

What Is, Is Not, and Might Be... Human Research

Objectives

- Define the role of the Institutional Review Board (IRB) and discuss how the NU IRB evaluates the conduct of human research
- Identify what constitutes “Human Research” and "Engagement"
- Compare & contrast examples of human research determinations
 - Instrument construction, Quality Improvement, Program Evaluation, Secondary Data-analysis

The Role of the Northwestern IRB

IRB Role in Research

The primary mission of the IRB is the protection of humans who participate in research.....

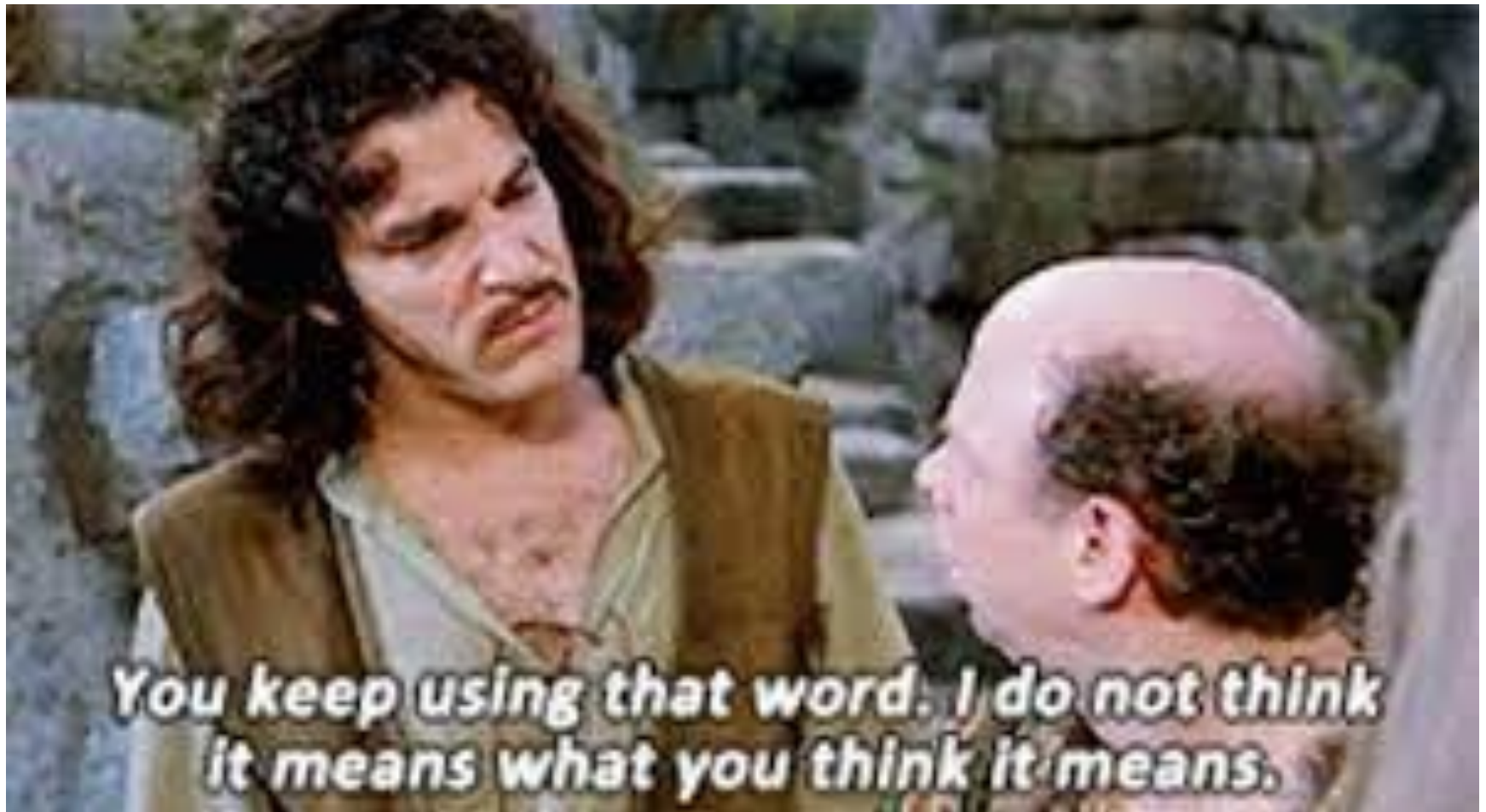
As part of that mission, the IRB:

- Establishes policies and procedures
- Monitors regulatory and institutional compliance
- Conducts independent review of research

Roles and Responsibilities



Dear IRB, I have a study that I think is exempt and I'm in a hurry. Since its not human research can you please expedite review?



IRB Oversight

Human Research?

- A systematic investigation intended to contribute to generalizable knowledge AND collecting information from & *about* people (e.g. via interaction/intervention or analysis of private identifiable data).
- [Human Research Determination](#) form available should you need/want IRB review and documentation.

Exempt

- Closed in the eIRB+ system once processed
- Minor modifications typically do not require further IRB review
- Changes in funding/PI require resubmission of the application

Expedited

- May be processed by a Designated Reviewer
- ALL modifications must be submitted to the IRB for review/approval
- Must be closed in the system once major milestones are complete

Convened Panel

- Greater than minimal risk
- Issues unresolved in Expedited Review
- Special Considerations
- Modifications, continuing reviews and study closure require review/approval

What constitutes Human Research?

Research

PART A: DETERMINATION OF “RESEARCH”

CFR 46.102(d): Research - a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.



...involve a systematic investigation?

- Involves a predetermined system, method, or plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing a theory.
- Includes collecting information or biospecimens and performing quantitative or qualitative analysis.

...designed to contribute to generalizable knowledge?

- Designed to draw general conclusions, inform policy, or generalize outcomes beyond the specific group, entity, or institution.
- Intent to publish in a peer-reviewed scientific journal is NOT a deciding factor.

Examples: NOT Generalizable

Program Evaluation, Quality Assurance and Quality Improvement Activities

When the purpose of the activity is to assess the success of an established program in achieving its objectives and the information will be used to provide feedback to improve the quality of a service, a program, a process.

Examples: QI/QA

Collecting provider or patient data for the purpose of evaluating program implementation, patient or provider satisfaction, or clinical effectiveness related to a practice



QI and HSR

Example: Implementation of an untested clinical intervention with the purpose of not only improving the quality of care but also collecting information to establish scientific evidence for how well the intervention achieves intended results.

IRB review and approval is required prior to the start of the project.



QI then HSR

Example: A surgeon implements a certain technique in their practice and tracks the results. The surgeon decides the results may benefit others, so they want to systematically analyze and generalize the outcomes.



Human Subjects

PART B: DETERMINATION OF "HUMAN SUBJECT"

CFR 46.102(f): Human subject - a living individual about whom an investigator (whether faculty, student, or staff) conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.



Interventions & Interactions

- **Intervention:** physical procedures by which information is gathered and manipulations of the subject or the subject's environment that are performed for research purposes.
 - Venipuncture, Educational Tools, therapeutic procedure or testing, completing puzzles, etc.
- **Interaction** includes communication or interpersonal contact between investigator and subject for research purposes.
 - Surveys, Interviews, interpersonal contact with participant to obtain research related info.

Identifiable Private Information

- **Private:** An individual can reasonably expect that no observation or recording is taking place and will not be made public
 - Medical Records, FERPA protected student data, comments made during an AA meeting
- **Identifiable:** Identity of the participant is/may be ascertained by the researcher and/or or associated with research information.
- **Coded data** are considered identifiable under the Common Rule.

Examples: Classroom based

- What to do when data collected while learning about research methods lead to a research question
- Program Evaluation and other assessments conducted to improve upon the class (e.g., intent is limited focus on one specific program/thing)



Examples: Secondary Use of Data

- Consider the original intent/purpose of the data collection
- Is the source public or private?
- Will NU have access to coded identifiers/key?



What does it mean to be Engaged?

An institution is considered engaged non-exempt human research when its employees or agents obtain (for the purposes of the research project):



- Informed Consent
- Data about the subject via intervention/interaction
- Access to private identifiable research information
- Recipient of an award/grant/contract/cooperative agreement directly from HHS
 - EVEN when all activities involving human subjects are carried out by employees/agents of another institution

Examples: HR, but NU not engaged

- Clinical trial taking place at another University, but NU is only involved in the analysis of de-identified data sets.
- Facilitating recruitment for a colleague (e.g. posting flyers, forwarding emails along, sharing a link to social media posts, etc.)
- NU PI provides general consult to colleagues from another institution (e.g. tips on study design, experience with use of specific instruments, etc.)

Human Research Scenario

- 4 year longitudinal study aiming to better understand the impacts of the COVID-19 pandemic on dating norms, with an added focus on refining standardized measures for remote locations.
 - Year 1 involves interviews with a community advisory board to validate and pilot the remote tool
 - Year 2-3 include interviewing and surveying participants (ages 15+) using various remote methods
 - Year 4 involves analysis of the final de-identified data set

How to Submit to the IRB

Training Pre-requisites

- Create an eIRB+ profile: <https://irb.northwestern.edu/submitting-to-the-irb/eirb/eirb+-registration.html>
- Northwestern offers three human subjects research (HSR) training options:
 1. Complete Northwestern basic or refresher training curriculum through CITI and allow 24 hours for training to sync with eIRB+:
<https://irb.northwestern.edu/compliance-education/human-research-protections-training/citi-training.html>
 2. If you previously completed HSR training through another entity, email irbtraining@northwestern.edu your transcript (CITI calls this a *Completion Report*), so we may verify requisites are met and update eIRB+
 3. If you do not have *and* will not obtain an NU NetID, complete one of three external training options and upload to applications' Supplemental Documents section: <https://irb.northwestern.edu/compliance-education/human-research-protections-training/training-options-external-collaborators.html>

NU IRB *only* accepts human research protections training; we do not accept GCP, RCR, or other non-HSR trainings.

Preparing the Application

- Know what you are trying to submit
 - Human Research Determination
 - Data/Specimen only Analysis
 - Research activities involving human participants
- Know what office will review your submission
- Use current IRB templates
 - Access templates directly from the IRB website
 - Read all instructional text and **delete** all instructions in the final protocol/consent templates
- Submit for IRB review via the **eIRB+** system
 - Single IRB planning: Know in advance if the plan is for NU to serve as IRB of record, or rely on another engaged site.



Protocol Tips

- Submit **one** protocol per application for review
 - A single study may have multiple conditions or phases, but a protocol should not describe “multiple studies” or “versions of studies”
- Provide specific details about the participants and how you plan to protect them
 - Go light on the background/literature review
- Detail which Aims/Phases you are submitting for approval
 - If not all phases and related materials are ready for approval, detail plans for modifying the study

Review Turnaround Time

Every project is reviewed on its own merit and when it enters the queue

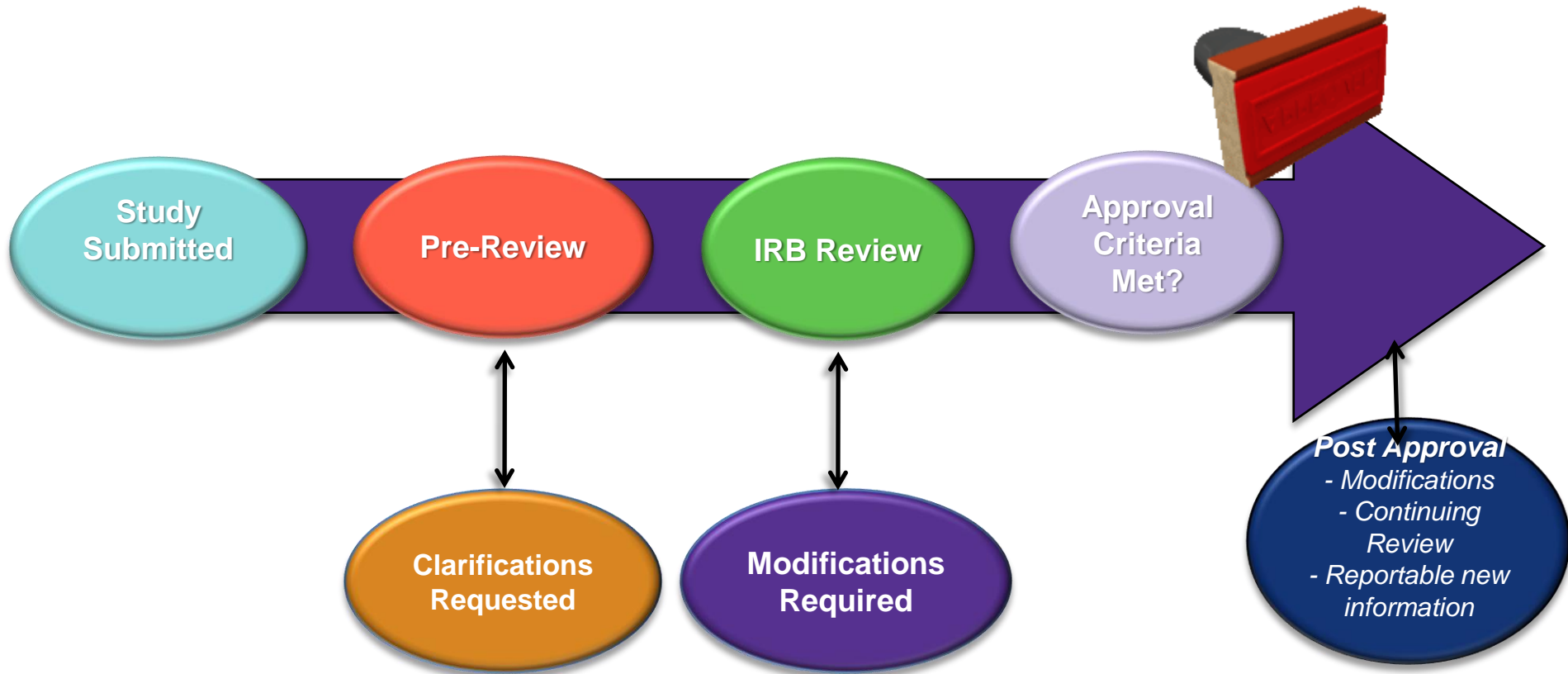


There are many factors that impact how long it takes for a study to get approved:

IRB work load/ Panel Assignments	Type of IRB review (e.g. Exempt, Expedited or Convened Panel)	Involvement of vulnerable populations	Procedures that require the use of a consultant	Submission quality	Conflict of Interest Office review	Reliance Agreements
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NU IRB Submission Process:

Completed through the eIRB+ system



Your study is approved... now what?!

- The Principal Investigator must **maintain compliant research documentation** through the life of the study, including but not limited to:
 - All IRB-approved versions of protocol and consent documents
 - All IRB-approved participant-facing materials (recruitment materials, participant brochures, etc.)
 - Copies of IRB approval letters
 - All email correspondence with IRB Office
 - Copies of current human participant training certificates for study personnel (CITI Training)
 - Documentation that contains research staff qualifications and delegation of responsibilities
- [Study Support Resources and Templates Page](#) contains helpful tools
 - [Regulatory Binder Checklist](#) & [Research Record Components](#)
 - Your organized research record may be electronically retained
 - The eIRB system does **not** serve as an electronic version of the research record
- Use the [Incident Assessment Tool \(HRP-1207\)](#) to document the event and [Corrective and Preventive Action \(CAPA\) Plan](#) and to determine whether to submit a Reportable New Information
- Promptly respond to any [Post-Approval Monitoring](#) requests from the IRB Office
- **Close out** the study in eIRB+ when ready for [closure](#)
- [Research Document Retention Requirements for Principal Investigators \(HRP-1914\)](#)
- Additional PI responsibilities:
 - [Principal Investigator Responsibilities, Eligibility, and Permissions Page](#)
 - [Investigator Manual \(HRP-103\)](#)

COMPLIANCE



Resources and Guidance

- Please visit our website for further guidance
 - [Templates and Forms](#) includes required protocol, consent, and supporting documents templates
 - [Human Research Determination Form \(HRP-503\)](#)
 - [SOPs](#), [Checklists](#), [Worksheets](#), [Policies](#), and [Guidance Documents](#) are also available
- Sign-up to attend virtual office hours
 - [Social Behavioral Hours](#)
 - [Reliance Hours](#)

Questions??



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