BENAROYA RESEARCH INSTITUTE
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Use of Adobe Sign for Electronic Signature

This document provides steps to use Adobe Sign to capture an electronic signature while satisfying regulatory and institutional requirements.

Use of Adobe Sign:

BRI has an electronic signature software account through Adobe Sign. This online software can be used for any document you wish to obtain an electronic signature (e.g. consent from, contract, agreements, etc.). Since BRI has only 10 user accounts, you will need to seek out your department "primary user" to send out documents in the appropriate manner. Contact RPD staff for questions of who contact. The steps below are for primary users with Adobe Sign access.

NOTE: The study must be IRB-approved for the use of eIC prior to using Adobe Sign for an electronic signature.

- Adobe Sign: https://secure.echosign.com/public/login
- Video Tutorials: https://helpx.adobe.com/sign/tutorials.html

1. Familiarize yourself with the Adobe Sign software by watching the video tutorials on their website, and/or completing a training session with a member of the Research Protections Department.
2. Login into Adobe Sign, and create a new email by clicking "Send" or selecting a document from your library.
3. Add recipient's email address.
4. For consent forms being sent to subjects, select "Password" in the authentication menu. Include a private message to inform the recipient what their password is (e.g. "Your password is the last four digits of your SSN or date of birth"). This verification question should be agreed upon with the person consenting the subject.
5. If multiple signatures are required, enter them in the order in which their signatures should occur. (If a consent form is being sent, a password and private message must be entered for each recipient)
6. If any additional individuals need access to the signed eIC, but do not need to sign the document (e.g. unit manager), click "Show CC" and add their email address(es).
7. To password protect a signed eIC, select "Password Protect" under the "Options" section, and create a password.
8. Add files and update the email message as needed, then click "Next."
9. Add signature, name, date, etc. fields to the document(s) for each recipient, then click "Send."
10. Store signed eIC documents in a secure location, such as Box. BRI Compliance group will assist you on the appropriate process for tracking and retaining consents signed electronically by subjects

Adobe Sign info to assist signees of a document:

1. Signees should Click here to view a video tutorial on how to electronically sign a document.
2. They will receive an email from Adobe Sign with a link to their document and/or consent.
3. If signing a consent form:
    a. The email should include a description of the password needed to access the consent. The researcher will need to speak with the subject over the phone to provide this information.
    b. Once the signee has entered the password to open the consent document, the researcher should go over the consent on the phone and ask if there are any questions about the study before enrolling.
    c. If they decide to join the study, ask them to click the yellow start button. Direct them to the locations in the document that require to input or signature.
4. Once they have signed everywhere , click submit.
5. Tell the signee they will receive an email with their signed document so they can access the document anytime.

FAQs

What is eIC?
Electronic Informed Consent (eIC) refers to the use of any electronic system or process used to provide information about a study to assist in the informed consent process conducted by the study staff, and to document consent/assent of the research subject and/or their Legally Authorized Representative (LAR).

What is Adobe Sign?
BRI uses an enterprise-class e-signature service called Adobe Sign that lets you replace paper and ink signature processes with fully automated electronic signature workflows. You can easily send, sign, track, and manage signature processes using a browser or mobile device.

What issues does Adobe Sign solve?
Adobe Sign helps BRI transform the paper signing process, making 100% digital workflows available for certain purposes with trusted and legal e-signatures. With Adobe Sign:

- **Get signatures in minutes, not days** – easily request signatures from others, sign consents/documents, and track and manage the entire process electronically.
- **Work anywhere, on any device** – Signers click a link to sign documents from any location, at any time of day, using a browser or mobile device. No account sign-ups or downloads are required.

How do I work with Adobe Sign?
Because Adobe Sign is a cloud-based service, there are many ways to work with it. Adobe Sign lets you work in a web browser or mobile app to send, sign, track, and manage signature processes. Adobe Sign can also be used inside other applications. BRI has signed an agreement with Adobe Sign that allows us 10 primary users that may send up to 3000 documents (transactions) out for signature annually. You can go here and get a quick demo:
https://www.adobesigndemo.com/demo/

What security and legal regulations does Adobe Sign comply with?
Adobe Sign meets or exceeds stringent security and legal compliance standards. Adobe Sign is certified compliant with ISO 27001, SSAE SOC 2 Type 2, and PCI DSS. Additionally, Adobe Sign can be configured or used in a manner to allow organizations to meet industry-specific compliance requirements such as HIPAA, FERPA, GLBA, and FDA 21 CFR Part 11. BRI is responsible to work with Adobe Sign to make sure our system is configured in a manner that allow us to comply with our specific legal obligations.

Who at BRI has access to use this software?
Each research department should have the ability to assign a "Primary user". This will allow all staff in those particular departments the ability to send out documents on behalf of other staff. Contact your Unit Manager in this regard.

Where can I find additional information and regulatory guidance on electronic consenting?
Adobe assurance of 21 CFR Part 11 compliance: https://helpx.adobe.com/content/dam/help/en/sign/kb/Is-Adobe-Sign-21-CFR-Part-11-Compliant/_jcr_content/main-pars/download_section/download-1/21_cfr_part_11.pdf
Use of Electronic Informed Consent: Questions and Answers: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/index.html
Part 11, Electronic Records; Electronic Signatures — Scope and Application
https://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm
Use of Electronic Informed Consent Questions and Answers
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM436811.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery