| OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH | CATEGORY | Clinical Research: Project Activities |
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| | SUBJECT | Electronic Records and Signatures |
| | SOP # | 4.6 |
| | EFFECTIVE DATE | August 6, 2008 |
| | REVISION DATE | January 3, 2018 |

**OBJECTIVE**
Describe general management for all electronic clinical research data. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research conducted within the Hennepin County Medical Center campus.

**APPLICABLE REGULATIONS AND GUIDELINES**

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| 21 CFR 11 | Electronic Records |
| 21 CFR 312 | Investigational New Drug Application |
| 21 CFR 812 | Investigational Device Exemptions |

**REFERENCES TO RELATED SOPs**
SOP 2.1
SOP 4.1
SOP 4.2

**ATTACHMENTS**
None

1) Ensure that the protocol delineates when a computerized system will be used. Maintain a listing of the hardware and software used for each trial along with the provider of the hardware and software.

2) Use sponsor provided Electronic Data Capture systems only for the purposes for which they are provided.
   a) Work with the sponsor/vendor to facilitate set-up.
   b) Ensure that the software is 21 CFR 11 compliant as required.
   c) Assign a unique and secure user ID for each clinical research team member that will be entering electronic data.
   d) Establish and maintain a password-changing schedule.
   e) Invalidate stolen, lost, or compromised user IDs and/or passwords immediately.

3) Logging in/out
   a) Use own unique user ID and password combination when logging in.
   b) Do not give out a user ID or password to another individual.
   c) Do not use another individual's user ID or password.
   d) Log off the program when finished with computer entries.

4) Confirm that changes to electronic records are documented through the audit train and that the original entries are not overwritten.

5) Ensure that all entries are attributable with date, time, and electronic signature stamps.

6) Confirm with the sponsor that the research site will be provided copies of all case report forms along with the appropriate software after data lock.

7) Electronic medical records and/or documents converted to electronic form are considered equivalent to an original paper record. Electronic signatures are considered legally equivalent to a full hand written signature, initials, or other signing.

8) Paper copies of electronic records are considered equivalent to an original paper document when signed and dated by the research team member who certifies that it is an exact representation of the electronic record at the time it was printed.