NHG RESEARCH EDUCATION

Qualité

Education to facilitate high standards of research conduct

Screening Subjects Prior to Study Enrollment – Does This Require DSRB Approval?

Case Scenario – What went wrong?

In research, a screening process is commonly conducted to identify potential subjects for inclusion in the study. Recently, an investigator collected medical data from potential subjects for screening purpose. The investigator wanted to use the results from the screening process to estimate participation response rate and establish the study workflow before initiating an approved research (Study X). The investigator conducted the screening process using a modified unapproved informed consent document that is similar to the approved ICF document for Study X.

DSRB reviewed this and determined the screening process as a serious non-compliance. This is because the screening process, including the use of medical data and informed consent document, has not been reviewed and approved by DSRB.

DSRB Approval is Required for All Screening Tests

Screening tests that are conducted to identify potential subjects are considered part of the subject selection and recruitment process. These procedures done in anticipation of or in preparation for the research is part of the research process. Thus, IRB oversight is required and researchers should obtain DSRB approval prior to the conduct of any screening procedures.

DSRB approval is particularly important for studies in which the screening process may require the subjects to undergo invasive procedures such as blood taking and biopsy. Screening procedures that are performed solely for the research study and not part of the standard medical practice must be conducted only after (1) DSRB approval has been obtained and (2) the patient has given his or her informed written consent.

DSRB approval is also essential in order to use the data collected from standard medical procedures for research screening. These may include data collected on the diagnosis and treatment of medical conditions.

THE RQA SELF-ASSESSMENT CHECKLIST IS UNDERGOING A REVAMP!
DO LOOK OUT FOR UPDATES ON THE NHG RESEARCH WEBSITE.

Common Misconception

A common misconception that researchers have is where the screening process involves non-invasive procedures, DSRB approval is not required. This is not true. Even if the screening process includes non-invasive procedures such as reviewing databases or medical records, oral responses to questionnaires, or accessing private information, i.e., grades, medical test results, DSRB review is required. Collecting data for purposes of eligibility screening is part of research activity and therefore requires IRB approval prior to initiation.

References:

- *FDA Regulatory Information- Screening Tests Prior to Study Enrollment - Information Sheet: http://www.fda.gov/RegulatoryInformation/Guidances/ucm126430.htm*
- *OHRPP - Guidance and Procedure: Recruitment and Screening Methods and Materials: ora.research.ucla.edu/OHRPP/Documents/Policy/5/Recruitment.pdf*
- *PCR SOP 501-C02: Subject Recruitment and Screening*

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