

SilverLink User Guide

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This SilverLink User Guide provides a reference for SilverLink's features and functionality. Comments and/or questions may be directed to support@sterlingirb.com, where a member of Sterling's Software Department will respond to the request.

SilverLink is Sterling IRB's secure web portal. It can be used by Sponsors, CROs and Investigative Sites to submit forms and documents to the IRB, such as New Study submissions, Principal Investigator applications, Continuing Review reports, safety reports, recruitment/study materials, and final reports. It is also a means to instantly download documents issued by Sterling IRB like approval letters and acknowledgements.

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**Supported web browsers include Firefox, Chrome, Safari, Edge, and Opera.*

DEFINITIONS

- A **Master-site** is the study-site for study-wide submissions which is viewable only to the Sponsor or CRO. The Sponsor and CRO can view all PI study-sites for a study.

- A **Study-site** is the Principal Investigator's site for a specific study and is viewable by the associated research site personnel. This is where Principal Investigators and/or site personnel can submit site-level xForms and where Sterling will issue site-level determination documents.

- "**xForm**" is the term for Sterling's dynamic "smart" forms. All forms submitted via SilverLink are dynamic smart forms.

- An **Event** is the submission, review, and approval process of items to Sterling IRB. Think of it as a "folder" for each submission (New Study, Continuing Review, Safety Report, etc.) associated with a particular study-site, containing the submitted forms, attachments, and approval documents. The Event also tracks the completion dates for various steps in the submission and review process. Clicking on an Event's name displays Event-specific information and steps for event completion. Clicking on the number under the "Att" column will bring you to the applicable generated documents and attachments for that event.

LOGGING IN

SilverLink supports various user roles with various access levels:

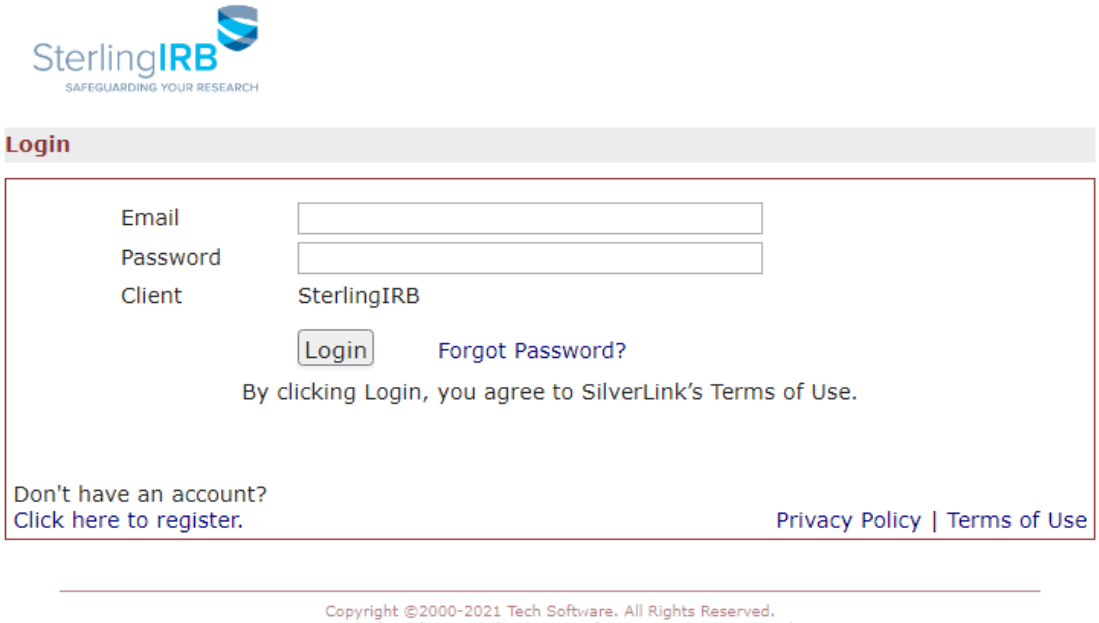
- **Sponsors/CRO Contacts** have access to all data and documents associated with any study(ies) and study-site(s) over which they preside (once access to the study has been requested in Silver Link). They can submit xForms and download existing documents but may not delete documents or edit data. Each study can have an unlimited number of Sponsor/CRO Contacts.
    - The Sponsor/CRO App Reviewer role is a Sponsor or CRO contact designated via the New Study Submission Application and will be notified to review PI Site Submission Applications prior to submission to the IRB.

- **Principal Investigators** automatically have access to all data and documents associated with their specific study-site on any study(ies) in which they participate. They can submit site-specific xForms and download existing site-specific documents, but do not have access to general study-level documents.

- **Site Contacts** have the same level of data and document access as the Principal Investigator (PI), but only for the specific site(s) with which they are associated. Access is granted to these users on a per-study basis, so they do not automatically have access to all the same studies/study-sites as their PI.

- Each user can have different roles on different studies and will only need one user account. All accounts must have a unique username (an email address) and password and cannot be shared by other users. User accounts will be granted the appropriate level of access to each study and/or study-site as applicable. You will receive document notifications for your associated studies unless requested otherwise.

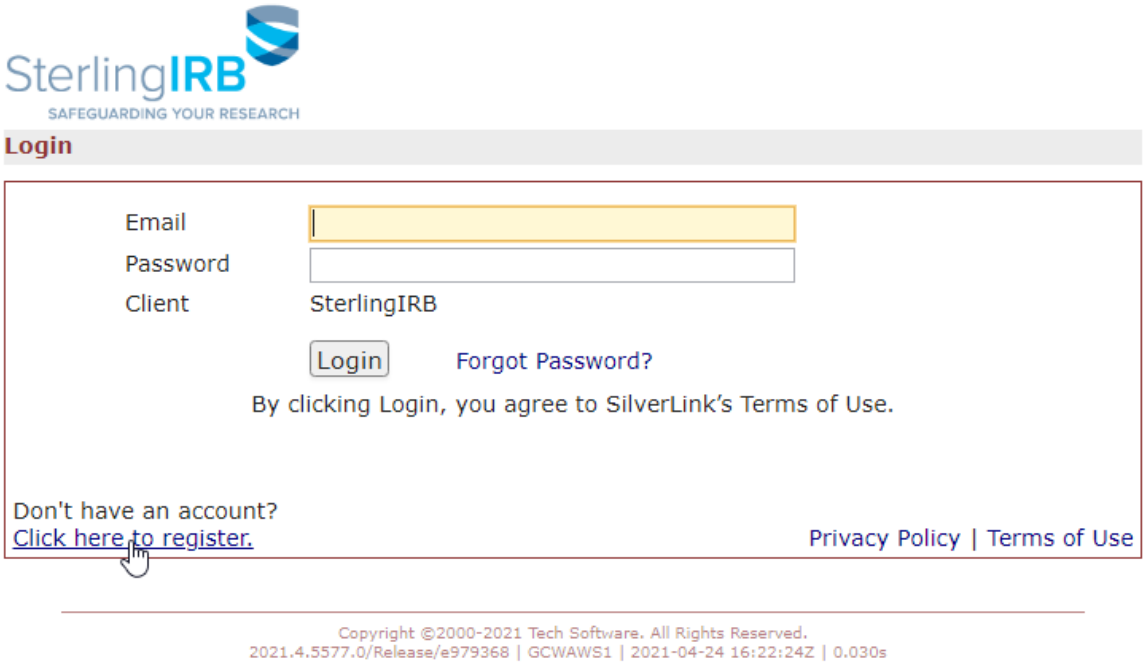
You can access SilverLink from Sterling IRB's website, www.sterlingirb.com,
or directly at: sterlingirb.my.irbmanager.com



Registering / New Users

Contact persons may create a SilverLink user account and request study or study-site access through several different methods, detailed below:

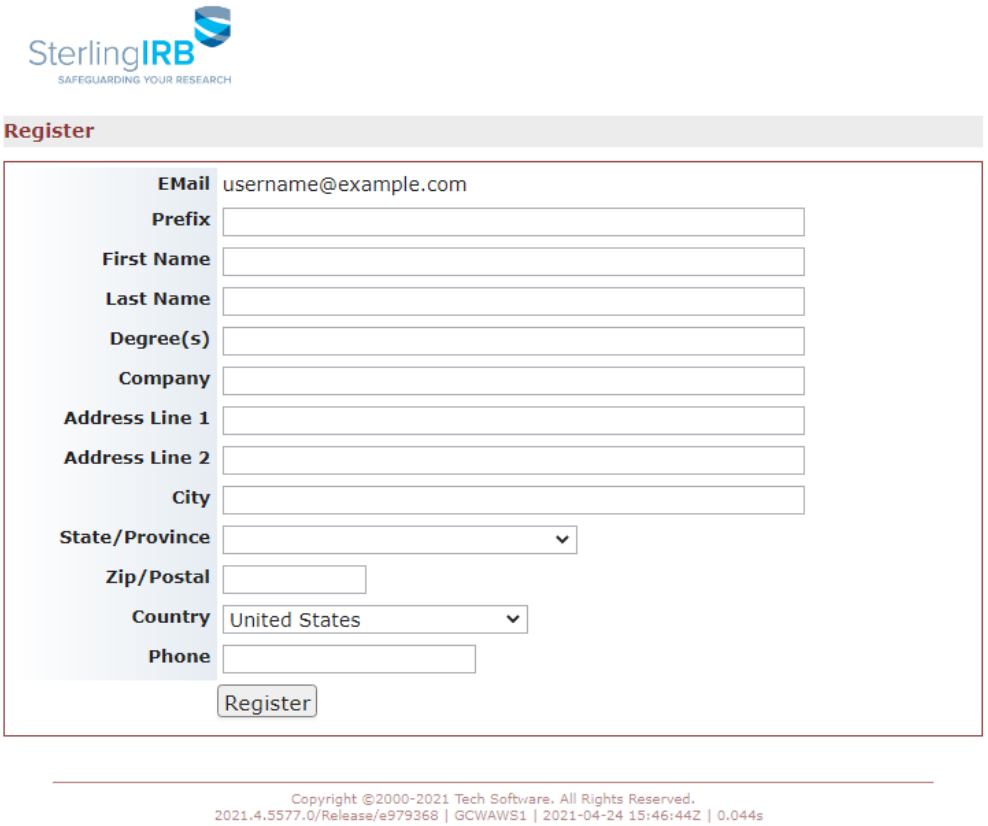
- Contact persons who do not yet have an account can register via SilverLink's Login screen, by clicking the "Click here to register" link, as seen below.
- Contacts can be added by including them on the New Study Submission Application Form or the Submission Application for Investigator/Site Form.
- Contact persons who already have a user account can submit requests for access and/or removal of Study or Study-site contacts via the SilverLink Access Request Form.
- Requests for access and/or removal may also be emailed directly to support@sterlingirb.com



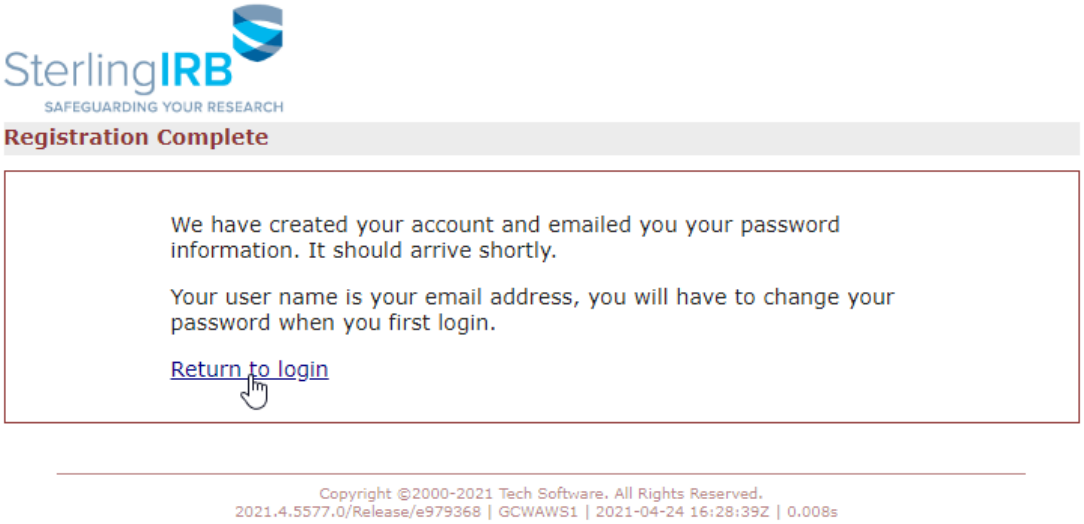
Clicking the self-registration link on the Login page will bring you to the following screen:



If the email address is already registered, the system will inform you that a user with that email address already exists and suggest recovering your password using the “Forgot Password?” link. (Read more information on this in the next section.) If the email address is not already associated with a user account, you will be provided the registration page, as seen below:



After completing the required fields and clicking the “Register” button, the system will create a new user account. After a few moments, the system will automatically send a notification to the email address with which you registered. This will not grant access to any studies or study-sites at this time.



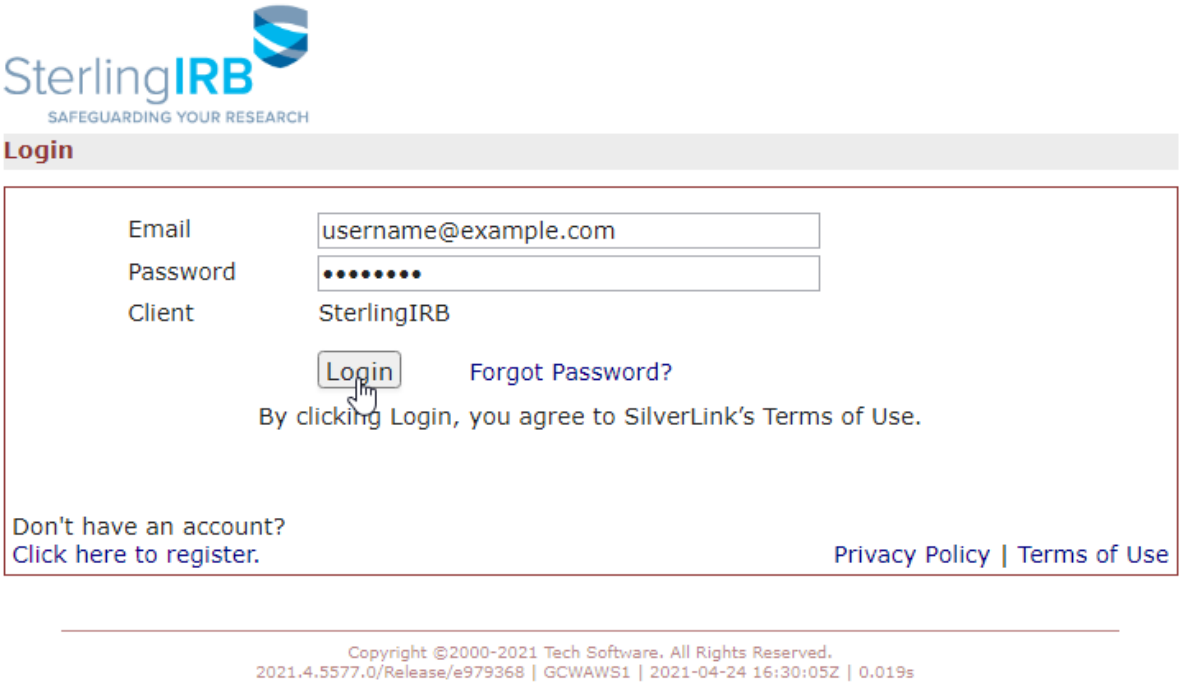
The email will provide a one-time-use password reset link that will be active for 24 hours. Be sure to check your spam folder if you do not receive an email with the password reset link after a few moments. After setting your password, you can access SilverLink. If you have any difficulty resetting your password, contact our support team at support@sterlingirb.com.

Log In

All users, regardless of permissions level, will log in to the same portal.

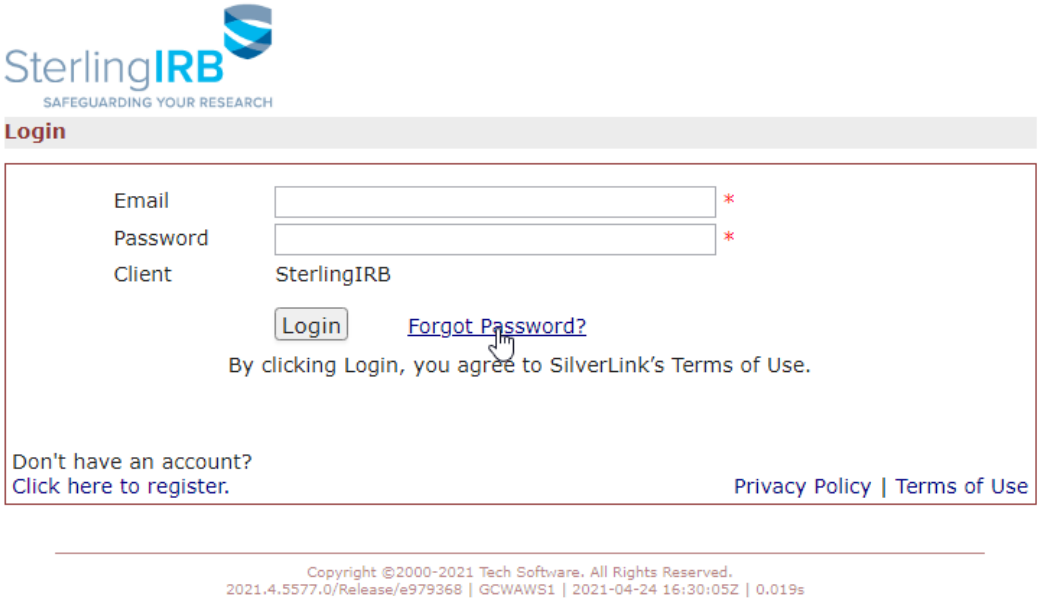
- The “EMail” is the email address associated with your account. Each user must have their own account and cannot share access with other users.

- The “Password” is the password you set.

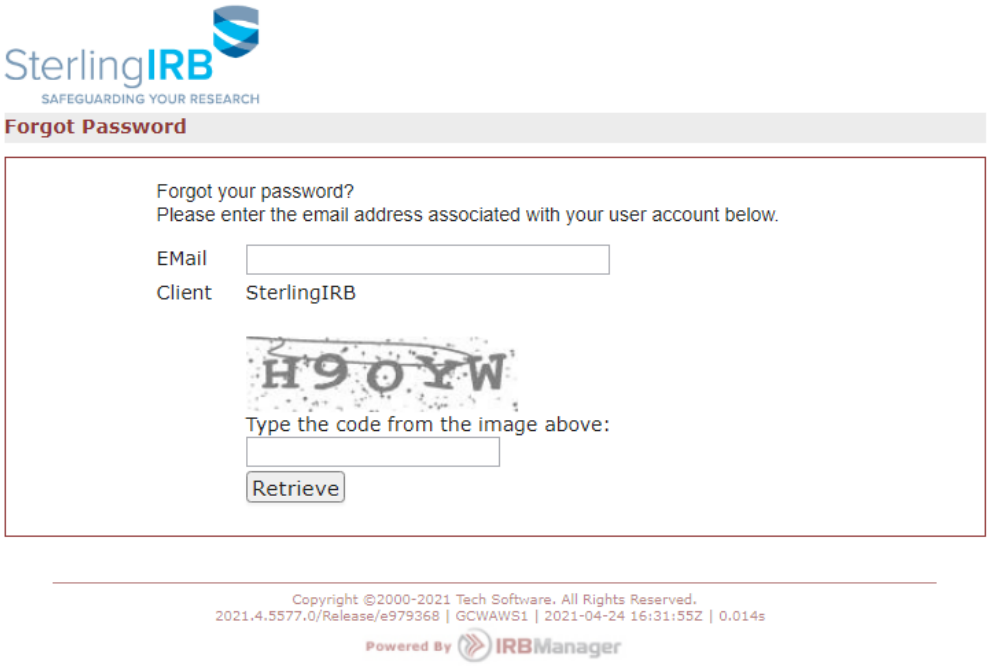


Forgot Password

Any user can reset their password by clicking “Forgot Password?” on the log in page.

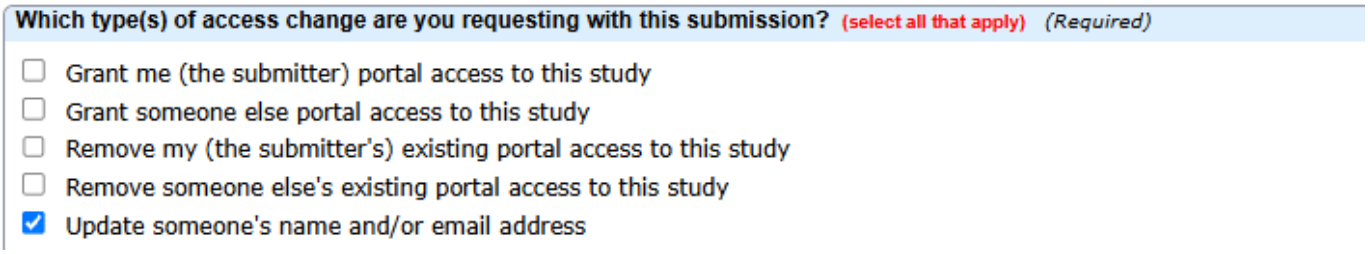


After entering the email address associated with the account and entering the randomized letter/number code displayed on the Forgot Password screen, an automated email will be sent with a link to reset your password. Users may also email support@sterlingirb.com for assistance.



Updating Email Addresses for Existing Users

If an email address has changed but the user still need access to the studies they are currently associated with in Silver Link under an old email address, you may use a SilverLink Access Request form, and select the “Update someone’s name and/or email address” option.

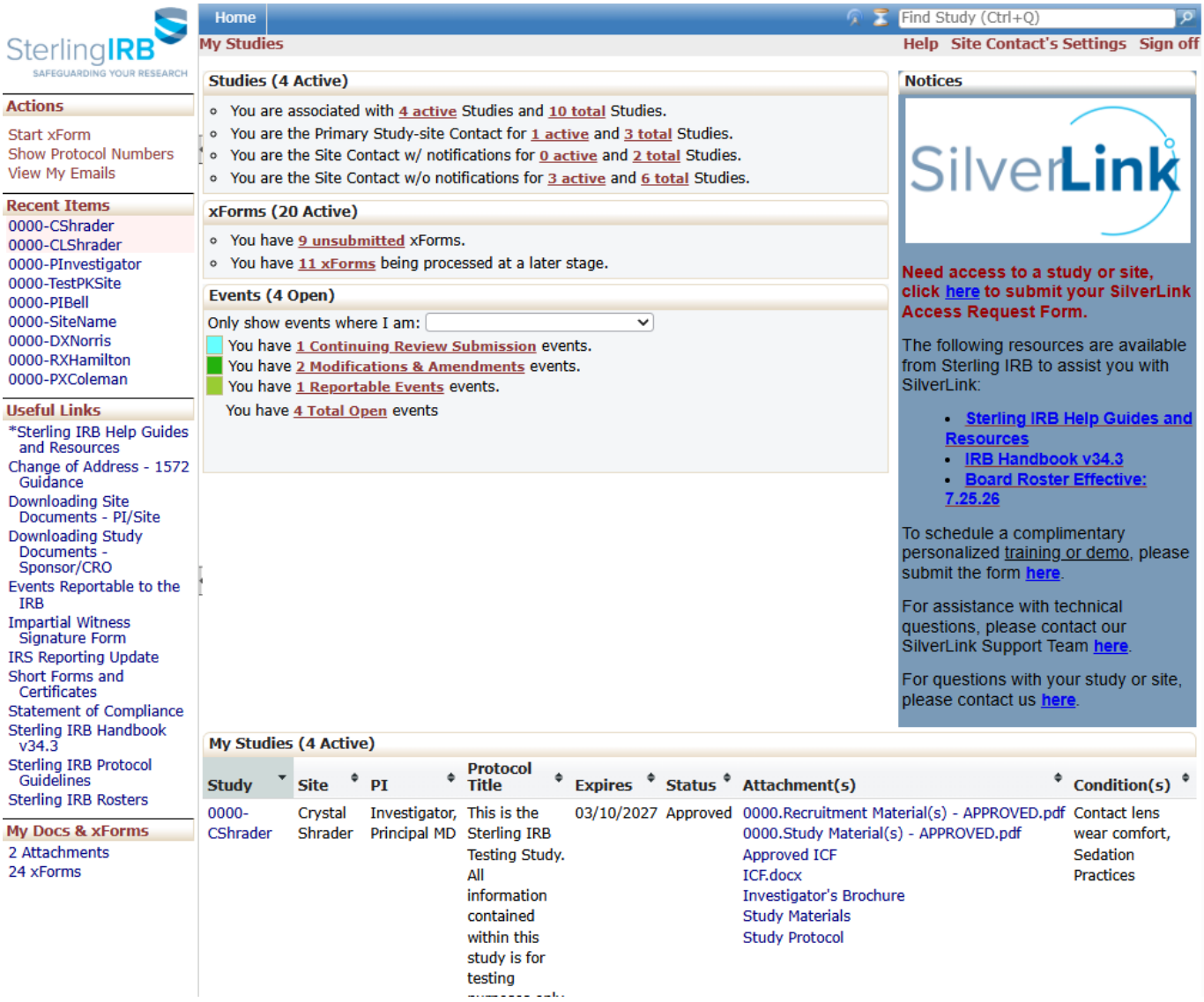


Alternatively, you may email support@sterlingirb.com with your request including your current or outdated email address, along with the new email address you are now using. This may apply in the event a user’s name changes or the domain name associated with an organization changes for all its current users. The Support team will be able to update the email which will then serve as the new username when logging in to Silver Link.

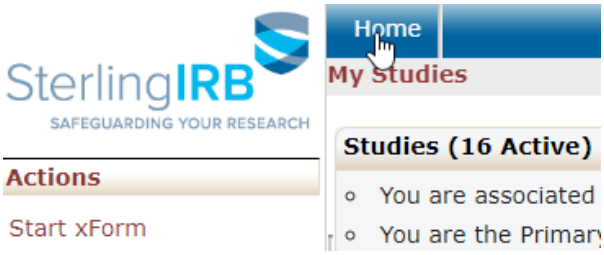
NAVIGATION

Sections of the Dashboard/Home Screen

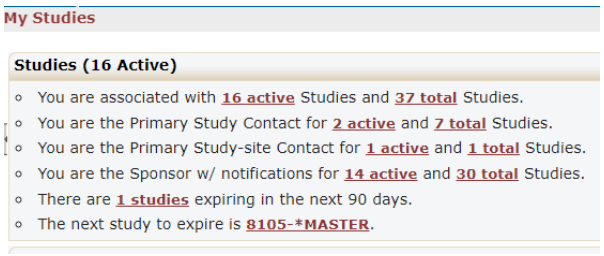
From the Dashboard/Home screen, users will have appropriate access to all applicable Studies, Study-Sites, and Events.



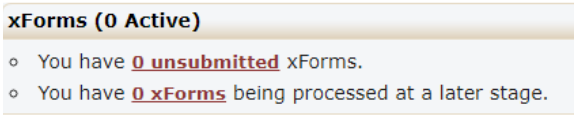
From any page in the system, the "**Home**" button (below) will always be available in the blue bar at the top of the screen and will bring you back to the Dashboard/Home screen.



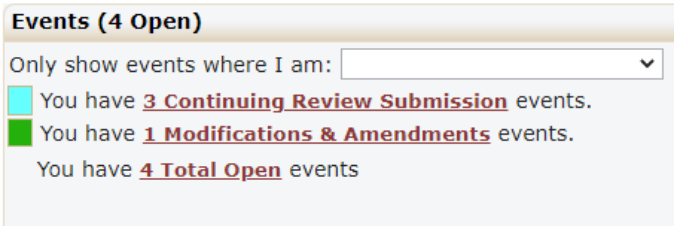
At the top center portion of the Dashboard is the "**Studies**" section. There you will see a summary of information regarding the number of studies you are associated with, both Active and Total (includes non-active/Closed studies). Prospective sites will not be labeled as "Active," but will be accessible under "Total Studies." You will also see a breakdown of your associated studies by your Role for the study.



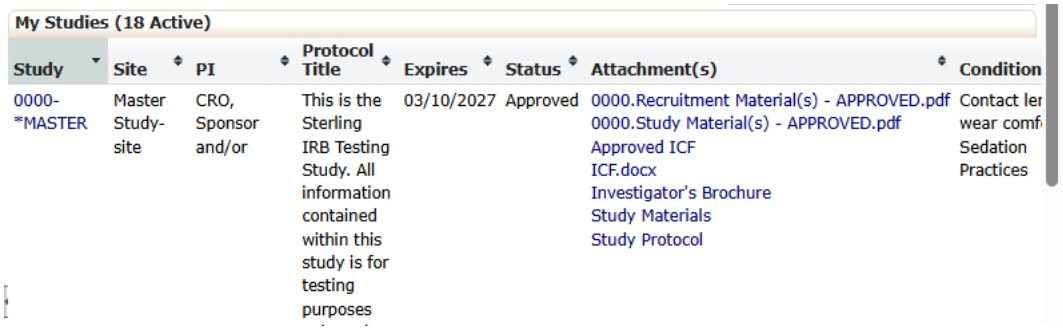
The next portion of the screen is the "**xForms**" section.. Here you will see the number of "unsubmitted" xForms you have started, and the number of submitted xForms being processed by Sterling IRB for ongoing events.



The next portion of the screen is the "**Events**" section.. This section will show you active/open events on all Studies/Study-Sites on which you are listed.



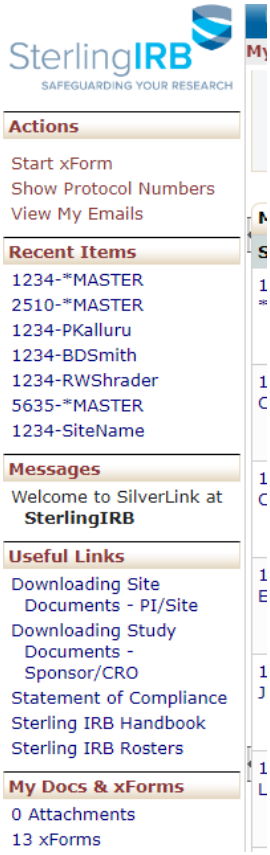
The last center portion of the screen is the "**My Studies**" section. This is a list of all active Studies and Study-Sites with which you are associated.


My Studies (18 Active)

Study	Site	PI	Protocol Title	Expires	Status	Attachment(s)	Condition
0000-*MASTER	Master Study-site	CRO, Sponsor and/or	This is the Sterling IRB Testing Study. All information contained within this study is for testing purposes	03/10/2027	Approved	0000.Recruitment Material(s) - APPROVED.pdf 0000.Study Material(s) - APPROVED.pdf Approved ICF ICF.docx Investigator's Brochure Study Materials Study Protocol	Contact ler wear comf Sedation Practices

The columns in the "My Studies" table, from left to right, are: IRB ID (read more below about how to switch between displaying Protocol Number and Sterling IRB ID),**Site Name** (the Sponsor's Study-Site will read "Master Study-site"), **Principal Investigator's name** (for the Master Study-site it will read "CRO, Sponsor and/or"), the Protocol Title, the Study-Site expiration date, and the site's current status with Sterling IRB.

The left side of the screen contains the "**Actions**" column. The Actions available will change depending upon the page you are currently viewing. The "Sterling xForms" section of this guide will further detail which actions and xForms are available from the dashboard/home screen versus on a specific study/site page.



The "**Start xForm**" Action will provide a list of xForms you can complete from this page.

On the Dashboard/Home screen, the "**Show Study Codes**" Action will change the Protocol Number in the "My Studies" section to display the Sterling IRB ID number instead or vice versa.

"**Recent Items**" is a list of the most recent links you have clicked within the system. You can "Pin" and "UnPin" as needed.

"**Messages**" will display notes from Sterling IRB

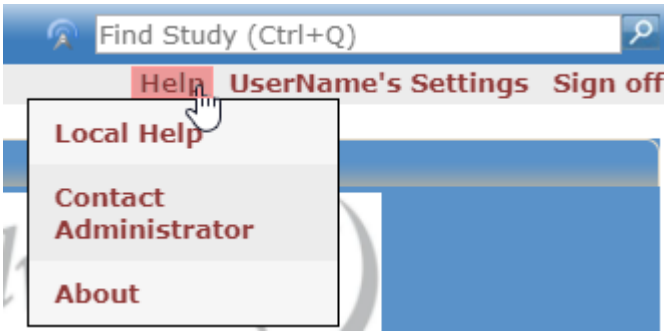
"**Useful Links**" are web links provided by Sterling IRB.

"**My Documents & Forms**" are links to "User Attachments" and "xForms".

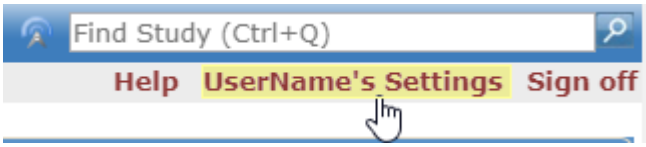
"**User Attachments**" are documents associated with your user account, uploaded to your profile, if applicable. This is not a list of attachments for a Protocol or Event. These attachments are not linked to any study or Event.

"**xForms**" are the dynamic smart forms associated with you as a user, across the entire system.

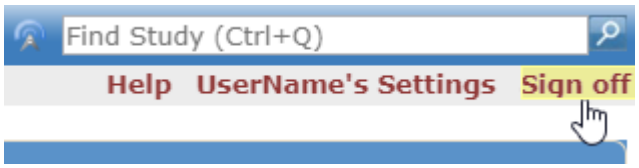
Hover over the “Help” link for a drop-down of available options.



The “Settings” link is where you can change your password, and update your profile including: name, phone number, address, and more.



Use the “Sign off” link to log out of the system. This link is available on every page in the system. For your protection, the system will automatically log you out after fifteen minutes of inactivity.

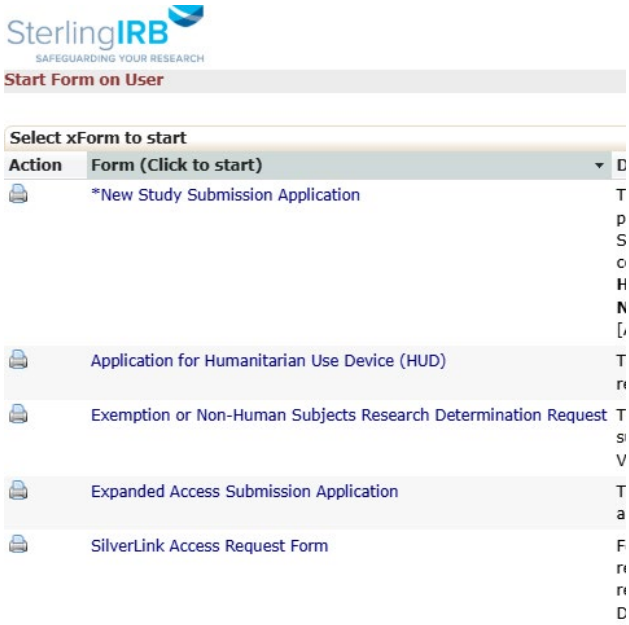


STERLING xFORMS

Submitting xForms

An xForm is a dynamic smart form. Each Sterling IRB form is available for submission within SilverLink.

From the **Home screen**, click “Start xForm” under “Actions” on the left side of the screen to submit any of the following xForms.



The **New Study Submission Application** is intended to be used by Sponsors and CROs or by Institutions serving as the study’s primary point of contact, to submit an entirely new Protocol/Study for Sterling review and approval.

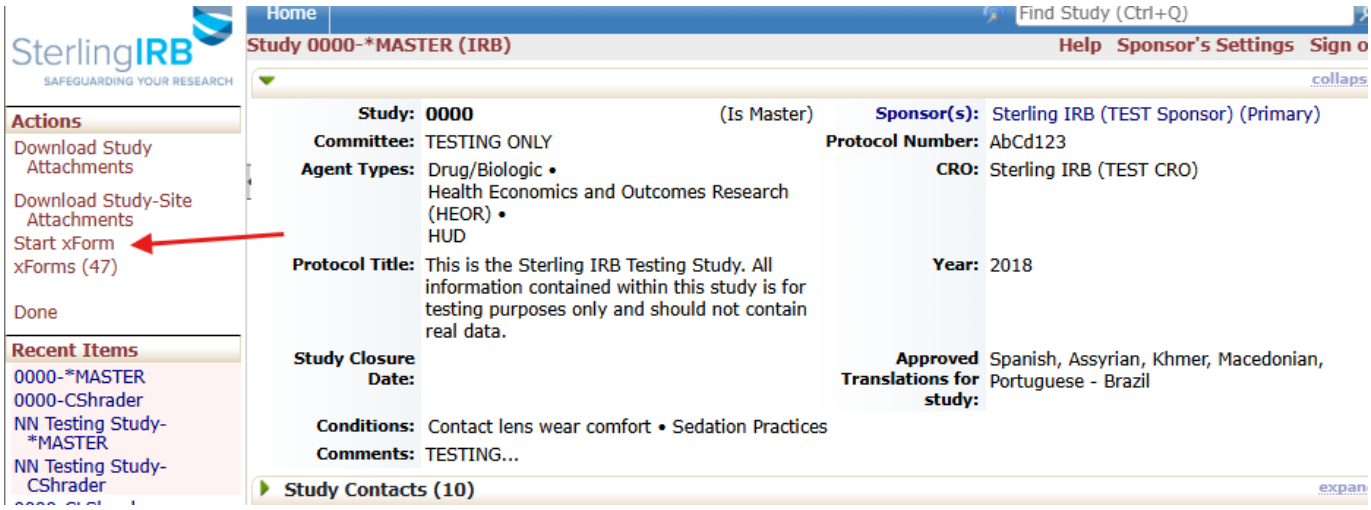
The **Exemption or Non-Human Subjects Research Determination Request** is completed and submitted to initiate the review of an exemption or NSHR

Application for Humanitarian Use Device (HUD) can be completed by a physician applicant to request Sterling IRB’s review of a HUD

Expanded Access Submission Application can be completed to request individual patient expanded access to a drug, biologic, or device.

SilverLink Access Request form can be completed by users of any permissions level (Sponsor/CRO or Investigative Site contacts) to add or remove personnel for a study under Sterling review or update the contact information for someone already associated with a site in SilverLink.

To submit a study-level xForm for an existing study (i.e. submissions related to the study as a whole, not to a specific PI/study-site), Sponsor/CRO Contacts should navigate to the study's MASTER-site and click the "Start xForm" link under "Actions" on the left side of the screen.

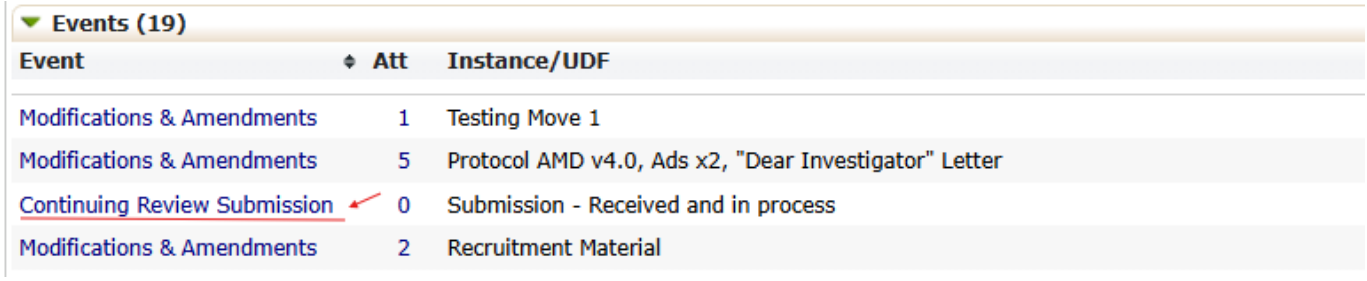


This is where Sponsor/CRO Contacts will submit study-wide xForms to Sterling IRB, such as: changes in research (Modifications and Amendments), safety reports (Reportable Events), and more.

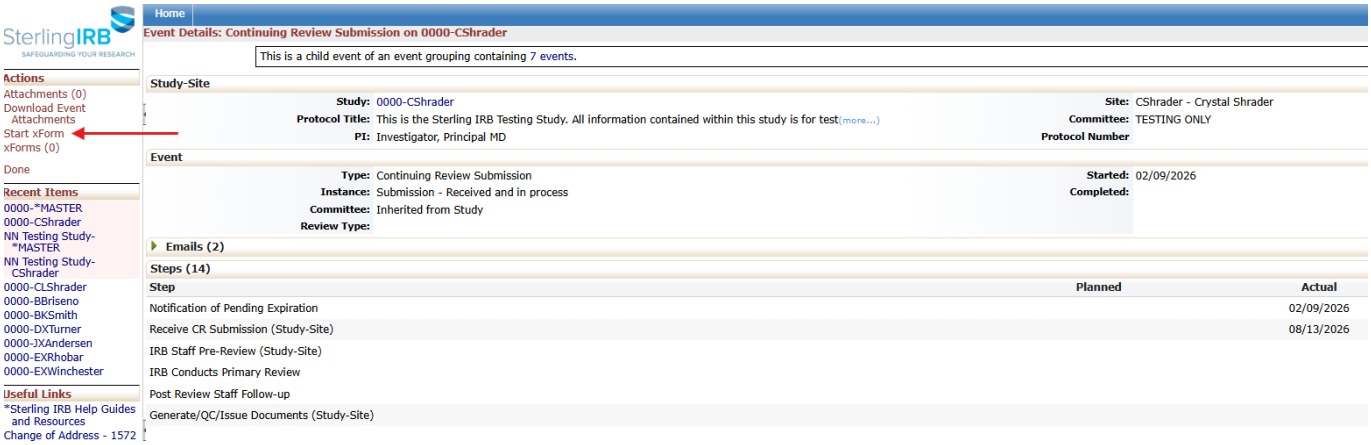
To submit a site-level xForm for an existing study-site, Contacts should navigate to the appropriate PI's study-site and click the "Start xForm" link under "Actions" on the left side of the screen.

This is where Contacts will submit site-specific xForms to Sterling IRB, such as: site initial review (Submission Application for the Investigator/Site), changes in research (Modifications and Amendments), safety reports (Reportable Events), site continuing review (Study Status Report) and closeout (Final Report), and more.

To submit an xForm on an existing Event, click on the Event's Name from the "Events" section. This is where Sponsor/CRO and Site Contacts will submit their Continuing Review forms ("Study Status Report").

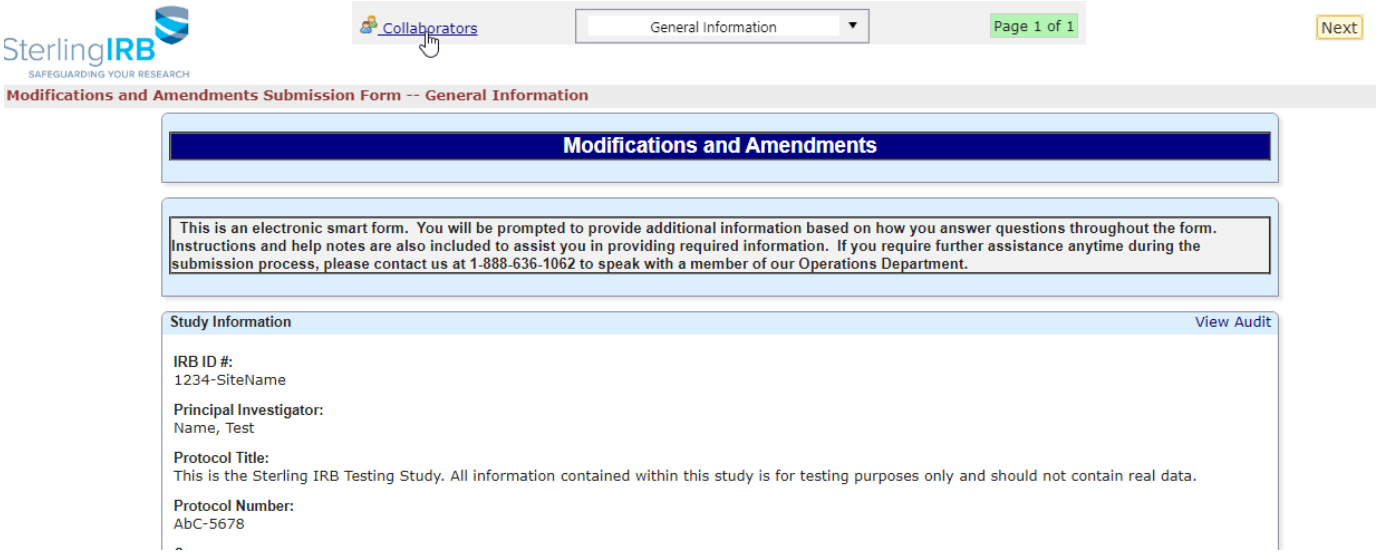


Inside the Event, click the "Start xForm" link under "Actions" on the left side of the screen to see a list of available forms to submit.



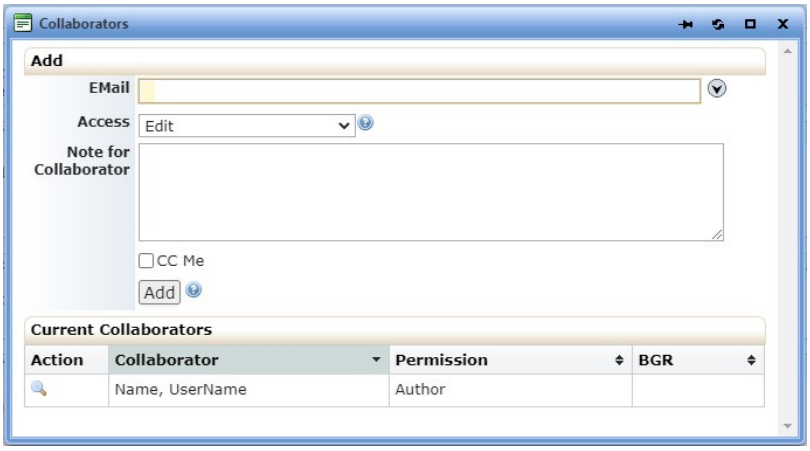
Adding Collaborators to xForms

After starting an xForm, you have the ability to add “Collaborators” to the xForm. Adding a Collaborator to an xForm invites that person to help you complete and/or submit the xForm. At the top of any page of the xForm, see the “Collaborators” link.



Clicking this link will open an on-screen “Collaborators” pop-up window. Here, you can see any existing Collaborators for this xForm and can enter the email address(es) of any person(s) you wish to add. Collaborators must already be a user in SilverLink (refer to the New Users section for instructions).

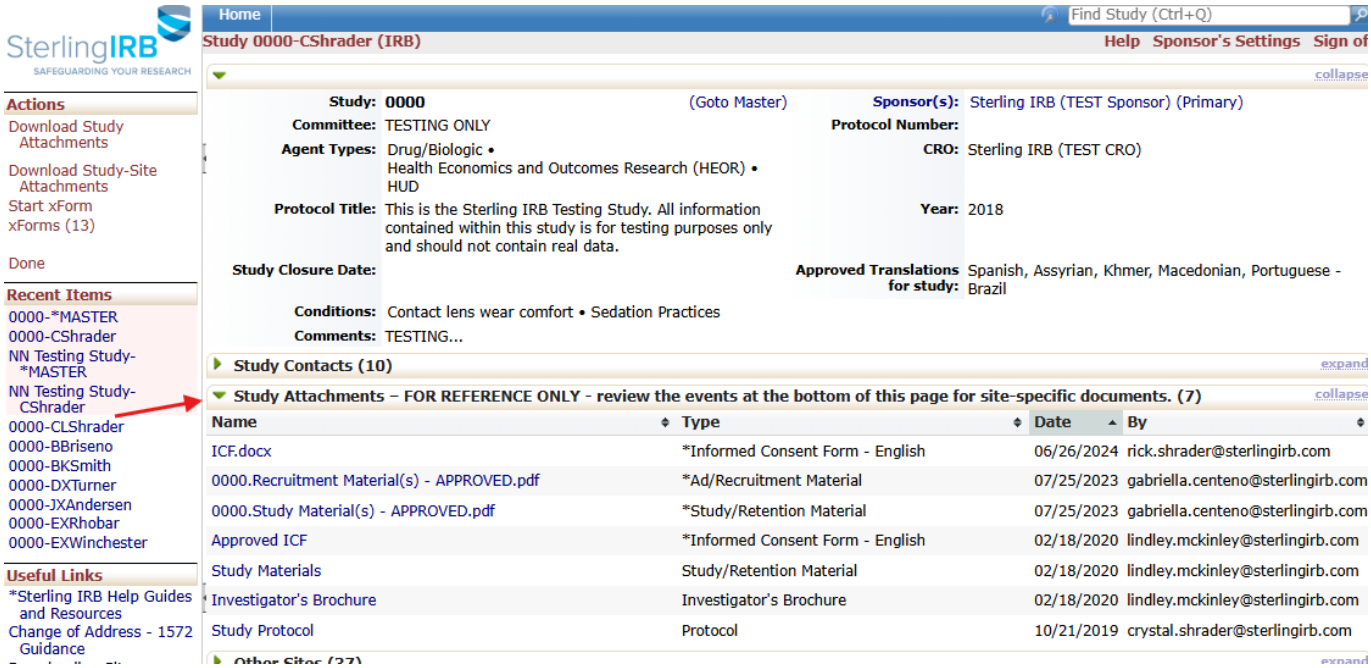
On the next line, select the level of “Access” this user should have: “Edit”; “Edit and manage”; or “Edit, manage and submit”. You can also add notes that will automatically be sent to the Collaborator(s). You can chose to be CC’d on the Collaborator email. Clicking “Add” will send an email invitation with a direct link to each new Collaborator.



ATTACHMENTS AND DETERMINATION LETTERS

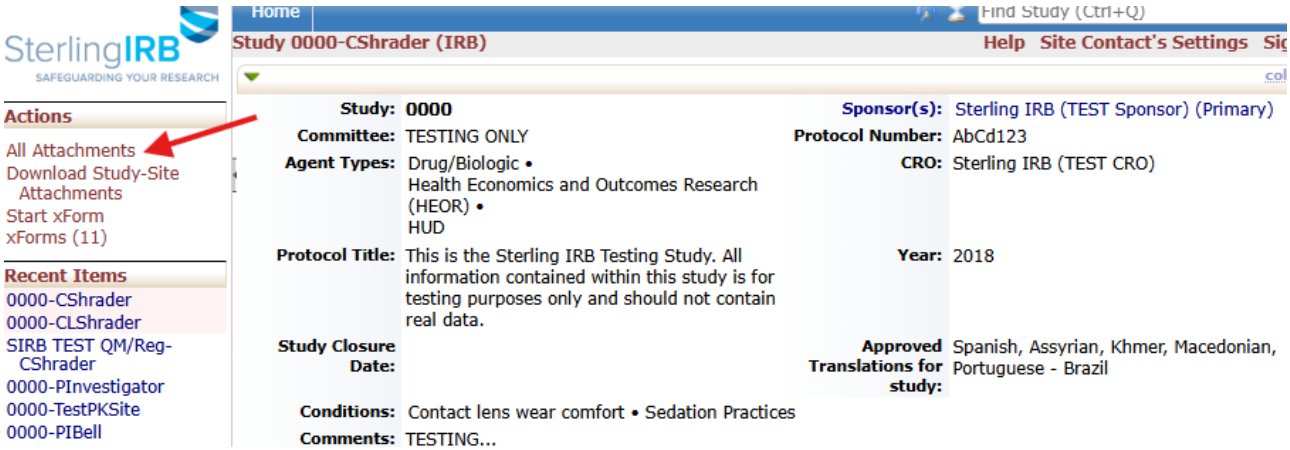
Locating Issued Documents on Sites

For documents approved by Sterling IRB for **study-wide** use (such as study-wide Ads/Recruitment Materials), you can find the most recently approved version on your study-site page, in the section titled "Study Attachments". Click on the name to open/download each approved document for this study.



All Attachments

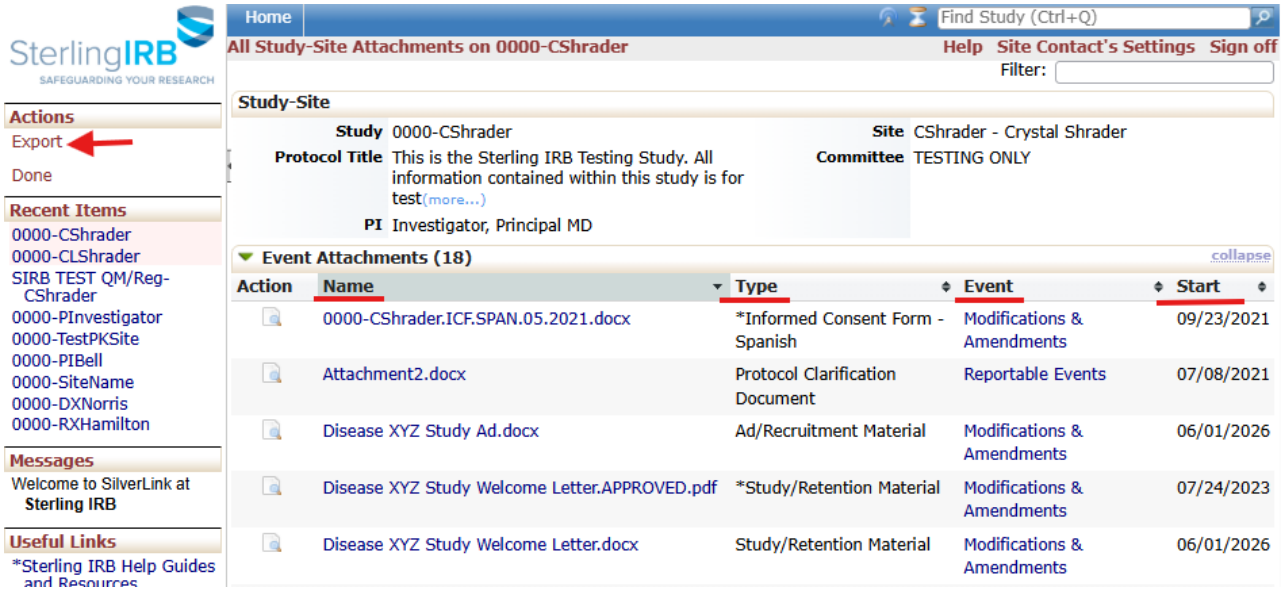
To see all study-site documents in one location, you may click “All Attachments,” on the left side under “Actions.”



This will bring you to a page containing all documents associated with your study-site. You can filter results by clicking on “Name,” “Type,” “Event,” or “Start” (event start date) to more easily sort and locate document(s).

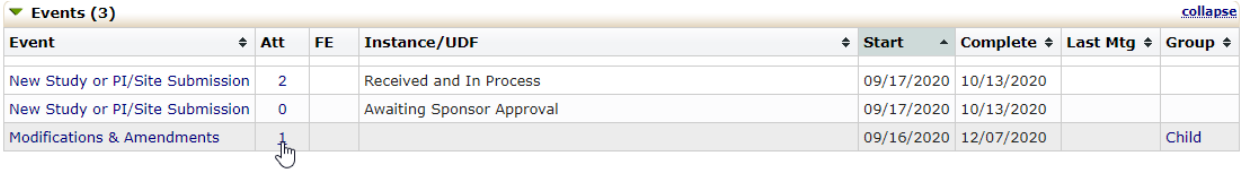
The Export option under “Actions” can be used to generate an Excel listing of all documents associated with the site.

Note: The attachment types “Generated Document” and “Approval Document” generally refer to the same category of documents. Due to a change in how the system classifies these documents, determination letters may appear under either type. We recommend reviewing both types when searching for a determination letter.



Locating Issued Documents on Events

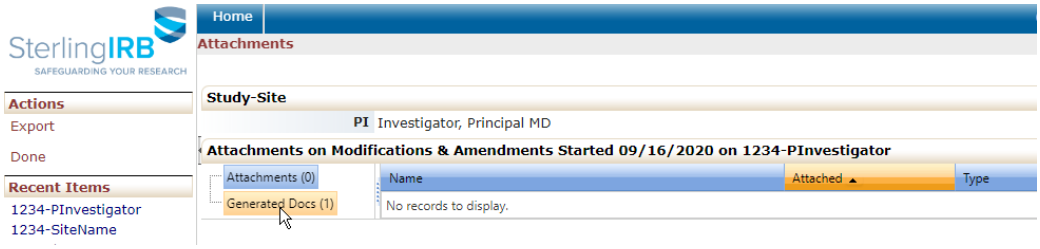
To locate/download approval documents for a specific submission/Event, navigate to the study-site page. At the bottom of the screen, find the "Events" section. In the "Att" (or 'Attachments') column, note the number displayed for each Event. Clicking on the number will take you to the Attachments page for that specific Event.



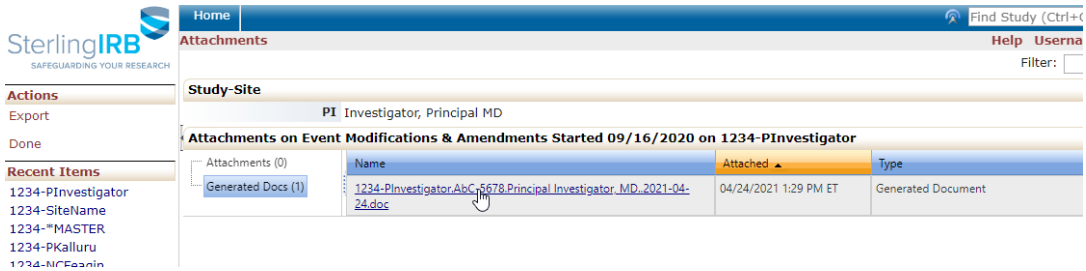
On the Attachments page, you can see two sections: Attachments and Generated Docs.

- "Attachments" may include documents attached to the submission form, copies of IRB-approved consent forms, copies of IRB-approved site-site specific Ads/Recruitment Materials etc.
- "Generated docs" will include Approval documents and acknowledgements issued by Sterling IRB

Clicking "Attachments" or "Generated Docs" will display documents in that section for that Event.

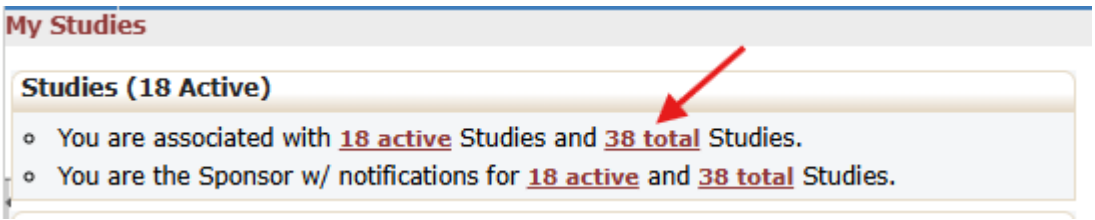


Click on a document's name to open/download that document.

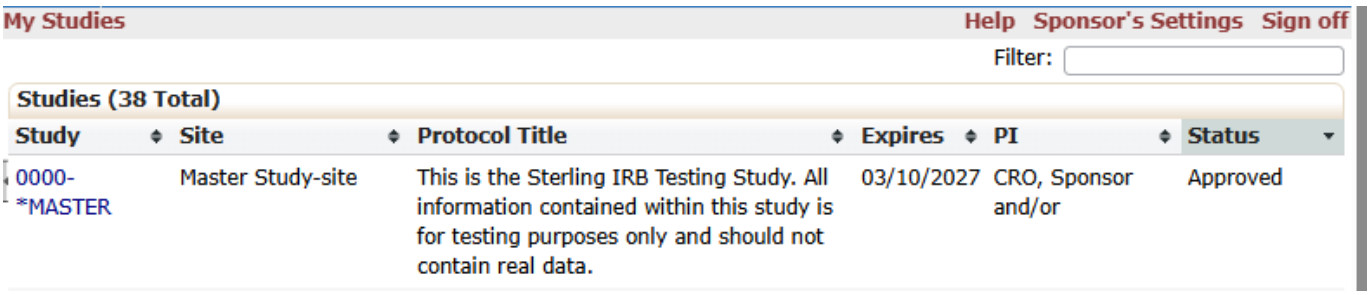


Accessing Documents after Study Closure

Documents can still be accessed after a study's closure; the key difference is where you will find the study from your dashboard. Since the status has changed from Approved to Closed, it will no longer be listed among the Active studies or in the "My Studies" (Active) section. Instead, you must select Total Studies, which can be found under My Studies at the top of your dashboard screen.



Within Total Studies, you may use the "Study," "Site," "Protocol Title," "Expires," "PI," or "Status" columns to more easily sort and locate your study.



More detailed How-to videos can be found on our Introduction to SilverLink Web Page:
https://www.sterlingirb.com/irb-services/silverlink-web-portal/