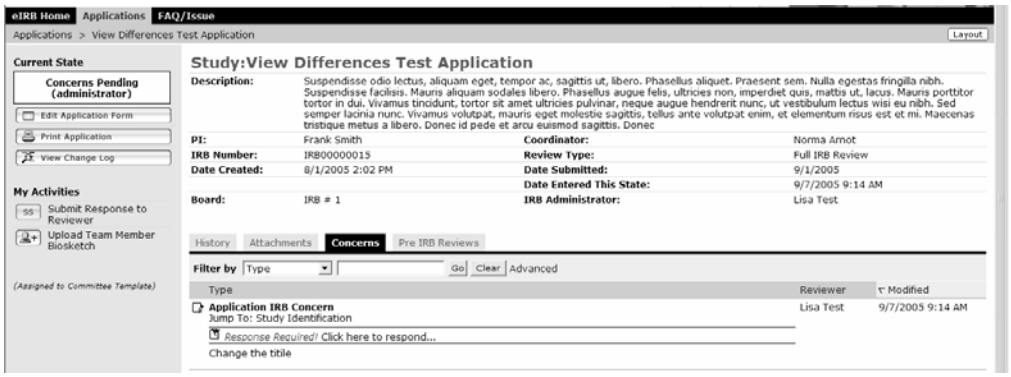
How do I view reviewer concerns?

- During the course of the review process in eIRB, the study team will be required to address the concerns of the IRB Administrator and Board.
- When IRB Administrator or Board concerns are sent to the study team, the application will be returned to the Personal Workspace (My Home) Inbox of all study team members with an indication in the History log that concerns have been added.
- An email will also be sent to study team members alerting them that concerns need to be addressed.

1 Use the link in your Personal Workspace Inbox or on your email to enter the Study's Workspace.



2 Click the Concerns tab to see what concerns have been added.

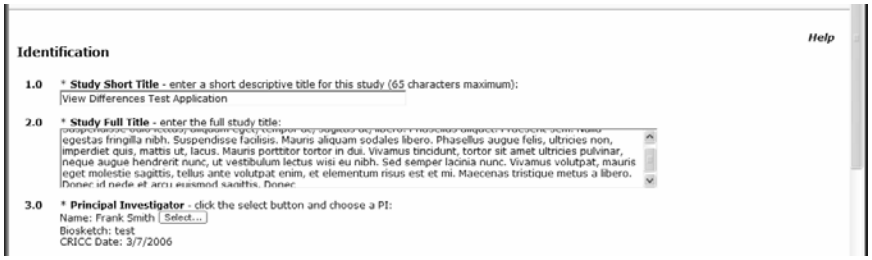


Responding to reviewer concerns

Objective Address the concerns of reviewers

How do I respond to reviewer concerns?

1 Use the *Jump To:* link to go to the section of the application where concerns have been added.

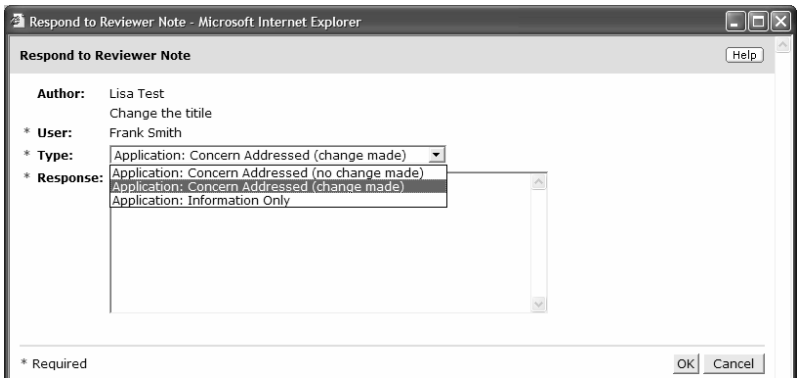


✓ Concerns will be listed at the top of each page, along with the reviewer and date modified.

2 Make the necessary changes.

3 Once the changes have been made on the application, use the *Click here to respond* link at the top of the page to summarize your response to the reviewer.

4 Select the appropriate category and give your response.



5 Click *OK*.

6 When finished, *Save* and *Exit* the application form and return to the Study Workspace.

7 Click the *Submit Response to Reviewer* button to return the application to the reviewer⇒.

Amendments

Objective Submit an amendment request for an approved study

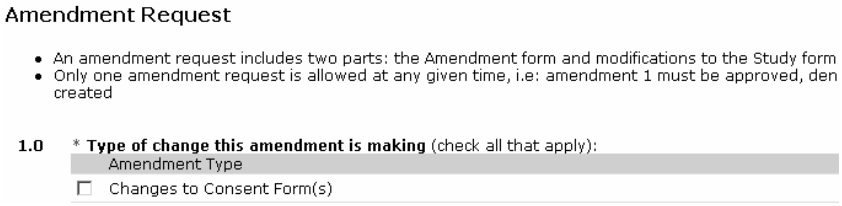
How do I create an amendment request?

- Amendments can be submitted for approved active studies only.
- Amendments may be submitted by the Principal Investigator, Study Coordinator or Student co-Investigator.
- An amendment request includes two parts: the Amendment form and modifications to the Study form.
- Only one amendment can be in process at a time for each study.

1 Navigate to the Study Workspace of the approved active study.

2 Click the *New Amendment* button on the left to start a new amendment submission. ⇒ 

3 Complete the required information on each page of the *Amendment Request* form.


Amendment Request

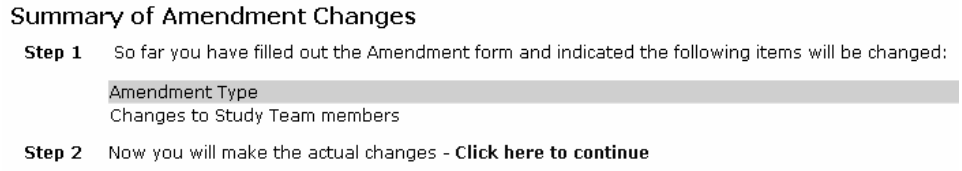
- An amendment request includes two parts: the Amendment form and modifications to the Study form
- Only one amendment request is allowed at any given time, i.e: amendment 1 must be approved, den created

1.0 * **Type of change this amendment is making** (check all that apply):

Amendment Type

☐ Changes to Consent Form(s)

4 When you reach the *Summary of Amendment Changes* screen, click the *Click here to continue* link.


Summary of Amendment Changes

Step 1 So far you have filled out the Amendment form and indicated the following items will be changed:

Amendment Type

Changes to Study Team members

Step 2 Now you will make the actual changes - **Click here to continue**

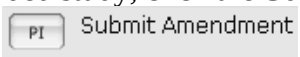
✓ You will now begin to make changes to the data contained in the IRB application for this research study.

5 Click *Continue*.

✓ On the following page(s) you will edit a copy of the current application.

6 Click *Continue* to return to the Amendment Workspace.

✓ The amendment has not been submitted at this point.

7 After making all changes to the amended study, click the *Submit Amendment* button on the left. ⇒ 

8 Click *OK*.

✓ If the amendment includes changes to the study team members, the newly added study team members will need to accept their role prior to submission.

✓ You can track the progress of the amendment in your Personal Workspace.

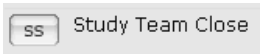
✓ Once the amendment is approved, it can be viewed on the *Amendments* tab.

Continuing Reviews

Objective Create a continuing review for an application

Continuing Reviews

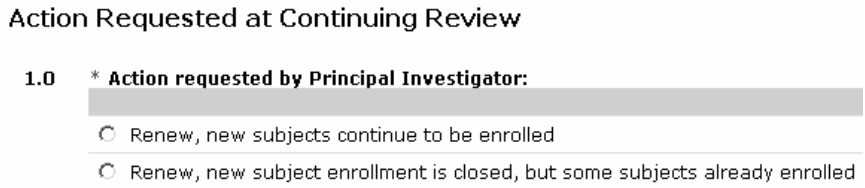
- Study team members will receive an email reminder that their application is due for a continuing review 60 and 30 days prior to the study expiration date.
- Continuing reviews can be submitted for approved active studies only.
  - A continuing review can not be created while an amendment is in progress.
- Scheduled continuing review applications should be submitted at least twenty-one days before the approval is to expire.
- Only IRB-requested changes can be made at the time of continuing review. Study team initiated changes must be filed before or after the continuing review via amendment.
- If you do not need an extension of IRB approval (funding has expired, data collection and analysis is complete, etc.), click on the *Study Team Close* button, found in the Study Workspace to close your study. ⇒



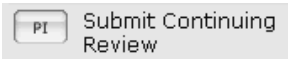
How do I create a continuing review?

1. Navigate to the Study Workspace of the approved active study.
2. Click the *New Continuing Review* button on the left to start a new continuing review submission. ⇒

3. Complete the required information on each page of the *Action Requested at Continuing Review* form.



4. Click *Finish* at the end of the continuing review.
5. Click *Submit Scheduled Continuing Review* button on the left. ⇒



6. Click *OK*.

✓ You can track the progress of the continuing review in your Personal Workspace.

✓ Once the continuing review is approved, it can be viewed on the *Continuing Review* tab.

Printing applications and Informed Consents

Objective Print an eIRB application or Informed Consent

How do I print an eIRB application?

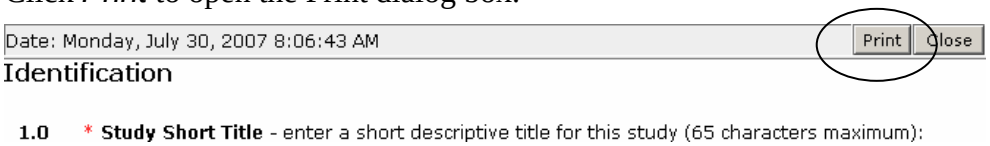
- Studies can be printed from the Study Workspace or from within the study application form.
- The print version of the study includes only the required application sections. Detailed information is printed at the end of the document.

1 Navigate to the Study Workspace.

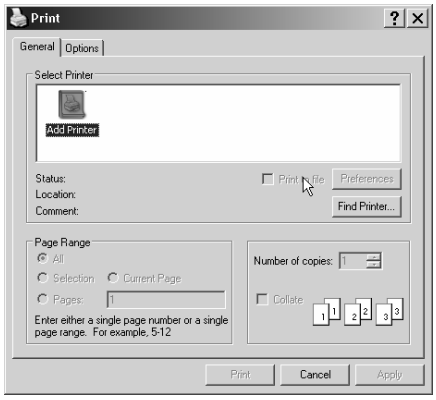
2 Click the *Print-Friendly Application* button. ⇒

✓ You can also open the study application and click the *Print* button at the top of the screen to print specific pages of the application.

3 Click *Print* to open the Print dialog box.



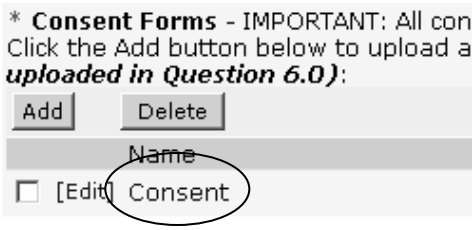
4 Select a printer and click *Print*.



How do I print an Informed Consent?

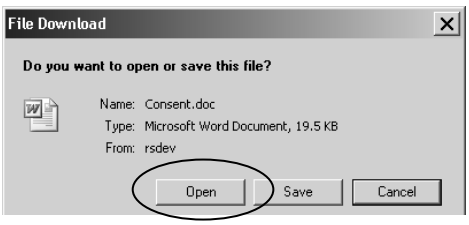
- Informed Consent documents need to be printed and distributed to Study subjects.

1 From the Study application, click the *Name* of the Consent form to open it. ⇒



✓ Informed Consent forms should be opened from within eIRB top ensure that the electronic watermark is included.

2 When asked to *Open* or *Save* the file, select *Open*. ⇒



3 Once the file is opened, select File•Print.

4 Select a printer and click *Print*.

Filing eIRB email

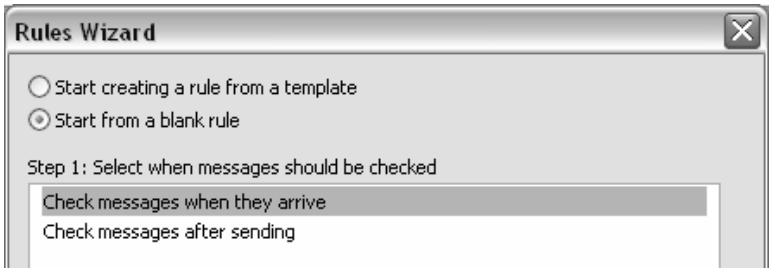
Objective File eIRB email using Outlook

File email notifications in Outlook

- You may choose to create a rule in Outlook to file all messages from eIRB.

1 In Outlook, select Tools•Rules and Alerts.

2 From the E-Mail Rules tab, select *New Rule…*



3 Select the radio button beside *Start from a blank rule*.

✓ Make sure *Check messages when they arrive* is selected.

4 Click *Next*.

5 In Step 1, select *from people or distribution list*.

6 In Step 2, click the *people or distribution list* link at the bottom of the screen.

7 Choose *eIRB – Institutional Review Board* from the pick list.

8 Click *Next*.

9 In Step 1, select *move it to the specified folder*.

10 In Step 2, click the *specified* link at the bottom of the screen.

11 Choose the folder where you want to file the messages.

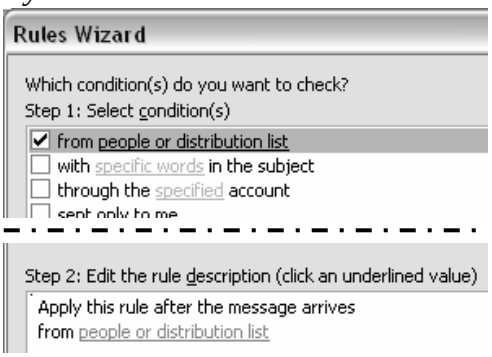
12 Click *Next*.

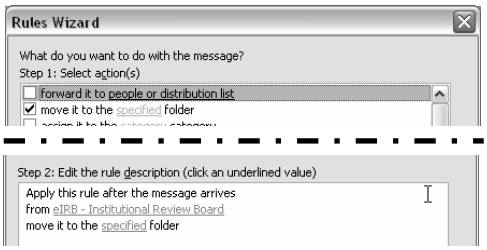
13 Click *Next*.

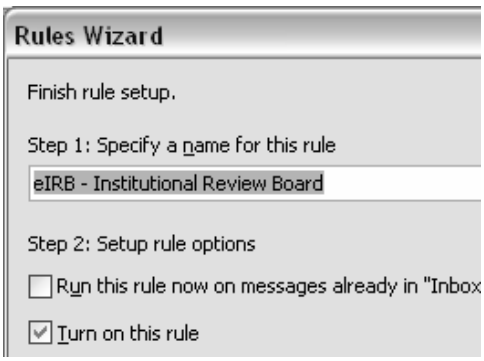
14 In Step 1, give the rule a meaningful name.

15 In Step 2, select the checkbox next to *Turn on this rule*.

16 Click *Finish*.







Forwarding eIRB email

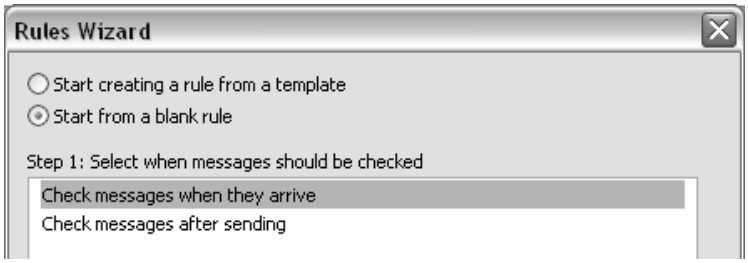
Objective Forward eIRB email using Outlook

Forwarding email notifications in Outlook

- You may choose to create a rule in Outlook to forward all messages from eIRB to someone else.

1 In Outlook, select Tools•Rules and Alerts.

2 From the E-Mail Rules tab, select *New Rule…*



3 Select the radio button beside *Start from a blank rule*.

✓ Make sure *Check messages when they arrive* is selected.

4 Click *Next*.

5 In Step 1, select *from people or distribution list*.

6 In Step 2, click the *people or distribution list* link at the bottom of the screen.

7 Choose *eIRB – Institutional Review Board* from the pick list.

8 Click Next.

9 In Step 1, select *forward it to people or distribution list*.

10 In Step 2, click the *people or distribution list* link at the bottom of the screen.

11 Choose the recipient of the forwarded messages from the pick list.

12 Click *Next*.

13 Click *Next*.

14 In Step 1, give the rule a meaningful name.

15 In Step 2, select the checkbox next to *Turn on this rule*.

16 Click *Finish*.

Terminology

Objective Become familiar with eIRB vocabulary

Terms defined

- **Activity** – An action that a person can perform on a project.
  - Submit Application is the first activity that is performed on an Application.
  - Activities create an entry in the history log and often cause a change in state.
  - Activities also send email notifications.
- **Back button** – eIRB submission Smart Forms have a *Back* button that allows you to navigate backwards in the application.
  - This is not the same as the *Back* button on your browser.
  - Clicking *Back* saves the current page and moves to the previous logical application Smart Form.
  - You should not use the *Back* button in your browser when you are completing the application since data loss may occur.
- **Exit** – The *Exit* link exits the submission, not eIRB.
  - Clicking the *Exit* link opens an alert window warning that any unsaved data will be lost when you exit.
  - Always click *Save* before you click *Exit* to make sure you don't lose data.
- **Finalize Documents** – This activity embeds information in the Informed Consent documents and places them in the Approved Documents area of the *Documents* tab in the Study Workspace.
  - The Finalize Documents activity is performed by the IRB Administrator.
- **History Log** – A list of events, most recent on top, which charts the movement of the project through the review process.
  - The history log will only display the events that the current user is allowed to see.
- **Inbox** – Your Inbox is the default tab displayed whenever you log into eIRB.
  - Studies that appear in your Inbox require action, which differs based on your role.
- **Jump-to** – The *Jump-to* button allows you to jump directly to any Smart Form section in a submission.
- **My Role** – This section of your Personal Workspace allows you to see all of the roles you have in eIRB.
  - It is important to select the correct role as you have different activities available based on your role.

Terminology – cont.

- **Notification** – eIRB notifies you of certain events by sending email messages to your normal email mailbox.
  - When you receive notification depends on your role in eIRB.
  - Notifications contain a link that, after you log in, takes you directly to the submission requiring action.
- **Personal Workspace / My Home** – A personal area with a layout customized based on user role.
  - Study Staff Personal Workspaces are designed to initiate and monitor projects while IRB Staff Personal Workspaces are designed to process projects in the review process.
- **Pre Submission** – This state is the default state of any newly created study and means that the study staff has not submitted the application, amendment, or adverse events report for review.
  - The study is editable by the study staff.
- **Smart Form** – Smart Forms are pages in eIRB that contain logic which route you through the application.
  - Smart Forms allow you to complete only the section of the application that is required.
  - Smart Forms rely on the *Continue* and *Back* button to use the logic embedded in them.
- **State** – The current status of a study.
  - When a study team creates a new Application, it is in the state "Pre Submission".
  - State changes are caused by activities.
  - When a new application is submitted by the PI, the application's state changes from "Pre Submission" to "IRB Administrator Review".
- **Study Workspace** – A homepage for the study that allows people to interact with it and monitor its progress through the review process.
  - The Study Workspace is the base of operations for all study specific actions.
- **User Role** – A designated role in the system that determines the level and type of access a person has in the system.
  - A person may have multiple user roles such as Board Member and PI.
  - In this case the user will have two Personal Workspaces customized to allow the person to perform the actions of each role.