



USER GUIDE

**for the Philadelphia Department of Public
Health Institutional Review Board**

Version 1.1 March 2025

Contents

Dictionary of OneAegis Terminology	3
What is OneAegis?.....	4
How to Access OneAegis	5
Login for Users with Single Sign On (SSO) Accounts.....	5
Login with OneAegis Issued Username/Password	5
Creating a OneAegis Account (If you do not currently have one)	6
Password Reset.....	7
SSO Users Password Reset.....	7
Non-SSO Users Password Reset.....	7
Navigating the Dashboard	8
Dashboard Tabs.....	9
Managing Forms in OneAegis (i.e., xForms).....	11
Completing an xForm	12
Submitting the xForm.....	12
How to start a New Proposal Submission Application	13
Checking the Status of an xForm.....	13
Stage Types and Definitions	14
Navigating the Study Record	14
Events.....	14
Accessing Previous IRB Study Documents.....	15
Helpful Hints.....	16
Frequently Asked Questions	17

Dictionary of OneAegis Terminology

xForm: OneAegis uses web-based forms called xForms. Users submitting to the PDPH IRB will submit the xForm appropriate to the type of request. Some requests (e.g., a Revision Request Form) will not be immediately available on your dashboard, but instead, will become available inside an already approved project.

Event: Your submission (from an xForm) to the IRB creates an “Event” on the study record within OneAegis. After final approval is given, additional “Events” can be created, such as when revisions are requested, when a continuing review is required, or when an SAE/PV report needs to be reported to the PDPH IRB.

Study: A Proposal Submission Application and an IRB Exempt Application creates a Study record within the OneAegis system based on the information provided within the xForm submitted. The Study record contains all pertinent information, lists study sites, and any event submitted for that study.

Study Site: Represents the location of research interventions.

What is OneAegis?

OneAegis is an online submission, workflow, and data management system for PDPH's Institutional Review Board (IRB). OneAegis is a fully web-based system, meaning users can login anywhere they have internet access.

The electronic forms provided within this system (known as xForms), allow users to complete submission for each phase of the research process. This includes forms for new studies, continuing review, revision requests, serious adverse events or protocol deviations, and study closures.

Investigators and research staff have access to view their past studies that have been added to the OneAegis system, and studies that they have submitted through the OneAegis system which have been reviewed by the PDPH IRB. All initial submissions (Proposal Submission Application and IRB Exempt Application), after review, are recorded in the OneAegis system as "studies".

Each study has a primary study-site, which provides a list of "events" that have been submitted to the PDPH IRB. Each event will contain all associated forms and supporting documents, along with a listing of review steps, which are updated to notify the investigators where the submission is within the review process.

Study staff indicated on the initial application will have access to the study record and applicable documents within OneAegis.

How to Access OneAegis

Go to <https://pdph.oneaegis.com>

Login for Users with Single Sign On (SSO) Accounts

To activate your account, users will need to log in to OneAegis following the instructions below:

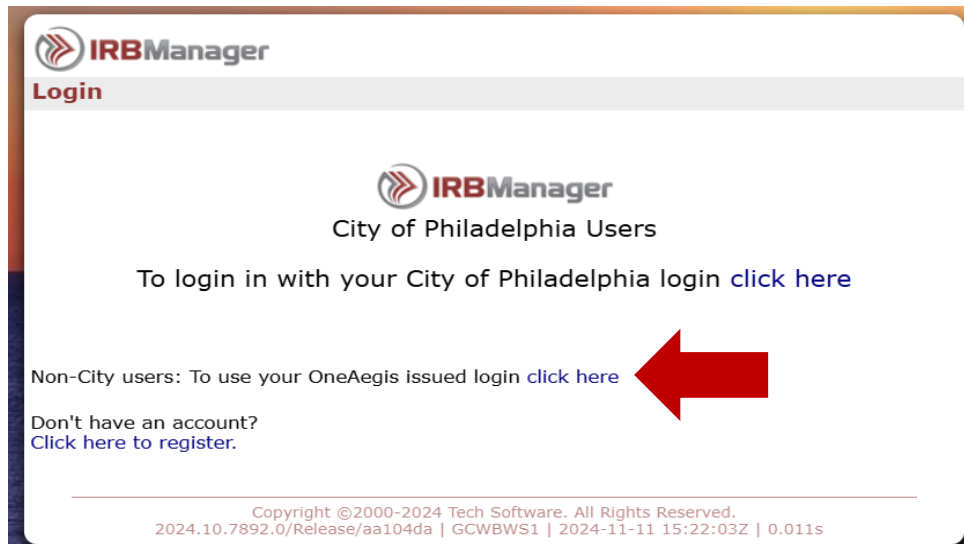
1. Click on "Click here" on the homepage, this will direct your to the PDPH sign-in page



2. Enter your PDPH ID and password
3. Click on "Sign In"

Login with OneAegis Issued Username/Password

Click on "OneAegis issued login" link to login with your OneAegis issued username and password.

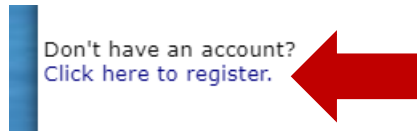


Your username and temporary password/password reset were sent to you in a separate email.

Please note: your username is typically your email address.

Creating a OneAegis Account (If you do not currently have one)

To create a OneAegis account go to <https://pdph.oneaegis.com> and click on "Click here to register"



Fill in the registration prompts:

Enter a valid email address. This email address will be entered in twice to ensure it was spelled correctly.

The screenshot shows the IRBManager Register page. It features the IRBManager logo at the top left. Below the logo, the word "Register" is displayed in a bold, dark font. The form contains two input fields for "EMail" and "Confirm EMail". A "Next" button is positioned below the second field. At the bottom of the form, there is a small copyright notice: "Copyright ©2000-2024 Tech Software. All Rights Reserved. 2024.7.7718.0/Release/5a24929 | GCWBWS1 | 2024-10-11 17:33:39Z | 0.013s".

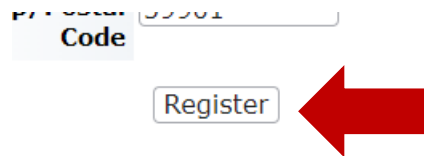
**Please note this email address will receive emails from the OneAegis system regarding your submissions and studies.*

This screenshot shows the IRBManager Register page with the form filled out. The "EMail" field contains "jessiemsager@gmail.com". The "Organization" field is empty. The "Prefix" field is empty, with a note "(e.g. Mr., Mrs., Dr., Prof.)". The "First Name" and "Last Name" fields are empty. The "Degree" field is empty. The "Phone" field has a dropdown menu set to "Business" and an empty input field. The "Address" section includes a dropdown for "Address Type", a dropdown for "Country" set to "United States", and input fields for "Street", "Line 2", "Line 3", "City", "State/Province", and "Zip/Postal Code". A "Register" button is located at the bottom of the form. The same copyright notice as in the previous screenshot is visible at the bottom: "Copyright ©2000-2024 Tech Software. All Rights Reserved. 2024.7.7718.0/Release/5a24929 | GCWAWS1 | 2024-10-14 15:58:23Z | 0.057s".

Fill out the required fields:

- Prefix
- Degree
- Phone
- Organization
- Address Fields (including Address type)
- First Name
- Last Name

Click 'Register' when you complete answering the required fields



Password Reset

Follow the instructions below to recover or reset your password. If you are unsure if you are signing in with SSO credentials or with your OneAegis issued login credentials, please refer to the sections and screenshots above on signing into OneAegis.

If you are still uncertain, please contact the IRB Office at IRB_submissions@phila.gov

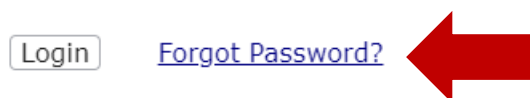
SSO Users Password Reset

If you sign in with your organizational credentials for Single-Sign On (SSO), then you must go through the PDPH IT Department for help recovering or resetting your password. You can reach out to the PDPH IT Department at HealthTechs@phila.gov or 215-685-5356.

Non-SSO Users Password Reset

*This can only be used for individuals who were issued OneAegis Login Credentials. *

If you've forgotten your password and do not use Single-Sign On (SSO), click on 'Forgot Password' from the main login screen on OneAegis.



This will then take you to the 'Forgot Password' screen where it asks you for the email address that the account is linked to.

IRBManager
Forgot Password

Forgot your password? Please provide your email and client id below.

Email



Type the code from the image above:

Copyright ©2000-2024 Tech Software. All Rights Reserved.
2024.7.7718.0/Release/5a24929 | GCWAWS1 | 2024-10-14 16:15:34Z | 0.014s

**You must input the RECAPTCHA as it is shown. If you cannot view this RECAPTCHA or it shows as a grey block, refresh your browser or do a F5 refresh.*

An email will be sent to the email address on the OneAegis account.

To:
Subject: OneAegis Password Reset Request - PDPH

Someone (hopefully you) requested a password reset for your account in OneAegis.

Your username is:

The link to reset your password is below, and is good for 24 hours, but you can always request another.

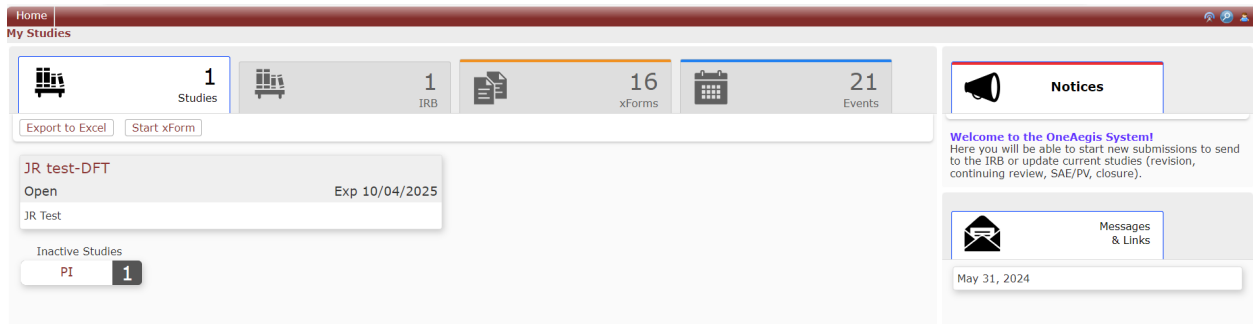
https://pdph.oneaegis.com/public/PasswordReset.aspx?token=Mp6FlojluE2oGdP_DbnCaBEAAACbk3UdRZSLR5AgPP9xiYFE0&ClientId=PDPH

Click on the link within the email and follow the prompts to reset your OneAegis issued password.

Navigating the Dashboard

When you are signed into OneAegis you will be brought to the 'Dashboard' as shown below:

Please note each dashboard may look different depending on associated studies, xForms, etc. each person has.

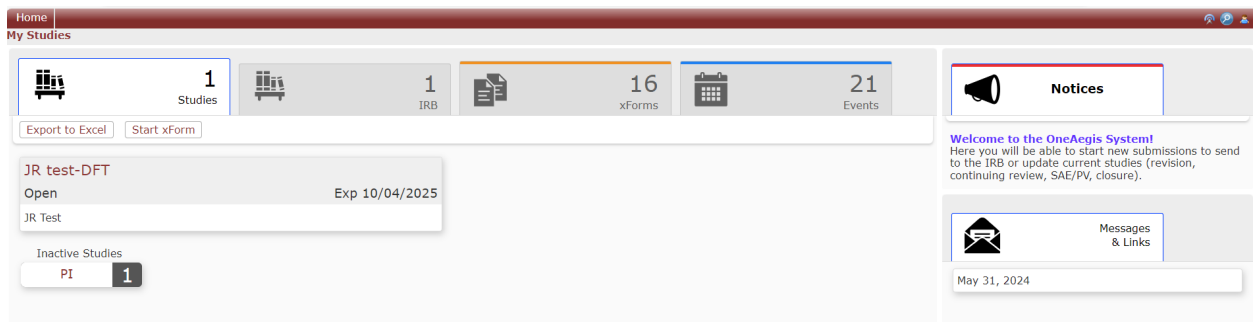


Dashboard Tabs

The tabs you see on your dashboard depend on if you have been added as a contact on a Study, have started any xForms or been assigned an xForm, etc.

Studies Tab will show if you are already a study-contact on an existing study within OneAegis.

Note: By clicking on the underlined link to active or total studies, the user will be able to view the details of their associated projects. Users will be able to access studies based on their role in the studies.



xForms Tab is if you have started an xForm or have been assigned to an xForm to either sign off or collaborate on an xForm. **xForms** are any form filled out within the application. This includes new studies, continuing reviews, revision requests, reviewers checklists, etc.

Home My Studies

1 Studies 1 IRB 16 xForms 21 Events

Start xForm Export to Excel

3 Awaiting Your Attention 13 Being Processed At A Later Stage

Closure Report (Draft) Final review letter Study Closure IGNORE-DFT As of 06/07/2024	Continuing Review Submission Form (Draft) Administrative Review Continuing Review IGNORE-DFT As of 08/29/2024	Continuing Review Submission Form (Draft) Administrative Review Continuing Review IGNORE-DFT As of 08/29/2024	Continuing Review Submission Form (Draft) Final Review Letter Continuing Review JR test-DFT As of 10/03/2024 at 3:52 PM ET
Continuing Review Submission Form (Draft) Under Review Continuing Review JR test-DFT As of Monday at 10:46 AM ET	Continuing Review Submission Form (Draft) Under Review Continuing Review JR test-DFT As of 09/26/2024 at 2:00 PM ET	Continuing Review Submission Form (Draft) Data Entry Continuing Review IGNORE-DFT Started on 09/09/2024	Continuing Review Submission Form (Draft) Final Review Letter Continuing Review IGNORE-DFT As of 09/30/2024 at 5:35 PM ET
Continuing Review Submission Form (Draft) Post review processing Continuing Review IGNORE-DFT As of 09/12/2024 at 10:45 AM ET	Revision Request Form (Draft) JR test Data Entry Revision Request JR test-DFT Started on 09/26/2024 at 12:49 PM ET	Revision Request Form (Draft) JR test Under Review Revision Request JR test-DFT As of Thursday at 11:31 AM ET	Revision Request Form - Personnel (Draft) Administrative review Revision Request Form - Personnel IGNORE-DFT As of 07/15/2024
Revision Request Form -	Serious Adverse	Serious Adverse	Serious Adverse

Notices: Welcome to the OneAegis System! Here you will be able to start new submissions to send to the IRB or update current studies (revision, continuing review, SAE/PV, closure).

Messages & Links: May 31, 2024

Events Tab will only show if you have incomplete submissions on a study. If you click on the event name you can see what is still pending:

Home My Studies

1 Studies 1 IRB 16 xForms 21 Events

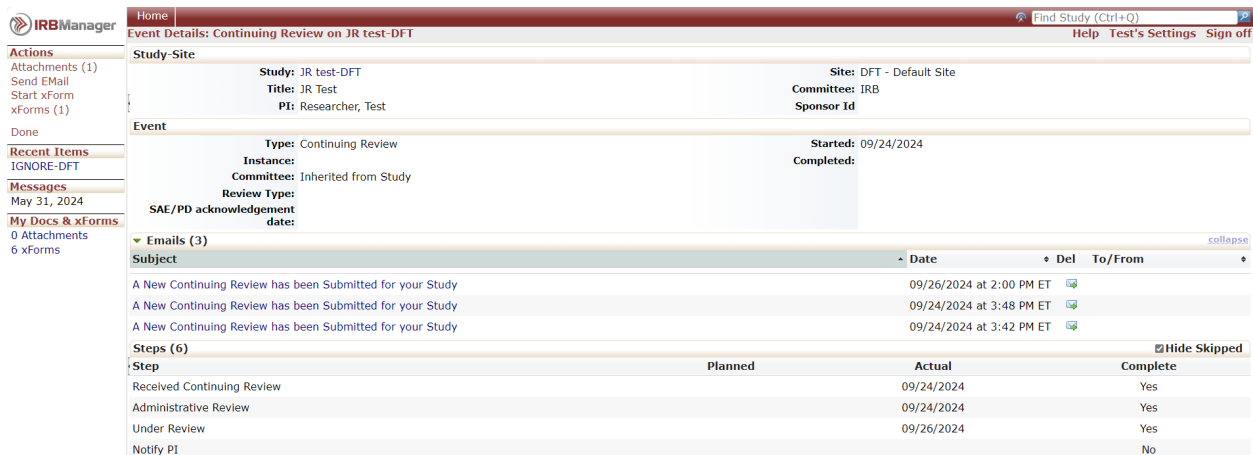
21 PI 2 Administrative Closure of an Expired Study 10 Continuing Review 1 Initial Submission 3 Revision Request

2 Revision Request Form - Personnel 3 Study Closure

Revision Request JR test-DFT 10/10/2024 Researcher, Test	Revision Request JR test-DFT 10/09/2024 Researcher, Test	Continuing Review JR test-DFT 10/07/2024 Researcher, Test	Continuing Review JR test-DFT 10/03/2024 Researcher, Test
Revision Request JR test-DFT 09/27/2024 Researcher, Test	Continuing Review JR test-DFT 09/24/2024 Researcher, Test	Continuing Review IGNORE-DFT 09/20/2024 Researcher, Test	Continuing Review IGNORE-DFT 09/20/2024 Researcher, Test
Continuing Review IGNORE-DFT 09/12/2024 Researcher, Test	Continuing Review IGNORE-DFT 09/06/2024 Researcher, Test	Continuing Review IGNORE-DFT 08/29/2024 Researcher, Test	Continuing Review IGNORE-DFT 08/29/2024 Researcher, Test
Administrative Closure of an Expired Study IGNORE-DFT 08/29/2024 Researcher, Test	Continuing Review IGNORE-DFT 08/28/2024 Researcher, Test	Administrative Closure of an Expired Study IGNORE-DFT 08/22/2024 Researcher, Test	Revision Request Form - Personnel IGNORE-DFT 07/15/2024 Researcher, Test N/A

Notices: Welcome to the OneAegis System! Here you will be able to start new submissions to send to the IRB or update current studies (revision, continuing review, SAE/PV, closure).

Messages & Links: May 31, 2024



Managing Forms in OneAegis (i.e., xForms)

Proposal Submission Application

Use this form to propose research that does not fall into an exempt category that involves human subjects.

IRB Exempt Application

Use this form if the research activities fall into one or more of the exempt categories as defined by OHRP.

New Contact Form

Use this form if you want to add research personnel to a submission, but the personnel are currently not in the OneAegis system.

*Be sure the person/persons are not already in the OneAegis system otherwise you will create a duplicate account for that person/persons and that will create issues for them.

Other Forms

There may be other forms that need to be completed that may not show up when selecting "Start xForm" from your dashboard (e.g., Revision Request Forms, Continuing Review Forms, etc.). These forms are not available until after your project has been given final approval and are located in the event itself. To access these forms:

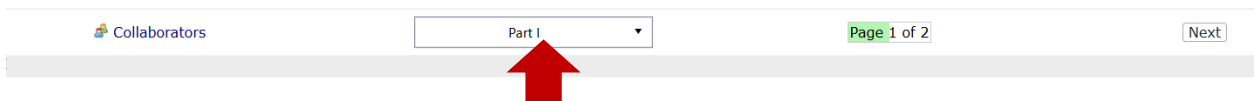
1. Go to your dashboard and choose the study you are working on
2. On the left-hand action menu, under Study-Site, select "Start xForm"
3. Choose the appropriate form you want to start

Completing an xForm

You must fill in all required questions (which are labeled with *required* on the right side of the question), or the xForm will not allow you to submit it. Depending on your answers, additional questions may appear within the xForm.

To navigate an xForm, you can click 'Next' to move on to the next page of the xForm. Click 'Previous' to move to an earlier page. You can only move on to the next page by clicking 'Next' if all required questions on that page have been answered.

If all the required questions have not been answered, but you would still like to work ahead, you can use the drop-down at the top-center of the xForm to navigate between pages.

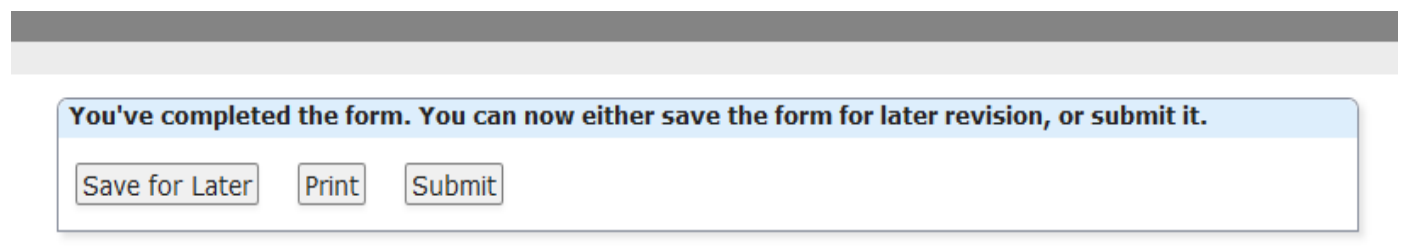


You can click on 'Save for Later', at the bottom of the xForm, to save the work you've completed if you are not ready to submit it. The xForm can be reopened by going to your dashboard, click on the xForms tab, and find the appropriate xForm under 'Unsubmitted'.

Submitting the xForm

Note: Before submitting an xForm, review the form completely and ensure all documents have been uploaded to the xForm. Changes cannot be made once an xForm is submitted unless the IRB requests changes.

After all pages on the form are complete, and you reach the last page, you will see:

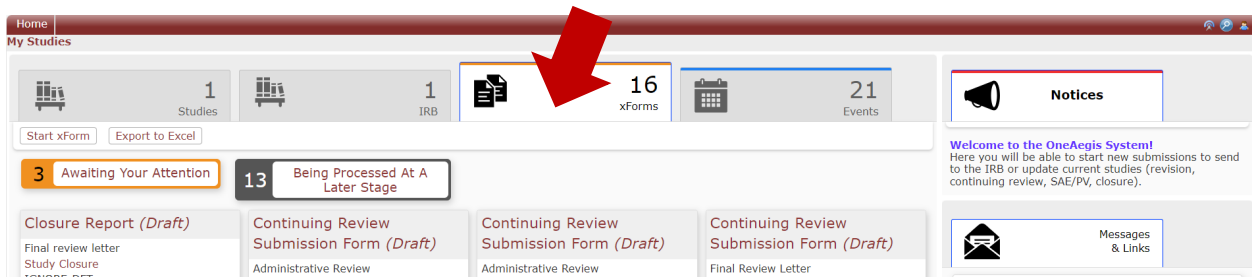


Note: The xForm will not move to the next stage if 'Submit' is not clicked on this screen.

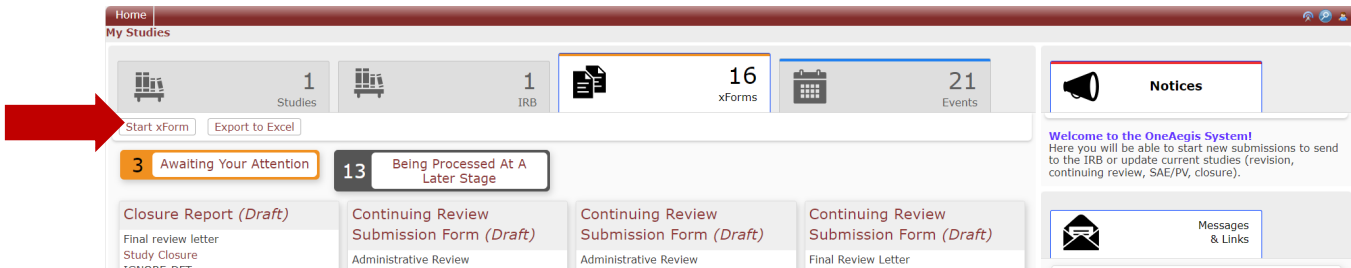
How to start a New Proposal Submission Application

A Proposal Submission Application is not tied to an existing study record, rather it creates the study record with the information you provide on it after the IRB Office reviews this submission. This xForm is to be started from the Dashboard.

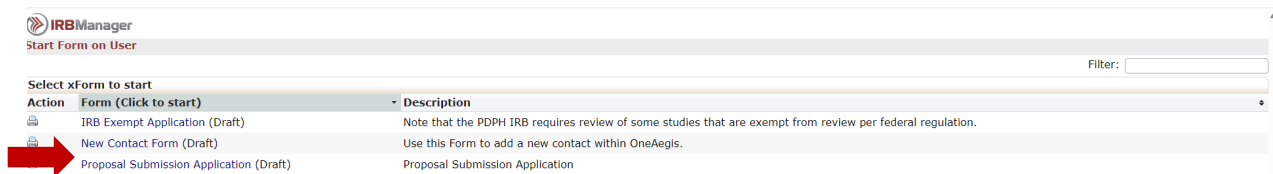
To start the Proposal Submission Application go to your Dashboard, click on the xForms or Studies tab:



Then, click on 'Start xForm':



Click on the application you are wanting to submit to the IRB. For this example, you would select the 'Proposal Submission Application':



Checking the Status of an xForm

The status of an xForm that was submitted can be tracked in two different ways:

1. You can review that stage in which the xForm is in (e.g., IRB Pre-review, PI Signature for non-PI submission, etc.). This can be viewed from the dashboard, under the xForms tab.
2. You can look at the event (if one has been created for that submission yet) to see which steps have been completed.

Stage Types and Definitions

Data Entry: The xForm is currently with the user (research team, typically) to complete or make changes as requested by the IRB.

PI Signature for Non-PI Submission: The Form Creator (the person who started the xForm) is not the PI, therefore, the xForm needs to be signed by the PI before submitting to the IRB.

Administrative Review: The xForm is currently with the IRB Office for review before being sent to reviewer(s)

Navigating the Study Record

From the Dashboard, you have access to each study record you are associated with (meaning that you've been added to it in some role). Click on the Study number link to access the study record:

Home | My Studies

1 Reviews | 1 Docs to Sign | 2 Studies | 2 IRB | 8 xForms | 26 Events

Export to Excel | Start xForm

IGNORE-DFT Open Exp 09/20/2026
IGNORE this test study

JR test-DFT Open Exp 10/04/2025
JR Test

Inactive Studies
PI 1

Events

This section lists all the 'Events' (i.e., the submissions via an xForm) that have been or are happening to a Study. You can find the events on the Study Record:

Date:					
Study-Site					
Site(s): DFT - Default Site		PI: Researcher, Test			
Status: Open		Additional: N			
Approval: October 29, 2024		Expiration: September 20, 2026			
Initial Approval: July 15, 2024		Other Expirations:			
▼ Events (18) collapse					
Event	Att	Instance/UDF	Start	Complete	Last Mtg
Continuing Review	0		11/06/2024		
Continuing Review	1		10/25/2024		
Continuing Review	2		09/20/2024		10/25/2024
Continuing Review	4		09/20/2024		10/25/2024
Continuing Review	1		09/12/2024		
Continuing Review	2		09/06/2024		10/25/2024
Administrative Closure of an Expired Study	0		08/29/2024		10/25/2024
Administrative Closure of an Expired Study	0		08/29/2024	08/29/2024	
Continuing Review	1		08/29/2024		
Continuing Review	1		08/29/2024		
Continuing Review	4		08/28/2024		10/25/2024
Administrative Closure of an Expired Study	0		08/22/2024		
Revision Request Form - Personnel	0	N/A	07/15/2024		
Revision Request Form - Personnel	1	N/A	07/15/2024		10/25/2024
Study Closure	1		06/07/2024		10/25/2024
Study Closure	0		06/07/2024		
Study Closure	1		06/03/2024		10/25/2024
Initial Submission	0		07/19/2016		10/25/2024

On the event you can find the associated xForms, attachments, and determination letters.

Accessing Previous IRB Study Documents

PDPH has converted over previous studies that were submitted through the old method (prior to the OneAegis system implementation). You will have access to these study records the same way as studies submitted through the OneAegis system. You can find them on your dashboard.

If you are not seeing a study that was reviewed and approved by the PDPH IRB, then please contact the IRB Office at IRB_submissions@phila.gov for further assistance.

Helpful Hints

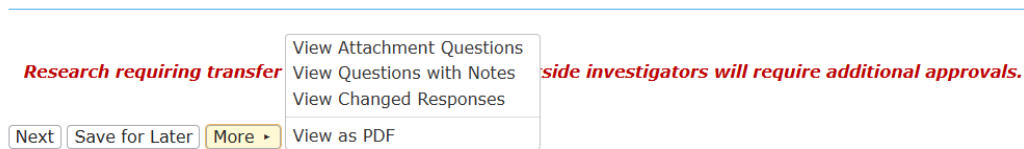
For any further questions regarding your study, submission, or other questions regarding the OneAegis system, contact the IRB Office at IRB_submissions@phila.gov or by phone at (215) 685-0869.

Email Notifications

- Email notifications will be sent to the study team from OneAegis via IRB Office no-reply@pdph.oneaegis.com
- All required signatories will receive an email with a link to the xForm they are being requested to review and sign off on.
- Email notifications will be sent to the study team when the determination of an event has been completed.

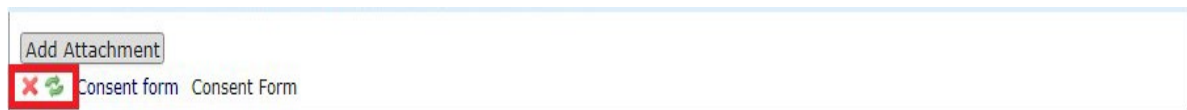
Downloading PDF copies of your application

At the bottom of your xForm, there is a button labeled 'More', click on this and it will give you the option to save your application as a PDF:



Replacing old versions of documents (attachments) on an xForm

There are times when the IRB will ask for changes to certain documents. When submitting an edited version, you can replace the old version by clicking the green arrows next to the red X button on the attachment you need to replace.



Frequently Asked Questions

Why can't my study team see the xForm I created?

The only contacts of the study team that have access to an unsubmitted xForm that is not an Initial Submission xForm (Proposal Submission Application and IRB Exempt Application) are the PI, Co-I, and Coordinator.

Should a study team member other than the Form Creator of that xForm and the PI require access to that xForm while it is being completed, they can be added as a collaborator by the Form Creator.

This function is form specific. Collaborators will only be able to see each xForm they have been added to and access does not carry over to other xForms within the same study.

Does everyone on my study team need to receive email notifications?

The short answer is no. However, if you are listed as a study team member on the application, you can always access the emails sent by the IRB by going into the study and selecting the appropriate event.

I am trying to add a study team member to the xForm and am getting an error "contact not found"?

If you are receiving the "contact not found" message that usually means that the person you are attempting to add has not logged into the OneAegis system to activate their user account, which creates a contact within the system. (Please refer back to how to log into the OneAegis system).

All SSO users just need to sign in to have their contact created within the OneAegis system.

All non-SSO users need to register an account to have a contact created in the system for them.

****Please ensure you spell their name correctly on the xForm before requesting a new account****