1. PURPOSE

To define the procedures utilized to select protocols for the purpose of conducting compliance activities.

2. SCOPE

This procedure applies to all compliance activities performed by the Education and Compliance Office.

3. RESPONSIBILITIES

The IRB Executive Committee, IRB Chair or RCCO leadership will be responsible for notifying the Education and Compliance Office of requested “for cause” audits occurring as a result of known or suspected problems in the conduct of human subject research.

The Office for Investigator-Sponsored IND and IDE Support will notify the Education and Compliance Office of protocols involving investigator-sponsored INDs or IDEs.

The Education and Compliance Coordinators are responsible for selecting protocols for all other compliance activities.

4. PROCEDURES

4.1 For RISE interviews, the Education and Compliance Coordinator will review the list of recently approved protocols using the following criteria for selection:

- Source of funding (federal or internal funding)
- Greater than minimal risk
- Investigator new to the University
- Established investigator who has never undergone a RISE review
- PI is graduate or doctoral student
- Focus of research considered high profile
- Gene transfer intervention
- Radioactive drug research
- Coordinating Center Protocol
- Greater than minimal risk protocol conducted in a transnational setting
4.2 The ECO will base its selections of schools/departments/divisions for full departmental QA audits on information including but not limited to:

- Date of last audit within the respective area
- Number of previous audits performed in the respective area
- IRB protocol reconsideration rate of the respective area
- Recommendations received from the IRB

5. REFERENCES/DOCUMENTATION

NA

Original: 8/1/01
Reviewed/Revised: 11/20/03
Reviewed: 9/3/04
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Reviewed/Revised: 1/17/06
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