SilverLink Quick Start Guide

What is SilverLink?

SilverLink is Sterling IRB's secure web-based solution allowing full electronic submission and management of your studies. It can be used by Sponsors, CROs, and Investigative sites for all submissions 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 way to download Sterling IRB-issued documents, such as approvals and acknowledgements.

Logging In: https://sterlingirb.my.irbmanager.com

1. Create an account by clicking the link: [**Click here to register.**] on the lower left of the page.
2. Set or reset your Password by clicking the link: [**Forgot password?**] on the lower right.
3. **Your User Name is your email address**.

Commonly Used Terms:

- An **Event** is the term for the submission, review, and approval process of any submission to Sterling IRB (e.g.: New Study, Safety, Modifications and Amendments, Continuing Review, and more). Each Event contains the submitted forms, attachments, and approval documents for the submission. The Event also tracks the completion dates for various steps in the submission and review process.
- An **xForm** is the term used for the electronic "smart" versions of Sterling IRB's standard paper submission forms.
- A **study-site** is the term for a PI and research location approved for a specific study, and is viewable to the associated site-specific contacts (PI, Sub-Investigators, other research site staff). The Sponsor/CRO and other study-level contacts can view all study-sites for a study.
- A **Master-site** is a special study-site for study-wide submissions which is viewable only to the Sponsor/CRO and other study-level contact persons.

Notices on the Dashboard/Home Screen:

On the right side of your screen, in the "Notices" section, there are several helpful links. Clicking these links will automatically take you to our website where there are documents are available for download.

- The following links are available on our Introduction to SilverLink web page:
  - o SilverLink Quick Start Guide
  - o SilverLink User Manual
  - o SilverLink Frequently Asked Questions (FAQ)
  - o Links to watch helpful videos about SilverLink

Submitting xForms:

- To **submit a new protocol/study** or to **request access**, from the **Dashboard/Home screen**, click "**Start xForm**" in the "Actions" column on the left side of the screen and select the xForm you wish to complete.

- For **study-wide submissions** from the Sponsor/CRO for an ongoing study: Navigate to the study's **Master-site** page, click "**Start xForm**" in the "Actions" column on the left side of the screen and select the xForm you wish to complete (e.g. IND Safety Reports, Reportable Events, Modifications and Amendments, Waiver Applications).

- For **site-specific submissions** from the PI/Site for an ongoing study: Navigate to the **PI/Site's study-site** page for the study, click "**Start xForm**" in the "Actions" column on the left side of the screen and select the xForm you wish to complete (e.g. PI/Site Submission Application, Reportable Events, Modifications and Amendments, Waiver Applications, and Study Status Report for site closure).

- For **Continuing Review**, 60 days before the Expiration Date, study and site contacts will receive an email notification with a link to a new Continuing Review Event on your study/site page. You can also navigate to your study/site page, locate the most recent Continuing Review Event in the "Events" section. Navigate to this **new Continuing Review Event**, click "**Start xForm**" in the "Actions" column on the left side of the screen and select the "**Study Status Report**" xForm from inside the Event.

Locating IRB-Issued Documents:

- On your study's Master-site or a PI/Site's study-site page, scroll down to see the "Events" section. Events are ordered by date, with the oldest at the bottom and most recent at the top. Next to any Event, **click on the number in the "Att"** (or Attachments) **column**. This will open the Attachments page for that Event.
  - o Click on the "**Generated Docs**" folder to see any Sterling-issued determination documents and/or acknowledgements.
  - o Any Sterling-issued attachments for any approval or acknowledgment documents will be found in the "**Attachments**" folder.
  - o Clicking on the name of a document will download it to your computer as your web browser's preferences are set.

Locating Documents Migrated from the Legacy System:

- Active/ongoing studies will be migrated into SilverLink 4.0 from our previous system. On your study's Master-site or a PI/Site's study-site page, scroll down to see the "Events" section. For studies migrated into SilverLink 4.0, the **first Event at the bottom of the Events section** will be called "**Historical Documents**" and will house all previously submitted and issued documents in the "Attachments" page of this Event.
  - o (*for study-level documents*) Navigate to the **Master-site page for the study** and locate the "**Historical Documents**" Event.
  - o (*for site-specific documents*) Navigate to the **PI's study-site page for the study** and locate the "**Historical Documents**" Event.
  - o Click on the number in the "**Att**" (or Attachments) column of "Historical Documents" Event. This will open the Attachments page of the Event.

Clicking on the name of any document in the Event's Attachments page will download it to your computer as your web browser's preferences are set.