

Feinberg School of Medicine (Feinberg) is committed to excellence in the conduct of research. Due to the complexity of clinical and translational sciences, Feinberg is instituting monitoring procedures that pertain to the conduct of human 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.

**What actions are required from the clinical research community?**

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](#).

**How are clinical research studies selected for review?**

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).

**What will happen during the review?**

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.

**How will I know if my study was selected for review?**

The Principal Investigator and clinical research coordinator (if applicable) will be notified via email that their study was selected for review. The review of study files will take place based on a mutually agreed upon time.

**How will the review results be communicated?**

At the end of the review, the results will be shared via email with the Principal Investigator and clinical research coordinator (if applicable). The department chairs, division chiefs, and unit administrators will receive a quarterly summary on the studies reviewed and results for their respective units. Significant findings will be communicated as they arise to the study team, department chairs, division chiefs, unit administrators, and relevant school and central offices (e.g., IRB, etc.).

**Whom should I contact if I have questions?**

Please contact the Office for Regulatory Affairs at [fsm-compliance@northwestern.edu](mailto:fsm-compliance@northwestern.edu) or 312.503.2855.

**Monitoring and Training Resources**

- [Human Research Quality Assurance Policy](#)
- [NUCATS Good Clinical Practices](#)
- [IRB Templates, Forms and Standard Operating Procedures](#)