Agenda

• Compliance and Education Team
• Compliance Roots
• Post-approval monitoring
• Metrics
• Take Aways & Study Support Resources
• Check your knowledge
• Questions
Who are we?

Mission Statement:
Enhance the caliber of research performed
Increase the effectiveness of the Human Research Protection Program
Ensure research at Northwestern and its affiliates complies w/ federal regulations and institutional policies that govern human research
Design our unit to ensure YOU have the educational resources and guidance necessary to conduct research SUCCESSFULLY and COMPLIANTLY

irbcompliance@northwestern.edu & irbtraining@northwestern.edu
Compliance & Education Activities

- Complaints, Allegations of Non-Compliance, and Miscellaneous Investigations
- Conducting effective training and education
- Developing effective lines of communication
- Conducting post-approval monitoring and auditing
- Collaborate with HRPP stakeholders
- Reporting of monthly, quarterly, and annual compliance metrics
- Mission and vision, defining organizational compliance culture
Why is **Research Compliance** Important?

- Research should be conducted in an ethical and responsible manner
- Ensure researchers are following all applicable laws and regulations related to their research
- Protects participants and institutions by reducing risk and enhancing safety
- Maintain the integrity and credibility of research findings
Compliance Roots

- Regulatory Requirements
- Ethical principles
- Best Practices
- Institutional policies
Compliance Roots

**Regulatory Requirements**
- The Common Rule
- FDA Regulations
- Additional Federal Agency Criteria (NIH, DoD, VA, etc.)

**Ethical Principles and Guidance**
- The Belmont Report
- International Council on Harmonization (ICH) & Good Clinical Practice (GCP)

**Institutional Policies**
- Northwestern University Policies
- IRB Office Policies & Guidance
- Office for Research Policies and Guidance
- Feinberg School of Medicine (FSM) and Department/School Policies
Applicability: Compliance Roots

All Human Research at Northwestern University must adhere to:

- Ethical Principles
- Northwestern University Human Research Protection Program (HRPP)
- Northwestern IRB Office Policies, SOPs
- Other institutional (school or department-related) Policies and Procedures relevant to human research
- Human Research Protections Training
- Principal Investigator Responsibilities
- Informed Consent & HIPAA, PHI, & PII (when applicable)
- Data and Participant Safety
- Documenting Deviations and (when applicable) Reporting Events that Occur
- Research Document Retention Requirements for Principal Investigators
- Post-Approval Monitoring
Applicability: Compliance Roots

- **All Northwestern University researchers** are responsible for upholding the highest standards of ethical conduct as defined in University policies, procedures, and guidelines, and sponsoring agency policies and regulations.

- **AAHRPP**: The Association for the Accreditation of Human Research Protection Programs
  - Voluntary, peer-driven, educational model to ensure HRPP meets rigorous standards for quality and protection.
  - AAHRPP accreditation = "gold standard" of quality for IRBs.

- **Diversity, Equity, and Inclusion considerations**
  - Fostering Accessibility and Inclusivity in Research (FAIR)
Keeping Up With Compliance…can be challenging!

- Evolving regulations
- Compliance at multiple points during a research study
- Compliance is a moving target
Post-Approval Monitoring!

Pam, Pam, Pam
Post-Approval Monitoring (PAM) Self-Assessments

Description:
• Education-focused, routine compliance review
• Monitor active studies to confirm the research is being conducted as approved by the IRB
• Ensure compliance with institutional, state, and federal regulations, policies, and guidelines
• Promote best research practices

Types:
• Self-Assessment
• Corrective And Preventive Action (CAPA) Plan Assessment
• New Investigator Assessment
• New! Study Status Assessment
PAM Self-Assessment Monthly Selection

- **All currently open** non-exempt human research studies are eligible for review

- Studies are **randomly selected** each month from a variety of departments and study types:
  - Studies approaching expiration & Studies without an expiration date
  - Studies under the Northwestern University IRB & Studies reviewed by External IRB

- **Goal = monitor 3-5% of the open research portfolio**, so the number varies year to year

- FY23 Monthly Selections are based off our active portfolio:
  - Biomedical Research (66%)
  - Social and Behavioral Research (34%)
  - Studies reviewed by an external IRB (13%)
PAM Self-Assessment Process

- **eIRB+ generates a report of Studies**
- **Studies are randomly selected**
- **Compliance Analyst notifies PI and sets due date.**
- **PI completes PAM checklists and returns via email.**
- **Compliance Analyst review PAM checklists, request clarifications, and provide observations and best practice recommendations.**
- **Work with PI/Study team to address observations and take required actions.**
- **Compliance Analyst records a summary of the completed assessment.**
- **Reported to the IRB Chairs at the monthly meeting.**
- **Metrics also used for targeted education, communication, and support.**
What Analysts Look For In Self-Assessment Checklists

- Consistency and accuracy of information between checklists and eIRB+ application, and documents (protocol, consent documents, etc.)
- Adherence to the IRB-approved protocol and documents
- Adherence to federal, state, local, and institutional regulations, policies, and best practices
- Educational opportunities including sharing resources and best practices
Responding to PAM Observations

IRB Compliance:
• The Compliance Analyst may provide the following with an observation:
  – Required Actions
  – Best Practice recommendations
  – Education or Resource(s) provided
• Include the regulation / policy / law or best practice the observation is rooted in
• May find PAM is as expected with no observations.

You:
• Respond to each observation via email in line, bold or change color of your text
• Take any required actions
• Respond to requested actions, providing supporting documentation if asked to
• Do not need to send revised checklists unless asked to
Closing a PAM Self-Assessment

• We guide you in making corrections or reconciliations with your research record
  – Required vs. Recommended actions
• Once all observations are addressed, we send a closure notification email
• The results of the PAM self-assessment are reported in aggregate at monthly IRB Chairs' meetings
• PAM metrics are recorded and used for reports, targeted education, support, and communications
  – Education needed
  – Ready for closure
  – Submissions required
  – Checklist/Section(s) with observations
Common PAM Observations

- Study ready for closure
- Outdated funding or study personnel
- Consent forms
  - Blank lines or no witness signature obtained when required
  - Non-IRB-watermarked consent version used
  - Optional procedures not appropriately marked

Principal Investigator Oversight:
- Inadequate documentation
  - Storage and retention of research records
  - Missing IRB correspondence or approvals
- Enrolling over the IRB-approved target enrollment number
  - Including retrospective chart reviews!
- Failure to meet IRB reporting timeframes
  - Use of Short Form consent process
Common Observations

Required Actions

• Continuing Review
• Modification
  – Update funding sources
  – Remove personnel no longer working on study
  – Update eIRB+ and study documents
• Reportable New Information (RNI)
• Filling missing CVs or Human Participant Research Training (CITI)
• Note to File
Common Observations

Required Actions

• DSMB reports indicating no changes to the study must be submitted at time of CRs
• Closing a study in a timely manner when study is ready for closure
• Maintain CITI training for all study personnel within the research record
• Record retention and regulatory documentation

Remember, eIRB+ is not your regulatory binder.
Best Practices and Recommended Actions

- Creating a **Delegation of Authority (DOA) Log**
  - Document study team qualifications & delegation
- Using an **Eligibility Checklist**
  - Track screening, enrollment, withdrawals
- **Including** Non-English-Speaking participants
  - Enhance diversity, equity, inclusion, & justice in research
- Maintaining **documentation** when implementing **Corrective and Preventive Action (CAPA) Plans**
- Documenting a **Note To File**
  - Add context/additional information to your research record
FY22 PAM Metrics

PAM Activities: FY22

- **Notifications Sent:** 225
- **Reviews Completed:** 223

- Biomedical
- Social-Behavioral

Note: 3% of IRB project portfolio underwent routine PAM

PAM Activity Types: FY22

- Self-Assessment 90%
- New Investigator 5%
- CAPA Assessment 5%

Note: All routine post-approval monitoring occurred remotely during FY22
FY22 PAM Metrics

Action Items for Completed PAMs:

- 47% Required Submission (MOD/CR/RNI) to IRB
- 27% Ready for IRB Closure
More Metrics!

- No Expiration Date
- Non-Exempt
- Open in eIRB+

3,808 studies
Introducing a new Post-approval Monitoring Checklist: **Study Status Assessment**

**HRP-433 Studies Without Expiration Date PAM Checklist**

- Adding to our toolkit – a *new* post-approval monitoring checklist and assessment type that is tailored specifically to monitor non-exempt studies that **do not have an expiration date**.

- **AKA Continuing Review is not required annually**
Post-approval Monitoring Assessment: Study Status Assessment

- Target minimal risk studies without an IRB approval expiration date. These studies may be prospective or retrospective chart reviews, specimen collection and retention, registries, interview-only, etc.

- Possible Outcomes: Records reconciliation, Study closure, updating the study team list or modifications

- Monthly PAM assessments may utilize this checklist

- Empower PIs to KEEP UP WITH COMPLIANCE by conducting an internal review annually or every 2-3 years
The Post Approval Monitoring Checklists are available for you to use at any point. You can complete the checklists after the first participant has been enrolled to ensure your research records are in compliance.
Resources & Guidance

Throughout the lifecycle of a research study, many regulations, policies, and standard operating procedures apply—from the initial submission, through continuing reviews and modifications, and finally to study closure. Our resources can provide navigation for the research community, as well as for IRB analysts and reviewers.

- It is important to always download these resources directly from the IRB website, instead of saving a personal copy or re-using from a previous study, to ensure you have current information since our resources may be updated at any time.

Definitions

- Protocol Templates & Forms
- Consent Templates & HIPAA Requirements
- Study Support Resources
- Recruitment Materials & Guidelines
- Policies & Guidance
Study Support Resources and Templates

The Northwestern University Institutional Review Board (IRB) provides a variety of resources to help investigators conduct compliant human participant research. The tools below were created to support investigators in properly organizing paper based or electronically retained regulatory documentation and research data.

Investigators are encouraged to maintain a real-time accounting of all study related documents and data. Investigators should have all regulatory and participant-related information properly documented, as it plays a crucial role in validating research results throughout the life of the study.

Not all documents in the table below will be applicable to all studies. All study support resources and templates are editable. The user is encouraged to make changes to the tools to suit the study specific needs.

<table>
<thead>
<tr>
<th>Activity/Process</th>
<th>Resources:</th>
<th>Instructions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment</td>
<td>Assent and Parental Permission Enrollment Log</td>
<td>Tracks participant enrollment in real-time (including screening and withdrawals).</td>
</tr>
<tr>
<td></td>
<td>Screening, Enrollment, &amp; Withdrawal Log</td>
<td></td>
</tr>
<tr>
<td>Delegation of Authority (DOA)</td>
<td>Biomedical Research DOA</td>
<td>Tracks the roles and responsibilities of study team members over time. With minor edits, you can also track training and CV/resume expiration dates.</td>
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<tr>
<td></td>
<td>Clinical Trial DOA</td>
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<tr>
<td></td>
<td>Social Behavioral Research DOA</td>
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<tr>
<td>Consent Process</td>
<td>Documentation of Consent Process Form (Word)</td>
<td>Documents the consent process for individual participants in real-time.</td>
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<tr>
<td></td>
<td>Consent Form Collection Alternative (Excel)</td>
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5 Key Takeaways

Set yourself up for success before the study starts, regularly check-in, and use the IRB Office resources to KEEP UP WITH COMPLIANCE

1. We are in this together!
   Familiarize yourself with the Compliance Roots:
   – Investigator Manual HRP-101
   – Human Research Resources, Policies, SOPs, & Guidance

2. Principal Investigator Responsibilities & Oversight
   – PI must provide the necessary oversight for all aspects of the study
   – Principal Investigator Responsibilities, Eligibility, and Permissions

3. Documentation!
   – Research Document Retention Requirements
   – Regulatory Binder / Research Record

4. Expect the Unexpected
   – Incident Assessment Tool and reporting timelines: Reportable New Information
   – Corrective and Preventive Action (CAPA) Plans
   – Protocol Deviation Log, Note To File

5. Use the IRB Office Resources: we are here to help!
   – Study Support Resources and Templates
   – SOPs
   – Recruitment Materials & Guidelines
   – Checklists & Worksheets: Find PAM Checklists here
Check Your Knowledge!
I am doing a department-funded survey/interview study.

What are the requirements that apply?
a. FDA
b. Common Rule
c. Institutional and ethical principles and guidance
d. All of the above
Why is Research Compliance Important?
a. Research is conducted in an ethical and responsible manner
b. Ensure researchers are following all applicable laws and regulations related to their research
c. Protects participants and institutions from risk and enhance safety
d. Maintain the integrity and credibility of research findings
e. All of the above
How do I close a study without an expiration date?
a. Wait for the IRB to close it administratively
b. Email the IRB office asking to close the study
c. Submit a continuing review application in eIRB+ for closure.
d. Take no action - if there is no expiration date the study does not need to be closed
Contact Us!

Contact Us

- Reach out! The IRB Office may be able to support your department and school through targeted education or resources. See the Education Page for the Training Request Form.

- IRBCompliance@northwestern.edu
- IRBTraining@northwestern.edu
Questions

IRBCompliance@northwestern.edu
Thank you