

Learn More: Human Research Protections & IRB Updates

RESEARCH ENTERPRISE SERVICES
December 2018



Learning Objectives

- Quick overview of federal regulations and policies that protect human research subjects;
- Understand upcoming changes to the Common Rule, including how to identify studies involving human subjects; projects that are eligible for “self-determination” exemptions to 45 CFR 46 and when research requires additional reviews by the IRB or Privacy Officer;
- 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



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.



45 CFR 46

The Common Rule



Human Subjects Protections Training



Subscriptions ▾

Courses ▾

Resources

Support ▾

Register

Log In

Change from NIH Human Subjects Training

View All

CE Certified Courses

Animal Care and Use (ACU)

Bioethics

Biosafety and Biosecurity (BSS)



Clinical Research Coordinator
(CRC)

Clinical Trial Billing Compliance
(CTBC)

Human Subjects Research (HSR)

HSR provides foundational training in human subjects research and includes the historical development of human subject protections, ethical issues, and current regulatory and guidance information.

ORGANIZATIONS

LEARN MORE

LEARNERS

BUY NOW

Questions?
Contact Us



Human Subjects Research

Humans subject means a living individual about whom an investigator conducting research obtains information or biospecimens.

- **Data: PHI, PII**
- **Materials**
- **Secondary Data Use & Analysis**



Human Subjects Research

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.



Human Subjects Determination Form



Northeastern University

HUMAN SUBJECT RESEARCH PROTECTION OFFICE

<http://www.northeastern.edu/research/hscp>

HUMAN SUBJECT RESEARCH DETERMINATION FORM

Instructions: Only certain activities require review and approval by the Institutional Review Board (IRB). Because of funding, publication or other legal requirements a written determination that an activity is not "Human Subject Research" may be needed. The Human Subject Research Protection Office makes the determination as to whether an activity is Human Subject Research requiring IRB review and approval.

Please attach the grant application and, if available, notice of award. Please complete and sign this form and return it to: n.regina@northeastern.edu.

Principal Investigator: _____

Funding Agency: _____

1. Research: Research is defined as a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalized knowledge.

- | | | |
|--|----|-----|
| a. Is the planned activity a systematic investigation? | No | Yes |
| b. Is the activity designed to develop or contribute to generalizable knowledge? | No | Yes |

2. Human Subjects: Human subject means a living individual about whom an investigator conducting research.

- | | | |
|--|----|-----|
| a. Are living individuals participating in the study? | No | Yes |
| b. Does the activity gather data about the individuals participating in the study?
<small>(Note: if any information about the individual, for example, the individual's opinions, personal information, physical characteristics, etc., is obtained as part of the study select "Yes".)</small> | No | Yes |
| c. The information about the individual is obtained through intervention or interaction with the individual? | No | Yes |

3. Private, Personally Identifiable Information (Data): is information or data about an individual that an individual would reasonably expect to remain private or not be made public (e.g. sensitive information)

- | | | |
|--|----|-----|
| a. Are you gathering personally identifiable information? | No | Yes |
| b. If 3.a. is "yes", does the study collect or use Protected Health Information (PHI)? | No | Yes |

3.1. De-Identified Data

- | | | |
|--|----|-----|
| a. Are you using PHI data that has been de-identified? | No | Yes |
|--|----|-----|

4. Human Biospecimens:

- | | | |
|---|----|-----|
| a. Does the study involve the use of human materials (tissues, blood, cells, etc.)? | No | Yes |
| b. If 4.a. is "yes", are the biomaterials human stem cells? | No | Yes |
| c. If 4.a. is "yes", are the biospecimens from a commercial provider? | No | Yes |

Principal Investigator _____

Date _____



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.

**Effective Date:
January 21, 2019**



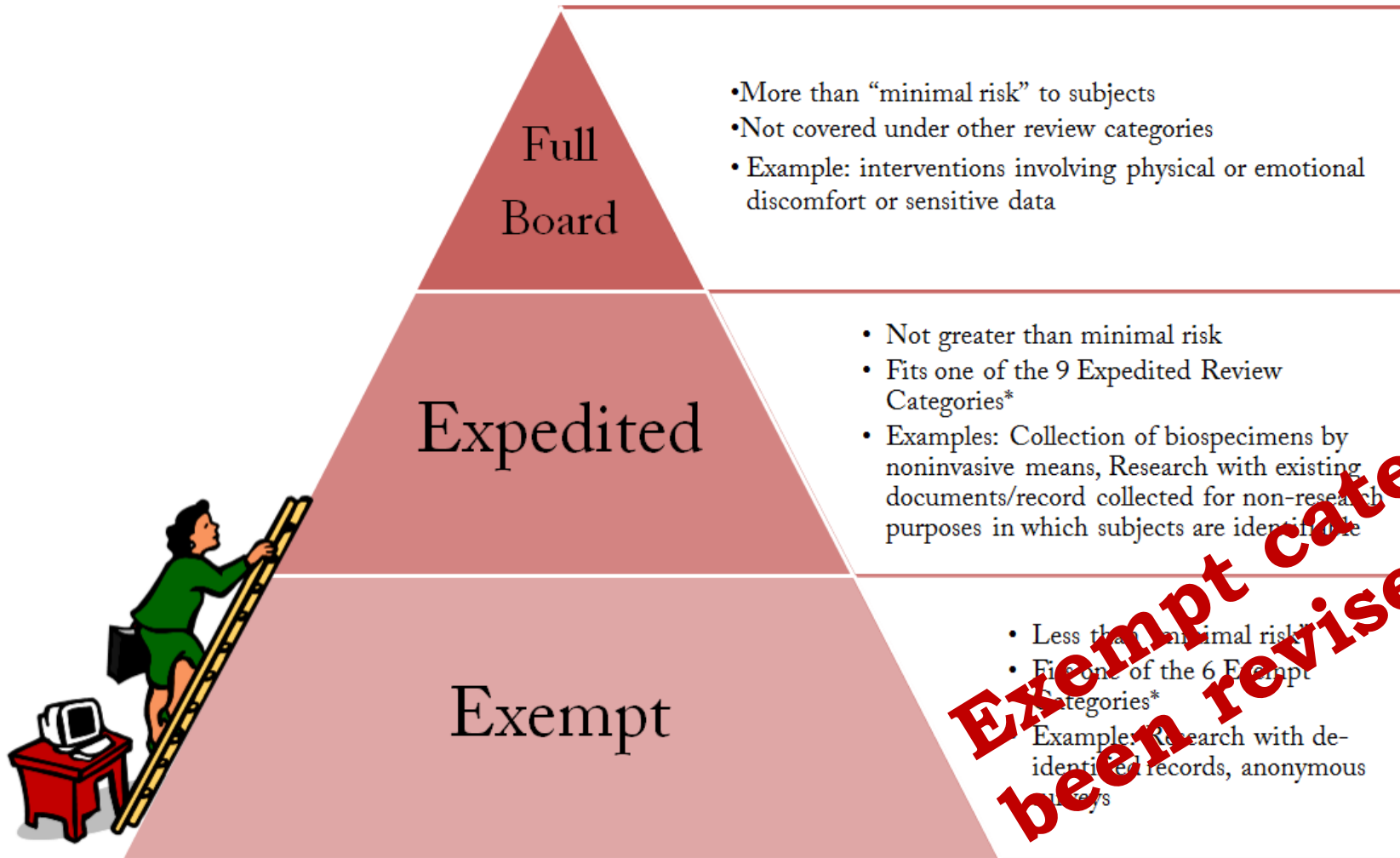
<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>

Changes to the Common Rule

- ✓ Continuing Reviews
- ✓ Exempt Categories - *Self Determination & Limited Reviews*
- ✓ Informed Consent
- ✓ Single IRB



Levels of IRB Review



Exempt categories have been revised and expanded!

*Defined by federal regulation (45 CFR 46)



Human Subjects Research

Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or test



Studies Exempt from 45 CFR 46.

Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories in paragraph (d) of this section are exempt from the requirements of this policy, except that such activities must comply with the requirements of this section and as specified in each category.

45 CFR 46.104(d)



Self Determination of Exempt Studies (IRB oversight) and Limited IRB Reviews

- ✓ Educational Studies
- ✓ Surveys, Interviews, Educational Tests & Observation of Public Behavior
- ✓ Benign Behavioral Interventions
- ✓ Secondary Research Projects
- ✓ Federal Demonstration Projects



Self Determination of Exempt Studies (IRB oversight) and Limited IRB Reviews



IRB Review

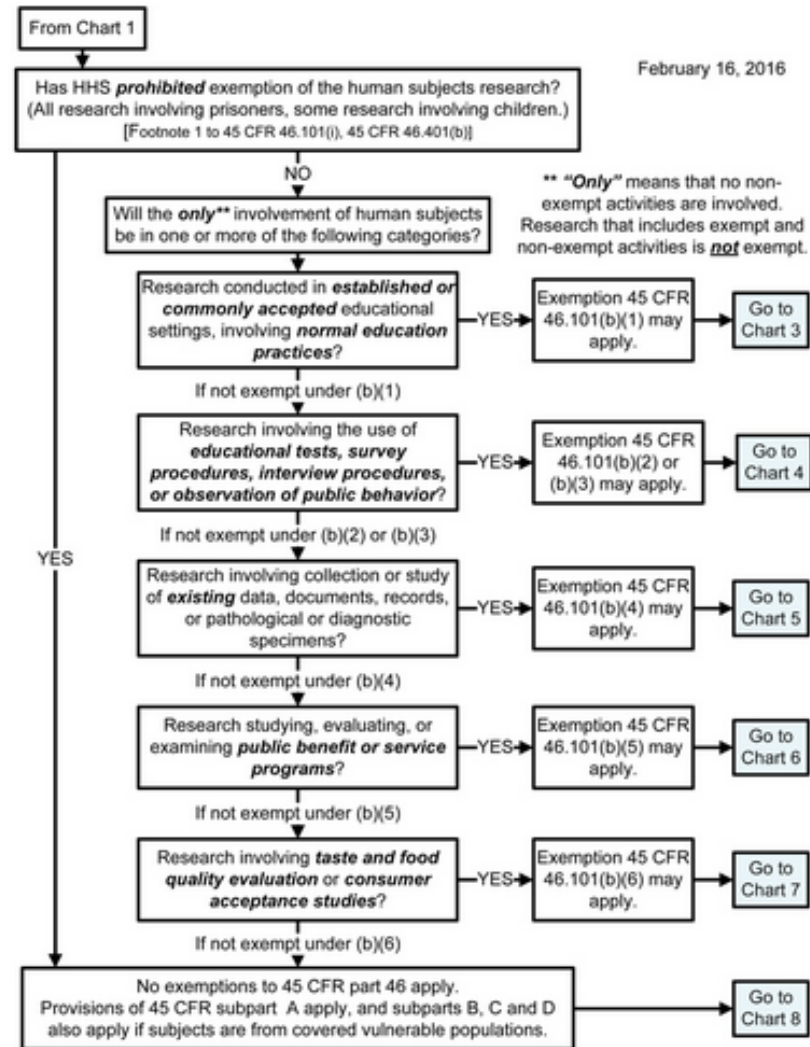
- ✓ **More than Minimal Risk**
- ✓ **At risk populations, e.g., minors**
- ✓ **Student Educational Records (FERPA)**
- ✓ **Involves sensitive data, PHI or PII**
- ✓ **Physiological Data Collection**
- ✓ **Deception**



Exempt Determination

Chart 2: Is the Human Subjects Research Eligible for Exemption?

[View text version of Chart 2](#)



<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html>



NU-RES Oversight & Procedure – Self Determined Exempt Studies

- 1. Investigator Completes Self-Determination Form**
- 2. Submits to the IRB**
- 3. IRB Provides Concurrence or Requests Additional Information for a Limited, Expedited or Full Review**
- 4. For all sponsored research projects, a copy of the self-determination IRB Form is maintained with the award record.**



Federal Wide Assurance & IRB Certification

FWA requires IRB of 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)

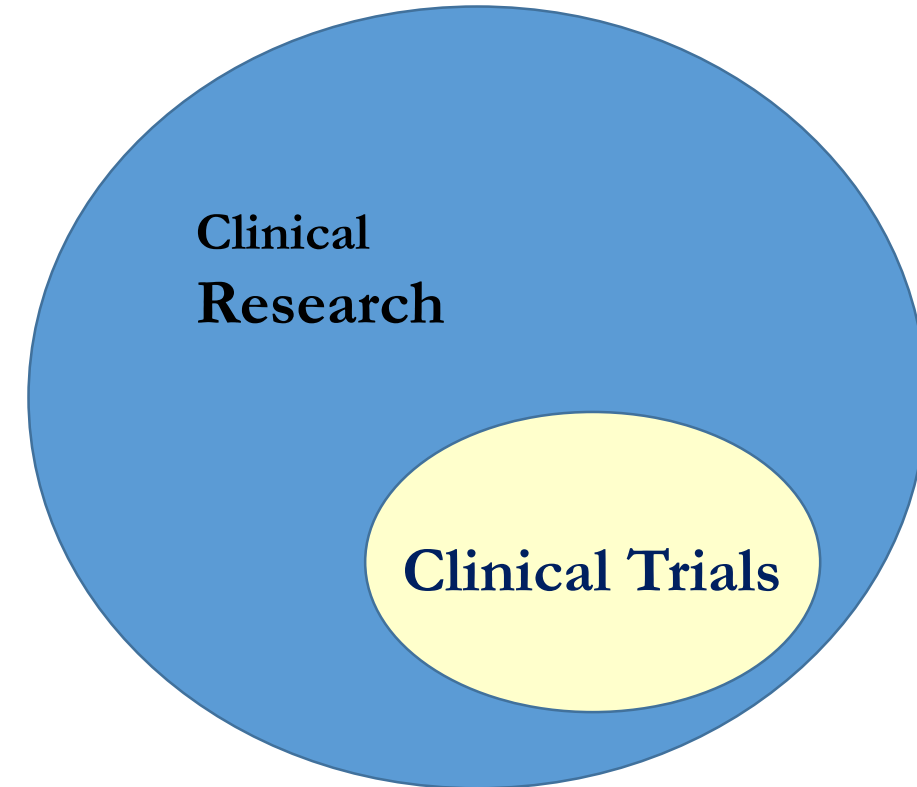
If less than one year approval, provide expiration date

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.



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**.



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](#).



TEST YOUR KNOWLEDGE: HUMAN SUBJECTS RESEARCH

- ✓ **Federal Wide Assurance & Institutional Review Board (IRB)**
- ✓ **Privacy: Protected Health Information (PHI)/HIPAA; Personally Identifiable Information (PII)**
- ✓ **Training: HSP and GCP**
- ✓ **Common Rule Changes**
- ✓ **Exempt ?**
- ✓ **IRB Certification of Research Awards**
- ✓ **Clinical Trials; *ClinicalTrials.gov*;**



Additional Resources

Contact

Research Home ▸ Human Subject Research Protection ▸ Contact

Contact Information for Investigators

Nan Clark Regina, Director, HSRP
Phone (617) 373-4588 | Fax (617) 373-4595 | Email:
n.regina@northeastern.edu

Andrea B. Goldstein, Coordinator,
HSRP
Phone (617) 373-7570 | Fax (617) 373-4595 | Email:
an.goldstein@northeastern.edu

Mailing Address*:
Northeastern University
Human Subject Research Protection
360 Huntington Avenue, Mail Stop: 560-177
Boston, MA 02115

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

(at the corner of Huntington Avenue and Belvidere Street)

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

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

Contact Information for CPS Investigators

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

Contact Information for Research Participants

If you have any questions about your rights as a research participant, please contact HSRP at the mailing address above, via telephone: (617) 373-4588 or via email: n.regina@northeastern.edu. You may call anonymously if you wish.

For a list of questions to consider asking before volunteering to participate as a research subject, please visit the U.S. Dept. of Health & Human Services Office for Human Research Protections [public outreach web site](#). To learn more, you can visit their "[About Research Participation](#)" page.