Subject: **Research Compliance**	Page **1**	Policy # **Version: 1**
Title: **Human Research Quality Assurance Policy**	Revision of:	Effective Date: **November 1, 2018**
		Removal Date:

I. PURPOSE

Due to the complexity of clinical and translational sciences, Feinberg School of Medicine (Feinberg) is instituting monitoring procedures that pertain to the conduct of human research. The policy outlines the details for the quality assurance processes.

II. PERSONS AFFECTED:

All Feinberg faculty, staff, students and trainees involved in the conduct of human research.

III. POLICY STATEMENT

Feinberg is committed to excellence in the conduct of research. Using a risk-based approach, a sample of clinical research studies will be selected quarterly to assess their compliance with institutional policies and federal regulations. Any area that demonstrates a pattern of insufficient compliance will undergo increased monitoring of its studies.

This endeavor will complement other monitoring processes. Reviewers will coordinate with Northwestern University Clinical and Translational Sciences Institute's (NUCATS) Center for Clinical Research and Northwestern University's Institutional Review Board (IRB) to prevent duplication of efforts.

IV. PROCEDURE STATEMENT

The following provides an overview of the study selection process and review procedures.

Review Selection Process

A risk-based approach will be used to determine the sample of studies to review. The risk factors considered include but are not limited to the following:

- Studies that pose a significant risk to the participant.
- Studies involving investigational new drugs (INDs) or devices (IDEs).
- Studies in which there is an investigator-held IND/IDE.
- Studies enrolling vulnerable populations.
- Studies that reported an incident the IRB determined was serious and/or continuing non-compliance or an unanticipated problems involving risk to subjects or others.
- Studies with limited or no internal or external monitoring reviews (e.g., investigator-initiated trials).

Review Procedures

Study files will be reviewed and interviews may be conducted with study personnel. The following provides examples of specific review procedures.

- Review of regulatory documentation to identify specific study requirements. The documentation includes, but is not limited to, the grant, progress reports, and the IRB approved protocol and consent form.
- Review recruitment materials and subject screening and enrollment logs to confirm that study participants were properly solicited, enrolled, consented, and compensated for the

study.
- Review monitoring/auditing logs to confirm that adverse events and other critical milestones were properly reported and documented.
- Review study records to confirm compliance.

V. ROLES AND RESPONSIBILITIES

The reviews will be coordinated by the Office for Regulatory Affairs. Principal Investigators, study coordinators and other research personnel should continue their existing monitoring practices. Monitoring and training resources are available from NUCATS and the IRB.

VI. DEFINITIONS

Common definitions related to the conduct of human research can be found here.

VII. POLICY UPDATE SCHEDULE:

The policy will be reviewed annually to determine if updates are warranted.

VIII. REVISION HISTORY:

N/A

IX. RELEVANT REFERENCES:

Please contact the Office for Regulatory Affairs at fsm-compliance@northwestern.edu or 312.503.2855.

The following includes monitoring and training resources.

- NUCATS Good Clinical Practices
- IRB Templates, Forms and Standard Operating Procedures