

# Naval Medical Research Center

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## 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.

**IMPORTANT NOTE:** Unless specifically stated to the contrary, reference to the NMRC facilities, employees and agents includes its Detachment in Lima, Peru.

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

Navy Medicine's Human Research Protection Program (HRPP) requires that all personnel who may be involved in the conduct, review and 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.

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).

### References

DoD Directive 3216.2, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, March 25, 2002

Chief, BUMED Letter 3900 Ser 04UM00RIE1/0252 of 15 July 2004 – Interim Guidance for Integrating Requirements for the Ethical Protection of Human Research Subjects

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

Office of Research Integrity, PHS Policy of Instruction in the Responsible Conduct of Research (RCR) – December 1, 2000 (Suspended)

## Chapter 2

### Program Requirements

NMRC's policy for the responsible conduct of human subject research education program meets the following BUMED education program requirements:

- An ongoing program to include an initial education and continuing education component.
  - Content appropriate to the individuals' level of involvement 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.
- a. **Initial Education.** All NMRC personnel 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:
- National Cancer Institute (NCI)'s "Human Participant Protections Education for Research Teams" training course available at: <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>
  - Collaborative IRB Training Initiative (CITI) Initial Education modules available at <http://www.miami.edu/citireg/>
  - Training modules or courses as directed by BUMED.
  - Other educational programs if deemed equivalent to the above by the ORA Director.

The NCI's web-based course presents information about the rights and welfare of human participants in research. The training involves a two-hour tutorial and is designed for individuals conducting research involving human participants.

NMRC requires that all individuals currently involved in the conduct, review or support of human subject research, regardless of prior training, complete initial education program unless specifically waived by the ORA Director. The following are the various groups of research team members who are required to participate in initial and ongoing training.

1. **Commanding Officer, Executive Officer and Officer-In-Charge.** Individuals in these positions 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.

Additionally, to qualify for a DoD Navy Assurance or 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. IRB Chairs and Members.** IRB Chairs and members must complete their initial education requirement prior to participating in the review 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 DoD Navy Assurance, 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>.

- 3. ORA Director.** As the designated primary contact for NMRC's human research protection program, the ORA Director 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 DoD Navy Assurance, the ORA Director 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. 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.
- 5. Investigators, Key Research Personnel, and Medical 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

not be accepted and will be returned without review.

If there are Associate Investigators (AI) or key research personnel who have not completed the initial education requirement, the new research protocol will be accepted; however, final approval of the research protocol may be withheld until the education requirements have been met. 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.

- 6. 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.

- 7. 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, approval or support of research. The requirement differs depending on the level of the individual's involvement. There are no exceptions to this requirement.

If the PI or NMRC Lead Investigator has not completed the continuing education requirement, then new research protocols will not be accepted and will be returned until the requirement has been met.

Only those educational offerings that are directly relevant to research ethics, human subjects protections and the responsible conduct of research will meet BUMED-HRPP's continuing education criteria and accepted as evidence of continuing education. Individuals may choose among many educational offerings to meet the continuing education requirement. The chart below lists some of the possible alternatives available to meet the continuing education requirements.

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 BUMED-HRPP
- Programs sponsored by DoD, US Army or US Air Force (including NMRC, NMRCO, or WRAIR)
- 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.)

## **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.

ORA will verify whether individuals listed in the protocol have met the education requirements prior to routing research protocols for IRB review.

## 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 the University of Miami, 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.

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

- 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 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/ORA/pages/index.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/>
- Applied Research Ethics National Association (ARENA) - <http://www.arena.org>
- Online Ethics Center for Engineering and Science - <http://onlineethics.org>