• Regulatory background
• Types of post approval monitoring activities
• For cause audits – process & preparation
• Review of Responses to Findings
• Commonly Sited
• Tips
Background

• FDA and HHS regulations allow for inspection
• Per 21CFR56.109(f) and 45CFR46.109(e) the IRB has the authority to observe or have a third party observe the consent process and research
• All active human subject research studies under the purview of the Northwestern University IRB can be chosen for review.
IT'S NOT AS BAD AS IT SEEMS! (Usually.)
• **Post Approval Monitoring**: a routine compliance review of the study documents and/or the observation of the consent process.

• **Types of Post Approval Monitoring**:  
  – Consent Form Monitoring  
  – Recruitment  
  – Panel Requested or Staff Initiated  
  – Randomly Selected
Consent Process Checklist

1. Is informed consent obtained from each subject prior to the start of any study procedures? (including screening procedures to determine eligibility)

2. Is the IRB approved consent form (approval stamp on the last page or approval date in footer (eIRB)) used to consent each subject?

3. Is the original dated and signed consent form on file for each subject?

4. Did all consented subjects receive a copy of their signed and dated consent form?

5. Do you document your files to indicate each subject received a copy of their signed and dated consent form?

6. Was a copy of each subject’s signed consent form placed in subject’s medical record? (if appropriate)

7. Where do you keep signed consent forms for this study?

http://irb.northwestern.edu/policies/compliance
Consent Observation and Process Checklist
• Randomly selected

• Accuracy checked

• Contact information is confirmed
Recruitment Materials & Guidelines

**Required elements**
- Study title and IRB study number
- The word "research"
- "Northwestern University"
- PI's department
- Contact name and either phone number or e-mail.
- Eligibility criteria
- Compensation

**Recommended elements**
- State the purpose
- Subject activities
- Time commitment
- Research location
- Avoid phrases such as “help needed” or "subjects wanted." The recommended wording is "You are invited" or "Participants invited."
Post Approval Monitoring of Recruitment Flyers

DO YOU SUFFER FROM LOW BACK PAIN?

ARE YOU AGE 18 OR OLDER?

YOU MAY BE ABLE TO PARTICIPATE IN A CLINICAL RESEARCH STUDY THAT MAY INVOLVE TREATMENT.

RESEARCHERS AT NORTHWESTERN UNIVERSITY ARE TRYING TO UNDERSTAND THE BRAIN AND WHAT CAUSES BACK PAIN.

CALL 312-503-0100 TO LEARN MORE.
• An IRB submission may identify a potential need for assistance or education.
Randomly Selected Post Approval Monitoring

- Risk level
- Investigational new drugs (INDs) or devices (IDEs)
- An investigator-held IND/IDE
- Vulnerable populations
- Frequent continuing review
- Randomly selected active studies
For-Cause Audits
• **For-Cause Audits**: not a routine compliance review and are usually triggered by the following events:
  • Subject complaint
  • Employee complaint
  • Whistle blower
  • IRB request due to new information that might affect the rights and welfare of research subjects
Reporting Potential Noncompliance

• Email: irbcompliance@northwestern.edu or

• Report via Ethics Point: 866-294-3545 or ethicspoint.com or

• Contact:
  - Eileen Yates eyates@northwestern.edu (3-6011)
  - Piper Hawkins-Green piper@northwestern.edu (3-7929)
  - Olga Jonas okwiecien@northwestern.edu (3-6012)
Next Steps

• Email Notification
• Reserve a conference room or work space
• Have all study materials available:
  o Consent forms
  o Subject files
  o Drug dispensing log
  o Printed IRB correspondence and approvals
  o Regulatory binder(s)
Handouts

- Self Assessment Checklist
- Regulatory Binder List
- Sample Delegation Log
- Subject Recruitment and Enrollment Log
- Documentation of Informed Consent Process
- Consent Process Checklist
• [http://irb.northwestern.edu](http://irb.northwestern.edu)
• http://irb.northwestern.edu/policies/compliance

Post-approval monitoring is a routine compliance review of the study documents and/or the observation of the consent process. Studies are selected for monitoring according, but not limited to, the following criteria:

1. Risk level of the study.
2. Studies involving investigational new drugs (INDs) or devices (IDEs).
3. An investigator-held IND/IDE.
4. Studies enrolling vulnerable populations.
5. Studies requiring more than annual review by the IRB.
6. Randomly selected from active studies in eIRB.

FOR-CAUSE AUDITS

For-cause audits are not a routine compliance review and are usually triggered by the following events:

- Subject Complaint
- Employee complaint
- Whistle blower
- IRB request due to new information that might affect the rights and welfare of research subjects.

Overview of the Review Process

The IRB will contact the Investigator and Study coordinator via e-mail and ask for the following: availability of the PI and study staff and an allocation of resources, such as files, space, and/or access to electronic records. On the day of the review, the study file(s) will be reviewed and interviews may be conducted with study staff.

PREPARING FOR A MONITORING OR AUDIT VISIT

- Contact the IRB office with any questions and communicate concerns regularly about the visit.
- Download and review the Self-Assessment Checklist.
- Use the Consent Observation and Process Checklist to assess your current practice of obtaining consent.
- Review the Six Steps to Writing a Corrective Action Plan for “best practices”.

Upon completion of the review, a meeting with the PI and study team will be held regarding next steps. A final report is submitted to the PI and study team. If there are findings that need to be reported, then that report along with response is submitted to the NU IRB for review and consideration via the Safety/Other form under the PRINC category in eIRB.

ADDITIONAL REGULATORY RESOURCES
Review of Findings

Post Approval Monitoring

• Up to two weeks to receive the findings.
• Two weeks to respond.
• Compliance team review of response.
• IRB Chairs review at monthly meeting.
• Receipt of closeout letter (usually after requested submissions have been approved).
• Staff training (if necessary).

For Cause Audit

• ~Two weeks to receive findings (varies by issues).
• ~Two weeks to respond (varies by recommendations).
• Submit complete response via RNI
• Submit modifications and additional RNI’s as requested.
• IRB committee reviews response
• Staff training (if necessary)
• No closeout letter issued.
• Consent forms:
  o Expired consent, not printing and/or signing names, marking the document, optional procedures not appropriately marked

    ▪ Missing IRB correspondence or approvals

    ▪ Data
      o storage and retention
      o incomplete data

    ▪ Inadequate regulatory binders

    ▪ Failure to report or meet reporting timeframes
Helpful Tips

• We cannot take your study materials with us, please reserve a conference room.

• eIRB is not appropriate as a regulatory binder, please store the approvals and protocol/revision versions either electronically or in the regulatory binder.

• Maintain your binder throughout the study.

• Date all study documents.

• Corrective Action Plans.

• Don’t stress!
General questions or concerns: irb@northwestern.edu

eIRB and eIRB+ questions: eIRB+ Contact Form

Training and education: irbtraining@northwestern.edu

Compliance issues: irbcompliance@northwestern.edu