SilverLink – Frequently Asked Questions

SterlingIRB
SAFEGUARDING YOUR RESEARCH

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 acknowledgments.

Is SilverLink secure?
SilverLink is secure and allows you to keep all study information confidential. SilverLink is 21 CFR 11 compliant.

What hours will SilverLink be operational?
SilverLink is operational 24 hours a day, 7 days a week.

How do I reach the SilverLink Helpdesk?
The hours of operations are 9:00 am – 5:30 pm ET, Monday – Friday. You may call Sterling IRB at **888-636-1062** and request to speak with the SilverLink helpdesk. The email address for the help desk is **support@sterlingirb.com**.
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How do I sign up?
Signing up is easy! Navigate to the SilverLink login page and complete our SilverLink Registration Form by clicking [Click here to register.] in the lower left-hand corner of the page. Once your account has been created, you will receive an automated email with login instructions and a link to create your password. You can also e-mail us directly at **support@sterlingirb.com**; please include your name, email address, and which studies (if any) you need access to. Your request will be reviewed by a Sterling IRB staff member who will set up your account and grant you access to the studies you requested.

Please note: Each person that is registered must have a separate unique email address.

How do I reset my password?
My account is locked out. What do I do?
If you enter your password incorrectly 3 times, your account will be locked. You may unlock your own account and reset your password at any time by clicking [Forgot password?] on SilverLink's login page.

Will training be provided?
SilverLink is easy to use. There are short videos and user guides available on our website, and we will be glad to setup a Zoom training as needed. This short form can be used to submit the training request.

What is a Master-site or Study-Site?
A study-site is a PI and research location approved for a specific study and is viewable to the associated site-specific contact persons (PI, Sub-Investigators, other research site staff). 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. The Sponsor/CRO and other study-level contacts can view all study-sites for a study.

What is an Event?
An Event is what we call the submission, review, and approval process of any submission 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. An Event is created once a submission is accepted into SilverLink.

What will show on my Dashboard/Home screen?
Information about your studies and submissions will show on your Dashboard: the status of your studies, your xForms, and your ongoing Events. Your active studies will display on the bottom of the screen. The left column on the Dashboard shows actions available, recently viewed items, and Messages and Useful Links from Sterling IRB. Return to your Dashboard from any page in SilverLink by clicking the "Home" button in the blue bar at the top of the screen.

What is an xForm?
"xForm" is the term used for the electronic "smart" versions of our standard paper submission forms. The "xForms" section of your Dashboard will contain links to any xForms you have started but have not yet submitted to Sterling IRB and any submitted xForms which are being processed by Sterling IRB. You can check on the status of your xForms by clicking the links on your Dashboard.

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What are Investigator profiles?
Each Investigator in SilverLink will have a profile where Sterling IRB can retain copies of CVs, Medical Licenses, Agency Letters, and other documents which are frequently submitted to the IRB. This will ensure submissions will require fewer attachments. Automated notifications will remind you if Sterling needs an updated CV or Medical License.

How do I add/remove Contacts?
You may request access to be granted or removed, for yourself or others, by completing the SilverLink Access Request Form. After logging into SilverLink, access this form by clicking [Start xForm] on the upper left-hand side of the page and selecting from the list of available xForms. Please limit each Access Request Form to a single protocol/study. If you need assistance, contact Sterling IRB by phone at **1-888-636-1062** or by email at **support@sterlingirb.com**.

How do I submit documents?
Document submissions should be attached to appropriate xForms. From your Dashboard, you can start xForms for new study submissions. From your study-site page, you can start xForms such as PI/site applications, safety reports, modifications/amendments, and waiver applications. Continuing Review and Reinstatement xForms are started from within special Events on your study-site page. If you need assistance, contact Sterling IRB by phone at **1-888-636-1062** or by email at **support@sterlingirb.com**.

How do I download documents from Sterling IRB?
Sterling IRB has two detailed User Manuals with instructions on downloading documents within SilverLink. We provide links to these documents within the *Useful Links* section of the Navigation Pane within Silverlink.

Where can I find my site's most recent ICF?
ICFs can be found after navigating to the study-site page, in the Events Section. Within the Events section, a revised/new ICF will be under a "Modifications & Amendments" event. If a site's ICF has not been modified since initially submitted and approved, the ICF will be located within the "New Study or PI/Site Submission." You will find the ICF and other approval documents by clicking on the NUMBER under the column labeled "Att" for attachments.

How do I submit Continuing Review?
Your site will receive an email reminder within 60 days of pending expiration. Within that email there is a link provided that will take you directly to the Study Status Report form.

How do I close a study site?
To close a study-site, you must submit a Final Report form. This can be found after navigating to the specific site you wish to closeout, on the left side under Actions → Start xForm.

When do I receive SilverLink notifications?
You will receive an automated email from Sterling IRB when any of the following occur:

- When you request a password reset
- When you have been granted access to a new study-site
- When you submit an xForm to Sterling IRB
- When new documents from Sterling IRB are made available
- Other actions, such as Continuing Review reminders or when your response is requested regarding a submission

How can I access documents for a Closed Study?
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.