1. PURPOSE

To define the procedures utilized to review electronic research records.

2. SCOPE

This procedure applies to compliance activities where use of electronic research records is involved.

3. RESPONSIBILITIES

The Education and Compliance Coordinators are responsible for reviewing electronic research records where the use of such records are involved in research records selected for a compliance activity.

4. PROCEDURES

4.1. For research studies that involve the use of electronic records, the Education and Compliance Office staff will ascertain the following information, where applicable:

a) Who was responsible for the software/hardware installation?
b) Are staff required to complete training prior to receiving access and is training documented?
c) Who has access to the data and is access password-protected?
d) Were there any record-keeping problems experienced during the course of the study?
e) What is the source of the data entered into the computer, e.g. direct, case report form, office record, other?
f) Who enters data and when?
g) How are changes made to previously entered data?
h) How are data submitted to the sponsor (i.e. modem, network, fax, hard disk, electronic transfer, mail, and messenger)?
i) If the sponsor discovers an error, omissions, etc., in the data received, what contacts are made with the investigator? How are corrections implemented, and how are they documented?
j) Does the investigator retain a copy of the electronic data for the appropriate time period?
k) Where is it stored, on a server or laptop or both?
l) How is data backed-up?
m) Is it stored with or without identifiers?
n) Is encryption software utilized?

5. REFERENCES/DOCUMENTATION

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