

IRBNet for Researchers! Step by Step Instructions

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I. IRBNet Glossary of Terms

In an attempt to help standardize the online review of Human Subjects research applications, Oakland University will adopt the naming logic used by IRBNet. In most cases these are terms that have widespread acceptance by Institutional Review Boards and are used by the United States Department of Health and Human Services. Please take a few minutes to look at the following glossary. It may make it a little easier to navigate the IRBNet waters.

Project

A **Project** is an online version of the research proposal/protocol being submitted to Oakland University's IRB for review. Once a project has been created, all subsequent submissions are submitted through the same project.

Project Package

A **Project Package**, or just "**Package**", is a submission containing any number of documents that are required by the IRB to conduct their review of a research Project. The Project Package for a new submission will include the appropriate Human Subjects Research Application, the full research proposal, the research funding proposal, if applicable, any surveys or instruments, consent forms, any advertisement or recruiting materials, a Conflict of Interest Disclosure Statement form from ALL **Key Personnel** listed on the project and any other documents requested by the IRB (See the first page of each submission application for a more detailed list of submission materials). Subsequent Project Packages will contain one or more revisions of documents previously submitted in the project package that the Researcher makes in response to IRB requests. Continuing reviews, amendments to approved projects, event reports, etc., should also be submitted as new packages to the existing project and labeled appropriately. Please note that these documents should **not** be submitted as a new project.

A five digit number is assigned to each **new Project** that is submitted to the IRB for review through IRBNet. Each five digit number is followed by a dash and the number after the dash indicates the **Package number** for that **Project**. There may be many **Packages** associated with each **Project**. For example, 12345-1 means that this is the first **Package** for the Project; 12345-2 indicates the second **Package** for the Project, etc. Examples of submissions that would require the submission of additional **packages** to an existing **project** include revisions, amendments, continuing review applications, event reports, etc.

Submission

IRBNet uses the term **Submission** to denote a total **Project Package** that has been submitted for official review.

Researcher

A **Researcher** is the individual submitting the Project for IRB review. There are three Researcher categories that will be used by IRBNet:

- *Oakland University Faculty Researchers*
- *Oakland University Student Researchers*
- *Oakland University Staff Researchers*

Principal Investigator

IRBNet uses the term **Principal Investigator** (or PI) to designate the person with overall responsibility for studies submitted by Oakland University Student researchers, Oakland University Faculty researchers and Oakland University Staff researchers.

Amendments

Amendments are changes that the researcher wishes to make after a study is approved by the IRB. The researcher will use an Amendment Form to make changes to previously approved studies BEFORE the IRB approval period has expired. Researchers must submit an Amendment Form and any additional documentation as a new Project Package to the existing project in IRBNet for IRB approval. This Package number will consist of the five digit number assigned at the time the initial application was submitted, followed by the package number. If the study was initially approved in RAM 2.0, and the amendment is the first submission in IRBNet, a new project must be created for the submission of the amendment.

Revision

A **Revision** is a change (or changes) required by the IRB *before* a Project can be approved. The researcher creates a new **Project Package (NOT a new application/Project)** in IRBNet to address any required revisions.

Reviewer

A **Reviewer** is an IRB Board member or designee that is involved in the review of a Project.

Type of Reviews

The **Type of Review** is the level of IRB review the researcher is requesting for their Project. *Please note that the Oakland University IRB will be adopting the naming convention used by IRBNet and the Office of Human Research Subjects (OHRP) to categorize the type of IRB review. The three levels will include **Exempt**, **Expedited** and **Full Committee Review**.*

Exempt: Proposals are exempt from federal regulations and more detailed review if the research described poses no more than minimal risks (risk level similar to what is encountered in everyday activities) to subjects and proper procedures are used to implement ethical principles for the protection of human subjects. The chair or designee of the IRB determines whether a research project will undergo an exempt review. As necessary, the chair or designee will consult with other IRB members when making this decision. The following types of research may fall into the exempt category (See 45CFR46 or Oakland University IRB guidelines for a more detailed description of OHRP Exempt Categories):

- Anonymous survey/interview procedures or observation (without intervention) of public behavior;
- Survey/interviews in which the participant cannot be linked and information obtained is innocuous. Disclosure of this information would NOT reasonably place the participant at risk of criminal or civil liability or be damaging to the participants' financial standing, employability or reputation; and/or
- A project using existing data or pathological specimens providing the information is recorded anonymously.

Expedited: The expedited review category is used for certain types of research involving no more than minimal risk, as well as for minor changes to research previously approved by the full committee during the period for which approval has been authorized. Proposals can be reviewed by one or more members of the University's IRB. Reviewers may refer the proposal to the full committee. The following types of research may fall into the expedited review category (See 45CFR46 or OU IRB guidelines for a more detailed description of OHRP Expedited Categories):

- Surveys which can be linked to participant and may request "sensitive" information;
- Blood draws;
- Non-stressful research on individuals or group behavior;
- A project using existing data or pathological specimens if the information recorded can be linked to participant;

- Recording of data using non-invasive procedures; and/or
- Surveys which can be linked to participant and may request "sensitive" information.

Full Committee Review: Any research not covered under the exempt or expedited review categories is referred to the IRB for full committee review. The PI may be invited to attend the IRB committee meeting. The committee will either: (i) approve the research as written or pending specific minor changes; (ii) require modifications to secure approval; or (iii) not approve the research. The committee will notify the principal investigator in writing about the committee's decision. The following types of research may fall into the full committee review category:

- Invasive medical treatments;
- Physical or psychological risk;
- Special populations (minors, pregnant women, prisoners, incompetent participants); and/or
- Criteria for exempt or expedited review are not met.

Required Signatures

The **Required Signatures** are captured on each of the IRB submission forms. Required signatures include those of the PI and Department Chair. If the PI is a student, the student's Faculty Advisor **MUST** also sign the application. If the PI or Faculty Advisor is also the Department Chair, the Dean of the School must sign the application form.

The PI must also electronically sign the package prior to submission to the IRB. Please note that if the submission is missing any of the required signatures, the project will not be reviewed.

Review Status

IRBNet uses the following terms to denote the status of studies submitted for review.

Acknowledged: The committee or office acknowledges the receipt of the information.

Approved: The submission has been approved.

Exempt: The submission is exempt from review in accordance with federal regulations.

Modifications Required: The committee requires changes to the submission to secure approval.

Pending Review: The submission is awaiting committee review.

Not Approved: The concerns of the committee are substantive in content.

Not Research: The committee has determined this project does not meet the definition of "research" under the committee's purview.

Work in Progress: The project has not yet been submitted to an IRB for review. The project can be managed and edited without generating a new IRBNet ID number.

Researchers will be updated on the review status of their submission through an e-mail notification generated through IRBNet.

Permissions

Permissions are levels of access that a researcher grants to IRBNet users. Different levels of access may be given to co-investigators, students, or IRB staff. Permission is given to others by "sharing this project." The "sharing this project" option tab can be found on the Submission Detail page. IRBNet allows the following levels of access.

Full: The individual may manage and control all aspects of the project (e.g., write, share, submit, edit, etc.). For instance, a PI may want to give another individual full access to the project if that individual will be involved in making edits to the project or submitting the project to the IRB.

Write: The individual may collaborate on project documentation, but may not share the project with others, submit packages for review, or take certain other actions reserved solely for the project owners.

Read: The individual has read only access to the project.

All access levels have the ability to electronically sign a project package where necessary.

Researchers, administrators or others must be registered in IRBNet in order to be granted any level of access.

Project Mail

Project mail is used to communicate with IRB committee members, staff or other members of the project team who have been given access to the project. Please note that project mail is sent to the individual's registered e-mail account. Researchers or others should not respond to project mail through regular e-mail, but should log into IRBNet, open up the message under the *Messages and Alerts* tab and "**reply**" to the message. An audit trail will be lost if the researcher responds through regular e-mail. The project mail tab is located under Project Administration on the Submission Detail page.

Reviews

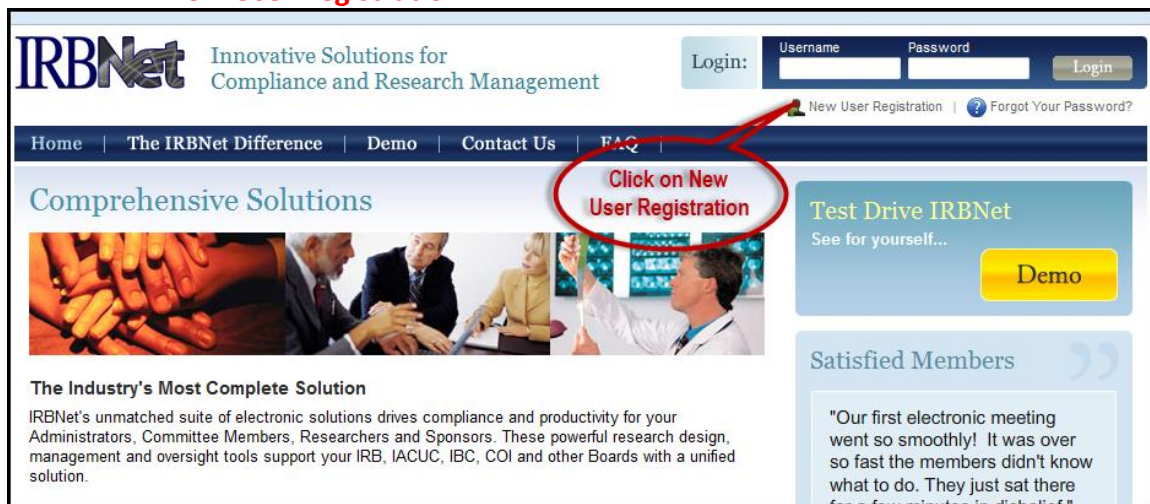
Board actions and other board documents (i.e. Approval letter, Modification letter, etc.) are communicated to researchers under the Reviews Tab which is located under Project Administration on the Submission Detail page.

Project History

Project history is a summary of all packages submitted under a project.

II. Register as an IRBNet User and Log-in for the First Time

1. Go to <http://www.irbnet.org>
2. In the upper right-hand corner of the screen, under the login boxes, click on **"New User Registration."**



3. Fill in your first and last name, create a user name and password, and then click **"Continue."**

The screenshot shows the 'New User Account Information' registration form. The form includes fields for 'First Name', 'Last Name', 'Username', 'Password', 'Confirm Password', and 'Password Hint'. The 'Continue' button is highlighted with a red circle and an arrow pointing to it. A red circle with an arrow also points to the 'Continue' button, with the text 'Fill in all required information and then click on "Continue"' inside the circle. The form also includes a 'Cancel' button and a note that '*' indicates required fields.

4. On the next screen about **"Terms and Conditions"** please read and then click **"Accept."**

7. Next you will see the **"Registration Screen."** Enter your contact information in all the required fields and click **"Continue"** to register with IRBNet.

Registration

Your Contact Information

Specify your contact information at **Oakland University, Rochester, MI**. The email address that you specify will be used for communications related to Oakland University projects.

Telephone Number * - - ext.

Fax Number - - ext.

Email *

Verify Email *

Complete All Required Information then click 'Continue'

* required fields

8. You will then receive an e-mail from IRBNet with the subject **"Activation Required."** Go to your e-mail and click on the link or copy and paste it in your browser. Return to the IRBNet website. Log-in with your "User Name" and "Password" to authenticate your registration.

IRBNet Activation Required

Welcome to IRBNet!

Please confirm your affiliation with Oakland University by clicking on the following link:
<http://training.irbnet.org:80/training/public/act.jsp?i=826387&a=TljAqi2Biq>

If you cannot click on the above link, you may copy and paste the link into your browser to confirm your affiliation.

Thank you,
The IRBNet Support Team

www.irbnet.org

Click on (or copy and paste) the IRBNet link in your e-mail message

9. Please note that after you have completed registration, all others who want or require access to the project (i.e. faculty advisor for student researcher) must register in IRBNet. Access to the project is granted through sharing the project (see "Permissions" under IRBNet Glossary).

Congratulations! Once you are activated, you may now log back into to IRBNet to add your training documentation or other credentials and begin creating a new research project!

III. Submitting Training Documentation and Creating a New Project

NOTE: All Investigators and Key Personnel **MUST** complete or have current CITI training **BEFORE** a project application can be reviewed by the IRB. CITI training can be accessed at <https://www.citiprogram.org/> .

A. Training Documentation/Credentials on IRBNet

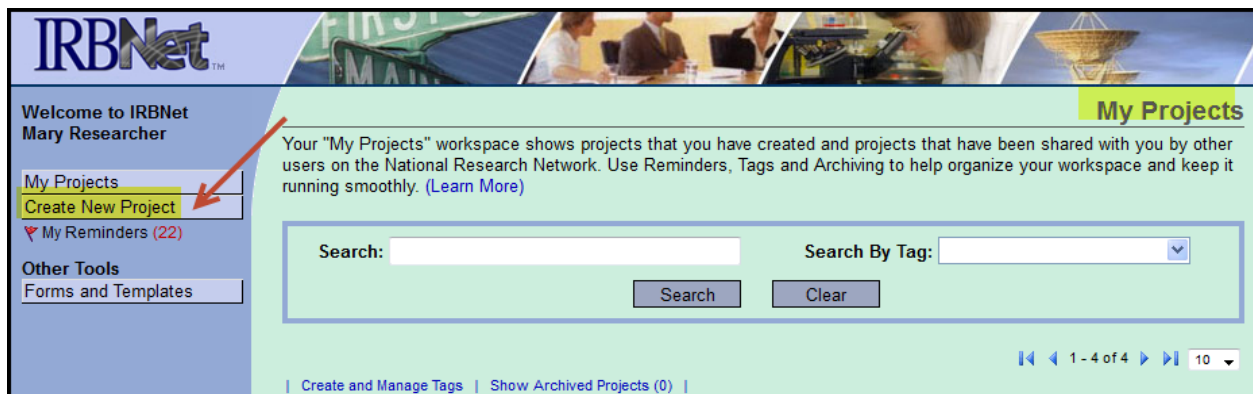
All new IRB submissions require documentation of CITI training. Documentation of CITI training can be submitted in IRBNet by one of two means. One involves uploading the CITI completion report; the other is completion and uploading of the Assurance of CITI training form found in the Forms and Template library of IRBNet.

To submit documentation of your CITI training or other credentials, log in to IRBNet. Click on **"User Profile"** at the top of the screen. Under **"Training and Credentials"** select **"Add a New Record."** Follow the instructions on the screen. You can upload either your CITI training completion report or The Assurance of CITI training form found in the Forms and Templates library of IRBNet. Once you have identified the required training document, click on **"Submit"** to upload it into IRBNet. You may attach additional credentials (e.g. CV or special permission to serve as a Principal Investigator) as needed. Please note that once these training and credentials records are uploaded into IRBNet, they can be linked to any subsequent new project submission. Please see step III. D. 21 below for details on how to link credentials to a specific project.

B. Creating a New Project

After your training credentials have been uploaded into IRBNet, the following steps should be followed to create a new project.

1. Log back into IRBNet.
2. In the **blue** menu bar on the left-hand side of the **"My Projects"** page, choose **"Create New Project."**



3. Fill out all **"Required Fields"** and click **"Continue."** Entering Keywords is optional. If your project will be sponsored research (e.g., NIH), enter the sponsor's name.

Welcome to IRBNet
Mary Researcher

Project Information

Create a New Project

To create a new project, first provide the basic project information below. Once your project is created you may attach project documentation and share the project with other users.

Research Institution:

Title:

Local Principal Investigator: First Name: Last Name: Degree(s):

Keywords:

Sponsor:

You may specify an internal account number, billing identifier or reference number for this project.

Internal Reference Number:

* required fields

Fill Out All Required* Fields and Click "Continue"

4. Next you will see the **"Designer"** page. Under Step 1, click on the dropdown arrow to view the IRB documents that may be necessary in submitting your application package. Select a document from the dropdown menu and click **"Download."**

IRBNet ID: 47927-1

USER PROFILE LOGOUT

Welcome to IRBNet
Mary Researcher

Project Administration

Project Overview

Designer

Share this Project

Sign this Package

Submit this Package

Delete this Package

Send Project Mail

Project History

Messages & Alerts

Other Tools

Forms and Templates

[47927-1] Examining the Healths Beliefs Model in University Psychology Students

Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library:

Select a Document:

- 1. Application IRB Exempt
- 2. Application Expedited or Full Board Review
- 3. Application Continuing Review
- Appendix A - Additional Key Personnel
- Appendix B - International Research
- Appendix C - Deception in Research
- Appendix D - Waiver of Consent
- Appendix E - Waiver of Consent Documentation
- Appendix F - Research with Children
- Appendix G - Decisionally Impaired
- Appendix H - Pregnant Women-Fetus-Neonates
- Appendix I - Research with Prisoners
- Appendix J - Internet Research
- Appendix K - HIPAA Waiver of Authorization
- Appendix N - Waiver of Parental Permission
- Checklist IRB Submissions
- Form - Conflict of Interest Disclosure
- Form - Event Reporting
- Form - Principal Investigator Assurance
- Form - Protocol Amendment

Step 2:
Assemble your document package, IRBNet also allows you to link your project team's documents in this Package.

There are no Training & n-Link Training Records

NOTE: These 2 Documents are "REQUIRED" for all NEW Project Applications

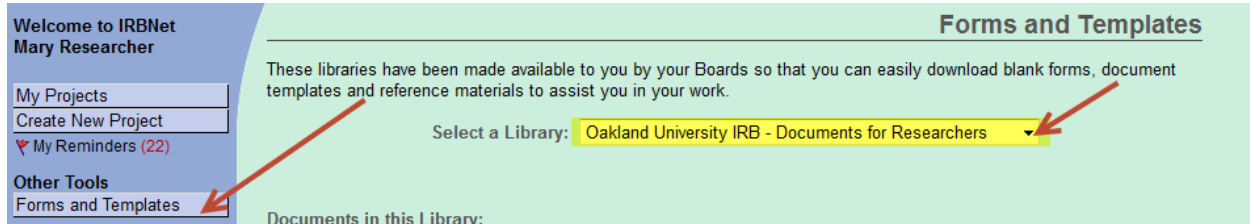
1 Designer

2

3

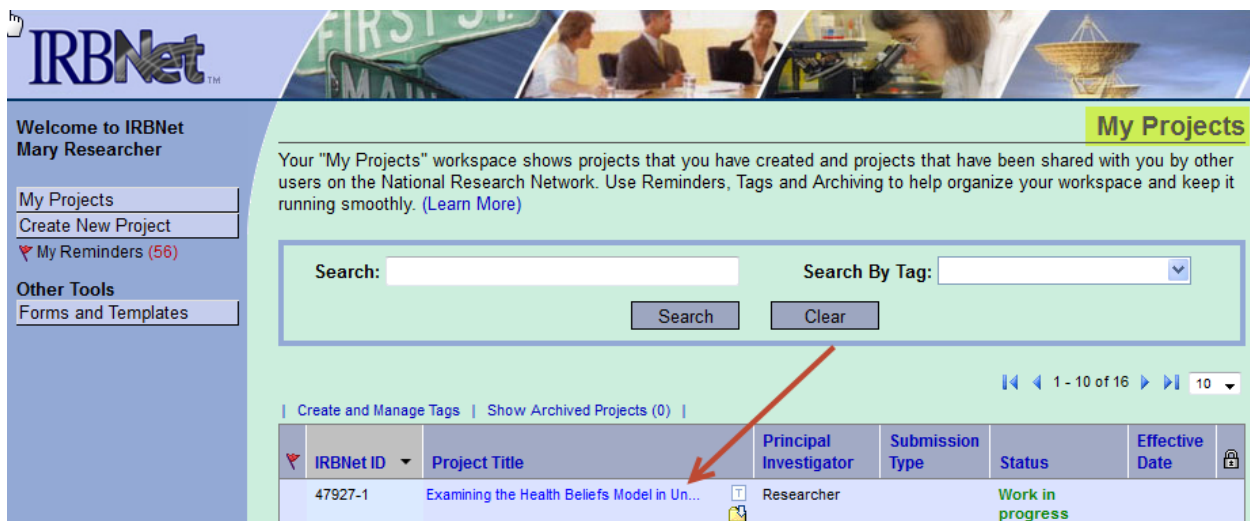
5. Save the document to your desktop or a folder you have created for this project. You can only download one document at a time. **Note: A "Conflict of Interest Form" is required for all "Key Personnel" on the project. Key Personnel is defined in the Exempt and Expedited/Full Board Applications.**

6. If you discover that you need an additional document (e.g., Appendix D – Waiver of Consent) while filling out the downloaded application, simply log back into IRBNet, and click on **“Forms and Templates”** on the left-hand side of the screen in the blue menu bar. You will see the dropdown of available documents again. Select the document you need, download it and save it to your desktop or project folder.



C. Attaching a Document

7. Once you have completed the IRB application and all the required forms, you are ready to upload the forms to IRBNet.
8. Log back into IRBNet.
9. On the **“My Projects”** page, click on the project you wish to add documents to. In this case, we are working with the project titled *“Examining the Health Belief Model in University Psychology Students.”*



10. The following **“Project Overview”** screen will appear (see screenshot on the next page). On the left hand side of the screen, click on **“Designer.”**

IRBNet ID: 47927-1 USER PROFILE LOGOUT

Text Resize Monitor

IRBNet

Welcome to IRBNet
Mary Researcher

My Projects
Create New Project
My Reminders (56)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Project History
Messages & Alerts

Other Tools
Forms and Templates

Project Overview

[47927-1] Examining the Health Beliefs Model in University Psychology Students

You have Full access to this project. [\(Edit\)](#)

Research Institution Oakland University, Rochester, MI
Title Examining the Health Beliefs Model in University Psychology Students
Principal Investigator Researcher, Mary
Status Work in progress

The documents for this project can be accessed from the [Designer](#).

Click [here](#) to submit this package for review.

Shared with the following IRBNet users

IRBNet User	Organization	Access Type
Mary Researcher	Oakland University, Rochester, MI	Full

11. Once you have opened the “Designer” page, under step 2, click on “Add New Document.”

Welcome to IRBNet
Mary Researcher

My Projects
Create New Project
My Reminders (56)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Project History
Messages & Alerts

Other Tools
Forms and Templates

Designer

[47927-1] Examining the Health Beliefs Model in University Psychology Students

Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library:
Select a Document:

Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.

Documents in this Package:

There are currently no documents in this package.

There are no Training & Credentials records linked to this package. | [Link / Un-Link Training Records](#) |

12. As shown in the following screenshot, on the “Attach Document” page, click on the drop down arrow to view the type of document you wish to upload. Select the document type.

Welcome to IRBNet
Mary Researcher

My Projects

Create New Project

My Reminders (56)

Project Administration

Project Overview

Designer

Share this Project

Sign this Package

Submit this Package

Delete this Package

Send Project Mail

Project History

Messages & Alerts

Other Tools

Forms and Templates

Attach Document

[47927-1] Examining the Health Beliefs Model in University Psychology Students

You may attach documents to this package by clicking the "Browse..." button to locate a document and then by clicking "Attach". The "Document Type" and optional "Description" are informational fields to assist you in managing your attached documents.

Document Type * Application Form 1

Description

File * Application Form 2

* required fields

Browse...

13. In the **"Description"** field, type in a brief description of the document you are attaching. Next, click the **"Browse"** button to locate the document you wish to attach to your Project Package.

IRBNet ID: 47927-1

IRBNet

Welcome to IRBNet
Mary Researcher

My Projects

Create New Project

My Reminders (56)

Project Administration

Project Overview

Designer

Share this Project

Sign this Package

Submit this Package

Delete this Package

Send Project Mail

Project History

Messages & Alerts

Other Tools

Forms and Templates

Attach Document

[47927-1] Examining the Health Beliefs Model in University Psychology Students

You may attach documents to this package by clicking the "Browse..." button to locate a document and then by clicking "Attach". The "Document Type" and optional "Description" are informational fields to assist you in managing your attached documents.

Document Type * Application Form 1

Description Expedited/FullBoard Application

File * 2

* required fields

Browse...
Attach Cancel

14. Once you have located the file on your computer, select it from your computer and click **"Attach"** at the bottom of the screen.

15. The application is now attached to your project in IRBNet. Continue this process until all required forms are attached to your project.

D. Delete, Edit or Replace Documents Once Attached










OOOPS, I MADE A MISTAKE!!!

Before submitting your Project, there are three methods to modify the documents you have already attached to your **"Project Package:"** **A) "Delete" an attached document,** **B) "Edit" a document, or C) "Replace or Overwrite" an attached document.**

16. **A) “Delete” an Attached Document:** There will be occasions when you will want to remove an attached document from your project package altogether. Click on the **Red X** icon to delete a document. A dialog box will appear asking if you want to delete this file.

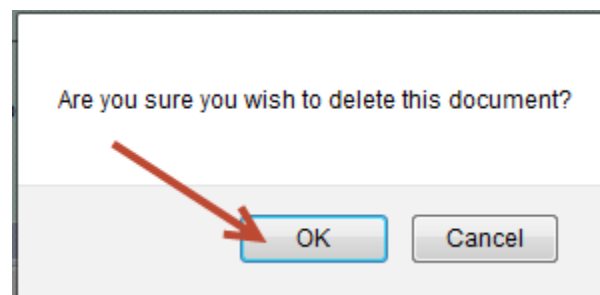
Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.


Documents in this Package:

Document Type	Description	Last Modified	
Application Form	Full Board Revised	09/21/2012 07:28 AM	  
Consent Form	Consent form	09/21/2012 07:29 AM	  
Other	Appendix A - Additional Key Personnel	09/22/2012 07:59 AM	  

There are no Training & Credentials records linked to this package. | [Link / Un-Link Training Records](#) |

17. Below is the dialog box. Once you click the **"OK"** button, the file is gone forever from the Project Package or until you re-load it.



18. **B) “Edit” a Document:** To edit a document that has already been attached to your Project Package (in this example we will select the “Consent Form”), click on the document you wish to edit . Your document will appear. Make the changes to the document and then save it to your desk top or project folder. (You may wish to create a different file name just to keep a history of what you submitted. Next, delete the old document you wish to replace by using the **RED X** and then upload the “New Document” as in step 15. Researchers usually use this when there are only minor changes and wish to use the original document they submitted first.

My Projects

Create New Project

My Reminders (47)

Project Administration

Project Overview

Designer

Share this Project

Sign this Package

Submit this Package

Delete this Package

Send Project Mail

Project History

Messages & Alerts

Other Tools

Forms and Templates

Step 1:

Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library: Oakland University IRB, Rochester, MI







Select a Document: 1. Application IRB Exempt

Download

Step 2:

Assemble your document package. In addition to adding project documents to your package, IRBNet link your project team's Training & Credentials to your package.


Documents in this Package:

Document Type	Description	Last Modified	
Application Form	Full Board	09/20/2012 09:07 AM	  
Consent Form	Consent Form	09/20/2012 09:53 AM	  

There are no Training & Credentials records linked to this package. | [Link / Un-Link Training Records](#) |

Add New Document







Click on the document you want to edit.

19. **C) "Replace or Overwrite" a Document:** In some instances you may also wish to just **"Replace or Overwrite"** a document you have attached. For example, let's say you attached a "Consent Form" but you realize you attached the wrong consent form, one from a different study. The **"Pencil" Icon**  will allow you to simply overwrite the attached form with the correct form without having to delete it and upload it again. This can only be done prior to submitting the Project Package.

Step 2:


Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.

Documents in this Package:

Document Type	Description	Last Modified	
Application Form	Full Board Revised	09/21/2012 07:28 AM	  
Consent Form	Consent form	09/21/2012 07:29 AM	  

There are no Training & Credentials records linked to this package. | [Link / Un-Link Training Records](#) |

Add New Document



20. Click on the **"Pencil Icon"** . You will see the following screen.

You are updating an attachment. To help you identify the file that was attached:

- This attachment was loaded from the file **Application - IRB Expedited_Full Board V 1.0 IRBNet.doc.**
- It was attached on **09/10/2012.**
- It has a size of **402432 bytes.**

Document Type * Consent Form

Description Revised Consent Form

File * C:\Users\Staples\Desktop\IRBNet Forms Protected Researcher: Browse...

Update Cancel

* required fields

Select the appropriate file from your computer to "replace" the previously attached Consent Form

Select the **"Document Type"** from the drop down menu. Next click the **"Browse"** button. Locate the file on your computer you wish to **"Replace or Update."** Click on **"Update."** Note this function replaces the file previously attached with the new file you have selected.

21. Link training records/ credentials to the project

Once all documents have been added to IRBNet, be sure to link your training records/credentials to the project. The link to training records can be found at the bottom of the Designer page. Click on "Link Training Records." (in blue)

Welcome to IRBNet
Mary Researcher

My Projects
Create New Project
My Reminders (56)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Project History
Messages & Alerts (9)

Other Tools
Forms and Templates

Designer

[47927-1] Examining the Health Beliefs Model in University Psychology Students

Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library: Oakland University IRB, Rochester, MI

Select a Document: 1. Application IRB Exempt Download

Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.

Documents in this Package:

Document Type	Description	Last Modified
Application Form	Expedited/Full Board Application	09/10/2012 10:58 AM

The Application is now attached.

There are no Training & Credentials records linked to this package. | Link / Un-Link Training Records |

Add New Document

Click here to add another document.

E. Sharing the Project with other Key Personnel

22. Now that you have attached all the required documents, you may share access to this project with other members of the research team.

- If you are an Oakland University faculty or staff member (non-student) who is also the PI on this project, you are required to obtain signatures from your department chair. Therefore, you MUST share your project with your department chair. You may also choose to share the project with others if needed (e.g., Co-PI, Key Personnel etc.).
- If you are NOT the PI for this project, it will be necessary for you to share the project with the PI.

- If you are unaffiliated with Oakland University, it will be necessary for you to share the project with the Oakland University faculty sponsor for your project.
- If you are a student, make sure your faculty advisor is registered with IRBNet and you share your project with your advisor.
- Signatures of the PI, department chair, faculty advisor, and dean are captured on the submission application. However, each person signing for the project is expected to have read the application and reviewed the other submission documents. Thus, it is essential to have shared the project with all individuals whose signature will be obtained.

In order to **“Share”** the project, click the **“Share this Project”** button on the left-hand side of the screen. The following screen will appear. In most cases you will choose the **“Share”** option rather than **“Multi-site”** or **“Transfer”** option. Click on the **“Share”** link; the first option.

Welcome to IRBNet
Mary Researcher

My Projects
Create New Project
My Reminders (56)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Project History
Messages & Alerts

Other Tools
Forms and Templates

Share Project

[47927-1] Examining the Health Beliefs Model in University Psychology Students

You may share this project with other Researchers, Committee Members, Administrators and Sponsors. You may also send a complete copy of this project to a Principal Investigator at another site if this is a multi-site project. You may also transfer ownership of this project to another individual.

Share: Use this option if you wish to share your project with other Researchers, Committee Members, Administrators or Sponsors at your own institution or any other institution. For example, you may wish to share this project with other members of your research team so that you may collaborate in the design and development of the project, or with a selected Committee Member or Administrator to solicit feedback prior to submitting your project for review. You may provide any individual with **Full**, **Write** or **Read** access.

- **Multi-site:** Use this option only if your project is a multi-site project and you wish to send a complete and independent copy of this project to a Principal Investigator at another site. The local Principal Investigator will be able to obtain project documents from the lead site and may modify their copy of these documents (such as consent forms) to meet the requirements of their local Board. You will be able to monitor the progress of this project at every local site. The other local Principal Investigators will also be able to monitor the progress of this project at every local site (including your own).
- **Transfer:** Transfer your ownership of this project to another user. In doing so you will relinquish all access to this project and the designated user will be granted **Full** access.

You will be taken to a screen where you will be asked to select an organization where the individuals you wish to share your project with are located. From the drop down menu, select **“Oakland University.”**

NOTE: Before you can share the project, the person you wish to share it with **MUST:**

- Register with IRBNet <https://www.irbnet.org>
- Complete the “User Profile”
- Affiliate Oakland University (unless a Co-PI is located at a different institution)
- Reply to the IRBNet e-mail to complete registration.

23. In the **“Search Bar”** search by name for the individual you wish to share the project with. Select the level of access you wish to grant to the individual from **“Permission Access”**. Select the level of access: **“Full, Write or Read.”** The default option is **“No Access.”** Continue the process until you have given access to as many individuals as you wish.

Welcome to IRBNet
Mary Researcher

My Projects

Create New Project

My Reminders (56)

Project Administration

Project Overview

Designer

Share this Project

Sign this Package

Submit this Package

Delete this Package

Send Project Mail

Project History

Messages & Alerts

Other Tools

Forms and Templates

Share Project

[47927-1] Examining the Health Beliefs Model in University Psychology Students

Specify the access that you wish to grant to each user at **Oakland University**. You should grant each user only the minimum level of access necessary to perform their work on this project.

- **Signature Only (Read):** Users whose only role is to sign off on project documentation should be granted "Read" access. Users with Read access can view project documentation, communicate with the project team and add their signature. This would typically include advisors, department heads, and other individuals who are required to sign off on the project documentation prior to submission but do not otherwise have a day-to-day role on the project.
- **Read:** Users that are granted "Read" access can view project documentation, collaborate with other users and add their signature, but may not edit project documents or perform any other administrative functions.
- **Write:** Users that are granted "Write" access can view and edit project documents, collaborate with other users and add their signature, but may not grant access to other users, submit packages for review or perform any other administrative functions.
- **Full:** Users that are granted "Full" access can perform all functions without restriction. This includes editing project documents, sharing the project with other users, submitting document packages for review and deleting document packages. Only Project Owners with day-to-day responsibility for the project should be granted Full access. Users with Full access will receive automatic email copies of all project notifications and alerts that are sent to the Project Owners.

IRBNet User	Permission Access
Kilbourn, Earl	<input checked="" type="radio"/> Full <input type="radio"/> Write <input type="radio"/> Read <input type="radio"/> No Access

F. Signing the Project Package

24. It is time to electronically **"Sign"** the package preparing it for submission. The **"Signed Package"** screen allows IRBNet users with access to a Project to record that they have read the Project's documentations in their entirety and agree that they are ready for submission to the IRB for review. From the **"Project Overview"** page, click on **"Sign this Package."** The **"Project Overview"** page appears each time a Project is opened in IRBNet.

Welcome to IRBNet
Mary Researcher

My Projects

Create New Project

My Reminders (56)

Project Administration

Project Overview

Designer

Share this Project

Sign this Package

Submit this Package

Delete this Package

Send Project Mail

Project History

Messages & Alerts

Other Tools

Forms and Templates

Project Overview

[47927-1] Examining the Health Beliefs Model in University Psychology Students

You have Full access to this project. ([Edit](#))

Research Institution	Oakland University, Rochester, MI
Title	Examining the Health Beliefs Model in University Psychology Students
Principal Investigator	Researcher, Mary
Status	Work in progress

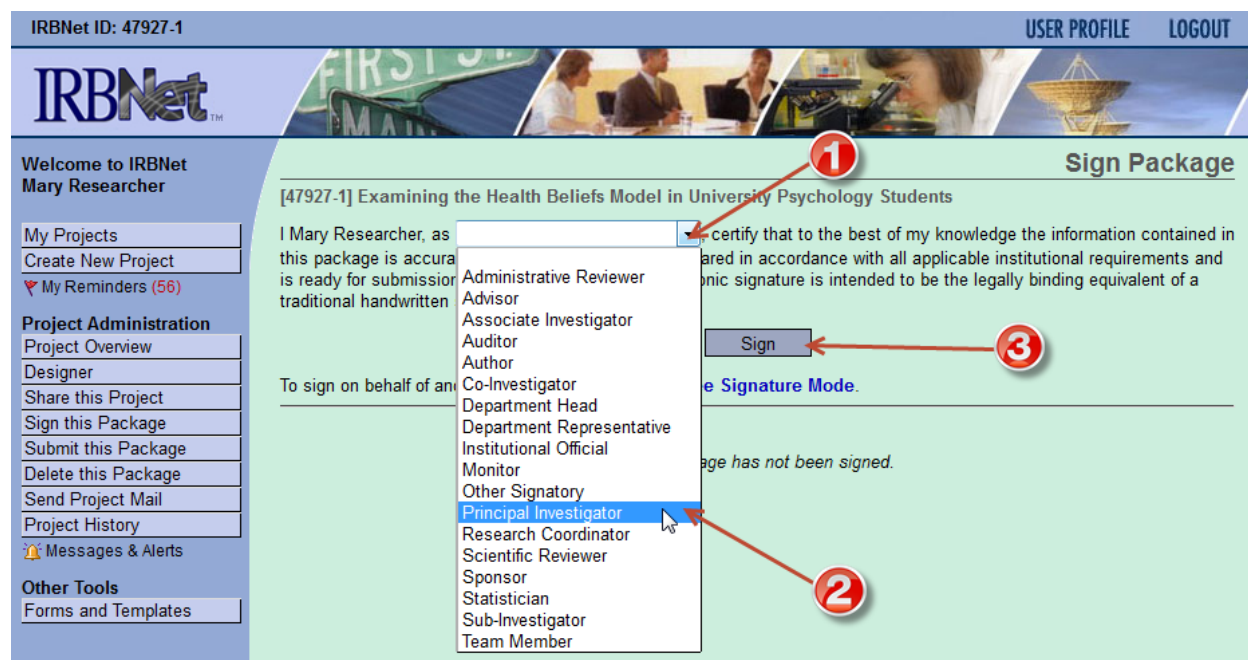
The documents for this project can be accessed from the [Designer](#).

Click [here](#) to submit this package for review.

Shared with the following IRBNet users

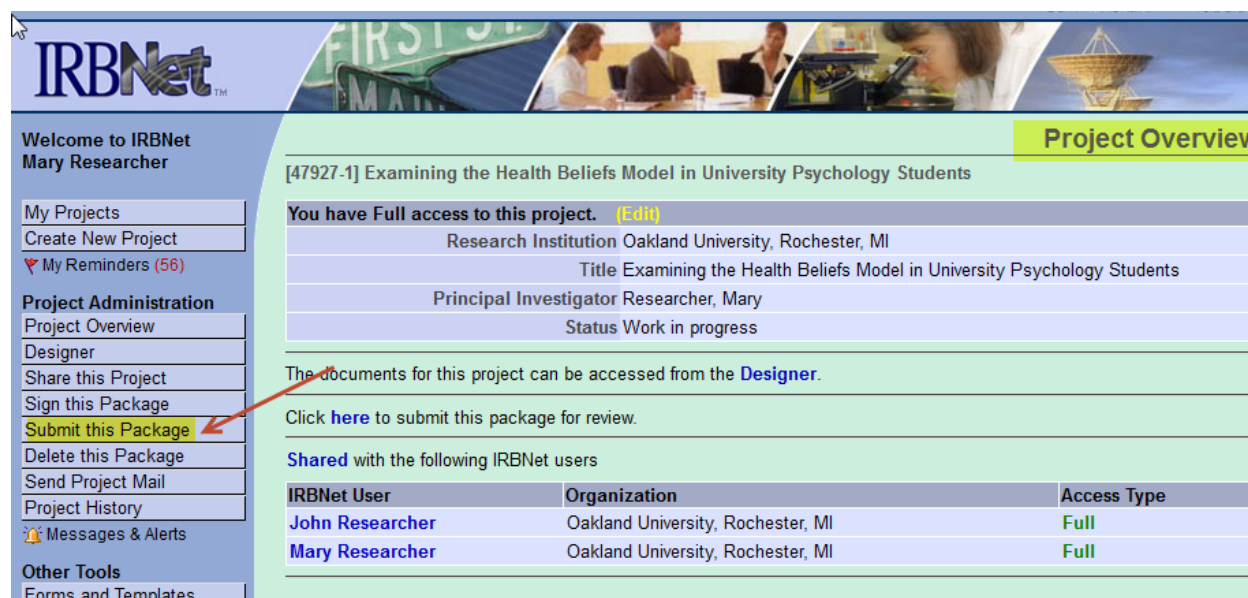
IRBNet User	Organization	Access Type
John Researcher	Oakland University, Rochester, MI	Full
Mary Researcher	Oakland University, Rochester, MI	Full

25. On the next screen, use the drop-down box to view and select your role in the project. Click on your appropriate role, and then click **“Sign.”** In this example, Mary Researcher is a student and the PI and has shared the project with her faculty advisor "John Researcher". Mary is signing as the Principal Investigator on the project.



G. Submitting the Project Package

26. The **“Submit this Package”** page is where you will deliver your completed Project Package to the IRB for review. On the **“Project Overview”** page click on **“Submit this Package.”** This will take you to the **“Submit this Package”** page.



27. On the **“Submit this Package”** page, ensure that **“Oakland University IRB, Rochester, MI”** is selected, and then click **“Continue.”**

The screenshot shows the IRBNet interface. On the left is a sidebar with navigation links: 'My Projects', 'Create New Project', 'My Reminders (56)', 'Project Administration' (with sub-links: Project Overview, Designer, Share this Project, Sign this Package, Submit this Package, Delete this Package, Send Project Mail, Project History, Messages & Alerts), and 'Other Tools' (Forms and Templates). The main content area is titled 'Submit Package' and contains the following text: 'Welcome to IRBNet Mary Researcher', '[47927-1] Examining the Health Beliefs Model in University Psychology Students', and a paragraph explaining the submission process. Below this is a section 'Please select a Board:' with a search box and a list of organizations. 'Oakland University IRB, Rochester, MI' is highlighted in blue. A red circle with the number '1' points to this selection. Below the list are 'Continue' and 'Cancel' buttons. A red circle with the number '2' points to the 'Continue' button. A red asterisk indicates required fields.

28. After clicking **“Continue”** you will be taken to the following screen. Click on the drop-down menu next to **“Submission Type.”** Select the appropriate option. In this case the PI is submitting a **“New Project”** that has not been previously approved by the IRB. The PI, therefore, selects **“New Project”** as the **“Submission Type.”** You may also add comments to the IRB in the comment box if you choose. This is optional.
29. The last step is to click on the **“Submit”** button. **NOTE: Once you have submitted your application, it CANNOT be deleted!** If you wish to **“DELETE”** this application for any reason, it **MUST** be deleted **BEFORE** you click on **“Submit.”** See the following section (IV Delete a Package Before Submission) to **“Delete”** an application.

The screenshot shows the next step in the IRBNet submission process. The main content area displays the list of IRBNet users at Oakland University IRB who will be notified: Administrator, Whitney; Administrator, Mike; and Administrator, Erin. Below this is a section with a 'Submission Type:' dropdown menu, a 'Your Comments:' text area, and 'Submit' and 'Cancel' buttons. A red circle with the number '1' points to the 'Submission Type' dropdown menu, which has 'New Project' selected. A red circle with the number '2' points to the 'Your Comments' text area. A red circle with the number '3' points to the 'Submit' button.

That is it! You have completed all the steps required to register, log-in, and submit a new study in IRBNet!

IV. Delete a Package before Submission

Deleting a project package before submitting it to the IRB for review is simple but as noted above, it **MUST** be done **BEFORE** you click the **“Submit”** button.

1. Logon to IRBNet. You will be taken to the **“My Projects”** page. Click on **“My Projects”** on the left-hand side of the screen. A list of your projects will be listed. Click on the project you wish to delete. In this example we are going to delete the project we have been working on: **“Examining the Health Belief Model in University Psychology Students.”** Note: in the title bar the **“Status”** of the project reflects that the project has not been submitted; it is still **“Work in Progress.”**

Welcome to IRBNet
Mary Researcher

My Projects

Your "My Projects" workspace shows projects that you have created and projects that have been shared with you by other users on the National Research Network. Use Reminders, Tags and Archiving to help organize your workspace and keep it running smoothly. ([Learn More](#))

Search: Search By Tag:

Search Clear

1 - 10 of 16

Create and Manage Tags | Show Archived Projects (0)

IRBNet ID	Project Title	Principal Investigator	Submission Type	Status	Effective Date
47927-1	Examining the Health Beliefs Model in Un...	Researcher		Work in progress	

2. Once you have clicked on the project you wish to delete, the **“Project Overview”** screen will appear. Click on **“Delete this Package.”**

Welcome to IRBNet
Mary Researcher

Project Overview

[47927-1] Examining the Health Beliefs Model in University Psychology Students

You have Full access to this project. ([Edit](#))

Research Institution	Oakland University, Rochester, MI
Title	Examining the Health Beliefs Model in University Psychology Students
Principal Investigator	Researcher, Mary
Status	Work in progress

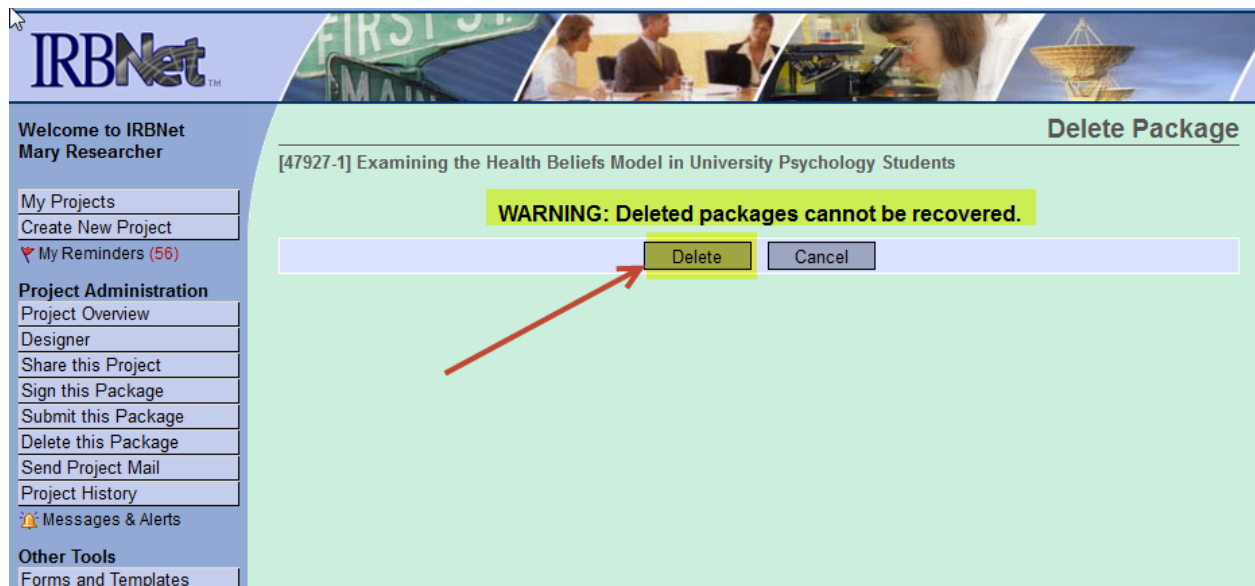
The documents for this project can be accessed from the [Designer](#).

Click [here](#) to submit this package for review.

Shared with the following IRBNet users

IRBNet User	Organization	Access Type
John Researcher	Oakland University, Rochester, MI	Full
Mary Researcher	Oakland University, Rochester, MI	Full

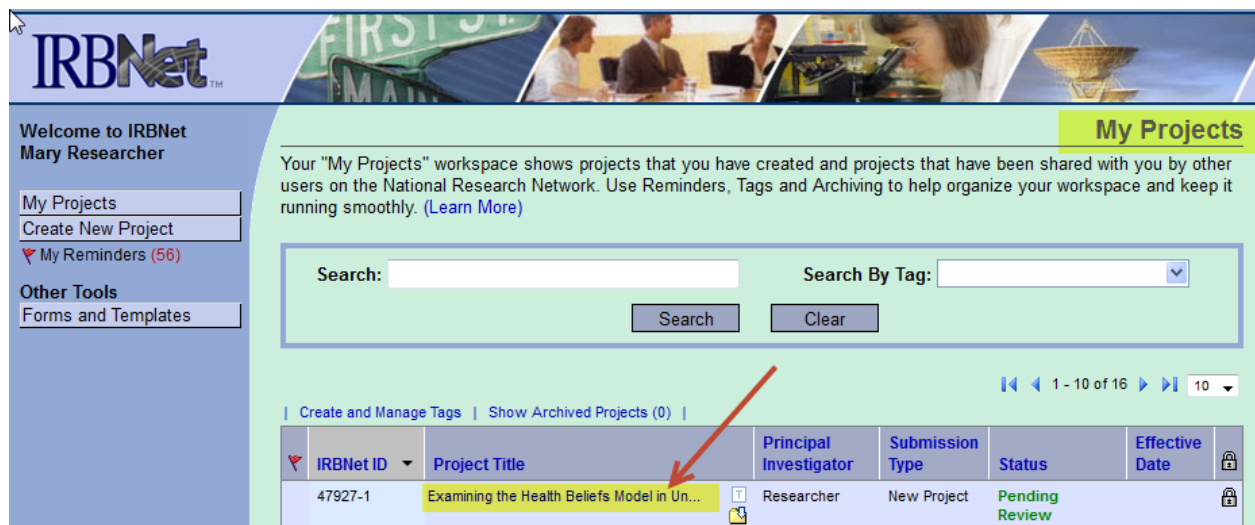
- On the **"Delete Package"** screen, click on **"Delete."** The project package will be deleted. Note the **"Warning"** and make sure you want to permanently delete the project package.



V. Send Project e-Mails

The **"Send Project Mail"** function allows members of the research team to send e-mails without leaving IRBNet and helps to organize e-mail correspondences relating to a project. IRB members can also send Researchers e-mail via this function. If you do this, you **MUST** also send the e-mail to the IRBNet Administrators.

- Log in to IRBNet. From the **"My Project"** page, click on the project you wish to send research team members an e-mail.



- On the **“Project Overview”** page (under **“Project Administration”**), click on the **“Send Project Mail”** button.

Welcome to IRBNet
Mary Researcher

My Projects
Create New Project
My Reminders (56)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts

Other Tools
Forms and Templates

Project Overview

[47927-1] Examining the Health Beliefs Model in University Psychology Students

You have **Full** access to this project. ([Edit](#))

Research Institution Oakland University, Rochester, MI

Title Examining the Health Beliefs Model in University Psychology Students

Principal Investigator Researcher, Mary

Status Pending Review

Lock Status **Locked**

The documents for this project can be accessed from the [Designer](#).

Submitted to:
Oakland University IRB 09/14/2012 **Pending Review**. [Review details](#).

Shared with the following IRBNet users

IRBNet User	Organization	Access Type
Phyllis Kilbourn	Oakland University, Rochester, MI	Full
John Researcher	Oakland University, Rochester, MI	Full
Mary Researcher	Oakland University, Rochester, MI	Full

- Select e-mail recipients. Type a message in the box and click the **“Send”** button.

Welcome to IRBNet
Mary Researcher

My Projects
Create New Project
My Reminders (56)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts

Other Tools
Forms and Templates

New Project Message

[47927-1] Examining the Health Beliefs Model in University Psychology Students

Use this page to send communications to the Project Team or to the Board Contacts for any submitted package. Your message will also be automatically posted to the Project Messages & Alerts. Messages sent from this page become part of the project record and can be viewed by the Project Team and other users who have been granted access to this project as well as by Committee Members and Administrators that review this project.

Project Team:

[Select All Project Owners Only](#) | [Select All](#) | [Un-Select All](#)

User	User Organization	Send Mail
Kilbourn, Phyllis	Oakland University, Rochester, MI	<input checked="" type="checkbox"/>
Researcher, John	Oakland University, Rochester, MI	<input checked="" type="checkbox"/>
Researcher, Mary	Oakland University, Rochester, MI	<input checked="" type="checkbox"/>

Board Contacts:

[Select All](#) | [Un-Select All](#)

Pkg #	Pkg Type	Board	Contact Name	Send Mail
1	New Project	Oakland University IRB, Rochester, MI	Administrator, Erin	<input type="checkbox"/>
1	New Project	Oakland University IRB, Rochester, MI	Administrator, Mike	<input type="checkbox"/>
1	New Project	Oakland University IRB, Rochester, MI	Administrator, Whitney	<input type="checkbox"/>

Subject * IRBNet message from Mary Researcher

Message * Re: [47927-1] Examining the Health Beliefs Model in University Psychology Students

Please logon and review the consent form for this project again. We have been asked to clarify paragraph 2.


Regards,
Mary Researcher

Send **Cancel**

* required fields

VI. Submitting a Revision for your Project While it is in “Review.”

You may have to make one or more changes to your Project before the IRB can grant approval. IRBNet enables you to make revisions to your original **“Project Package”** and track changes throughout the IRB review process. If revisions are needed, you will receive the following Decision Letter document in your e-mail.

 **Institutional Review Board for the Protection of Human Subjects**

Office of Research Administration
Rochester, Michigan 48309-4401
(248) 370-2762 Fax: (248) 370-2973

You will receive a 'Decision Letter' notifying you of the modifications (or revisions) needed before your project can be approved.

DATE: 9/18/2012

TO: Mary Researcher
FROM: Oakland University IRB
PROJECT TITLE: Examining the Health Beliefs Model in University Psychology Students
REFERENCE #: N/A
SUBMISSION TYPE: New Application

ACTION: MODIFICATIONS REQUIRED

APPROVAL DATE: N/A
EXPIRATION DATE: N/A
REVIEW TYPE: Full Board

Thank you for your submission of the “New Application” materials for this project. The Oakland University IRB has determined that the following MODIFICATIONS are REQUIRED in order to secure approval:

1) Clarification of the exclusion criteria

Research activities in accordance with this submission may not begin until this committee has received a response to these conditions and issued final approval.

This submission has received “New Application” based on applicable federal regulations.

If you have any questions, please contact Judette Haddad, Ph.D. at (248) 370-4898 or haddad@oakland.edu. Please include your project title and name in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Oakland University's IRB records.

1. When you log in to IRBNet, the **"My Projects"** screen will show under the **"Status"** column that **"Modifications are Required."** Click on the project that requires modifications.

Welcome to IRBNet
Mary Researcher

My Projects

Your "My Projects" workspace shows projects that you have created and projects that have been shared with you by other users on the National Research Network. Use Reminders, Tags and Archiving to help organize your workspace and keep it running smoothly. ([Learn More](#))

Search: Search By Tag:

Search Clear

1 - 10 of 17

IRBNet ID	Project Title	Principal Investigator	Submission Type	Status	Effective Date
48023-1	Becky's practice	Sandborg		Work in progress	
47927-1	Examining the Health Beliefs Model in University Psychology Students	Researcher	New Project	Modifications Required	09/18/2012

2. You will be taken to the **"Project Overview"** page. Click on **"Project History"** on the left-hand side of the screen. You will be taken to the **"Project History"** page.

Welcome to IRBNet
Mary Researcher

Project Overview

[47927-1] Examining the Health Beliefs Model in University Psychology Students

You have Full access to this project. ([Edit](#))

Research Institution	Oakland University, Rochester, MI
Title	Examining the Health Beliefs Model in University Psychology Students
Principal Investigator	Researcher, Mary
Status	Modifications Required
Lock Status	Locked - Revisions Complete

The documents for this project can be accessed from the [Designer](#).

Submitted to:
Oakland University IRB 09/14/2012 **Modifications Required** 09/18/2012. [Review details](#).

Shared with the following IRBNet users

IRBNet User	Organization	Access Type
Phyllis Kilbourn	Oakland University, Rochester, MI	Full
John Researcher	Oakland University, Rochester, MI	Full
Mary Researcher	Oakland University, Rochester, MI	Full

- On the **"Project History"** page click on **"Create New Package."**

Welcome to IRBNet
Mary Researcher

My Projects
Create New Project
My Reminders (63)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (6)

Other Tools
Forms and Templates

Project History

[47927-1] Examining the Health Beliefs Model in University Psychology Students

The following document packages are available in Project History:

Pkg #	Package Type	Status	Create Date	Submission Date	Review Date
1	New Project	Modifications Required	09/10/2012	09/14/2012	09/18/2012

One Package found.

You are currently viewing this package.

Your current document package has already been submitted and is presently locked by your Board. You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package.

Create New Package

- Notice on the **"Project History"** page that a **"NEW Document Package"** has been created when the "Create New Package" option has been clicked (See arrow number 1 in the screenshot below) IRBNet uses the same project number (47927-1 in this example) but changes the package number from 1 to 2. (47927-2 as shown in arrow number 2). This allows for all revisions in an application to be tracked. The status of this **Project Package** is now **"Work in Progress"** as shown by arrow number 3. Do **NOT** confuse a **"New Document Package"** with a **"New Project"**. There may be many **"Packages"** associated with each project. For Example: when a continuing review application is submitted for a specific study/protocol, a **"New Package"** will be created again and submitted under the existing project if one has been created.

Click on **"New Document Package"** to begin the process of modifying your Project Package. You will be taken back to the **"Designer"** page.

Welcome to IRBNet
Mary Researcher

My Projects
Create New Project
My Reminders (63)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (6)

Other Tools
Forms and Templates

Project History

[47927-2] Examining the Health Beliefs Model in University Psychology Students

The following document packages are available in Project History:

Pkg #	Package Type	Status	Create Date	Submission Date	Review Date
2	New Document Package	Work in progress	09/19/2012		
1	New Project	Modifications Required	09/10/2012	09/14/2012	09/18/2012

2 Packages found, displaying all Packages.

You are currently viewing this package.

5. The **"Designer"** page will show information for the **"New Document Package."** From this page you can either **"Add New Document"** if you have a new document to add that was NOT previously submitted (for example: a new questionnaire) or update a document submitted in a previous Project Package.

There are two options on the "Designer" page to add documents to the **"New Project"** package. The following helps to clarify when to use these options.

Add a New Document. Use the **"Add New Document"** button option when the document you are adding is **NOT** a revised or updated version of an existing project document. The "new" document will not be tied to the Document History of any existing document, and it will not have any Document History of its own since it is a completely new addition to your project.

Revise an Existing Document. Use this **"Pencil Icon"** option when you want to add a new version of an existing project document. IRBNet adds the new version of your document while retaining all historical versions as part of your Document History. The new version will be automatically tied to the Document History. You may view the historical versions of any document by clicking on the Document History icon.

Welcome to IRBNet Mary Researcher

My Projects
Create New Project
My Reminders (69)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (9)

Other Tools
Forms and Templates

Designer
[47927-2] Examining the Health Beliefs Model in University Psychology Students

Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library:
Select a Document:

Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.

New and Revised Documents in this Package:

There are currently no documents in this package.

No Documents in the "New Document Package Yet."

There are no Training & Credentials records linked to this package. [Link / Un-Link Training Records](#)

IRBNet allows you to revise your existing project documents and maintain version history, or add entirely new documents to your package. [Learn more.](#)

(When should I do this?)

OR

Documents from Previous Packages that you can Revise: (When should I do this?)

Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status	
1	Application Form	Expedited/Full Board Application	09/10/2012 10:58 AM	09/14/2012	Modifications Required	
1	Consent Form	Consent Form	09/10/2012 11:11 AM	09/14/2012	Modifications Required	


Download Existing Document/Make Revisions

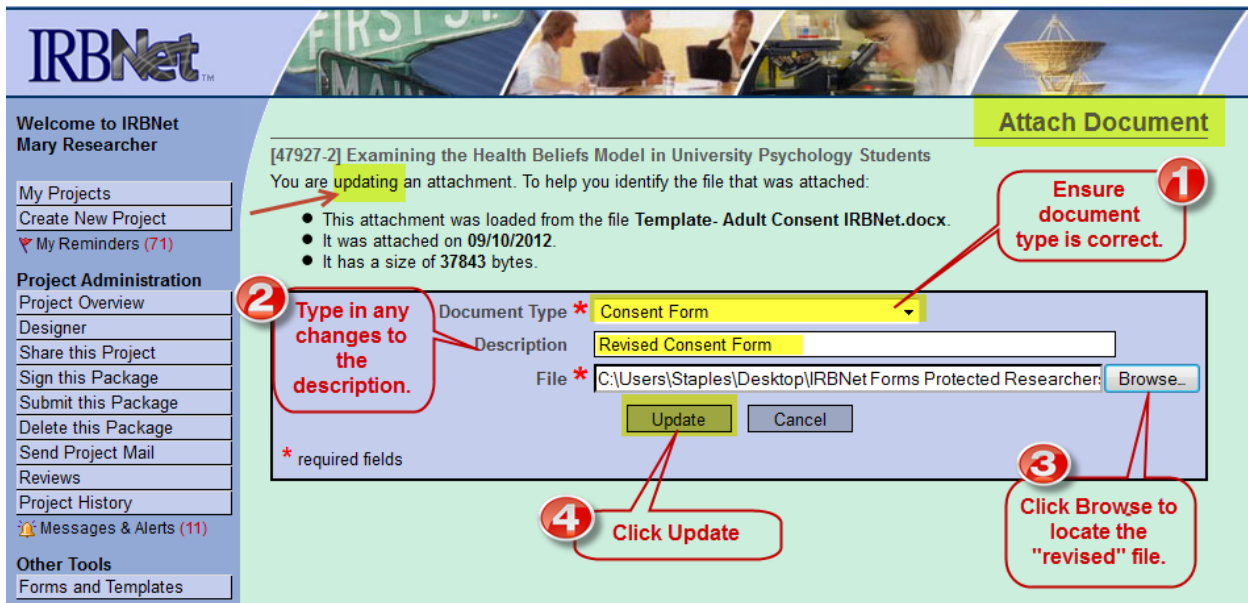
Use the "Add New Document" function to add a document that is NOT in the previous Project Package.

Use the "Pencil" to Upload the "Revised" Consent Form.

6. In this example, Mary Researcher has received notice that she must modify her Consent Form by clarifying the study's exclusion criteria. She would update the

document from the **"New Document Package"** she created. This process allows IRBNet and the researcher to track all changes to the project.

7. Because Mary Researcher is making revisions to an existing document that she previously submitted in her first package, on the screenshot of the **"Designer"** page above, Mary should select options from the **"Documents from Previous Packages that you can revise"** selection. This section of the **"Designer"** page allows researchers to revise previously submitted documents.
8. Mary can access the Consent Form she needs to revise by either clicking on the Paper Icon next to the Consent Form under Document Type and downloading it to her desktop, or accessing the document from her personal project files.
9. Once all the changes to the consent form have been made, the consent should be updated with the most current version date and saved to your personal project files.
10. To add the revised consent, click on the "Pencil Icon" .
11. At the top of the **"Attach Document"** page, it will show you that you are "updating" an attachment and when the original form you are editing was loaded.



The screenshot shows the IRBNet interface. On the left is a navigation menu with sections: 'Welcome to IRBNet Mary Researcher', 'My Projects' (with links for 'Create New Project' and 'My Reminders (71)'), 'Project Administration' (with links for 'Project Overview', 'Designer', 'Share this Project', 'Sign this Package', 'Submit this Package', 'Delete this Package', 'Send Project Mail', 'Reviews', 'Project History', and 'Messages & Alerts (11)'), and 'Other Tools' (with link for 'Forms and Templates'). The main content area is titled 'Attach Document' and shows a message: '[47927-2] Examining the Health Beliefs Model in University Psychology Students. You are updating an attachment. To help you identify the file that was attached:'. Below this message is a list of details: 'This attachment was loaded from the file Template- Adult Consent IRBNet.docx.', 'It was attached on 09/10/2012.', and 'It has a size of 37843 bytes.' Four numbered callouts are present: 1. A red circle with the number '1' and the text 'Ensure document type is correct.' pointing to the 'Document Type' dropdown menu which is set to 'Consent Form'. 2. A red circle with the number '2' and the text 'Type in any changes to the description.' pointing to the 'Description' text box which contains 'Revised Consent Form'. 3. A red circle with the number '3' and the text 'Click Browse to locate the "revised" file.' pointing to the 'Browse...' button next to the 'File' field. 4. A red circle with the number '4' and the text 'Click Update' pointing to the 'Update' button. The 'File' field shows a path: 'C:\Users\Staples\Desktop\IRBNet Forms Protected Researcher\'. There are also 'Update' and 'Cancel' buttons at the bottom of the form area.

12. Ensure that the **"Document Type"** drop-down box contains the correct information.
13. Type in any changes to the file **"Description"** in the Description Text Box.
14. Click the **"Browse"** button to locate your revised version of your document.

15. Click the **"Update"** button to finish uploading the revised version. You will then be taken back to the **"Designer Screen."**

Welcome to IRBNet
Mary Researcher

My Projects
Create New Project
My Reminders (71)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (1)

Other Tools
Forms and Templates

Designer

[47927-2] Examining the Health Beliefs Model in University Psychology Students

This package is: **Locked - Revisions Complete** | [View History](#) |

Get stamped documents, approval letters and other board documents, and track reviews for this package: [Review details](#).

Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library: **Oakland University IRB, Rochester, MI**
Select a Document: **1. Application IRB Exempt** **Download**

Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.

New and Revised Documents in this Package:

Document Type	Description	Last Modified
Consent Form	Revised Consent Form	09/23/2012 03:33 PM

There are **2** documents in this package.

Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status
2	Consent Form	Revised Consent Form	09/23/2012 03:33 PM	09/19/2012	Pending Review
1	Consent Form	Consent Form	09/10/2012 11:11 AM	09/14/2012	Modifications Required

new documents to

Document

Pkg #

1 A

10:58 AM

Required

After all required modifications have been made, click on "Sign this Package."

16. Looking at the example above, you can see that the **"Revised Consent Form"** document is now located under the **"New and Revised Documents"** heading along with the original **"Consent Form"** which can no longer be accessed and revised from the first Project Package.
17. Click on the paper stack icon to view all versions of the Consent Form.
18. After all required modifications have been made and any other new documents attached, click on **"Sign this Package."** Use the drop-down box to select your role in the Project and then click the **"Sign"** button. In this example, Mary Researcher is signing the project package as the PI.

Welcome to IRBNet
Mary Researcher

My Projects
Create New Project
My Reminders (71)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (11)

Other Tools
Forms and Templates

[47927-2] Examining the Health Beliefs Model in University Psychology Students

I Mary Researcher, as Principal Investigator, certify that to the best of my knowledge the information contained in this package is accurate and ready for submission in accordance with all applicable institutional requirements and that my electronic signature is intended to be the legally binding equivalent of a traditional handwritten signature.

To sign on behalf of an

This package has been signed on 09/19/2012 03:02 PM M

Sign

Signature Mode.

Role	Details
Advisor	

19. On the **"Submit Package"** page, ensure that Oakland University is selected and click on **"Continue."**

Welcome to IRBNet
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Other Tools
Forms and Templates

Submit Package

[47927-2] Examining the Health Beliefs Model in University Psychology Students

IRBNet supports multiple models of review. Using the IRBNet "Submit" feature, you may electronically submit this document package to either a single Board, or to multiple Boards. Each Board you submit to will be notified of your submission and given access to view your electronic documents. Each Board will also be permitted to electronically record their review decision, which will be stored as a permanent part of your project record. You will be automatically notified when the review decision is electronically recorded.

Please select a Board:

Search for an Organization

Select a Board *

Continue

Cancel

* required fields

20. After clicking **"Continue,"** you will be taken to the following screen.

Welcome to IRBNet
Mary Researcher

My Projects
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My Reminders (71)

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Submit Package

[47927-2] Examining the Health Beliefs Model in University Psychology Students

The following IRBNet users at **Oakland University IRB** will be automatically notified of your submission:

Administrator, Erin
Administrator, Whitney
Administrator, Mike

Submission Type: *

You may also specify additional comments to

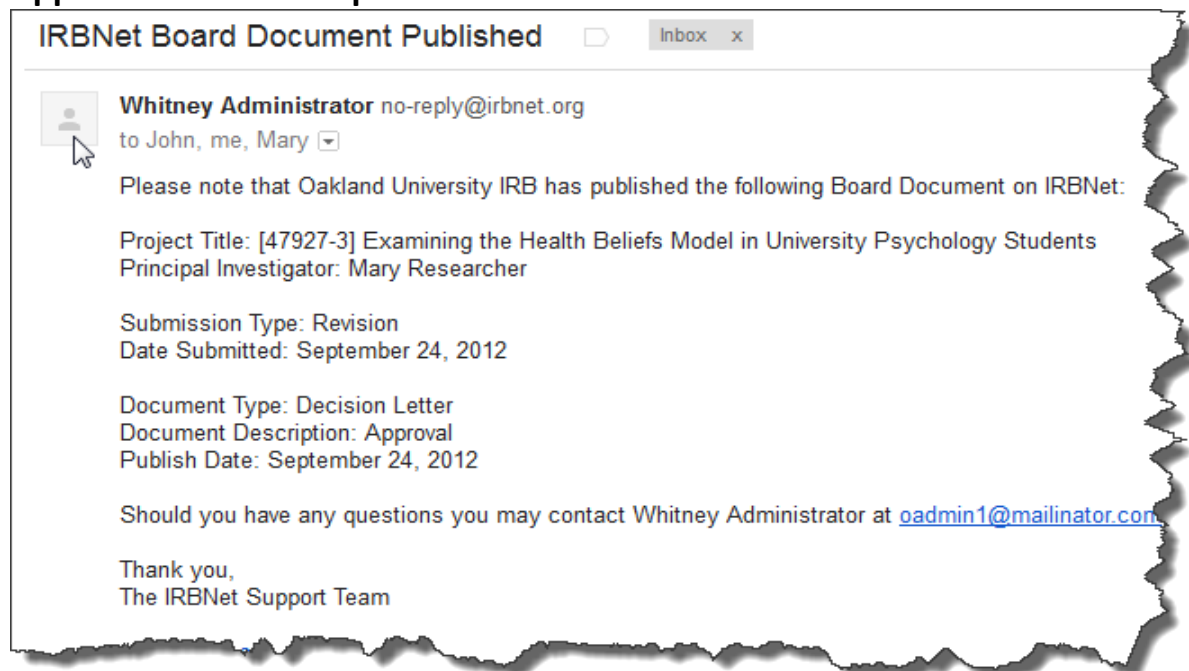
Your Comments:

Submit


Cancel

21. Click on the drop-down menu next to **"Submission Type."** Select the appropriate option. In this case the PI is submitting a new Project Package created to make changes and/or revisions required by the IRB to gain **"Initial"** approval. Therefore, the PI would select **"Revision"** as the Submission Type in this case.
22. Click the **"Submit"** button, and you are done with submitting your new Project Package.
23. If the IRB Board approves your project, you will receive an e-mail and a decision letter notifying you that the research project has been approved. It is also possible you may be informed that your study needs further revisions, or that the research was not approved by the IRB.
24. In order to view your notification letter, log in to IRBNet and open your project. Click on the **"Reviews"** tab on the **"Project Overview"** page which will display a list of published board documents including approval and modifications letters.
25. If you have any questions regarding notifications you receive from IRBNet please contact the Regulatory Compliance Coordinator in the Office of Research Administration at (248) 370-4898.

Approval E-Mail Example



Approval Decision Letter Example

	Institutional Review Board for the Protection of Human Subjects
	Office of Research Administration Rochester, Michigan 48309-4401 (248) 370-2762 Fax: (248) 370-2973
DATE:	9/27/2012
TO:	Mary Researcher
FROM:	Oakland University IRB
PROJECT TITLE:	Examining the Health Beliefs Model in University Psychology Students
REFERENCE #:	47927
SUBMISSION TYPE:	New Application
ACTION:	Approved
APPROVAL DATE:	9/27/2012
EXPIRATION DATE:	9/27/2013
REVIEW TYPE:	Full Board
<p>Thank you for your submission of your new study materials for this project. The Oakland University IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.</p> <p>This submission has received full board review based on applicable federal regulations.</p> <p>Please remember that if you need to make any changes to your submission, you must submit a new application with a description of the project.</p>	

VII. Submitting New Packages: Amendments, Continuing Reviews, etc.

For previously approved studies, a **"Modification/Amendment"** form is used to request any changes to the Project. If the study was initially approved in RAM2.0, a new project must be created in IRBNet. If a project has already been created, a **new package** must be submitted. A **"Continuing Review/Renewal"** submission type is used to ask for an extension of the initial approval period (usually one year). **The submission process is nearly identical for all Project Packages, with the exception of determining the "Submission Type."** **Each of these submissions would be submitted to the IRB as a new package under an existing project.**