

JCHR eConsent Information Guide

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HEADER INFORMATION

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- **Version:** 1.0
- **Author:** Jeannie Perkins
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VERSION HISTORY

Version	Author	Approver	Effective Date	Revision Description
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1.0	Tiffany Campos; Sarah Frey; Zachary Duff	Jeannie Perkins	10 Apr 2026	Integrated the eConsent Application overview into this document to summarize for external audiences; included a link for the JCHR Electronic Consent Process Overview demo.
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OVERVIEW

The intent of this document is to provide written assurance that JCHR’s proprietary electronic consenting application (JCHR CRF System “eConsent App”) being used to capture legally effective informed consent as required under 45 CFR 46 and 21 CFR 50, including a valid electronic signature (“eSignature”), meets all of the applicable legal and technical requirements therein, including those specified in 21 CFR 11.

SCOPE

As this is an externally facing document to summarize JCHR's eConsent App for external audiences, JCHR staff are not required to review and sign off on this guide.

DETAILS

Compliance Statements

JCHR assures that the eConsent App includes the following:

- The consent form will be provided electronically and the participant can save, print or request paper copies from the study office at any time at no cost (specified in the forms)
- The software requirements to access/read it the form(s) (as shown on the login screen for eConsent), which states “All reports on this site require Adobe Acrobat Reader. Click [HERE](#) to download a free copy of Adobe.” in accordance with the federal Electronic Signatures in Global and National Commerce (E-Sign) Act as applicable.
- Participants may elect to withdraw their consent by simply notifying the study doctor or staff (as specified in the form).

JCHR acknowledges it is responsible for ensuring compliance with all applicable rules, laws and regulations pertaining to eConsent and eSignatures. The JCHR eConsent App follows the requirements of the Health Insurance Portability and Accountability Act (“HIPAA Privacy Rule”) and international data protection regulations such as the General Data Protection Regulation (“GDPR”) as well as current best practices for ensuring technical security including, but not limited to

- having a disaster recovery plan,
- maintaining validation logs,
- daily data back-up or mirrored database,
- encrypted servers,
- regular security updates, and
- user authentication.

JCHR policies and procedures and other supporting documentation of these measures shall be provided upon request.

JCHR also has in place research agreements/contracts and written study instructions that apply to study institutions, study investigators, and their staff that define the obligations and responsibilities of each party, outlines the requirements about how the confidentiality and security of the data stored in the system will be maintained, and addresses notification and liability in the event of a data breach.

Compliance Contacts

For questions or concerns regarding compliance, please contact:

Chief Research Compliance Officer	Jeannie M Perkins, MS, CCRP, CIP, RQAP-GCP	DPO@jaeb.org
JCHR Director of the HRPP	Zachary Duff, JM, MS, CCRP, CIP	HRPP@jaeb.org

Who can use the App?

Certain JCHR study staff, trained and qualified Site personnel, potential/actual participants or their Legally Authorized Representatives (“LARs” – generally a parent) can access the eConsent App. The eConsent App may be used in conjunction with written consent-related documents, as needed (see the “Are there any limitations to the App” section below for considerations).

How does the App work?

The following sections summarize the steps of the eConsent App. Please consider reviewing the ***JCHR Electronic Informed Consent Process Overview*** demo found on the JCHR Internet page at [jaeb.org/HRPP](https://www.jaeb.org/HRPP) as well.

Study Preparation

The JCHR IRB has provided study teams with eConsent and eAttestation templates to support the effective documentation of the eConsent process (the Attestation is the language that explains what the eSignature means in the context of the document such as “By eSigning below you are saying that you have read the form, had your questions addressed, agree to be in the study at this time, etc.”). JCHR study teams use these templates to complete as required for their specific studies. These customized templates are then submitted to the IRB of Record for review. If/when approved by the IRB of Record, the sites are provided with the approved materials to customize further to meet their institutional and local requirements while the sites are going through the study certification process (study onboarding, which includes site personnel creating their username and password and training on the eConsent process). The site customizations are then provided back to the IRB of Record for review. If/when approved, one study team member uploads each site’s consent materials as a PDF. A

second study team member then reviews and verifies that the uploaded material is complete and correct. Once a site is certified, the App is made available to the applicable site personnel to be consenting.

Participant Registration

The consenting Investigator (or designee if permitted by the IRB of Record) creates a single use Registration link via the eConsent App. The Registration link is then emailed to participant or Legally Authorized Representative (LAR) along with a PDF of the current IRB-approved consent form template for their review. The participant/LAR completes the Registration Form and:

- Confirms their relationship to the study participant (if LAR)
- Reviews the study information
- Submits registration

Link Creation & Distribution

Once the Registration is completed, the Investigator (or designee) verifies registration data. If the data is correct, then the Investigator (or designee) creates a Consent Action Link and specifies who will be obtaining consent from a dropdown list of individuals at the site that have been approved to obtain consent. The Consent Action Link is a unique hyperlink specific to this participant. The participant's unique user ID is automatically assigned when this Link is created. The consenting Investigator (or designee) schedules a contact to review the consent-related materials with the participant and/or LAR. The Consent Action Link should not be emailed to the participant or LAR until the consent contact occurs.

Identify Verification, Authentication & eSignature Attestation

During the scheduled contact, the consenting Investigator (or designee) confirms that the participant or LAR can access the Consent Action Link. They also provide the participant or LAR with their unique user ID. The participant or LAR will create their own unique password upon accessing the Consent Action Link. Consent-related materials are displayed electronically, discussed, and study-related questions or concerns are addressed. If the participant and/or LAR wish to proceed, they must review the full consent materials and then enter the password they created to provide eConsent signature (or Attestation as used herein).

Note: Optional study-specific questions may be included as approved by the IRB of Record (e.g., optional procedures, notification to primary care provider, etc.).

Confirmation & Document Access

The participant or LAR receives confirmation of successful consent. They can then download the eSigned Consent documents and HIPAA Authorization as applicable. The printouts include their eSignatures (Attestations) with date/time stamp(s).

Investigator eSignature Attestation

The consenting Investigator (or designee) then completes Investigator Attestation and:

- Confirms protocol adherence
- eSigns using their unique User ID and Password (Investigator Attestation)
- Prints the eSigned consent-related materials and Attestations to file in the participant charts at the site.

The consenting Investigator (or designee) is also instructed to complete a consent process note that described and verifies that the eConsent process has been completed as required.

JCHR Monitoring

In addition to the monitoring to ensure that the complete and correct consent materials have been uploaded for use by the applicable sites, the JCHR study monitors also require site personnel to upload eConsent process notes and any other consent-related materials that may have been completed on paper (see the “Are there any limitations to the App” section below for examples) for remote monitoring of uploaded materials.

JCHR Internal Audit

During routine internal audits conducted by the JCHR Quality Assurance team, the auditors review not only the eConsent App but also the IRB approvals and the actual PDFs of the eConsent materials, eSignatures (Attestations), monitoring records, and site consent process notes via JCHR’s secure file sharing.

Reconsent

In the event that reconsent is required due to new information or a participant turning of age, the process above will be repeated (except that participants or LARs do not need to register again for reconsent due to new information).

Are there any limitations to the App?

There are some limitations of the eConsent application as follows.

- Consent is available only for adult participants or one LAR of one participant. This means that this App cannot be used to capture:
 - More than one parental/LAR eSignature for consent on behalf of a participant as may be required by the IRB or institution
 - If study involves child participants, and multiple children in the same family trying to enroll, then they cannot under the same LAR (one parent can eConsent for one child, but then the

other parent must eConsent for the other child with a different registration, User ID and Password)

- A participant's eSignature to document assent as may be required by an IRB or institution (the app only permits the LAR to attest that verbal assent was provided by the participant, referred to as Assent Attestation, as noted below)
- Assent Attestation may be permitted by the IRB or institution whereby the LAR is permitted to attest with documentation that the assent process requirements were met, however, the App cannot be used if:
 - More than one parent/LAR is required to provide that Assent Attestation (e.g., greater than minimal risk but no prospect of direct benefit)
 - Re-Assent Attestations might be required (i.e., the App allows re-consent for new information on a new version of a consent form, but does not allow re-Assent Attestation if the IRB or institution requires that the participant provide re-Assent verbally)
- Custom Attestations are permitted by study, but not by site. If the IRB or institution requires that the site utilize unique attestation language, then that attestation would have to be collected on paper.
- Custom HIPAA Authorizations are permitted either within the body of the consent form PDF that is uploaded to the App, or as a separate PDF if required, however, if the HIPAA Authorization has fillable fields within, then this will have to be collected on paper.

Does JCHR share any information collected in the App?

Only certain trained and qualified JCHR staff that have a justifiable reason to have access to the data in the App are permitted to have access (i.e., to monitor the App and eConsent). Other JCHR staff (e.g., audit, IRB) and certain external entities (e.g., FDA) may request copies of records on a need-to-know basis and only for justifiable reasons in accordance with the law, which are provided via JCHR's secure file sharing. Reports can also be provided from the app to verify information such as audit trails.

A site can access the completed eConsent documents by navigating to the participant's data entry menu page and selecting Participant Information at any time. This page will allow sites to view and/or print a PDF of the participant's completed eConsent documents with eSigned attestation pages attached.

Otherwise, no other access or sharing is permitted other than as described in the consent form and HIPAA Authorization.

What data security measures are in place?

JCHR implements administrative, technical, and physical safeguards to protect personal data and protected health information, including encryption, access controls, audit logging, daily backups, mirrored databases, validation logs, disaster recovery, and secure storage as described in JCHR processes and procedures, in accordance with the explicit informed consent, and as specified in legal contracts.

Does JCHR retain data from the App?

JCHR does retain personal data and/or protected health information only as long as necessary to fulfill the purposes described in the explicit informed consent and legal contracts as required by law, such as:

- HIPAA (generally 6 years from creation or last effective date)
- GDPR (storage limitation principle; retained only as long as necessary for the purposes for which it was collected)
- Under 21 CFR 312 and 812, JCHR is required to retain the records and reports as required in the regulations for the following time periods:
 - If a marketing application is approved: Records must be retained for two (2) years after approval of the drug or device application.
 - If a marketing application is not submitted or not approved: Records must be retained until two (2) years after shipment and delivery of the investigational product is discontinued and the FDA has been notified.
 - If no marketing application is ever submitted: Records must still be retained for two (2) years after the investigational use of the product has been terminated and the FDA has been notified.

JCHR applies the longer of the applicable retention periods when determining the required timeframe for maintaining records associated with a particular study.

Sites are instructed to print PDF the completed informed consent materials for the site's records for maintenance throughout the record retention period. JCHR maintains the audit trails and data tables that support the eConsent processes in the App throughout the record retention period as well.

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