

UWM IRB Manager User Guide for Researchers

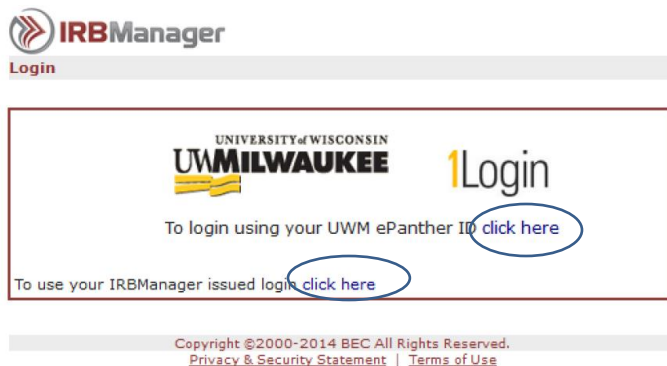
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1. IRBManager

IRBManager is a web based IRB submission and management system. It allows researchers to securely submit their IRB submissions and maintain their entire IRB file online.

2. Logging into your IRBManager Account

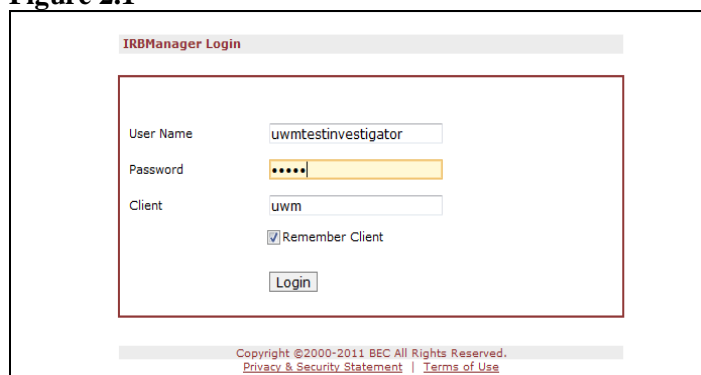
You may now log into IRBManager using your UWM ePantherID and password by following the "1Login" link in the center of the login box. (If you prefer, you may continue to use your independent IRBManager user name and password with UWM as the client by clicking on the login link at the bottom of the box.)



Based on this new feature, there are now two ways to log in to IRBManager:

1. **UWM faculty, staff and students** may now log in using their UWM ePanther ID user name and password throughout IRBManager by selecting the 1Login link in the center of the IRBManager login box. (Alternatively, UWM faculty, staff and students may also continue to use their independent IRBManager user name and password by clicking on the login link at the bottom of the box.)
2. **Non UWM personnel** (without an ePanther ID), may request an IRBManager account through the UWM IRB office. These users will continue to have a user name and password specific to IRBManager. Enter the client as "uwm". If you check the "Remember Client" box, "uwm" will be automatically entered each time you enter the IRBManager site from this computer.

Figure 2.1



Based on this feature, there are also now two methods to obtain an IRBManager account:

1. **UWM faculty, staff and students** without an account may simply log in to IRBManager by selecting the 1Login link in the center of the IRBManager login page. An account will automatically be created.
2. **Non UWM personnel**, complete the form on the UWM IRB web page to request an account. These accounts are generated by UWM IRB staff during regular business hours (Monday through Friday, 8am-4pm).

3. Changing your IRBManager password

1. Upon initial log in, you will be required to change your password. (See Figure 3.1)

Figure 3.1

Your Password Has Expired

Your password has expired. You must now select a new password. A valid password must be at least 8 characters long and contain characters from at least 1 of these groups: uppercase letters, lowercase letters, numbers, special characters (!, @, #, etc).

User: Anderson, A PhD
Username: aanderson
Old Password:
New Password:
New Password Confirm:

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2. To change your password at another time, select “UWM’s Settings” from the upper right menu. (See Figure 3.2)

Figure 3.2

IRBManager

Select Protocol

Protocol Code	Site	Investigator	Study Title	Expires	Status
01-111-Psy	Psychology	Test Investigator, UWM PhD	Test Study Survey	09/14/2009	Active Study
0110.1-Nurs	Nursing	Test Investigator, UWM PhD	Test Study - Expedited 1		New From PI
0110.2-Psy	Psychology	Test Investigator, UWM PhD	Expedited Study Test #2		New From PI
0310.1-Psy	Psychology	Test Investigator, UWM PhD	Test Study Mar-01		New From PI
0310.10-Nurs	Nursing	Test Investigator, UWM PhD	TEST EXPEDITED REVIEW MARCH 24 #5	03/23/2011	Active Study
0310.11-Nurs	Nursing	Test Investigator, UWM PhD	Test expedited review March 24 #6	03/23/2011	New From PI
0310.12-Nurs	Nursing	Test Investigator, UWM PhD	Expedited Study March 25 #1	01/20/2012	New From PI
0310.13-Nurs	Nursing	Test Investigator, UWM PhD	Test Study - Expedited Review - March 29 - #1	03/28/2011	New From PI
0310.2-Nurs	Nursing	Test Investigator, UWM PhD	Test - Expedited Review 2		New From PI
0310.3-Nurs	Nursing	Test Investigator, UWM PhD	Test - Expedited Review 3		New From PI

3. Click on “**Change my password**” to revise your current password. Figure 3.3 shows the change password screen.

Figure 3.3

The screenshot shows the IRBManager web application interface. On the left is a sidebar with a logo and navigation links: 'Actions', 'Recent Items' (listing various study identifiers like 0311.2-UWM, 01-111-Psy, etc.), and 'Messages' (showing a welcome message). The main content area is titled 'Change Password' and displays the user's current information: 'User: Test Investigator, UWM PhD' and 'Username: uwmttestinvestigator'. Below this are three input fields: 'Old Password', 'New Password', and 'New Password Confirm'. An 'Update' button is located at the bottom right of the form. The top of the page has a navigation bar with 'Home', 'Change Password', and a search bar. The bottom right corner contains links for 'Help', 'UWM's Settings', and 'Sign off'.

- i. To change your current password:
 1. Enter your old (current) password
 2. Enter a new password
 3. Re-enter the new password
 4. Press update for the change to be effective.
- ii. **Please note:** if you press the back key, home key, or any other button that takes you out of this screen prior to clicking on “update,” your password change will not be recognized by the system.

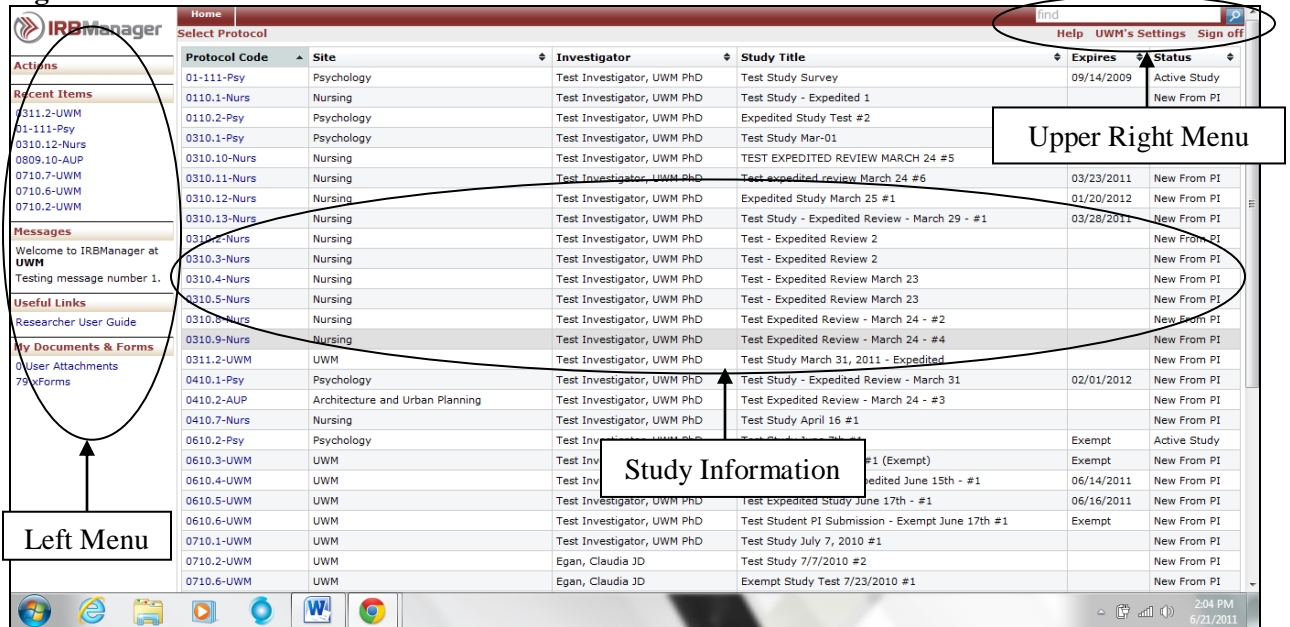
4. Home Page

After you log into IRBManager, you will be directed to your Home Page.

The Home Page is slightly different, depending on your status (researcher, IRB Member, IRB Administrator, etc.).

- IRB Members will view a search screen to find studies (either their own study or a study assigned to them).
- Researchers will view IRB studies that they have been granted access to view and/or edit (see Figure 4.1).

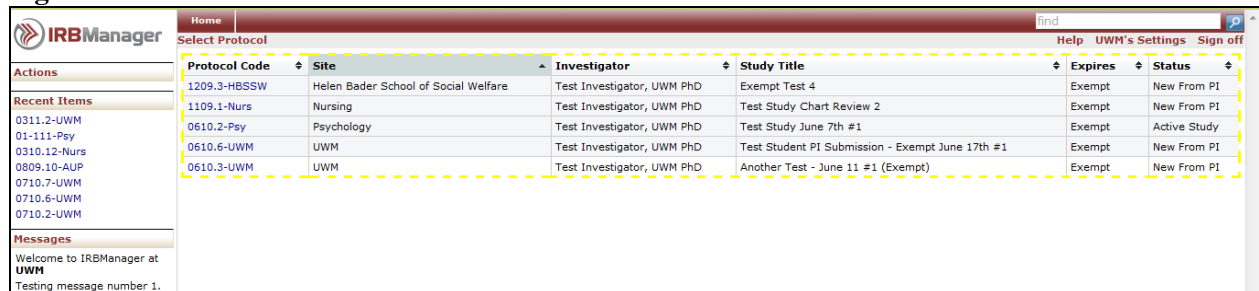
Figure 4.1



1. On the **left** side of the home page screen, you will see a menu that includes the following:
 - a. **Actions** - Depending on the page you are viewing, the selections in this category will change. The items within the actions category enable you to perform an action that will impact the page you are viewing. For example, on some pages you will be able to add an attachment or an xForm or send an email. “Done” is often a choice and will take you to the previous page.
 - b. **Recent Items** will list items recently viewed. To return to the recently viewed item, select the desired item.
 - c. **Messages** will display important messages from the UWM IRB.
 - d. **Useful Links** will display items that may be helpful for the user such as a link to commonly used forms, templates and user guides.
 - e. **My documents and forms**
 - i. **User Attachments** will display any attachments associated with you that have not been associated with a specific event or study within IRBManager
 - ii. **xForms** will display any xForms that you are associated with. In addition, you will be able to initiate new xForms within this section. (See Section 7 for instructions on “Submitting a New Study.”)

2. Your **study information** will be listed in the center of the page.
 - a. Each study will be listed by UWM IRB number, followed by the department, primary investigator, study title, expiration date, and the study status.
 - b. You can view more details about the study by left clicking on the UWM IRB number (or protocol code).
 - c. The data is sorted by the column highlighted in blue. You change the sort category by clicking on the arrows in the header of the desired column.
 - d. Data can also be filtered by clicking on a specific box. For example, if you want to view only exempt studies click on an “exempt” box and a screen with all of your exempt studies will be shown. See Figure 4.2

Figure 4.2

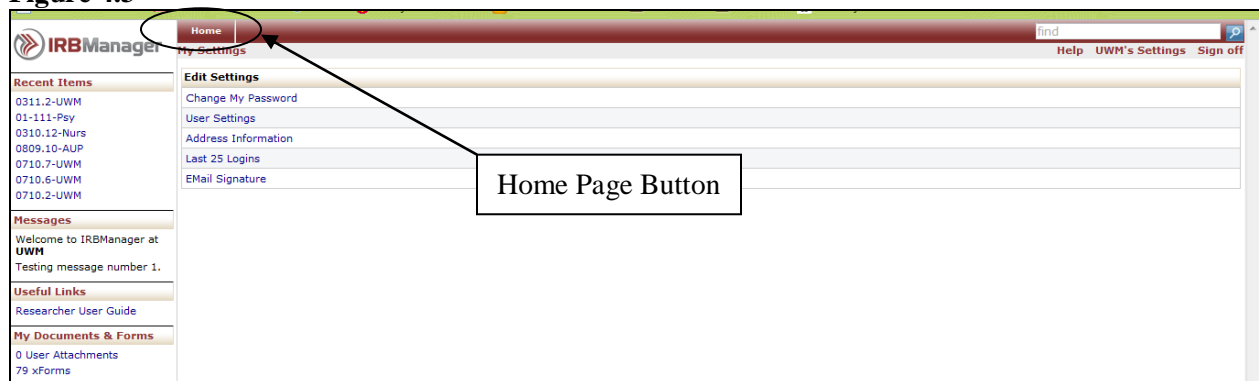


The screenshot shows the IRBManager interface. On the left is a sidebar with 'Recent Items' and 'Messages'. The main area features a table with columns: Protocol Code, Site, Investigator, Study Title, Expires, and Status. The 'Expires' column is highlighted in blue. A search bar and navigation links (Home, Help, UWM's Settings, Sign off) are at the top right.

Protocol Code	Site	Investigator	Study Title	Expires	Status
1209.3-HBSSW	Helen Bader School of Social Welfare	Test Investigator, UWM PhD	Exempt Test 4	Exempt	New From PI
1109.1-Nurs	Nursing	Test Investigator, UWM PhD	Test Study Chart Review 2	Exempt	New From PI
0610.2-Psy	Psychology	Test Investigator, UWM PhD	Test Study June 7th #1	Exempt	Active Study
0610.6-UWM	UWM	Test Investigator, UWM PhD	Test Student PI Submission - Exempt June 17th #1	Exempt	New From PI
0610.3-UWM	UWM	Test Investigator, UWM PhD	Another Test - June 11 #1 (Exempt)	Exempt	New From PI

3. On the **upper right** of the screen you will see another menu that includes the following:
 - a. **Find** will enable you to search for a specific study by entering a study number. The study number must be an exact match, including numbers, letters, symbols and spaces.
 - b. **Help** is currently not functional. Please contact the UWM IRB (414-229-3173 or irbinfo@uwm.edu) with questions about the IRBManager program.
 - c. **My Settings** will enable you to change your user account information.
 - d. **Sign Off** will sign you out of your IRBManager account and return you to the IRBManager log in page.
4. Clicking on **My Settings** in the **upper right menu** will direct you to another menu where you can view and edit any personal account or user specific settings. (See Figure 4.3) Please note: while in “**My Settings**,” you may return to your home page at any time by clicking on the “**HOME**” icon.

Figure 4.3



- b. Click on “**Change my password**” to revise your current password.
Figure 4.4 shows the change password screen.

Figure 4.4

The screenshot shows the IRBManager web application. On the left is a sidebar with a 'Recent Items' list containing several entries like '0311.2-UWM' and '01-111-Psy'. The main area is titled 'Change Password'. At the top, there's a navigation bar with 'Home', 'Change Password', and a search bar. Below the navigation bar, the user's current details are shown: 'User: Test Investigator, UWM PhD' and 'Username: uwmttestinvestigator'. The form contains three input fields: 'Old Password', 'New Password', and 'New Password Confirm'. An 'Update' button is positioned at the bottom right of the form area.

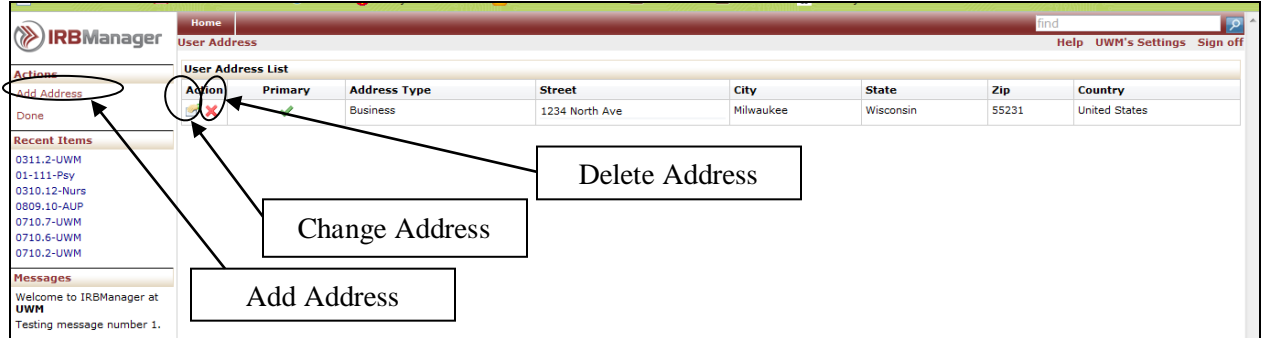
- i. To change your current password:
 1. Enter your old (current) password
 2. Enter a new password
 3. Re-enter the new password
 4. Press update for the change to be effective.
 - ii. **Please note:** if you press the back key, home key, or any other button that takes you out of this screen prior to clicking on “update,” your password change will not be recognized by the system.
- c. Click on “**User Settings**” to make a change to your first name, last name, phone number or email address. Enter the new information in the appropriate section(s) and press update for the change to be effective.
(See Figure 4.5)

Figure 4.5

The screenshot shows the IRBManager web application's 'User Settings' page. The sidebar on the left is identical to Figure 4.4. The main content area is titled 'User Settings'. Below the navigation bar, the user's current details are shown: 'User: Test Investigator, UWM PhD' and 'Username: uwmttestinvestigator'. The form is titled 'Change User Information' and contains four input fields: 'First Name' (with 'UWM' entered), 'Last Name' (with 'Test Investigator' entered), 'Phone Number' (with '800-555-5555' entered), and 'Email Address' (with 'UWM.TEST.INVESTIGA' entered). An 'Update' button is located at the bottom left of the form area.

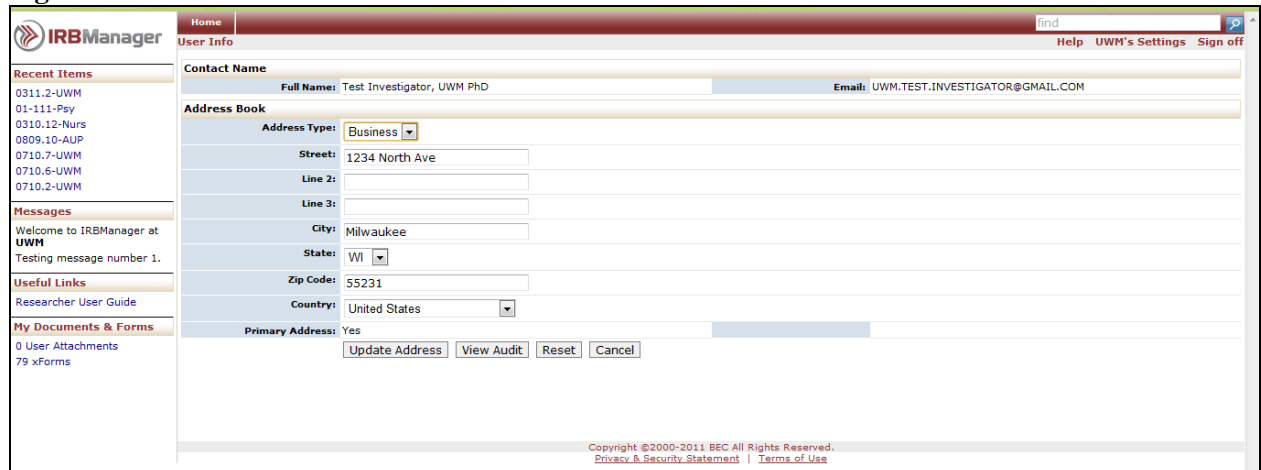
- d. Click on “**Address Information**” to make a change to your address or add a secondary address.
 - i. To make a **change** to your address press the “hand pointing to the paper” See Figure 4.6
 - ii. To **delete** the address information press the “x” button on the line displaying the address.
 - iii. To **add** a secondary or new address click on “add address” under the actions section in the left menu.

Figure 4.6



- iv. When you select to **change** the address or add a new address, you will be directed to the page shown in Figure 4.7
 1. Change or add any applicable information
 2. Be sure to press update address for the change to be effective
 3. The “view audit” button will allow you to view the most recent changes made to your address information
 4. Reset will cancel any changes made (before the “update” button has been pressed)
 5. Cancel will take you back to the previous section

Figure 4.7



- e. Click on “**Last 25 Logins**” to view your last 25 logins. As shown in Figure 4.8, the date, time, IP address and status of the logins will be viewable.

Figure 4.8

Login Time	Source IP	Status
Tue 06/21/11 03:04:25 PM	107.8.142.77	Success
Mon 06/06/11 02:22:20 PM	107.8.142.77	Success
Mon 06/06/11 10:44:46 AM	107.8.142.77	Success
Fri 04/01/11 09:58:00 AM	129.89.201.139	Success
Fri 04/01/11 09:22:19 AM	129.89.201.139	Success
Thu 03/31/11 05:02:46 PM	129.89.26.244	Success
Thu 03/31/11 03:07:54 PM	129.89.26.244	Success
Fri 03/04/11 04:47:29 PM	129.89.26.244	Success
Wed 02/02/11 05:01:43 PM	129.89.26.244	Success
Wed 02/02/11 04:09:35 PM	129.89.26.244	Success
Wed 02/02/11 04:07:50 PM	129.89.26.244	Success
Wed 02/02/11 03:53:51 PM	129.89.26.244	Success
Fri 01/21/11 02:49:07 PM	129.89.26.244	Success
Fri 01/21/11 02:36:43 PM	129.89.26.244	Success
Fri 01/21/11 01:48:29 PM	129.89.26.244	Success
Fri 01/21/11 12:20:24 PM	129.89.26.244	Success
Thu 01/20/11 01:34:48 PM	129.89.26.244	Success
Wed 01/19/11 03:12:27 PM	129.89.26.244	Success
Wed 01/19/11 02:30:26 PM	129.89.26.244	Success
Mon 11/22/10 02:04:12 PM	129.89.26.125	Success
Wed 10/20/10 02:20:46 PM	129.89.26.125	Success
Mon 08/23/10 02:36:01 PM	129.89.26.191	Success
Mon 08/23/10 02:25:11 PM	129.89.26.191	Success
Wed 08/11/10 02:57:02 PM	129.89.26.191	Success
Tue 08/10/10 11:10:02 AM	129.89.26.191	Success

- f. **Email signature** will allow you to add an automatic signature for emails sent from the IRBManager system. Be sure to click on “save” for any changes to be effective. (See Figure 4.9)

Figure 4.9

Test Investigator, PhD
Assistant Professor
University of Wisconsin - Milwaukee
Engelmann Hall 270
2033 E. Hartford Avenue
Milwaukee, WI 53201

5. Study/Protocol Page

Return to your home page at any time by clicking on the “**HOME**” icon.

1. To view information about a specific study you are involved with, click on the IRB **study number** (in blue) from the home page. (See Figure 5.1)

Figure 5.1

Protocol Code	Site	Investigator	Study Title	Expires	Status
01-111-Psy	Psychology	Test Investigator, UWM PhD	Test Study Survey	09/14/2009	Active Study
0110.1-Nurs	Nursing	Test Investigator, UWM PhD	Test Study - Expedited 1		New From PI
0110.2-Psy	Psychology	Test Investigator, UWM PhD	Expedited Study Test #2		New From PI
0310.1-Psy	Psychology	Test Investigator, UWM PhD	Test Study Mar-01		New From PI
0310.10-Nurs	Nursing	Test Investigator, UWM PhD	TEST EXPEDITED REVIEW MARCH 24 #5	03/23/2011	Active Study
0310.11-Nurs	Nursing	Test Investigator, UWM PhD	Test expedited review March 24 #6	03/23/2011	New From PI
0310.12-Nurs	Nursing	Test Investigator, UWM PhD	Expedited Study March 25 #1	01/20/2012	New From PI
0310.13-Nurs	Nursing	Test Investigator, UWM PhD	Test Study - Expedited Review - March 29 - #1	03/28/2011	New From PI
0310.2-Nurs	Nursing	Test Investigator, UWM PhD	Test - Expedited Review 2		New From PI
0310.3-Nurs	Nursing	Test Investigator, UWM PhD	Test - Expedited Review 2		New From PI
0310.4-Nurs	Nursing	Test Investigator, UWM PhD	Test - Expedited Review March 23		New From PI
0310.5-Nurs	Nursing	Test Investigator, UWM PhD	Test - Expedited Review March 23		New From PI
0310.8-Nurs	Nursing	Test Investigator, UWM PhD	Test Expedited Review - March 24 - #2		New From PI
0310.9-Nurs	Nursing	Test Investigator, UWM PhD	Test Expedited Review - March 24 - #4		New From PI
0311.2-UWM	UWM	Test Investigator, UWM PhD	Test Study March 31, 2011 - Expedited		New From PI
0410.1-Psy	Psychology	Test Investigator, UWM PhD	Test Study - Expedited Review - March 31	02/01/2012	New From PI
0410.2-AUP	Architecture and Urban Planning	Test Investigator, UWM PhD	Test Expedited Review - March 24 - #3		New From PI
0410.7-Nurs	Nursing	Test Investigator, UWM PhD	Test Study April 16 #1		New From PI
0610.2-Psy	Psychology	Test Investigator, UWM PhD	Test Study June 7th #1	Exempt	Active Study
0610.3-UWM	UWM	Test Investigator, UWM PhD	Another Test - June 11 #1 (Exempt)	Exempt	New From PI
0610.4-UWM	UWM	Test Investigator, UWM PhD	Another test study - Expedited June 15th - #1	06/14/2011	New From PI
0610.5-UWM	UWM	Test Investigator, UWM PhD	Test Expedited Study June 17th - #1	06/16/2011	New From PI
0610.6-UWM	UWM	Test Investigator, UWM PhD	Test Student PI Submission - Exempt June 17th #1	Exempt	New From PI
0710.1-UWM	UWM	Test Investigator, UWM PhD	Test Study July 7, 2010 #1		New From PI
0710.2-UWM	UWM	Egan, Claudia JD	Test Study 7/7/2010 #2		New From PI
0710.6-UWM	UWM	Egan, Claudia JD	Exempt Study Test 7/23/2010 #1		New From PI

Figure 5.2

1. Protocol Section

2. Protocol Site

3. Contacts

4. Attachments

5. Events

6. Notes

7. Generated Documents

Figure 5.2 (previous page) shows the information found within each study file.

1. Protocol Section

- a. Provides basic information about your study such as:
 - i. IRB number, sponsor, review committee, study title, risk level, review category
- b. This section will be read only – these items are created based on the New Study Form responses and/or IRB administration.
- c. Clicking on the blue link for “Sponsor(s)” will provide you with more details about the study sponsor.

2. Protocol Site

- a. This section will describe additional study information such as:
 - i. Primary Investigator, PI department, study status, approval period, study expiration date, and a brief study description.
- b. Again, this section is read only and the items are based on data generated from the New Study Form responses and/or IRB administration.
- c. The blue links will provide additional information about:
 - i. Click on “Investigator” to view the Investigator history
 - ii. Click on “Status” to view the status history of the protocol.
 - iii. Click on “Approval” to view the approval history and dates.

3. Contacts for this Protocol Site

- a. This section will list study contacts (as provided in the xForm). These people will have access to the study through IRBManager.
- b. By clicking on an individual contact’s name, you will be provided with any information about the contact that is within the IRBManager system

4. Attachments

- a. Attachments associated with the study may be located in this section, although most attachments are found within specific study events. Click on the attachment name to open the file.

5. Events

- a. Events include all IRB submissions – such as new study submissions, continuing reviews, amendments. Each submission is listed as an individual event.
- b. Actions will be listed by type. Such as new protocol, continuing review, amendment, etc.
 - i. Continuing reviews can be differentiated by start (also the submission) date.
 - ii. Amendments can be differentiated by the brief description listed in the “Instance” column or by the Start (submission) date.
- c. More details about the individual events can be found by clicking on the event name (in blue). See Figure 5.3

Figure 5.3

IRBManager Home find Help UWM's Settings Sign off

Protocol 0310.10

Last Review: Agent Type: B. Interviews/Focus Groups , C. Questionnaires/Surveys , I. MRI, fMRI, X-Rays, DXA, etc
Next Review: CRO:
Study Title: TEST EXPEDITED REVIEW MARCH 24 #5
Year: 2010
Level of Risk: Minimal Risk
Conditions:
Comments:

Protocol-Site
Site: Nurs - Nursing
Status: Active Study
Investigator: Test Investigator, UWM PhD
Approval: March 24, 2010 for 12 months
Additional: N
Initial Approval Date: March 24, 2010
Expiration: March 23, 2011
Comments: FAFGAGASD
Additional Site Date:

▼ Contacts for this Protocol Site (0)

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

▼ Attachments (0)

There are no attachments for this site.

▼ Events (3)

Action	Event	Alt	FE	Instance/UED	Start	Complete	Primary	Secondary	Last IRB
	Continuing Review - Expedited				08/10/10	08/10/10	Not Displayed	Not Displayed	
	Continuing Review - Expedited				07/09/10		Not Displayed	Not Displayed	
	New Protocol Submission - Expedited				03/24/10		Not Displayed	Not Displayed	

▼ Notes (0)

There are no notes for this site.

▼ Generated Documents (0)

There are no generated documents for this site.

https://irbmanager.becrb.com/admin/StudyEventDisplay.cfm?StudyEventRowGUID=558d5d30-1d94-407c-8ed3-8c0ba4d04db&retURL=%2Fadmin%2FstudyDetails%2Ecfm%3FProtocolSiteRowGUID%3D7d0566b2-42d8-4435-bb48-7493a83cb2ea

6. **Notes** - General notes about the study may be included here. Keep in mind that most notes are associated with an event and will be found within an individual event not on the main protocol page.
7. **Generated Documents** - General Documents associated with the study may be included here. Although most generated documents (such as approval letters) are found within specific study events.
8. Please note the **left menu** is slightly different within the protocol page view. See Figure 5.4.

Figure 5.4

IRBManager Home find Help UWM's Settings Sign off

Protocol 0310.10

Protocol: 0310.10
Committee: Committee #1
Reviewer: Not Displayed
Reviewer: Not Displayed
Last Review:
Agent Type: B. Interviews/Focus Groups , C. Questionnaires/Surveys , I. MRI, fMRI, X-Rays, DXA, etc
Study Title: TEST EXPEDITED REVIEW MARCH 24 #5
Level of Risk:
Conditions:
Comments:

Sponsor(s):
Category: 3. Biomedical
Sponsor Protocol:
Grants:
Next Review:
CRO:
Year: 2010

Protocol-Site
Site: Nurs - Nursing
Status: Active Study
Investigator: Test Investigator, UWM PhD
Approval: March 24, 2010 for 12 months
Additional: N
Initial Approval Date: March 24, 2010
Expiration: March 23, 2011
Comments: FAFGAGASD
Additional Site Date:

▼ Contacts for this Protocol Site (0)

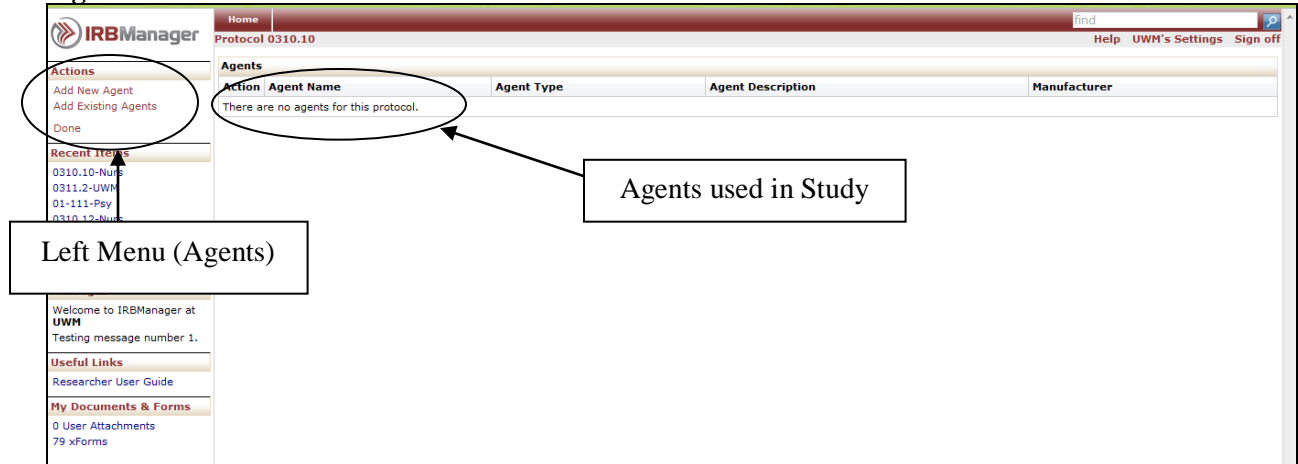
Action	Name	Role	Primary
There are no contacts for this site.			

▼ Attachments (0)

There are no attachments for this site.

- a. **Agents** – Selecting agent will allow you to view any “agents” utilized for your research study. “Agents” refer to drugs or devices. Once selected, you may view agents already listed for your study or you may add or remove agents by using the left menu (see Figure 5.5). Once an agent is entered in the IRBManager system, the details about the agent are saved. The agent can be searched for and may be used for multiple studies.

Figure 5.5



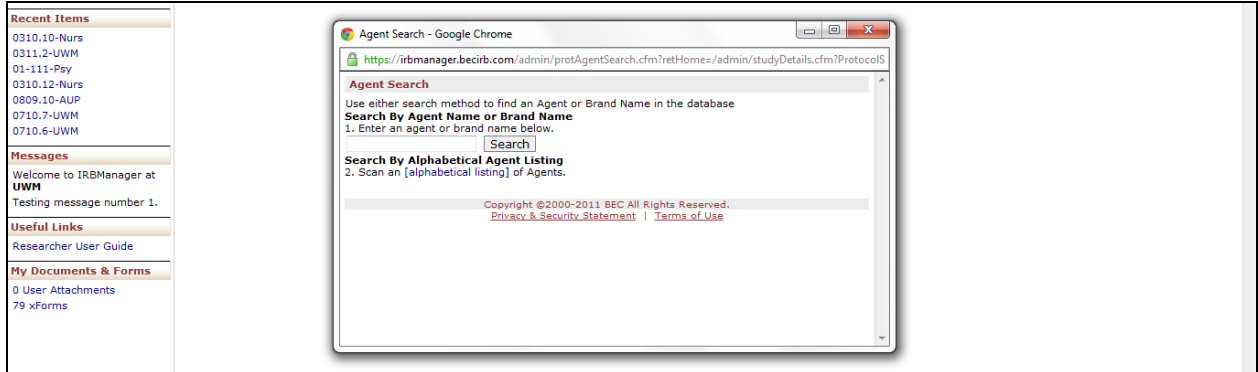
- i. When adding a **new agent**, provide details about the agent such as the type of agent, manufacturer, IND or IDE number, etc. See Figure 5.6

Figure 5.6

The screenshot shows the 'Add a New Agent' form in the IRBManager interface. The form is divided into two columns. The left column contains fields for: Agent Name, Agent Type (dropdown), Dosage Form (dropdown), FDA Approved (radio buttons for Yes/No), Manufacturer, Address, City, State (dropdown), Zip, Phone, and Fax. The right column contains fields for: Agent Description, IND/IDE #, Strength(s), Date filed with FDA, Country (dropdown), Alt. Address, Alt. City, Alt. State (dropdown), Alt. Zip, Alt. Phone, and Alt. Fax. At the bottom of the form are buttons for 'Add Agent', 'Reset', and 'Cancel'.

- ii. When adding an **existing agent**, you may search the UWM IRBManager system by entering the agent name or by searching through an alphabetical list of existing agents. (See Figure 5.7)

Figure 5.7



- b. **Generate Doc** – By selecting this option from the left menu, you can add a document to the study if a template is available. However, at this time templates are not available for researchers, and in most cases, documents will be attached to individual events.
- c. **xForms** – Selecting this option from the left menu will enable you to view any xForms that have been created for this study. Please note, once the xForm is accepted by the IRB a new event is generated for the event and can be found in the Event section (Item 5 above).
- d. **Start xForm** – Select this option to start a new xForms specific to this study (such as an amendment, continuing review, or reportable event). See Figure 5.8. If you would like to initiate a new IRB study separate from this specific study, you may also return to your home page and then select xForms from the left menu. (See section 7 for instructions on submitting a new study to the IRB).

Figure 5.8



- e. **Send email** – You can send an email from within IRBManager by selecting this option. See Figure 5.9.

Figure 5.9

The screenshot shows the IRBManager web application interface. The top navigation bar includes 'Home', 'Send E-Mail', and a search bar. The left sidebar contains sections for 'Actions' (Add/Remove Attachment(s)), 'Recent Items' (listing various study IDs like 0310.10-Nurs, 0311.2-UWM, etc.), 'Messages' (Welcome to IRBManager at UWM), 'Useful Links' (Researcher User Guide), and 'My Documents & Forms' (0 User Attachments, 79 xForms). The main content area is titled 'Send E-Mail' and features a form with fields for 'From' (Test Investigator, UWM PhD (UWM.TEST.INVESTIGATOR@GMAIL.COM)), 'To', 'CC', 'Attachment(s)', and 'Subject'. There are 'Send' and 'Cancel' buttons. Below the form is a rich text editor with a toolbar containing icons for bold, italic, underline, text color, background color, bulleted list, numbered list, link, unlink, and font size. The text area contains the following text: 'Test Investigator, PhD', 'Assistant Professor', 'University of Wisconsin - Milwaukee', 'Engelmann Hall 270', '2033 E. Hartford Avenue', 'Milwaukee, WI 53201'.

6. Event Page

- a. Events include all IRB submissions – such as new study submissions, continuing reviews, amendments, and reportable events. Each submission is listed as an individual event.
- b. Actions will be listed by type. Such as new protocol, continuing review, amendment, etc.
 - i. Continuing reviews can be differentiated by start (also the submission) date.
 - ii. Amendments can be differentiated by the brief description listed in the “Instance” column or by the Start (submission) date.
- c. More details about the individual events can be found by clicking on the event name (in blue). See Figure 6.1

Figure 6.1

The screenshot shows the IRBManager interface. On the left is a sidebar with navigation links like 'Actions', 'Recent Items', 'Messages', 'Useful Links', and 'My Documents & Forms'. The main content area is titled 'Protocol 0310.10' and contains several sections: 'Protocol' details, 'Protocol-Site' information, 'Contacts for this Protocol Site', 'Attachments', and 'Events'. The 'Events' section is expanded, showing a table of three events. The first event, 'Continuing Review - Expedited', is highlighted with a blue border and a callout box labeled 'Event' pointing to it.

Action	Event	Att	FE	Instance/UED	Start	Complete	Primary	Secondary	Last IRB
	Continuing Review - Expedited	(2)		5 and 7	08/10/10	08/10/10	Not Displayed	Not Displayed	
	Continuing Review - Expedited	(1)			07/09/10		Not Displayed	Not Displayed	
	New Protocol Submission - Expedited	(3)		5 and 7	03/24/10		Not Displayed	Not Displayed	

- d. After selecting a specific event (see Figure 6.2):
 - i. The main (center of the) page will provide details such as:
 1. IRB study number, PI, type of event, date of IRB receipt, date of approval, review category, event description, etc.
 2. Notes from the IRB (if any)
 3. Status (Step) of the IRB review and expected completion dates

Figure 6.2

Left Menu (Event)

Main Page (Event)

Planned	Actual	Resp.	Complete	Optional	Minutes
08/10/2010	08/10/2010		Yes	N	N/A
08/10/2010	08/10/2010		Yes	N	N/A
08/24/2010	08/10/2010		Yes	N	N/A
08/24/2010	09/03/2010		No	N	N/A
08/24/2010	08/10/2010		Yes	N	N/A

ii. The left menu options include:

1. **Attachments** will take you to any documents and/or letters attached to this specific study event. (See Figure 6.3) You may open attachments by selecting the document or letter listed in blue.

Figure 6.3

Left Menu (Attachment)

Individual Attachments

Action	Display Name	Attached On	Type
	Protocol Summary	08/10/10	PI: Protocol Summary Form
	Consent	08/10/10	PI: Consent Form

- a. **Add Attachment** – Selecting add attachment from within this page will enable you to add additional attachments to the study. See Figure 6.4. Name the attachment, select the type of attachment from the drop down menu, and attach the file by selecting “browse” to find the appropriate document from your computer. When complete select “attach.” The document will be accessible from the “Attachments” section.

Figure 6.4

The screenshot shows the IRBManager interface for adding an attachment. The left sidebar provides navigation options, including recent items, messages, and document management. The main form allows users to specify the attachment's name, type, and file source, with an 'Attach' button to complete the process.

2. **Generate Doc** – By selecting this option from the left menu, you can add a document to the event if a template is available. However, at this time templates are not available for researchers.
3. **xForms** – Selecting this option from the left menu will enable you to view any xForms that have been created for this study event.
4. **Start xForm** – Select this option to start a new xForm. (See section 7 for instructions on submitting a new study to the IRB).
5. **Done** – Selecting Done will take you back to the study’s Protocol Page.

7. Submitting a New Submission

- Return to your HOME page by clicking on the “HOME” icon.
- In the left menu, under the heading “My Documents & Forms,” select **xForms** (Figure 7.1)

Figure 7.1

Protocol Code	Site	Investigator	Study Title	Expires	Status
01-111-Psy	Psychology	Test Investigator, UWM PhD	Test Study Survey	09/14/2009	Active Study
0110.1-Nurs	Nursing	Test Investigator, UWM PhD	Test Study - Expedited 1		New From PI
0110.2-Psy	Psychology	Test Investigator, UWM PhD	Expedited Study Test #2		New From PI
0310.1-Psy	Psychology	Test Investigator, UWM PhD	Test Study Mar-01		New From PI
0310.10-Nurs	Nursing	Test Investigator, UWM PhD	TEST EXPEDITED REVIEW MARCH 24 #5	03/23/2011	Active Study
0310.11-Nurs	Nursing	Test Investigator, UWM PhD	Test expedited review March 24 #6	03/23/2011	New From PI
0310.12-Nurs	Nursing	Test Investigator, UWM PhD	Expedited Study March 25 #1	01/20/2012	New From PI
0310.13-Nurs	Nursing	Test Investigator, UWM PhD	Test Study - Expedited Review - March 29 - #1	03/28/2011	New From PI
0310.2-Nurs	Nursing	Test Investigator, UWM PhD	Test - Expedited Review 2		New From PI
0310.3-Nurs	Nursing	Test Investigator, UWM PhD	Test - Expedited Review 2		New From PI
0310.4-Nurs	Nursing	Test Investigator, UWM PhD	Test - Expedited Review March 23		New From PI
0310.5-Nurs	Nursing	Test Investigator, UWM PhD	Test - Expedited Review March 23		New From PI
0310.8-Nurs	Nursing	Test Investigator, UWM PhD	Test Expedited Review - March 24 - #2		New From PI
0310.9-Nurs	Nursing	Test Investigator, UWM PhD	Test Expedited Review - March 24 - #4		New From PI
0311.2-UWM	UWM	Test Investigator, UWM PhD	Test Study March 31, 2011 - Expedited		New From PI
0410.1		Test Investigator, UWM PhD	Test Study - Expedited Review - March 31	02/01/2012	New From PI
0410.2		Test Investigator, UWM PhD	Test Expedited Review - March 24 - #3		New From PI
0410.7-Nurs	Nursing	Test Investigator, UWM PhD	Test Study April 16 #1		New From PI
0610.2-Psy	Psychology	Test Investigator, UWM PhD	Test Study June 7th #1	Exempt	Active Study
0610.3-UWM	UWM	Test Investigator, UWM PhD	Another Test - June 11 #1 (Exempt)	Exempt	New From PI
0610.4-UWM	UWM	Test Investigator, UWM PhD	Another test study - Expedited June 15th - #1	06/14/2011	New From PI
0610.5-UWM	UWM	Test Investigator, UWM PhD	Test Expedited Study June 17th - #1	06/16/2011	New From PI
0610.6-UWM	UWM	Test Investigator, UWM PhD	Test Student PI Submission - Exempt June 17th #1	Exempt	New From PI
0710.1-UWM	UWM	Test Investigator, UWM PhD	Test Study July 7, 2010 #1		New From PI
0710.2-UWM	UWM	Egan, Claudia JD	Test Study 7/7/2010 #2		New From PI
0710.6-UWM	UWM	Egan, Claudia JD	Exempt Study Test 7/23/2010 #1		New From PI

- In the xForms page (Figure 7.2)
 - The main page shows any xForms that have been created by the user.
 - The left menu has three options:
 - Start Form** – Select to initiate an xForm for a new submission (Figure 7.4).
 - Notification View** enables you to view any items that have been requested by the IRB that are awaiting response from the logged in user or any xforms that are not complete.
 - Show complete / Hide Complete** enables you to view all xForms you have created (Show Complete, Figure 7.2) or to view only the xForms that have not been submitted or have not been accepted by the IRB (Hide Complete, Figure 7.3)

Figure 7.2

Left Menu - xForms

Main Page - xForms

Action	Form	Identifier	Stage	Started	Submitted
	New Study Form	test	New Study data entry	06/06 at 2:22 PM	
	New Study Form	Test Study March 31, 2011 - Expedited	Expedited and Full Board Reviewer Form	3/31/2011	
	Reportable Event Form	Expedited Study March 25 #1	Notify PI	2/2/2011	
	Continuing Review	Expedited Study March 25 #1	Continuing Review Notify PI	1/21/2011	
	Continuing Review	Expedited Study March 25 #1	Continuing Review Notify PI	1/21/2011	
	Amendment Form	Exempt Study Test 7/23/2010 #1	Hold for Revisions	1/21/2011	
	Amendment Form	Test Study - Expedited Review - March 31	Hold for Revisions	1/20/2011	
	Amendment Form	Test Expedited Study June 17th - #1	Amendment Load, Load Att and Notes, Notify PI	1/19/2011	
	Amendment Form	Test Expedited Review August 11, 2010 #1	Hold for Revisions	1/19/2011	
	Amendment Form	TEST EXPEDITED REVIEW MARCH 24 #5	Amendment Load, Load Att and Notes, Notify PI	11/22/2010	
	Amendment Form	Test Expedited Review August 11, 2010 #1	Error	10/20/2010	10/20/2010
	Amendment Form	Test Study - Expedited Review - March 31	Complete	8/23/2010	8/23/2010
	New Study Form	Test Expedited Review August 11, 2010 #1		8/11/2010	8/11/2010
	Continuing Review	TEST EXPEDITED REVIEW MARCH 24 #5		8/10/2010	8/10/2010
	Amendment Form	Expedited Study March 25 #1		8/10/2010	8/10/2010
	New Study Form	Test Expedited Submission August 10, 2010 #1	Review Form	8/10/2010	
	New Study Form	Test Expedited Review August 9, 2010 #1	Hold for Revisions	8/9/2010	
	Continuing Review	Test Study - Expedited Review - March 29 - #1	Complete	8/9/2010	8/9/2010

Figure 7.3

Left Menu - xForms

Main Page - xForms

Action	Form	Identifier	Stage	Started	Submitted
	New Study Form	Test Expedited Review - March 24 - #3	Hold for Revisions	4/1/2010	
	New Study Form	Test Study - Expedited Review - March 29 - #1	Expedited and Full Board Reviewer Form	3/29/2010	
	New Study Form	TEST EXPEDITED REVIEW MARCH 24 #5	Expedited and Full Board Reviewer Form	3/24/2010	
	New Study Form	Test Expedited Review - March 24 - #2	Error	3/24/2010	
	New Study Form	Test Expedited Review - March 24	New Study Load, Load Att and Notes, Notify PI	3/24/2010	
	New Study Form	Test - Expedited Review March 23	Expedited and Full Board Reviewer Form	3/23/2010	
	New Study Form	Test - Expedited Review March 23	Expedited and Full Board Reviewer Form	3/23/2010	
	New Study Form	Test - Expedited Review 2	Expedited and Full Board Reviewer Form	3/23/2010	
	New Study Form	Test - Expedited Review 2	Expedited and Full Board Reviewer Form	3/22/2010	
	New Study Form	Test Study Mar-01	Expedited and Full Board Reviewer Form	3/15/2010	
	New Study Form	testing revisions	New Study data entry	3/10/2010	
	New Study Form	Expedited Study Test #2	Expedited and Full Board Reviewer Form	1/28/2010	
	New Study Form	Test Study - Expedited 1	Expedited and Full Board Reviewer Form	1/7/2010	
	New Study Form	Ben test showing PI assurance page	Accept into IRBmanager	11/6/2009	
	New Study Form	test study for committee	New Study data entry	11/6/2009	
	New Study Form	test 3 expedited	Expedited and Full Board Reviewer Form	11/6/2009	
	New Study Form	New Test Expedited Study	Expedited and Full Board Reviewer Form	11/5/2009	
	New Study Form	Ben test showing newly submitted	Accept into IRBmanager	11/5/2009	
	New Study Form	Submission test 11/04/2009	New Study data entry	11/4/2009	
	New Study Form	abc	New Study data entry	8/20/2009	

20 completed xForms are Hidden

- d. After selecting “Start Form” from the left menu to initiate a new submission, you may print a copy of the form by selecting the printer icon or you may enter the xForm by selecting “**New Study Form**” in blue font. See Figure 7.4.

Figure 7.4

- e. While completing the xForm, follow the instructions provided. Other things to consider when completing a New Study xForm:
 - i. The PI and Student PI must have an IRBManager account before being listed under such roles on a study. See Section 2 for instructions on obtaining a new IRBManager account.
 - ii. Questions are asked in a variety of formats: short answer, check boxes, drop down menus, etc.
 - v. Section notes provide details and helpful information about what the question is asking, what to include, etc.
 - vi. Add a note allows the researcher to enter any special circumstances or notes that you want the reviewer to be aware of. This option may be useful for making revisions to a study / protocol. See Figure 7.5.

Figure 7.5

- vii. Options at the bottom of the screen will enable you to move through the form (Figure 7.6):
 - 1. **Previous** takes you to previous screen/question.
 - 2. **Next** will move you to the next question. If there is a required field you have not completed, the form will not advance. Your work will be saved after selecting Next.

- ### Figure 7.6

- viii. At end of the xForm, attach any additional documents required for IRB review (Figure 7.7). Examples may include, but are not limited to:
 1. Protocol Form (Link to current form available here also)
 2. Consent (Link to consent/assent templates available here also)
 3. Recruitment material
 4. Surveys
 5. Interview guide
 6. Chart review collection guide
 7. Grant Application

Figure 7.7

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f. Submission

- i. The submission page (Figure 7.8) requires reading and agreeing to each item followed by entering the submitter's password.

Figure 7.8

The screenshot shows the 'New Study Form -- Z. Assurances' page in the IRBManager system. At the top, there is a 'Submitted by:' section with fields for 'Test Investigator, UWM PhD', 'Email: UWM.TEST.INVESTIGATOR@GMAIL.COM', and 'Business: 800-555-5555'. Below this is section 'Z.1 As Principal and Student Principal Investigator, I certify the following: (Required)'. It contains a list of 11 items (a-k) with checkboxes, all of which are checked. To the right of the list is a note: 'All must be checked.' and a link 'Add Note'. Below section Z.1 is section 'Z.2 Entering your user password, you have read and understood the above assurances. (Required)'. It contains a password field with four asterisks and a note: 'To create valid signature, please enter password for uwmttestinvestigator on 6/25/2011'. To the right of the password field are links 'Add Note' and 'View Audit'. At the bottom of the form are buttons 'Previous', 'Next', and 'Save for Later'. The footer contains copyright information: 'Copyright ©2000-2011 BEC All Rights Reserved. Privacy & Security Statement | Terms of Use'.

- ii. The following screen will appear when the xForm has been submitted to the IRB. (Figure 7.9).

Figure 7.9

The screenshot shows the 'Form Submitted' confirmation screen in the IRBManager system. At the top, there is a header bar with the IRBManager logo and the date 'Saturday Jun 25 08:30 PM'. Below the header is a blue box with the text 'Form Submitted' and 'Your form has been submitted. You may close this window.' The footer contains copyright information: 'Copyright ©2000-2011 BEC All Rights Reserved. Privacy & Security Statement | Terms of Use'.

- iii. If someone other than the PI completes and submits the xForm, the PI will receive an email stating he/she needs to review and approve the submission in order to submit the study to the IRB for review. The email will contain a link to the xForm.
 1. After reviewing the xForm and attachments, The PI can save the review for later, print a copy, accept the study and submit to the IRB by entering the password in the "Submit" box, or send the xForm back to the student PI for revisions / corrections by completing the "Reject" box. (See Figure 7.10)

Figure 7.10

2. participant: inbox (1) | 1. data: irb: 102133 Created Study Re... | **Form Complete** | 1. data: irb: 102133 Created Study Re... | 1. data: irb: 102133 Created Study Re...

IRBManager

You've completed this stage of the form. You can now either save the form for later revision, submit it and let it continue to the next stage, or reject the form to an earlier stage.

Save For Later

Submit

Please enter your password:

Reject

Enter your reason for rejecting this stage of the form:

Select the stage for the form to continue at: ▼

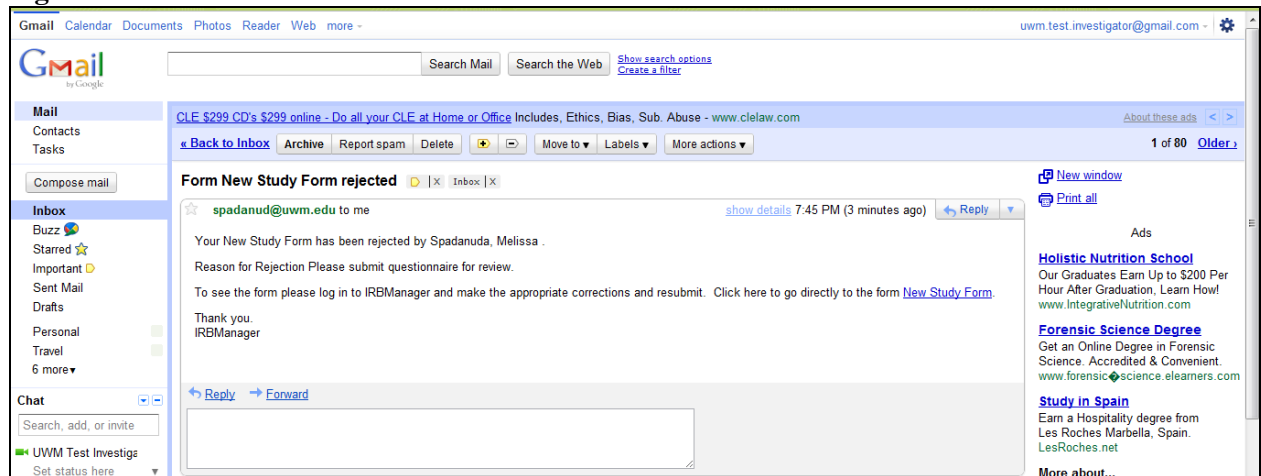
Copyright ©2000-2011 BEC All Rights Reserved.
[Privacy & Security Statement](#) | [Terms of Use](#)

-
- The screenshot displays a Gmail interface from 2010. The top navigation bar includes links for +Melissa, Gmail, Calendar, Documents, Photos, Reader, Web, and more. The main header shows the Gmail logo and search bars. The left sidebar lists various email categories like Mail, Contacts, Tasks, and a list of emails including 'A Disney Trip 2010' and 'Associated Bank'. The main content area shows an email titled 'Form New Study Form rejected' from 'UWM.TEST.INVESTIGATOR@gmail.com'. The email body states that the user's new study form has been rejected by the Test Investigator at UWM PhD. It provides a reason for rejection (questionnaire) and instructions to log in to IRBManager to make corrections and resubmit. A yellow warning banner at the top of the email text says 'This message may not have been sent by: UWM.TEST.INVESTIGATOR@gmail.com'. The right sidebar shows a profile for 'uwm.test.investigator' with a link to 'M.Ed. Online in 16 Months'.
- Figure 7.11**
- Figure 7.11 is a screenshot of a Gmail inbox. The top navigation bar includes links for +Melissa, Gmail, Calendar, Documents, Photos, Reader, Web, and more. The main header shows the Gmail logo and search bars. The left sidebar lists various email categories like Mail, Contacts, Tasks, and a list of emails including 'A Disney Trip 2010' and 'Associated Bank'. The main content area shows an email titled 'Form New Study Form rejected' from 'UWM.TEST.INVESTIGATOR@gmail.com'. The email body states that the user's new study form has been rejected by the Test Investigator at UWM PhD. It provides a reason for rejection (questionnaire) and instructions to log in to IRBManager to make corrections and resubmit. A yellow warning banner at the top of the email text says 'This message may not have been sent by: UWM.TEST.INVESTIGATOR@gmail.com'. The right sidebar shows a profile for 'uwm.test.investigator' with a link to 'M.Ed. Online in 16 Months'.

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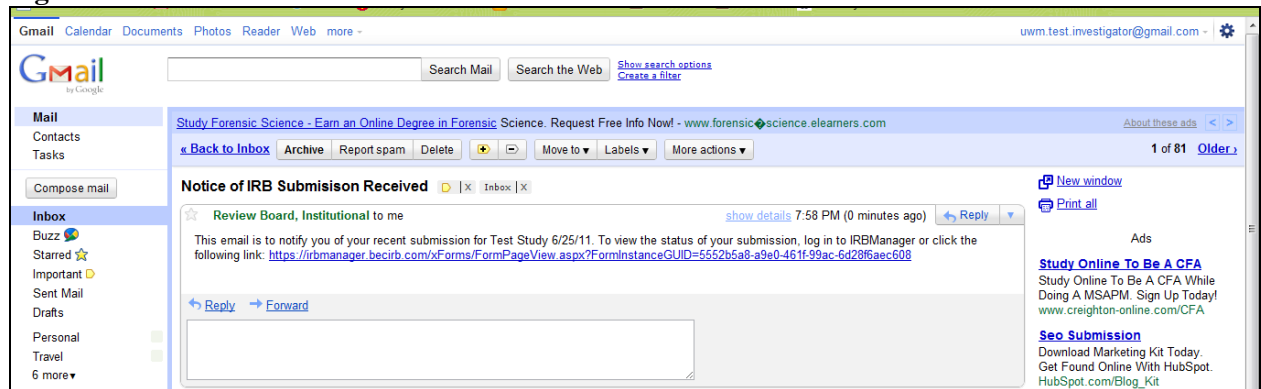
1. You can then re-open the x-form and complete the revisions. If additional explanation of the change is needed, please include comments by using “Add a Note” in the section of the requested revision.
2. After the changes have been made, you may resubmit as described in Section (f.)
3. Please note: If the student PI or other study personnel make the revisions, the PI will be required to approve the submission again before the IRB will receive it. The changes will be highlighted in yellow.

Figure 7.12



- vi. If the study is accepted by the IRB, the PI, Student PI and any others listed as primary contacts will receive an automated “IRB Submission Received” email notice (Figure 7.13) that includes a link to the study in IRBManager.

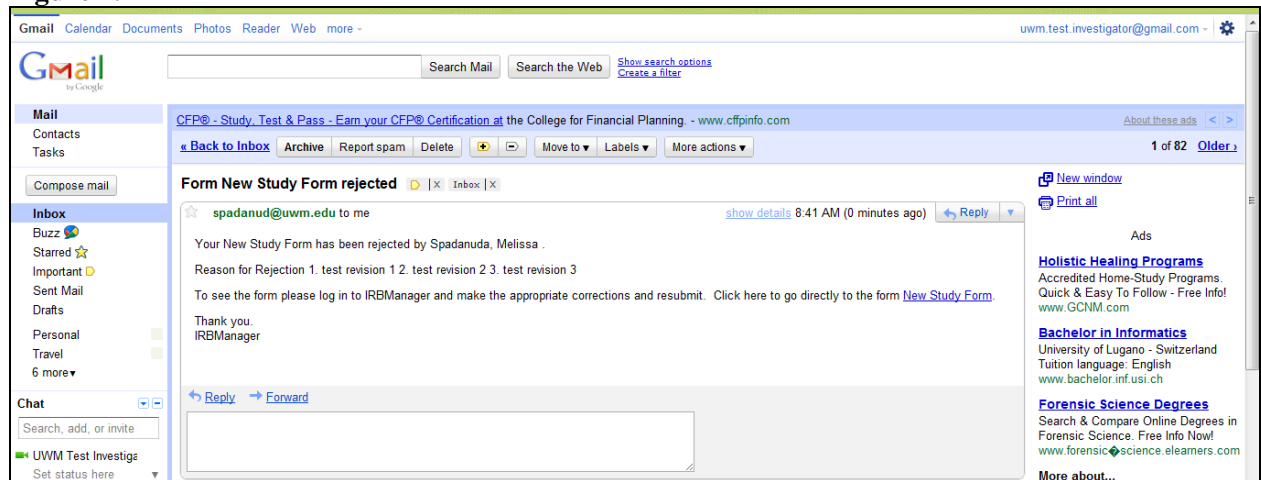
Figure 7.13



- ix. After the IRB accepts the study, it will be assigned an IRB number and viewable on your home page. See Section 5 (Study / Protocol Page) for details.
- x. The study will then be reviewed by the designated IRB member(s).

- xi. If revisions are requested after the IRB has accepted the study, the person that created the study will receive an email listing the requested revisions (see Figure 7.14). Return to the form by clicking on the link in the email. Please note: there will also be a requested revisions letter that can be found in the attachments section of the new submission event. Return to the form by clicking on the link in the email or from your IRBManager Home page under xForms in the lower left.

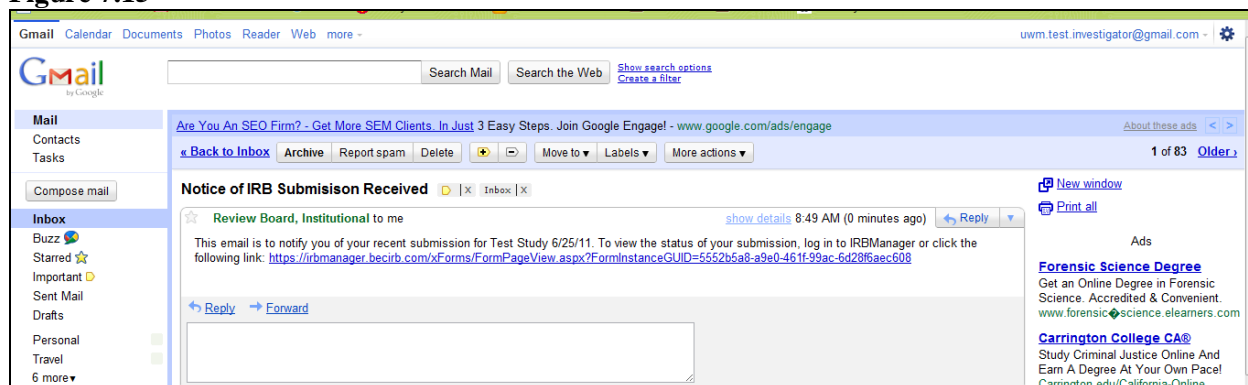
Figure 7.14



1. Re-enter the x-form and complete the revisions. If additional explanation of the change is needed, please include comments by using “Add a Note” in the section of the requested revision. See Figure 7.5.
2. If changes are requested on attached documents (such as a consent form, protocol form, recruitment flyer), update the applicable document (highlight, underline, or bold the changes) and reattach in the xForm with the version number.
3. Write a memo to address each change made and also attach this document to the xForm.
4. After the changes have been made, you may resubmit as described in Section (f.)
5. Please note: If the student PI or other study personnel make the revisions, the PI will be required to approve the submission again before the IRB will receive it. The section(s) with changes will be highlighted in yellow.

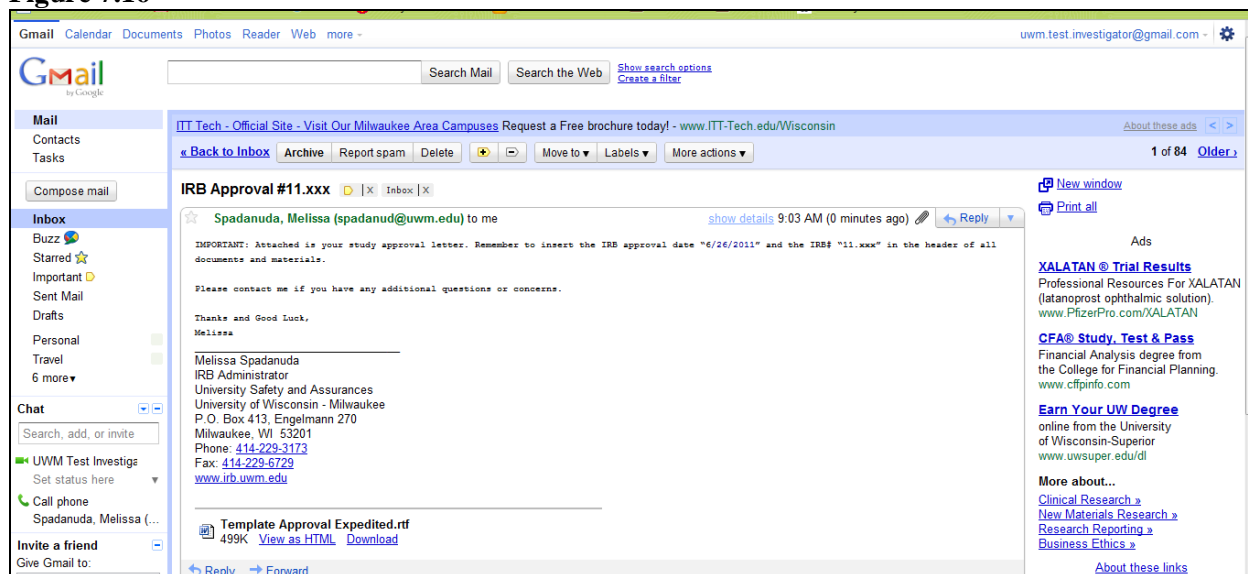
- vii. When the revisions are accepted by the IRB, the PI, Student PI and any others listed as primary contacts will receive an automated email notice (Figure 7.15) that includes a link to the study in IRBManager. If additional changes are requested again after IRB member review, you will receive another rejected study email listing the required changes. (Figure 7.12)

Figure 7.15



- xii. When the study is approved, the PI, Student PI and any others listed as primary contacts will receive a notice through email with the approval letter attached. (Figure 7.16) The approval letter will also be found in the attachments section of the new study event (see section 6.d.ii.2). You may now begin your human subject research.

Figure 7.16



8. Submitting a Continuing Review, Amendment or Reportable Event

- Return to your home page by clicking on the “Home” icon.
- In the center of the page, select the study number of the protocol needing a continuing review, amendment or reportable event (Figure 8.1).

Figure 8.1

Protocol Code	Site	Investigator	Study Title	Expires	Status
1209.3-HBSSW	Helen Bader School of Social Welfare	Test Investigator, UWM PhD	Exempt Test 4	Exempt	New From PI
1209.2-HBSSW	Helen Bader School of Social Welfare	Test Investigator, UWM PhD	New Exempt Submission Test 2		New From PI
1209.1-HBSSW	Helen Bader School of Social Welfare	Test Investigator, UWM PhD	Test New Exempt Submission #1		New From PI
1109.5-Psy	Psychology	Test Investigator, UWM PhD	test 3 expedited		New From PI
1109.4-Nurs	Nursing	Test Investigator, UWM PhD	Expedited Test 2		New From PI
1109.3-AUP	Architecture and Urban Planning	Test Investigator, UWM PhD	New Test Expedited Study		New From PI
1109.1-Nurs	Nursing	Test Investigator, UWM PhD	Test Study Chart Review 2	Exempt	New From PI
10.999-Nurs	Nursing	Test Investigator, UWM PhD	Testing create a study		Active Study
0810.3-UWM	UWM	Test Investigator, UWM PhD	Test Expedited Review August 11, 2010 #1	08/10/2011	New From PI
0810.2-UWM	UWM	Test Investigator, UWM PhD	Test Expedited Submission August 10, 2010 #1	08/09/2011	New From PI
0810.1-UWM	UWM	Test Investigator, UWM PhD	Test Expedited Review August 9, 2010 #1		New From PI
0809.10-AUP	Architecture and Urban Planning	Test Investigator, UWM PhD	training title test 1		New From PI
0710.7-UWM	UWM	Test Investigator, UWM PhD	Another Test July 27, 2010 Exempt #1		New From PI
0710.6-UWM	UWM	Egan, Claudia JD	Exempt Study Test 7/23/2010 #1		New From PI
0710.2-UWM	UWM	Egan, Claudia JD	Test Study 7/7/2010 #2		New From PI
0710.1-UWM	UWM	Test Investigator, UWM PhD	Test Study July 7, 2010 #1		New From PI
0611.1-UWM	UWM	Test Investigator, UWM PhD	Test Study 6/25/11	06/25/2012	New From PI
0610.6-UWM	UWM	Test Investigator, UWM PhD	Test Student PI Submission - Exempt June 17th #1	Exempt	New From PI
0610.5-UWM	UWM	Test Investigator, UWM PhD	Test Expedited Study June 17th - #1	06/16/2011	New From PI
0610.4-UWM	UWM	Test Investigator, UWM PhD	Another test study - Expedited June 15th - #1	06/14/2011	New From PI
0610.3-UWM	UWM	Test Investigator, UWM PhD	Another Test - June 11 #1 (Exempt)	Exempt	New From PI
0610.2-Psy	Psychology	Test Investigator, UWM PhD	Test Study June 7th #1	Exempt	Active Study
0410.7-Nurs	Nursing	Test Investigator, UWM PhD	Test Study April 16 #1		New From PI
0410.2-AUP	Architecture and Urban Planning	Test Investigator, UWM PhD	Test Expedited Review - March 24 - #3		New From PI
0410.1-Psy	Psychology	Test Investigator, UWM PhD	Test Study - Expedited Review - March 31	02/01/2012	New From PI
0311.2-UWM	UWM	Test Investigator, UWM PhD	Test Study March 31, 2011 - Expedited		New From PI

- From within the study’s protocol page, select “Start xForm” from the left menu (see Figure 8.2).

Figure 8.2

Protocol 0611.1

Protocol: 0611.1

Sponsor(s):

Category:

Sponsor Protocol:

Grants:

Next Review:

CRO:

Year:

Site: UWM - UWM

Status: New From PI

Approval: June 26, 2011 for 12 months

Initial Approval Date: June 26, 2011

Comments:

Agent Type: B. Interviews/Focus Groups , C. Questionnaires/Surveys

Study Title: Test Study 6/25/11

Investigator: Test Investigator, UWM PhD

Additional: N

Expiration: June 25, 2012

Additional Site Dates:

▼ Contacts for this Protocol Site (0)

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

▼ Attachments (0)

There are no attachments for this site.

▼ Events (1)

Action	Event	Att	FE	Instance/UED	Start	Complete	Primary	Secondary	Last IRB
	New Protocol Submission - Expedited	(4)		7	06/25/11		Not Displayed	Not Displayed	

▼ Notes (0)

There are no notes for this site.

- d. After selecting “Start xForm,” you may print a copy of a form by selecting the printer icon to the left or you may enter an xForm by selecting the form in blue font. See Figure 8.3.

Figure 8.3

- e. While completing the xForm, follow the instructions provided. Other things to consider when completing the form include:
- The PI and Student PI must have an IRBManager account before being listed under such roles on a study. See Section 2 for instructions on obtaining a new IRBManager account.
 - Questions are asked in a variety of formats: short answer, check boxes, drop down menus, etc.
 - Section notes provide details and helpful information about what the question is asking, what to include, etc.
 - Add a note allows the researcher to enter any special circumstances or notes that you want the reviewer to be aware of. This option may be useful for making revisions to a study / protocol. See Figure 8.4.

Figure 8.4

- v. Options at the bottom of the screen will enable you to move through the form (Figure 8.5):

Figure 8.5

IRBManager
Amendment Form -- Amendment Rationale

Next

B1. Explain the rationale for the proposed modification/ amendment below. (Required) Add Note

test test

B2. Explain how the new information (modification/ amendment) will be communicated to currently enrolled subjects? (Required) Add Note

test test

If currently enrolled participants are unaffected by the modification/ amendment or consent is not obtained from subjects, explain below.

- Example: The amendment is for a change in co-investigator who does not interact with the subjects.
- Example: The amendment is an administrative change and this study is an anonymous telephone survey.
- Example: The amendment is to revise the study design to include an additional intervention. The subjects will be re-consented at the time of their next study visit using the revised consent form which is being submitted for IRB approval along with this amendment request.

Previous Next Save for Later

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1. **Previous** takes you to previous screen/question.
 2. **Next** will move you to the next page. If there is a required field you have not completed, the form will not advance.
 3. **Save for later** allows you to save your work and return at a later time to complete. This option will take you out of the xForm. Incomplete xForms can be found by selecting xForms from the left menu on your HOME page. xForms will then be listed by date started (Figure 7.2 and 7.3).
- vi. At end of the xForm (see figure 8.6), attach any additional documents required for IRB review. Examples may include, but are not limited to:
1. Protocol Summary
 2. Consent
 3. Recruitment material
 4. Surveys
 5. Interview guide
 6. Progress Reports
 7. Approvals from other Institutions

Figure 8.6

IRBManager
Amendment Form -- Amendment Upload

Next

C1. Attach any supporting documents. Add Note View Audit

Add Attachment

No Attachments.

- If the amendment requires changes to the consent form or Protocol Summary Form, revise and attach them here.
- Use bolding or highlights to identify revised sections of the affected document.
- For example:
 1. Adding a new survey instrument may require revisions to the Protocol Summary Form and consent form identifying activities and duration of participation;
 2. Changing the payment compensation may require changes to the Protocol Summary Form, consent form, and recruitment flyers.

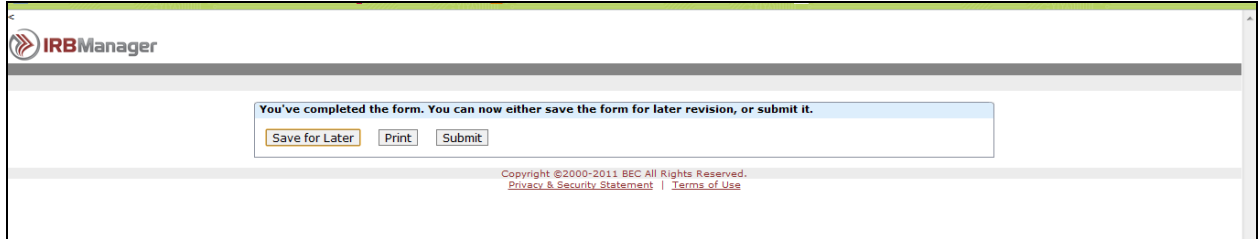
Previous Next Save for Later

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g. Submission

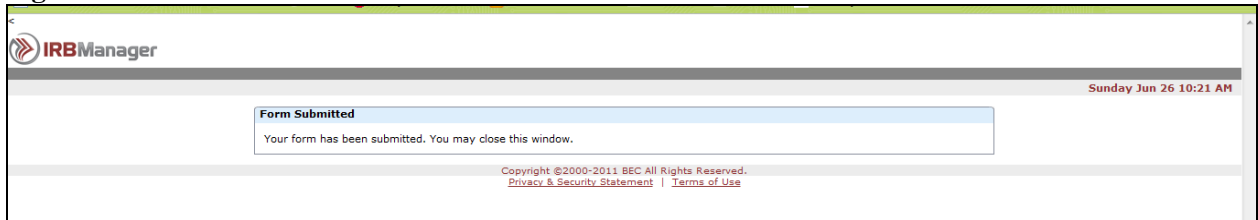
- i. The submission page (Figure 8.7) provides the choices of saving for later, printing the form, or submitting the form to the IRB.
- ii. If someone other than the PI completes and submits the xForm, the PI will receive an email stating he/she needs to review and approve the submission in order to submit the study to the IRB for review.
 1. Please note: The PI can send the study back to the Student PI (or other submitter) if he/she wants changes made. See 7.f.iii.

Figure 8.7

The screenshot shows the IRBManager web interface. At the top left is the IRBManager logo. A central message box states: "You've completed the form. You can now either save the form for later revision, or submit it." Below this message are three buttons: "Save for Later" (highlighted with an orange border), "Print", and "Submit". At the bottom of the page, there is a copyright notice: "Copyright ©2000-2011 BEC All Rights Reserved." followed by links for "Privacy & Security Statement" and "Terms of Use".

- iii. The following screen will appear when the xForm has been submitted to the IRB. (Figure 8.8)

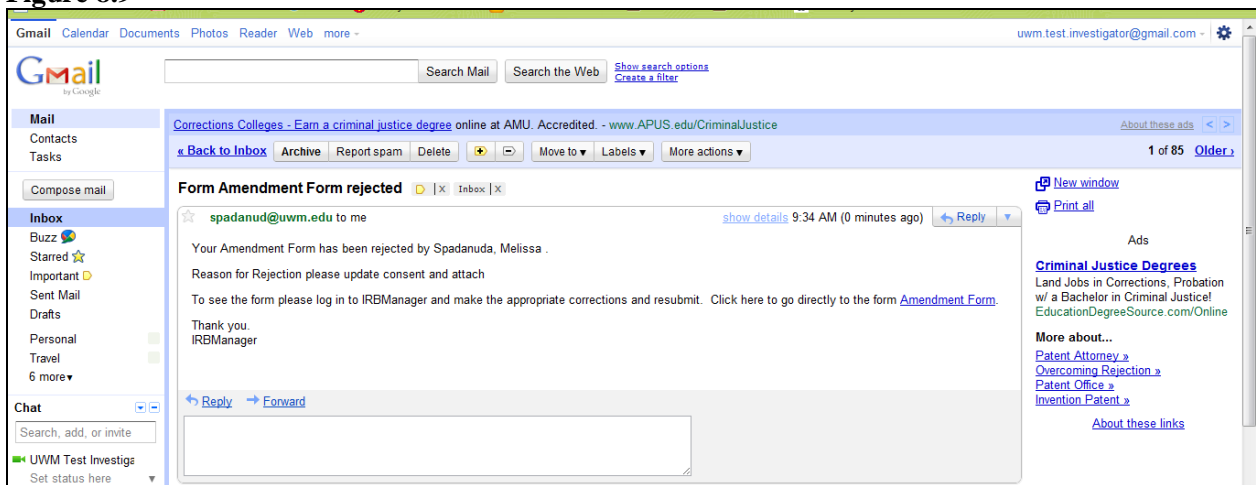
Figure 8.8

The screenshot shows the IRBManager web interface after a form has been submitted. The IRBManager logo is at the top left. In the top right corner, the date and time "Sunday Jun 26 10:21 AM" are displayed. A central message box titled "Form Submitted" contains the text: "Your form has been submitted. You may close this window." At the bottom of the page, the same copyright notice and links as in Figure 8.7 are present: "Copyright ©2000-2011 BEC All Rights Reserved." with links for "Privacy & Security Statement" and "Terms of Use".

- iv. Once the form is submitted to and accepted by the IRB, you will be able to view the form from your home page under xForms. However, you will not be able to make any changes to the form at this time. (Figure 7.2)

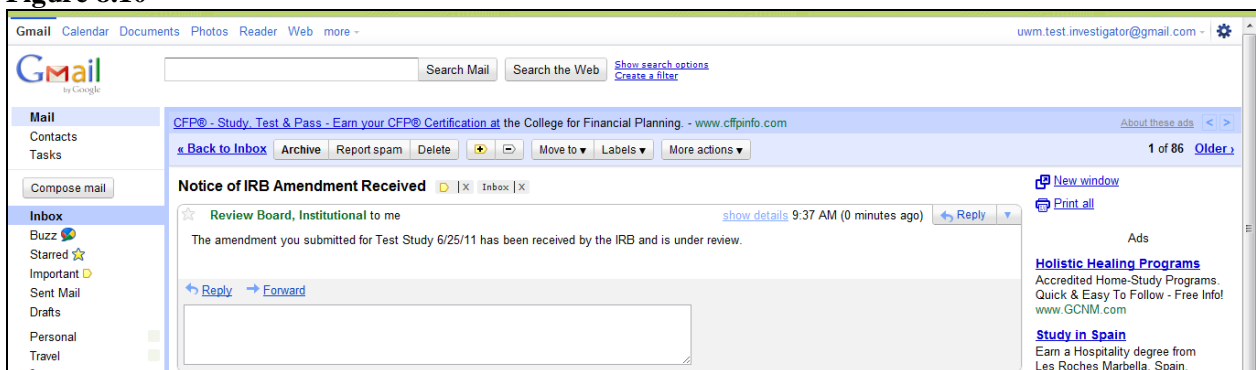
- v. If the IRB requests changes before accepting the xForm into the system, the person that created the study will receive an email listing the requested revisions. See Figure 8.9. Return to the form by clicking on the link in the email.
 1. Re-enter the x-form and complete the revisions. If additional explanation of the change is needed, please include comments by using “Add a Note” in the section of the requested revision.
 2. After the changes have been made, you may resubmit as described in Section (f.)
 3. Please note: The PI will be required to approve the submission again before the IRB will receive it. The changes will be highlighted in yellow.

Figure 8.9



- vi. If the study is accepted by the IRB, the PI, Student PI and any others listed as primary contacts will receive an automated “IRB Submission Received” email notice (Figure 8.10) that includes a link to the study in IRBManager.

Figure 8.10



- vii. After the IRB accepts the submission, it will be viewable on the study protocol page, under the events section (Figure 8.11)

Figure 8.11

The screenshot shows the IRBManager interface for Protocol 0611.1. The left sidebar contains navigation links like 'Actions', 'Recent Items', 'Messages', 'Useful Links', and 'My Documents & Forms'. The main content area displays protocol details, including 'Protocol-Site' information and a table of 'Events'. The 'Events' table is circled, showing two entries: 'Amendment Submission' and 'New Protocol Submission - Expedited'.

Action	Event	Att	FE	Instance/UED	Start	Complete	Primary	Secondary	Last IRB
	Amendment Submission	(0)		test amendment	06/26/11	Complete	Not Displayed	Not Displayed	
	New Protocol Submission - Expedited	(4)	7		06/25/11		Not Displayed	Not Displayed	

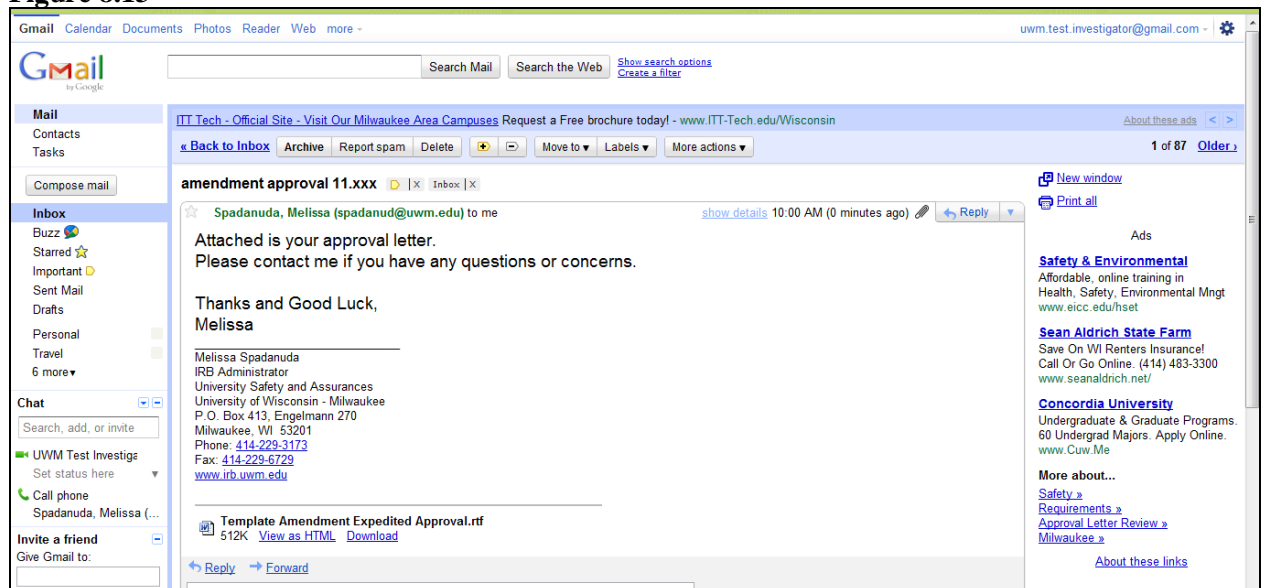
- vii. The study will then be reviewed by the designated IRB member(s).
- viii. If revisions are requested after the IRB has accepted the study, the person that created the study will receive an email listing the requested revisions (see Figure 8.12). Return to the form by clicking on the link in the email. Please note, there will also be a requested revisions letter that can be found in the attachments section of the new submission event. Return to the form by clicking on the link in the email.

Figure 8.12

The screenshot shows a Gmail inbox with an email from spadanud@uwmm.edu. The email subject is 'Form Amendment Form rejected'. The body text reads: 'Your Amendment Form has been rejected by Spadanuda, Melissa. Reason for Rejection please update consent and attach. To see the form please log in to IRBManager and make the appropriate corrections and resubmit. Click here to go directly to the form Amendment Form.' The email also includes a 'Reply' button and a 'Forward' button.

1. Re-enter the x-form and complete the revisions. If additional explanation of the change is needed, please include comments by using “Add a Note” in the section of the requested revision. See Figure 8.4.
 2. If changes are requested on attached documents (such as a consent form, protocol form, recruitment flyer), update the applicable document (highlight, underline, or bold the changes) and reattach in the xForm with the version number.
 3. Write a memo to address each change made and also attach this document to the xForm.
 4. After the changes have been made, you may resubmit as described in Section (f.)
 5. Please note: The PI will be required to approve the submission again before the IRB will receive it. The changes will be highlighted in yellow on the xForm.
- viii. When the revisions are accepted by the IRB, the PI, Student PI and any others listed as primary contacts will receive an automated email notice (Figure 8.10) that includes a link to the study in IRBManager. If additional changes are requested you will receive another rejected study email listing the required changes. (Figure 8.12)
- ix. When the submission is approved, the PI and student PI will receive a notice through email with the approval letter attached. (Figure 8.13) The approval letter will also be found in the attachments section of the new study event (see section 6.d.ii.2).

Figure 8.13



9. Collaboration – Instructions for Sharing xForms in IRBManager

You may now share an xForm with others during the writing/editing stage. Collaboration will allow a person other than the author of the form to edit, manage, and/or submit an xform. This option will allow other co-investigators or team members (with an IRBManager account) to assist the author of the form with reviewing, editing and/or submitting.

As an example:

Previously, a faculty PI was only able to review a student's xform after the student submitted it to the PI for "sign off." If the PI found an error or wanted a correction, the PI would need to "reject" the form back to the student for revisions.

NOW, the student can add the faculty PI as a collaborator and the faculty PI can review the form as the student works on it, make changes to the form, add attachments to the xform, and/or submit the form to the IRB. As soon as the student adds the PI as a collaborator, the PI will receive an automatic email with a link to the xform. In addition, the faculty PI will be able to find the xform in the "xForms awaiting your attention" section of his/her IRBManager Home page.

The author of a form can share access to an IRBManager xform by:

1. At the top of each page of the xForm, select "Collaborators."

The screenshot shows the IRBManager xForm interface. At the top, there is a navigation bar with the IRBManager logo and a 'Collaborators' button highlighted with a red circle. An arrow points from the 'Collaborators' button to the 'A. SECTION NOTES' section. The 'A. SECTION NOTES' section contains instructions for adding collaborators. Below this, there is a section for 'A1. Full Study Title' with a text input field and a 'Draft Form' watermark. The footer of the page includes copyright information and a page generation timestamp.

2. A new box will open:

Collaborators

Add

Email

Access

Note for collaborator

Current Collaborators

Action	Collaborator	Permission
	Spadanuda, Melissa	Author

AddCollaborator.aspx?fis=62dca2b1-f1dd-48b2-9ffb-5b747a073743

- a. Enter the email of the person you wish to share access to the form with.
 - b. Select the type of access you want the person to have:
 - i. Edit – This will allow the person to edit the form.
 - ii. Edit and Manage – This will allow the person to edit the form AND invite new collaborators.
 - iii. Edit, manage and submit – This will allow the person to edit the form AND invite new collaborators AND submit the study.
 - c. You may add text to the “Note for Collaborator” box and this information will be included in the automatic email that notifies the collaborator that they have access to the form.
 - d. Select the “Add” Box.
 - e. The collaborator will automatically be sent an email to notify him/her that he/she has access to the form. The email will include a link to the form. In addition, the collaborator can find the form in the “xForms awaiting your attention” section of his/her IRBManager Home page.
 - f. The list of current collaborators will be listed at the bottom of the box.
3. You may view, add or remove collaborators at any time by selecting the “Collaborators” link at the top of each page of the xForm.