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 (i.e., US Food and Drug Administration (FDA)), the Institutional Review Board (IRB) of record, study sponsor and/or sponsor's representative, and/or organizational 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 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

2.1 This SOP applies to all electronic IRB records for research studies and trials where Mentor IRB is utilized by this organization. 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 This SOP applies to IRB Members, IRB Office Staff, Key Research Personnel who utilize Mentor IRB for the submission, review, maintenance, and/or storage of documents from the time of initial submission through study closure, effective for studies starting on or after May 1, 2022.

2.3 Legacy studies are 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.

2.4 The IRB Office Staff serve as Mentor Administrators.

3.0 RESPONSIBILITIES

3.1 Mentor Administrator(s) are responsible for maintaining study documents in a timely and organized fashion.

3.2 Mentor Administrator(s) are responsible for ensuring that the appropriate Users (including external monitors and auditors), have the necessary access and permissions to the Mentor IRB system.

3.3 Mentor Administrator(s) will have the capability to access all records in the system. All document views are automatically recorded in the audit trail, which is not alterable by Mentor Administrator(s).

3.4 Mentor Administrator(s) will ensure that all PHI will be redacted on any materials housed within the system.

4.0 PROCEDURE

4.1 Account Creation and Access Control

4.1.1 All new user requests must be vetted by the Mentor Administrator(s) prior to obtaining access into the Mentor IRB system.

4.1.2 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.

4.1.3 Users, the study principal investigator or designated research coordinators should notify a Mentor Administrator about any change of employment status, including any termination of employment or leave of absence.

4.1.4 Users with a TCHHN account will use Single Sign-On for authentication and will comply with TCHHN password requirements. All non-TCHHN users (External User) are required to maintain a unique, secure, and private password.

4.2 User Account Creation

4.2.1 Prospective Users, study principal investigator or designated research coordinator must submit a request with the Mentor Administrator(s).

4.2.2 CITI training, CV/resume and medical license, if applicable, must be provided and linked with the new user account.

4.2.3 Mentor Administrator(s) will initiate the new User's account to create access to the system.

4.2.4 Users with a TCHHN account will be registered using the User's unique authorized organization email address. External Users without a TCHHN account will be registered utilizing their external organizational email address. All Users will have an appropriate role and access dates assigned. This will grant the User the permissions for system access.

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

4.2.6 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.

4.3 User Account Modification/Deactivation

4.3.1 Temporarily inactive Users can have access dates turned off and roles maintained without access. Examples of temporarily inactive Users includes Users on a leave of absence with plans to return.

4.3.2 Upon a change in employment status for a User that 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.

4.4 Electronic Document Management

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

4.4.2 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.

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

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

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

4.5 Electronic Certified Copies

4.5.1 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 ICH E6(R2), the data is to 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.

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

4.5.3 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.

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

4.6 Monitor, Auditor, and Inspector Access

4.6.1 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.

4.6.2 All access is monitored via the audit trail.

4.7 Document Version Control

4.7.1 Version tracking within Mentor IRB can be utilized for version tracking of approved documents such as IRB approved Informed Consents, Protocol Versions, etc.

4.7.2 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.

4.8 Electronic Signatures

4.8.1 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.

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

4.8.3 Mentor Administrator(s) will verify the identity of each User per the Account Creation and Access Control section above. 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.

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

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

4.9 Signature Requests

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

4.9.2 The electronic signature request must specify the following:

4.9.2.1 User who needs to sign the document

4.9.2.2 Document that requires the electronic signature, as applicable.

4.9.2.3 Reason/meaning of the signature

4.10 Signing Documents

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

4.10.2 The email contains a unique direct link to access the document. The User may also log into the Mentor system using their Username (authorized organization email address) and password.

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

4.10.4 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.

4.11 IRB Review of Submissions and Conveyance of IRB Determinations

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

4.11.2 The Reviewer receives an email notification that they have been assigned a new review.

4.11.3 The Reviewer logs onto Mentor IRB with their username (authorized organization email address) and password.

4.11.4 The IRB Reviewer completes the checklist following their review and makes a determination. Each review is timestamped and recorded in Mentor IRB to reflect the new electronic signature, and the date and time of execution.

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

4.12 Record Retention

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

5.0 DOCUMENTS

Not Applicable

6.0 DEFINITIONS

None

7.0 REFERENCES

7.1 SOP 1.03 - IRB Records

7.2 DHHS 45 CFR 46.115 – IRB Records

7.3 FDA 21 CFR 56.115 – IRB Records

7.4 FDA 21 CFR Part 11 Electronic Records; Electronic Signatures

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

7.4.2 Part 11, Electronic Records; Electronic Signatures – Scope and Application

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

7.5 FDA 21 CFR 312.62(c) – Investigational New Drugs – Drugs for Human Use

7.6 FDA 21 CFR 812 – Investigational Device Exemption

7.7 FDA Industry Guidelines and Information Sheets

7.8 FDA Compliance Policy Guidance Programs

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

7.10 ICH GCP Essential Documents for the Conduct of a Clinical Trial

ADDENDUM

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1.0 PREVIOUS VERSIONS

Date Revised	Reason For Change	Revised By

2.0 APPROVALS

IRB Chair, Steve Roberts, MD	Date of Approval