1 PURPOSE
This procedure serves as a companion to SOP 702, Clinical Research Data Management. It provides additional guidance concomitantly required when all or portions of the clinical data that are required by an FDA predicate rule for a submission or inspection are collected, managed and/or transmitted electronically, or include the use of electronic signatures in required records.

2 GENERAL INSTRUCTIONS AND RESPONSIBILITIES
The Sponsor is responsible for ensuring that:

a) Electronic data management activities occur as required by applicable regulations.

b) All participating clinical sites have the appropriate tools for and are properly trained in collecting, evaluating, correcting, and transmitting subject data via electronic systems, as well as the timelines for submission.

c) Each participating site has the information technology personnel available to participate as required in the implementation, monitoring, and security of computerized systems used at the site.

d) Computerized systems used in clinical study data management at all facilities are in compliance with applicable regulations with regards to design, validation, and routine use (21 CFR Part 11).

3 SPECIFIC PROCEDURES
3.1 Electronic Systems Set-up
The Sponsor will do the following:

a) The Sponsor is responsible for determining and documenting which elements of the study are subject to 21 CFR 11 (Electronic Records, Electronic Signatures). The Sponsor
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is responsible for creating an electronic data management plan that specifies data management systems and procedures needed for the studies.

b) Record all anticipated hardware and software that will be used in the conduct of a study on the Electronic Data Management Form (See SOP 703 Attachment A).

c) Arrange to acquire all the necessary hardware and software applications needed for the study.

d) Be responsible for identifying system validation needs for off-the-shelf and customized software applications for intended uses.

Participating Site Set-up where MHS is the lead research site:

When setting up the Electronic Data Capture (EDC) capabilities at participating sites, the Sponsor will do the following:

a) Assess the ability of each site to conform to the Sponsor’s electronic data requirements during the site qualification visit.

b) Provide all appropriate electronic data management tools (hardware, software, forms) to each clinical site and ensure that they are compliant with the requirements set forth in 21 CFR 11 including the required paperwork for system validation, access, users, audit trails, etc.

c) Work with site key personnel (including site information technology or other IT personnel) to facilitate setup, security, implementation, and maintenance of FDA-compliant computerized system.

d) Work with the site IT staff to ensure that computerized systems used in clinical studies have a logoff or comparable security function after a designated period of inactivity.

e) Request the site’s IT personnel/HIM (Health Information Management) ensure that personnel who have access to the computerized system(s) are assigned a unique and secure User ID/password combination.

f) Request the site’s IT personnel to establish and maintain a schedule for changing, each individual’s 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.

g) Request the site’s IT personnel ensure that proper computer system function is routinely monitored, and new versions upgraded and validated regularly.

h) Instruct the site Investigator to ensure that the Sponsor-provided computerized systems are used only for the purposes for which they were intended and validated.

i) Require the site Investigator to ensure that computerized systems are securely stored when not in use.

j) Request the site’s IT personnel to work with the Investigator to establish and securely maintain individual identifiers if the Sponsor requires a cryptographic digital signature rather than a handwritten signature.

k) Have the Monitor and other qualified personnel train appropriate site personnel on the proper use of a Sponsor-provided electronic system used to capture study data (direct entry, electronic patient diary, e-CRF), and on the relevant regulatory requirements, prior to and/or during the study initiation visit.
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1. Instruct site personnel not to divulge their unique User ID/password communications to anyone else for any purpose.

2. Instruct site personnel 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.

3. Instruct site personnel to log off when computer data entry/management activities are completed.

4. Train the site Investigator to conduct appropriate reviews of electronic data and audit trails at designated time periods.

5. Have the Monitor assess compliance with Sponsor requirements regarding electronic data management during routine monitoring visits.

3.2 Electronic Data Collection and Transcription

The Sponsor will ensure that:

a) The clinical protocol identifies at which steps a computerized system will be used.

b) All site personnel who are responsible for data entry will enter all required data into the appropriate fields of the CRFs.

c) The audit trail documents all changes to electronic records (who, when, why) and ensures that the original entries are not overwritten.

d) All annotations to electronic records are attributable as to who and when (date, time) the annotations are made.

3.3 Electronic Data Management

The Sponsor will ensure that:

a) An original or certified copy of all electronic source documents and audit trail records are retained on file at the site.

b) With respect to an FDA inspection, all key study personnel should treat electronic records, as they would paper records.

c) The Sponsor will ensure that the site investigator performs and documents audit trail reviews at defined intervals.

d) The site Investigator will retain audit trail records according to regulatory and Sponsor requirements.

4 REFERENCES TO OTHER APPLICABLE SOPS

- 301 Clinical Protocol Development, Implementation and Compliance
- 701 Case Report Forms
- 702 Clinical Research Data Management
5 ATTACHMENTS
   A. Electronic Data Management Form

6 APPLICABLE REGULATIONS AND GUIDELINES
   • Electronic Records, Electronic Signatures (21 CFR 11)
   • Investigator Recordkeeping and Record Retention (21 CFR 312.62)
   • Records (21 CFR 812.140)
   • The Principles of ICH GCP (ICH E6, Section 2.10)
   • Records and Reports (ICH E6, Section 4.9)
   • Quality Assurance and Quality Control (ICH E6, Section 5.1)
   • Trial Management, Data Handling and Record Keeping (ICH E6, Section 5.5)
   • FDA Guidance for Industry: Computerized Systems Used in Clinical Trials (April 1999)
   • Guidance for Industry Annotated Part 11 Electronic Signature - Scope and Application August 2003