Learn More: Protecting Human Subjects Participating in Research and their Personal Privacy

+ NIH Clinical Trial & Common Rule Updates

RESEARCH ADMINISTRATION

November 2017

Learning Objectives

- Understand which federal regulations and policies affect research involving human subjects;

- Understand how research involving personal information may require IRB oversight;

- Understand how administrators can assist their investigators:

  - ✓ Prepare grant applications
  - ✓ IRB Protocols; Human Subjects Research Training
  - ✓ Authorization Agreements/Reliance Agreements
  - ✓ JIT/IRB Certifications
  - ✓ Good Clinical Practice Training

- How you can help facilitate the internal review processes.

Institutional Certifications and Assurances

- Northeastern University, as a grantee, provides at the time of proposal submission and throughout the life-cycle of an award certification and assurances that it is in full compliance with all relevant laws, rules and regulations.

- How each grantee implements its research management responsibilities varies but all grantees should include documented practices that address specific regulatory requirements.

- Some regulations required that the grantee monitor the covered activity; monitoring involves verification and tracking of compliance with a specific term or condition of the award.

Northeastern University
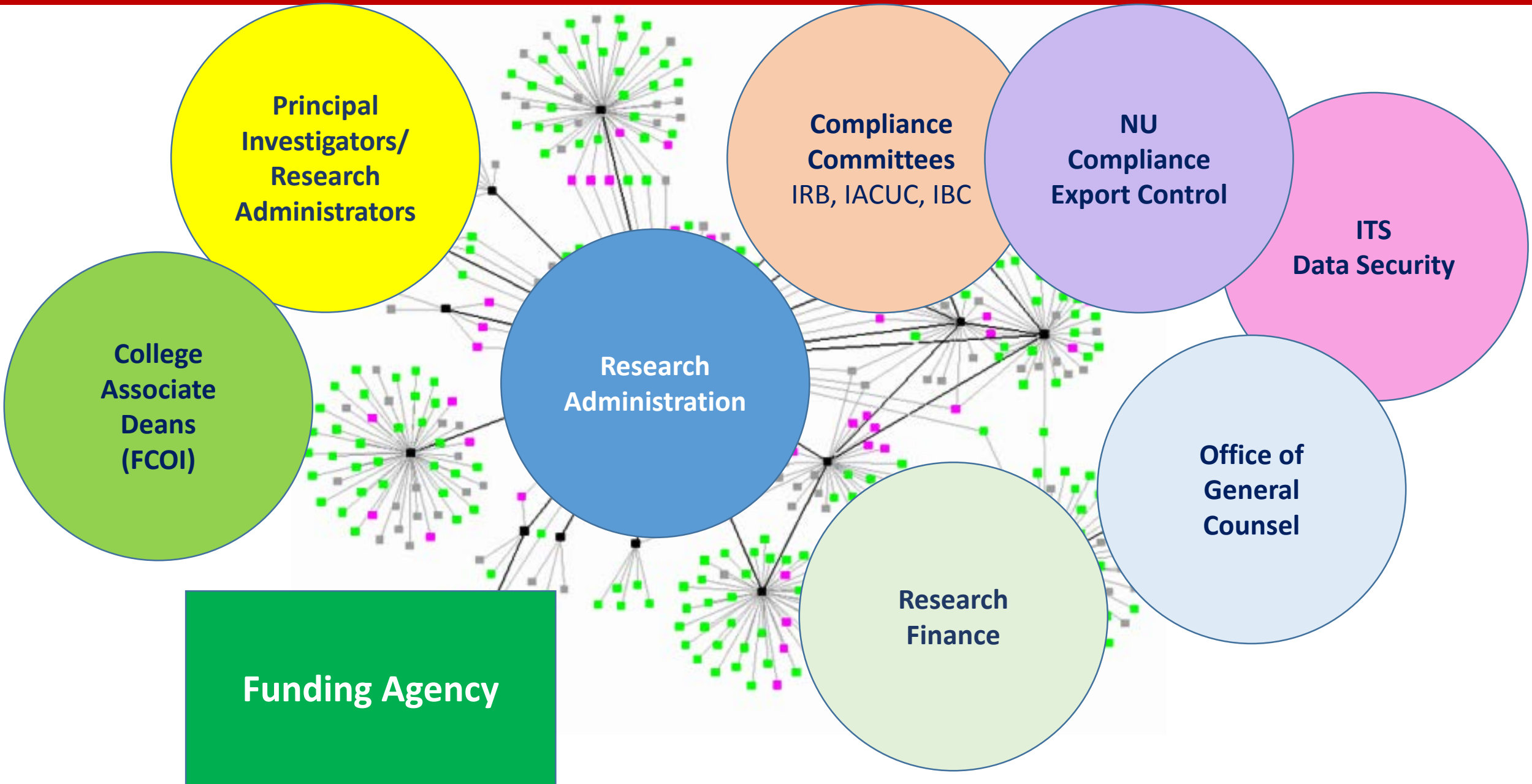
HUMAN SUBJECTS RESEARCH

- ✓ **Federal Wide Assurance & Institutional Review Board (IRB)**

- ✓ **Privacy:** Protected Health Information (PHI)/HIPAA; Personally Identifiable Information (PII)

- ✓ **Training: HSP and GCP**

- ✓ **IRB Certification of Research Awards**

- ✓ **Clinical Trials**

- ✓ *ClinicalTrials.gov*

- ✓ **Special Agency Requirements:** NIH Application Forms, DoD Agency Reviews
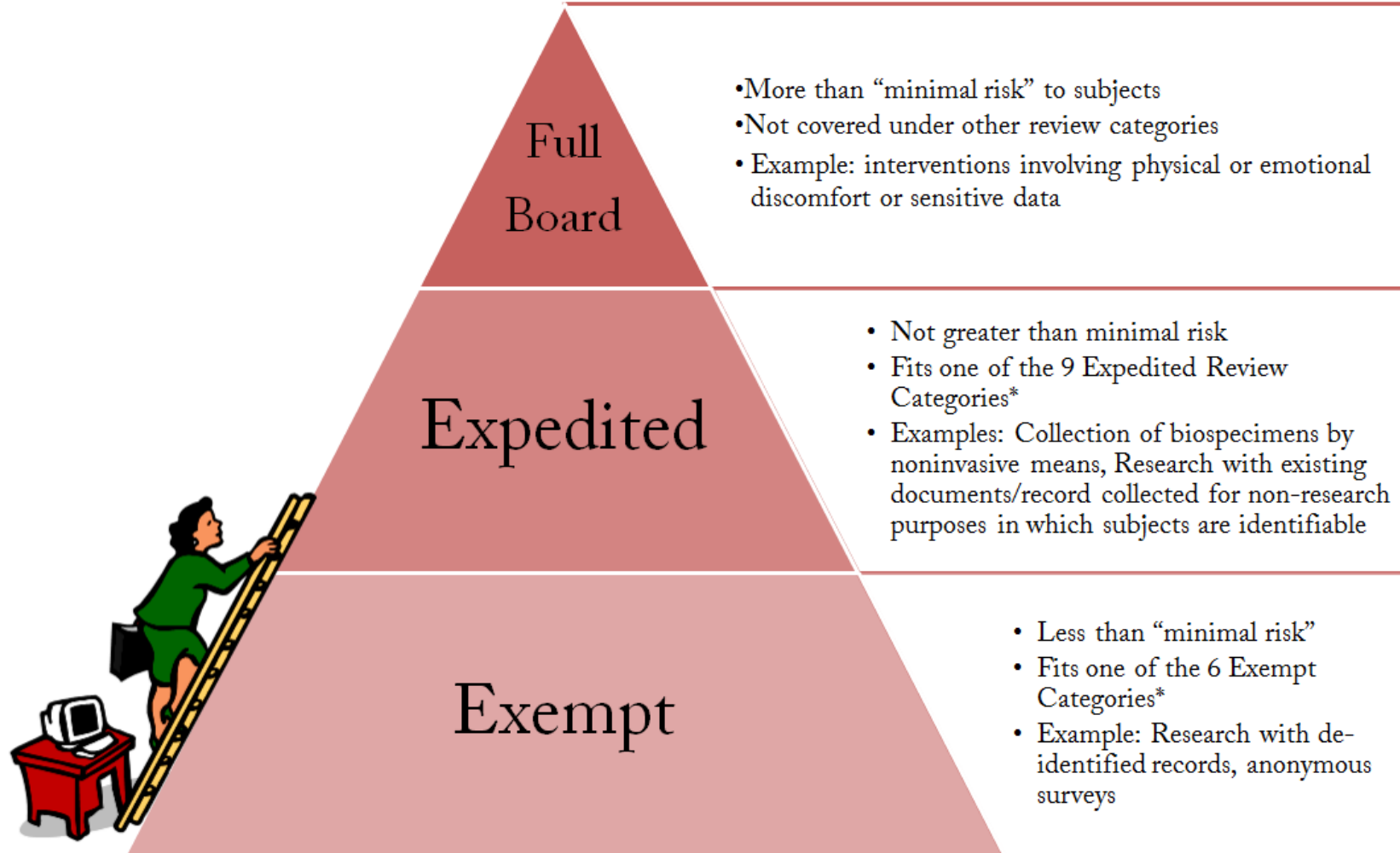
- ✓ **Restricted Awards**

45 CFR 46

The Common Rule

Human Subjects Research

- **Humans**

- **Human Biomaterials – tissue, blood, cells, etc.**

- **Data: PHI/PII**

Levels of IRB Review

Full Board
- More than "minimal risk" to subjects
- Not covered under other review categories
- Example: interventions involving physical or emotional discomfort or sensitive data

Expedited
- Not greater than minimal risk
- Fits one of the 9 Expedited Review Categories*
- Examples: Collection of biospecimens by noninvasive means, Research with existing documents/record collected for non-research purposes in which subjects are identifiable

Exempt
- Less than "minimal risk"
- Fits one of the 6 Exempt Categories*
- Example: Research with de-identified records, anonymous surveys

*Defined by federal regulation (45 CFR 46)

Human Subjects Protections Training

Federal Wide Assurance & IRB Certification

NU's FWA requires that the IRB review all research involving human subject regardless of source of funding (internal or extramural).

IRB Certification required for all funded research projects.   The IRB reviews the grant application and the protocol to certify that the work proposed is governed by an approved protocol.

IRB CERTIFICATION

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[ ] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
   by: [ ] Full IRB Review on (date of IRB meeting) _____ or
[ ] Expedited Review on (date)
            [ ] If less than one year approval, provide expiration date
_____
[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects
   covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

NIH and Clinical Research

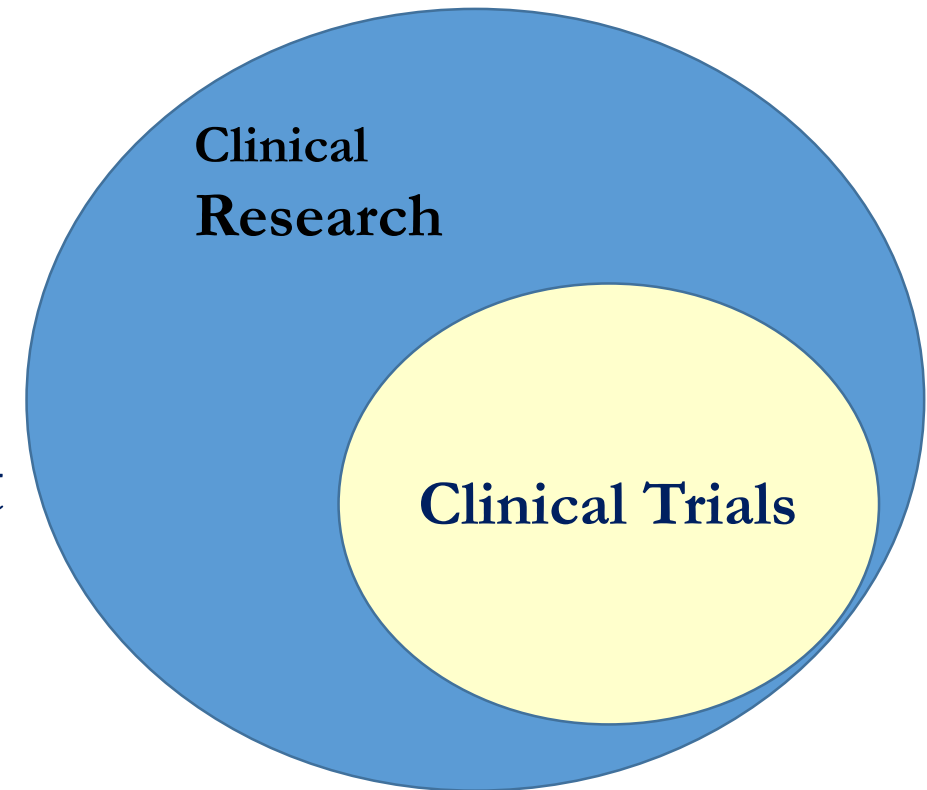https://grants.nih.gov/policy/clinical-trials.htm

Clinical Research … NIH Clinical Trials

Clinical Research includes all research involving human participants. It does not include secondary studies using existing biological specimens or data collected without identifiers or data that are publicly available.

Clinical **Research**

**Clinical Trials**

NIH Definition of a Clinical Trial

A research study in which one or more human subjects* are **prospectively** assigned to one or more **interventions** (which may include placebo or other control) to **evaluate** the effects of those interventions **on health-related biomedical or behavioral outcomes**.

NIH Clinical Trials

Prospectively Assigned: As related to the definition of a clinical trial, a pre-defined process (e.g., randomization) specified in an approved protocol that **stipulates the assignment of research subjects** (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

Intervention: As related to the definition of a clinical trial, a **manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes** and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.
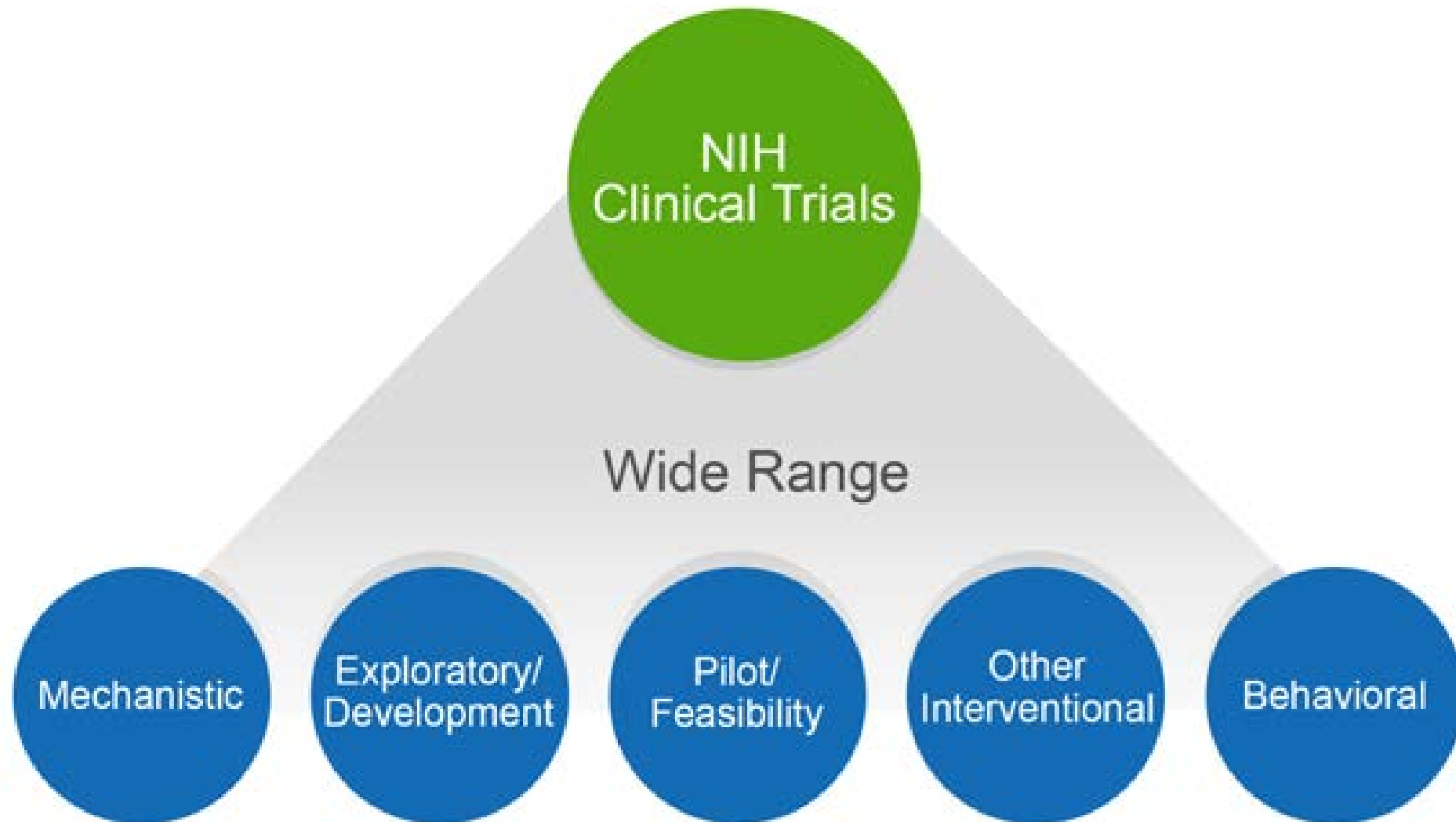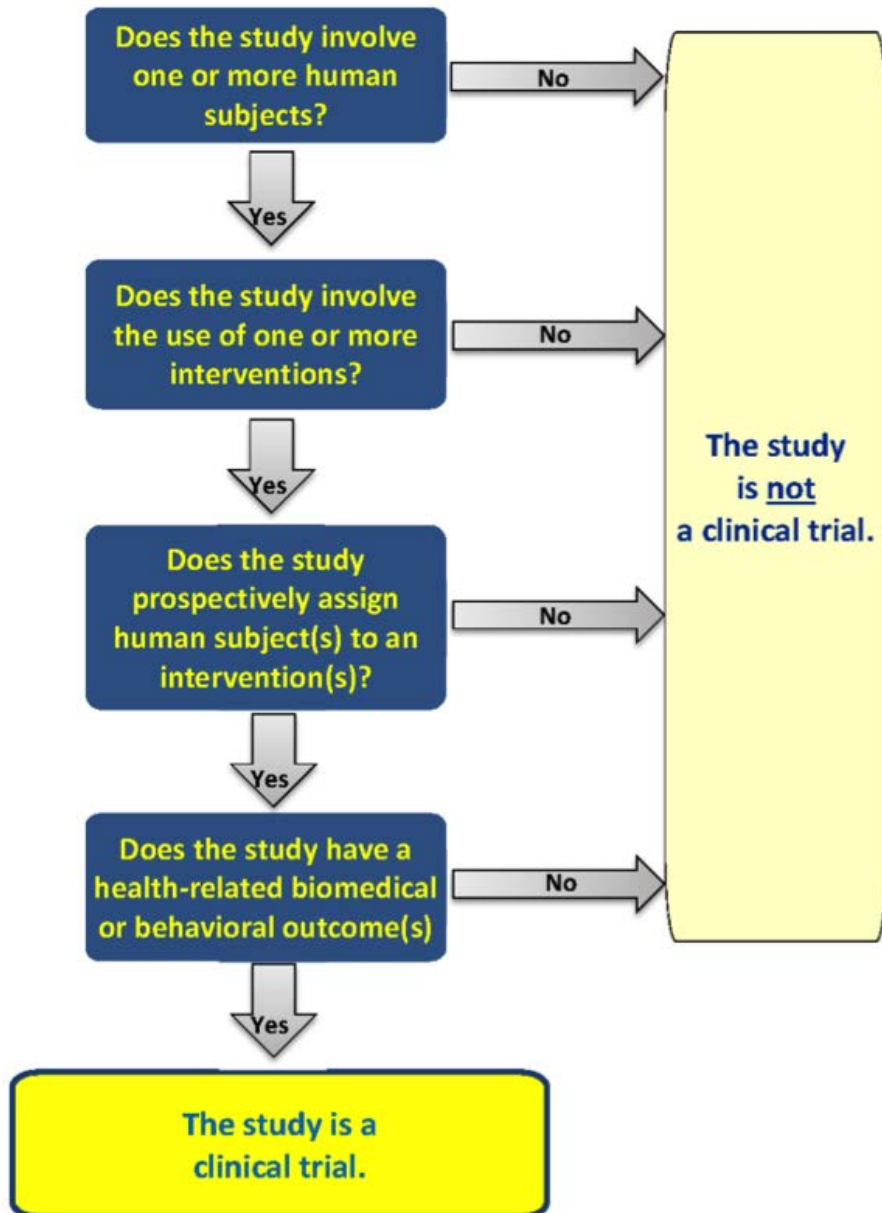
4 *?s* and Case Studies

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

https://grants.nih.gov/policy/clinical-trials/case-studies.htm

Still unclear if your research constitutes a NIH Clinical Trial? Each FOA lists scientific contacts.

E.g. Scientific/Research Contact(s) …Scientific/Research Contact information is listed on [R01 Clinical Trial Required IC-Specific Scientific Interests and Contact website](#).

Who Ya' Gonna' Call?

Program Director   Scientific Review Officer   Grants Specialist

NIH Applications Forms

https://grants.nih.gov/grants/guide/parent_announcements.htm

NIH Applications Forms
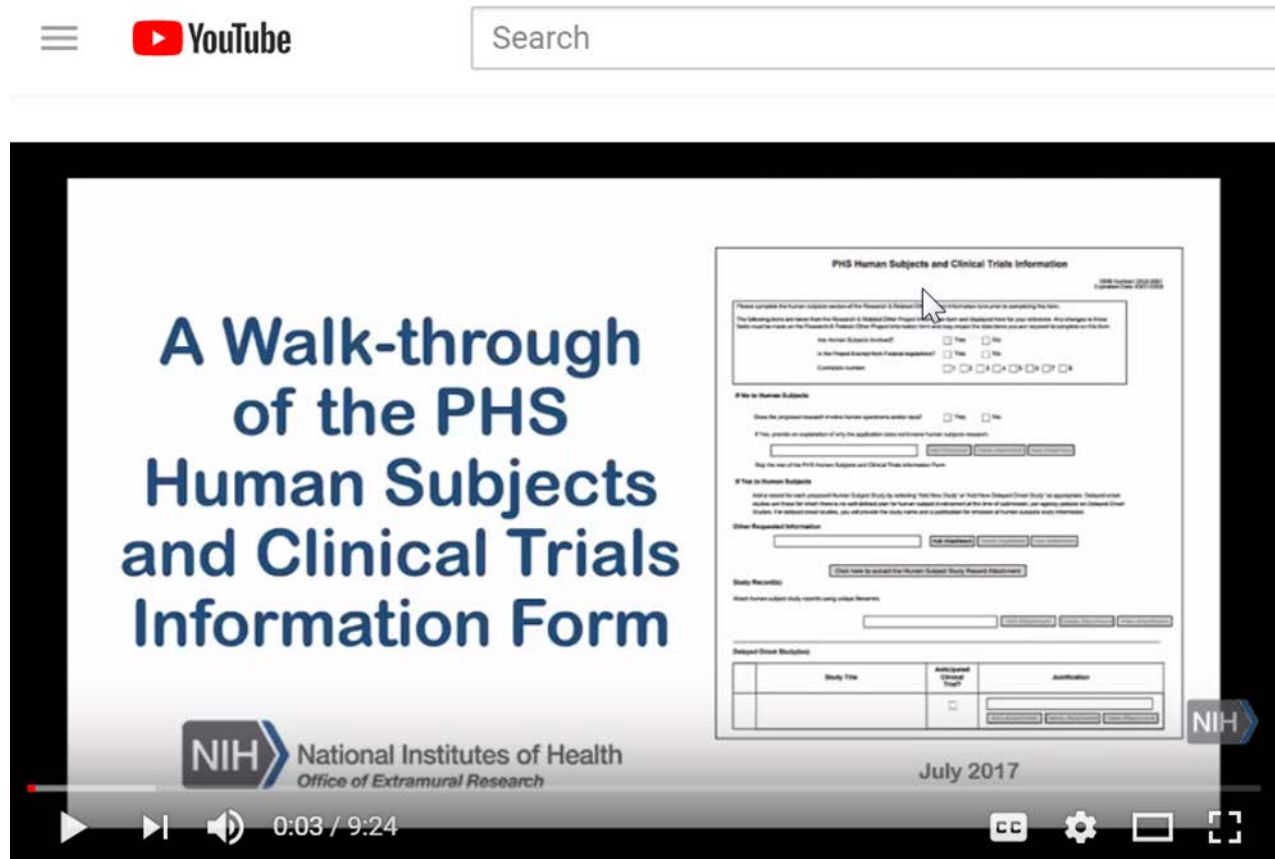
PHS Human Subjects and Clinical Trials Information Form Walk-through

https://www.youtube.com/watch?v=nz9NWFhYOG8

https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm

Single IRB for Multi-Site Research

Applicants will be expected to include a plan for the use of a sIRB in the grant applications and contract proposals they submit to the NIH (for due dates on or after January 25, 2018).

https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm

Northeastern University

Clinical Trial.gov

NIH U.S. National Library of Medicine

ClinicalTrials.gov

Find Studies ▾

ClinicalTrials.gov is a database of privately and
conducted around the world.

**Explore 259,039 research studies in
all 50 states and in 201 countries.**

ClinicalTrials.gov is a resource provided by the
U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has
been evaluated by the U.S. Federal Government.
Read our disclaimer for details.

Before participating in a study, talk to your health
care provider and learn about the risks and
potential benefits.

Good Clinical Practice Training

Effective January 1, 2017 – NIH expects all NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice (GCP).

Recipients of GCP training are expected to retain documentation of their training. GCP training should be refreshed at least every three years in order to stay up to date with regulations, standards, and guidelines.

https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm

Restricted Award Obligations

Changes to the Common Rule

FOR IMMEDIATE RELEASE
January 18, 2017

Contact: HHS Press Office
202-205-0143
ashmedia@hhs.gov

Final rule enhances protections for research participants, modernizes oversight system

Significant changes made in response to public comments

The U.S. Department of Health and Human Services and 15 other federal agencies today issued a final rule to update regulations that safeguard individuals who participate in research. Most provisions in the new rule will go into effect in 2018.

The new rule strengthens protections for people who volunteer to participate in research, while ensuring that the oversight system does not add inappropriate administrative burdens, particularly to low-risk research. It also allows more flexibility in keeping with today's dynamic research environment.

The current regulations, which have been in place since 1991, are often referred to as the "Common Rule." They were developed at a time when research was conducted predominantly at universities and medical institutions, and each study generally took place at a single site. Since then, research with human participants has grown in scale and become more diverse and data has become digital.

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html

Additional Resources

Contact Information for Investigators

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Boston, MA 02115

Please send CPS applications and correspondence via email to k.skophammer@northeastern.edu

Office Location
Human Subject Research Protection
177 Huntington, 560-177

(at the corner of Huntington Avenue and Belvidere Street)

Appointments and meetings must be confirmed ahead of time to be added to the building's login system

Thank you!