

Naval Medical Research Center

Research Education and Training



Policies and Procedures for Education and Training in Human Subject Protections

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INTRODUCTION

The purpose of this policy and procedure manual is to establish a process and procedure for educating institutional officials, IRB members, IRB staff and research personnel in the area of human subjects protections.

IRB members should also refer to the “Institutional Review Board (IRB) Policies & Procedures for the Protection of Human Subjects in Research”, which provides additional guidance for reviewing and approving human subject research.

For additional reference materials and resources, institutional officials, IRB members and research personnel are welcome to contact the Office of Research Administration (ORA).

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Chapter 1 Background

Effective October 2000, the National Institutes of Health (NIH) implemented an education requirement for investigators and key research personnel (NIH Notice OD-00-039 of June 5, 2000; revised August 25, 2000). NIH developed and launched a web site for meeting its own training requirement for its personnel. Although the training is geared towards NIH staff, the site is available to other institutions for their use.

To meet NIH requirements, a group of experts in human research protections created the Collaborative IRB Training Initiative (CITI) for their own institutions. Shortly thereafter, the group made CITI available to all institutions. The web-based, self-contained course for initial and continuing education modules for human subject protections is oriented to both biomedical and social behavioral research.

The NIH Notice of June 2000 also included related training requirements and noted that the Office of Research Integrity (ORI) would be developing policy to implement an extension of the training requirement for the responsible conduct of research (RCR).

In response to a Department of Defense (DoD)-wide initiative to raise the awareness of and improve compliance with human research protections, the Department of the Navy Human Research Protection Program (DON HRPP) issued a policy in November 2006 requiring initial and continuing research ethics training. This mandatory training is for all personnel who may be involved in the conduct, review, management, oversight, approval or support of human subject research are required to complete training in the responsible conduct of research. The training requirement involves both initial and continuing education in the responsible conduct of research, including research subject protections.

All Navy personnel were required to complete initial training by 30 March 2007.

References

Department of the Navy Human Research Protections Program Education and Training Policy for Research Ethics and the Responsible Conduct of Research issued 15 April 2011

SECNAV Instruction 3900.39D, 3 November 2006

DoD Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, November 8, 2011

National Institutes of Health (NIH) Notice: OD-00-039 of June 5, 2000 (Revised August 25, 2000)

Chapter 2

Program Requirements

NMRC's policy for the responsible conduct of human subject research and research ethics meets the following DON HRPP education program requirements:

- An ongoing program to include an initial education and continuing education component.
 - Content appropriate to the individuals' level of involvement and duties in the responsible conduct or support of research.
 - Clearly documented program content and objectives, speaker qualifications, attendance, etc.
 - Ability to evaluate the attendee's knowledge, learning or meeting objectives.
 - Ability for attendees to evaluate the program content and speakers.
 - Plans for continually evaluating and refining training needs.
- a. **Initial Education.** All NMRC personnel involved in the conduct, review, approval, support management or oversight of human research protocols are required to successfully complete an initial education program prior to their involvement in the responsible conduct or support of research. To meet this requirement, all research team members participate in one the following:
- Collaborative IRB Training Initiative (CITI) Initial Education modules available at <https://citiprogram.org/default.asp>
 - Training modules or courses as directed by DON HRPP
 - Other educational programs if deemed equivalent to the above by the Head of ORA or the IRB Chair

<p>Note: National Cancer Institute (NCI)'s "Human Participant Protections Education for Research Teams" training does not meet DON HRPP training requirements as it is specific to NIH policies and procedures and has a biomedical focus.</p>
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NMRC requires that all individuals currently involved in the conduct, review, approval, support, management or oversight of human subject research, regardless of prior training, complete initial education program training. The following are the various groups of research team members who are required to participate in initial and ongoing training.

1. **Commanding Officer and Executive Officer.** Individuals in these positions must complete the initial education requirements within 60 days of

assignment to their position. If equivalent initial training has been conducted prior to appointment, then such training will satisfy NMRC's training and education requirement.

Additionally, to qualify for an Office for Human Research Protections (ORHP) Federalwide Assurance, the Commanding Officer who serves as the Institutional Official, as well as the Executive Officer or other individual who acts for the Commanding Officer, must also complete at least Module 1 of the OHRP Human Subject Assurance Training course available at:
<http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>.

The Commanding Officer, who serves as the Command's Institutional Official and Approving Authority, as well as the Executive Officer, must be familiar with the NMRC IRB Policies and Procedures for the Protection of Human Subjects in Research.

2. **Directors and Department Heads:** Directorate Directors and Department Heads must complete their initial training requirement within 30 days of position assignment.
3. **IRB Chairs and Members.** IRB Chair, Vice Chairs and members must complete their initial education requirement **prior** to participating in the review, deliberation and voting on research protocols. If equivalent initial training has been conducted prior to appointment, then such training will satisfy NMRC's training and education requirement.

Additionally, to qualify for a FWA, IRB Chairs must complete Modules 1-3 of the OHRP Human Subject Assurance Training course available at:
<http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>.

4. **Scientific Review Board (SRB) Chair and Reviewers:** The SRB Chair and SRB Reviewers must complete the initial education requirements within 30 days of assignment to their position. It also must be completed **prior** to the conduct of scientific review for research protocols. If equivalent initial training has been conducted prior to appointment, then such training will satisfy NMRC's training and education requirement.
5. **Head, Office of Research Administration (ORA).** As the designated primary contact for NMRC's human research protection program, the Head, ORA must complete the initial education requirements within 30 days of assignment to the position. If equivalent initial training has been conducted prior to appointment, then such training will satisfy NMRC's training and education requirement.

Additionally, in order to qualify for a FWA, the Head, ORA must complete Modules 1-3 of the OHRP Human Subject Assurance Training course available at:
<http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>.

6. **IRB Staff.** IRB staff must complete the initial education requirements within 30 days of assignment to their position. If equivalent initial training has been conducted prior to appointment, then such training will satisfy NMRC's training and education requirement.
7. **Investigators, Key Research Personnel, and Research Monitors.** All investigators and key research personnel (principal investigators, associate investigators, and all research personnel listed in the protocol) must complete the initial education requirement *prior to submitting new research protocols* for IRB review. If the Principal Investigator (PI) or NMRC Lead Investigator has not completed the initial education requirement, research protocols will be accepted but final approval will not be granted until training is complete.

If there are Associate Investigators (AI) or key research personnel who have not completed the initial education requirement, they will not be allowed to participate in the research until training is provided for them. No individual may participate in the conduct of research until the initial education requirement has been met.

Collaborators from other institutions must meet their institution's initial training and education requirements. If their institution does not have an initial education program, then the collaborating investigator must meet NMRC's requirements. Collaborating investigators **may not** submit NCI's "Human Participant Protections Education for Research Teams" training to meet the NMRC training requirement.

8. **Research Coordinators, Clinical Coordinators, and Research Administrators:** Individuals who serve in these roles must complete the most comprehensive requirements. Initial training must be complete within 30 days of assignment to position. If equivalent initial training has been conducted prior to appointment, then such training will satisfy NMRC's training and education requirement.
9. **Research Support Personnel.** Individuals whose role supports human subject research must complete the initial education requirements within 30 days of assignment to their position. If equivalent initial training has been conducted prior to appointment, then such training will satisfy NMRC's training and education requirement.

This includes individuals who handle identifiable private information related to research records, clinical procedures or research procedures and individuals who provide support and guidance to the review committees. Examples are: individuals conducting clinical or research procedures (laboratory, pharmacy, radiology), legal counsel, grants, contracts, CRADA managers, privacy officers, etc.

10. **Individuals in Multiple Roles.** Individuals serving more than one role must complete the most comprehensive requirements.

- b. Continuing Education.** All personnel are required to complete three to six (3-6) hours of appropriate, research ethics related, continuing education every three years for as long as they are involved in the conduct, review, management, oversight, approval or support of research. The requirement differs depending on the level of the individual's involvement. The only exceptions to this requirement are the Scientific Review Board Chair and members and research support personnel..

If the PI or NMRC Lead Investigator has not completed the continuing education requirement, the new research protocols will be accepted; however, final approval of the research protocol will not be granted until that training is complete.

Only those educational offerings that are directly relevant to research ethics, human subjects protections and the responsible conduct of research will meet DON HRPP's continuing education criteria and be accepted as evidence of continuing education. Individuals may choose among many educational offerings to meet the continuing education requirement. The chart below (Table 1) shows each of the requirements by training group.

Continuing education requirements may be met by attending or completing research-ethics related programs through the following options, although this list is not meant to be inclusive of all possibilities:

- CITI Continuing Education Modules
- Programs sponsored by DON HRPP
- Programs sponsored by DoD, US Army or US Air Force (including NMRC, WRAIR, HRPO USUHS)
- Programs sponsored by the Applied Research Ethics National Association (ARENA)
- Programs sponsored by the Society of Research Administrators (SRA) International
- Conferences sponsored by Public Responsibility in Medicine and Research (PRIM&R)
- Programs sponsored by the Office of Research Integrity (ORI)
- Programs sponsored by the Office of Human Research Protections (OHRP)
- Programs sponsored by the Food and Drug Administration (FDA)
- Programs included in research ethics journals (home study)
- Ethics symposia and seminars – Poynter Center, Kennedy Institute, etc.

- Book - Protecting Study Volunteers in Research Protecting Study Volunteers in Research, Cynthia Dunn, M.D. and Gary Chadwick, PharmD., M.P.H., C. I. P. (Developed in accordance with ACCME. Readers can apply for CME credits or nursing contact hours. An exam is provided with each manual and is also available online.)

Continuing Education requirements by learner groups follow in Table 1:

Table 1

Learner Group	Continuing Education Training Requirements
Commanding Officer and Executive Officer	Three (3) hours every three (3) years.
Directors, Department Heads	Three (3) hours every three (3) years
Investigators, Key Research Personnel, Medical Monitors	Six (6) hours every three (3) years
Scientific Review Board Chair, Members, Reviewers	No requirement
IRB Chair, Vice Chairs, Members	Six (6) hours every three (3) years
HRPP and IRB Staff	Six (6) hours every three (3) years
Research Coordinators, Clinical Coordinators, Research Administrators	Six (6) hours every three (3) years
Research Support Personnel	No requirement

For more specific requirements within the CITI web-based program, please refer to the Department of the Navy Human Research Protection Program Education Policy - Collaborative Institutional Training Initiative (CITI) enclosure (1).

Chapter 3

Documenting Training & Education

Individuals are responsible for maintaining source documentation of their own initial and continuing education. If not already on file, investigators and key research personnel must provide verification and/or copies of documentation with submission of new research protocols or requests to add personnel to already approved research protocols to ORA.

NMRC is responsible for verifying and storing training documents/electronic and/or paper copy. ORA has been delegated responsibility for this function and will verify whether individuals listed in the protocol have met the education requirements prior to routing research protocols for IRB review.

Chapter 2, “Program Requirements”, discusses specific responsibilities for research learner groups.

Chapter 4

Training for Grants with USUHS

All Principal Investigators (PI), Associate Investigators (AI) and Medical Monitors who participate on grants at the Uniformed Services University of the Health Sciences (USUHS) and who participate in human subjects research must take either the human subjects training provided by CITI or have attended IRB 101 at USUHS (offered periodically).

- a. **Initial Education.** The CITI training <http://www.citiprogram.org/> is available to investigators through USUHS. PIs, AIs and Medical Monitors need to complete the Biomedical module.
- b. **Continuing Education.** USUHS requires continuing education on an annual basis. This is different from the NMRC's continuing education period, which is every 3 years. This is enforced when NMRC Investigators participate on USUHS supported research projects.

To meet the USUHS requirement, investigators and medical monitors can complete the refresher course offered by CITI for the annual updated training.

When NMRC Investigators participate in NMRC-supported and reviewed research projects, USUHS defers to the policies and procedures set forth at NMRC..

- c. **Documentation for Training.** Verification of an updated human subjects training course must be completed to provide initial and continuing approval for research protocols. Completion certificates must be provided to USUHS and ORA for the grant files. Training conducted for the USUHS requirements will count towards the NMRC continuing education requirements.

Chapter 5

Training for DoN-Supported Extramural Performers

- a. **Initial Training:** All individuals who collaborate with NMRC investigators on research funded by the US Navy must complete initial training that is equivalent to DON HRPP requirements prior to initiating work involving human subjects.

If an institution does not have training requirements, its personnel must follow DON HRPP requirements (4-6 hours). If this training is being completed through the CITI program, the individual should follow the module for Principal Investigators.

If an institution uses CITI to meet its training requirements, its personnel must also complete the DON-specific module (15 minutes). The personnel should register as “DON-supported Extramural Performer.”

If an institution’s training requirement is not equivalent to DON requirements or CITI, its personnel must follow DON HRPP requirements. The NIH web-based program “Human Participant Protections Education for Research Teams” is not adequate to meet DON HRPP training requirements even for employees of NIH who are NMRC collaborators.

- b. **Continuing Education:** All individuals who collaborate with NMRC investigators on research funded by the US Navy must complete continuing education training that is equivalent to DON HRPP requirements prior to initiating work involving human subjects.

If an institution does not have continuing education training requirements, its personnel must follow DON HRPP requirements. If this training is being completed through the CITI program, the individual should follow the module for Principal Investigators.

If an institution uses CITI to meet its training requirements, its personnel must also complete the DON-specific module (15 minutes). The personnel should register as “DON-supported Extramural Performer.”

If an institution’s training requirement is not equivalent to DON requirements or CITI, its personnel must follow DON HRPP requirements.

Chapter 6

Additional Resources

a. On-line tutorials from academic organizations

- Marshfield Medical Research & Education Foundation. Computer based training for investigators. Choose the link "Institutional Review Board" and then "IRB Education, CBT."

<http://www.marshfieldclinic.org/research/dept/irb>

Non-Marshfield Clinic employees and staff can view the module by entering a zero (0) in the User ID field.

- University of Wisconsin-Madison - Human Subjects Training module. Follow the instructions for proceeding with completion of the modules. A certificate can be printed upon completion.

<http://info.gradsch.wisc.edu/research/compliance/humansubjects/tutorial/>

b. General list of websites/sources of information:

- NMRC Office of Research Administration – http://www.nmrc.navy.mil/RES_SVC/nmrc_res_srv_ora.htm
- FDA Home Page - <http://www.fda.gov>
- DHHS- Office of Research Integrity - <http://ori.dhhs.gov>
- DHHS – Office for Human Research Protection - <http://www.hhs.gov/ohrp/>
- IRB Discussion Forum - <http://www.irbforum.org>
- Association of Clinical Research Professionals - <http://www.acrpnet.org/>
- Online Ethics Center for Engineering and Science - <http://onlineethics.org>