1. PURPOSE

To define the procedure utilized to select research participants’ records for review during an audit.

2. SCOPE

This procedure applies to all investigator site audits performed by the Education and Compliance Office.

3. RESPONSIBILITIES

The Education and Compliance Coordinators are responsible for selecting research participants’ records for review during investigator site audits.

4. PROCEDURES

4.1. Prior to the audit, the principal investigator/study coordinator will be requested to provide a list of all study participants to the Education and Compliance Office. To ensure the confidentiality of the research participants, the list will be limited to the research participant’s initials or unique identification number and their date of study enrollment.

4.2. From this list, the Education and Compliance Office will select 20-25% of the participant population. For large studies with enrollment greater than 100, 5-10% of the participant population will be selected. The list of subjects selected for audit will be provided to the PI/coordinator so that all records containing information relevant to the study may be assembled, i.e., research records, clinic charts, hospital records. Access to all selected subjects’ records and associated documents should be provided to the Education and Compliance Office.

At the time of the audit, the ECO staff may request additional records for review. If no problems are identified with the research records or if a systematic error or omission is identified, the ECO may elect to review a square root of the total number of subjects enrolled in lieu of a percentage of subjects enrolled.

4.3. In the case of a “for cause” audit, the Education and Compliance Office may review 100% of the research participants’ records. In cases where the safety of the research subject may be in immediate jeopardy, the Education and Compliance Office may request the research subject’s name and social security number to expedite the review of the subject’s medical record if applicable.
5. REFERENCES/DOCUMENTATION

NA

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