UWM IRB Manager User Guide for Researchers
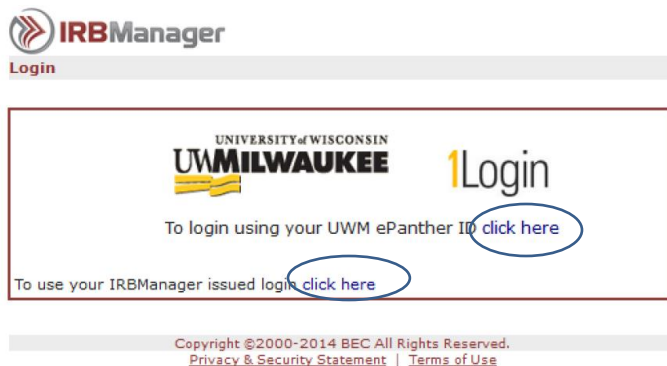
1. IRBManager
IRBManager is a web based IRB submission and management system. It allows researchers to securely submit their IRB submissions and maintain their entire IRB file online.

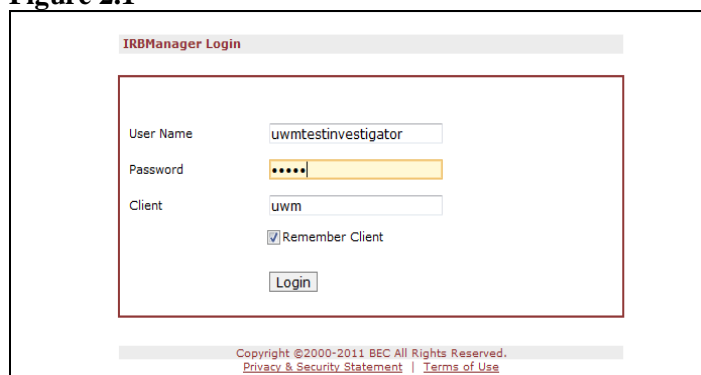## 2. Logging into your IRBManager Account

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

   2. To change you password at another time, select "UWM's Settings" from the upper right menu. (See Figure 3.2)

Figure 3.2

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

Figure 3.3

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.
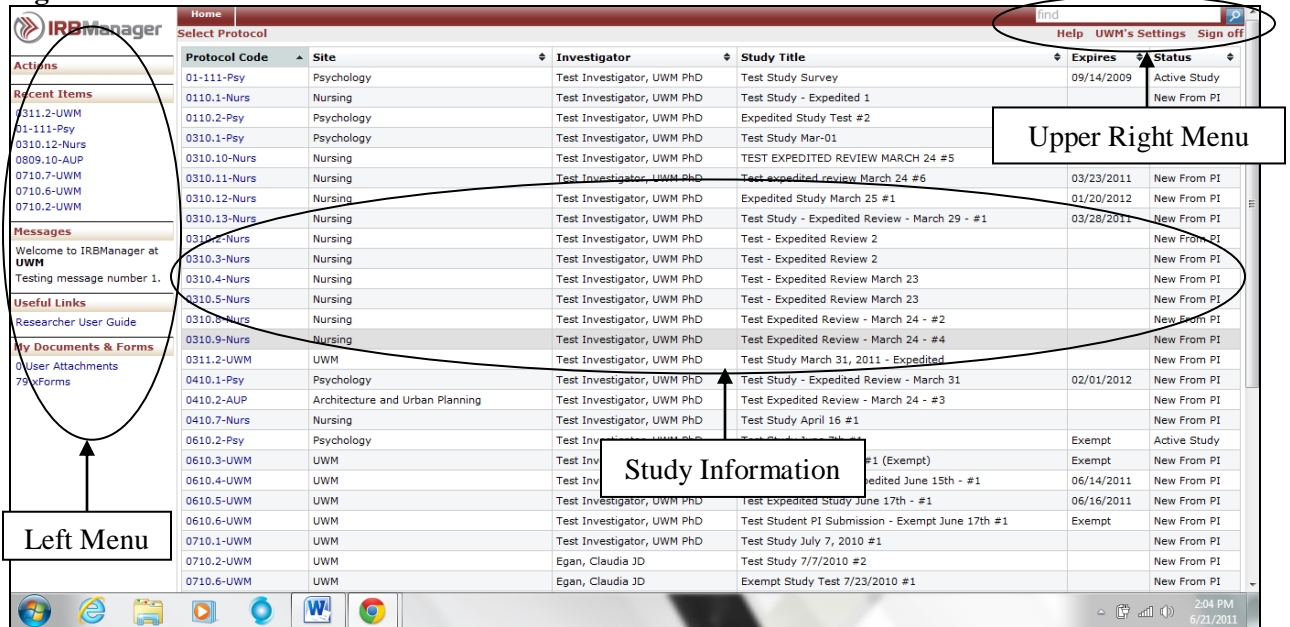
4. **Home Page**

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).
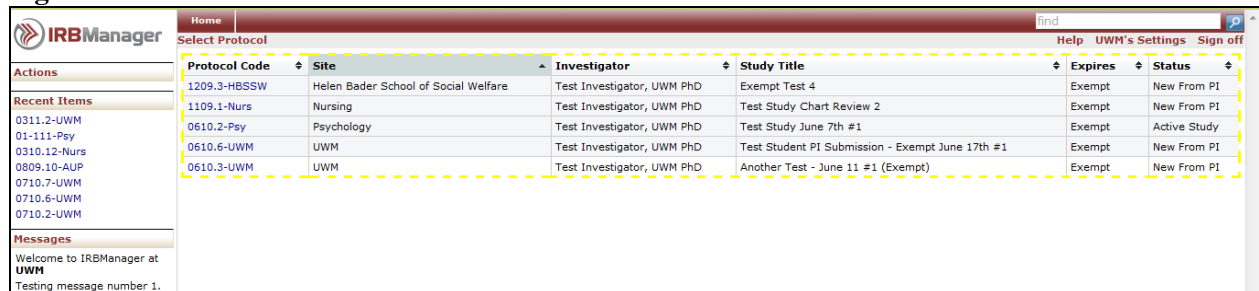
Figure 4.1

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

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

Home Page Button
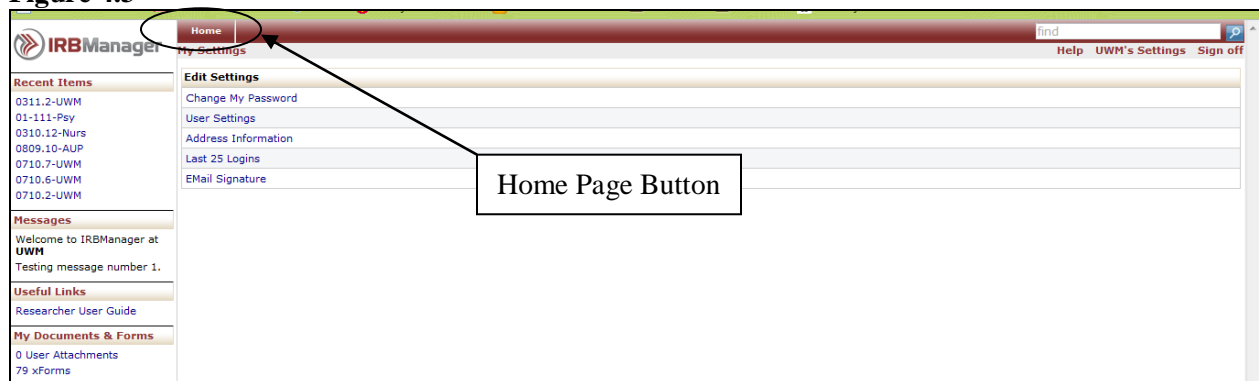
b. Click on "**Change my password**" to revise your current password. Figure 4.4 shows the change password screen.
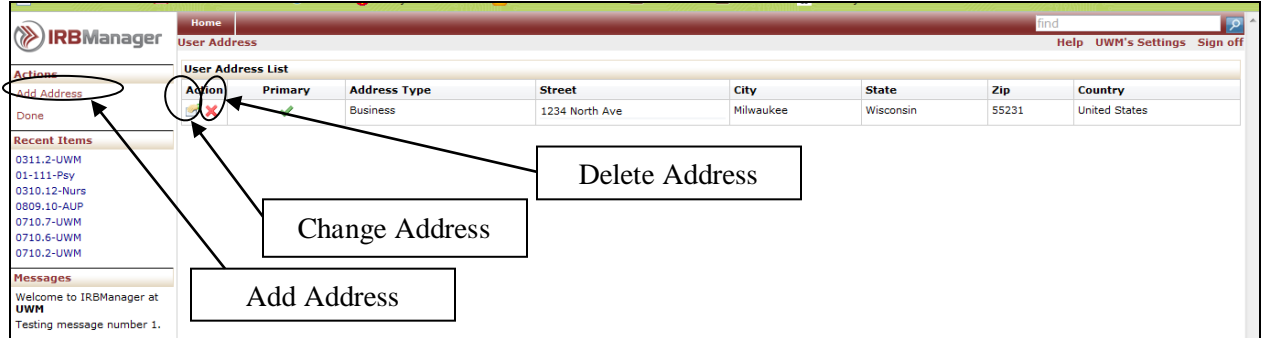
Figure 4.4

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

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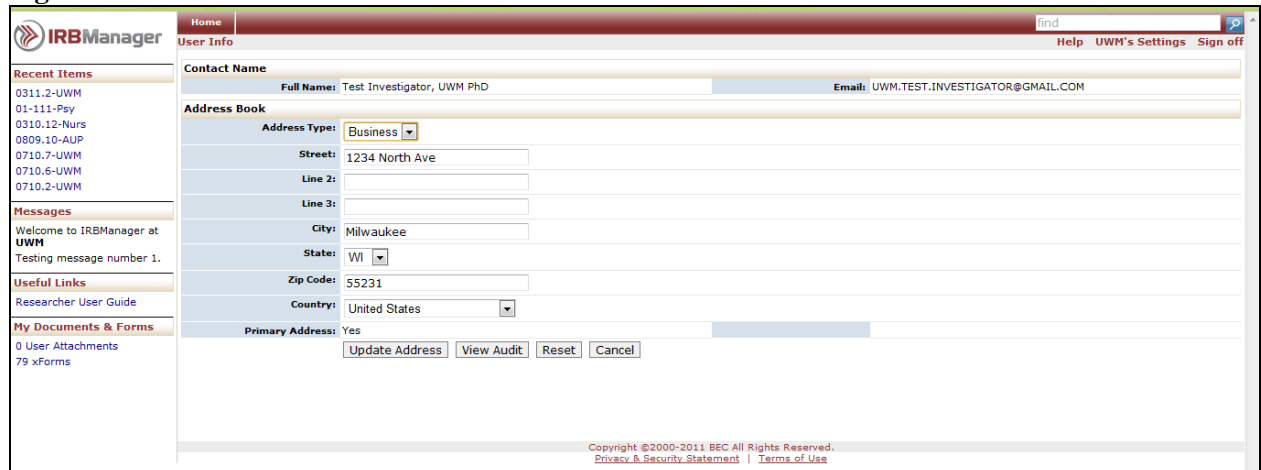
e. Click on "**Last 25 Logins**" to view your last 25 logins. As shown in Figure 4.8, the date, time, IP address and status of the logins will be viewable.

Figure 4.8

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

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

Study Number

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

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

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.
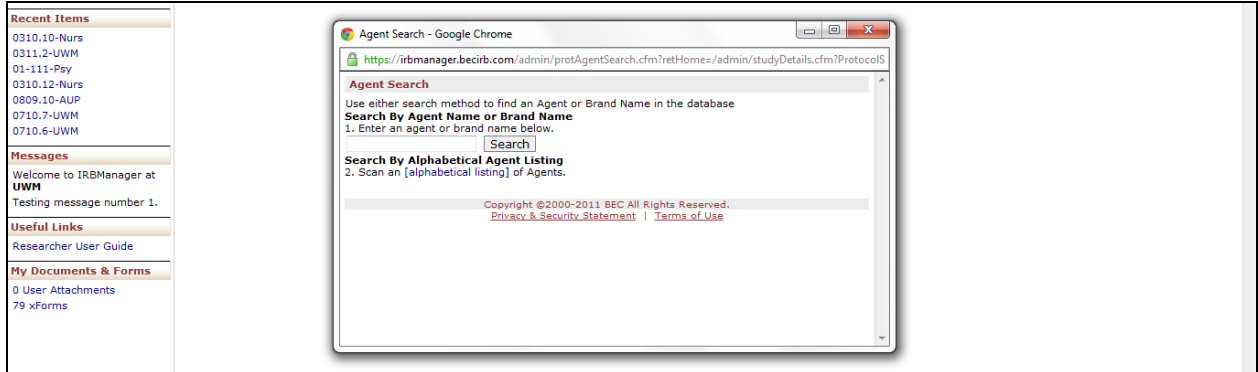
Figure 5.5
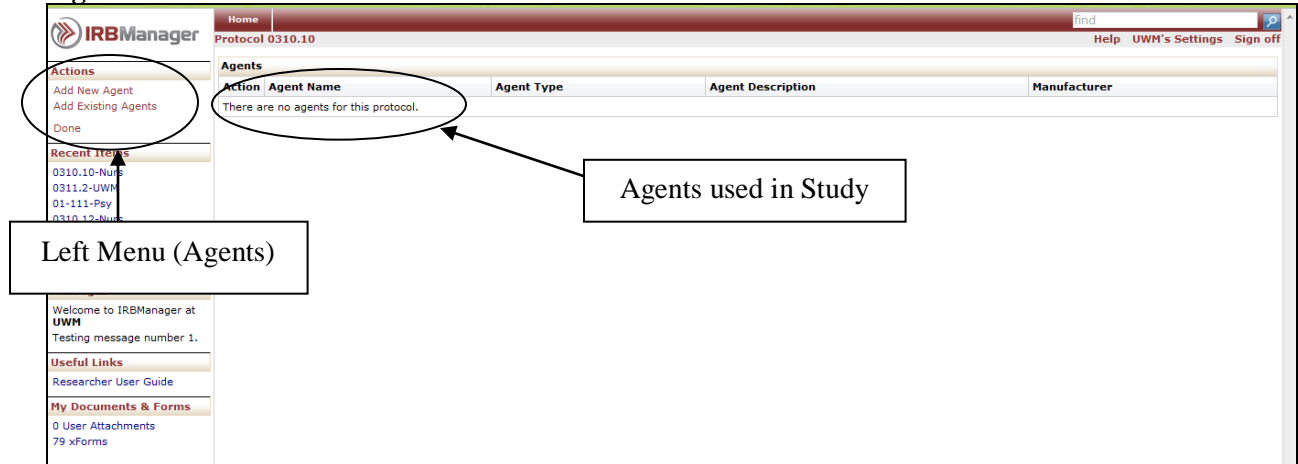
i. When adding a **new agent,** provide details about the agent such as the type of agent, manufacturer, IND or IDE number, etc. See Figure 5.6

Figure 5.6

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

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

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

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

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

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

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

Figure 7.1

c. In the xForms page (Figure 7.2)
   iii. The main page shows any xForms that have been created by the user.
   iv. The left menu has three options:
   1. **Start Form** – Select to initiate an xForm for a new submission (Figure 7.4).
   2. **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.
   3. **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

Figure 7.3

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.

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).

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

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

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

Figure 7.9

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. If the PI requests changes, the student PI will receive an email listing the changes with a link to the xForm (see Figure 7.11). After making the corrections the student PI will re-submit the xForm and the PI will receive another email requesting PI approval.

Figure 7.11

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

v. If the IRB requests changes before accepting the study into the system, the person that created the study will receive an email listing the requested revisions. See Figure 7.12. Return to the form by clicking on the link in the email.

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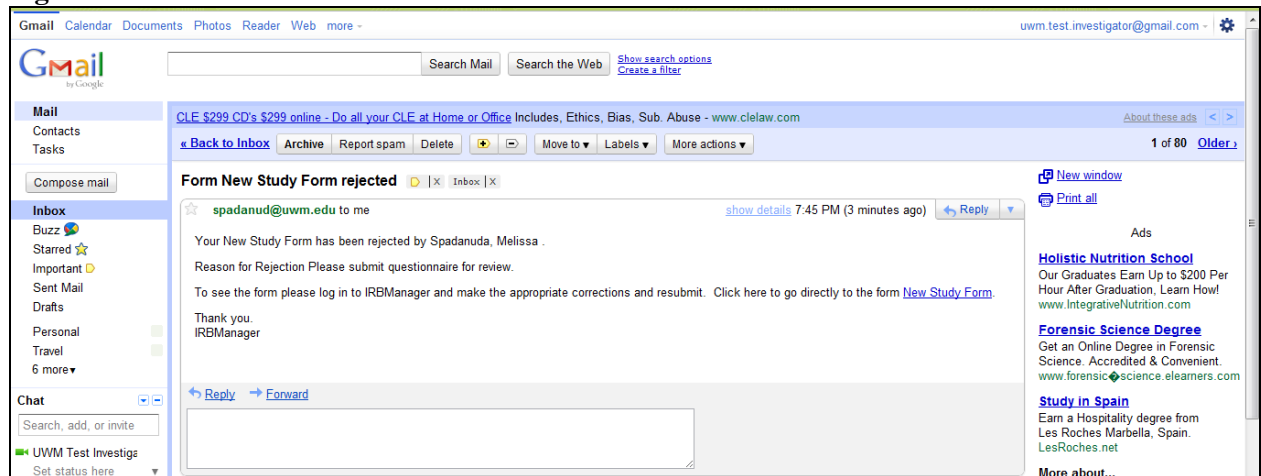
vi. If the study is accepted by the IRB, the PI, Student PI and any others listed as primary contacts will receive an automated "IRB Submission Received" email notice (Figure 7.13) that includes a link to the study in IRBManager.

Figure 7.13
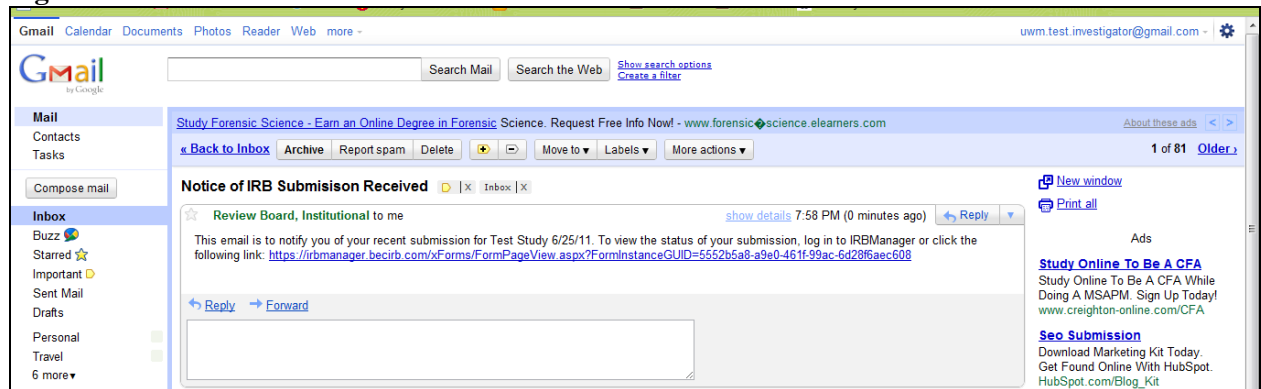
ix. After the IRB accepts the study, it will be assigned an IRB number and viewable on your home page. See Section 5 (Study / Protocol Page) for details.

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.
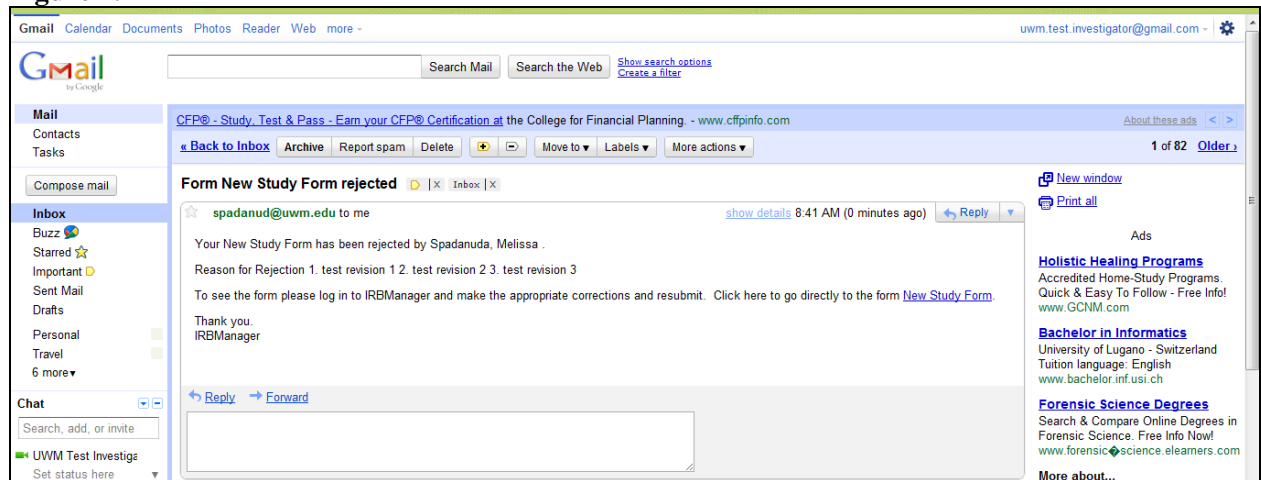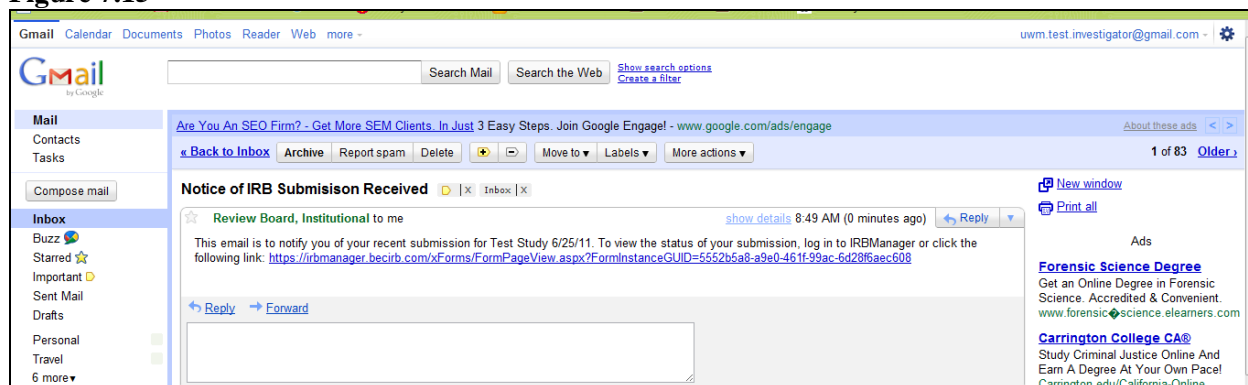
Figure 7.14

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
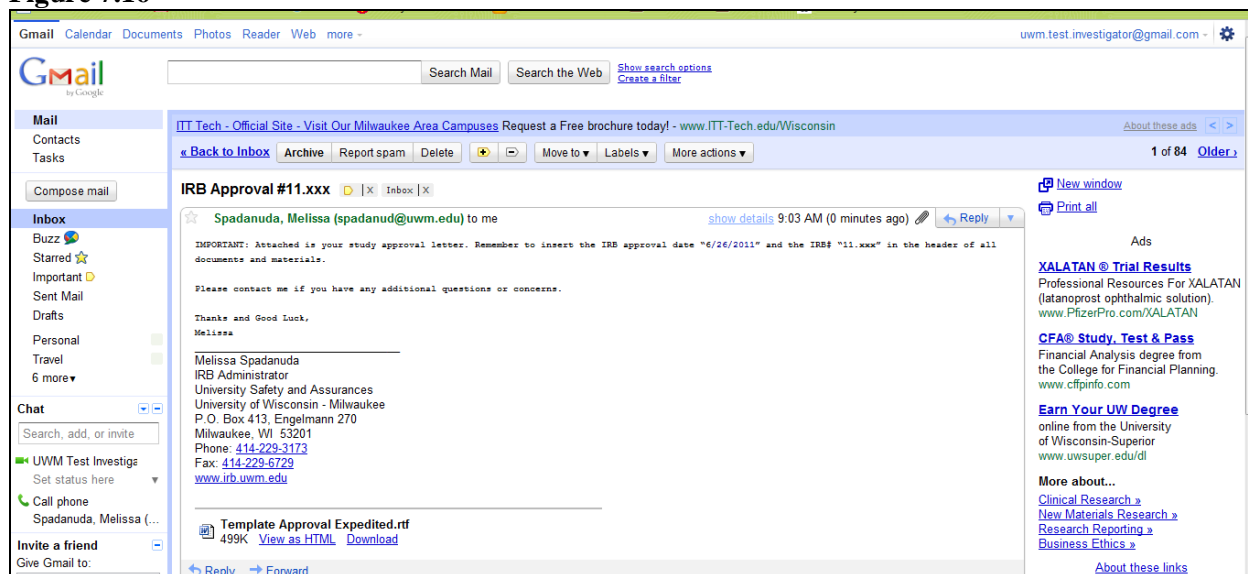
8. Submitting a Continuing Review, Amendment or Reportable Event

    a. Return to your home page by clicking on the "**Home**" icon.

    b. 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

    c. From within the study's protocol page, select "Start xForm" from the left menu (see Figure 8.2).

Figure 8.2

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:

  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.

  iii. Section notes provide details and helpful information about what the question is asking, what to include, etc.

  iv. 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

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

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

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

Figure 8.8

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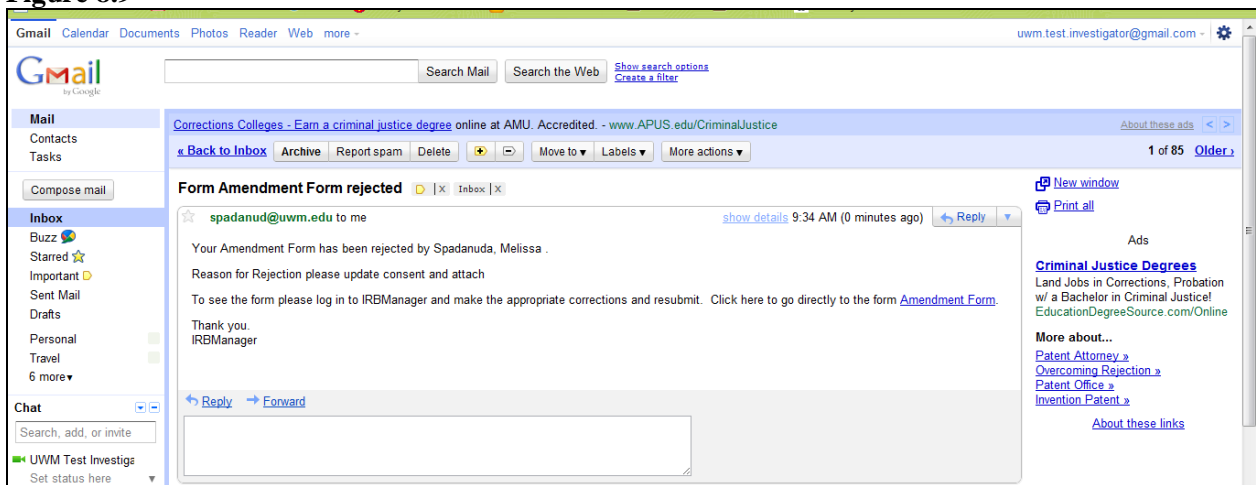
vi. If the study is accepted by the IRB, the PI, Student PI and any others listed as primary contacts will receive an automated "IRB Submission Received" email notice (Figure 8.10) that includes a link to the study in IRBManager.

Figure 8.10
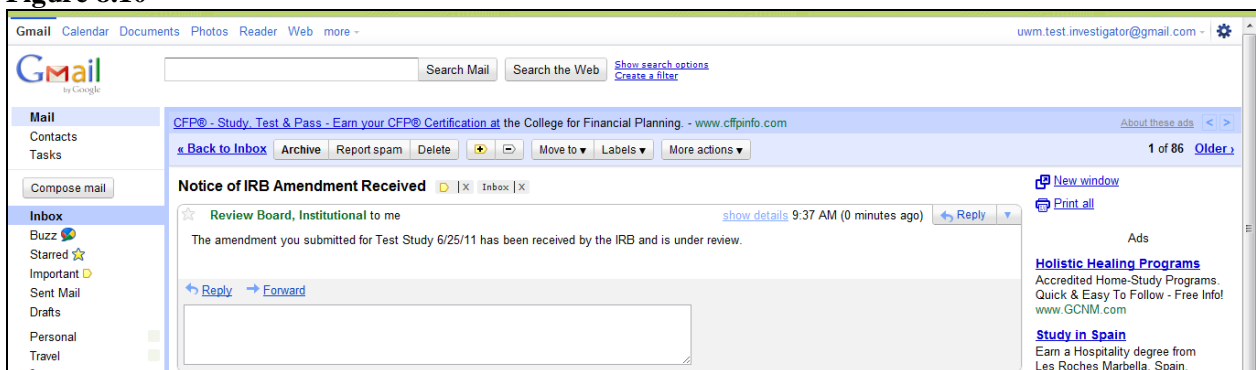
vii. After the IRB accepts the submission, it will be viewable on the study protocol page, under the events section (Figure 8.11)

Figure 8.11

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

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
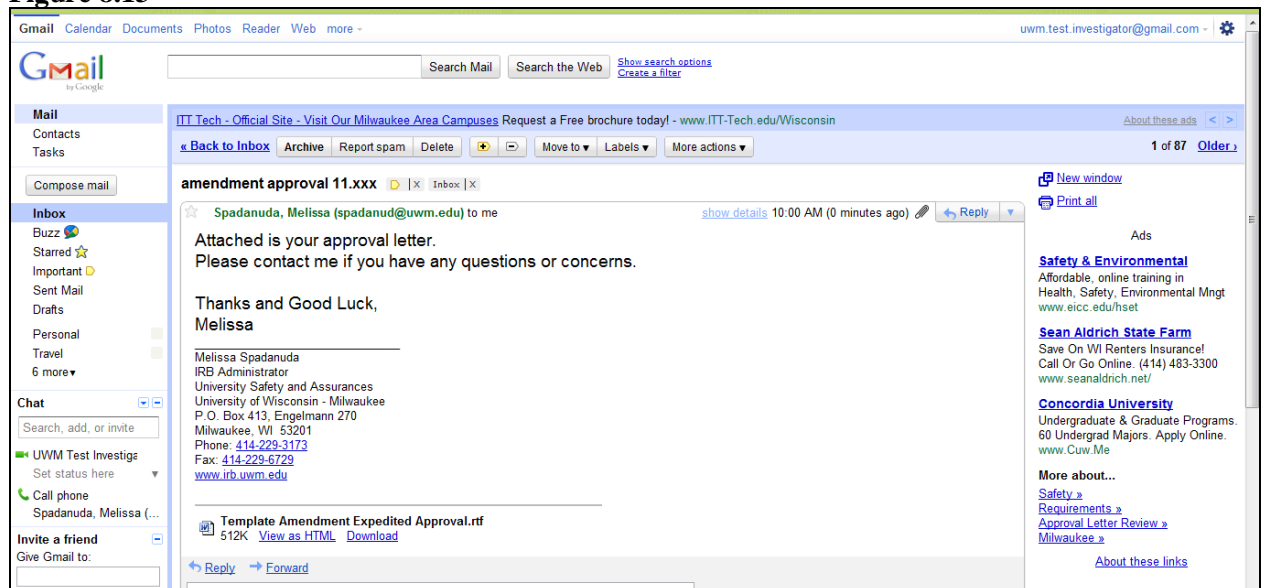
9. Collaboration – Instructions for Sharing xForms in IRBManager

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 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."

2. A new box will open:

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.