The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Use of Mentor IRB for Electronic Records and Electronic Signatures

1.0 PURPOSE

1.1 Federal regulations require adequate documentation of the preparation and maintenance of all IRB activities. The IRB is responsible for maintaining regulatory documents in accordance with applicable federal regulations, International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines, Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements, and departmental procedures.

1.2 Regulatory documents for research studies must be readily accessible at all times for review and/or inspection by the regulatory agency (e.g., US Food and Drug Administration (FDA)), the Institutional Review Board (IRB) of record, study sponsor and/or sponsor's representative, and/or institutional personnel as appropriate.

1.3 This Standard Operating Procedure (SOP) describes the identification and storage of IRB regulatory documents for clinical research studies and trials in The Christ Hospital IRB's electronic record management system, Mentor IRB; outlines how the IRB office staff/Mentor administrator(s) control user access; describes how electronic documents are managed and how electronic signatures are applied to documents.

2.0 SCOPE

This SOP applies to the following:

2.1 All electronic IRB records for research studies and trials where Mentor IRB is utilized by The Christ Hospital Health Network. Documents with more than one purpose or that are applicable to more than one study may be stored centrally, in a non-study specific location.

2.2 IRB members, IRB office staff, and Key Research Personnel who utilize Mentor IRB for the submission, review, maintenance, and/or storage of documents related to studies, and from the time of initial submission through study closure, effective for studies starting on or after May 1, 2022.

2.3 Legacy studies, defined as studies that were activated prior to the use of Mentor IRB. Legacy original paper documents or electronic documents will be maintained according to SOP 1.03 IRB Records.

3.0 RESPONSIBILITIES

The IRB office staff will serve as Mentor Administrators whose responsibilities include:

3.1 Maintaining study documents in a timely and organized fashion;
3.2 Ensuring that the appropriate Users, including external monitors and auditors, have the necessary access and permissions to the Mentor IRB system;
3.3 The capability to access all records in the system; and
3.4 Ensuring that all Private Health Information (PHI) will be redacted on any materials housed within the system.

4.0 PROCEDURE

4.1 Account Creation and Access Control

Mentor Administrator(s) will create, modify, and terminate User accounts, assign roles, manage access dates, and conduct periodic reviews to verify the status of all Users.

4.1.1 User Account Creation

4.1.1.1 All New User requests must be vetted by the Mentor Administrator(s) prior to obtaining access to the Mentor IRB system.
4.1.1.2 Prospective Users, study principal investigators or designated research coordinators must submit a request for account creation for prospective new Users with the Mentor Administrator(s). The "Mentor IRB New User Request Form" may be utilized for this purpose.
4.1.1.3 CITI training, CV/resume, and medical license (if applicable) must be provided and linked with the New User account for credentialing.
4.1.1.4 Mentor Administrator(s) will initiate the New User's account to create access to the system.
4.1.1.5 Users with a The Christ Hospital Health Network (TCHHN) account will be registered using the User's unique authorized organization email address, will utilize Single Sign On (SSO) for authentication, and will comply with TCHHN password requirements.
4.1.1.6 External Users without a TCHHN account will be registered utilizing their external organizational email address and are required to maintain a unique, secure, and private password.
4.1.1.7 All Users will have an appropriate role and access dates assigned and will be granted permissions for system access.

4.1.2 Account Access Control

4.1.2.1 The Mentor Administrator(s) must conduct periodic reviews to ensure that all Users have the correct permissions and are still active.

4.1.2.2 Study principal investigators and/or designated research coordinators must conduct periodic reviews of key research personnel for their research protocols to ensure that all Users are still active Users.

4.1.2.3 The study principal investigator, or designated research coordinator(s) should notify a Mentor Administrator of any change of employment status of any Mentor User including any leave of absence or termination of employment.

4.2 User Account Modification/Deactivation

4.2.1 Temporarily inactive Users can have access dates turned off and roles maintained without access. Temporarily inactive Users includes (for example) Users on a leave of absence with plans to return.

4.2.2 Upon a change in employment status for a User who discontinues the need for specific protocol access and/or Mentor IRB use, Mentor Administrator(s) remove all permissions for the User. An automatic notification is sent to the study team(s) with which this deactivated user is affiliated.

4.3 Electronic Document Management

4.3.1 Requirements for documentation, record keeping, and record retention apply to electronic records as for paper systems.

4.3.2 Regulatory study documents will be managed, stored, and presented electronically. Sponsors and auditors should be notified of this policy prior to study initiation and before any audits or inspections.

4.3.3 User access control to electronic documents is described in the Account Creation and Access Control section above.

4.3.4 Electronic security controls, secure backup schedule, and routine vulnerability testing in the Mentor IRB system are performed through Amazon Web Services (AWS).

4.3.5 Retention and/or destruction of electronic documents in Mentor IRB at the conclusion of the study is performed in accordance with local institution/IRB/Independent Ethics Committee (IEC) policies and procedures as established in U.S. Federal regulations.

4.4 Electronic Certified Copies

4.4.1 Electronic documents may include a blend of original and certified copies. Electronic certified copies are defined as copies that have been created and verified against the original and tracked with a dated signature. Electronic signatures with an audit trail demonstrate evidence of authenticity. Per IRB Standard Operating Procedures, the data shall include the context, content, and structure, as the original. For studies regulated by the US FDA, the copy is to have all the same attributes and information as the original.

4.4.2 Only the User who possesses the original copy may create the Electronic Certified Copy.

4.4.3 The User who possesses the original copy of the document will upload an electronic copy of the document into Mentor IRB, review and verify the

uploaded document for completeness and readability and then sign the document as a Certified Copy.

4.4.4 The audit trail will track and record the timestamp and uploading User for authenticity and responsibility.

4.5 Monitor, Auditor, and Inspector Access

4.5.1 Monitors, auditors, and inspectors will be given access to Mentor IRB by following the guidelines described in the Account Creation and Access Control section above.

4.5.2 All access is monitored via the audit trail.

4.6 Document Version Control

4.6.1 Version tracking within Mentor IRB can be utilized for version tracking of approved documents such as IRB-approved informed consents, protocol versions, etc.

4.6.2 Version tracking maintains each version of the document and the audit trail logs, the action of modification by authorized Users, date of modification, as well as the time stamp of modification to verify compliance with GCP.

4.7 Electronic Signatures

4.7.1 This section applies to all documents and clinical research studies and trials where Mentor IRB is utilized by this organization and where electronic signatures and handwritten signatures executed to electronic documents are intended to be equivalent to paper records and handwritten signatures.

4.7.2 Users are responsible for reviewing their accounts for pending signature requests on a regular basis.

4.7.3 The Mentor Administrator(s) will verify the identity of each User per the Account Creation and Access Control section above. The IRB Office Staff/Mentor Administrator(s) is also responsible for ensuring that the appropriate individuals have the necessary User permissions and access to signature requests in Mentor IRB.

4.7.4 Each electronic signature request shall be unique, using the individual's organization email address as the unique identifier in Mentor IRB.

4.7.5 The time and date of each electronic signature is visible on the document itself and recorded in Mentor IRB.

4.8 Signature Requests

4.8.1 Signature requests can be made by individuals with the appropriate permission and access to do so within Mentor IRB.

4.8.2 The electronic signature request must specify:

4.8.2.1 The User who needs to sign the document,

4.8.2.2 The document that requires the electronic signature (as applicable), and

4.8.2.3 The reason/meaning of the signature.

4.9 **Signing Documents**

4.9.1 Electronic signature requests are sent to the authorized organizational email address.

4.9.2 The email contains a unique direct link to access the document. The User may also log into the Mentor system using his/her Username (i.e., authorized organization email address) and password.

4.9.3 The individual signing the document reviews the document and the reason requested for the signature in Mentor IRB.

4.9.4 The signature addendum page and audit trail for the document are updated to reflect the new electronic signature, its reason/meaning, and the date and time of execution.

4.10 **IRB Review of Submissions and Conveyance of IRB Determinations**

4.10.1 IRB Office Staff reviews new submissions for completeness and assigns a Reviewer.

4.10.2 The Reviewer receives an email notification of the assignment of a new review.

4.10.3 The Reviewer logs onto Mentor IRB using his/her username (authorized organization email address) and password.

4.10.4 The IRB Reviewer completes the checklist following his/her review and makes a determination. Each review is time-stamped and recorded in Mentor IRB to reflect the new electronic signature, and the date and time of execution.

4.10.5 The IRB Office Staff generates and sends a notification conveying the determination (including the time and date of electronic signature) in Mentor IRB.

4.11 **Audit Trail**

All document views and activities are automatically recorded in the audit trail in Mentor. The audit trail is not alterable by Mentor Administrators.

4.12 **Record Retention**

IRB records are kept in accordance with SOP 1.03 – IRB Records.

5.0 REFERENCES

5.1 **IRB Standard Operating Procedure**

SOP 1.03 - IRB Records

5.2 **Codes of Federal Regulations**

5.2.1 U.S. Department of Health and Human Servies

45 CR 46.115 – IRB Records

5.2.2 U.S. Food and Drug Administration

5.2.2.1 FDA 21 CFR 56.115 – IRB Records

5.2.2.2 FDA 21 CFR Part 11 Subpart B Electronic Records

5.2.2.3 FDA 21 CFR Part 11 Subpart C Electronic Signatures

5.2.2.4 Part 11, Electronic Records; Electronic Signatures - Scope and Application; Guidance for Industry

5.2.2.5 Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 - Questions & Answers

5.2.2.6 FDA 21 CFR 312.62(c) - Investigational New Drugs; Drugs for Human Use; Investigator Recordkeeping and Record Retention

5.2.2.7 FDA 21 CFR 812 - Investigational Device Exemptions

5.2.2.8 FDA Compliance Program Manual

5.2.2.9 E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1), Guidance for Industry

5.2.2.10 General Principles of Software Validation; Final Guidance for Industry and FDA Staff

5.3 **The International Council for Harmonisation**

ICH GCP Essential Documents for the Conduct of a Clinical Trial