

# Naval Medical Research Unit Six

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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.

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

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## **Chapter 1**

### **Background**

The Department of the Navy's Human Research Protection Program (DON HRPP) requires that all personnel who may be involved in the conduct, review and approval, management, oversight 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.

To meet DON requirements for research ethics training, institutions may use their own institutional program or use existing programs that meet the requirements in the DON policy. Whether institutions use already available programs or create their own, the training program must meet the following requirements.

- a. Training programs must include initial and continuing programs
- b. Content must be appropriate to the individuals' level of involvement and their duties and responsibilities.
- c. Program content, learning objectives, speaker qualifications, attendance, etc., must be documented clearly.
- d. Training programs must evaluate attendees' knowledge, learning or meeting of the objectives.
- e. Attendees must have an opportunity to evaluate program content and speakers.
- f. Plans for continually evaluating and refining training needs.

The Collaborative IRB Training Initiative (CITI), a web-based, self-contained course oriented to both biomedical and social behavioral research, meets these requirements. CITI is currently available for all Navy installations.

The NIH web-based training program "Human Participant Protections Education for Research Teams," does not meet DON HRPP training requirements, as it is specific to NIH policies and procedures and has a biomedical focus.

### **References**

DON HRPP Education Policy, November 9, 2006.

Peruvian Regulation of Clinical Trials 2006, with its modification in 2007.

DoD Directive 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, April 24, 2007

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

SECNAVINST 3900.39D

NMRC Instruction 3900.6B

NAMRU-6 Instruction 3900.6J

## Chapter 2

### Program Requirements

NAMRU-6'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 NAMRU-6 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:
- Collaborative IRB Training Initiative (CITI) Initial Education modules available at <https://www.citiprogram.org>.
  - Training modules or courses as directed by BUMED
  - Training sessions designed by the NAMRU-6 RAP.
  - Other educational programs if deemed equivalent to the above by the DON HRPP Education Coordinator.

NAMRU-6 requires that all individuals currently involved in the conduct, review, management, oversight or support of human subject research, regardless of prior training, complete initial education program through the <https://www.citiprogram.org> unless specifically waived by the RAP Director. The following are the various groups of research team members who are required to participate in initial and ongoing training.

1. **Commanding Officer.** 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 NAMRU-6's training and education requirement.

Additionally, to qualify for a DoD Navy Assurance or Office for Human Research Protections (OHRP) Federalwide Assurance, the Commanding Officer, who serves as the Institutional Official, must complete CITI training

available at: <http://www.citiprogram.org>.

The Commanding Officer, in his role as the Institutional Official and Approving Authority, must be familiar with the NAMRU-6 IRB Policies and Procedures for the Protection of Human Subjects in Research.

- 2. IRB Chair, Vice-Chairs, and Members.** IRB Chair, Vice-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 NAMRU-6's training and education requirement.

Additionally, to qualify for a DoD Navy Assurance, IRB Chair must complete CITI training available at: <http://www.citiprogram.org>.

- 3. Research Administration Program Director.** As the designated primary contact for NAMRU-6's human research protection program, the RAP 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 NAMRU-6's training and education requirement.

Additionally, in order to qualify for a DoD Navy Assurance, the RAP Director must complete CITI training available at: <http://www.citiprogram.org>.

- 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 NAMRU-6's training and education requirement.
- 5. Scientific reviewers:** copies of CVs and training certificates obtained by each of the scientific reviewers will be requested and kept in the Research Administration Office files. CITI or other equivalent training that these reviewers may have obtained through their host organizations will be accepted.
- 6. 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 NAMRU-6 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 NAMRU-6's requirements.

- 7. 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 NAMRU-6's training and education requirement. Investigators are responsible for ensuring that their field research staff receive relevant training. When needed and upon request, RAP staff and IRB members may also support investigators with human subject protections workshops for field personnel.

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.

- 8. 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 NAMRU-6 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 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 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 the Peruvian Instituto Nacional de Salud or by the Peruvian IRB Network
- Programs sponsored by DoD, US Army or US Air Force (including NMRC, NAMRU-6, 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 RAP. IRB and SRB members training will be updated once a year and maintained on file at RAP.

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

## Chapter 4

### 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>
- NAMRU-6 Research Administration Program - <http://www.med.navy.mil/sites/nmrcd/rap/Pages/default.aspx>
- 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>