

Midwest Health System Institutional Review Board

**IRB Manager©  
Instruction Manual**

## Contents

Definitions.....	2
Logging into IRB Manager	
New User.....	3
Returning User.....	3
Basic Navigation of IRB Manager	
Home Page.....	4
Protocol Page.....	6
Creating an Application.....	7
Attaching Documents.....	11
Creating an Application for an existing study.....	12
Continuing Review Submissions.....	13
Amendments/Addendums to IC or Protocol.....	14
Final Review Submissions.....	15
Protocol Deviation Submissions.....	17
Serious Adverse Events/Unanticipated Problems.....	17
New SAE's or UP's.....	17
Follow-up or Final SAE's or UP's.....	18
Safety Report Submissions.....	19
Investigator Brochure Update Submissions.....	20
Expedited Reviews.....	21
IRB Study Exemptions.....	22
Frequently Asked Questions.....	23
Appendix Application Forms (A-J)	
A. New Study Application	
B. Continuing Review Application	
C. Amendment/Addendum Application	
D. Final Review Application	
E. Protocol Deviation Application	
F. SAE/UP Application	
G. Safety Report Application	
H. Investigators Brochure Application	
I. Expedited Review Application	
J. IRB Exemption Application	

## Definitions

**Adverse Event/Serious Adverse Event:** An undesirable and unintended, although not necessarily unexpected, result arising during the course of a research protocol.

**Assent:** Agreement by an individual not competent to give legally valid Informed consent to participate in research (e.g., a child).

**Consent:** Agreement to do something. Informed consent is agreement to do something based upon a complete understanding of that task.

**Exemption:** Research falling under one of six federally defined exemptions is not required to undergo IRB review and the investigator is not required to abide by the requirements for obtaining informed consent. [45 CFR 46.101(b)] \*\*Only the MHS IRB can make the determination that a protocol is exempt.\*\*

**Expedited:** Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire convened IRB. There are nine federally defined categories that qualify for expedited review.

**Minimal Risk:** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102(i)].

**Humanitarian Device Exemption:** As defined in 21 CFR 814.3(n), a HDE is a “medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.”

**Investigative Device Exemption:** IDE refers to the regulations under 21 CFR 812. An approved IDE means that the IRB (and FDA for significant risk devices) has approved the sponsor’s study application and all the requirements under 21 CFR 812 are met.

**Investigational New Drug:** The Food and Drug Administration's Investigational New Drug (IND) program is the means by which a pharmaceutical company obtains permission to ship an experimental drug across state lines (usually to clinical investigators) before a marketing application for the drug has been approved. The FDA reviews the IND application for safety to assure that research subjects will not be subjected to unreasonable risk. If the application is approved, the candidate drug usually enters a Phase 1 clinical trial.

**Privacy:** Concealment from others of information about oneself.

**Risk:** The probability of harm or injury occurring as a result of participation in a research study.

Logging into IRB Manager for New and Returning Users:

- In your internet address space enter the following: <http://www.irb.hcamidwest.com>
- Select the Submission located on the right side of the screen
- Under New Study Submission Select the IRB Manager hyperlink <http://irbmanager.becirb.com/>

Returning Users:

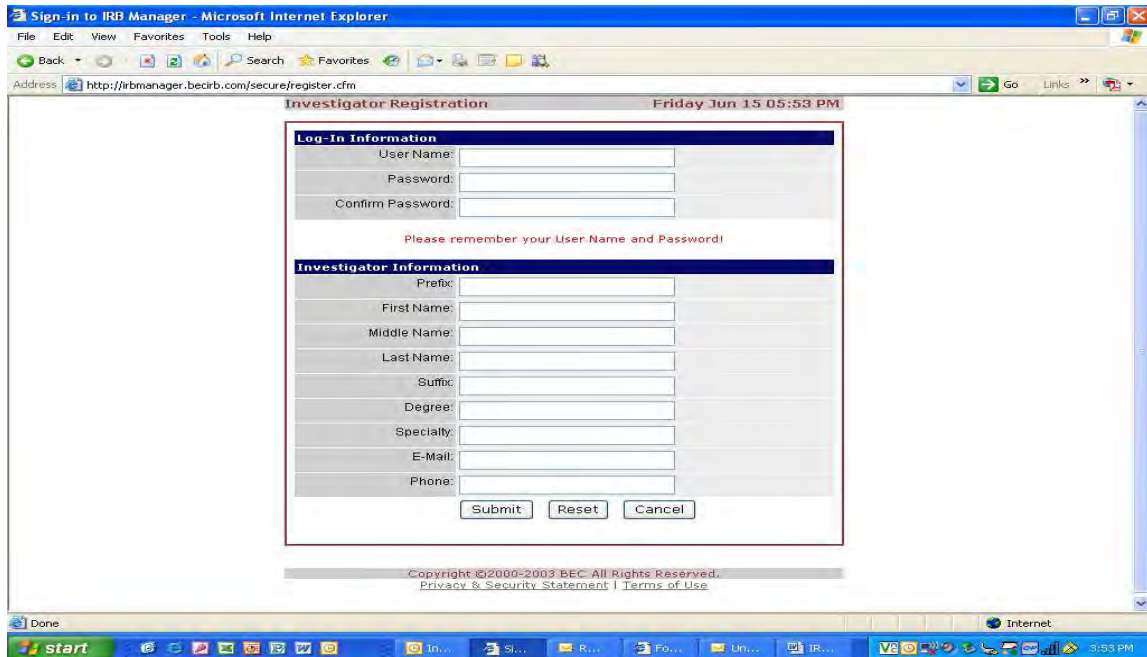
- Enter your user name and password.
- The client should always be MHS (Midwest Health System)
- Select <Login> to continue
- Forgot Your Password?
  - Contact the IRB office at 816-246-3921.
  - Although the office cannot look up your password, a temporary password can be assigned to you.
  - You will be able to change the password after it has been granted to you.

New Users:

**If you have not had a protocol previously reviewed by the Midwest Health System IRB please contact the IRB office at 816-246-3921 to obtain a user name and password to access the system (although you haven't accessed the system before you are probably already built as a user and need only to have a password assigned). This includes all studies that were transferred from Patient Advocacy Council (PAC) IRB to the Midwest Health System IRB.**

Once you have received your user ID and password:

- Enter the user name and password.
- The client should always be MHS (Midwest Health System)
- Select <Login> to continue
- Once you have logged in select <my settings> at the top of the page and change your password.



## Basic Navigation

Once your User name and password have been created, you will now be logged into the system. As you enter studies into IRB Manager and are entered into studies as the investigator, co-investigator, or coordinator these studies will appear on your home screen.

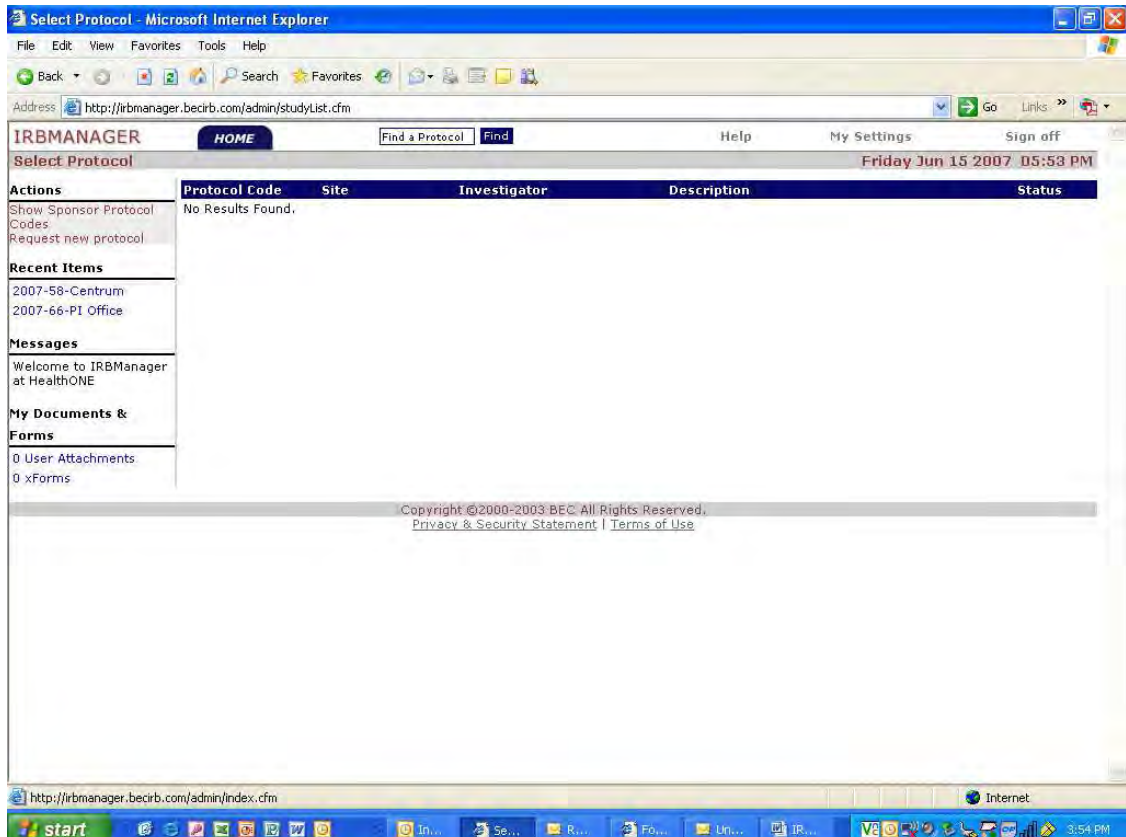
### Home Screen Navigation:

On the left side of the page:

- Actions – this heading allows you to perform specific actions to change the current page that is displayed.
- Recent items – the hyperlinks under this heading shows what the most recent protocol that the user has reviewed. The hyperlinks can be utilized to return to another protocol previously viewed.
- Messages – this heading is an area that the IRB Office may communicate to all of the users within the system. An example message would be, “All submissions are due to the IRB office by the first of every month prior to the IRB meeting.”
- My Documents & Forms – this heading shows how many attachments and xforms the user has submitted.

Tabs at the top of the page:

- Home tab – this tab will always bring you back to your sign on page.
- Find Protocol – this area allows the user to enter the IRB assigned protocol number for easy access.



**IRB Manager Tips:**

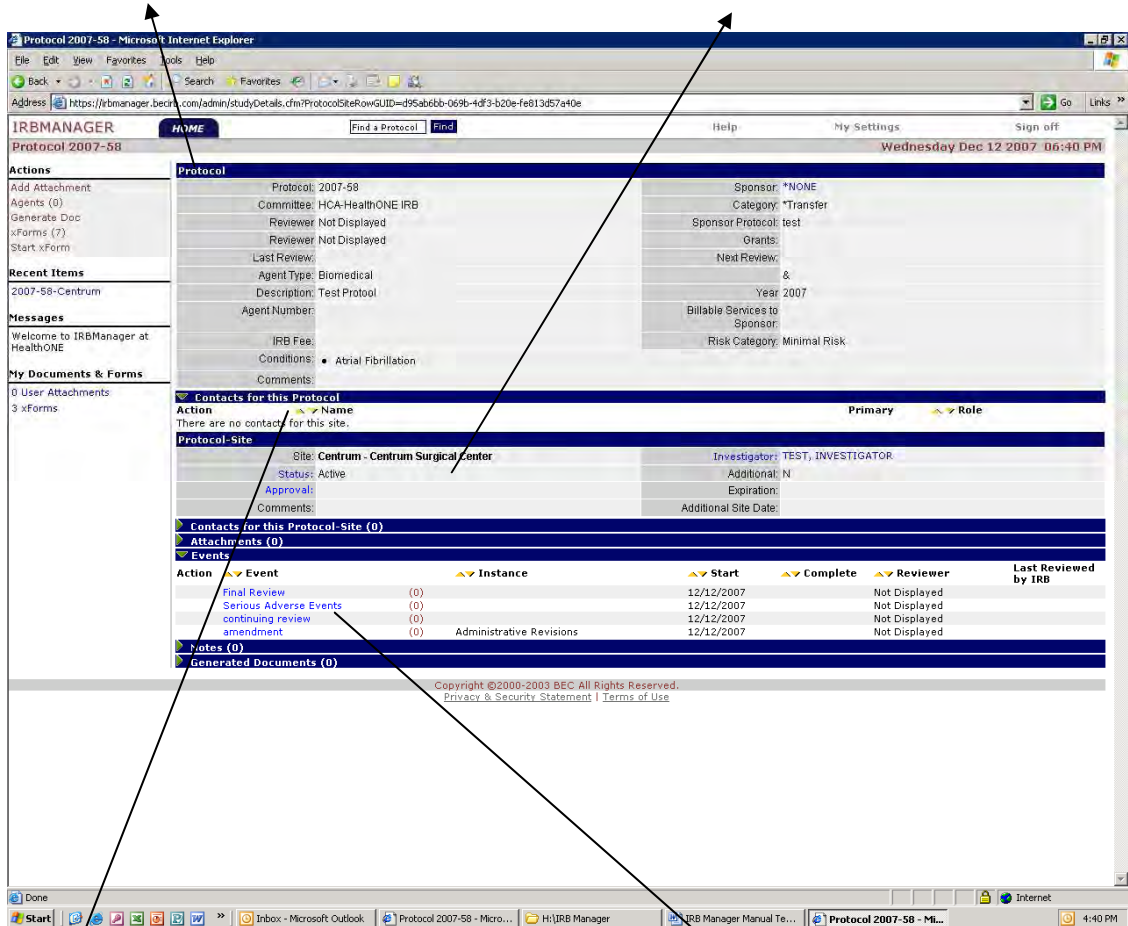
Please review the following tips related to entering information into IRB Manager:

- Double check information on the screen before selecting <Next>. There currently are **NO EDITING OPTIONS**.
- Do NOT use the browser <back> button, your information may be lost if you select to go back to edit.

**Study Protocol Navigation:** On the protocol page there are several study items that can be viewed.

Protocol Information  
(IRB study number, protocol title, sponsor, agents, risk category, etc.)

Protocol sites, Investigators, status (approved, closed to new enrollment, new study submission, etc.



Contacts for this study site (coordinators and sub/co-investigators)

Events, number of attachments, event instance, event start date, last reviewed by IRB, etc.

## Creating an Application for a New Study

The next steps will explain how to submit a new study into IRB Manager for IRB review. Please note that once you start an application, **complete all the sections before you exit**. The information is automatically saved and submitted to the HCA Midwest Health System IRB Office for review.

- Select **Request New Protocol** to begin entering. This is under Actions in the upper left corner.
- The IRB protocol number will automatically be assigned by IRB Manager for all new submissions.
- Select <Next>.

If you wish to join an existing protocol as a new investigator please enter our protocol number below. To start a new protocol just click 'Next'.

Protocol

IRB Manager will begin the new protocol request:

Copyright ©2000-2003 BEC. All Rights Reserved.  
[Privacy & Security Statement](#) | [Terms of Use](#)

**Category** - is a dropdown list for the area of specialty in which you will be conducting this research. Select the specialty area from the drop down list highlighting the category with the computer mouse.



**Sponsor** – If your study has a sponsor please select your sponsor from the dropdown list. If it is not there, please select “Other.”

**Agent Type** - is the type of procedure you will use.

**Sponsor Protocol** - is for the sponsor assigned protocol number that you can enter.

**Agent Number** - Please list the IND/IDE/HDE that is being utilized in this study. Include the FDA number and description of the IND/IDE/HDE in this field.

**Billable Services to Sponsor** – Please indicate in this field what if any services or items will be billed to the sponsor or PI of the study. Please be as specific as possible so that the IRB can assist the facility in operationalizing the study.

**IRB Fee** – this field is for the IRB office use only.

**Risk/Level** - a dropdown list, please select if you think your research is Minimal Risk , Greater than Minimal Risk, Non-Significant Risk (devices only), or Significant Risk (devices only).

**Title** – Please enter the protocol title as it appears in the grant or sponsor documentation.

**Comments Section** - This section must be populated with your purpose statement. This is important for the Midwest Health System IRB review process. Failing to enter your purpose may add more time to the review process.

Select **<Next>** to continue (be sure to double check the information before selecting this button).

The screenshot shows a web browser window titled "New Protocol Request - Microsoft Internet Explorer". The address bar shows the URL: <http://irbmanager.becib.com/admin/PINewProtocol3.cfm?CFID=7620198&CFTOKEN=47465771>. The page header includes "IRBMANAGER" and navigation links like "HOME", "Find a Protocol", "Find", "Help", "My Settings", and "Sign off". The main content area is titled "New Protocol Request" and shows a form with the following fields:

- Protocol: 2007-68
- Sponsor: Boston Scientific Corp.
- Site: Centennial Medical Plaza
- Investigator PI, Test: [Empty]
- Comments: Enter additional study sites where this study may be conducted at

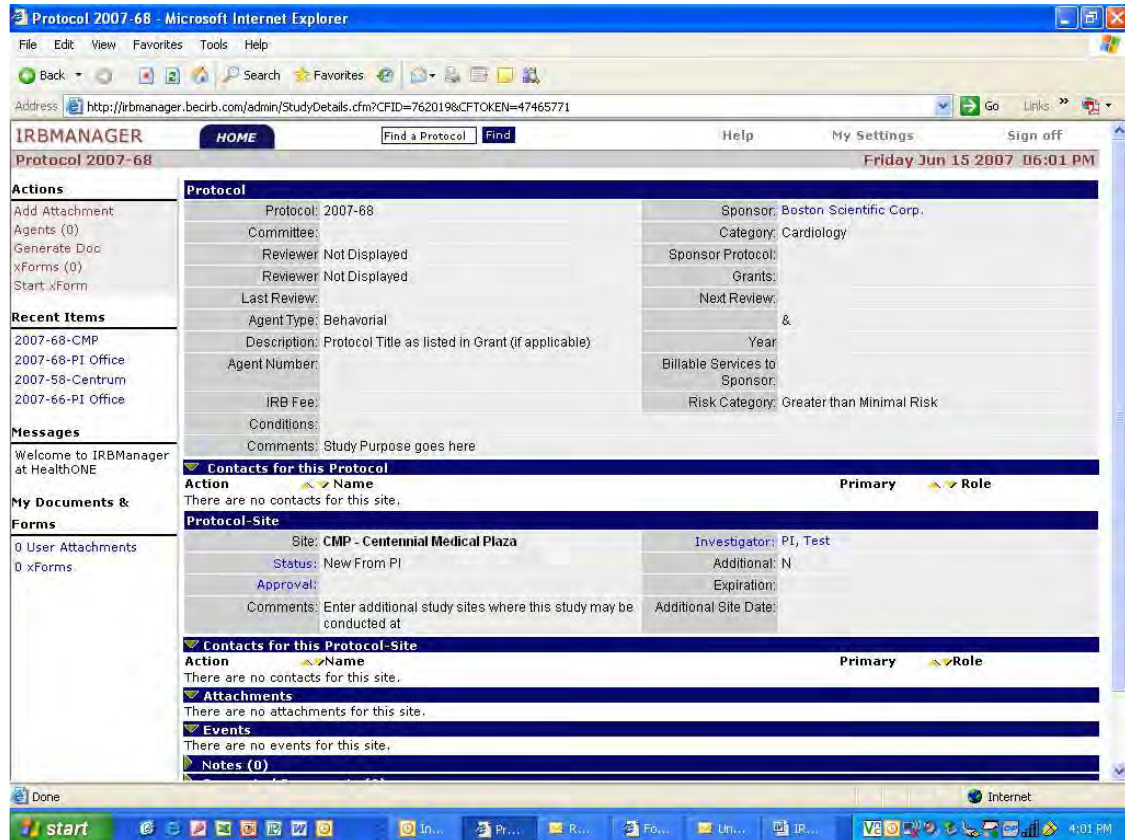
A callout box with an arrow points to the "Protocol" field, containing the text "Number assigned by the system". At the bottom of the form, there is a "Next ---->" button. The footer of the page contains the text: "Copyright ©2000-2003 BEC All Rights Reserved. Privacy & Security Statement | Terms of Use".

**Site** – select the primary site where the study will be conducted.

**Comments** - Utilize this section to list any additional sites that you may be using (HCA Midwest Division Facilities, physicians' offices, etc.).

Before selecting <Next>, double check all the information provided. You will not be able to edit this information once you enter this button.

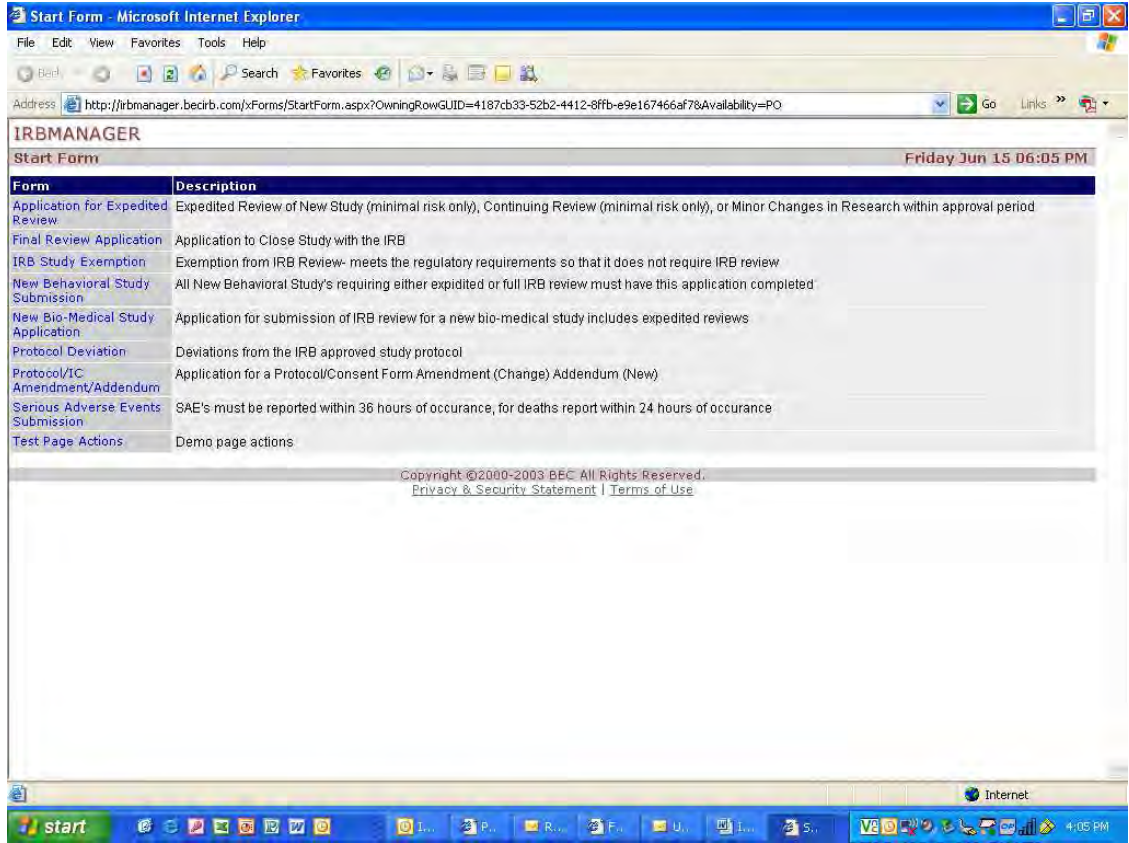
The below screen will now be the main protocol page that you have created with your entered study information.



In order to complete the new study application process the following steps must be completed:

1. To submit the new study submission form select <START xForm> on the left side of the page under the Actions header.
2. Select either the New Biomedical or Behavioral Study hyperlink (Appendix A).
3. Complete each question as directed in the form.
4. If you wish to stop the process in the middle of the form select the button that states save for later. To re-access the form simply go into the protocol and select <xforms> under the actions header on the left side of the page. The system will identify how many xforms are either submitted or in progress with the number of documents in the parenthesis after the xforms link. Select the hyperlink to the form that is already in progress.
5. When the form is at the end enter your IRB Manager password to sign the form.
6. You will now be prompted to either save the form for later or submit the form. If you choose to submit the form, it will be locked for IRB office review.

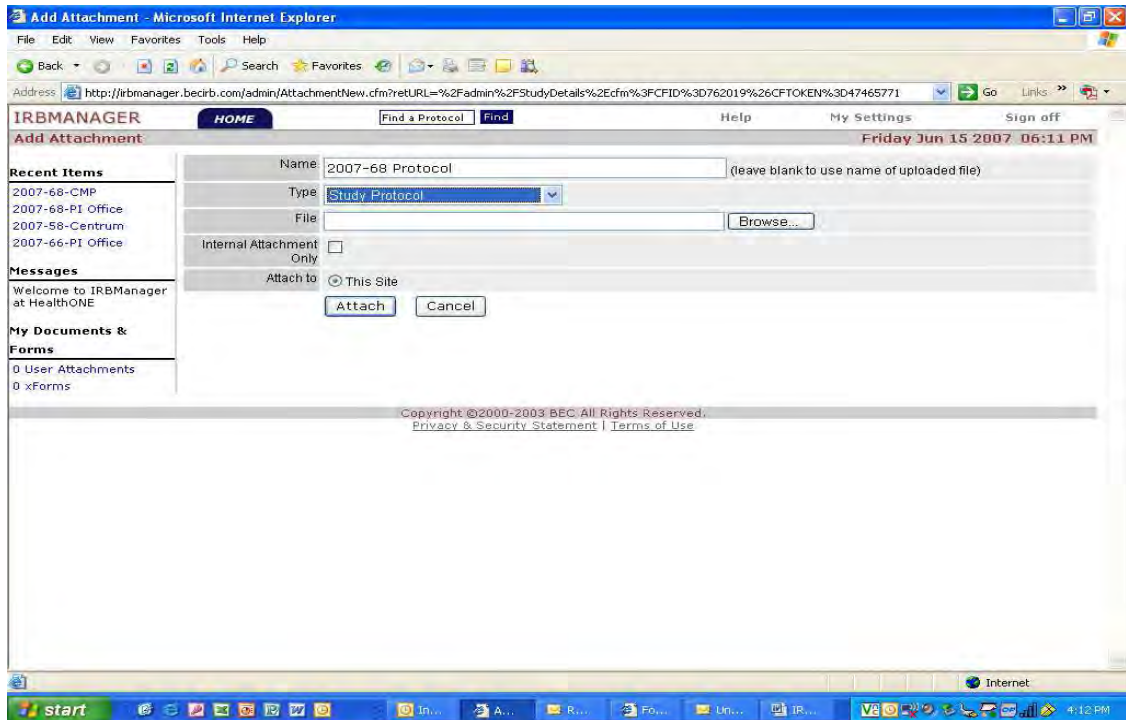
**\*\*Before you submit the form, be sure to validate accuracy\*\***



## Attaching Documents

Protocols, IC's, recruitment material, investigators agreements, etc, can all be attached to the protocol by selecting the **<Add Attachment>** under actions in the upper left hand corner of the screen, within the protocol event.

- Complete the **<name>** of the attachment by first entering the IRB assigned study number and the type of document that you are attaching. For example, if you were attaching the study protocol for the study below it would be named *2007-68 study protocol*.
- Select the **<type of document>** that you are attaching from the drop down box provided.
- Select the **<Browse>** button to locate the file on your computer you intend to attach.
- You will want it attached to this site, so keep this option selected.
- Select **<Attach>** to finish the process.



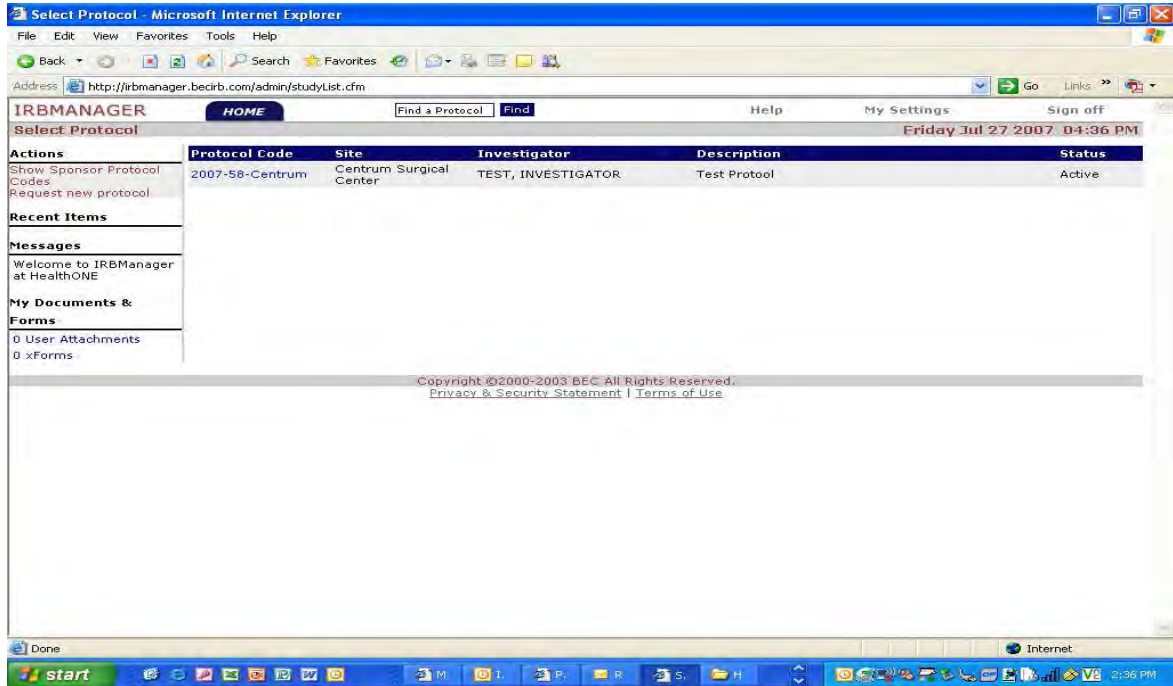
Tip

Many forms of documents can be attached such as Word (doc), Excel (xls), Adobe (pdf), Rich Text (rtf), etc. If you don't have an electronic version to attach, fax the document to the IRB office at 816-969-6267. The IRB office can then electronically attach it to the protocol event.

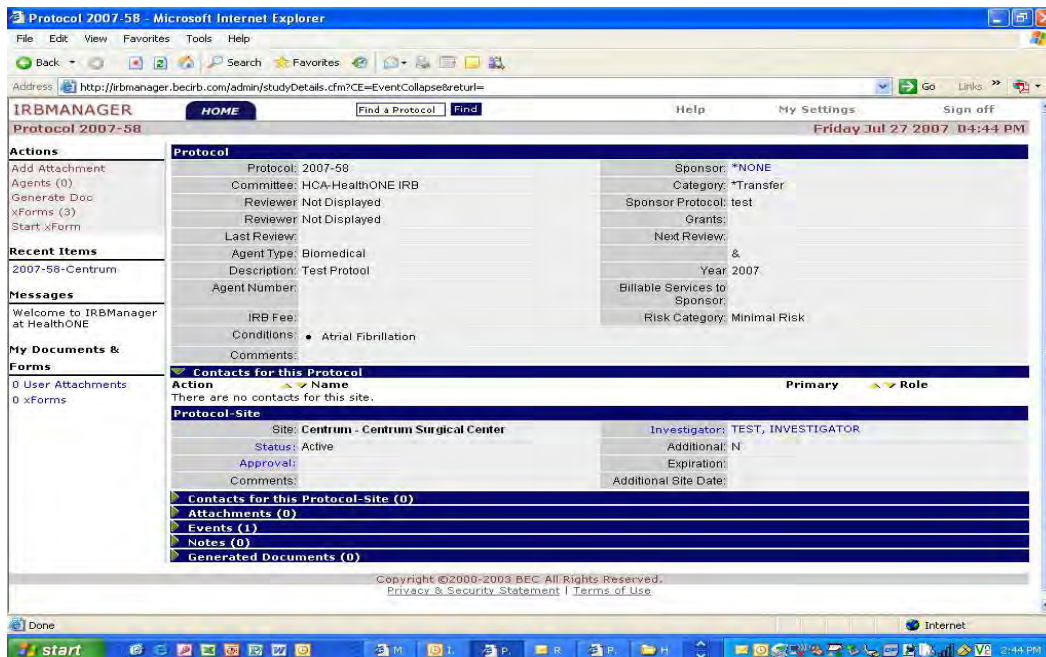


## Creating an Application for an Existing Study

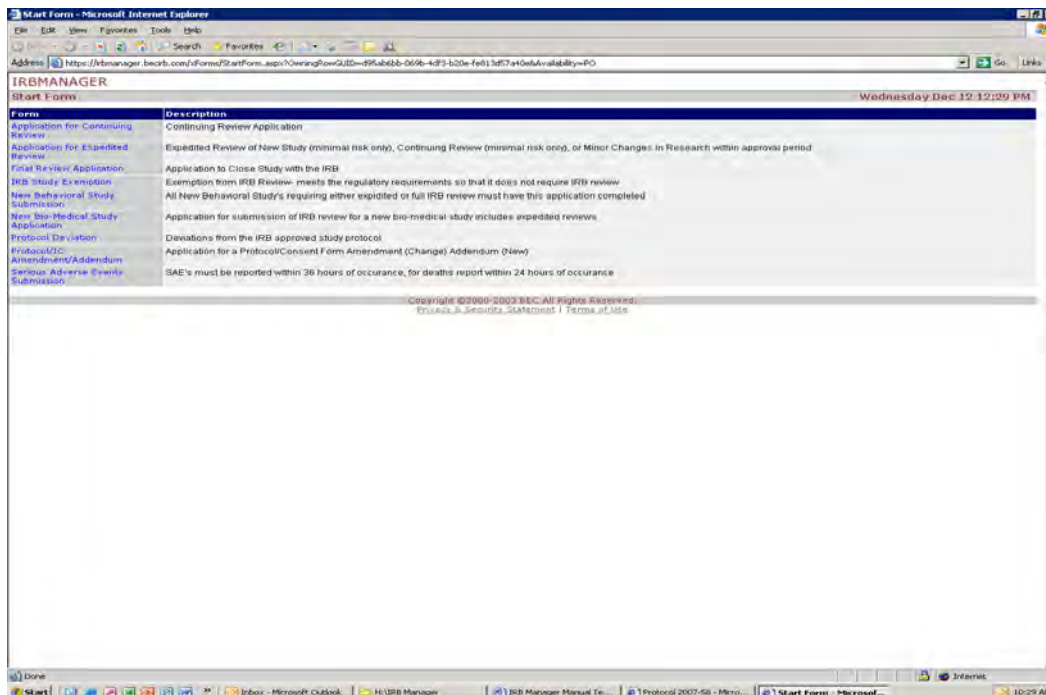
- 1) Access the study by either selecting the study from the home page or entering the IRB study number in the find protocol field.



- 2) Once the protocol is displayed select the **<Start xforms>** hyperlink from the left hand side of the page to begin the study application process.



- a) Select the type of application that you would like to submit for your study:



Available forms are:

b) **Continuing Review** (Appendix B)

- i) Select **<start xform>**. The IRB study number, study title, and Investigator information will be automatically “loaded” into your continuing review form.
- ii) Please answer all requested questions. If you fail to answer a mandatory field, a message error will appear. The system will not allow you to continue until the field has been populated.
- iii) You will be prompted to attach the study Informed Consent IC (clean), study protocol (clean), and any other document you determine is required.

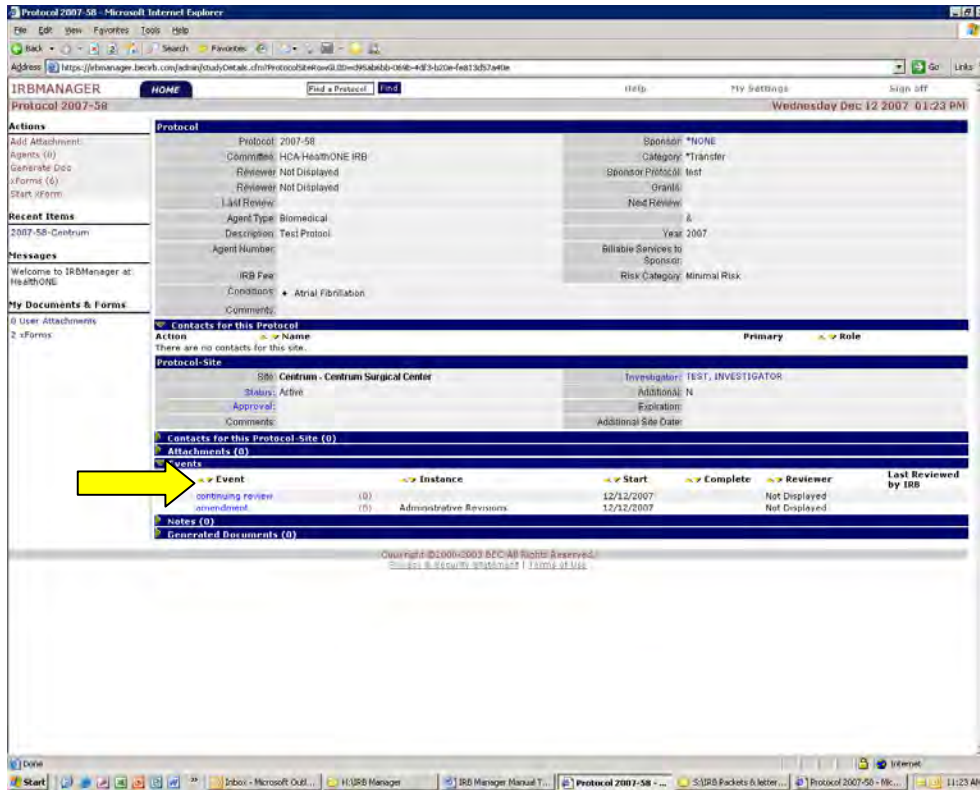
Select the **<attachment>** button:

- (1) Select the **<Browse>** button to locate the file on your computer you intend to attach.
  - (2) Select **<Attach>** to finish the process.
- iv) When the form has been completed you will then be instructed to enter your IRB Manager password.
  - v) You will now be prompted to either save the form for later or submit the form. If you choose to submit the form, it will be locked for IRB office review.

**\*\*Before you submit the form, be sure to validate accuracy\*\***

- vi) Once the form has been completed IRB Manager will automatically assign a study event for the continuing review. Open the event by selecting the hyperlink **<continuing review>** next to the event.

The event will now be displayed.



c) **IC and/or protocol amendments/addendums (Appendix C)**

- i) Select **<start xform>**. The IRB study number, study title, and Investigator information will be automatically “loaded” into your continuing review form.
- ii) Please answer all requested questions. If you fail to answer a mandatory field, a message error will appear. The system will not allow you to continue until the field has been populated.
- iii) You will be prompted to attach the study IC (clean and tracked), study protocol (clean and tracked), and any other document you determine are necessary.

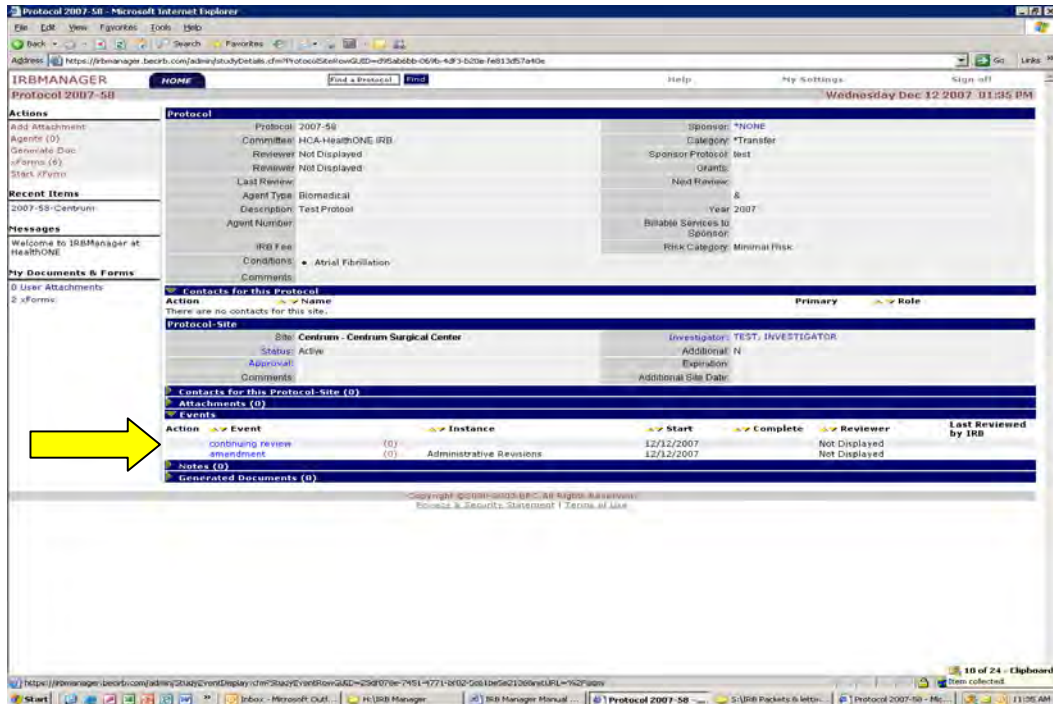
Select the **<attachment>** button:

- (1) Select the **<Browse>** button to locate the file on your computer you intend to attach.
- (2) Select **<Attach>** to finish the process.
- iv) When the form has been completed you will be instructed to enter your IRB Manager password.
- v) You will now be prompted to either save the form for later or submit the form. If you choose to submit the form, it will be locked for IRB office review.

**\*\*Before you submit the form, be sure to validate accuracy\*\***

- vi) Once the form has been completed IRB Manager will automatically assign a study event for the amendment review. Open the event by selecting the hyperlink **<amendment>** next to the event.

The event will now be displayed.



d) **Final Review (Appendix D)**

- i) Select **<start xform>**. The IRB study number, study title, and Investigator information will be automatically “loaded” into your continuing review form.
- ii) Please answer all requested questions. If you fail to answer a mandatory field, a message error will appear. The system will not allow you to continue until the field has been populated.
- iii) When the form has been completed you will be instructed to enter your IRB Manager password.
- iv) You will now be prompted to either save the form for later or submit the form. If you choose to submit the form, it will be locked for IRB office review.

**\*\*Before you submit the form, be sure to validate accuracy\*\***

- v) Once the form has been completed IRB Manager will automatically assign a study event for the final review.



Protocol 2007-58 - Microsoft Internet Explorer

Address: https://irbmanager.becrb.com/admin/studyDetails.cfm?ProtocolSiteRowGUID={95abcb6b-069b-4d93-b20e-f6813d57e40e}

IRBMANAGER Protocol 2007-58

Wednesday Dec 12 2007 06:40 PM

**Actions**

- Add Attachment
- Agents (0)
- Generate Doc
- xForms (7)
- Start xForm

**Recent Items**

2007-58-Centrum

**Messages**

Welcome to IRBManager at HealthONE

**My Documents & Forms**

- 0 User Attachments
- 3 xForms

**Protocol**

Protocol: 2007-58  
 Committee: HCA-HealthONE IRB  
 Reviewer: Not Displayed  
 Reviewer: Not Displayed  
 Last Review:  
 Agent Type: Biomedical  
 Description: Test Protocol  
 Agent Number:  
 IRB Fee:  
 Conditions: Atrial Fibrillation  
 Comments:

Sponsor: \*NONE  
 Category: \*Transfer  
 Sponsor Protocol: test  
 Grants:  
 Next Review:  
 &  
 Year 2007  
 Billable Services to Sponsor:  
 Risk Category: Minimal Risk

**Contacts for this Protocol**

Action Name Primary Role

There are no contacts for this site.

**Protocol-Site**

Site: Centrum - Centrum Surgical Center  
 Status: Active  
 Approval:  
 Comments:  
 Investigator: TEST, INVESTIGATOR  
 Additional: N  
 Expiration:  
 Additional Site Date:

**Contacts for this Protocol-Site (0)**

**Attachments (0)**

**Events**

Action	Event	Instance	Start	Complete	Reviewer	Last Reviewed by IRB
Final Review	(0)		12/12/2007		Not Displayed	
Serious Adverse Events	(0)		12/12/2007		Not Displayed	
continuing review amendment	(0)	Administrative Revisions	12/12/2007		Not Displayed	
	(0)		12/12/2007		Not Displayed	

**Notes (0)**

**Generated Documents (0)**

Copyright ©2000-2003 BEC All Rights Reserved.  
 Privacy & Security Statement | Terms of Use

Done

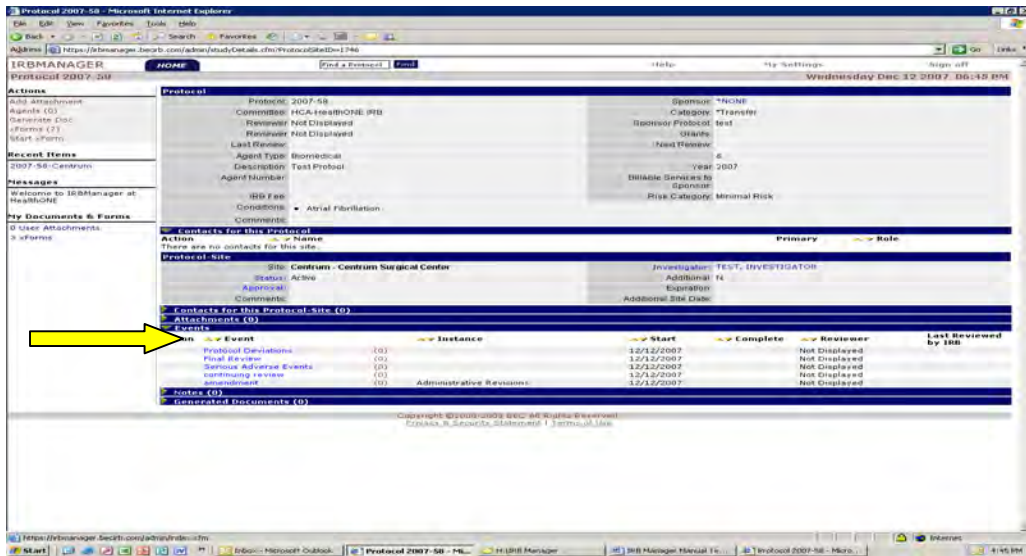
Start | Inbox - Microsoft Outlook | Protocol 2007-58 - Micro... | H:\IRB Manager | IRB Manager Manual Te... | Protocol 2007-58 - ML... | 1:40 PM

e) **Protocol Deviation (Appendix E)**

- i) Select <start xform>. The IRB study number, study title, and Investigator information will be automatically “loaded” into your continuing review form.
- ii) Please answer all requested questions. If you fail to answer a mandatory field, a message error will appear. The system will not allow you to continue until the field has been populated.
- iii) When the form has been completed you will be instructed to enter your IRB Manager password.
- iv) You will now be prompted to either save the form for later or submit the form. If you choose to submit the form, it will be locked for IRB office review.

**\*\*Before you submit the form, be sure to validate accuracy\*\***

- v) Once the form has been completed IRB Manager will automatically assign a study event for the final review.



f) **Serious Adverse Events (Appendix F)**

**\*\*Use this process if this is an initial SAE\*\***

- i) Select <start xform>. The IRB study number, study title, and Investigator information will be automatically “loaded” into your continuing review form.
- ii) Please answer all requested questions. If you fail to answer a mandatory field, a message error will appear. The system will not allow you to continue until the field has been populated.
- iii) You will be asked to indicate as to whether this is the initial, follow-up, or final review of this SAE.
- iv) When the form has been completed you will be instructed to enter your IRB Manager password.
- v) You will now be prompted to either save the form for later or submit the form. If you choose to submit the form, it will be locked for IRB office review.

**\*\*Before you submit the form, be sure to validate accuracy\*\***

- vi) Once the form has been completed IRB Manager will automatically assign a study event for the final review. The IRB staff will complete the event instance for the SAE.

The screenshot displays the IRB Manager interface for Protocol 2007-58. The main content area is divided into several sections:

- Protocol Information:** Protocol: 2007-58, Committee: HCA-HealthONE IRB, Reviewer: Not Displayed, Last Review: Not Displayed, Agent Type: Biomedical, Description: Test Protocol, Agent Number: Not Displayed, IRB Fee: Not Displayed, Conditions: Atrial Fibrillation, Comments: Not Displayed.
- Protocol-Site Information:** Site: Centrum - Centrum Surgical Center, Status: Active, Approval: Not Displayed, Comments: Not Displayed, Investigator: TEST, INVESTIGATOR, Additional: N, Expiration: Not Displayed, Additional Site Date: Not Displayed.
- Events Table:**

Action	Event	Instance	Start	Complete	Reviewer	Last Reviewed by IRB
Final Review	Final Review	(0)	12/12/2007		Not Displayed	
Serious Adverse Events continuing review amendment	Serious Adverse Events continuing review amendment	(0)	12/12/2007		Not Displayed	
Administrative Revisions	Administrative Revisions	(0)	12/12/2007		Not Displayed	

A yellow arrow points to the 'Final Review' event in the table. The interface also includes a sidebar with navigation options like 'Add Attachment', 'Agents (0)', 'Generate Doc', 'Start xForm', and 'Messages'.

**\*\*Use the following steps if this is a follow-up or final SAE\*\***

- vii) Open the applicable SAE event that was previously created (you can identify the SAE by the date of the initial SAE and the subjects initials/DOB) by selecting the hyperlink **<serious adverse event>** next to the event.
- viii) Access **<Start x-form>** under the actions on the left side of the screen.
- ix) Select the SAE follow-up/Final form.
- x) The IRB study number, study title, and Investigator information will be automatically "loaded" into your continuing review form.
- xi) Please answer all requested questions. If you fail to answer a mandatory field, a message error will appear. The system will not allow you to continue until the field has been populated.
- xii) You will be asked to indicate as to whether this is the follow-up or final review of this SAE.
- xiii) When the form has been completed you will be instructed to enter your IRB Manager password.
- xiv) You will now be prompted to either save the form for later or submit the form. If you choose to submit the form, it will be locked for IRB office review.

**\*\*Before you submit the form, be sure to validate accuracy\*\***

g) **Safety/DSMB Reports (Appendix G)**

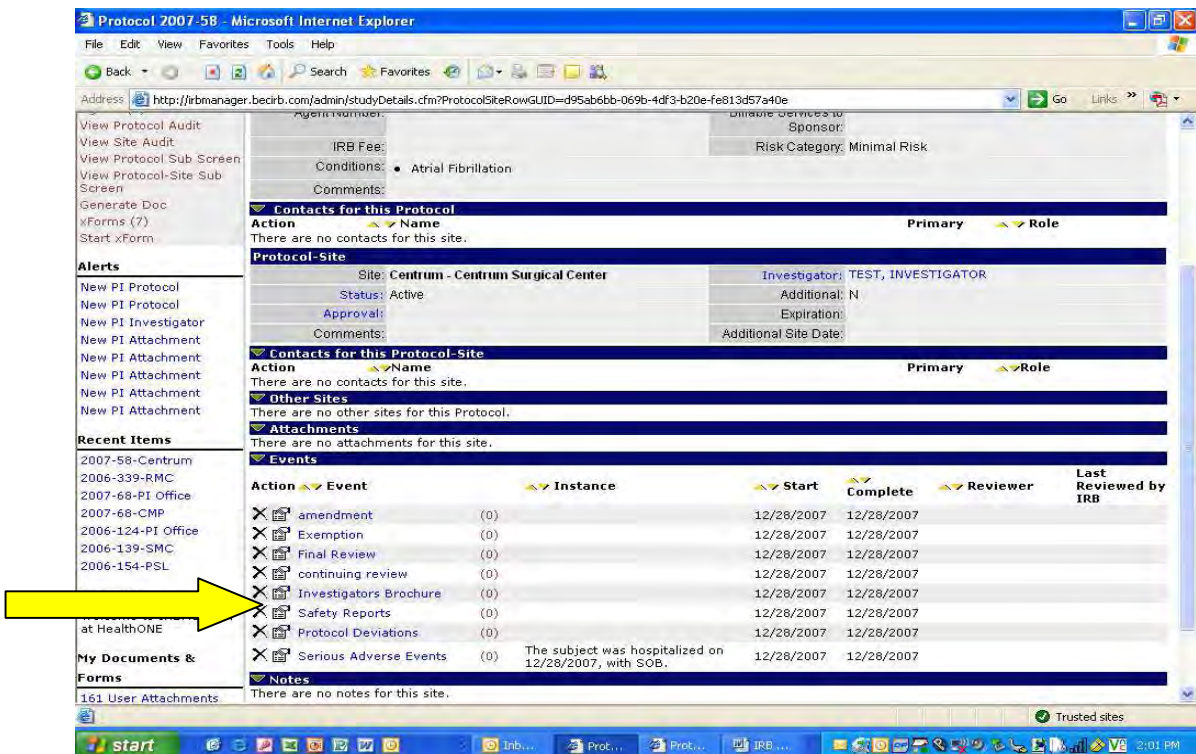
- i) Select **<start xform>**. The IRB study number, study title, and Investigator information will be automatically “loaded” into your continuing review form.
- ii) Please answer all requested questions. If you fail to answer a mandatory field, a message error will appear. The system will not allow you to continue until the field has been populated.
- iii) You will be prompted to attach the safety report.

Select the **<attachment>** button:

- (1) Select the **<Browse>** button to locate the file on your computer you intend to attach.
- (2) Select **<Attach>** to finish the process.
- iv) When the form has been completed you will be instructed to enter your IRB Manager password.
- v) You will now be prompted to either save the form for later or submit the form. If you choose to submit the form, it will be locked for IRB office review.

**\*\*Before you submit the form, be sure to validate accuracy\*\***

- vi) Once the form has been completed IRB Manager will automatically assign a study event for the Safety/DSMB Report submission. Attach the safety report to the event as per previous instruction on page 11 of 24.





h) **Investigator Brochure Revisions (Appendix H)**

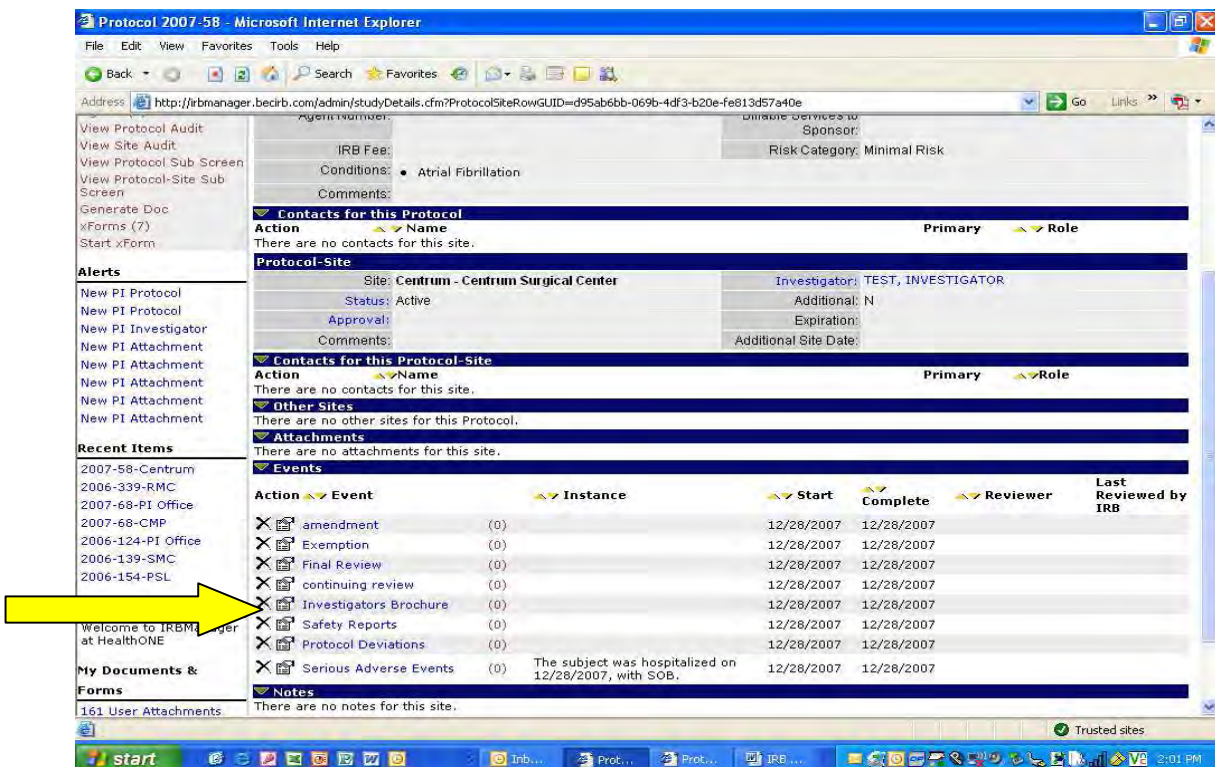
- i) Select **<start xform>**. The IRB study number, study title, and Investigator information will be automatically “loaded” into your continuing review form.
- ii) Please answer all requested questions. If you fail to answer a mandatory field, a message error will appear. The system will not allow you to continue until the field has been populated.
- iii) You will be prompted to attach the investigators brochure.

Select the **<attachment>** button:

- (1) Select the **<Browse>** button to locate the file on your computer you intend to attach.
- (2) Select **<Attach>** to finish the process.
- iv) When the form has been completed you will be instructed to enter your IRB Manager password.
- v) You will now be prompted to either save the form for later or submit the form. If you choose to submit the form, it will be locked for IRB office review.

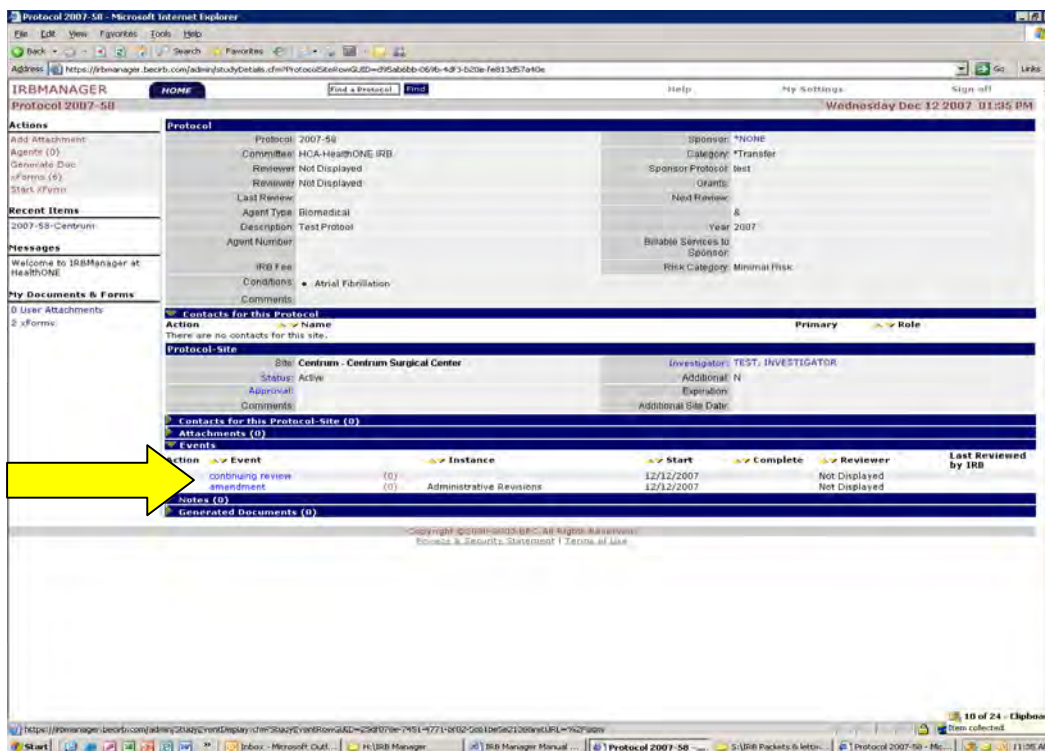
**\*\*Before you submit the form, be sure to validate accuracy\*\***

- vi) Once the form has been completed IRB Manager will automatically assign a study event for the Investigator Brochure Revisions submission.

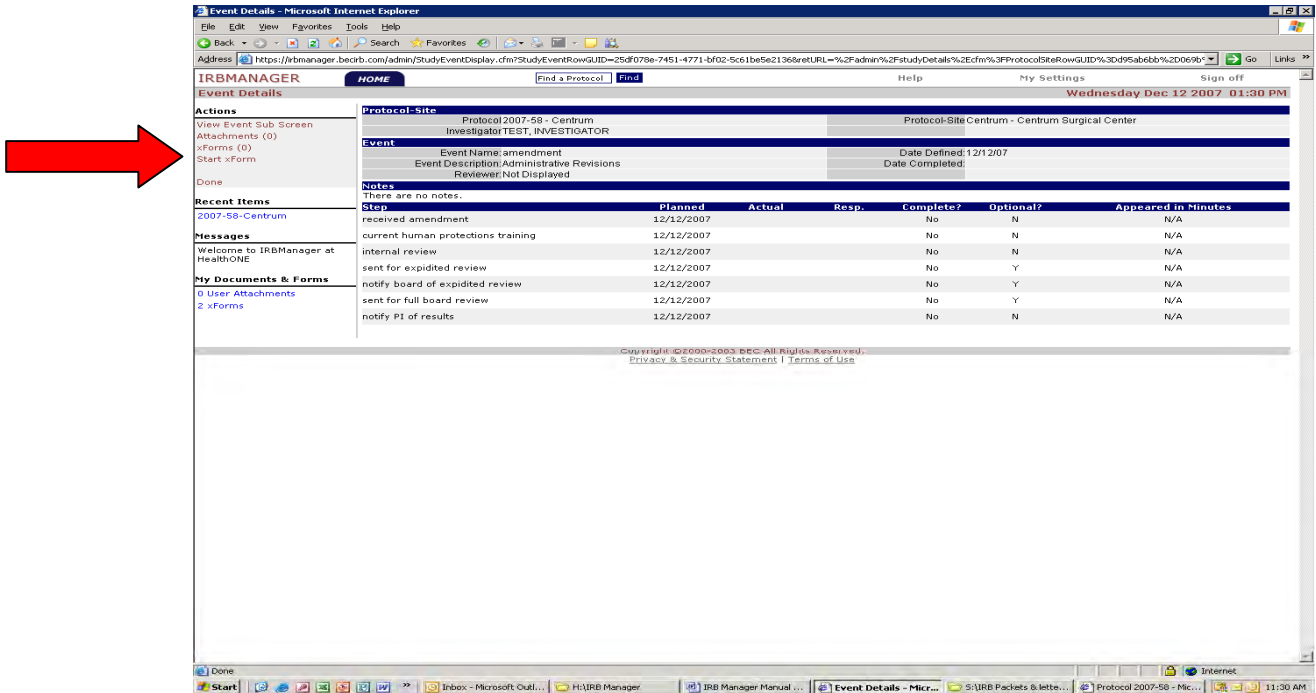


**Expedited Review (Appendix I):** will always be submitted in addition to another submission such as a new study application, continuing review, or amendment.

- i) Select the event hyperlink **<amendment>** or **<continuing review>** or **<new study>** that you wish to expedite.



- ii) Within that event select **<start xform>**.



- iii) Select the expedited review application.
- iv) Please answer all requested questions. If you fail to answer a mandatory field, a message error will appear. The system will not allow you to continue until the field has been populated.
- v) When the form has been completed you will be instructed to enter your IRB Manager password.
- vi) You will now be prompted to either save the form for later or submit the form. If you choose to submit the form, it will be locked for IRB office review.

**\*\*Before you submit the form, be sure to validate accuracy\*\***

**New study exemptions (Appendix J):** will always be submitted in addition to the new study application (biomedical or behavioral).

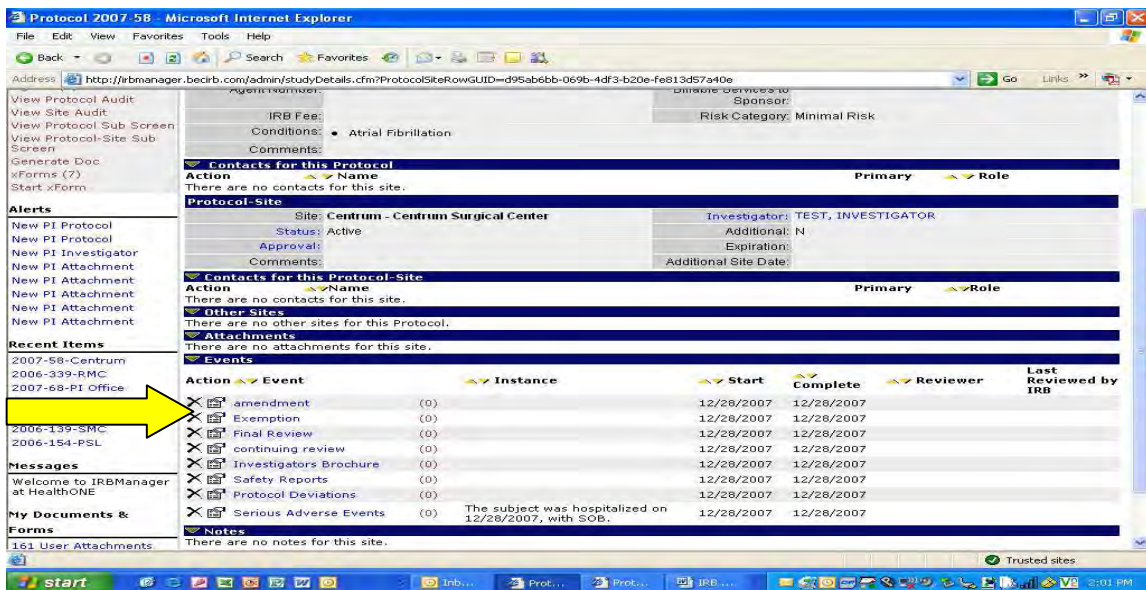
- i) Enter the new study into the system as per page 7 of 24.
- ii) Once the new study has been created select the **<start xform>** on the left side of the page.
- iii) Select the exemption application.
- iv) Please answer all requested questions. If you fail to answer a mandatory field, a message error will appear. The system will not allow you to continue until the field has been populated.
- v) When the form has been completed you will be instructed to enter your IRB Manager password.
- vi) You will now be prompted to either save the form for later or submit the form. If you choose to submit the form, it will be locked for IRB office review.

**\*\*Before you submit the form, be sure to validate accuracy\*\***

- vii) Once the form has been completed IRB Manager will automatically assign a study event for the review. Open the event by selecting hyperlink **<exemption>** next to the event.

- viii) A new study application (biomedical or behavioral) will also need to be submitted by selecting the **<start xforms>** link with the exemption event.
- ix) Please answer all requested questions. If you fail to answer a mandatory field, a message error will appear. The system will not allow you to continue until the field has been populated.
- x) When the form has been completed you will be instructed to enter your IRB Manager password.
- xi) You will now be prompted to either save the form for later or submit the form. If you choose to submit the form, it will be locked for IRB office review.

**\*\*Before you submit the form, be sure to validate accuracy\*\***



### Frequently Asked Questions:

#### I forgot my password, how do I obtain a new password?

- Contact the IRB office at 816-969-6411.
- Although the office cannot look up your password, a temporary password can be assigned to you.
- You must change the temporary password after it has been granted to you by selecting the **<my settings>** option in the right corner of the home screen.

#### How do I know if my study qualifies for IRB exemption or can be expedited?

All of the regulations for both exemptions and expedited reviews can be access on the Midwest Health System IRB website. If you are still unable to determine if your study qualifies, call the IRB office for further assistance.

#### Can I check on the progress of my submission?

Yes!

- 1) Access the study protocol via the home page



- 2) Once on the study protocol page access the applicable event that you wish to check on the progress. Within the event the submission steps indicate whether they have been completed by either yes or no answers.

**What should I do if I am unsure whether I have previously had a study approved by the Midwest Health System IRB?**

Users are set up by their own names, so if you have participated in any study in which the Midwest Health System IRB has oversight you should call the IRB to obtain your user ID and password.

**Why can't I view a protocol for a study that the Midwest Health System IRB has oversight?**

In order to view a protocol you have to be identified as a site contact. Call the IRB at 816-969-6411, to be added to the study protocol!

**I know I have entered an xform, but now I cannot view it on my main protocol page and an event was not created by the system.**

Studies are often conducted at multiple sites; the IRB staff assigns the sites to each protocol. The main site will always be *ACTIVE*. The other sites will be *AFFILIATED WITH MAIN SITE*. Thus it is very important that only the active site is selected when requesting reviews! If you have made an error, don't worry; call the IRB office at 816-969-6411 so that it can be corrected.

**I made a mistake and attached the wrong version of an IC. How do I delete it?**

The IRB Manager end users do not have access to delete attachments. Call the IRB office at 816-969-6411 so that the staff can delete the incorrect documents.

**When I went to complete the new biomedical study application, the investigator didn't automatically load. Why?**

If all of the questions were not completed in full when the study was first entered it will not pull the information forward into the forms. Contact the IRB office to correct the problem.

**Is there a way to view the sponsor/site study numbers instead of the IRB assigned numbers?**

Yes. On the home page under the actions section select **<show sponsor protocol codes>**.

**The application process appears to be longer than the paper forms. Why?**

To make it easier for the PI to submit study applications, the IRB office has attempted to combine several forms into one. For example, the biomedical application now consists of the supplementary new drug form, supplementary IDE/HDE form, vulnerable populations form, etc. The good news is that you will only have to answer questions that you have indicated are applicable, such as the IDE questions. If you answer yes there is an IDE, you will be re-directed to the applicable questions.

One of the most frustrating things to occur for both the IRB staff, members, and the investigators/coordinators is to find out that the IRB required more information to be able to review a study. This will prevent that from occurring, because the applicable fields are mandatory.

Contact the Midwest Health System IRB Office for more information at 816-969-6411 or email [Julie.iseman@hcamidwest.com](mailto:Julie.iseman@hcamidwest.com).