University of South Alabama
Office of Research Compliance and Assurance

IRBNet Guide

For Submissions to the:
Institutional Animal Care and Use Committee (IACUC)
Institutional Biosafety Committee (IBC)
And the
Institutional Review Board (IRB)
Preface

This guide is intended to serve as a roadmap for faculty, staff, students, and community members who either serve a role on an institutional committee or are involved in research activities governed by these committees.

This guide is broken up in sections. The first four sections are grouped by roles: researcher, mentor, key personnel (protocol associates), and reviewers (committee members). These sections cover the topics most pertinent to each given role. Because of this, there are both some topics not covered in each section and some topics which are repeated in multiple sections. The subsequent section provides visual aids to both prepare individuals for the process and illustrate the necessary steps to utilize IRBNet for protocol, amendment, and monitoring submissions.

This guide was authored by performing a step-by-step walkthrough of each task and recording the procedures. Under this design any individual in any role should have a detailed guide covering their respective needs on IRBNet. We hope that this will serve a powerful foundation and reference for both current and future researchers. Please feel free to contact us with any questions or comments; contact information is provided below.

Office of Research Compliance and Assurance (ORCA)

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If unable to reach any of the above:

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The Title of each section is a link to the section. Also, this PDF utilizes bookmarks for your convenience; use of these varies depending on your PDF reader.

If Acrobat, access to bookmarks are grant through the blue-ribbon at the upper-left of the page.

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Guide for Researchers

This guide is intended to be a step-by-step walkthrough for Researcher.

New User Registration: Registering for IRBNet

1. Click: New User Registration (unless you have already created a user name and password).
2. Enter your legal first and last names in the appropriate fields. (Please use appropriate capitalization as you register into the system; the system does not always alphabetize names that begin with lower-case letters.)
3. Create your User Name and Password; confirm your password, and enter a password hint.
4. Click: Continue.
5. Accept the Terms of Use.
6. On the next screen, type “South Alabama” in the “Search for an organization” field and click “Search” OR scroll to and select “University of South Alabama” and the respective board for which you intend to submit (Institutional Review Board (IRB), Institutional Biosafety Committee (IBC), or Institutional Animal Care and Use Committee (IACUC) from the list on the screen.
   NOTE: If you are also serving as a mentor, please contact the IRB Administrator for additional instructions.
7. Click: Continue.
8. On the next screen, enter your telephone number and email address; click: Continue.
9. On the final screen, click Register.
10. You will receive an email from IRBNet with a link that you need to click in order to activate your account. Your name will appear on USA’s list after you activate your account.
**My Projects: Accessing Submissions/Projects**

1. Log into IRBNet: (www.irbnet.org)
   (If you are also a committee member, “Submission Manager” will open, but select My Projects from the menu of options at the left of your screen.)
3. All Projects will appear on this page. To remove old or unneeded Projects, you may choose to Archive Projects (click , as seen in screenshot above). To see archived projects simply click Show Archived Projects.
4. You can access Reminders about specific Projects by clicking the ¬ or going to the Reminders menu item in the Left Navigation Pane.
5. By clicking here, one can open a Project for more information or editing, by clicking on the title that appears in blue font.

**Project Overview: Project Information (see screenshot below)**

1. Once you have selected an existing Project, you are taken to the Project Overview page.
2. Here you will find information specific information about the Project. This includes Status and Sharing details.
3. To access the documents associated with the Project, you must access the Designer from this page.

**Create New Project: Beginning a New Project (see screenshot below)**

1. If you want to start a new project, select Create New Project from the Left Navigation Pane.
2. Now you are on the Project Information page.
3. Here you will enter information about this new Project. This includes Title, PI Name, and any keywords, etc.
4. When finished, click Continue. This will take you to the Designer.
Designer: Adding/Editing Information (see screenshot below)

1. On the Designer page, there are two states: Existing (documents attached) and New (no documents attached). These will display either with the list of existing documents or without-see screenshot below). To make this simple, this guide will separate the Designer page process into New Project Designer and Amendment/Modification Project Designer. In reality this is the same page.

New Project Designer: Adding Information

1. In Step 1, you may download any committee specific forms which are required. This will be based upon your committee (IACUC, IBC, or IRB) and review type (exempt, expedited, full board, etc.).
2. These forms should be filled out and saved on your PC for upload during Step 2.
3. In Step 2, there are components: Linking Training Documentation and Adding New Documents (see screenshot in screenshot above).
4. To Link Training Documentation click Link/UnLink Records. This will take you to a linking page with all the Training and Credentials for everyone who is Shared on the project (including self) loaded to your IRBNet user profile (THIS IS REQUIRED; see this section of the guide).
5. Simply check the boxes of the documentation which you want to attach and select Save (see screenshot below).
6. To add the on-line documents and the ones you downloaded and filled out earlier, click Add New Documents.

7. You are now on the Attach Document page, where you have two tools (see screenshot below).

8. **We recommend utilizing the On-Line Document tool, (lower blue box) first.** This is your more basic required information. Here, you must select the appropriate document for your committee. **Be Aware that IBC and IACUC share the same On-Line Document, but IRB has a separate On-Line Document.** Once the proper document is selected, click Add.

9. Now you are given the choice to “clone” a previous Online Document or to create a new one. Cloning will save you time by already filling in all the information from a previous submission. However, you MUST review all fields to ensure they are correct for the current study. It is likely that some fields will require revisions.

10. Now you are on the IRBNet Document Wizard page. This is a series of questions and instructions which will guide you in the process of providing the necessary information about the characteristics of your project.

11. You may navigate these pages through the Save & Exit, Preview, and Next buttons. Once you have made progress within this tool you can use the Jump to: drop-down to move between sections (see screenshot below).
12. Once complete, the **Wizard** will generate a PDF file and automatically attach it to the Project. It will return you to the **Designer** page.

13. You must then select **Add New Documents** to return to the **Attach Document** Page to now add you previously downloaded and filled-out forms.

14. Now, you will use the **Attach Document** tool in the upper blue box. First, select the **Document Type**. If unsure, please see the Table at the end of this section as a guide for choosing the correct type. Then enter a brief **Description** to help you identify this document for later use. The click Choose File, to locate it on your PC.

15. Once selected, click **Attach**. You will then be taken to the **Designer** page.

16. Please repeat this process attaching all the necessary paperwork for your committee and review type.

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**Amendment/Modification Project Designer: Adding/Revising Information**

1. From **My Projects**, choose a package you want to edit.

2. From the **Designer** page, you may edit documentation or add new documents to the existing project.

3. To edit documentation, select the pencil (♡) (on the **Designer** page) from the line of the document you wish to edit. This will take you to a **Package is Locked** screen (see screenshot).

4. To add documentation, select the **Add New Document** button at the bottom of the page. This will take you to a **Package is Locked** screen (see screenshot).
5. On the **Package is Locked** page, you are warned that the package is locked and you must contact an administrator to unlock it. Unlocking will only be authorized on packages which have **NOT** been reviewed. In this case, use the **Send Project Mail** menu item in the Left Navigation Pane to send request to the committee administrator. To **MODIFY** or **AMEND** a protocol/package, you must select to **Create New Package** from this screen. This is important because your modification/amendment must be connected to your previous protocol/submission.

6. Once you select **Create New Project**, you will be taken to the **Designer** page for the new project. This page will have your previous documents and the option to add additional documents (see screenshot below with both previous and new documents).
7. For Modifications/Amendments, please edit the appropriate documents.
   A. If the document was generated from an **On-Line Document** wizard, selecting to edit the document will return you to the wizard with the answers as you previously answered them. When complete, the new document will automatically be attached to this package.
   B. If the document was a Downloaded Document, that you downloaded, filled-out, and then uploaded, you will be able to download it, edit it and re-upload it to the package.

8. If you are editing your package as a result of a **committee request** for clarification/modification, you MUST also upload a Clarification/Modification Response Memo to this package. This memo should reflect a response to each of the specific points discussed in your clarification/modification required memo provided to you from the committee. (This is unnecessary for Amendments at the request of the researcher.)

9. If your Modification/Amendment includes the addition of **protocol associates**, then you must Share (see section below) this package with them. **Link** their Training/Credentials Documentation to the Project prior to **Signature** and **Submission**.

10. Please Sign and Submit.

**Annual Monitoring: IRBNet & PI Initiated Review**
1. Once you receive an IRBNet **Reminder/Message/Alert** stating that it is time for your protocol’s annual review, you should perform the following steps ASAP.
   2. From **My Projects**, choose a relevant package requiring Monitoring.
   3. From the **Designer** page, you will add a new documents (IACUC Monitor Form from the PI Library) to the existing project.
   4. Once this form (and any additional documents if needed) have been added to the package, please **Sign** and **Submit** to your committee.

**Sharing the Package: Who and How**
1. **Sharing** the package with your protocol associates and anyone who must sign it is **MANDATORY** since this is how they will link training to your package.
   2. To do this, first you must select a project from the My Projects page (see instructions above). Then, select **Share this project** from the Left Navigation Pane.
   3. The **Share Project** page will have a description of the three types of Sharing: **Share**, **Multi-site**, and **Transfer** (see screenshot below). Below the descriptions is a list of personnel who currently have Share access to the package.
   A. For the purposes of protocol associates and signatories, **Share** is the option you will choose.
   B. If you believe that you have the need to utilize **Multi-site** or **Transfer**, please contact ORCA for assistance.

   ![Share Project screenshot](image-url)

   4. Once you choose **Share**, you will be taken to another screen where you will select the organization (University of South Alabama should be pre-selected). Once chosen, click **Select Organization**.
   5. From the next screen you can search for the users you wish to share with. **DO NOT** forget to...
include your department head and all protocol associates.**

6. Once selected, you can choose the Access levels (listed below in sequence of progressing permissions). It may be wise to do this in more than one step, so that you may add different comments to your protocol associates than your department head (see #7 below).

   A. **Signature Only**- This access allows users to view, communicate, and Sign ONLY. This is the level your department head and any administration oversight should be granted. **Read**- This access allows all of the above permissions, but should be used for individuals with a more regular role on the project.

   B. **Write**- This access allows a user all permissions EXCEPT adding other users or submitting the package.

   C. **Full**- This access denies the user no permissions.

7. You may add Comments at the bottom of the page. These comments will be in the body of the notice sent to each user when you select Save. Here you might want to say, “Please link training to package” or “Please review and sign”; whichever is appropriate.

8. Once you click Save, you will be returned to the Share Projects page.

**Signing the Package: Who is required and How to do it**

1. First it is important to note that all signatory agents must have an IRBNet user profile and be granted at least **Signature (read only) Access** to the project from the Sharing screen.

2. Since protocol submission and amendment is handled electronically, the signature tool is utilized to recognize that the appropriate individuals have reviewed, endorsed, and/or support the project. This is Mandatory.

3. No matter to which committee the application belongs, it must be signed by the submitting Investigator, the respective Department Head (please Share it with them and notify them via phone, email, etc. that a package requires signature), and the Mentor (if it is a student application-please Share it with them and notify them via phone, email, etc. that a package requires signature). Additional signatures may be required based upon study type, location, or parameter or by your committee’s request.

4. Now, choose **Sign this Package** from the Left Navigation Pane. This will take you to the Sign Package page.

5. Read the statement, select the appropriate role in the drop-down box (see screenshot below), and if agreed, select the Sign button.

6. If you are authorized to sign on the behalf of another party, you can choose the **Designee Sign Mode** option by clicking the blue font towards the bottom of this page (see screenshots below).

7. In this case, you must designate who you are signing in place of immediately after you choose his/her role on the project. The Designee Sign option should be used with discretion.

**Submitting the Package: The final step**
1. Once package is complete and ready for submission (**MUST BE SIGNED BY ALL PARTIES**), choose **Submit this Package** from the Left Navigation Pane.

2. On the **Submit Package** page, you must select the proper institution and committee. At USA you must choose between the following (see screenshots below)
   - University of South Alabama Institutional Animal Care and Use Committee (IACUC)
   - University of South Alabama Institutional Biosafety Committee (IBC)
   - University of South Alabama Institutional Review Board (IRB)

3. Once the committee is chosen, select **Submit**. On the next page (screenshot below), you must choose the **Submission Type**, add **Comments** (if desired), then click **Submit**.

4. You may submit the package to multiple committees, if pertinent, but each submission must be done one at a time. Once one is complete, start the process again by choosing **Submit this Package** from the Left Navigation Pane again.
Guide for Mentors/Signatories

This guide is intended to be a step-by-step walkthrough for Mentors or other agents that simply need to review and sign off on a Project.

New User Registration: Registering for IRBNet

1. Click: New User Registration (unless you have already created a user name and password).
2. Enter your legal first and last names in the appropriate fields. (Please use appropriate capitalization as you register into the system; the system does not always alphabetize names that begin with lower-case letters.)
3. Create your User Name and Password; confirm your password, and enter a password hint.
4. Click: Continue.
5. Accept the Terms of Use.
6. On the next screen, type “South Alabama” in the “Search for an organization” field and click “Search” OR scroll to and select “University of South Alabama” and the respective board on which you serve (Institutional Review Board (IRB), Institutional Biosafety Committee (IBC), or Institutional Animal Care and Use Committee (IACUC) from the list on the screen.
   NOTE: If you are also serving as a mentor, please contact the IRB Administrator for additional instructions.
7. Click: Continue.
8. On the next screen, enter your telephone number and email address; click: Continue.
9. On the final screen, click Register.
10. You will receive an email from IRBNet with a link that you need to click in order to activate your account. Your name will appear on USA’s list after you activate your account.

Sample Screenshot of My Projects
**My Projects: Accessing Submissions/Projects**

1. Log into IRBNet: [www.irbnet.org](http://www.irbnet.org)
2. The **My Projects** page will appear.  
   (If you are also a Member, “Submission Manager” will open, but select My Projects from the menu of options at the left of your screen.)
3. You should receive a message through IRBNet indicating that a project has been **Shared** with you.  
   The PI may choose to include additional comments or not.
4. All Projects which are **Shared** with you will appear on this page.  To remove old or unneeded Projects, you may choose to **Archive Projects** (click ![archive](archive.png), as seen in screenshot above).  To see archived projects simply click **Show Archived Projects**.
5. You can access **Reminders** about specific Projects by clicking the ![reminders](reminders.png) or going to the **Reminders** menu item in the Left Navigation Pane.
6. You can open a Project for more information, by clicking on the title that appears in **blue font**.

**Project Overview: Project Information (see screenshot below)**

1. Once you have selected an existing Project, you are taken to the **Project Overview** page.
2. Here you will find information specific information about the Project.  This includes **Status** and **Sharing** details.
3. To access the documents associated with the Project, you must access the **Designer** from this page.

**Sample Screenshot of Project Overview**

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**Designer: Viewing Information (see screenshot below)**

11. From the **Designer** page, you may view all documentation.
12. To view documentation, select the page ![page](page.png) (on the **Designer** page) from the line of the document you wish to view (see screenshot).  This will download the document (most are in PDF format).
8. Since protocol submission and amendment is handled electronically, the signature tool is utilized to recognize that the appropriate individuals have reviewed, endorsed, and/or support the project. This is Mandatory.

9. No matter to which committee the application belongs, it must be signed by the submitting Investigator, the respective Department Head, and the Mentor (if it is a student application). Additional signatures may be required based upon study type, location, or parameter or by your committee’s request.

10. First it is important to note that all signatory agents must have an IRBNet user profile and be granted at least Signature (read only) Access to the project from the Sharing screen.

11. Now, choose Sign this Package from the Left Navigation Pane. This will take you to the Sign Package page.

12. Read the statement, select the appropriate role in the drop-down box (see screenshot below), and if agreed, select the Sign button.

13. If you are authorized to sign on the behalf of another party, you can choose the Designee Sign Mode option by clicking the blue font towards the bottom of this page (see screenshots below).

14. In this case, you must designate who you are signing in place of immediately after you choose his/her role on the project. The Designee Sign option should be used with discretion.

**Signing the Package: Who is required and How to do it**

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**Sample Screenshot of Designer**

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**Sample Screenshot of Sign Package**
Submitting the Package: This will be done by the PI; information included for informative purposes only.

5. Once package is complete and ready for submission (MUST BE SIGNED BY ALL PARTIES), the PI will choose Submit this Package from the Left Navigation Pane.

6. On the Submit Package page, the PI must select the proper institution and committee. At USA the PI must choose between the following (see screenshots below)
   - University of South Alabama Institutional Animal Care and Use Committee (IACUC)
   - University of South Alabama Institutional Biosafety Committee (IBC)
   - University of South Alabama Institutional Review Board (IRB)

7. Once the committee is chosen, select Submit. On the next page (screenshot below), the PI will choose the Submission Type, add Comments (if desired), then click Submit.

8. The PI may submit the package to multiple committees, if pertinent, but each submission must be done one at a time. Once one is complete, the PI will start the process again by choosing Submit this Package from the Left Navigation Pane again.

Sample Screenshot of Submit Package
Guide for Key Personnel

This guide is intended to be a step-by-step walkthrough for Key Personnel or protocol associates that simply need to review and sign off on a Project.

New User Registration: Registering for IRBNet

1. Click: New User Registration (unless you have already created a user name and password).
2. Enter your legal first and last names in the appropriate fields. (Please use appropriate capitalization as you register into the system; the system does not always alphabetize names that begin with lower-case letters.)
3. Create your User Name and Password; confirm your password, and enter a password hint.
4. Click: Continue.
5. Accept the Terms of Use.
6. On the next screen, type “South Alabama” in the “Search for an organization” field and click “Search” OR scroll to and select “University of South Alabama” and the respective board on which you serve (Institutional Review Board (IRB), Institutional Biosafety Committee (IBC), or Institutional Animal Care and Use Committee (IACUC) from the list on the screen.
   **NOTE:** If you are also serving as a mentor, please contact the IRB Administrator for additional instructions.
7. Click: Continue.
8. On the next screen, enter your telephone number and email address; click: Continue.
9. On the final screen, click Register.
10. You will receive an email from IRBNet with a link that you need to click in order to activate your account. Your name will appear on USA’s list after you activate your account.

Sample Screenshot of My Projects
My Projects: Accessing Submissions/Projects

1. Log into IRBNet: (www.irbnet.org)
   (If you are also a Member, “Submission Manager” will open, but select My Projects from the menu of options at the left of your screen.)
3. You should receive a message through IRBNet indicating that a project has been Shared with you. The PI may choose to include additional comments or not.
4. All Projects which are Shared with you will appear on this page. To remove old or unneeded Projects, you may choose to Archive Projects (click , as seen in screenshot above). To see archived projects simply click Show Archived Projects.
5. You can access Reminders about specific Projects by clicking the or going to the Reminders menu item in the Left Navigation Pane.
6. You can open a Project for more information, by clicking on the title that appears in blue font.

Linking Training: Adding your Training/Credentials (see screenshot below)

1. Once you have selected an existing Project, you are taken to the Project Overview page.
2. You must go to the Project Designer by clicking the Designer below the overview information (see screenshot to the right).
3. Once on the Designer page (screenshot below), click the Link/Un-Link Record button at the bottom.
4. Once on the Link Training and Credentials page (screenshot below), simply check the boxes next to the appropriate training documents and select Save. This can be performed by the PI or each Shared user. Once all training is complete, you should notify the PI that all your training is linked.
Guide for Committee Members

This guide is intended to be a step-by-step walkthrough for Committee members, which are referred to as Members by IRBNet.

New User Registration: This has already been done for you!

1. Click: New User Registration (unless you have already created a user name and password).
2. Enter your legal first and last names in the appropriate fields. (Please use appropriate capitalization as you register into the system; the system does not always alphabetize names that begin with lower-case letters.)
3. Create your User Name and Password; confirm your password, and enter a password hint.
4. Click: Continue.
5. Accept the Terms of Use.
6. On the next screen, type “South Alabama” in the “Search for an organization” field and click “Search” OR scroll to and select “University of South Alabama” and the respective board on which you serve (Institutional Review Board (IRB), Institutional Biosafety Committee (IBC), or Institutional Animal Care and Use Committee (IACUC) from the list on the screen.
   NOTE: If you are also serving as a mentor, please contact the IRB Administrator for additional instructions.
7. Click: Continue.
8. On the next screen, enter your telephone number and email address; click: Continue.
9. On the final screen, click Register.
10. You will receive an email from IRBNet with a link that you need to click in order to activate your account. Your name will appear on USA’s list after you activate your account.

Submission Manager: Accessing Submissions

1. Log into IRBNet: (www.irbnet.org)
2. The Submission Manager page will appear.
   (If you are also a mentor, “Study Manager” will appear in the menu of options at the left of your screen.)
3. The default setting of the “View by Agenda” drop-down menu on the Submission Manager page is set to next meeting and the checkbox to the right is always checked to “only show those submissions awaiting review.” (The studies are sorted by submission date with the most recent on top.)
   a. To view “All Submissions”:
      (1) Select “All Submissions” from the drop-down menu.
      (2) Click on the checkbox to “un-select” that “only show those submissions awaiting review”.
      (3) Click the “Show Submissions” button. All submissions will appear.
   b. To view “All Submissions” that have not yet been reviewed
      (1) Select “All Submissions” from the drop-down menu, but do not “un-select” the box, showing “only show those submissions awaiting review”;
      (2) Click the “Show Submissions” button. All the submissions that have not yet been reviewed will appear.
   c. To view “Submissions by Agenda”:
      (1) Select the appropriate date from the drop-down menu.
      (2) If you wish to see only those that you have not reviewed, leave the checkbox selected.
      (3) Click the “Show Submissions” button; the submissions for that month will appear.
4. Next to the Title, may be either 1 star (STAR = Primary Reviewer), two stars (STAR = Secondary or Vet Reviewer), or a circle with a check (CHECK = your review is marked complete).
   a. The remaining columns provide detail information about the submission including: the IRBNet assigned ID#, PI’s last name, review type, Action (status), Internal Board Ref # (USA assigned #), submission date, and whether the package is locked/unlocked (LOCK or UNLOCK) which prevents
those with access from changing the submission).

b. At the bottom of this page any minutes or agendas will appear for the upcoming meeting.

6. Clicking on the title will bring up the “Submission Detail” for that particular study.

a. To access individual projects, simply click on the name of the document that appears in blue font. (See the screenshot that follows: Titles are in the orange box.

b. To access notifications about this submission, simply click the red flag ( ) that is in the first column.

Sample Screenshot of Submission Manager

Submission Detail: Accessing Submission Documents

1. Once you click the Submission Title (6a above). You are taken to Submission Detail.

2. This screen provides you with all the information and documents associated with the selected submission: Current Status, Package Details, Submission Details, Review Details, New and Revised Documents in the Package, Package Signatures, Board Documents, Submission Access (Shared), and Comments—see screenshot on following page.

A. Current Status- This provides the most up-to-date information about the submission.

B. Package Details- This is the standard who and what information.

C. Submission Details- This is the standard when and type (new, amendment, etc.) information.

D. Review Details- This provides information about what meeting, review type, committee action, effective & expiration dates are associated with the submission.
1. One may access the assigned agenda (meeting) by clicking the icon.
2. The review may be edited by clicking the icon.

E. It is important to note that the date fields will be blank until submission is approved. **New and Revised Documents** - This section will show you all documents which have been changed or uploaded since the last review.

1. To view old documents, the Designer Menu must be used (on the left navigation pane).
2. The flag ( ) which may precede a document title indicates that that document requires review. *Note: During review of documents, if you make comments directly on the researcher's documents, you will need to save the document onto your computer and upload your saved copy.*

F. **Other Sections** - Any document may be retrieved by clicking its title, which appears in blue font.

Sample Screenshot of Submission Detail
Recording a Decision or Recommendation: Adding Comments and Decisions

1. If selected as a Reviewer (Primary or Secondary) for a specific protocol (you will be notified via IRBNet Alerts). Once you have evaluated the protocol, scroll to the bottom of the “Submission Detail” page (see above).

2. Click “Add comments and reviewer documents to this submission” at the bottom of the screen.

3. On the next screen, you should upload the Review Form (can be found in IRBNet Library), by choosing “Add Document”. If you have an unofficial comment (no form needed) you may enter your comments in the rich-text field (500 character limit) and your recommendation. If using the text box you must click the “Save” button. (see screenshot below). If your review is complete, please designate so prior to saving (this will help you and others keep track of what has and needs to be reviewed).

4. You may update your document at any time.

Sample Screenshot of Reviewer Comments
**Agendas & Minutes: Accessing Meeting Information (same method for both file types)**

1. The Submission Manager page will appear at login.
2. At the bottom of the screen, you will see Agenda, Minutes and other Administrative Documents for this Meeting.
3. Click the icon at the bottom of the screen (in screenshot below).
4. Then click “Open” to view a PDF of the agenda for the next month’s meeting if it has been published.
5. To access agendas from previous months, click the “Agendas and Minutes” link at the left of the screen.
6. On the Agenda Manager page, select the “Document” icon to the right of the meeting date you wish to access (e.g., 03/19/2008).
7. On the Agenda Documents page, click Agenda.
8. Then click “Open” to view a PDF of the agenda for the meeting.

   Note: Agendas will include the titles of all studies approved through expedited procedures for the review period.

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**Sample Screenshot of Submission Manager**

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**Reminders and Messages & Alerts : Tools for communication**

1. **Reminders:** These IRBNet generated notifications about either profile or submission information. These are personal and can be both silenced (archived) or retrieved (unarchived). These are only visible to the specifically named user to which they are addressed.
2. **Messages & Alerts:** These IRBNet generated notifications about either profile or submission information. These are similar to Reminders except they are specifically attached to submissions and can be viewed by anyone with access (administrative or shared) to the submission. These are most commonly official notices of approval, agenda assignment, etc.
3. **Reminders** appear at login in the left hand navigation pane (indicated by in the screenshot below.)
4. **Messages & Alerts** are available only from a submission once it has been selected from the **Submission Manager** screen (indicated by the ![ ] ).

Sample Screenshot of Submission Manager
Are you ready to submit to IRBNet?

The process to the below describes the conditions under which a Protocol or Amendment may be submitted through IRBNet. To ensure a smooth and uninterrupted process please follow the tree, PRIOR to package creation.

Once you reach the , you may begin package creation which is the process of creating and submitting the required paperwork.
IRBNet Protocol Assembly & Submission
IRB: What review type is my study?

Below is a chart to help you understand what review type your project may be eligible for. It is important to note that the chart represents eligibility, not requirement. Any project may be reviewed at a level of greater depth than its eligibility may qualify it for.
IRB Required Documents

Below is a diagram to illustrate the required documentation for IRB submissions on IRBNet. Note: That some forms or materials are required for all three, but others may only be required some of the time.

Forms in IRBNet Library
PI generated paperwork
IRB provided templates

Exempt
Application Part A (IRBNet On-Line Document)
Application Part B Exempt
(Cat 1 & 2)
Information sheet (Cat 1 & 2)
Waiver letter (Cat 4)

Expeditied
Application Part B Expedited
Questionnaire or Survey
(Cat 1 & 2)
Permission letter (if external site is used)
Tools (flyers, standardized forms)
Protocol
Invetigator’s Brochure

Full Board Review
Application Part B Full Board Review
Waiver of Subject Authorization
FDA 1572 (Signed)
Consent Form
Checklist for Children
Checklist for Prisoners
Checklist for Pregnant women/fetus/neonates
HIPAA Waiver

Training Documentation is REQUIRED for ALL Review Levels. This is NOT part of the IRBNet package documents, but it MUST be linked to the package for every protocol associate, (which requires an IRBNet user profile and shared access to the protocol associates). NO EXCEPTIONS.
IACUC & IBC Required Documents

Below is a diagram to illustrate the required documentation for IACUC or IBC submissions on IRBNet.

Note: That some forms are only needed if it is one protocol or the other, while both sets are required if there are protocols for both committees.

Training Documentation is REQUIRED for ALL Review Levels. This is Not part of the IRBNet package documents, but it MUST be Linked to the package for every protocol associate. (which requires an IRBNet user profile and shared access to the protocol associates) NO EXCEPTIONS.