

Midwest Health System Institutional Review Board

IRB Manager©
Instruction Manual

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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 Midwest Health System
- Select <Login> to continue
- Forgot Your 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 will be able to change the password after it has been granted to you.

New Users:

If you have had a protocol previously reviewed by the Midwest Health System IRB please contact the IRB office at 816-969-6411 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 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.

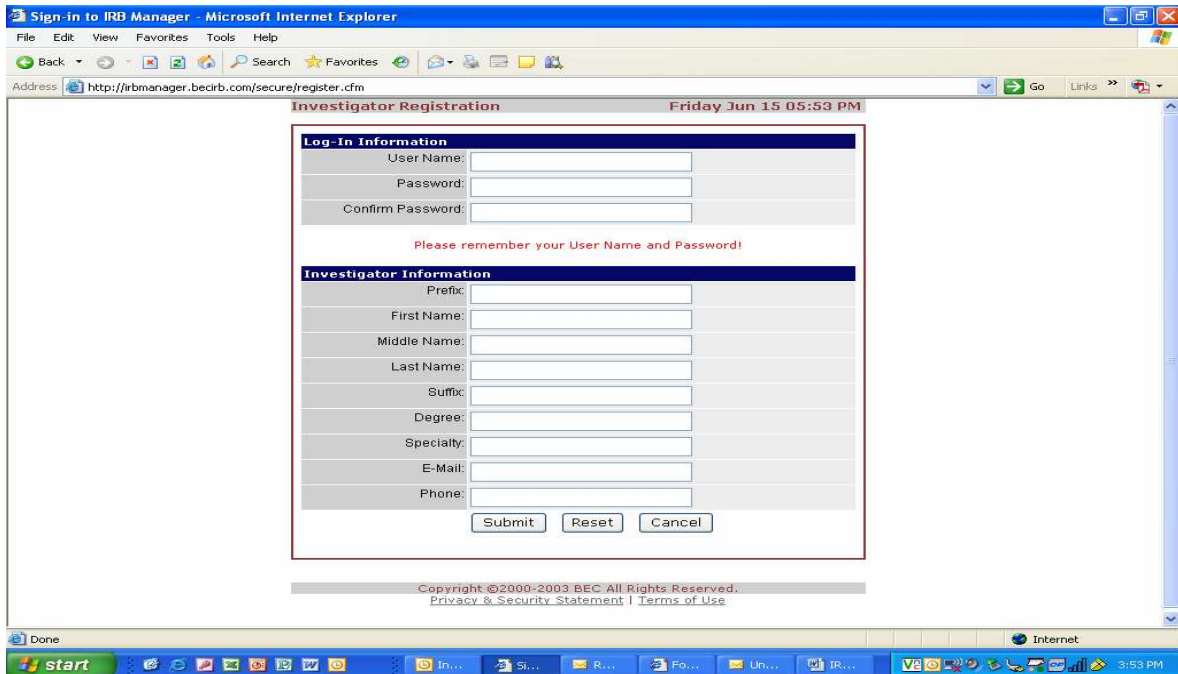
If you have never had a study reviewed or approved by the Midwest Health System IRB:

1. Logging into IRB Manager as a New User (**You have never had a protocol reviewed by the IRB**):
 - In the User Name field enter : newpi
 - In the Password field enter: newpi
 - The Client should always be Midwest Health System IRB
 - Select the <Login>

Creating User Name and Password

Enter your personal information in the next screen. Please create a user name and password that you will easily remember for future uses.

- Once populated, select <Submit>.



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.

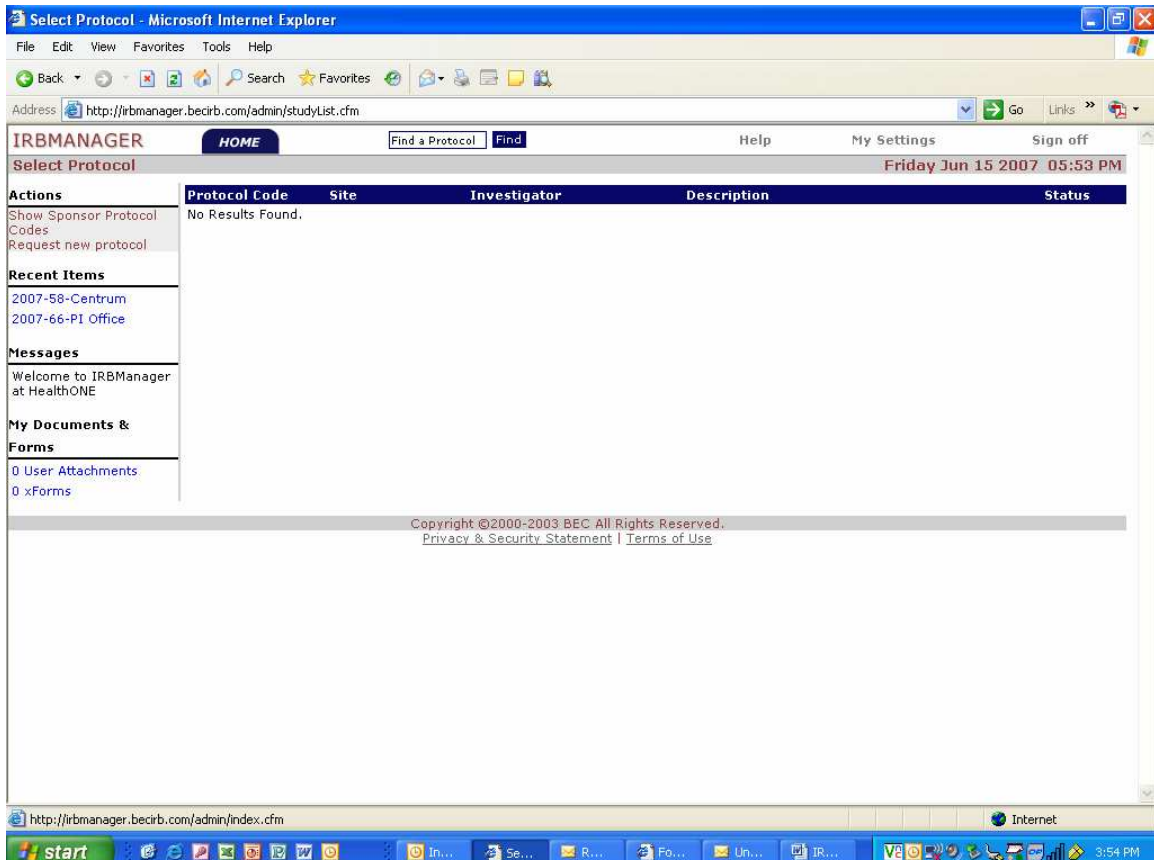
Home Screen Navigation:

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:

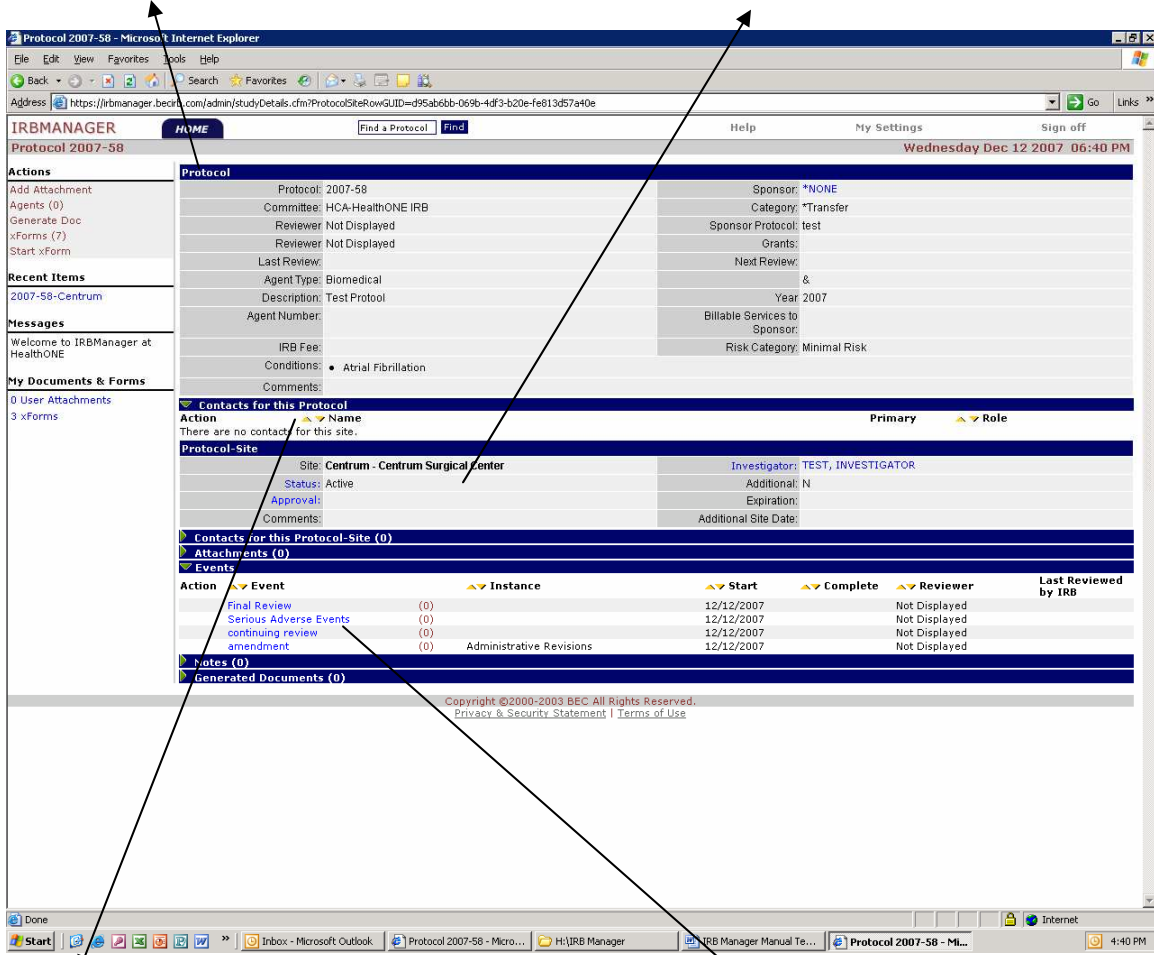
Please review the following tips related to entering information into IRB Manager:

- 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:

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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 the IRBMANAGER web application interface. The browser window title is "New Protocol Request - Microsoft Internet Explorer". The address bar shows the URL: <http://irbmanager.becib.com/admin/PINewProtocol3.cfm?CFID=762019&CFTOKEN=47465771>. The page header includes "IRBMANAGER", "HOME", "Find a Protocol", "Find", "Help", "My Settings", and "Sign off". The main content area is titled "New Protocol Request" and shows the following information:

The Protocol	
Protocol 2007-68	Sponsor Boston Scientific Corp.
Approved	Desc
Desc: Protocol Title as listed in Grant (if applicable)	

Your request

Investigator PI, Test	Site Centennial Medical Plaza
Comments	Enter additional study sites where this study may be conducted at

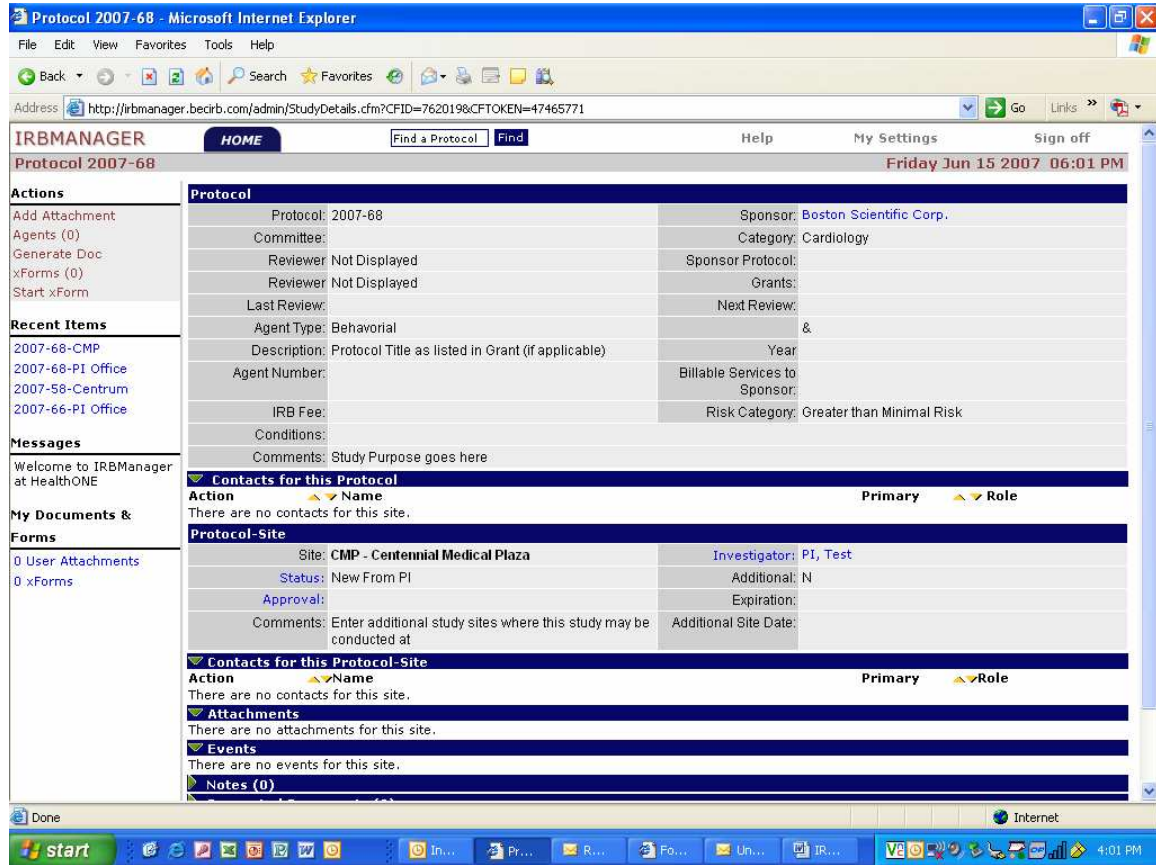
At the bottom of the form is a "Next --->" button. A callout box points to the "Protocol 2007-68" field with the text "Number assigned by the system". The footer of the page contains copyright information: "Copyright ©2000-2003 BEC All Rights Reserved. Privacy & Security Statement | Terms of Use".

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.

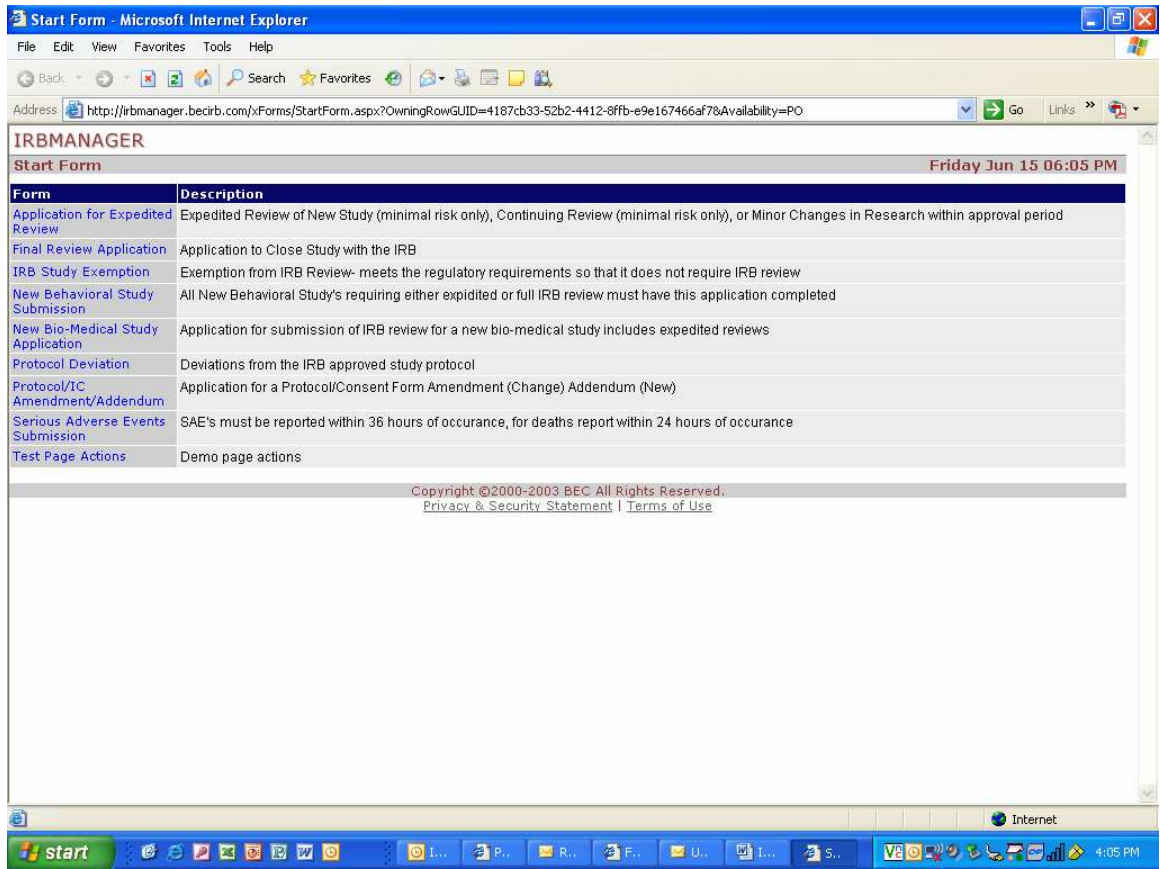
The below screen will now be the main protocol page that you have created with your entered study information.



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 you IRB Manger 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.

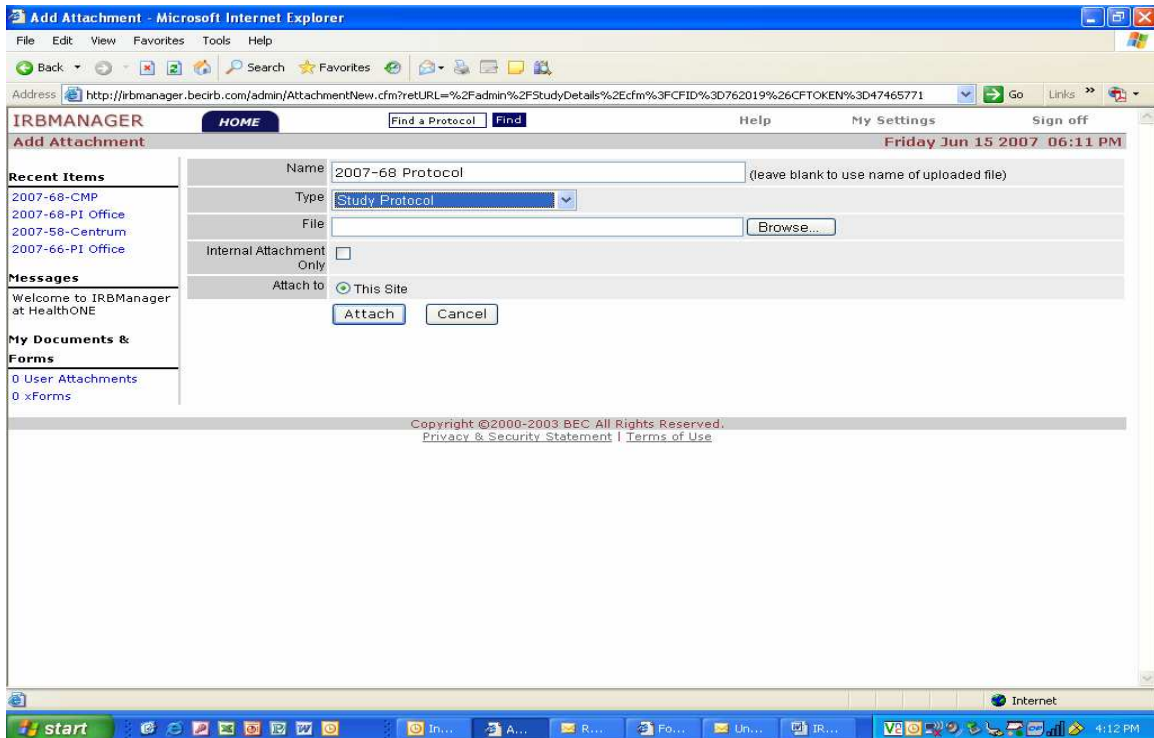
****Before you submit the form, be sure to validate accuracy****



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.

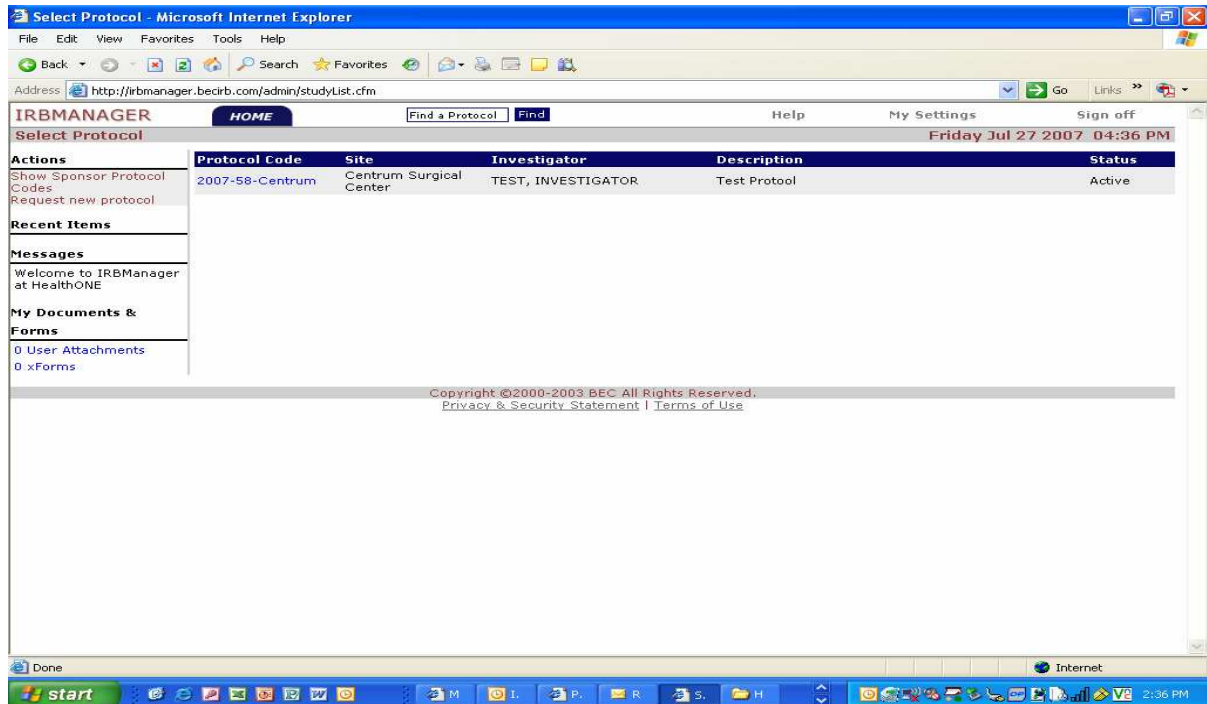


Tip

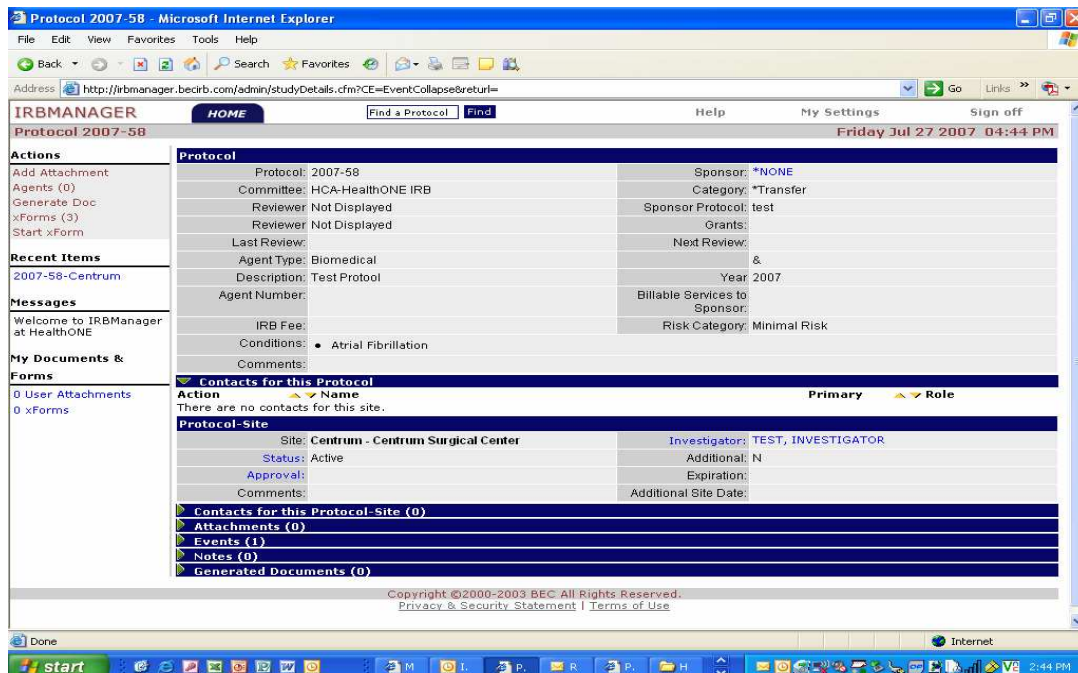
Many forms of documents can be attached such as Word (doc), Excel (xls), Adobe (pdf), Rich Text (rtf), etc. If you don't have an electronic version to attach, fax the document to the IRB office at 816-969-6267. The IRB office can then electronically attach it to the protocol event.

Creating an Application for an Existing Study

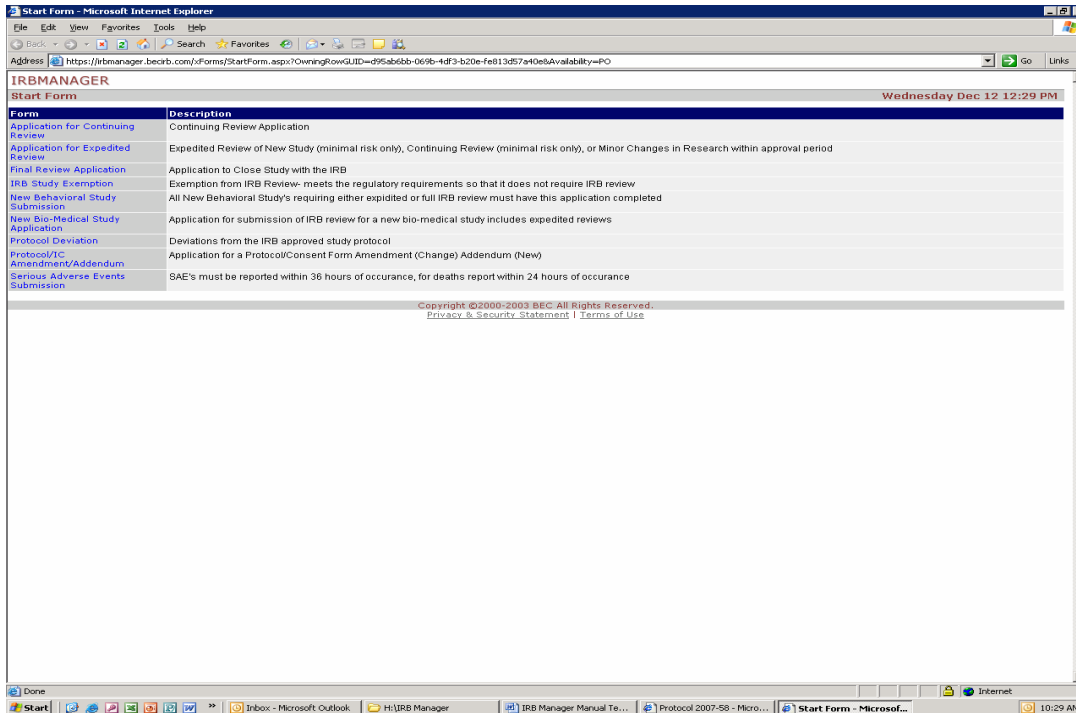
- 1) Access the study by either selecting the study from the home page or entering the IRB study number in the find protocol field.



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

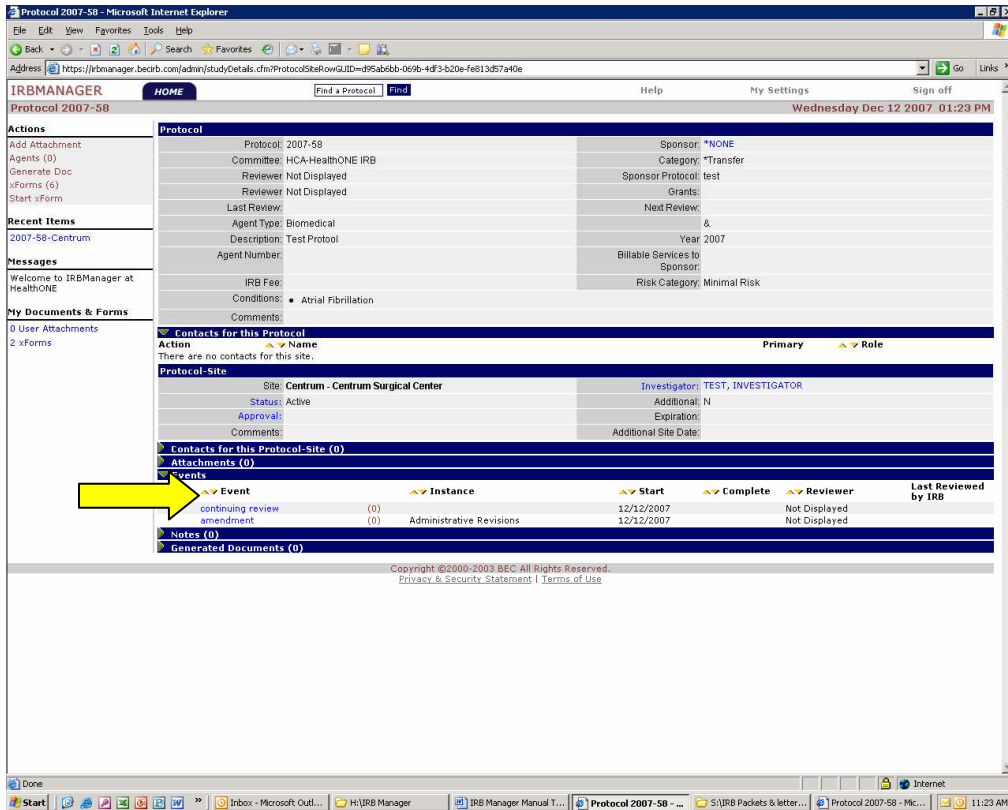
Select the **<attachment>** button:

- (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.

Protocol 2007-58

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

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

Action	Event	Instance	Start	Complete	Reviewer	Last Reviewed by IRB
	continuing review	(0)	12/12/2007		Not Displayed	
	amendment	(0)	12/12/2007		Not 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.becib.com/admin/studyDetails.cfm?ProtocolSiteRowGUID=d95ab0bb-069b-4df3-b20e-fe813d57a10e

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	Sponsor:	*NONE
Committed:	HCA-HealthONE IRB	Category:	*Transfer
Reviewer:	Not Displayed	Sponsor Protocol:	test
Reviewer:	Not Displayed	Grants:	
Last Review:		Next Review:	
Agent Type:	Biomedical	&	
Description:	Test Protocol	Year:	2007
Agent Number:		Billable Services to Sponsor:	
IRB Fee:		Risk Category:	Minimal Risk
Conditions:	Atrial Fibrillation		
Comments:			

Contacts for this Protocol
 Action Name Primary Role
 There are no contacts for this site.

Protocol Site

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

Contacts for this Protocol-Site (0)

Attachments (0)

Events

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	(0)	12/12/2007		Not Displayed	
amendment	(0) Administrative Revisions	12/12/2007		Not Displayed	

Notes (0)

Generated Documents (0)

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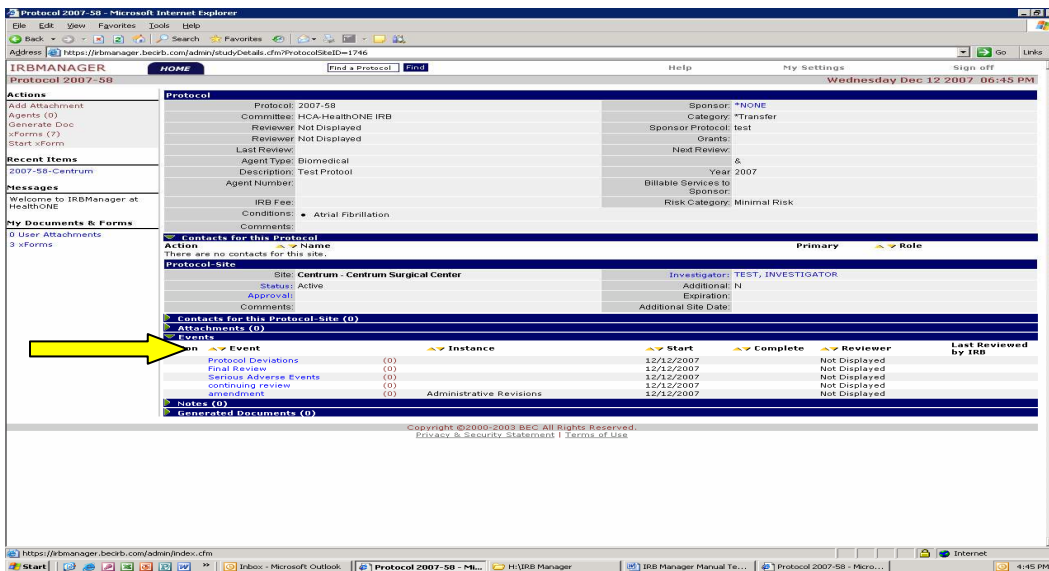
Done
 Start | In-box - Microsoft Outlook | Protocol 2007-58 - Micro... | H:\IRB Manager | IRB Manager Manual Te... | Protocol 2007-58 - M... | 4:40 PM

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. On the left, there are navigation menus for 'Actions', 'Recent Items', 'Messages', and 'My Documents & Forms'. The main content area shows details for Protocol 2007-58, including a 'Protocol' section with fields like Protocol, Sponsor, and Description. Below this is a 'Contacts for this Protocol' section, followed by 'Attachments (0)', 'Events', and 'Generated Documents (0)'. The 'Events' section contains a table with columns for Action, Instance, Start, Complete, Reviewer, and Last Reviewed by IRB. A yellow arrow points to the 'Final Review' event in this table.

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

****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)**

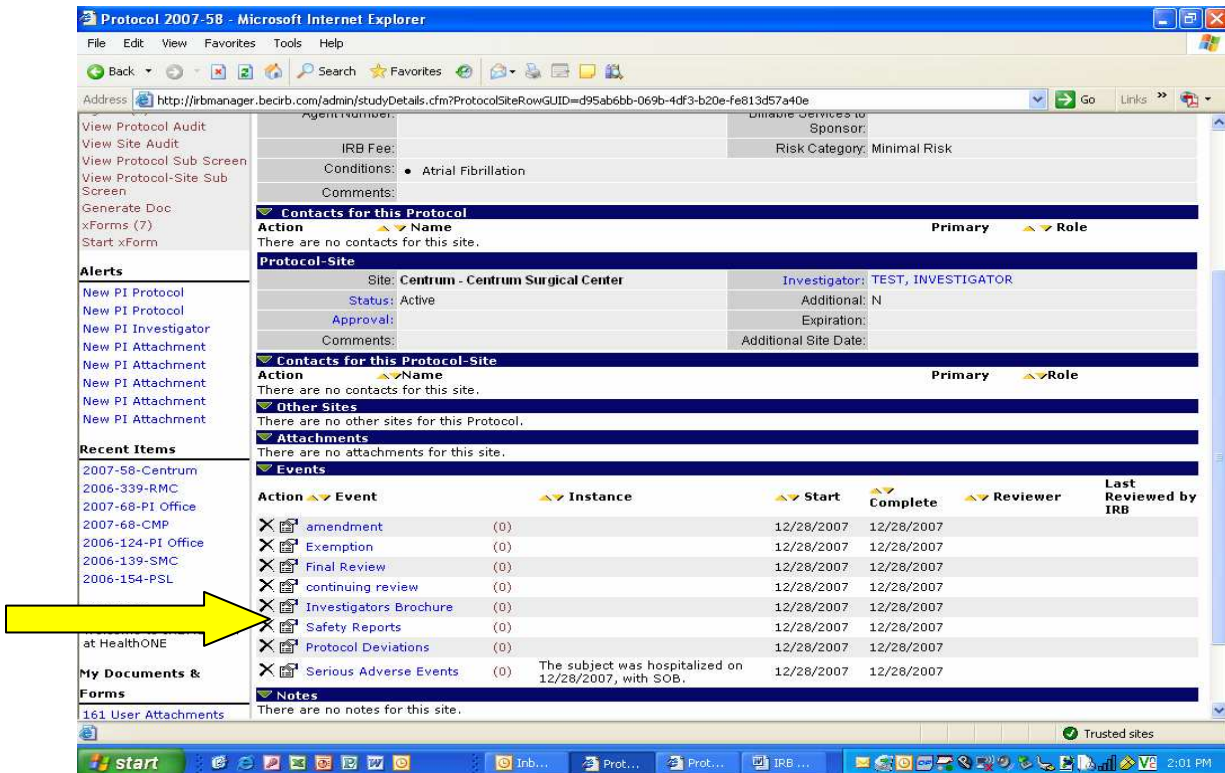
- i) Select **<start xform>**. The IRB study number, study title, and Investigator information will be automatically “loaded” into your continuing review form.
- ii) Please answer all requested questions. If you fail to answer a mandatory field, a message error will appear. The system will not allow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

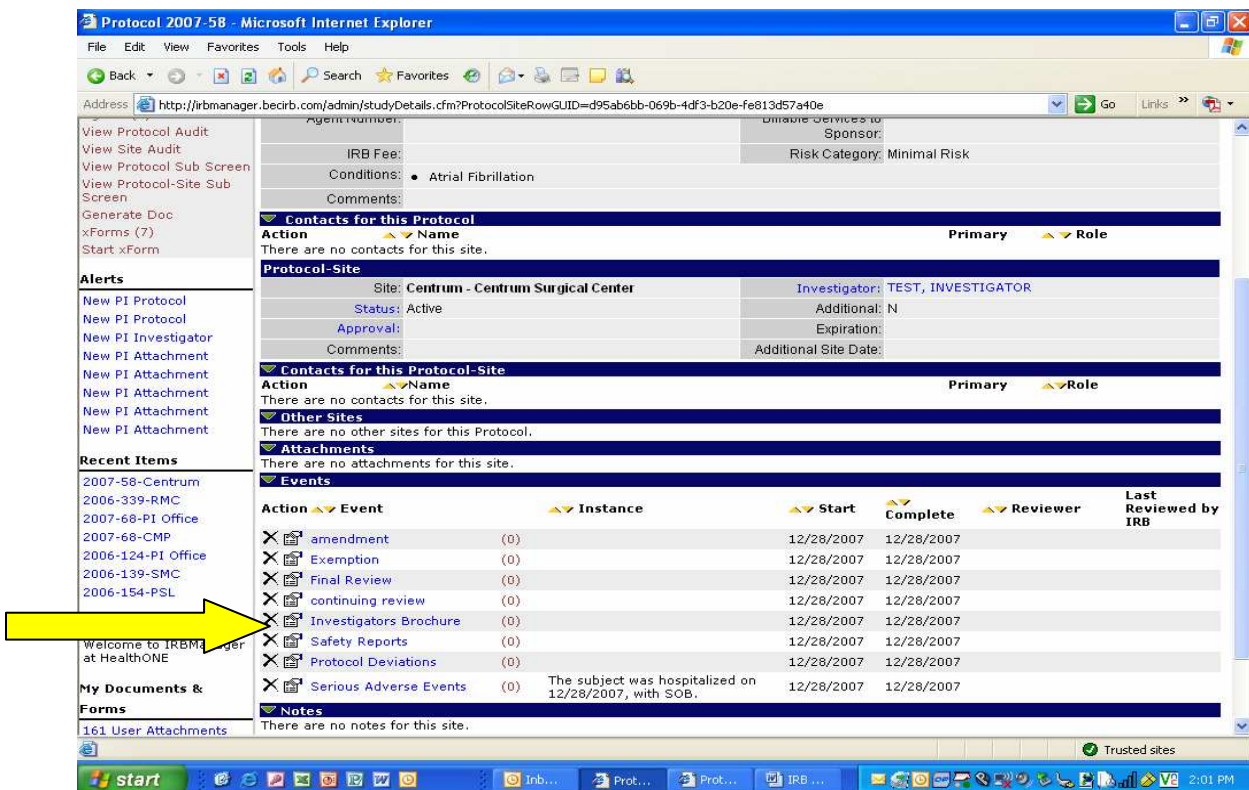
- i) Select **<start xform>**. The IRB study number, study title, and Investigator information will be automatically “loaded” into your continuing review form.
- ii) Please answer all requested questions. If you fail to answer a mandatory field, a message error will appear. The system will not allow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

The screenshot shows the IRBMANAGER interface for Protocol 2007-58. The 'Events' table is expanded, showing the following data:

Action	Event	Instance	Start	Complete	Reviewer	Last Reviewed by IRB
	continuing review	(0)	12/12/2007		Not Displayed	
	amendment	(0)	12/12/2007		Not Displayed	

A yellow arrow points to the 'continuing review' event. The interface also shows protocol details such as 'Sponsor: *NONE', 'Committee: HCA-HealthONE IRB', and 'Site: Centrum - Centrum Surgical Center'.

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



Steps	Planned	Actual	Resp.	Complete?	Optional?	Appeared in Minutes
received amendment	12/12/2007		No	N		N/A
current human protections training	12/12/2007		No	N		N/A
internal review	12/12/2007		No	N		N/A
sent for expedited review	12/12/2007		No	Y		N/A
notify board of expedited review	12/12/2007		No	Y		N/A
sent for full board review	12/12/2007		No	Y		N/A
notify PI of results	12/12/2007		No	N		N/A

- 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).

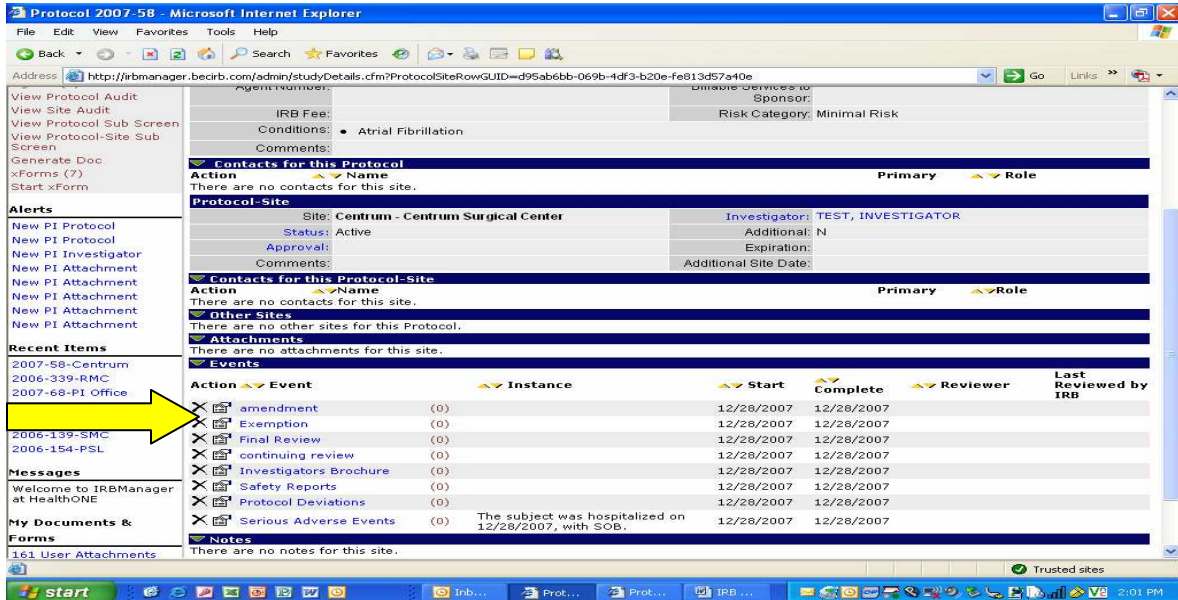
- i) Enter the new study into the system as per page 7 of 24.
- ii) Once the new study has been created select the **<start xform>** on the left side of the page.
- iii) Select the exemption application.
- iv) Please answer all requested questions. If you fail to answer a mandatory field, a message error 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.