Using the IRBManager Online System

Note for Cal Poly Faculty, Students, and Staff: We are working with campus IT to configure single sign-on (SSO) integration that, once it has been established, will allow you to access the IRBManager system via your Cal Poly portal credentials. Until that is complete, please be sure to follow the instructions below in regards to using ONLY your complete Cal Poly email address (e.g., jfaculty@calpoly.edu) as your username and email account.

CREATING AN ACCOUNT

Cal Poly users (pre-SSO integration with Cal Poly portal) and non-Cal Poly users, create an account using the registration option ("To register for an account click here") on the system login screen:

https://calpoly.my.irbmanager.com

EMail --
Cal Poly users: ONLY use your Cal Poly email address, such as "jfaculty@calpoly.edu".

Non-Cal Poly users: Enter your preferred email account for IRB matters.

Confirm Email by re-typing.

Click on **NEXT** to open the registration screen.

On the registration screen:

EMail --
Cal Poly users: Make sure you are using ONLY your Cal Poly email address.

Enter your Organization, Prefix, First Name, Last Name, Degree(s), and Phone number, as required.

Click on **REGISTER.**

If you would prefer, you can request an account to be set up for you by contacting Debbie Hart, dahart@calpoly.edu. To do so, please provide your email address, first and last name, organization (if not Cal Poly), and phone number.

1 LOGIN

Access the system login screen: https://calpoly.my.irbmanager.com

For Cal Poly faculty, staff, and students -- your User Name is your Cal Poly email address. Use the entire string including "@calpoly.edu", e.g., jfaculty@calpoly.edu

User Name --
Cal Poly users: Use your *complete* Cal Poly email address.
Non-Cal Poly users: Use the email address you provided for your account request.

Password –
Enter your password or, if you don't already have a password, click on "Forgot Password?" and you will receive an email to create/reset your password.

Client –
Is *always* CalPoly (one word). Some internet browsers may use autofill to change this field; ensure that it says "CalPoly".

Click on **LOGIN.**

Pre-SSO integration and non-Cal Poly users: If you don't already have a password -- once you have received notice that your account is set up, and you are accessing the system for the first time -- click on "Forgot Password?" Complete the information on the Forgot Password screen. An email will be sent to you to reset your password, and you can use the link provided in the email to create your specific password.

To create/reset your password:

Email –
Use your complete Cal Poly email address or, for non-Cal Poly users, the email address provided to create the account.

Type the code to prove you're not a machine.

Click on **RETRIEVE**.

2 DASHBOARD

After login, your individual (Home) dashboard will open. It shows information on your projects and submissions (xForms); words and numbers in blue are active links which you can use to access the forms and projects. The left navigation menu provides quick links to actions available to you and your documents and forms.

To request review for a new project, click on "Start Protocol Approval Form" under Actions.

3(A)
See page 4

Use "Take a tour…" for assistance.

Use the red links **to access existing forms and projects**. You can also access forms and projects by using the blue links.

3(B), (C), (D)
See pages 5-7

To request an extension (Continuing Review form), OR
To request review of modifications (Modification Request form), OR
To file a report for an adverse event, unanticipated problem, or complaint (Reportable Event form) …
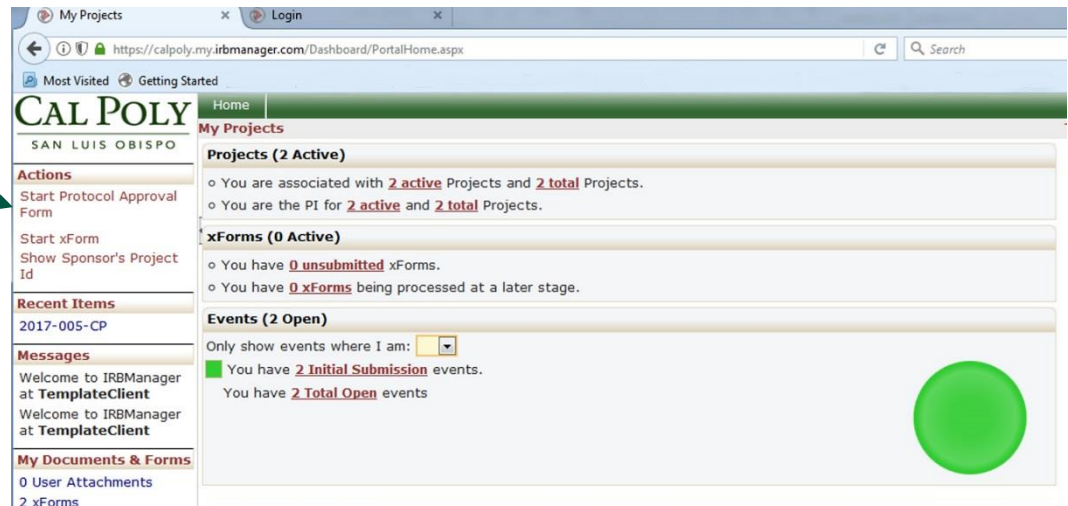
Click on the blue link related to the appropriate project in My Projects (Active). The system will open a project dashboard which will provide access to these forms.

3(A) NEW PROJECT

To submit a new project for review, click on "Start Protocol Approval Form" in the left menu under Actions. A Protocol Approval Form will open. There are 5 pages to the Protocol Approval Form which all must be completed. More detailed information on what to include on the form is on the form itself, but to summarize:

On the first page, the Submitter fields will be populated using account information, but submitters must respond to all required questions/fields. (Note: Projects do not have to be submitted by the PI). You will be asked to provide the title of the project; the type of research; and contact information for PIs, co-PIs, faculty advisors, and additional researchers (as applicable). After completing the first page, select NEXT to proceed (or SAVE, if desired).

On the second page, you will have to provide information on the funding source (if any), the start and completion dates, the methodology(ies), the location of the research, and the populations involved. This page will *require* you to upload your research protocol. As with the first page, once completed, select NEXT. Don't forget to SAVE if you choose.

On the third page, you will have to provide answers to the IRB's evaluation criteria (i.e, risks, subject selection, informed consent, deception, data monitoring and security, and subject debriefing. This page provides upload options for documents such as recruitment materials, informed consent forms, and related supporting documents. Select NEXT (or SAVE).

On the fourth page, there are a set of questions to assist you (and the IRB) in determining what level of review will be required. Once you have answered these questions, select NEXT (or SAVE).

The last page is where you will enter your password and select NEXT, and then on the next page select SUBMIT. This will submit the form and create an electronic signature.

Please note: If you receive an "Required" note for any fields on the form that appear to be completed, you can clear this condition by refreshing your browser.

3(B) MODIFICATIONS

*NOTE: This is for projects that were initially submitted in IRBManager; if your project was approved using the previous paper-based system, please contact Debbie Hart, dahart@calpoly.edu, **before proceeding,** so that the project can be created in IRBManager (the existing paperwork will be loaded). Once that has been done, return to IRB Manager and follow the instructions below to create your modification request.*

To request modifications, you must start on your Home dashboard (which opens when you first login or by clicking the Home tab). Once you are there, click on the Project number link (in blue). This will open the Project dashboard; on this dashboard, select "Start xForm" in the left menu under Actions. Click on the blue link for Modification Request. This will open a new xForm (for the modification request) within the project.

To request a review for proposed modifications, click on the Project number link to open the Project dashboard.

After the Project dashboard opens, click on "Start xForm" under Actions.

To request a review for proposed modifications, click on Modification Request in the list of Forms

The Modification Request Form will open. Some information in the project file will auto-populate, but you will have to respond to some questions and fields, such as: the type of modification; if the modification has already been implemented; and if the modification increases risk, alters confidentiality, or includes elements not included in the original approval. You also must provide a description of the proposed changes and upload any modified documents.

At the end of the form you will enter your password and select NEXT, and then on the next page select SUBMIT. This will submit the form and create an electronic signature.

3(C) EXTENSION/RENEWAL

*NOTE: This is for projects that were initially submitted in IRBManager; if your project was approved using the previous paper-based system, please contact Debbie Hart, dahart@calpoly.edu, **before proceeding,** so that the project can be created in IRBManager (the existing paperwork will be loaded). Once that has been done, return to IRB Manager and follow the instructions below to create your extension request.*

To request an extension/renewal, you must start on your Home dashboard (which opens when you first login or by clicking the Home tab). Once you are there, click on the Project number link (in blue). This will open the Project dashboard; on this dashboard, select "Start xForm" in the left menu under Actions. Click on the blue link for Continuing Review. This will open a new xForm (for the extension request) within the project.

To request an extension for an approved project, click on the Project number link to open the Project dashboard.

After the Project dashboard opens, click on Start xForm under Actions.

To request an extension, click on Continuing Review in the list of Forms.

The Continuing Review Form will open. Some information in the project file will auto-populate, but you will have to respond to some questions and fields, such as: if have any modifications that need to be approved (if so, you will be instructed to complete a Modification Request Form), or if you have any adverse events or unanticipated problems to report.

At the end of the form you will enter your password and select NEXT, and then on the next page select SUBMIT. This will submit the form and create an electronic signature.

3(D) REPORTABLE EVENT

*NOTE: This is for projects that were initially submitted in IRBManager; if your project was approved using the previous paper-based system, please contact Debbie Hart, dahart@calpoly.edu, **before proceeding,** so that the project can be created in IRBManager (the existing paperwork will be loaded). Once that has been done, return to IRB Manager and follow the instructions below to submit your report.*

To submit a report on an adverse event, unanticipated problem, or subject complaint, you must start on your Home dashboard (which opens when you first login or by clicking the Home tab). Once you are there, click on the Project Number link (in blue). This will open the Project dashboard; on this dashboard, select "Start xForm" in the left menu under Actions. Click on the blue link for Reportable Event Form. This will open a new xForm (for the reportable event form) within the project.

To submit a report on a problem or complaint, click on the Project number link to open the Project dashboard.

After the Project dashboard opens, click on Start xForm under Actions.

To submit a report on a problem or complaint, click on Reportable Event Form in the list of forms.

The Reportable Event Form will open. Some information in the project file will auto-populate, but you will have to respond to some questions and fields, including providing information on the event and attaching any relevant documents. At the end of the form you will enter your password and select NEXT, and then on the next page select SUBMIT. This will submit the form and create an electronic signature.

4 REVIEW

IRB staff will be notified of your submission and as the project is being processed, you may receive emails with updates or instructions. If there are instructions regarding missing information or changes needed, please make sure to use the link provided in the email to access the appropriate form and revise the form as requested. Once the project is approved, you will receive an email notice of approval.

5 EXPIRATION

Project approvals are good for one year (or less) from date of approval. IRBManager will send email notifications of impending expiration dates. If you receive a notification, please use the link provided in the email to access the project and complete the Continuing Review Form.

Questions or Assistance?

Contact Debbie Hart, dahart@calpoly.edu or (805) 756-1508.