

SilverLink Frequently Asked Questions

1. What is SilverLink?

SilverLink is Sterling IRB's secure web portal. It can be used by Sponsors, CROs and Investigative Sites to submit all 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 from Sterling IRB like approval letters and acknowledgements. SilverLink is compliant with 21 CFR Part 11 federal regulations.

2. How do I sign up?

It is easy to sign up! You may e-mail us directly at portal-access@sterlingirb.com, or you may visit www.sterlingirb.com and complete our SilverLink Registration Form by clicking [REGISTER] in the upper right-hand corner of the page (above SILVERLINK LOGIN). Please include your name, email address, and which studies (if any) you need access to. Your request will be reviewed by Sterling staff, who will set up your account and grant you access to the studies you requested. Once your account has been created, you will receive an automated email with login instructions, including a link to create your password.

3. How do I add/remove users?

Multiple users may be added to each study and investigative site. Email portal-access@sterlingirb.com to add people to a study. Please include the new user's email address, the study's protocol number and/or Sterling IRB ID number and the Principal Investigator's name, if applicable.

If individuals are reassigned so that they no longer need access to some or all studies or leave your company and should no longer have access to the system, please email us at portal-access@sterlingirb.com to have their access removed.

4. How do I reset my password?

If you are a Sponsor/CRO user, click [here](#), or if you are a PI/Site Contact user, click [here](#). Otherwise, you may reset your own password by clicking the "[Forgot your password?](#)" link on SilverLink's login page.

5. How do I submit documents?

After logging in, click the large Submit Documents button. Then, select the study/PI/site (varies depending on user type) from the drop-down menu(s), upload the document(s) you wish to submit, and enter additional comments, if needed. Then click the Submit Documents and Finalize Submission button in the bottom-right corner of the page.

6. How do I download documents from Sterling IRB?

After logging in, click the large View Documents button. Then, select the study/PI/site (varies depending on user type) from the drop-down menu(s). Click the filename of any document to open or download it. If you need to download multiple documents at once, select each document you wish to download and click "Download selected docs as zip file" in the bottom-right corner of the page.

7. Are smartforms available with electronic signature?

Yes! A smartform is form-filler software to help you complete forms electronically, not manually. It is designed to be an easy-to-use, accurate representation of the equivalent paper form. Currently Sterling IRB offers our Site Continuing Review Status Report, which must be signed by the Principal Investigator. If you prefer not to use smartform, you are still able to upload the completed status report.

IMPORTANT: A PI user may not share their login credentials, per the SilverLink Electronic User Signature Agreement and 21 CFR Part 11 federal regulations.

8. When do I receive SilverLink notifications?

You will receive an automated email from Sterling IRB when any of the following occur:

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

9. Are SilverLink Demos Available?

Scheduled demo sessions are offered to all SilverLink users. Please contact us at portal-help@sterlingirb.com to request a demonstration.