

**Learn More: Protecting Human
Subjects Participating in Research
and their Personal Privacy
+ NIH Clinical Trial & Common
Rule Updates**

RESEARCH ADMINISTRATION

November 2017

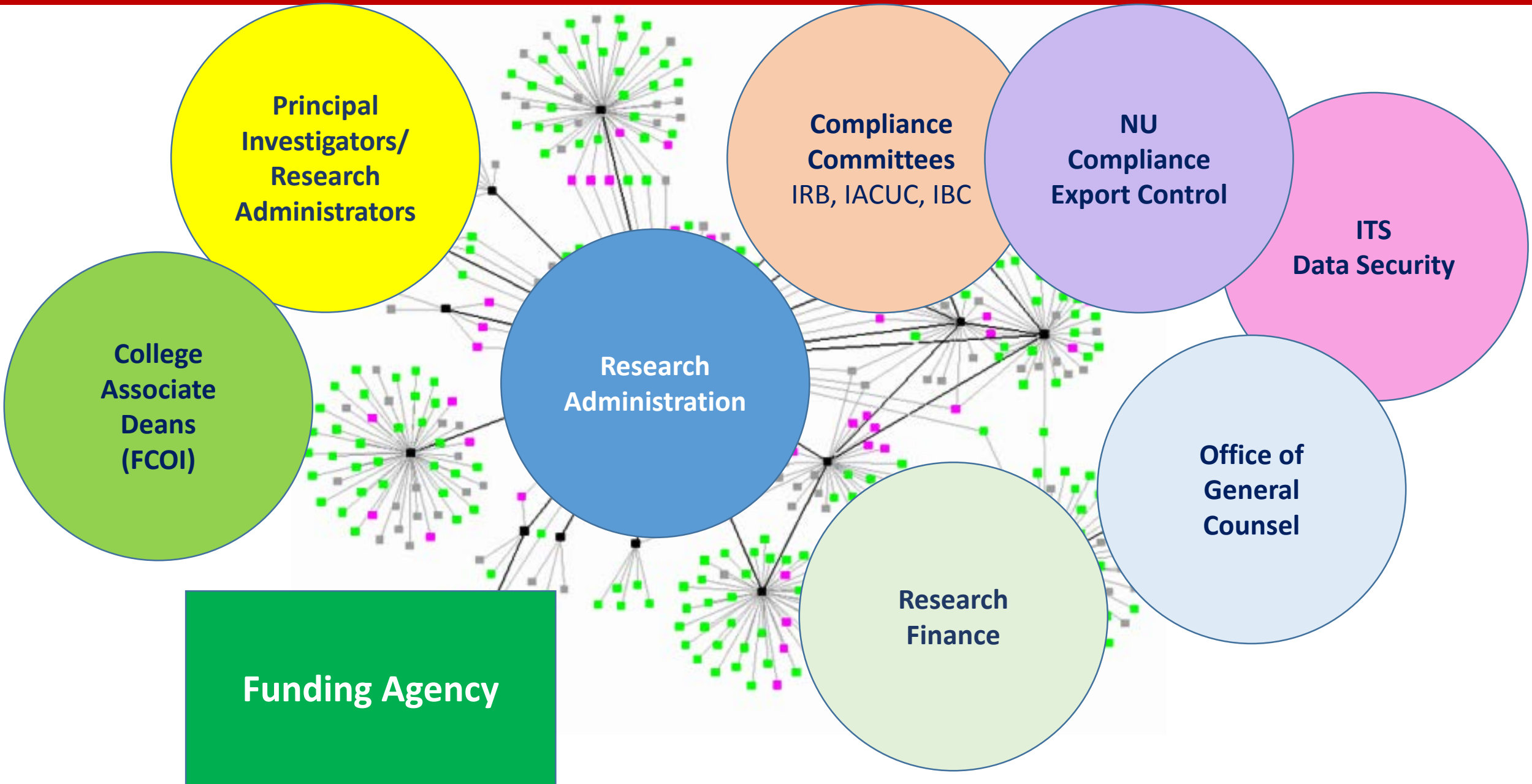
Learning Objectives

- 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

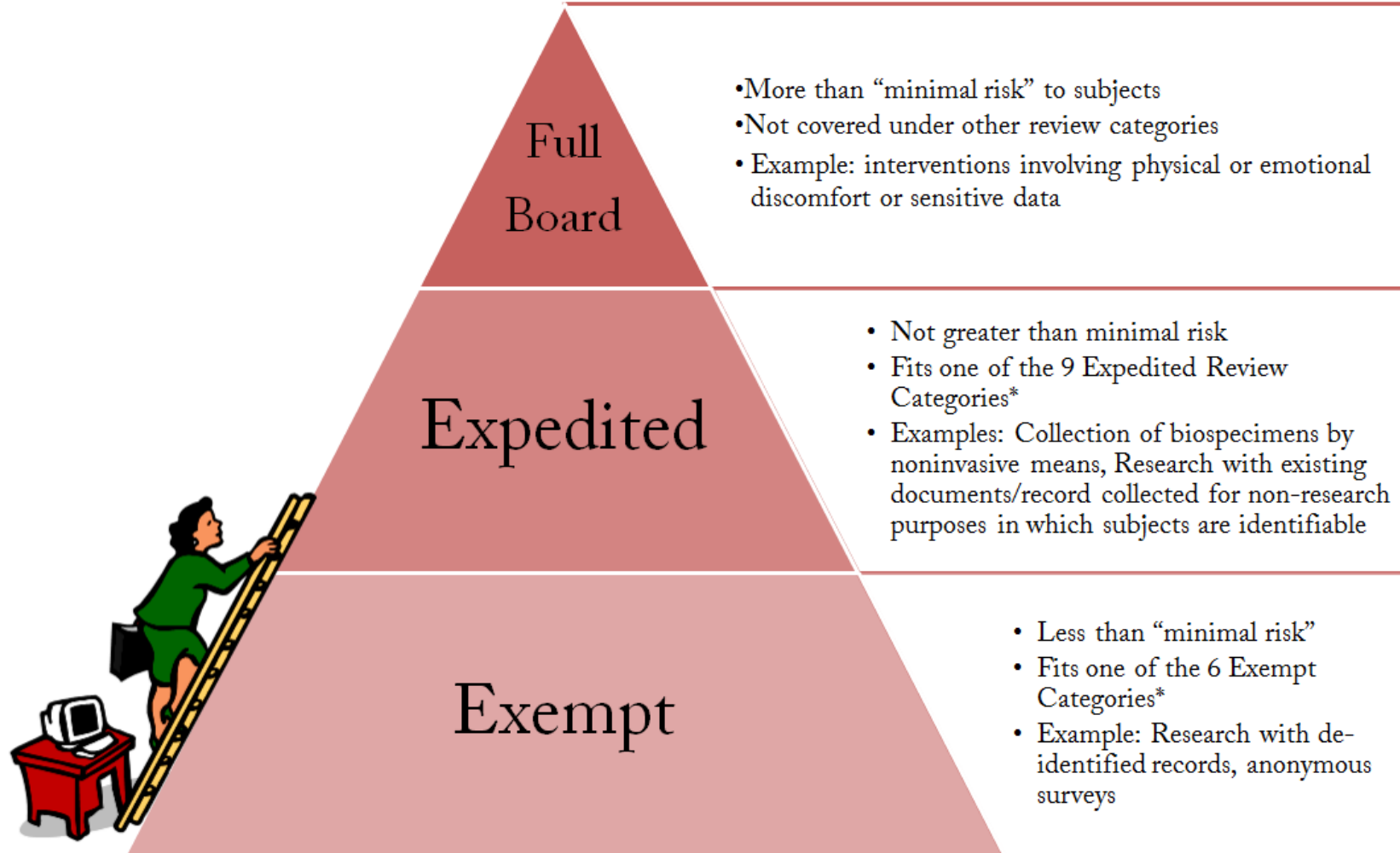
The Common Rule



Human Subjects Research

- **Humans**
- **Human Biomaterials – tissue, blood, cells, etc.**
- **Data: PHI/PII**


Levels of IRB Review



*Defined by federal regulation (45 CFR 46)

Human Subjects Protections Training

- Investigator
- Institution
- Peer Review
- Special Awards

 [Am I doing Human Subjects Research? Questionnaire](#)


Additional Resources

NIH Process for Applications that Propose Research Involving Human Subjects

Resources

- NIH Reports on Human Subjects Research
- NIH Forms and Applications

HS Home

A- A+ 

Resources

Human Subjects Protections Training

- [Frequently Asked Questions on Human Subjects Research - Requirement for Education](#)
- The NIH does not endorse any specific programs to fulfill the requirement for education on the protection of human subjects. NIH believes that institutions are in the best position to determine what programs are appropriate for fulfilling the education requirement. Institutions may require a particular program or may choose to develop a program to meet the requirement.

As a public service, the NIH Office of Extramural Research offers a free tutorial on [Protecting Human Research Participants](#) that institutions may elect to use to fulfill requirement for education in the protection of human subjects. A Spanish language version is also available: [Protección de los participantes humanos de la Investigación](#).

- [Other Trainings and Case Studies](#)
- [Inclusion of Women/Minorities](#)

Other Resources

- **Bioethics:**
 - [NIH Bioethics Resources on the Web](#)
 - [NLM Bioethics Web-Based Resource Page](#)
- **International Research:**
 - [The International Compilation of Human Subject Research Protections \(PDF - 1.15 MB\)](#)
- **NIH Guide for Grants and Contracts:**
 - [Funding Opportunities and Notices](#)

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

Clinical Trial Processes



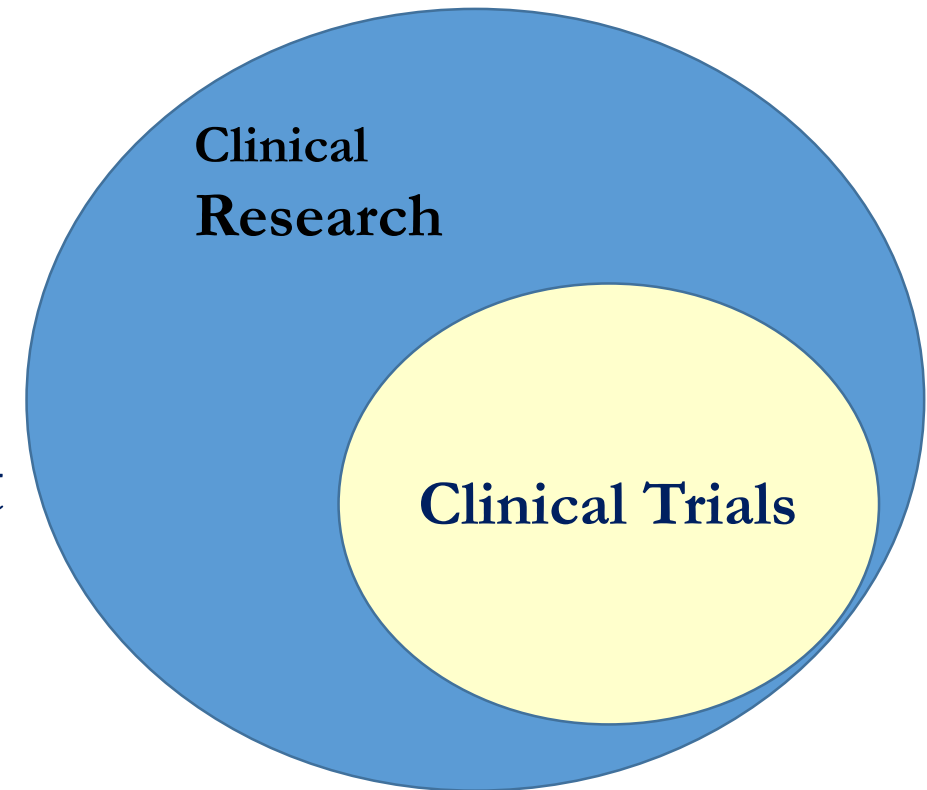
New NIH Reforms & their start dates



<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.



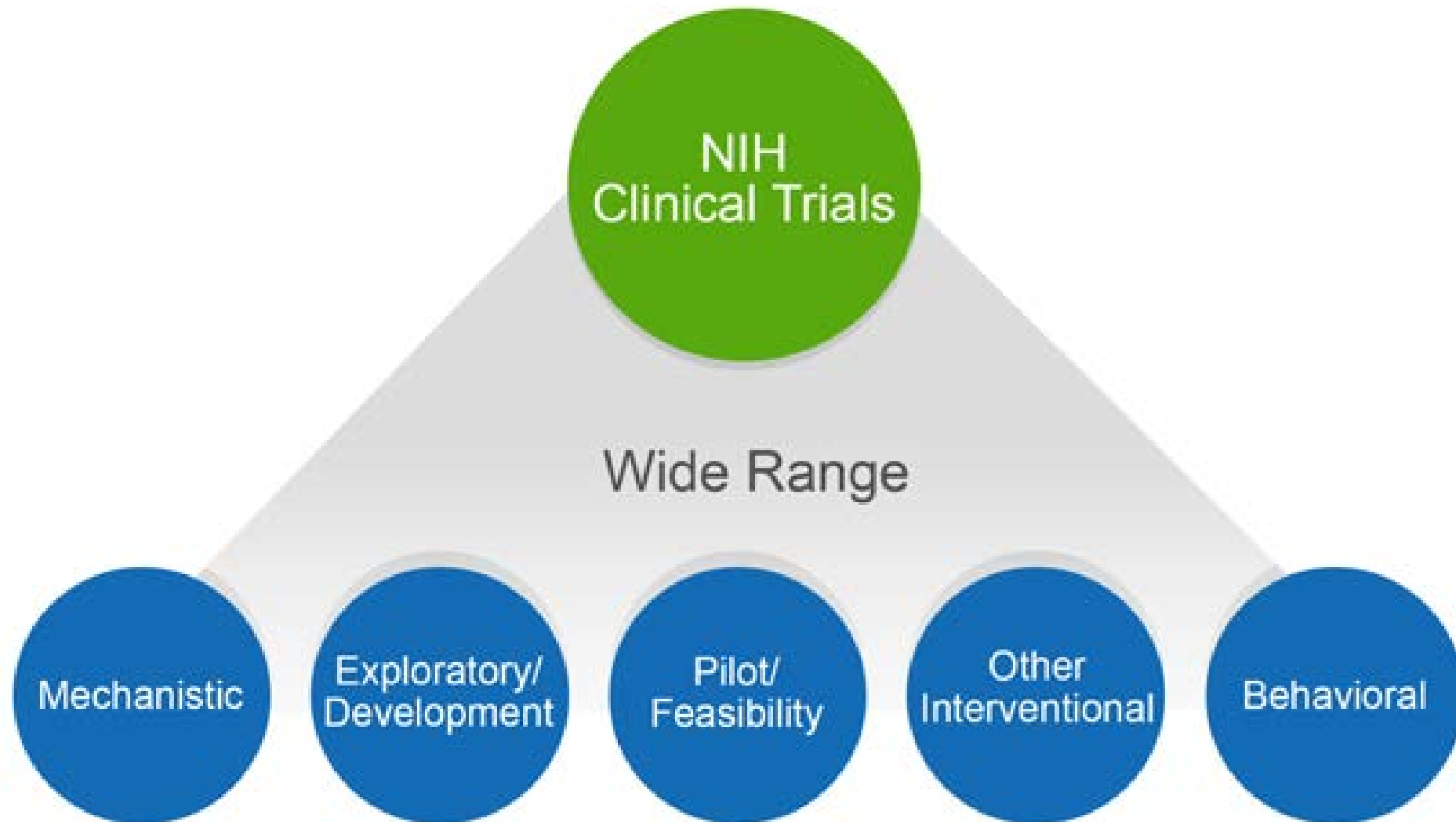
NIH Definition of a Clinical Trial

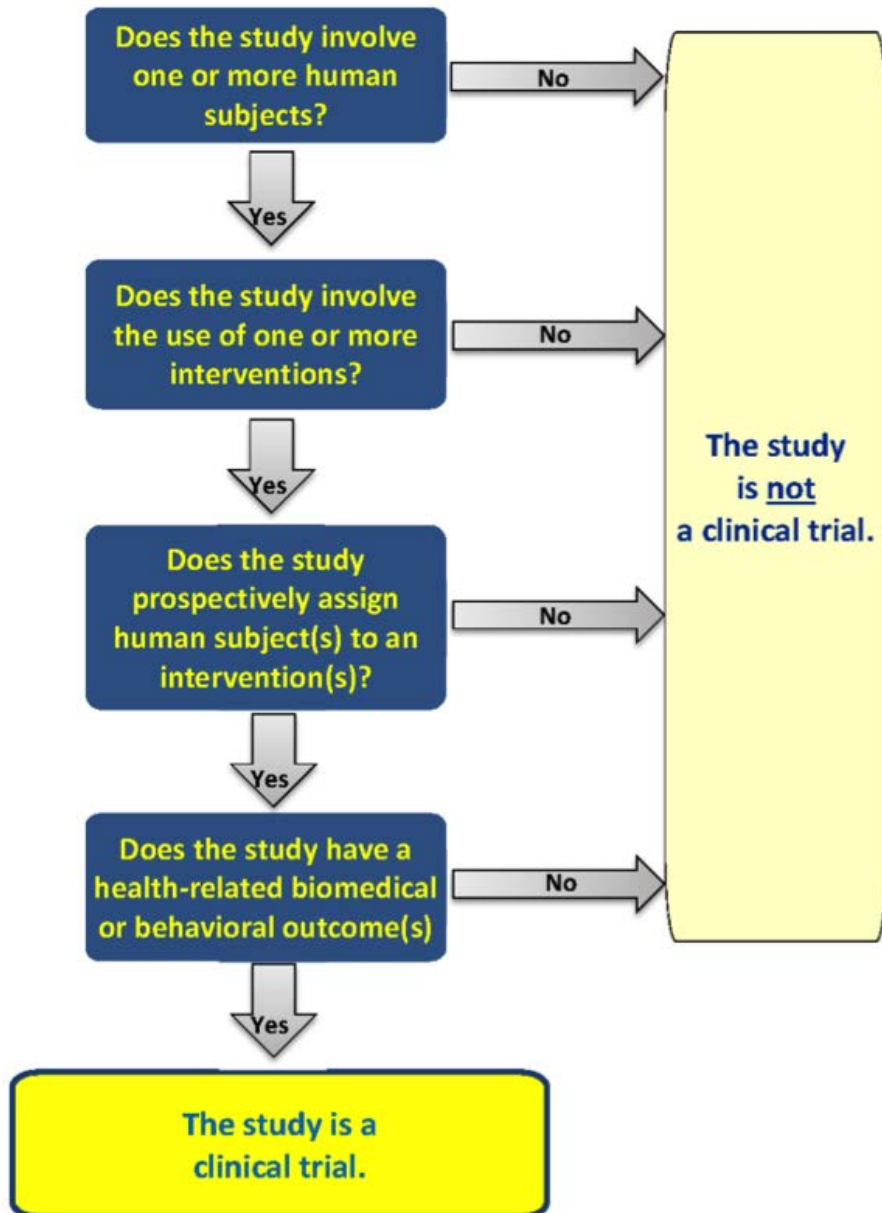
A research study in which one or more human subjects* are **prospectively** assigned to one or more **interventions** (which may include placebo or other control) to **evaluate** the effects of those interventions **on health-related biomedical or behavioral outcomes.**

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?

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



Home » Funding » Parent Announcements (For Unsolicited or Investigator-Initiated Applications)

Parent Announcements (For Unsolicited or Investigator-Initiated Applications)

Parent announcements are broad funding opportunity announcements allowing applicants to submit investigator-initiated applications for specific [activity codes](#). They are open for up to 3 years and use [standard due dates](#).

Not all NIH Institutes and Centers participate on all parent announcements. Before submitting your application, make sure the NIH Institute or Center that might be interested in your research is listed as a participating organization in the announcement.

The following **Parent Announcements are available** (sorted by Activity Code):

[[Research \(R\)](#) | [Research Training \(T\)](#) | [Career Development \(K\)](#) | [Fellowships \(F\)](#) | [Admin Supplements](#) | [Post-award Administrative Action](#)]

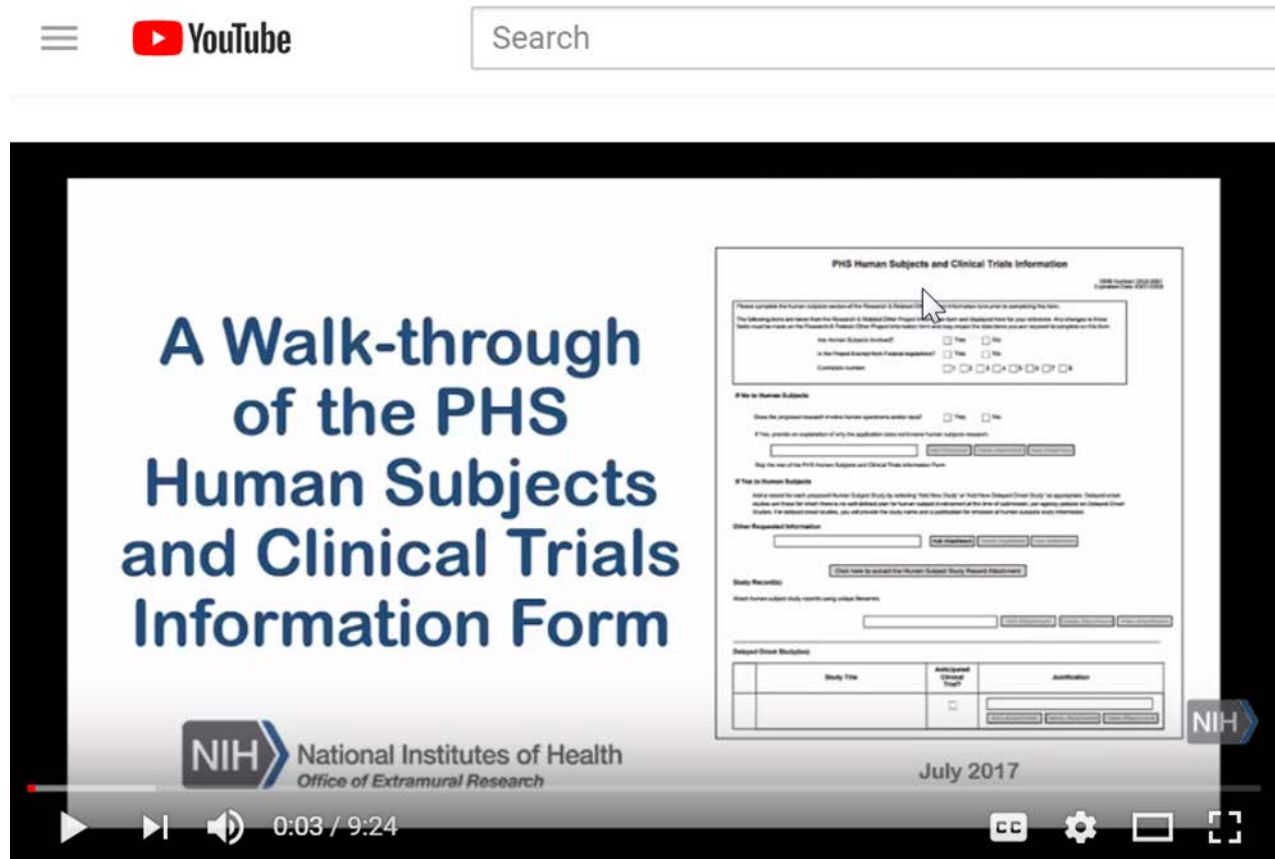
Research (R) Announcements

Activity Code(s)	Title	Announcement Number	Issuing Organization	Release Date	Opening Date (SF424 Only) ?	Expiration Date
R01	NIH Research Project Grant (Parent R01 Clinical Trial Required)	PA-18-345	NIH	11/03/2017	01/05/2018	01/08/2021
R01	NIH Research Project Grant (Parent R01)	PA-16-160	NIH	03/31/2016	05/05/2016	05/08/2019



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>

Clinical Trial.gov

NIH U.S. National Library of Medicine

ClinicalTrials.gov

Find Studies ▾

ClinicalTrials.gov is a database of privately and publicly conducted clinical trials 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

NU Office of Research Administration **AWARD OBLIGATION SETUP**

Award Overview

PI: [] Dept Admin: [] Institute Proposal (IP) #: [] Award Type: []

PI ID: [] Funding Agency: [] Banner Grant #: [] OMB Function Program Type: []

Dept: [] Prime Funding Agency: [] FAIN #: [] Activity: []

College: [] Funding Agency Award #: [] CFDA #: [] Total Project Award Period: []

Org Code: [] Start: [] End: []

Title: []

Obligated by This Action

Obligation Period:
 Start: [] End: [] Budget Period: [] F&A Calculation: []

Advanced Account Established G0000 [] Rate: [] TDC: []

Cost-Share Account Required Agreement Type: [] Base: [] F&A: []

Separate Sub/Child Account Required Total Award Cap/Limited Amount Obligated by this Action: []

Additional Information

Sub Award(s): [] Consultant/Investigator(s): []

Next Scientific Report Due: [] NCE Request Due: []

Future Recommended: []

Cumulative Amount to Date: []

Total Anticipated Award: []

Comments/Notes: []

RA Contact: [] To Research Finance: []

Projected NU Contribution to Research

Salary Cap: \$ []

Voluntary Committed Cost-Share: \$ []

Mandatory Committed Cost-Share: \$ []

Direct Cost Subtotal: \$ []

Under Recovery of F&A:

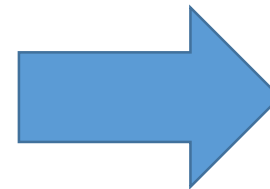
Voluntary: \$ []

Mandatory: \$ []

DC CS/Cap Related: []

Indirect Cost Subtotal: \$ []

Total: \$ []



Restrictions

- IRB/HSDf
 - PHI
 - HIPAA
 - IACUC
 - IBC
 - DURC
 - Automatic Carryforward
 - FCOI
 - RCR
 - E Verify
 - Proprietary
 - COI
 - International
 - Restricted
 - SCRO
 - Export Controls
 - Classified
 - sUAS
 - ClinicalTrials.gov
 - Pass-Through
 - Approvals in Backup
 - Federal Funds
 - Award Restrictions
- (See NOA for details)

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.

Additional Resources

Contact Information for Investigators

Nan Clark Regina, Director, HSRP
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HSRP
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Julia E. Helms, Coordinator, HSRP
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Contact Information for CPS Investigators

Kate Skophammer, IRB Coordinator, *College of Professional Studies*
Phone (617) 390-3450 | Email: k.skophammer@northeastern.edu

Mailing Address

Northeastern University
Human Subject Research Protection
360 Huntington Avenue, Mail Stop: 560-177
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!