

How to Maintain Research Compliance During the Life of a Study

Presented by:
Priya Tripathi, MS
IRB Compliance Analyst

Today's Agenda

- What is Research Compliance?
- Why is Research Compliance Important?
- Regulations, Requirements, and Best Practices
- Study Support Resources and Templates
- Tips and Tricks for Maintaining Compliance
- Q&A

What is research compliance?

- As a researcher, you are expected to follow the federal, state, and university policies regarding the protection of human subjects
 - Compliance is measured by the adherence to these policies and procedures



Why is research compliance important?



- Protection of human subjects
- Required for audits and/or monitoring visits
- Maintenance of data integrity
- Ensures adherence to protocol

Regulations, Requirements, and Best Practices

- Federal regulations
 - Common Rule
 - FDA
- Clinical trials
 - ICH GCP
- State laws
 - Illinois Mental Health Confidentiality Act
 - Illinois Nursing Home Act
- Institutional policies
 - Retention policy
 - Research data
 - Investigator manual
- Best practices



Federal Regulations

- Common Rule ([45 CFR 46](#))
 - Outlines the criteria and mechanisms for IRB review of human subjects research
 - Revised Common Rule went into effect on January 21, 2018
 - Key changes include no continuing review for minimal risk research (MODS, RNIs still required)
 - “Key Information” section in consent form followed by “Detailed Information” to facilitate participant comprehension
- FDA regulations ([Title 21 CFR](#))
 - Regulations governing human subject protection and the conduct of clinical trials
 - Protection of Human Subjects (21 CFR 50)
 - Institutional Review Boards (21 CFR 56)
 - Investigational New Drug (21 CFR 312)
 - Investigational Device Exemptions (21 CFR 812)

Clinical Trial Requirements

- [ICH GCP](#) (International Conference on Harmonization Guidelines for Good Clinical Practice)
 - A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of **clinical trials**
- Essential documentation per GCP:
 - Investigator's Brochure
 - Protocol
 - Consent Form(s)
 - Recruitment Material
 - IRB Approvals
 - CVs (Qualifications)
- Essential documentation per GCP:
 - Normal Lab Reference Ranges
 - Lab Manual
 - Investigational Product Accountability (Shipping, Dispensing, & Return/Destruction)
 - Monitoring Reports

Most common format of regulatory binders

State Laws

- [Illinois Mental Health Confidentiality Act](#)
 - Protect the privacy of information relating to mental health care and developmental disabilities services
 - When collecting mental health information in research, the following is required:
 - A consent form expiration date
 - A witness signature

Thorough documentation of the consent process!

State Laws

- [Illinois Nursing Home Act](#)
 - Protect the rights of nursing home residents who may be vulnerable to exploitation, neglect or abuse
 - Research in nursing homes in the state of Illinois require additional state approvals
 - Research conducted in nursing homes outside the state of Illinois may also require additional approvals
 - Contact the IRB office for assistance and see HRP-103 Investigator Manual for additional information

Institutional Policies

- [Retention of University Records](#)
 - Records should be maintained for at least 3 years after the closure of a study, after which they should be appropriately destroyed or archived
- Research Data
 - Reasonable plans and procedures in place to maintain the confidentiality of the research data consistent with [NUI](#) policies and [Feinberg data security policies](#) (if applicable) *[info can be found on page 11 of current Investigator manual]*
- [Investigator Manual](#)
 - Designed to guide researchers through policies and procedures related to the conduct of human research that are specific to this institution
 - Can be found within the [Policies](#) tab of the IRB website

Best Practices

- Best practices are recommendations to maintain research compliance
 - Often they overlap with regulations and policies that may not be applicable to your research but would be beneficial to adhere to
 - Examples include: CV retention, delegation of authority (DOA) logs, enrollment logs, eligibility checklists, documentation of consent process form, etc.



Study Support Resources and Templates

- Tools 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 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
 - You are also encouraged to design/create forms that you find are needed (i.e. phone log)
- Can be found within the [Policies](#) tab of the IRB website

The screenshot shows the Northwestern University IRB website. The navigation bar at the top includes links for Home, About, eIRB+, Submission Process, Templates Forms & SOPs, Training & Education, Policies (circled in red), Panels, and Contact. Below the navigation bar, the 'NU Policies' section is visible, with a list of links: Writing an Effective Corrective Action Plan, Post-Approval Monitoring and For-Cause Audits, Regulatory Agencies, Research Ethics, and Study Support Resources and Templates (circled in red). The main content area displays the title 'Study Support Resources and Templates' and a brief description: '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.'

Study Support Resources and Templates

Enrollment

- Assent and Parental Permission Enrollment Log
- Screening, Enrollment, & Withdrawal Log

Tracks participant enrollment in real-time (including screening and withdrawals)

Study Support Resources and Templates

Delegation of Authority (DOA)

- Biomedical DOA Log
- Clinical Trial DOA Log
- Social Behavioral DOA Log

Tracks the roles and responsibilities of study team members over time. With minor edits, you can also track training and CV/resume expiration dates

Study Support Resources and Templates

Consent Process

- Documentation of Consent Process Form
- Consent Form Collection Alternative

Documents the consent process for individual participants in real-time

Study Support Resources and Templates

Participant Eligibility

- Biomedical Research Eligibility Checklist
- Social Behavioral Eligibility Checklist

Documents participant eligibility (whether they have been included or excluded appropriately)

Study Support Resources and Templates

Drug or Device

- Device Accountability Log
- Drug Accountability Log

Tracks study product dispositions and/or device utilization

Study Support Resources and Templates

Regulatory Binder or Research Record

- Regulatory Binder Checklist
- Research Record Components

Ensures complete regulatory files or research records. Essential documentation assists in the successful management of a protocol

Study Support Resources and Templates

Participant Documentation

- Participant Identifier Log
- Research Payment Log
- Visit Checklist

Stores participant identifiers, track in real-time participant payments, or documents an individual participant's study visit cycle

Study Support Resources and Templates

Protocol Adherence

- Protocol Deviation Log
- Note to File Template

Provides context, additional information, or justification for items that may need clarity within the record

Tips and Tricks for Maintaining Research Compliance



Strive for improving your processes.

- **DOCUMENTATION, DOCUMENTATION, DOCUMENTATION!**
- Don't wait until the study is already in progress or over – prepare before the study starts
- Become familiar with the requirements, policies, and regulations
- The research record/regulatory binder can be in paper form, electronic, or a mixture of both
 - Note: eIRB+ is **not** a valid source to serve as a research record/regulatory binder
- Update records in real time

Tips and Tricks for Maintaining Research Compliance

- Utilize resources that already exist – no need to reinvent the wheel
- Be consistent across your research portfolio
- If errors/discrepancies are noted, report them to the IRB if needed and correct as soon as possible
- Ask the IRB – we are here as a resource



Contact Information and Resources

- IRB Compliance: irbcompliance@northwestern.edu
- IRB Website: <https://irb.northwestern.edu/>
 - Within Policies tab of website:
 - [Writing an Effective Corrective Action Plan](#)
 - [Post-Approval Monitoring & For-Cause Audits](#)
 - [Study Support Resources and Templates](#)
 - [Investigator Manual](#)
 - Within Submission Process tab of website:
 - [Reportable New Information](#)
 - Within Templates, Forms, & SOPs tab of website:
 - [HRP-025 - SOP Directed Review Audits](#)
 - [HRP-028 - SOP Post-Approval Monitoring](#)
 - [HRP-427 - CHECKLIST Post Approval Monitoring: Clinical Trial](#)
 - [HRP-428 - CHECKLIST Post Approval Monitoring: Participant File](#)
 - [HRP-429 - CHECKLIST Post Approval Monitoring: Biomedical Research](#)
 - [HRP-430 - CHECKLIST Post Approval Monitoring: Social Behavioral Research](#)

