Children's Hospital of Chicago Medical Center

Administrative Policy and Procedure Manual

I. Purpose

This policy outlines the process for granting regulatory authorities, sponsors and/or authorized representatives access to medical records or certified copies needed to examine, analyze and verify research data.

II. Definitions – as per International Conference on Harmonisation, Good Clinical Practice E6 (ICH GCP) 2016:

Source Data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

Source Documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, CT, MRI, ultrasound, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

Sponsor: An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial

Direct Access: Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsor's monitors and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor's proprietary information.

Certified Copy: A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original.

II. Policy Statements

In compliance with the ICH GCP (E6) and United States Food and Drug Administration (FDA) Guidelines, with appropriate Health Insurance Portability and Accountability Act (HIPAA) authorization, regulatory authorities, sponsors and/or their representatives will be given either direct access to medical records that serve as source data/documents or certified copies.

A. Direct Access:

a. EpicCare Link: Representatives (study monitors, auditors, regulators, etc.) of government agencies (for federally funded or regulated research) and non-government research sponsors, or their agents, will be given access to medical records via EpicCare Link, in order to examine, analyze, verify, and reproduce any records or reports that are important to the evaluation of a research study.
b. Epic Hyperspace: Exceptions to access via EpicCare Link may be granted on a case-by-case basis (i.e. if specific sections of the medical record are not available through the EpicCare Link tool which are needed for adequate monitoring) by joint approval of leadership from the Clinical Trials Office, Health Information Management (HIM), the Office of Sponsored Programs, and the Privacy Officer.

B. Certified Copies
Representatives (study monitors, auditors, regulators, etc.) of government agencies (for federally funded or regulated research) and non-government research sponsors, or their agents may be given access to certified true and accurate copies (paper or electronic) of medical records. Electronic records will be provided on a password protected, non-editable USB drive. HIM Certification letter (with records specified) will be provided upon request.

III. Procedures for Obtaining Direct Access to Medical Records

A. EpicCare Link
a. A Service Catalog request through the Help Desk should be submitted to the User Access team by the study team as far in advance as possible (i.e., 2 weeks), but a minimum of 10 days is required. Exceptions to this timeline may be made for unexpected regulatory audits. Instructions for this process are outlined in the applicable Tip Sheet on the Research Learning Home Dashboard. Access may be granted for up to one year, then an amended access Service Catalog request must be submitted to extend access if needed.
b. The User Access team will import the user account into Symantec, and trigger an activation email to be sent to the monitor & copy the requestor.
c. The study team is responsible for releasing the patient records to the specific study for the monitor, the release is active for up to 14 days.

B. Epic Hyperspace (exceptions to EpicCare Link)
a. Agencies requiring direct access via Epic Hyperspace must have a fully executed *Epic Agreement* on file with Lurie Children's HIM before direct access to medical records is provided.

i. Study teams may inquire with the Clinical Trials Office to determine if the specific agency has an Epic Agreement on file.

b. Exception requests to EpicCare Link must be include the *Research Monitor EMR Access Request Form* completed, signed by the monitor/auditor and should be submitted to the Clinical Trials Office at CRS@luriechildrens.org for review by applicable leadership.
c. Once approved, a Service Catalog request through the Help Desk should be submitted to the User Access team including the *Research Monitor EMR Access Request Form.*
d. HIM will provide login credentials for the specific monitor and time frame noted.

IV. Procedures for Obtaining Certified Copies of Medical Records

A. A request for certified copies of medical records should be made as far in advance as possible (i.e., 2 weeks), but a minimum of 48 hours is required. Exceptions will only be made for unexpected regulatory audits.
B. A completed *HIM Medical Record Request for Research Form* should be forwarded to HIM at ROI@luriechildrens.org specifying the medical records needed.
C. HIM will produce and certify a true and accurate copy (paper or electronic) of the specified medical records.
D. Certified copies may be picked up from HIM (Main Hospital, 9th Floor Rm. 111) or delivered to the requestor via interoffice mail.
E. A copy of the *HIM Medical Record Request for Research Form* and HIM Certification letter (with records specified) should be printed and maintained in the regulatory binder.
F. The certified copies (electronic or paper) are to be stored with the regulatory binder until study files are destroyed as mandated by the federal regulations and/or clinical study agreement.

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Stanley Manne Children's Research Institute 16/FEB/2018
Health Information Management Committee 27/MAY/2020