

Human Research Protection Program



NEWTON-WELLESLEY
HOSPITAL

Training, Education, and Outreach for the Research Community

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Introduction

One of the responsibilities of the Office of Research is to provide training, education, and outreach related to the **protection of human subjects in research** to members of the Hospital community who engage in human subject research. The Office of Research uses a multi-faceted approach to training, education, and outreach.

Activities can take many forms and are provided in a number of venues, from developing on-line resources and electronic newsletters, to formal customized classroom instruction requested on-demand, or one-on-one meetings with investigators. All personnel at all levels of the Human Research Protection Program (“HRPP”) are required to complete initial and refresher training related to the protection of human subjects in research. This includes investigators and study staff, Office of Research staff, the Institutional Official (IO) and members of the Institutional Review Board (IRB).

Mandatory Training of Investigators

Initial Certification Training – Collaborative Institutional Training Initiative (CITI)

All study personnel involved in human subject research must complete education in the protection of human research subjects through the Collaborative Institutional Training Initiative (CITI) ***prior to receiving an Insight login required for the submission of a research protocol to the IRB.*** This training requirement applies to all study personnel involved in the research and includes all investigators—principal, co-principal, or other investigators; all persons involved in the consent process—discussing participation or obtaining consent; and all persons engaged in the design, conduct, analysis, or reporting of the research (to include other personnel involved in collecting survey information via any method).

The Office of Research will not process a protocol unless all study personnel have completed the required training and it is documented. Although some human subject research is exempt from IRB review, the requirement still exists for investigators conducting such research to complete training in the protection of human subjects.

CITI Training modules are organized by various “Learner Groups” based on the type of research being undertaken. For example, social, behavioral and educational researchers comprise one Learner Group while biomedical researchers comprise another Learner Group. All key personnel conducting research at NWH must complete:

- **Group 1 Biomedical Research Investigators and Key Personnel – Basic**

In addition, PIs and co-PIs must complete the following:

- **Good Clinical Practice**

On 16 September 2016, the National Institutes of Health (NIH) issued a new policy ([Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials; NOT-OD-16-148](#)) stating that NIH-funded investigators and staff should be trained in Good Clinical Practice (GCP). This policy takes effect 1 January 2017.

The policy applies to all NIH-funded investigators and staff and it mandates that those “who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2).”

The CITI Program offers several GCP courses that are acceptable to fulfill the GCP training for the NIH policy. These four GCP ICH E6 Investigator Site Training courses also meet the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

Acceptable GCP Courses

Basic Courses - Available in English, Spanish, and Portuguese

- GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
- GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)

Refresher Courses - Available in English (Spanish and Portuguese Coming Winter 2017)

- GCP FDA Refresher
- GCP ICH Refresher

Training is considered valid and current for a three (**3**) year period following successful completion. A CITI refresher course must be completed every three years thereafter. If CITI training expires before a refresher course is completed, all IRB submissions to include new studies, revisions, continuing reviews/renewals will not be processed until the CITI refresher course has been completed.

<https://www.citiprogram.org/>

Individuals who have documentation of human subject protections training completed at another institution within the three year period can use that training to meet initial training requirements of Newton-Wellesley Hospital. **PLEASE NOTE:** The **Responsible Conduct of Research** course **does NOT** satisfy the human subjects training requirement.

CITI Refresher Training

Training in the protection of human subjects must be completed every three years. The refresher training modules may be accessed through CITI from the Newton-Wellesley Office of Research website. It is the responsibility of the Principal Investigator to monitor the training requirements of all members of the study team. No member may be assigned to the study team until training requirements have been completed.

Training of New IRB Members

There are various mechanisms by which newly appointed members receive training and become oriented with respect to the IRB's functions, policies, and procedures. Regular voting members of the IRB and IRB Chairs are expected to complete both IRB Orientation training and CITI Training in human subjects protection.

Orientation training is scheduled for new members on an as needed basis. Training is scheduled and conducted by the research compliance manager in conjunction with the current IRB Chair.

Orientation training provides a foundation for serving as an IRB member and covers a wide range of topics which may include: review of The Belmont Report, Newton-Wellesley Hospital Policy on Human Research, the Decision Flowcharts, Criteria for Exemption from IRB Review, Expedited Review Criteria, and the Checklist for

IRB Review of Protocols. Members are also introduced to the types of applications (initial, continuing review and modifications); the consent document & Consent Checklist; requirements for child assent; requirements for continuing review, protocol modifications and final reports; and reporting of unanticipated problems and adverse events.

In addition to orientation training, newly appointed IRB members are required to complete the same training as that required of investigators through the Collaborative Institutional Training Initiative (CITI). This training may be accessed via the Newton-Wellesley Hospital website at <https://www.citiprogram.org/>

Participation in on-going professional development training activities, to include workshops and conferences, is also an expectation of IRB membership and a pre-requisite for re-appointment.

IRB members and alternates (if applicable) are expected to remain abreast of evolving issues related to human subject research protections through attendance at professional conferences, workshops and local training events. Resources to attend such professional development opportunities will be made available through the Office of Research.

Continuing Education of IRB Members

CITI training serves as the foundation for IRB members' ongoing and formal continuing education. All IRB members complete the CITI biomedical refresher course every three years.

IRB members' continuing education is generally coordinated around monthly IRB meetings. Changes in policies, regulations or other requirements affecting human subject protection are included on meeting agendas and discussed.

Articles from the literature relevant to research are also included as continuing education agenda items and are distributed to IRB members prior to meetings. The sources of these articles vary and most recently include popular press (e.g., *Boston Globe*, *New York Times*, *New Yorker Magazine*) and medical journals (e.g., *New England Journal of Medicine*, *American Journal of Orthopedics*). Past sources have included news media, government, and professional organizations' publications.

Journal articles reporting results of research conducted by Newton-Wellesley Hospital investigators are distributed to IRB members whenever possible to keep them apprised of published results.

Brief 15-20 minute educational sessions are regularly scheduled and presented to members at each convened IRB meeting. These educational sessions are researched and presented by other board members and appear on the agenda for each meeting. The sessions cover topics generally selected by board members based on topics that have presented challenges to the board or have recently undergone revision or update. These may include regulatory issues, protocol specific questions, or the most recent headline or topic appearing in publications related to human subject research. IRB members are also provided various opportunities to attend conferences and seminars sponsored or presented by PRIM&R and other professional organizations related to the human subject research protections or research ethics.

Optional Education and Training Provided by the Office of Research

Presentations and Workshops on Demand

The Office of Research staff offers various training sessions, lectures, and educational seminars for physicians and professional staff conducting research with human subjects. These training sessions and workshops are available upon request. Training and workshops are developed for the hospital community based on demand. In addition to the topics above, workshops may be custom designed and tailored to meet the needs of a particular group.

Topics that may be of interest include:

- Overview of Human Subject Research and the Role of the IRB in Human Subject Protections
- When is it Human Subjects Research?
- Navigating the IRB Process: A Road Map
- Deciphering the Types of Review by the IRB
- Continuing Review of Research (Renewals)
- Certificates of Confidentiality: Overview and Requirements
- Considerations with On-line Survey Research
- An Overview of Special Protections for Vulnerable Populations
- How to Avoid Delays in the IRB Approval Process
- Informed Consent, Parental Permission and Assent
- Special Topics: Research with Minors
- Special Topics: Collaborative Research
- Special Topics: Unanticipated Problems and Adverse Event Reporting
- Using Protected Health Information in Research, the HIPPA Privacy Rule, and Data Use Agreements
- Requirements for Data and Biospecimen Repositories

HSR Essentials Series

HSR Essentials is a quarterly series of scheduled interactive sessions with the Office of Research staff covering a number of “hot topics.” These one hour informal info/Q&A sessions are in a format that facilitates close dialogue between investigators and the Office of Research staff. The schedule and topics for HSR Essentials is published in advance and may be found on the Office of Research website.

Research Update Electronic Newsletter

The Office of Research will coordinate the publication of a Quarterly Newsletter, *Research Update*, that will be emailed to all active investigators as well as electronically published on the website. The newsletter will highlight the results of recent NWH research studies, funding of new studies, and emerging issues related to research compliance and human subject research.

OHRP/PRIM&R Investigator 101 CD ROM

This CD ROM that is available to investigators on a temporary loan basis was developed jointly by OHRP and Public Responsibility in Medicine (PRIM&R). A number of topics related to protection of human subjects in research are covered. CME credits can be earned and a certificate of completion awarded by PRIM&R for individuals who view the CD training modules and complete the post training test with a passing score of 70 percent or higher (the test must be returned to PRIM&R for scoring).

External Resources for Additional Human Subject Protections Training

In addition to mandatory CITI training modules, a variety of additional on-line training options are available through a number of sources that cover a wide array of topics related to the ethical principles governing human subject research and human subject research protections.

OHRP YouTube Channel

- 12 videos produced by OHRP about a variety of compliance issues

[OHRP YouTube Channel](#)

OHRP Training Modules

OHRP offers an on-line tutorial that includes three modules related to roles, requirements, and procedures in conducting research involving human subjects. This tutorial consists of three modules and an introduction:

1. [Tutorial Introduction](#)
2. [HHS Regulations & Institutional Responsibilities](#)
3. [Investigator Responsibilities & Informed Consent](#)
4. [Human Research Protections Program](#)

Click on any module title to be taken to the tutorial log-in page.




OHRP Assurance Training

The following is a link to online assurance training from OHRP:

[OHRP Assurance Training](#)

Human Subjects Training from Health Resources and Services Administration

This training resource should take you about 90 minutes to complete; however, you can complete each module independently of the others. Each Module is a brief video covering a specific topic. Module 1 is 22 minutes. Module 2 is 28 minutes and Module 3 is 36 minutes.

- [Module 1](#) : *Evolving Concern: Protection for Human Subjects*
- [Module 2](#) : *The Belmont Report: Basic Ethical Principles and Their Application*
- [Module 3](#) : *Balancing Society's Mandates: Criteria for Protocol Review*

The Research Clinic

This is a one hour interactive training video produced by the Office of Research Integrity (ORI) and the Office for Human Research Protections (OHRP) designed for clinical and social researchers. The video discusses the importance of appropriately protecting research subjects and avoiding research misconduct. It allows the viewer to assume the role of one of four storytellers – like a choose your own adventure, you can determine the outcome.

[The Research Clinic](#)

Training Modules from the Online Ethics Center

- [Responsible Collection, Retention, Sharing, and Interpretation of Data](#)
- [Special Issues in Conducting Human Genetic Research](#)
- [Ethical Challenges in Research with Human Biological Materials](#)
- [Ethics of Research on Vulnerable Populations](#)
- [Ethics Of Research With Subjects Who Have Dementia](#)
- [Ethics Of Research With Children](#)
- [Ethics Of Research With Human Subjects Who are Mentally Ill](#)

Case Study Collection from the Ethics Education Library

This resource consists of a database of ethics cases from the fields of science, engineering, social sciences, and business (from the Illinois Institute of Technology). It is a great resource for professors looking to integrate ethics case studies into their curriculum.

[Case Study Collection from the Ethics Education Library](#)

Articles from the Ethics Education Library

This database consists of a collection of articles about research ethics (from the Illinois Institute of Technology) and is a great resource for professors looking for additional course readings

[Articles from the Ethics Education Library](#)

NIH – Protecting Human Research Participants Courses

- NIH's [Protecting Human Research Participants](#) training, which takes approximately three hours to complete and consists of seven modules on principles, regulations, policies, and guidance related to research using human subjects.
- Free to take, but you must register first.