


Standard Operating Procedures for Clinical Research at USF Health Morsani			
	PRINTING AND CERTIFYING MEDICAL RECORDS		
SOP#: 505	Effective Date:06/01/2016	Version: 1.0	Page: Page 1 of 3

PURPOSE: The purpose of this SOP is to describe the procedure for printing and certifying source documents from the electronic medical record for data abstraction and/or for monitoring visits.

SCOPE: This SOP applies to clinical research staff who abstract source data from electronic medical records to capture on a Case Report Form (CRF) and/or when preparing for a research study monitoring visit.

RESPONSIBILITIES: The Investigator and designated research personnel are responsible for complying with this SOP.

DEFINITIONS:

Case Report Form (CRF): A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject

Certified Copy: A copy of original information that has been verified, as indicated by dated signature, as an exact copy having all of the same attributes and information as the original

Data Abstraction: The process of identifying the pertinent data points from the subject's medical record.


Electronic Medical Record (EMR): A digital version of the traditional paper-based medical record for an individual. Also referred to as an Electronic Health Record (EHR)

Research Record: A folder containing COPIES ONLY of information from the medical record used primarily by clinicians in their offices or clinic settings. These COPIES of the relevant documents from the original medical record are NOT part of the patient's/subject's record.

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 and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, 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 that takes responsibility for and initiates a clinical research trial.

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PROCEDURE:

1. An Electronic Medical Record (EMR) shall be maintained for every individual who is evaluated or treated as an outpatient clinical patient in USF Health Medical Clinics.
2. Prior to a planned study monitoring visit or prior to source data capture on a CRF, PI-designated research personnel may obtain copies of original medical record documents by submitting a request to USF Health Medical Records Department or by asking the study participant to sign a release of medical records form for their non-USF Providers.
3. Documentation of this delegated task will be noted on the delegation log which is maintained with the regulatory documents for each clinical trial or per Sponsor requirements.
4. The requestor will provide medical records with the following information at least 7 days in advance:
 - Patient name
 - Patient's date of birth
 - Dates of service
 - Specific components of EMR that are needed for request
5. Research staff will be notified by medical records when the certified copies of medical records are available.
6. 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 should be treated with the same precautions.
7. Every copy of a study participant's printed medical record must be a certified copy. Designated study personnel will certify each set of printed medical records by marking "certified copy page 1 of X" on the first page of the set and will mark "certified copy page X of X" on the last page of the printed set of records.
8. Study personnel who print copies of the medical record will also initial and date each certified copy mark.
9. It is not necessary to certify each individual page of the printed medical record. By marking each set of records or each individual encounter, the designated study personnel is certifying that the printed copy is an exact replica of the electronic medical record, having all of the same attributes and information as the original.

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PROCEDURE (cont.):

10. Research staff will store printed and certified medical records as part of the subject's research record in a secure location accessible only to authorized personnel.
11. Staff will retain the records of source documents per the *USF HRPP Policy and Procedure Manual*, state and federal laws, and per sponsor requirements if longer than institutional policy and federal or state law.
12. Records must be securely destroyed (shredded) after all retention requirements have been met.

References	21 CFR Part 11: Electronic Records ICH E6 GCP Health Insurance Portability and Accountability Act (HIPAA) Privacy & Security Rule, 45 CFR Parts 160 and 164
Related Policies	SOP #202: Privacy and Confidentiality SOP #310: Site Monitoring Visits SOP #504: Archiving Study Records
Revision History	Keep a running history of all revision dates.

Approval Date	Effective Date	Review/Revision Date
01/01/2015	01/01/2015	06/01/2016