SilverLink User Guide

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 Support 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, Internet Explorer, Safari, and Opera.
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. 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.

- **Principal Investigators** 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 documents.

- **Site Contacts** have the same level of data and document access as the Principal Investigator (PI) group, but only for the specific site(s) to 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 study-site can have an unlimited number of Site Contacts.

- 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 others users. User accounts will be granted the appropriate level of access to each study and/or study-site as applicable. If you have requested document notifications for any study(ies) and/or study-site(s) to which you have been granted access, you will receive the notifications at your listed email address.

You can access SilverLink from Sterling IRB’s website, [www.sterlingirb.com](http://www.sterlingirb.com), or directly at: [sterlingirb.my.irbmanager.com](http://sterlingirb.my.irbmanager.com)
Registering / New Users

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

- Contact persons who do not yet have an account can register for a new user account via SilverLink’s Login screen, by clicking the “Click here to register” link, as seen below.

- Contacts can be added during study or study-site application 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 additional requests for access and/or removal 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 show you 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. After setting your password, you can access SilverLink at any time. If you have any difficulty resetting your password, contact our support team at support@sterlingirb.com.
Log In

All users, regardless of user type, will log in to the same portal.

- The “User Name” 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.

- The “Client” is “SterlingIRB” and should automatically populate.
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.
NAVIGATION

Sections of the Dashboard/Home Screen

Sterling IRB has developed SilverLink with the user in mind. 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. In this area you will see a summary of information regarding the number of active, and number of total (includes active and inactive), Studies and Study-Sites with which you are associated. You will also see a breakdown of your associated studies by your Role for the study.

![Studies Table](image)

The next portion of the screen is the “xForms” section. “xForms” are electronic smart forms. 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.

![xForms Table](image)

The next portion of the screen is the “Events” section. Events are the submission, review, and approval process for items submitted to Sterling IRB. This section will show you active/open events on all Studies/Study-Sites on which you are listed.

![Events Chart](image)

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 Table](image)

The columns in the “My Studies” table, from left to right, are: Study Protocol Number (read more below about how to switch this to show the 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. This column will change, depending upon the page you are currently viewing, to provide all available actions you may take on that 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. This also works in the reverse.

“Recent Items” is a list of the most recent links you have clicked within the system.

“Messages” will display notes from Sterling IRB, for example: upcoming holiday closure dates.

“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 any. 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 electronic smart forms associated with you as a user, across the entire system.
In the top right corner of the screen are several helpful links. Click the “Take a tour…” link on the Dashboard/Home screen to be reminded of what each section does. This link is only available on the Home screen.

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.
Studies, Study-Sites, and Events

Studies

Each study has a special site called the “MASTER” site. This is where the Sponsor and/or CRO will submit study-level xForms, and where Sterling IRB will issue and store study-level approvals and acknowledgements for the Sponsor/CRO.

The MASTER-site is only viewable by the associated Sponsors/CRO Contacts. They can access the study MASTER-site from the home page by clicking on it in the “Studies” section at the top of the Home screen, or by locating it from the list in the “My Studies” section at the bottom of the Home screen.

On the MASTER-site, the top “Study” section displays study information such as the Sponsor and CRO, the Protocol Number, the Protocol Title, and more. The “Study-Site” section below that displays the study approval status, the study’s current Approval Date, the study’s Expiration Date, and more.

Study-Sites

A study-site is a research site location approved for a specific study. This is where Principal Investigators, Sub-Investigators, and/or Site Contacts will submit site-level xForms, and where Sterling IRB will issue and store site-level approvals and acknowledgements.

A study-site is only viewable by the associated Investigators and Site Contacts and the study’s Sponsor/CRO Contacts. They can access the study-sites from their Home screen by clicking on it in the “Studies” section at the top of the Home screen, or by locating it from the list in the “My Studies” section at the bottom of the home screen.

On the study-site, the top “Study” section displays study-level information such as the Sponsor and CRO, the Protocol Number, the Protocol Title, and more. The “Study-Site” section below displays the study-site’s Status, current Approval Date, Expiration Date, and more.

Events

An Event is the submission, review, and approval process of items submitted to Sterling IRB.

On the MASTER-site or study-site, scroll to the bottom of the page and see the “Events” section. The MASTER-site contains study-level Events submitted by the Sponsor or CRO. Each study-site contains site-level Events associated with that specific study-site. Clicking on an Event’s name displays Event-specific information and the steps for Event completion.
STERLING xFORMS

Submitting xForms

An xForm is an electronic smart form. Each Sterling IRB form is available for electronic submission within SilverLink.

From the Home screen, click “Start xForm” under “Actions” on the left side of the screen to submit a new project submission application (New Study, HUD, Exemption/NHSR), request access to an existing study or site (SilverLink Access Request), or authorize/waive IRB jurisdiction (IRB Jurisdiction Form).

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 and closeout (Study Status 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). Clicking “Add” will send an email to each new Collaborator. These new Collaborators will receive an invitation via email, along with a direct link to the xForm.
LOCATING ISSUED DOCUMENTS

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 Reference Documents”. Click on the name to open/download each approved document for this study.
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.

<table>
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<th>Event</th>
<th>Att</th>
<th>FE</th>
<th>Instance/UDF</th>
<th>Start</th>
<th>Complete</th>
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<tr>
<td>Reportable Events</td>
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<tr>
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<td>09/01/2017</td>
<td>09/13/2017</td>
</tr>
</tbody>
</table>

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

- Approval documents and acknowledgements issued by Sterling IRB are found in the “Generated Docs” section of their corresponding Event.

- Other attachments (documents attached to the submission form, copies of IRB-approved consent forms, copies of IRB-approved site-specific ads/recruitment materials, etc.) can be found in the “Attachments” section of the corresponding Event.

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.