Kaiser Foundation Research Institute IRBNet User's Guide

Version 4/10/2018

INTRODUCTION

The Kaiser Permanente IRB is responsible for ensuring that any research study under its jurisdiction is in compliance with federal, state, and institutional regulations. All submissions must be submitted electronically to the Kaiser Permanente IRB through IRBNet. IRBNet is a hosted service that supports electronic, on-line submissions. Hard copies will no longer be accepted. IRBNET can be accessed at the following web address <u>www.irbnet.org</u>.

The purpose of this document is to provide guidance for submitting to the Kaiser Permanente IRB via IRBNet. Step-by-step instructions will be given for each type of submission.

If you have questions regarding this initiative, please email <u>eIRB.Support@kp.org</u>.

AVAILABLE TRAINING RESOURCES

Kaiser Foundation Research Institute (KFRI) Website

Within the <u>KFRI Website</u> you will find eIRB support and training information.

Training Videos and Handouts

IRBNet has developed training videos and handouts that take you through the steps of using their system. You may access the training videos and handouts by going to: http://www.irbnetresources.org/tresources/training.html

Username: kp Password: training

New User Registration Instructions provides instructions for Registering with IRBNet. New Project Submission video walks through the process of submitting an Initial Submission. Post-Submission Advanced Topics video walks through the process of submitting subsequent materials like Continuing Reviews, Amendments, Study Closures, etc.

The Sandbox

IRBNet has developed a training environment for hands-on, self-training purposes called the Sandbox. The Sandbox mirrors our institution's configuration of IRBNet. You may access the Sandbox by going to: <u>http://training.irbnet.org</u>

Username(s): kaiserresearch1 kaiserresearch2 kaiserresearch3 kaiserresearch4 Password: training

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1. USER PROFILE INSTRUCTIONS

IMPORTANT NOTE FOR RESEARCHERS AFFECTED BY THE eIRB MIGRATION:

- For migrated users/researchers your IRBNet account has been created on your behalf during the eIRB migration effort. Please contact your local IRB Office if you have NOT received your IRBNet Username and Temporary Password. Please follow the steps below for **MIGRATED USERS/RESEARCHERS.**
- All NEW users/researchers who were NOT registered with your local Kaiser Permanente Regional IRB system (prior to IRBNet) then please SKIP the next section and follow the NEW USER/RESEARCHER steps.

MIGRATED USER/RESEARCHER

Step 1: Go to <u>www.irbnet.org</u> and log in using your PROVIDED username and TEMPORARY password.

You will be prompted to create a new password.

7	IRBNet Login Help
Expired Password	
Your IRBNet password has expired. Please select a new password.	
Old Password	
New Password	
Confirm New Password	
Password hint	
Save Cancel	

Read and Accept the Individual User Terms of Use.

If you have problems activating your account please contact your local IRB Office for assistance.

NEW USER/RESEARCHER

Step 1: Go to <u>www.irbnet.org</u> and click on **'New User Registration'**.



Create your username and password. Fill out the required information and click **'Continue'**.

First Name *	
Last Name *	
User Name *	
Password *	
Confirm Password *	
Password Hint	
	Continue Cancel
* required fields	

Read and **Accept** the Individual User Terms of Use.

Step 2:You must add your affiliation. Type the word 'Kaiser Permanente' into the
search box. Click 'Display'. Select the appropriate 'Kaiser Permanente – YOUR
REGION' region from the organization box. Click 'Continue'.

	Registration
Add Affiliation	
	u are affiliated. If you are affiliated with more than one organization, you may add le the registration process by logging in to IRBNet and accessing your User Profile.
Search for an organization	kaiser permanente Search Clear
Organization types to display	Research Institutions Boards Sponsors Display
Your Organization *	Kaiser Permanente - Colorado Region, Denver, CO Kaiser Permanente - Georgia Region, Atlanta, GA Kaiser Permanente - Hid-Atlantic States Region, Rockville, MD Kaiser Permanente - Nid-Atlantic States Region, Rockville, MD Kaiser Permanente - Northwest Region, Portland, OR Kaiser Permanente - Southern California Region, Pasadena, CA Kaiser Permanente - Southern California Region, Pasadena, CA Kaiser Permanente - Washington Region, Seattle, WA Kaiser Permanente, Los Angeles, CA
If you do not se	e your organization listed you may add a new organization.
	Continue Cancel
* required fields	

Step 3: Enter your contact information.

Please note: Enter the email address you will want to receive all IRBNet communications from. Communications will include notification of IRB decisions, communications from your research team or administrator, etc.

Click 'Continue'.

Review the information you provided and edit as necessary. When you are satisfied, click '**Register**'.

IMPORTANT: An email will be sent to the email address you provided with **'IRBNet Activation Required'** in the subject line. If you do not receive the confirmation in a short period then check your junk folder to see if it is there.

You will need to click on the link provided in this registration email in order to activate your account. Clicking on the link will take you to the IRBNet homepage.

If you have problems activating your account or have forgotten your password, please click on the 'Forgot your Password?' text in the upper right corner of the IRBNet home page.

2. TRACK TRAINING TOOL

The following steps will guide you through linking your CITI and KP Learn training directly to your IRBNet account. **This section applies to ALL migrated and new users/researchers.** Linking your IRBNet profile to an external account allows information such as training records to be automatically available to you and your regional IRB.

Step 1: Log in to <u>www.irbnet.org</u> using your username and password.

Go to 'USER PROFILE'.

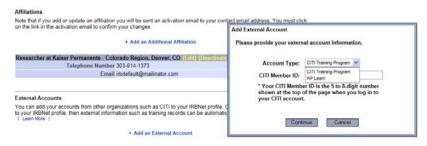
Step 2: Click 'Add an External Account' to link your CITI account to your IRBNet User Profile.

User Profile
Manage Your User Profile
You may access this page at any time to update your account information, change your password, manage your affiliations and external accounts, and manage your Training & Credentials records.
User Account Information and Password (Edit)
Username kpcoresearch1
First Name Pamela
Last Name Researcher
Affiliations Note that if you add or update an affiliation you will be sent an activation email to your contact email address. You must click on the link in the activation email to confirm your changes.
► Add an Additional Affiliation
Researcher at Kaiser Permanente - Colorado Region, Denver, CO (Edit) (Deactivate)
Telephone Number 3948594039
Email kpcoresearch1@mailinator.com
External Accounts
You can add your accounts from other organizations such as CITI to your IRBNet profile. Once you add an external account to your IRBNet profile, then external information such as training records can be automatically available to you in IRBNet.
► Add an External Account
There are currently no external accounts in your profile.
Training & Credentials
IRBNet allows you to track and share your training records, certifications, resumes and other personal credentials. Once added to your profile, your training and credentials can be easily linked to your projects from the Designer, are accessible by your project teams and can be quickly accessed and tracked by the boards that review your projects. Some boards also permit you to directly submit your training and credentials without requiring you to link these records to specific projects.
► Add a New Training & Credentials Record

Please note: To learn more about your CITI and KP Learn account verification process click **'Learn More'** (indicated above).

TRACK TRAINING TOOL

Select CITI Training Program from the dropdown menu and enter your **CITI Member ID** number.



Please Note: You can find your **CITI Member ID** under My Profile on the following CITI website <u>https://about.citiprogram.org/en/homepage/</u>. If you are still unable to obtain your CITI Member ID please contact your regional IRB Office.

Step 3: Follow the same instructions in **Step 2 to 'Add an External Account'** again. Now you will need to link your KP Learn account. Select KP Learn from the dropdown menu and enter your **KP NUID** number.

IMPORTANT: Once you add your CITI and KP Learn external accounts to your IRBNet profile, your external account will be automatically identified and you will then be requested to verify your ownership before the link will become active. To verify your ownership of the external account, you will receive a verification email at your account's email address.

Step 4: Per your regional IRB requirements, you may also be required to upload additional training and credentials (i.e., course certificates NOT linked with CITI or KP Learn, CV/resume, etc.) to your IRBNet User Profile.

Click 'Add a New Training & Credential Record'.

Select the **'Document Type'** from the dropdown menu, enter the **Effective Date**, and enter the document **Description**. Choose the file saved to your computer and attach.

Training & Credentials								
IRBNet allows you to track and share your training records, certifications, resumes and other personal credentials. Once added to your profile, your training and credentials can be easily linked to your projects from the Designer, are accessible by your project teams and can be quickly accessed and tracked by the boards that review your projects. Some boards also permit you to directly submit your training and credentials without requiring you to link these records to specific projects.				ssible by also				
						1	Show all V	/ersions
Y Doc ID Document Type	Description	Cr	Effective Date	Expiration Date	Last Modified	Status		
20261.1 CV/Resume	CV		11/28/2017		11/28/2017 03:14 PM	Accepted		Ø
							Submit	🌋 🖂

TRACK TRAINING TOOL

- **Step 3:** Click **'Submit'** to submit the document to your regional IRB.
- **Step 4:** You can track the status of your Training & Credential documents under the **'Status'** column.

To manage your Training & Credentials documents click on the **'Pencil'** icon. This will allow you to update your previously submitted document.

IRE ado you	Training & Credentials RBNet allows you to track and share your training records, certifications, resumes and other personal credentials. Once added to your profile, your training and credentials can be easily linked to your projects from the Designer, are accessible by your project teams and can be quickly accessed and tracked by the boards that review your projects. Some boards also bermit you to directly submit your training and credentials without requiring you to link these records to specific projects. Add a New Training & Credentials Record									
۲	Doc ID	Document Type	Description	Cr	Effective Date	Expiration Date	Last Modified	 Status	Show all '	√ersions
	20261.1	CV/Resume	CV		11/28/2017		11/28/2017 03:14 PM	Accepted	Submit	
		 IRB Training - OHRP - Research Use of Human Biological Specimens and Other Private Information 			10/05/2017		03/02/2018 12:37 PM		Submit	
	20374.1	 IRB Training - PRIM&R - IRB 250 	CONSENT FORM.docx		03/01/2018		03/02/2018 12:41 PM		Submit	

3. INITIAL SUBMISSION (Create a New Project)

To submit a study for review, you must first **CREATE A NEW PROJECT**. Any type of document can be uploaded, but your study MUST include all the required forms for a complete package before any action can be taken on behalf of the IRB. A good place to start is your regional **'Checklist – Initial Submissions'** which includes a list of the required forms for a new study. This and other guidance documents can be found under **OTHER TOOLS** (Forms and Templates) on the left side of your screen.

- **Step 1:** Log in to <u>www.irbnet.org</u> using your username and password.
- Step 2:The default page will be MY PROJECTS, where you will have access to all of your
existing studies as well as the ability to create new studies. Click CREATE NEW
PROJECT (on the left side of your screen).

Welcome to IRBNet Pamela Researcher		
🕜 Help		
My Projects		
Create New Project		
Y My Reminders (37)		
Other Tools		
Forms and Templates		

Fill in the relevant information about your project (Title, PI name), click 'Continue'.

IRBNet.	
Welcome to IRBNet Project Info	rmation
Pamela Researcher Create a New Project	
Help To create a new project, first provide the basic project information below. Once your project is created you ma	/ attach
My Projects project documentation and share the project with other users.	
Wy Reminders (34) Research Institution: Kaiser Permanente - Colorado Region, Denver, CO	
Other Tools	
Forms and Templates Title: *	
First Name:*	
Local Principal Investigator: Last Name:* Degree(s):	
Keywords:	
Sponsor:	
You may specify an internal account number, billing identifier or ref	rence
number for this project.	arenee
Internal Reference Number:	
Continue	
* required fields	

Step 3:You will now be on the DESIGNER page where you can download forms, templates,
and other materials to assemble a new study. Select 'Kaiser Permanente – YOUR
REGION' from the 'Select a Library' drop-down menu. (This should be your default
location and should be highlighted already).

Then select the necessary forms/templates that pertain to your project from the '**Select a Document'** drop down menu. Save these documents to your computer in a place where you can find them again (i.e., Desktop, My Documents, etc.).

IRBNet ID: 59137-1			USER PROFILE LOGOUT
IRBNet .	ARDIO.		
Welcome to IRBNet			Designer
Pamela Researcher	[59137] Helping new users to navigate	e IRBNet	
 Help 	Package: v 59137-1 Work in progress	(Not submitted)	
My Projects		· · · · ·	
Create New Project		Click to add a package description or notes.	
Y My Reminders (34)			
Project Administration Project Overview	Step 1: Download blank forms, document templ	ates and reference materials to assist you in asse	Hide Form Libraries
Designer			inbillig your document package.
Share this Project		ente - Colorado Region IRB, Denver, CO 🔻	
Sign this Package	Select a Document: -Read Me First	 Download 	
Submit this Package			
Delete this Package Send Project Mail	Step 2:	Management of the second secon	the second set of a second second set of the
Project History		. You can add new project documents, revise exis r project team's Training & Credentials to your pa	
1 Messages & Alerts			• · · · ·
Other Tools	Documents in this Package:		
Forms and Templates	Document Type	Description	Last Modified
	v (please select)	Consent Form	02/26/2018
	Conflict of Interest - Other Consent Form	Kaiser Permanente - IRB Core Data Form	02/26/2018
	Consent Waiver		
	The Continuing Review/Progress Report	rds linked to this package. Link / Un-Link Training	Records
	Cover Sheet		
	CV/Resume		
	Data Collection	Wizard OR Attach New Docume	ent (When should I do this?)

Once you find the document, click the 'Attach' button to upload the document.

Attach any applicable supporting documents for your initial submission package by clicking on **'Attach New Document'** and browsing your computer.

Label your documents appropriately using the **'Document Type'** drop-down list (i.e., Protocol, Consent Form, Letter, etc).

Please note: See Section 12 "How to Label Documents" for naming convention guidelines.

Step 4: Next, access the required **SMART Forms** from 'Start a Wizard.'

Please Note: The *Core Data Form* and the *Study Team Form* is required for <u>ALL</u> new studies.

IRBNet ID: 59137-1	USER PROFILE LOGOUT	
IRBNet		
Velcome to IRBNet Pamela Researcher	Designer [59137] Helping new users to navigate IRBNet	
Help	Package: v 59137-1 Work in progress (Not submitted)	
My Projects Create New Project	Click to add a package description or notes.	
My Reminders (34)		
Project Administration Project Overview Designer Share this Project Sign this Package Submit this Package	Step 1: Hide Form Libraries Download blank forms, document templates and reference materials to assist you in assembling your document package. Select a Library: Kaiser Permanente - Colorado Region IRB, Denver, CO ▼ Select a Document: Read Me First ▼	
Delete this Package Send Project Mail Project History Messages & Alerts Dther Tools Forms and Templates	Step 2: Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. Learn more Documents in this Package:	
	There are no documents in this package.	
	There are no Training & Credentials records linked to this package. Link / Un-Link Training Records Start a Wizard OR Attach New Document (When should do this?)	

Step 4: SHARE THIS PROJECT with your research team. Click the **'Share this Project'** button on the left side of your screen; click the blue **'Share'** link to grant access to this project.

- Share: Use this option if you wish to share your study with other Researchers, Committee Members, Administrators or Sponsors at your own institution or any other institution. For example, you may wish to share this study with other members of your research team so that you may collaborate in the design and development of the study, or with a selected Committee Member or Administrator to solicit feedback prior to submitting your study. You may provide any individual with Full, Write or Read access.
 Multi-site: Use this option only if your study is a multi-site study and you wish to send a complete and independent copy of this study to a Principal Investigator at another site. The local Principal Investigator will receive their own independent copy of all study documents 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 study at every local site. The other local Principal Investigators will also be able to monitor the progress of this study at every local site.
- (including your own).
 Transfer: Transfer your ownership of this study to another user. In doing so you will relinquish all access to this study and the designated user will be granted Full access.

Select 'Kaiser Permanente – **YOUR REGION**' from the organization box; click '**Select Organization**' and search for registered users with whom you'd like to share this project (i.e. your Principal Investigator, Co-Investigators, other study staff, etc.)

Grant each user a level of ACCESS: Full, Write, or Read.

Please Note: To 'Share' your research project with someone, they must be registered with IRBNet.

Selected users will be notified automatically via email that the project has been shared with them, and you may enter comments to be included within the email.

Step 5: When all the necessary documents are uploaded to the package, the Principal Investigator MUST sign the package.

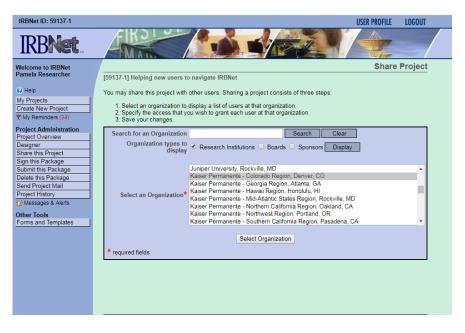
If the PI did not create the project then send an e-mail to the PI using the **'Send Project Mail'** function and request that the PI sign the package.

Click on **SIGN THIS PACKAGE**. Select the appropriate role from the dropdown box and click **'Sign'**.



Note: If a submission is submitted without the Principal Investigator signature, the submission will not be accepted for IRB review.

Step 6: Once the PI has signed the package, click **SUBMIT THIS PACKAGE**. Select 'Kaiser Permanente – **YOUR REGION**' in the **"Search for Organization**" drop down menu.



Then click the **'Continue**' button. In the Submission Type drop-down menu, select **'New Project'** and click **'Submit'**. Once you hit the **"Submit**" button, you will be given a confirmation showing the time your submission occurred.

INITIAL SUBMISSION (Create a New Project)

IRBNet ID: 59137-1	USER PROFILE LOGOUT
IRBNet.	
Welcome to IRBNet	Submit Package
Pamela Researcher	[59137-1] Helping new users to navigate IRBNet
🚱 Help	The following users at Kaiser Permanente - Colorado Region IRB will be automatically notified of your submission:
My Projects Create New Project	Administrator, Morgan Coordinator, Molly
V My Reminders (34)	Submission Type: * New Project
Project Administration Project Overview	You may also specify additional comments to be included in this notification.
Designer Share this Project	
Sign this Package	Your Comments:
Submit this Package Delete this Package	Four Comments:
Send Project Mail	
Project History Messages & Alerts	Submit Cancel
Other Tools	
Forms and Templates	

Once you hit the '**Submit**' button, you will be given a confirmation showing the time your submission occurred.

Step 7:To review what has been sent, click PROJECT OVERVIEW. The package (under
Board Action) should indicate 'Pending Review' status until a decision by the board
has been made. Once a decision letter is formulated, an email will be sent to
everyone who has full access.

User Tip: Keep in mind that once you click 'Submit' your study is now locked and no other changes can be made to this package. Take the time to be sure all documents are attached and in the final version **prior to submitting**. Any incomplete submissions will not be reviewed by the IRB and will be returned for corrections.

4. CONTINUING REVIEW SUBMISSION

- Step 1:Log in to www.irbnet.org. This will take you to the MY PROJECTS page.This is where all of the studies that you have access to will be housed.
- **Step 2:** Click on the Title of the project that you would like to continue/renew (or click on the exact IRBNet project referenced in the e-mail you received reminding you to renew your study). You may also utilize the search function on the **MY PROJECTS** page by searching for study title or project ID number.

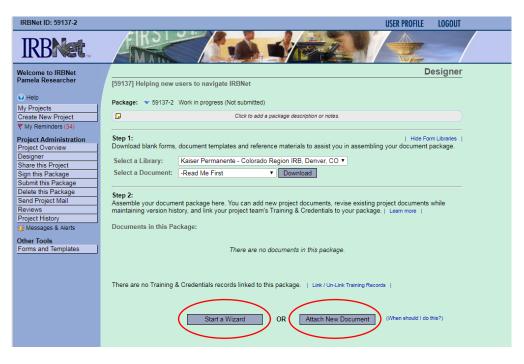
Then click on **CREATE A NEW PACKAGE**.

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Create a New Package
1 Messages & Alerts (8)

Step 3: You will now be on the **DESIGNER** page.

This is where you can access the library of forms from your regional library and through the **'Start a Wizard'** SMART forms.

Select **'Start a Wizard'** and from the drop-down menu and then select the required **'Continuing Review/Closure Form'** SMART Form. From here, you will complete the SMART form for the Continuing Review package.



Assemble your document package through clicking on '**Attach New Document'** until the all documents have been added.

In the **Document Type** drop-down box, pick the best match for the document you are uploading. If the type of document you are submitting is not in the list then choose "Other" and enter the type of document in the **Description** field.

Please note: See Section 12 "How to Label Documents" for naming convention guidelines.

IMPORTANT NOTE FOR RESEARCHERS WITH <u>MIGRATED</u> STUDIES ONLY:

When making your FIRST submission in IRBNet (modification or continuing review, whichever comes first) for a MIGRATED study you will be required to complete and submit the **IRB Core Data SMART Form** and the **Study Staff SMART Form** with your submission package.

Please contact your regional IRB Office if you have any questions about this process.

Step 4: When all the necessary documents are in the package, the Principal Investigator MUST sign the package electronically. If the PI did not create the package then send an e-mail to the PI using the "**Send Project Mail**" function and request that the PI sign the package.

Click on **SIGN THIS PACKAGE**. Select the appropriate role from the dropdown box and click '**Sign**'.

IRBNet ID: 59137-2	USER PROFILE LOGOUT
IRBNet	
Welcome to IRBNet	Sign Package
Pamela Researcher	[59137-2] Helping new users to navigate IRBNet
😢 Help	I Pamela Researcher, as
My Projects	in this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements and is ready for submission. I further certify that this electronic signature is intended to be the legally binding equivalent of a
Create New Project	traditional handwritten signature.
Y My Reminders (34)	
Project Administration Project Overview	Sign
Designer	To sign on behalf of another person, switch to Designee Signature Mode.
Share this Project	
Sign this Package Submit this Package	
Delete this Package	This package has not been signed.
Send Project Mail	
Reviews	
Project History	
Other Tools	
Forms and Templates	

Note: If a submission is submitted without the PI signature, the submission will not be accepted for IRB review.

Step 5:Once the PI has signed the package, click SUBMIT THIS PACKAGE. Select 'KaiserPermanente - YOUR REGION' in the "Search for Organization" drop down menu.

IRBNet ID: 59137-2	USER PROFILE LOGOUT
Welcome to IRBNet Pamela Researcher	Submit Package [59137-2] Helping new users to navigate IRBNet
Help My Projects Create New Project Wy Reminders (34)	IRBNet supports multiple models of review. Using the "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.
Project Administration Project Overview	Please select a Board:
Designer Share this Project Sign this Package	Search for an Organization Search Clear
Sign tills Fackage Delete this Package Send Project Mail Reviews Project History Wessages & Alerts Other Tools	Select a Board * Kaiser Permanente - Colorado Region IRB Kaiser Permanente - Georgia Region IRB Kaiser Permanente - Hawaii Region IRB Kaiser Permanente - Mid-Atlantic States Region IRB Kaiser Permanente - Northern California Region IRB Kaiser Permanente - Northwest Region IRB Kaiser Permanente - Southern California Region IRB Kaiser Permanente - Northwest Region IRB Kaiser Permanente - Washington Region IRB Kaiser Permanente - Washington Region IRB Termanente - Washington Region IRB Termanente - Washington Region IRB Kaiser Permanente - Washington Region IRB
Forms and Templates	Continue Cancel
	* required fields

Then click the **'Continue**' button. In the Submission Type drop-down menu, select **'Continuing Review/Progress Report'** and click **'Submit**'. Once you hit the **"Submit**" button, you will be given a confirmation showing the time your submission occurred.

IRBNet ID: 59137-2	USER PROFILE LOGOUT
IRBNet.	
Welcome to IRBNet	Submit Package
Pamela Researcher	[59137-2] Helping new users to navigate IRBNet
😧 Help	The following users at Kaiser Permanente - Colorado Region IRB will be automatically notified of your submission:
My Projects	Administrator, Morgan
Create New Project V My Reminders (34)	Coordinator, Molly
	Submission Type: * Continuing Review/Progress Report
Project Administration Project Overview	You may also specify additional comments to be included in this notification.
Designer	
Share this Project	
Sign this Package	Your Comments:
Submit this Package Delete this Package	
Send Project Mail	
Reviews	
Project History	Submit Cancel
Messages & Alerts	
Other Tools Forms and Templates	
r orms and remplates	

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User Tip: Keep in mind that once you click "Submit" your study is now locked. Take the time to be sure all documents are attached and in the final version **prior to submitting**. Any incomplete submissions will not be reviewed by the IRB and will be returned for corrections.

5. AMENDMENT/MODIFICATION SUBMISSION

- **Step 1:** Log in to <u>www.irbnet.org</u>. This will take you to the **MY PROJECTS** page.
- **Step 2:** Click on the Title of the project that you would like to amend/modify. You may also utilize the search function on the **MY PROJECTS** page by searching for study title or project ID number.

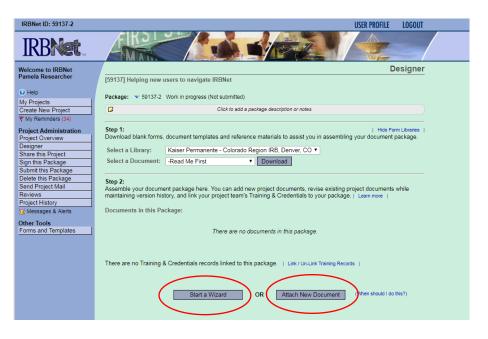
Project Administration Project Overview Designer Share this Project Sign this Package Submit this Package Delete this Package Send Project Mail Reviews Project History Create a New Package Messages & Alerts (8)

Then click on **CREATE A NEW PACKAGE**.

Step 3: You will now be on the **DESIGNER** page.

This is where you can access the library of forms from your regional library and through the **'Start a Wizard'** SMART form.

Select '**Start a Wizard'** and from the drop-down menu and then select the '**Modification Form.'** From here, you will complete the <u>required</u> Modification SMART form for the package.



Assemble your document package through clicking on '**Attach New Document'** until the all documents have been added.

In the **Document Type** drop-down box, pick the best match for the document you are uploading. If the type of document you are submitting is not in the list then choose "Other" and enter the type of document in the **Description** field.

Please note: See Section 12 "How to Label Documents" for naming convention guidelines.

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Click on **SIGN THIS PACKAGE**. Select the appropriate role from the dropdown box and click **'Sign**'.

IRBNet ID: 59137-2	USER PROFILE LOGOUT
IRBNet	
Welcome to IRBNet	Sign Package
Pamela Researcher	[59137-2] Helping new users to navigate IRBNet
🚱 Help	I Pamela Researcher, as v, certify that to the best of my knowledge the information contained
My Projects	in this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements and is ready for submission. I further certify that this electronic signature is intended to be the legally binding equivalent of a
Create New Project Wy Reminders (34)	traditional handwritten signature.
	2
Project Administration Project Overview	Sign
Designer	To sign on behalf of another person, switch to Designee Signature Mode.
Share this Project Sign this Package	
Submit this Package	This package has not been signed.
Delete this Package	nia puolugo nuo nu boen vignou.
Send Project Mail Reviews	
Project History	
1 Messages & Alerts	
Other Tools	
Forms and Templates	

Note: If a submission is submitted without the PI signature, the submission will not be accepted for review.

Step 5:Once the PI has signed the package, click SUBMIT THIS PACKAGE. Select 'KaiserPermanente - YOUR REGION' in the "Search for Organization" drop down menu.

IRBNet ID: 59137-2	USER PROFILE LOGOUT
IRBNet	
Welcome to IRBNet	Submit Package
Pamela Researcher	[59137-2] Helping new users to navigate IRBNet
🕜 Help	IRBNet supports multiple models of review. Using the "Submit" feature, you may electronically submit this document
My Projects	package to either a single Board, or to multiple Boards. Each Board you submit to will be notified of your submission and
Create New Project	given access to view your electronic documents. Each Board will also be permitted to electronically record their review
Y My Reminders (34)	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.
Project Administration	Please select a Board:
Project Overview	Please select a board.
Designer	Search for an Organization Search Clear
Share this Project	Only show My Default Boards
Sign this Package	Kaiser Permanente - Colorado Region IRB
Submit this Package	Kaiser Permanente - Georgia Region IRB
Delete this Package	Kaiser Permanente - Hawaii Region IRB
Send Project Mail Reviews	Select a Board * Kaiser Permanente - Mid-Atlantic States Region IRB
Project History	Raiser Fernanente - Northern California Region IRD
	Kaiser Permanente - Northwest Region IRB
Messages & Alerts	Kaiser Permanente - Southern California Region IRB Kaiser Permanente - Washington Region IRB
Other Tools	Kaiser Permahente - Washington Region Ro
Forms and Templates	Continue Cancel
	* required fields
	rednied lieuz

Then click the **'Continue**' button. In the Submission Type drop-down menu, select **'Amendment/Modification'** and click **'Submit**'. Once you hit the **"Submit**" button, you will be given a confirmation showing the time your submission occurred.

IRBNet ID: 58554-4	USER PROFILE LOGOUT
IRBNet	
Welcome to IRBNet Pamela Researcher	Submit Package [58554.4] IRBNet Training Project 2
 Help My Projects Create New Project ✓ My Reminders (34) Project Overview Designer Share this Project Sign this Package Delete this Package Delete this Package Delete this Package Send Project Mail Reviews Project History ⁽²⁾ Messages & Alerts (8) Other Tools Forms and Templates 	The following users at Kaiser Permanente - Colorado Region IRB will be automatically notified of your submission: Administrator, Morgan Coordinator, Molly Submission Type: * AmendmentModification You may also specify additional comments to be included in this notification. Your Comments: Submit Cancel

Once you hit the '**Submit**' button, you will be given a confirmation showing the time your submission occurred.

Step 6:To review what has been sent, click PROJECT OVERVIEW. The package (under
Board Action) should indicate 'Pending Review' status until a decision by the board
has been made. Once a decision letter is formulated, an email will be sent to
everyone who has full access.

User Tip: Keep in mind that once you click "Submit" your study is now locked. Take the time to be sure all documents are attached and in the final version **prior to submitting**. Any incomplete submissions will not be reviewed by the IRB and will be returned for corrections.

6. STUDY CLOSURE SUBMISSION

- **Step 1:** Log in to <u>www.irbnet.org</u>. This will take you to the **MY PROJECTS** page.
- **Step 2:** Click on the Title of the project that you would like to close. You may also utilize the search function on the **MY PROJECTS** page by searching for study title or project ID number.

Then click on **CREATE A NEW PACKAGE**.



Step 3: You will now be on the **DESIGNER** page.

This is where you can access the library of forms from your regional library and through the **'Start a Wizard'** SMART form.

Select '**Start a Wizard**' and from the drop-down menu and then select '**Continuing Review / Closure Form.**' From here, you will complete the required SMART form for the Closure package.

IRBNet ID: 59137-2	USER PROFILE LOGOUT
IRBNet	
Welcome to IRBNet	Designer
Pamela Researcher	[59137] Helping new users to navigate IRBNet
() Help	Package: v 59137-2 Work in progress (Not submitted)
My Projects Create New Project	Click to add a package description or notes.
Y My Reminders (34)	
Project Administration Project Overview	Step 1: Hide Form Libraries Download blank forms, document templates and reference materials to assist you in assembling your document package.
Designer Share this Project	Select a Library: Kaiser Permanente - Colorado Region IRB, Denver, CO 🔻
Sign this Package	Select a Document: -Read Me First Download
Submit this Package Delete this Package	
Send Project Mail	Step 2: Assemble your document package here. You can add new project documents, revise existing project documents while
Reviews	maintaining version history, and link your project team's Training & Credentials to your package. Learn more
Project History Messages & Alerts	Documents in this Package:
Other Tools	
Forms and Templates	There are no documents in this package.
	There are no Training & Credentials records linked to this package. Link / Un-Link Training Records
	There are no training & credentials records linked to this package. Link / Un-Link training Records
	Start a Wizard OR Attach New Document (then should I do this?)

STUDY CLOSURE SUBMISSION

Select '**Start a Wizard**' and from the drop-down menu and then select '**Continuing Review / Closure Form.**' From here, you will complete the required SMART form for the Closure package.

Assemble your document package through clicking on '**Attach New Document'** until the all documents have been added.

In the **Document Type** drop-down box, pick the best match for the document you are uploading. If the type of document you are submitting is not in the list then choose "Other" and enter the type of document in the **Description** field.

Please note: See Section 12 "How to Label Documents" for naming convention guidelines.

Step 4: When all the necessary documents are in the package, the Principal Investigator MUST sign the package electronically. If the PI did not create the package then send an e-mail to the PI using the "**Send Project Mail**" function and request that the PI sign the package.

Click on **SIGN THIS PACKAGE**. Select the appropriate role from the dropdown box and click '**Sign**'.



Note: If a submission is submitted without the PI signature, the submission will not be accepted for review.

Step 5:Once the PI has signed the package, click SUBMIT THIS PACKAGE. Select 'KaiserPermanente - YOUR REGION' in the "Search for Organization" drop down menu.

IRBNet ID: 59137-2	USER PROFILE LOGOUT
IRBNet	
Welcome to IRBNet	Submit Package
Pamela Researcher	[59137-2] Helping new users to navigate IRBNet
Help	IRBNet supports multiple models of review. Using the "Submit" feature, you may electronically submit this document
My Projects	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
Create New Project W Reminders (34)	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.
Project Administration Project Overview	Please select a Board:
Designer	Search for an Organization Search Clear
Share this Project	Only show My Default Boards
Sign this Package Submit this Package	Kaiser Permanente - Colorado Region IRB
Delete this Package	Kaiser Permanente - Georgia Region IRB Kaiser Permanente - Hawaii Region IRB
Send Project Mail	Kaisas Dasmananta, Mid Atlantis States Dasian IDB
Reviews Project History	Select a Board * Kaiser Permanente - Northern California Region IRB
Messages & Alerts	Kaiser Permanente - Northwest Region IRB Kaiser Permanente - Southern California Region IRB
Other Tools	Kaiser Permanente - Washington Region IRB
Forms and Templates	Continue Cancel
	* required fields
	required news

Then click the **'Continue**' button. In the Submission Type drop-down menu, select **'Closure/Final Report'** and click **'Submit'**. Once you hit the **"Submit**" button, you will be given a confirmation showing the time your submission occurred.

IRBNet ID: 58554-4	USER PROFILE LOGOUT
IRBNet.	
Welcome to IRBNet	Submit Package
Pamela Researcher	[58554-4] IRBNet Training Project 2
😧 Help	The following users at Kaiser Permanente - Colorado Region IRB will be automatically notified of your submission:
My Projects	Administrator, Morgan Coordinator, Molly
Create New Project Wy Reminders (34)	Submission Type: * Closure/Final Report
Project Administration Project Overview Designer Share this Project Sign this Package	You may also specify additional comments to be included in this notification.
Submit this Package Delete this Package Send Project Mail Reviews Project History	Submit Cancel
Messages & Alerts (8) Other Tools Forms and Templates	

Once you hit the '**Submit**' button, you will be given a confirmation showing the time your submission occurred.

Step 6:To review what has been sent, click PROJECT OVERVIEW. The package (under
Board Action) should indicate 'Pending Review' status until a decision by the
board has been made. Once a decision letter is formulated, an email will be sent to
everyone who has full access.

User Tip: Keep in mind that once you click "Submit" your study is now locked. Take the time to be sure all documents are attached and in the final version **prior to submitting**. Any incomplete submissions will not be reviewed by the IRB and will be returned for corrections.

STUDY CLOSURE SUBMISSION

7. REPORTABLE NEW EVENTS SUBMISSION

Reportable New Events submissions are typically made to the IRB for instances of Protocol Violations, Unanticipated Problems, Serious Adverse Events, Miscellaneous Compliance Concern, etc.

Please note: See Section 11 "How to Label Submissions" for guidelines.

- **Step 1:** Log in to <u>www.irbnet.org</u>. This will take you to the **MY PROJECTS** page.
- **Step 2:** Click on the Title of the project that you would like to submit a reportable event for. You may also utilize the search function on the **MY PROJECTS** page by searching for study title or project ID number.

Then click on **CREATE A NEW PACKAGE**.

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Create a New Package
1 Messages & Alerts (8)

Step 3: You will now be on the **DESIGNER** page.

This is where you can access forms from your regional library.

Please note: Reportable New Events packages do <u>NOT</u> utilize a SMART Form. You will need to download the Reportable New Events Form from your regional library.

Select 'Kaiser Permanente – <u>YOUR REGION</u>' from the '**Select a Library'** dropdown menu.

Download the Reportable New Events Form from the '**Select a Document**' dropdown menu. Save the Reportable New Events Form to your computer in a place where you can find it again (i.e., desktop, My Documents, etc.).

IRBNet ID: 59137-2	USER PROFILE LOGOUT
IRBNet	
Welcome to IRBNet	Designer
Pamela Researcher	[59137] Helping new users to navigate IRBNet
😯 Help	Package: v 59137-2 Work in progress (Not submitted)
My Projects	
Create New Project	Click to add a package description or notes.
Y My Reminders (34)	Star 4.
Project Administration Project Overview	Step 1: Hide Form Libraries Download blank forms, document templates and reference materials to assist you in assembling your document package.
Designer	Select a Library: Kaiser Permanente - Colorado Region IRB, Denver, CO V
Share this Project	Select a Document: -Read Me First V Download
Sign this Package Submit this Package	Download
Delete this Package	Step 2:
Send Project Mail	Assemble your document package here. You can add new project documents, revise existing project documents while
Reviews Project History	maintaining version history, and link your project team's Training & Credentials to your package. Learn more
Messages & Alerts	Documents in this Package:
Other Tools	
Forms and Templates	There are no documents in this package.
	There are no Training & Credentials records linked to this package. Link / Un-Link Training Records
	Start a Wizard OR Attach New Document (When should I do this?)

Assemble your document package through clicking on '**Attach New Document'** until the all documents have been added.

In the **Document Type** drop-down box, pick the best match for the document you are uploading. If the type of document you are submitting is not in the list then choose "Other" and enter the type of document in the **Description** field.

Please note: See Section 12 "How to Label Documents" for naming convention guidelines.

Repeat the steps to upload until all documents have been uploaded to your package.

Step 4: When all the necessary documents are in the package, the Principal Investigator MUST sign the package electronically. If the PI did not create the package then send an e-mail to the PI using the "**Send Project Mail**" function and request that the PI sign the package.

Click on **SIGN THIS PACKAGE**. Select the appropriate role from the dropdown box and click '**Sign**'.

IRBNet ID: 59137-2	USER PROFILE LOGOUT
IRBNet	
Welcome to IRBNet	Sign Package
Pamela Researcher	[59137-2] Helping new users to navigate IRBNet
😧 Help	I Pamela Researcher, as
My Projects	in this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements
Create New Project	and is ready for submission. I further certify that this electronic signature is intended to be the legally binding equivalent of a traditional handwritten signature.
Y My Reminders (34)	
Project Administration	Sign
Project Overview Designer	To sign on behalf of another person, switch to Designee Signature Mode.
Share this Project	
Sign this Package	
Submit this Package	This package has not been signed.
Delete this Package Send Project Mail	
Reviews	
Project History	
Messages & Alerts	
Other Tools	
Forms and Templates	

Note: If a submission is submitted without the PI signature, the submission will not be accepted for review.

Step 5:Once the PI has signed the package, click SUBMIT THIS PACKAGE. Select 'KaiserPermanente - YOUR REGION' in the "Search for Organization" drop down menu.



Then click the '**Continue**' button. In the Submission Type drop-down menu, select the appropriate submission type (see Section 11 for guidelines) and click '**Submit**'. Once you hit the "**Submit**" button, you will be given a confirmation showing the time your submission occurred.

IRBNet ID: 59137-4			USER PROFIL	E LOGOUT
IRBNet	ARD ON			_
Welcome to IRBNet Pamela Researcher			Submi	t Package
Pamela Researcher	[59137-4] Helping new users to navigate IR	BNet		
😧 Help	The following users at Kaiser Permanente -	Colorado Region IRB will be a	utomatically notified of your sub	mission:
My Projects		Administrator, Morgan		
Create New Project		Coordinator, Molly		
Y My Reminders (39)	Submission Type: *	Protocol Deviation/Violation	×	
Project Administration				
Project Overview	You may also specify additional comments to	be included in this notification.		
Designer				
Share this Project				
Sign this Package	Your Comments:			
Submit this Package				
Delete this Package				
Send Project Mail				
Reviews		Submit Cancel		
Project History				
1 Messages & Alerts (5)				
Other Tools				
Forms and Templates				

Once you hit the '**Submit**' button, you will be given a confirmation showing the time your submission occurred.

Step 6:To review what has been sent, click PROJECT OVERVIEW. The package (under
Board Action) should indicate 'Pending Review' status until a decision by the board
has been made. Once a decision letter is formulated, an email will be sent to
everyone who has full access.

User Tip: Keep in mind that once you click "Submit" your study is now locked. Take the time to be sure all documents are attached and in the final version prior to submitting. Any incomplete submissions will not be reviewed by the IRB and will be returned for corrections.

8. RESPONSE TO MODIFICATIONS REQUIRED

If you have submitted a package and the IRB has reviewed and made a determination Approved with Conditions, Deferred, Tabled without Action, Modifications Required, or Information Required then you will need to submit a subsequent 'Response/Follow-Up' package. This is called a 'Response to Modifications Required.'

Please note: See Section 11 "How to Label Submissions" for guidelines.

- **Step 1:** Log in to <u>www.irbnet.org</u>. This will take you to the **MY PROJECTS** page.
- **Step 2:** Click on the Title of the project of which you are submitting revisions to. You may also utilize the search function on the **MY PROJECTS** page by searching for study title or project ID number.

Then click on **CREATE A NEW PACKAGE**.

Project Administration				
Project Overview				
Designer				
Share this Project				
Sign this Package				
Submit this Package				
Delete this Package				
Send Project Mail				
Reviews				
Project History				
Create a New Package				
1 Messages & Alerts (8)				

Step 3: You will now be on the **DESIGNER** page.

This is where you can access forms from your regional library.

Please note: Response to Modifications Required packages do <u>NOT</u> utilize a SMART Form. You will need to download the Non-SMART Response to Modifications Required Form from your regional library.

Select 'Kaiser Permanente – <u>YOUR REGION</u>' from the '**Select a Library**' dropdown menu.

Download the Response to Modifications Required Form from the '**Select a Document'** drop-down menu. Save the Response to Modifications Required Form to your computer in a place where you can find it again (i.e., desktop, My Documents, etc.).

Step 1: Hide Form Libraries Download blank forms, document templates and reference materials to assist you in assembling your document package.							
Select a Library:	Kaiser Permanent	te - Colorado Region IRB, Denver, CC					
Select a Document:	-Read Me First	✓ Download					
Step 2: Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. Learn more Documents in this Package:							
		There are no documents in this packa	ge.				
There are no Training & Credentials records linked to this package. Link / Un-Link Training Records Start a Wizard OR Attach New Document (When should I do this?)							
Documents from Pre	vious Packages th		this?)	Submission			
^{Pkg} # Document Type		Description	Modified	Date			
3 Consent Form		Consent Form v1 2/28/2018	02/28/2018 10:04 AM	02/28/2018	🗋 🗘 🤌		
3 HIPAA Consent/Aut	horization	HIPAA Authorization	02/28/2018 10:04 AM	02/28/2018	📄 🗘 🤌		
3 Investigator's Broch	ure	Idelalisib Investigator Brochure Edition 7 12/21/2017	02/28/2018 10:04 AM	02/28/2018	📄 🗘 🤌		
3 Kaiser Permanente	- IRB Core Data Form	Kaiser Permanente - IRB Core Data Form	02/28/2018 10:07 AM	02/28/2018	📄 🗘 🤌		
3 Kaiser Permanente	- Study Team Form	Kaiser Permanente - Study Team Form	02/28/2018 10:09 AM	02/28/2018] 🗘 🤌		
3 Other		KPCO Local Context Form	02/28/2018 10:07 AM	02/28/2018] 🗘 🤌		
3 Protocol		Protocol v3 9/2/2017	02/28/2018 09:55 AM	02/28/2018	📄 🗘 🤌		

Step 4: Revise any applicable documents from the previous package requiring modifications. It is important that you maintain the document history by downloading the document from the previous package by clicking on the **'paper icon'**.

Make necessary changes and save the revised document(s) to your computer.

Please note: The paper stack icon will show you the document history (all versions of the document). This will allow a reviewer (and you) to see the original document and the revised document in one place.

Step 5: When you are ready to assemble your Response to Modifications Required package you can click on the **'pencil icon'** to upload your document. This maintains the document history throughout the life of the study.

Welcome to IRBNet	Att	ach Document
Pamela Researcher	[59137-4] Helping new users to navigate IRBNet	
Help	You are updating an attachment. To help you identify the file that was attached:	
My Projects	 This attachment was loaded from the file CONSENT FORM.docx. It was attached on 02/28/2018. 	
Create New Project	 It was attached on 02/20/2010. It has a size of 13051 bytes. 	
Wy Reminders (39)		
Project Administration	Document Type * Consent Form	
Project Overview	Description Consent Form v1 2/28/2018	
Designer Share this Project	File *	Browse
Sign this Package		
Submit this Package	Update Cancel	
Delete this Package	* required fields	
Send Project Mail		
Reviews		
Project History		
Messages & Alerts (5)		
Other Tools		
Forms and Templates		

RESPONSE TO MODIFICATIONS REQUIRED

In the **Document Type** drop-down box, the information will be pre-populated because you are updating a document from a previous package.

Repeat the steps to upload until all documents have been uploaded to your package.

If you are uploading new documents you can assemble your document package through clicking on **'Attach New Document'** on the **DESIGNER** page until the all documents have been added.

In the **Document Type** drop-down box, pick the best match for the document you are uploading. If the type of document you are submitting is not in the list then choose "Other" and enter the type of document in the **Description** field.

Please note: See Section 12 "How to Label Documents" for naming convention guidelines.

Step 6: When all the necessary documents are in the package, the Principal Investigator MUST sign the package electronically. If the PI did not create the package then send an e-mail to the PI using the "**Send Project Mail**" function and request that the PI sign the package.

Click on **SIGN THIS PACKAGE**. Select the appropriate role from the dropdown box and click **'Sign'**.



Note: If a submission is submitted without the PI signature, the submission will not be accepted for review.

Step 7:Once the PI has signed the package, click SUBMIT THIS PACKAGE. Select 'KaiserPermanente - YOUR REGION' in the "Search for Organization" drop down menu.

IRBNet ID: 59137-2	USER PROFILE LOGOUT
IRBNet.	
Welcome to IRBNet	Submit Package
Pamela Researcher	[59137-2] Helping new users to navigate IRBNet
 i Help My Projects Create New Project [™] My Reminders (34) 	IRBNet supports multiple models of review. Using the "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.
Project Administration Project Overview	Please select a Board:
Designer	Search for an Organization Search Clear
Share this Project Sign this Package Submit this Package Delete this Package Send Project Mail Reviews Project History '' Messages & Alerts Other Tools	Ony show My Default Baves Kaiser Permanente - Colorado Region IRB Kaiser Permanente - Georgia Region IRB Kaiser Permanente - Hawaii Region IRB Kaiser Permanente - Northver California Region IRB Kaiser Permanente - Northverst Region IRB Kaiser Permanente - Northverst Region IRB Kaiser Permanente - Northverst Region IRB Kaiser Permanente - Washington Region IRB
Forms and Templates	Continue Cancel * required fields

Then click the **'Continue**' button. In the Submission Type drop-down menu, select **'Response/Follow-Up'** and click **'Submit'**. Once you hit the **"Submit**" button, you will be given a confirmation showing the time your submission occurred.

IRBNet ID: 59137-4	USER PROFILE LOGOUT
IRBNet	
Welcome to IRBNet	Submit Package
Pamela Researcher	[59137-4] Helping new users to navigate IRBNet
😧 Help	The following users at Kaiser Permanente - Colorado Region IRB will be automatically notified of your submission:
My Projects	Administrator, Morgan
Create New Project	Coordinator, Molly
Y My Reminders (39)	Submission Type: * Revision
Project Administration	
Project Overview	You may also specify additional comments to be included in this notification.
Designer	
Share this Project	
Sign this Package	Your Comments:
Submit this Package	
Delete this Package	
Send Project Mail	
Reviews	Submit Cancel
Project History	
Messages & Alerts (5)	
Other Tools	
Forms and Templates	

Once you hit the '**Submit**' button, you will be given a confirmation showing the time your submission occurred.

Step 8:To review what has been sent, click PROJECT OVERVIEW. The package (under
Board Action) should indicate 'Pending Review' status until a decision by the board
has been made. Once a decision letter is formulated, an email will be sent to
everyone who has full access.

User Tip: Keep in mind that once you click "Submit" your study is now locked. Take the time to be sure all documents are attached and in the final version prior to submitting. Any incomplete submissions will not be reviewed by the IRB and will be returned for corrections.

9. RESPONSE TO AN INCOMPLETE SUBMISSION

If you submitted a package to the IRB and during the **pre-review** process it was determined that a revision is needed (i.e., missing document(s), document needs revision, etc.) then the IRB will 'Unlock' your package so you can make the requested revisions.

- Step 1:Log in to www.irbnet.org. This will take you to the MY PROJECTS page.This is where all of the studies that you have access to will be housed.
- **Step 2:** Click on the Title of the project that you need to respond to. You can identify the package by the red **'Unlocked'** icon.

1 0 0		
Welcome to IRBNet		My Projects
Pamela Researcher	Your "My Projects" workspace shows projects that you have created and projects that have been share	
😧 Help	users on the National Research Network. Use Reminders, Tags and Archiving to help organize your w running smoothly. (Learn More)	orkspace and keep it
My Projects		
Create New Project	Search: Search By Tag:	~
Y My Reminders (40)	Scaren by rag.	
Other Tools	Search Clear	
Forms and Templates		
	14 4 1	- 10 of 15 🕨 🔰 🔟 🗸
	Create and Manage Tags Show Archived Projects (0)	Project Status View
	Principal Submission	Effective
	▼ IRBNet ID ▼ Project Title Investigator Type Board Ac	tion Date
	Y 59137-4 Helping new users to navigate IRBNet T Researcher Revision Pending R	leview 🗊

User tip: You may also click on the IRBNet project referenced in the 'Messages and Alerts' you received notifying you that your package was 'Unlocked' due to an IRB pre-review of the package.

IRBNet ID: 59137-4					USER PROFILE LOGOUT
		R3			
Welcome to IRBNet				Projec	t Messages & Alerts
Pamela Researcher	[5913	7-4] Helping r	new users to navigate IRBNet		
🚱 Help	The fo	ollowing comm	unications have been posted for this p	project. You can set a personal remi	nder on any message or alert.
My Projects	Your	personal remin	nders will automatically appear in your	My Reminders list. Other users do	
Create New Project	remin	ders. You can	turn on or silence a personal reminde	r without affecting other users.	
Y My Reminders (39)					🔰 🖣 1-8 of 8 🕨 🔰 10 🗸
Project Administration	I Sila	nce All Reminder	- 1		
Project Overview	Sile	nce All Reminder			D-11
Project Overview Designer		IRBNet ID	Project Title	Message Type	Date
Project Overview Designer Share this Project	Sile			Message Type	Date 02/28/2018 11:04 AM
Project Overview Designer Share this Project Sign this Package		IRBNet ID	Project Title		
Project Overview Designer Share this Project Sign this Package Submit this Package	*	IRBNet ID 59137-3	Project Title Helping new users to navigate IRBNet	Board Document Published	02/28/2018 11:04 AM
Project Overview Designer Share this Project Sign this Package Submit this Package Delete this Package	*	IRBNet ID 59137-3 59137-3	Project Title Helping new users to navigate IRBNet Helping new users to navigate IRBNet	Board Document Published Board Action	02/28/2018 11:04 AM 02/28/2018 11:03 AM
Project Overview Designer Share this Project Sign this Package Submit this Package Delete this Package Send Project Mail	* * *	IRBNet ID 59137-3 59137-3 59137-3 59137-1	Project Title Helping new users to navigate IRBNet Helping new users to navigate IRBNet Helping new users to navigate IRBNet Helping new users to navigate IRBNet	Board Document Published Board Action Submission Notification Package Unlocked	02/28/2018 11:04 AM 02/28/2018 11:03 AM 02/28/2018 11:03 AM 02/28/2018 11:03 AM 02/27/2018 05:18 PM
Project Overview Designer Share this Project Sign this Package Submit this Package Delete this Package Send Project Mail Reviews	4 4 7	IRBNet ID 59137-3 59137-3 59137-3 59137-1 59137-2	Project Title Helping new users to navigate IRBNet Helping new users to navigate IRBNet	Board Document Published Board Action Submission Notification Package Unlocked Board Document Published	02/28/2018 11:04 AM 02/28/2018 11:03 AM 02/28/2018 11:03 AM 02/27/2018 05:18 PM 02/27/2018 05:17 PM
Project Overview Designer Share this Project Sign this Package Submit this Package Delete this Package Send Project Mail Reviews Project History	* * *	IRBNet ID 59137-3 59137-3 59137-3 59137-3 59137-1 59137-2 59137-2	Project Title Helping new users to navigate IRBNet Helping new users to navigate IRBNet	Board Document Published Board Action Submission Notification Package Unlocked Board Document Published Board Action	02/28/2018 11:04 AM 02/28/2018 11:03 AM 02/28/2018 11:03 AM 02/27/2018 05:18 PM 02/27/2018 05:17 PM 02/27/2018 05:16 PM
Project Overview Designer Share this Project Sign this Package Submit this Package Delete this Package Send Project Mail Reviews	4 4 4 7	IRBNet ID 59137-3 59137-3 59137-3 59137-1 59137-2 59137-2 59137-2	Project Title Helping new users to navigate IRBNet Helping new users to navigate IRBNet	Board Document Published Board Action Submission Notification Package Unlocked Board Document Published Board Action Submission Notification	02/28/2018 11:04 AM 02/28/2018 11:03 AM 02/28/2018 11:03 AM 02/27/2018 05:18 PM 02/27/2018 05:17 PM 02/27/2018 05:16 PM 02/26/2018 05:04 PM
Project Overview Designer Share this Project Sign this Package Submit this Package Delete this Package Send Project Mail Reviews Project History	* * *	IRBNet ID 59137-3 59137-3 59137-3 59137-3 59137-1 59137-2 59137-2	Project Title Helping new users to navigate IRBNet Helping new users to navigate IRBNet	Board Document Published Board Action Submission Notification Package Unlocked Board Document Published Board Action	02/28/2018 11:04 AM 02/28/2018 11:03 AM 02/28/2018 11:03 AM 02/27/2018 05:18 PM 02/27/2018 05:17 PM 02/27/2018 05:16 PM

Step 3: You will now be on the **PROJECT OVERVIEW** page.

Click **DESIGNER** (there are two places to do this illustrated below).

Overview
Overview
piration Date
27/2019
2/12019
Jump 🔻
eview Details
Туре

From here, you can address the issues stipulated in the communication from the IRB (i.e., submit a missing document, revise a submitted document, etc.).

Please note: Response to Incomplete Submissions do <u>NOT</u> utilize a Form.

Revise any applicable documents from the current package requiring revisions. It is important that you maintain the document history by downloading the document from the previous package by clicking on the **'paper icon'**.

Make necessary changes and save the revised document(s) to your computer.

Step 5: When you are ready to assemble your Response to Incomplete Submission you can click on the **'pencil icon'** to upload your document. This maintains the document history throughout the life of the study.

Welcome to IRBNet		Attach Document
Pamela Researcher	[59137-4] Helping new users to navigate IRBNet	
😧 Help	You are updating an attachment. To help you identify the file that was attached:	
My Projects	This attachment was loaded from the file CONSENT FORM.docx.	
Create New Project	 It was attached on 02/28/2018. It has a size of 13051 bytes. 	
Y My Reminders (39)		
Project Administration	Document Type * Consent Form V	
Project Overview	Description Consent Form v1 2/28/2018	
Designer		
Share this Project	File *	Browse
Sign this Package	Update Cancel	
Submit this Package	Opdate Cancel	
Delete this Package	* required fields	
Send Project Mail		
Reviews		
Project History		
Messages & Alerts (5)		
Other Tools		
Forms and Templates		

In the **Document Type** drop-down box, the information will be pre-populated because you are updating a document from a previous package.

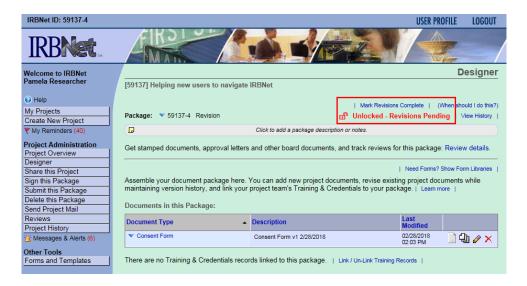
Repeat the steps to upload until all documents have been uploaded to your package.

If you are uploading new documents you can assemble your document package through clicking on **'Attach New Document'** on the **DESIGNER** page until the all documents have been added.

In the **Document Type** drop-down box, pick the best match for the document you are uploading. If the type of document you are submitting is not in the list then choose "Other" and enter the type of document in the **Description** field.

Please note: See Section 12 "How to Label Documents" for naming convention guidelines.

Step 6:When all the necessary documents are in the package, click 'Mark RevisionsComplete' at the top of the DESIGNER page.



RESPONSE TO AN INCOMPLETE SUBMISSION

The **'Unlocked'** icon will turn green and re-lock. The IRB will immediately be notified that the revisions have been completed.

IRBNet ID: 59137-4				USER PROFILE	LOGOUT
	EKOL V.				_/
Velcome to IRBNet					Designer
Pamela Researcher	[59137] Helping new users to navigate	IRBNet			
Help	Package: V 59137-4 Revision		O Lashad Davi	sions Complete	View History
My Projects	Package: • 59137-4 Revision		Locked - Revi	sions Complete	View History
Create New Project	D	Click to add a package description	on or notes.		
V My Reminders (40)					
Project Administration	Get stamped documents, approval letters	and other board documents,	and track reviews fo	r this package: Rev	iew details.
Project Overview					
Designer				Need Forms? Show	Form Libraries
Share this Project	Assemble your document package here.				ts while
Sign this Package	maintaining version history, and link your	project team's Training & Cree	dentials to your pack	age. Learn more	
Submit this Package	Documents in this Package:				
Delete this Package	Documents in this Fackage.				
Send Project Mail	Document Type	Description		Last Modified	
Reviews					
Project History	Consent Form	Consent Form v1 2/28/2018		02/28/2018 02:03 PM	🖽 🖉 🗙 📔
Create a New Package					
🕦 Messages & Alerts (6)	There are no Training & Credentials reco	rds linked to this package.			
Other Tools					
Forms and Templates					
	Otest - N		Designed	(When should I	do this?)
	Start a V	Vizard OR Att	tach New Document	(when should fi	uu uus :)

Please note: The PI does NOT need to sign or submit the package.

10. EXPLANATION OF IRBNet TERMS

	A Droject is an online version of the research protocol being submitted		
roject	A Project is an online version of the research protocol being submitted		
alzago	to the IRB.		
nckage	A package is a submission containing any number of documents that are		
	required by the IRB to conduct their review of a research Project (i.e.,		
de de l'Anne d'ante e	initial submission, modification, continuing review, protocol violation.		
rincipal Investigator			
D	with overall responsibility for studies submitted to the IRB.		
y Projects	Lists all projects you have created. You enter the study by selecting it		
	from the list		
oject Overview	Summarizes the selected project, displays the most recent submission,		
	and shows which users the project is shared with.		
esigner	This page contains two functions. (1) Lists the document library where		
	you can find forms to guide you or to fill out (i.e., checklists, templates,		
	etc.). (2) Allows you to upload your documents to a package.		
are This Project	Allows you to share your project with other researchers.		
gn this Package	All packages must include the Principal Investigator signature prior		
	to submission.		
ıbmit this Package	After the PI signs the package, you will need to submit the package to the		
	IRB. Once you submit a package, it remains in the system permanently.		
elete this Package	You can only delete a package before it is submitted to the IRB.		
end Project Mail	Allows you to send an IRBNet mail between project team members.		
oject History	Lists the all submissions related to the project.		
oard Documents	These are board determination letters and stamped documents (i.e.,		
	stamped consent forms, IRB Administrative Form, etc.) issued by the		
	IRB in response to your package submission.		
on-SMART Forms	Traditional forms (in fillable pdf or word format) located in the		
tandard Forms)	document library of IRBNet. These forms need to be manually		
	downloaded, saved, and uploaded from your computer.		
MART Forms	Electronic fillable forms that can be accessed by clicking the "Start a		
	Wizard" button on the Designer page.		
ccess	Full: Users can edit project documents, share the project with other		
ull, Write, Read)	users, submit document packages, and delete document packages. Users		
	will receive automatic emails of all project notifications and alerts.		
	Write: Users can view and edit project documents, add their signature,		
	but may <u>not</u> grant access to other users, submit packages for review or		
	perform any other administrative functions.		
	Read: Users can view project documentation, add their signature, but		
	may <u>not</u> edit project documents or perform any other administrative		
	functions.		
ocked & Unlocked	Once a package is submitted it will be 'Locked .' A package can only be		
encu a omotion	'Unlocked' by the IRB staff. This can be done if you've made an error in a		
	submitted package and you need to correct it or if the IRB Staff		
	determines that a revision needs to be made to the package (i.e.,		
	Incomplete Submission).		

11. HOW TO LABEL YOUR SUBMISSION

When making the following submissions, use the appropriate SUBMISSION TYPE within IRBNet:

SUBMISSION	SUBMISSION TYPE	
Exempt Initial Submission	New Project	
Initial Submission	New Project	
Continuing Review	Continuing Review/Progress Report	
Modification	Amendment/Modification	
Study Closure	Closure/Final Report	
Protocol Violation	Protocol Deviation/Protocol Violation	
Unanticipated Problem	Unanticipated Problem (UP)	
Serious Adverse Event	Serious Adverse Event (non-UP)	
Miscellaneous Compliance Concern	Other Reportable Event	
Response to Modifications Required with one of the following IRB Determinations: • Approved with Conditions • Tabled without Action • Deferral	Response/Follow-Up	
 Deferration Information Required Modifications Required 		

12. HOW TO LABEL YOUR DOCUMENTS

When attaching Non-SMART Form documents and other study documents in a package it is pertinent that you use an appropriate **'Document Type'** and **'Description'** to label your documents.

Document Type: Select the option that best describes the document.

Description should include the following:

- document name
- applicable version number
- applicable version date

Please note: If you are uploading a Non-SMART Form from your regional library ensure you are using the same naming convention (i.e., Local Context Form).

Step 1: Hide Form Libraries Download blank forms, document templates and reference materials to assist you in assembling your document package.					
Select a Library: Kaiser Permane	Kaiser Permanente - Colorado Region IRB, Denver, CO 🗸				
Select a Document: -Read Me First	-Read Me First V Download				
Step 2: Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. Learn more Documents in this Package:					
Document Type	Description	Last Modified			
▼ Consent Form	Consent Form v1 2/28/2018	02/28/2018 10:04 AM	ĸ		
 HIPAA Consent/Authorization 	HIPAA Authorization	02/28/2018 📄 迎 🔗 > 10:04 AM	ĸ		
 Investigator's Brochure 	Idelalisib Investigator Brochure Edition 7 12/21/2017	02/28/2018 📄 🔱 🔗 > 10:04 AM	ĸ		
Kaiser Permanente - IRB Core Data Form	Kaiser Permanente - IRB Core Data Form	02/28/2018 10:07 AM	ĸ		
Kaiser Permanente - Study Team Form	Kaiser Permanente - Study Team Form	02/28/2018 📄 🖓 🔗 >	ĸ		
▼ Other	KPCO Local Context Form	02/28/2018 📄 🗘 🔗 >	ĸ		
▼ Protocol	Protocol v3 9/2/2017	02/28/2018 📄 🖓 🔗 > 09:55 AM	ĸ		
There are no Training & Credentials records linked to this package Link / Up_link Training Records					

OR

Start a Wizard

Attach New Document

(When should I do this?)