IRB 101 for Research Administrators

research.northeastern.edu/research-compliance

Please post questions in the chat. They will be addressed at the end.

Overview + Definitions

Mission of the DHR

Promote a culture of safe and ethical research in a compliant environment.

Partner with investigators and our research community.

Provide administrative support to the Institutional Review Board.

Promote: AY 24-25

Promote a culture of safe and ethical research in a compliant environment by implementing:

- Internal **quality assurance and improvement**: To ensure the ongoing success of the NU research enterprise.
- **Post-approval monitoring**: Random and for-cause audits beginning with PI self-assessment checklist

Partner: AY 24-25

Partner with investigators and our research community by implementing:

- A comprehensive **eIRB** system
- A quarterly **newsletter** with updates and new initiatives
- **Website** facelift to be user-friendly and intuitive focusing on written documents, flow charts, videos…
- Frequent **office hours** and **education series**

Provide: AY 24-25

Provide administrative support to the Institutional Review Board by:

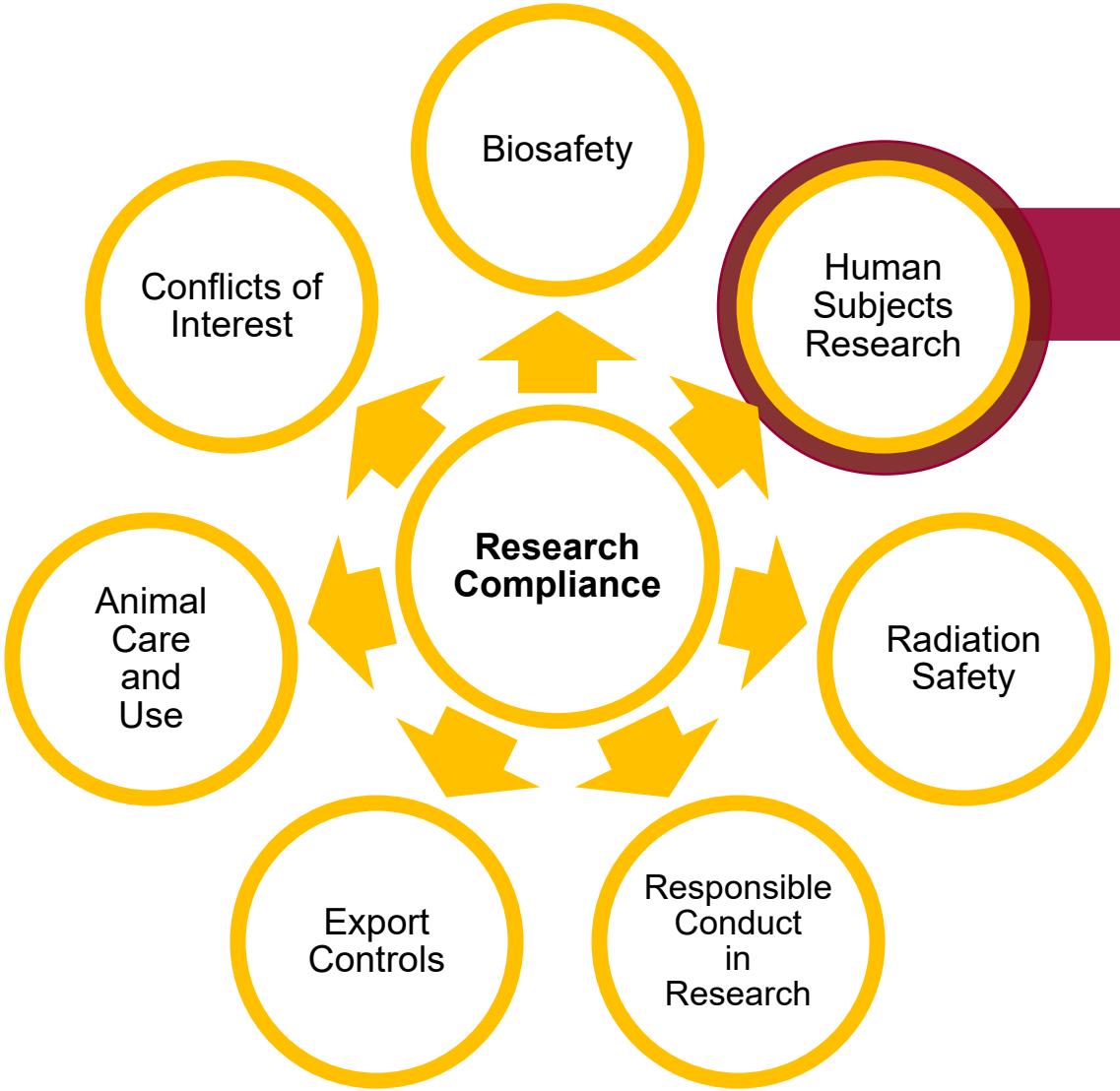
- Developing easy to use and regulatory compliant **resources** (checklists, templates, workflows, forms)
- Providing **specialized support** for high-user departments and colleges.
- Supporting IRB panel expertise by identifying **new board members** to better reflect a dynamic and evolving research portfolio.

Erik Williams, CIP

- Senior Coordinator
- er.williams@northeastern.edu

- Previous IRB experience at:

Overview – NU-RES Compliance Areas



Department of Human Research + IRB

The DHR supports the IRB in reviewing **Human Subjects Research** *or* **Clinical Investigations** to document and ensure that the activities are conducted ethically and in accordance with relevant regulatory criteria

NU Regulatory Stakeholders: DHR vs IRB

DHR

Department of Human Research (DHR) is a broader program that encompasses all aspects of human subjects research protection. It includes policies, procedures, training, post-approval monitoring, and administrative support to the IRB to ensure the ethical and responsible conduct of research.

&

IRB

Institutional Review Board (IRB) is a committee that reviews and approves research proposals to ensure the safety, rights, and welfare of the participants. It is one component of the DHR and focuses on a narrower scope of work and oversight.

IRB – who is on it and how are reviews conducted?

- Composed of faculty from across the campus and DHR staff.
- Current chair: Professor Derek Isaacowitz, Psychology
- Diverse IRB membership & expertise requirements
- Reviews are conducted by **individual members** or by **full board** meeting + vote (depending on risk)
- Core regulatory agency: ORHP under DHHS
- Other regulatory agencies (study dependent): FDA, DoJ, DoD, EPA, NSF, Department of the VA, others

Key Definitions: Defining Our Scope

What is Human Subjects Research[1]?

Research

"a **systematic** investigation, including research development, testing and evaluation, **designed** to develop or contribute to **generalizable** knowledge"

&

Human Subject

"a living individual about whom an investigator conducting research obtains data through **intervention** or **interaction** with the individual or **identifiable private information**"

1. FDA regulations have a different definition.

What is an FDA regulated Clinical Investigation of a Drug or Device[1]?

Drugs

Activities involving the administration of drugs, supplements, biologics, or similar substances to human subjects, excluding the use of marketed drugs in medical practice, require discussion with the IRB.

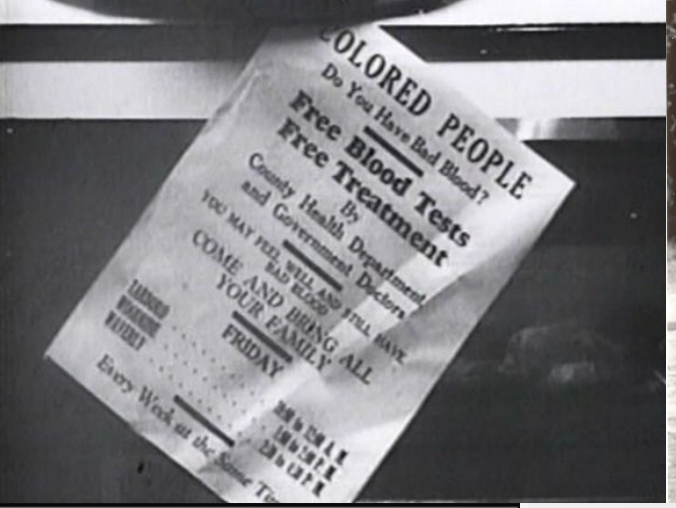
or

Devices

"Device" encompasses a wide range, including custom footwear, mobile apps, algorithms, or household products (such as a ladder, a Fitbit, etc.). A clinical investigation involves evaluating the safety or efficacy of any device in diagnosing, treating, or mitigating a disease or condition.

1. These are not official definitions.

History of Human Rights Violations in Research



The New York Times

Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER
The Associated Press

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

The study was conducted to determine from autopsies what the disease does to the human body.

Officials of the health service who initiated the experiment have long since retired. Current officials, who say they have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

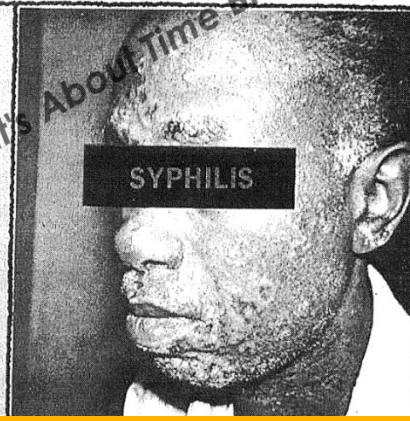
Dr. Merlin K. DuVal, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1932 with about 600 black men,

GERM WARFARE DECLARED AGAINST BLACKS!

HUNDREDS OF BLACK MEN DISCOVERED MASSACRED IN SYPHILIS "EXPERIMENT".

SEE ARTICLE INSIDE PAGE 2



Courtesy of It's About Time BPP

Tuskegee Syphilis Study

Tuskegee Syphilis Study 1932 to 1972

- Government-run project (US Public Health Service) w/Tuskegee U.
- Hundreds of impoverished black sharecroppers told they were being treated for “bad blood”. **No diagnoses were disclosed and no treatment was given.**
- 1947: penicillin had become standard treatment for syphilis. Scientist continue to withhold and prevent access to treatment.
- 1972: a leak resulted in study termination.
- Led to Belmont Report (1976) and development of IRBs
- President Clinton issued 1st formal apology in 1997.

Two Overlapping Regulations:

Belmont Report (1979)

&

The Common Rule (1981)

First US Guidance: Belmont Report (1976)

Respect for Persons

- Treat participants as autonomous + Informed Consent includes:
  - Accurate Information
  - Confirming Comprehension | Understanding
  - Voluntariness | Free from Persuasion

Beneficence

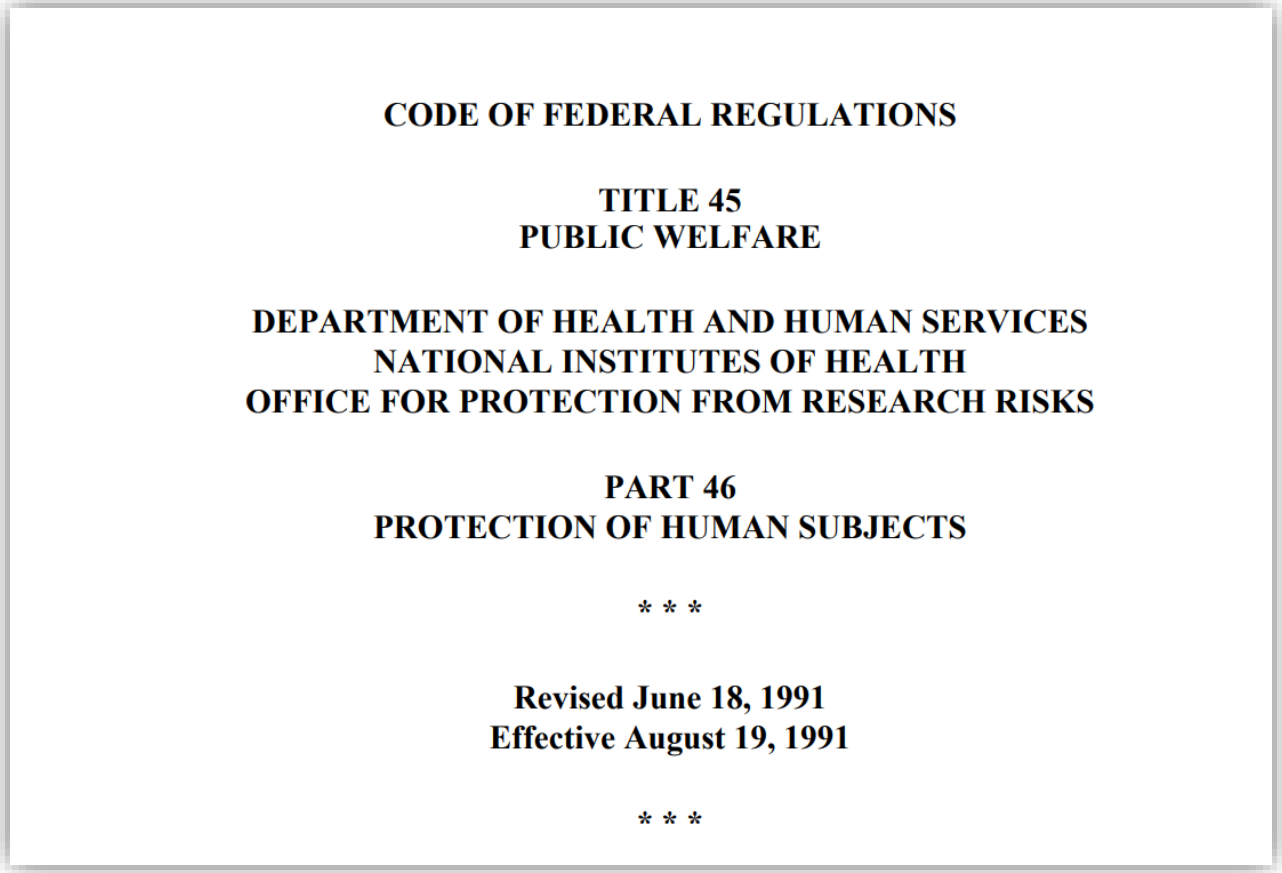
- Having the interests of research participants in mind
- Minimize risk and maximize benefit
- “Is another way that we could obtain the same knowledge but with lower risk"?

Justice

- Distribution of the burdens and benefits of research
- It should not be that one group in society bears the costs of research while another group reaps its benefits

The Common Rule: 45CFR46 (1981)

Updated in 1991 and again in 2017.



CODE OF FEDERAL REGULATIONS

TITLE 45
PUBLIC WELFARE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
OFFICE FOR PROTECTION FROM RESEARCH RISKS

PART 46
PROTECTION OF HUMAN SUBJECTS

* * *

Revised June 18, 1991
Effective August 19, 1991

* * *

IRB Review @ NU

What is the IRB's Purview and Mandate?

- The NU IRB approves **NU affiliated** students, faculty, and staff to conduct **specific procedures** using **specific materials** for research purposes. We do not approve grants or areas/types of research.
- All **NU affiliates** need some sort of NU IRB approval before they begin working on any **human subjects research**.
- Approval must be obtained **before** the any data collection or recruitment occurs.

When Do I Need To Submit?

At Northeastern, any projects which meet the definition of **Human Subjects Research or Clinical Investigation** must be reviewed + approved by the NU DHR/IRB **prior** to any recruitment or data collection.

Flashback: Definition of Human Subjects Research

Research

"a **systematic** investigation, including research development, testing and evaluation, **designed** to develop or contribute to **generalizable** knowledge"

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Human Subject

"a living individual about whom an investigator conducting research obtains data through **intervention** or **interaction** with the individual or **identifiable private information**"

Flashback: Clinical Investigation with Drug or Device[1]?

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"Device" encompasses a wide range, including custom footwear, mobile apps, algorithms, or household products (such as a ladder, a Fitbit, etc.). A clinical investigation involves evaluating the safety or efficacy of any device in diagnosing, treating, or mitigating a disease or condition.

1. These are not official definitions.

Does it need IRB review?

Resources and Processes

Does it need NU IRB review?

- 1. Is the activity Human Subjects Research
  - PI can self-determine
  - Unsure = PI completes + submits Human subjects research determination form
  - Sending us the grant ≠ information we need to make a determination

- 2. Is NU *engaged* in human subjects research?
  - Engagement Worksheet
  - See "IRB Reliance: Conducting Multi-Site Research" on Thursday

IRB Review Pathways

IRB Review Pathways

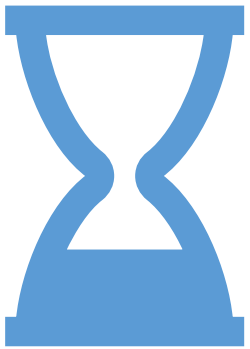
- 3. Research Not Yet Finalized (JIT or 118 request)
  - Just-in-Time/118 Request, 07.13.2023

- 4. Submit for review
  - Getting started page general steps:
    - Identify PI | Complete training | Complete Forms | Submit
  - **OR**

- 5. Submit for reliance
  - Reliance website
  - See “IRB Reliance: Conducting Multi-Site Research” on Thursday

A note about terms used

Exempt ≠
“exempt from review”



Expedited ≠
“faster”

Full Board Research

Greater than Minimal Risk

Minimal Risk

Expedited Research
(single IRB member review)

Federal Regs & DHR Requirements Apply

Exempt Research
(staff review)

DHR Requirements Apply

Reviewed by DHR/IRB

Self Determination

Non-Human Subjects
/ Not Research

No IRB Regs or DHR Reqs Apply

images from Flaticon.com

What do we do with a study when it comes in?

- Determine whether the study qualifies for an Exemption determination, qualifies for Expedited Review, or requires Full Board Review.
- For expedited/full board, the IRB reviews procedures, processes, and documents for consistency with:
  - The **7 ½ 111 criteria**.
  - The **Belmont Principles.**
  - Applicable regulations including Subpart B/C/D, FDA, DoD, DoED.
  - NU IRB policies such as training requirements and PI eligibility.

What do we do with a study when it comes in?

International Regulations:

- International Conference for Harmonization
- **International Compilation of Human Research Standards**
- **GDPR - EU**
- **PIPL – China**

CITI Training

- All study team members must complete **“Human Subjects Research Stage 1 – Basic Course”** before the IRB will approve them to work on a project:
- About 2-3 hours.
- CITI is a third party that provides training.
- Several modules which consist of a few paragraphs and a short quiz.
- https://research.northeastern.edu/hsrp/training/

Documentation and Determinations

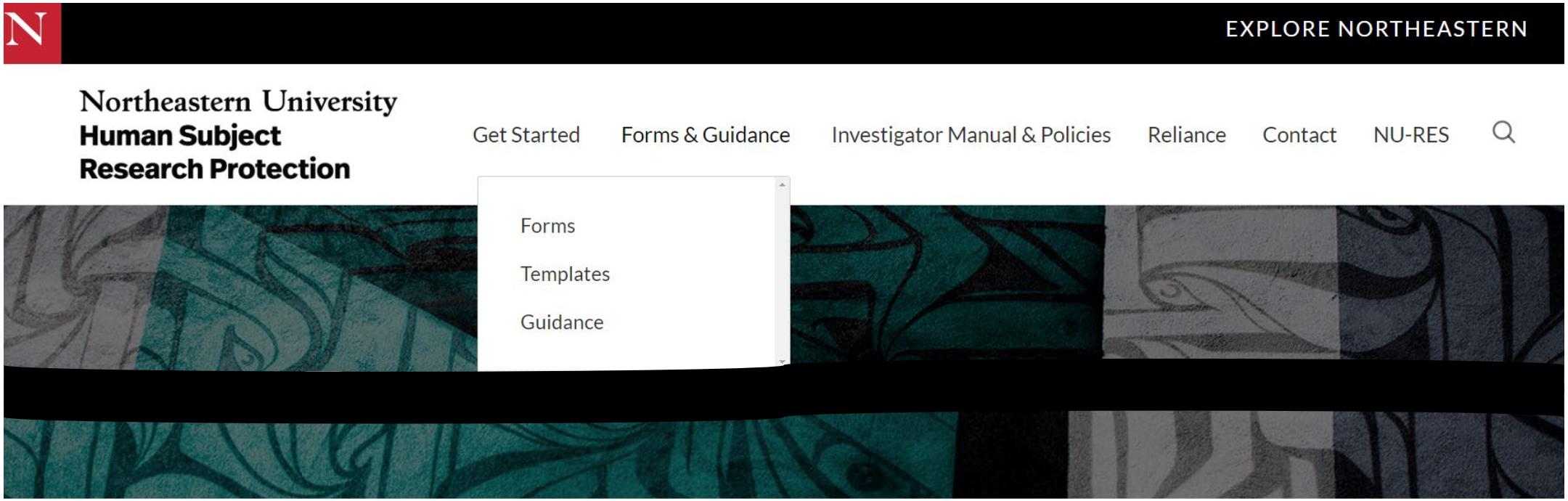
Documentation and Determinations our Office Makes

- Not Human Subjects Research or not engaged in Human Subjects Research
- 118 or Just in Time Letter
- Exempt Determination
- Expedited Approval
- Full Board Approval
- Modification Approval
- Continuing Review Approval
- Study Closure
- Reliance Acknowledgment
- Incident, Adverse Event, or Reportable New Information determinations

Other Aspects tangential to IRB Review

- Ancillary reviews: (COI, Export controls, RCR/Etc)
  - Points of contact: Various NU-RES compliance units
- Grant Congruency
  - Points of contact: responsibility of the research team and regulatory agencies.
- DUAs and MTAs
  - points of contact: NU-RES submitted via eCLAWs
- Study Team Updates
  - Needs to be submitted to the IRB via an amendment.
- Data classification and security
  - https://uds.northeastern.edu/wp-content/uploads/New-Document-Management-Guidelines.pdf
  - https://northeastern.sharepoint.com/sites/DA-DataClassification/SitePages/3locks.aspx

https://hsrp.research.northeastern.edu/



Latest News

Revisions to the Protocol Application Form – Exempt

The DHR has revised Protocol application form – exempt, 05.20.2024. Revisions were made to: Clarify PI eligibility requirements and expectations....

New Guidance Added 5/13/2024

The IRB has published new guidance, worksheets, and updates on the following: Good Document Practices (GDP) -- new guidance document...

New Guidance Added 4/24/2024

The IRB has published new guidance, worksheets, and updates on the following: Research in K-12 Schools -- new guidance document...

Upcoming Events

Full Convened IRB Meeting Date — Thursday, June 13, 2024

IRB Drop-In Hours (6/14 12-1pm EST)

IRB Drop-In Hours (6/21 12-1pm EST)

IRB Drop-In Hours (6/26 11am-12pm EST)

IRB Drop-In Hours (6/28 12-1pm EST)

More Events

Upcoming Workshops!

“Managing Dual Roles and Existing Relationships in Human Subjects Research” | 7/5 11am EST

“AI in Research: Applying the Regulatory Landscape to New Technologies” | 7/19 11am EST

https://hsrp.research.northeastern.edu/events/month/

IRB Drop-in Hours & Future Presentations!

https://hsrp.research.northeastern.edu/events/month/

Recommendations and requests for special sessions always welcome: er.williams@northeastern.edu

Feedback? Questions?

Useful links:

- Events
- Get Started
- Forms
- Guidance

- Check news on our homepage for new resources.