University of Nebraska Medical Center

Center for Clinical and Translational Research Administrative

Nebraska Medicine

Section **Clinical Research Center**

Title: **Certified Copies from EMR**

SOP Number: **SOP-68**

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PURPOSE:

To describe the process and procedures related to certifying copies of electronic source data to ensure documentation of findings during a clinical trial are complete and legible in compliance with Good Clinical Practice (GCP) as defined in ICH E6 (R2).

SCOPE:

The procedure applies to all employees of the Clinical Research Center.

DEFINITIONS:

- 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. (1)
- Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
- Electronic Medical Record (EMR): Electronic patient chart containing protected health information. May be used to capture original source data in clinical research.

PROCEDURES:

To reduce duplication of data, transcription errors and to reduce waste, source data will be captured in the Electronic Medical Record (EMR) whenever possible. It is not necessary to maintain paper copies of electronic source data. However, if for any reason a paper copy of electronic source is warranted, the following process will be followed:

1. An authorized EMR user may produce a printed copy.
2. The printed copy will be paginated and display the user ID, date and time.
3. The person certifying the copy will verify that all information is present and legible prior to certifying that it is an exact replica of the electronic medical record, having the same attributes and information as the original.

4. Research staff will exercise special care of medical records protected by the state and federal laws in order to safeguard private health information. Hard copy medical records and electronic medical records will be treated with the same precautions.

The above verified process confirms the record is complete, contains all important metadata, and is an acceptable certified copy.

If for any reason the printed copy does not adhere to the process outlined above, the authorized user will stamp the first page of the printout with a "Certified Copy" stamp. If a stamp is not available it is acceptable to hand write "Certified Copy" then sign and date that copy.

Sources:

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

Staff Accountability:

Developed By: Nurse Manager, Clinical Research Center
Associate Vice Chancellor for Clinical Research, Clinical Research Center
Reviewed By: Director of Clinical Research Operations, Clinical Research Center

Department Approval

Signed _____ Signed _____

Director of Clinical Research Operations Medical Director for Clinical Research Center