


Standard Operating Procedures for Clinical Research at USF Health Morsani			
	ELECTRONIC RECORDS		
SOP#: 503	Effective Date:06/01/2016	Version: 1.0	Page: Page 1 of 4

PURPOSE: The purpose of this SOP is to describe the procedures clinical research teams are required to follow for electronic records management at the CRC.

SCOPE: This SOP applies to electronic data management for all clinical studies conducted at the CRC.

RESPONSIBILITIES: This SOP applies to those members of the clinical research team who are involved in computerized system setup and use, and electronic data capture and management

DEFINITIONS:

Audit Trail: A secure, computer generated, time-stamped electronic record that allows reconstruction of the course of events relating to the creation, modification, and deletion of an electronic record.

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.

Computerized System: A computer hardware, software, and associated documents (e.g., user manual) that create, modify, maintain, archive, retrieve, or transmit in digital form information related to the conduct of a clinical trial.


Digital Signature: An electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.

Direct Entry: Recording data where an electronic record is the original capture of the data. Examples are the keying by an individual of original observations into the system, or automatic recording by the system of the output of a balance that measures subject's body weight. In these cases, the electronic document is the source document.

Electronic Case Report Form (e-CRF): An auditable electronic record designed to record information required by the clinical trial protocol to be reported to the sponsor on each trial subject.

Electronic Data Capture (EDC): A computerized system designed for the collection of clinical data in electronic format for use mainly in human clinical trials.

Electronic Patient Diary: An electronic record into which a subject participating in a clinical trial directly enters observations or directly responds to an evaluation checklist.

Standard Operating Procedures for Clinical Research at USF Health Morsani			
	ELECTRONIC RECORDS		
SOP#: 503	Effective Date:06/01/2016	Version: 1.0	Page: Page 2 of 4

DEFINITIONS (cont.):


Electronic Record: Any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

Electronic Signature: A computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

Handwritten signature: The scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark.

PROCEDURE:

1. The research protocol will describe how a computerized system will be used.
1. Only Investigator- designated research personnel who are designated will have access to the electronic data management system.
2. Research personnel using the clinical data processing system(s) must be trained in the use of the electronic system.
 - 2.1 For EDC, the sponsor Monitor should provide qualified study personnel training and instruction on the proper use of Investigator-provided electronic systems used to capture study data (direct entry electronic patient diary, e-CRF), and on the relevant regulatory requirements, prior to and/or during the site initiation visit.
 - All site personnel who are responsible for data entry will enter all required data into the appropriate fields of e-CRFs.
 - The audit trail documents all changes to electronic records (who, when, why) and that the original entries are not overwritten.
 - All annotations to electronic records are attributable as to who and when (date, time) the annotations are made.
 - The Investigator will check and correct (or annotate) all data before transmitting the e-CRF to the Sponsor.
 - 2.2 For access to the electronic medical record (EMR) at the Morsani, please refer to USF Information Technology to obtain the appropriate application and training.

Standard Operating Procedures for Clinical Research at USF Health Morsani			
	ELECTRONIC RECORDS		
SOP#: 503	Effective Date:06/01/2016	Version: 1.0	Page: Page 3 of 4

PROCEDURE (cont.):

3. Computerized systems used in clinical study data management at the CRC are required to be in compliance with applicable regulations, with regards design, validation, and routine use.
4. Research personnel who have access to the computerized system(s) must be assigned a unique and secure User ID and password.
5. Research personnel will not to divulge their unique User ID/password combinations to anyone else for any purpose.
6. Research personnel may not to use anyone else's unique User ID/password combination or perform any required computer functions under anyone else's User ID/password combination.
7. Study personnel are responsible for establishing and maintaining a schedule for changing his/her User ID/password combination at appropriate intervals and to invalidate stolen, lost or otherwise compromised User ID/password combinations and replace them with a new combination.
8. Study personnel must log off when computer data entry/management activities are completed.
9. Designated study personnel will ensure that the computerized system(s) are used only for the purposes for which they were intended and validated
10. Study staff will ensure that computerized systems are securely stored when not in use.
11. The research team is strongly encouraged to conduct appropriate reviews of electronic data and audit trails at designated time periods to assess compliance with requirements regarding electronic data management
12. The study team is aware that proper computer system function is routinely monitored.
13. The PI and study coordinator will ensure that an original or certified copy of all electronic source documents and audit trail records are retained on file at the site.
14. With respect to an FDA inspection, all key study personnel should treat electronic records, as they would paper records.
15. The Investigator will retain audit trail records according to regulatory requirements.

Standard Operating Procedures for Clinical Research at USF Health Morsani



ELECTRONIC RECORDS

SOP#: 503

Effective Date:06/01/2016

Version: 1.0

Page: Page 4 of 4

REFERENCES:	21 CFR 11: Electronic Records; Electronic Signatures Food and Drug Administration (FDA), Guidance for Industry: Computerized systems used in clinical trials, April 1999 General Responsibilities of Investigators Investigator Recordkeeping and Record Retention
RELATED POLICIES:	SOP 102: Training Clinical Research Staff SOP 103: Responsibilities of the Research Team SOP: Regulatory Documentation SOP 501: Case Report Form Completion SOP 502: Source Documentation
APPENDICES:	None
REVISION HISTORY: Keep a running history of all revision dates.	

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