1. PURPOSE

To define the procedures utilized to review research records maintained by the investigator for research study participants.

2. SCOPE

This procedure applies to all compliance activities performed by the Education and Compliance Office for Human Subject Research.

3. RESPONSIBILITIES

The Education and Compliance Coordinators are responsible for conducting reviews of research participant’s research records.

4. PROCEDURES

4.1. The Education and Compliance Coordinators will review the research records of human subjects enrolled into the respective research study. This review will:

   a) Evaluate the investigator’s methods of documenting research data in terms of their organization, condition, completeness, and legibility

   b) Determine whether there is adequate documentation to assure that all subjects did exist and were alive and available for the duration of their stated participation in the study.

   c) Compare the investigator’s research participant records, [i.e. the case report form(s)/data collection tool(s)], with the source documentation to verify the accuracy of the participant’s records relative to the source documentation.

   d) Determine whether each record contains documentation of:
      • Eligibility criteria met (or not met) for each subject
      • Screening, study and follow-up procedures implemented per the IRB-approved protocol
      • Adverse events and UPA reported in accordance with IRB and sponsor requirements
      • Observations, information, and data on the condition of the subject at the time the subject entered into the research study as well as throughout participation and study closure
      • Records of exposure of the subject to the test article, if applicable
      • The identity of all persons/departments responsible for the performance and analysis of all study-related procedures and dates the procedures were performed.
4.2 Record review findings will be documented on the audit worksheets to assess compliance with the IRB approved protocol.

4.4 In addition to the items outlined above, the ECO coordinator will evaluate:
- Consistency of procedures as outlined in the protocol and consent document
- Whether the protocol and consent document reflect “actual practice”
- Whether any modifications were implemented prior to IRB approval
- Whether any additional procedures are being performed that were omitted from the protocol and/or consent document

5. REFERENCES/DOCUMENTATION

NA

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