

Title: Selection of Studies for Routine Monitoring and Oversight Review
Effective Date: 1/15/08
Revision Date:

Purpose:

To ensure that the selection of studies for review is transparent and equitable to the investigator community while maintaining flexibility. The Review Plan will be approved by the Assistant Dean of Research or his/her designee. Due to the volume of clinical studies, not all studies can be reviewed. The purpose of this document is to describe the sampling strategies for routine, not-for-cause reviews by Monitoring and Oversight within this Review Plan.

Criteria for Determining Selection of Studies (including but not limited to the following):

- A. Federally Funded Studies
- B. Internally Funded Studies
- C. Studies that present a moderate to high degree of risk to the research subjects
- D. Studies with high enrollment #s
- E. Studies with vulnerable populations

Procedure for Selecting Protocols for Review by Monitoring and Oversight:

- A. Query of IRB database to include all active studies (those with IRB approval). No closed studies will be selected. The fields included in the query are:
 - 1. Department name
 - 2. IRB Protocol #
 - 3. Protocol Title
 - 4. Source of Funding
 - 5. Degree of risk
 - 6. Number of subjects enrolled to date
 - 7. Sponsorship
 - 8. Vulnerable population characteristics

- B. Random selection of individual studies from the database query will focus on the following criteria:
 - 1. Funding source
 - 2. Risk to subjects
 - 3. Enrollment numbers
 - 4. Vulnerable population characteristics

Studies selected for review will not be reviewed again within one calendar year of the date of first review, unless Monitoring and Oversight or the Institutional Review Board determines that additional follow-up and education is needed.