DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
2300 E STREET NW
WASHINGTON DC 20372-5300

IN REPLY REFER TO
3900
Ser M00R/11UM00R186
15 April 2011

From: Chief, Bureau of Medicine and Surgery

Subj: DEPARTMENT OF THE NAVY HUMAN RESEARCH PROTECTION PROGRAM (DON HRPP) TRAINING AND EDUCATION GUIDANCE

Ref: (a) DoD Directive 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research"
(b) SECNAVINST 3900.39 (series), "Human Research Protection Program"
(c) DoD Directive 6200.2, "Use of Investigational New Drugs for Force Health Protection"
(d) Title 48, Code of Federal Regulations, Parts 207.172; 235.072; and 252.235-7004, Defense Federal Acquisition Regulation Supplement (DFARS), "Protection of Human Subjects"
(e) DoD Instruction 3210.7, "Research Integrity and Misconduct"

Encl: (1) Descriptions of Research Roles
(2) Requirements for Initial, Continuing, and Refresher Training

1. Purpose. To provide Department of the Navy (DON) training and education guidance in applied research ethics and human research protections for DON personnel, Department of Defense-DON collaborators, and DON-supported extramural performers as prescribed in references (a) through (e).

2. Background. The DON is committed to upholding the highest standards of research conduct, including the ethical treatment and protection of human subjects in research. Research protections require understanding and knowledge of ethical principles, regulations, and policies and procedures when conducting, monitoring, or supporting human subject research.

3. General Requirements

a. Per reference (b) all personnel who conduct, review, approve, support, manage, or oversee DON-supported human subject research are required to complete initial and continuing research ethics training appropriate to their roles and responsibilities.

b. Enclosure (1) lists the roles of research personnel who must comply with the provisions of this guidance.

c. Education and training requirements apply regardless of type of support, funding, or area of research and must be completed prior to reviewing, approving, or conducting research involving human subjects or human-subject data.

d. Every three years, all personnel who conduct, review, approve, support, manage or oversee DON-supported human research must complete three to six hours of continuing research ethics and human subject protections training. The three to six hours of continuing training must be relevant to individuals' roles and responsibilities and meet DON HRPP criteria for continuing education. Individuals may choose among many training options. See enclosure (2) for more information.

e. Institutions may access DON-provided online training to meet the established training requirements.

4. DON Command and Intramural Institutions Requirements: DON Commands and Intramural Institutions are required to:

a. Ensure initial and ongoing research ethics training and education for all personnel involved in reviewing, approving, supporting, conducting, managing, or overseeing research involving human subjects. A portion of the training and education requirement may be fulfilled by completion of one or more national professional certifications in human research protection. See enclosure (2) for additional information.

b. Provide annual supplemental training and education specific to command needs and type of research.

c. Personnel must complete any additional training when changing research roles and responsibilities. For example, an investigator who becomes an Institutional Review Board (IRB) member must complete the additional training for that role.

d. Verify and document that principal investigators meet appropriate training requirements prior to accepting research protocols for scientific or ethics review.

e. Confirm that all other personnel involved in human subject research have met training requirements appropriate to their role and level of responsibility.

f. Verify that command HRPP staff members and others involved in research with human subjects meet any other training requirements related to human research protections, for example, the Health Insurance Portability and Accountability Act (HIPAA) or Responsible Conduct of Research (RCR). Training in RCR includes topics in research misconduct. See reference (e) for additional information.

g. Ensure training and education for investigational agent use for Force Health Protection as required in reference (c).

h. For IRBs or offices that support IRBs: verify that all principal investigators (PI), associate investigators (AI), and other key research personnel have met appropriate training requirements prior to recommending approval of research, and complete additional training as appropriate.

i. Maintain personnel training documents (electronic and/or paper copy). At a minimum, the training documentation must include the individual's name; title of the training or course; date(s) of training or date completed; and time, number of hours or credits.

j. Determine and describe in command-level HRPP policies and procedures, training requirements for research support personnel. Research support personnel are persons who conduct clinical or research procedures; provide assistance to review committees; are responsible for access and release of private identifiable information (PII) (e.g., through work with medical records and information systems); persons who conduct laboratory, pharmacy, radiology, or other procedures; legal counsel; etc.

k. Develop procedures for implementing and monitoring compliance with this policy.

l. Determine appropriate informational and educational material for potential research subjects.

5. DON Personnel Requirements. All DON personnel must complete and document initial and continuing research ethics and human subject protections training. Enclosure (1) provides descriptions of the most common roles in command HRPPs. Enclosure (2) provides specific training requirements for each role. Personnel are responsible for maintaining accurate records of their initial and continuing training. The specific roles and responsibility requirements are as follows:

a. Senior Level Leadership (as defined in enclosure (1)). Must complete initial research protections training requirements within 60 days of assignment to a command that conducts human subject research and maintain training while in that assignment. Deputy commanders, executive officers, assistant officers in charge (or officers in similar assignments) who may approve human subject research when acting for the Commander must submit documentation of current human research protection training with any request for a DoD-Navy Assurance. These officers must remain current in their human research protection training in order to maintain their Command's DoD-Navy Assurance and to retain research approval authority.

b. Assurance Officials. Institutional Officials (IOs), IRB Chair(s), and HRPP Points of Contact identified in a Command's DoD-Navy Assurance application must submit documentation of current human research protection training when submitting a request for a new/renewal of a DoD-Navy Assurance. The IO must complete continuing training as required in order to keep the Command's DoD-Navy Assurance current and to retain the authority to approve research. New IOs must complete training within 60 days of assuming IO duties.

c. IRB Leadership. Chairs, Vice Chairs, and Members must complete the required initial training prior to reviewing or voting on research protocols.

d. Investigators, Medical/Research Monitors, and other key research personnel. Must meet initial training requirements prior to submitting research protocols for review. Additional requirements are as follows:

(1) In cases where associate investigators (AI), Medical/Research Monitors, and/or other key research personnel have not completed the required initial training, new research protocols may be accepted for review, but final approval must be withheld until their training is complete.

(2) PIs are responsible for ensuring all research staff complete and document appropriate training.

(3) Investigators conducting research with pregnant women, children, prisoners, students, employees, or collaborating with the Department of Veterans Affairs (DVA) must complete additional appropriate training.

(4) Investigators conducting any DON-supported clinical research using drugs, devices, and biologics must complete training in Good Clinical Practices (GCP).

(5) Investigators and key research personnel must provide verification of current training records when submitting new research protocols and continuing review reports to the IRB.

(a) Command HRPP Staff: DON personnel assigned as HRPP staff members or otherwise involved in research with human subjects shall not participate in research activities until they have completed initial training.

(b) All other personnel must complete initial training within 30 days of assignment.

6. Extramural (Non-DoD) Performers and Collaborators.

a. Complete DON HRPP-provided training for extramural performers and collaborators.

b. Submit documentation of completed research ethics and human subject protections training by the IO, IRB Chair(s), and the Human Research Protections Administrator when applying for the DoD-Navy Addendum to the Federalwide Assurance (FWA).

c. Submit documentation of completed research ethics and human subject protections training by principal investigators. Principal investigators are responsible for ensuring all research staff members receive and document appropriate training.

7. DON Human Research Protection Official (HRPO). Personnel serving as a DON HRPO must complete training as outlined in enclosure (1), Research Role #11.

8. DON HRPP Responsibilities. It is the responsibility of the DON HRPP to:

a. Develop training and education policy.

b. Establish and provide initial and continuing research ethics and human subject protections training and education programs.

c. Verify completion and documentation of research ethics and human subject protections training during (a) review of DoD-Navy Assurances and DoD Addendums to the FWA; (b) post-approval review of DON IRB meeting minutes and research protocol submissions; and (c) visits to DON commands and institution HRPPs.

d. Maintain access to centralized electronic training documentation for the DON HRPP-provided web-based training program for all DON-affiliated personnel.

e. Provide access to training for all DON commands and personnel, as well as training on the unique DoD-DON human research protection requirements

f. Monitor and oversee implementation of command and institutional training and education programs.

g. Assess, upon request, an institution's existing training program(s) for equivalence with DON HRPP requirements.

M. L. Richard
By direction

Distribution: DON HRPP Directory

Research Roles of DON HRPP Personnel for Research Ethics Training

Research Role 1: Senior Naval and Command Leadership: Senior Navy and Marine Corps leadership including the Navy Surgeon General (SG); Chief of Naval Research (CNR); Deputy Commandant, Combat Development and Integration (DC, CDI); Commanders; Deputy Commanders; Chiefs of Staff; Chief Staff Officers; Commanding Officers; Executive Officers; Officers in Charge (or similar positions); Institutional Officials (IOs); and DON members of the DoD Coordinating Committee for Human Subject Research Protection (CCHSRP).

Research Role 2: Directors, Chairs and Managers: Systems, Fleet, and Type Command (or equivalent) Directors, Department Chairs, Program Managers/Officers, Department Directors, and Division Directors.

Research Role 3: Investigators and Key Research Personnel:

a. Principal investigators including student investigators, associate investigators (and other similar terms), key research personnel (personnel who are participating in a limited and defined part of the research protocol under the direct supervision or guidance of an investigator), and Faculty Advisors for student investigators.

b. Medical/Research Monitors: Physicians, dentists, psychologists, nurses, or other research monitors who oversee the progress of research protocols, especially issues of individual subject/patient management and safety.

Research Role 4: Scientific Review Personnel: Scientific Review Board Chair(s) and board member(s).

Research Role 5: IRB Chairs, Vice Chairs and Members: Institutional Review Board (IRB) Chairs, Vice Chairs, and all members of the IRB, including Intergovernmental Personnel Act (IPA) and consultants. Others who act as consultants to the IRB are not required to have the same level of education as the IRB members. Consultants should be educated on the ethics, policies, or other topics for which they are being asked to consult.

Research Role 6: DON HRPP and IRB Staff: Command HRPP and IRB support staffs, including Counsel directly supporting the HRPP, HRPP points of contact named in institutional Assurances, staff who are advising investigators, etc. and DON HRPP staff.

Research Role 7: Personnel responsible for conducting research under the supervision or guidance of investigators or personnel involved in the preparation and administration of research protocols including, research coordinators, clinical coordinators, study coordinators, and research administrators (and other similar positions).

Research Role 8: Research Support Personnel: Persons who carry out clinical or research procedures, collect data, support review committees, and are responsible for access and release of private identifiable information (e.g., medical records personnel and information systems personnel). Research support personnel may also include persons who conduct laboratory,

pharmacy, and radiology procedures, counsel, writers and editors supporting the HRPP, and privacy officers.

Research Role 9: Midshipman at the USNA: U.S. Naval Academy (USNA) Midshipmen, USNA Prep School students, and officer candidates assigned to the Naval Reserve Officer Training Corps (NROTC), Navy and Marine Corps Officer Candidate Schools (OCS), Broadened Opportunity for Officer Selection and Training (BOOST) program, etc.

Research Role 10: Ombudsmen: Personnel who are not members of research teams, but have been appointed by IRBs or are identified in IRB-approved protocols to act on behalf of the IRB (Ombudsman) or on behalf of research subjects (Subject Advocate).

Research Role 11: DON Human Research Protection Officials (HRPO): DON personnel who review extramural performer's paperwork submitted prior to award of research involving human subjects for compliance with DoD and DON requirements and DFARS 252.235-7004 for contracts.

Research Role 12: DON-supported Extramural Performers: Institutional Officials, IRB Chairs, Human Research Protection Program Administrators named in the DoD Addendum to the Federalwide Assurance; and extramural principal investigators.

Department of the Navy Human Research Protection Program
Initial, Continuing, and Refresher Training Options

Table 1 – Initial, Continuing, and Refresher Training Options

Research Role	Initial Training Options	Continuing, Ongoing, and Refresher Training Options
All DON Personnel: Individuals serving in several roles must complete the most comprehensive requirements. **Extramural Performers**: see Research Role #12	DON HRPP-provided web based training through the Collaborative Institutional Training Initiative (CITI) - Individuals must achieve an overall score of 80% to pass and receive a completion certificate. ***OR*** Professional certification in human research protection for specific role ***and*** DON HRPP Module (in CITI) Examples* include but are not limited to the following: • Certified IRB Professional (CIP) or Certified IRB Manager (CIM) for IRB Chair/members, Command HRPP and IRB staff, and DON HRPP Office staff : Roles 5 and 6 • Certified Clinical Research Professional (CCRP), Clinical Research Associate (CRA), Clinical Research Coordinators (CRCs) for Research Coordinators, Clinical Coordinators, Study Coordinators, and Research Administrators: Role 7 • Certified Physician Investigator (CPI) and Certified Trials Investigator (CTI) for Investigators: Role 3	Any combination of HRP-related training hours provided by recognized sources. Examples* include, but are not limited to: • DON HRPP-provided web based training through CITI • DoD-DDR&E (for example, DoD HRPP Training Day) • DoD components' HRPP (U.S. Army, U.S. Air Force, etc.) • Office of Human Research Protections (OHRP) • Office of Research Integrity (ORI) • Food and Drug Administration (FDA) • Public Responsibility in Medicine and Research (PRIM&R) or other recognized conference and training providers • Society of Research Administrators (SRA) International, Society of Clinical Research Associates (SOCRA) or other recognized professional societies • Poynter Center, Kennedy Institute or other ethics education institutions • Professional societies (such as American Medical Association) or other sources of relevant continuing education training ***OR*** Current professional certification in human research protection for specific roles **** Inclusion on this list is not intended and should not be construed as an endorsement of these programs and organizations by the DON HRPP***

Table 2 – DON HRPP-Provided Web Based Training through the Collaborative Institutional Training Initiative (CITI)

Research Role*	Initial Training	Continuing, Ongoing, and Refresher Training Options
1. Senior Naval and Command Leadership Estimated Time: 1 hour Refer to Enclosure (1), Role 1	**BIOMEDICAL FOCUS** 1. The Belmont Report and Introduction 2. History & Ethics for Biomedical Researchers 3. Department of the Navy Introduction 4. Defining Research with Human Subjects – Social Behavioral Research (SBR) 5. SBR for Biomedical Researchers 6. Department of the Navy HRPP Module for Senior Navy and Command Leadership 7. Department of the Navy Information & References **SOCIAL-BEHAVIORAL FOCUS** 1. The Belmont Report and Introduction 2. History & Ethical Principles – SBR 3. Department of the Navy Introduction 4. Defining Research with Human Subjects – SBR 5. Assessing Risks - SBR 6. Department of the Navy HRPP Module for Senior Navy and Command Leadership 7. Department of the Navy Information & References	Requirement: 3 hours every 3 years **BIOMEDICAL FOCUS** • CITI Biomedical 200 Refresher training, *and* • Department of the Navy HRPP Module for Senior Naval and Command Leadership **SOCIAL-BEHAVIORAL FOCUS** • CITI SBR 201 Refresher training, *and* • Department of the Navy HRPP Module for Senior Naval and Command Leadership ***OR*** Three hours total of continuing education activities as described in Table 1

*See Enclosure (1) for a full listing of personnel included within each Research Role.
Modules completed through the CITI "IRB Reference Resource" will not transfer to the requirements for any individual Research Role

Research Role*	Initial Training	Continuing, Ongoing, and Refresher Training Options
2. Directors, Chairs and Managers Estimated Time: 2 – 3 hours Refer to Enclosure (1), Role 2	**BIOMEDICAL FOCUS** 1. The Belmont Report and Introduction 2. History & Ethics for Biomedical Investigators 3. Defining Research with Human Subjects – SBR 4. Department of the Navy Introduction 5. SBR for Biomedical Researchers 6. Records –based Research 7. Genetic Research 8. Research with Protected Populations – Overview 9. Group Harms - Research with culturally or medically vulnerable groups 10. Privacy & Confidentiality – SBR 11. Conflict of Interest 12. Department of the Navy HRPP Module 13. Department of the Navy Information & References **SOCIAL-BEHAVIORAL FOCUS** 1. The Belmont Report and Introduction 2. History & Ethical Principles – SBR 3. Defining Research with Human Subjects – SBR 4. Department of the Navy Introduction 5. Assessing Risks – SBR 6. Records-based Research 7. Research with Protected Populations – Overview 8. Group Harms - Research with culturally or medically vulnerable groups 9. Privacy & Confidentiality – SBR 10. International Research - SBR 11. Conflicts of Interest 12. Department of the Navy HRPP Module 13. Department of the Navy Information & References	Requirement: 3 hours every 3 years • Repeat Initial Training: Biomedical or Social-Behavioral ***OR*** **BIOMEDICAL FOCUS** • CITI Biomedical 200 Refresher training, *and* • One (1) hour of other continuing training **SOCIAL-BEHAVIORAL FOCUS** • CITI SBR 201 Refresher training, *and* • Two (2) hours of other continuing training ***OR*** Three hours total of continuing education activities as described in Table 1

*See Enclosure (1) for a full listing of personnel included within each Research Role.
Modules completed through the CITI "IRB Reference Resource" will not transfer to the requirements for any individual Research Role

Research Role*	Initial Training	Continuing, Ongoing, and Refresher Training Options
3. Investigators and Key Research Personnel Estimated Time: 4 – 6 hours Note: Certified Physician Investigator (CPI) or Certified Trials Investigator (CTI) **and** DON HRPP Module meet this role's requirements. Refer to Enclosure (1), Role 3	**BIOMEDICAL FOCUS** 1. The Belmont Report and Introduction 2. History & Ethics for Biomedical Researchers 3. Defining Research with Human Subjects – SBR 4. Department of the Navy Introduction 5. Basic IRB Regulations & Review Process 6. Informed Consent 7. SBR for Biomedical Researchers 8. Assessing Risks – SBR 9. Records-based Research 10. Genetic Research 11. Research with Protected Populations – Overview 12. Group Harms - Research with culturally or medically vulnerable groups 13. Internet Research – SBR 14. Privacy and Confidentiality – SBR 15. FDA-regulated research 16. Hot Topics 17. Conflicts of Interest 18. Department of the Navy HRPP Module 19. Department of the Navy Information & References *If conducting research with pregnant women, children, prisoners, workers/employees, or with the VA, complete:* • Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero • Vulnerable Subjects - Research Involving Minors • Research Involving Prisoners • Workers as Research Subjects If conducting clinical research using drugs, devices, and biologics, must complete training in Good Clinical Practice (GCP.)	Requirement: 6 hours every 3 years • Repeat Initial Training: Biomedical or Social-Behavioral ***OR*** **BIOMEDICAL FOCUS** • CITI Biomedical 200 Refresher training, *and* • Four (4) hours of other continuing training **SOCIAL-BEHAVIORAL FOCUS** • CITI SBR 201 Refresher training, *and* • Five (5) hours of other continuing training ***OR*** Current Certified Physician Investigator (CPI) or Certified Trials Investigator (CTI) ***OR*** Six hours total of continuing education activities as described in Table 1

*See Enclosure (1) for a full listing of personnel included within each Research Role.
Modules completed through the CITI "IRB Reference Resource" will not transfer to the requirements for any individual Research Role

Investigators and Key Research Personnel (cont'd) Note: Certified Physician Investigator (CPI) or Certified Trials Investigator (CTI) **and** DON HRPP Module meet this role's requirements. Refer to Enclosure (1), Role 3	**SOCIAL-BEHAVIORAL FOCUS (SBR)** 1. The Belmont Report and Introduction 2. History and Ethical Principles-SBR 3. The Regulations and SBR 4. Department of the Navy Introduction 5. Informed Consent - SBR 6. Defining Research with Human Subjects – SBR 7. Assessing Risks – SBR 8. Records-based Research 9. Research with Protected Populations – Overview 10. Group Harms - Research with culturally or medically vulnerable groups 11. Internet Research – SBR 12. Privacy and Confidentiality – SBR 13. Hot Topics 14. Conflicts of Interest 15. Department of Navy HRPP Module 16. Department of the Navy Information & References *If conducting research with children, prisoners, workers/employees, or with the VA, complete the following:* • Research with Children - SBR • Research in Public Elementary/Secondary Schools - SBR • Research with Prisoners – SBR • Workers as Research Subjects • Human Subjects Research at the VA	

*See Enclosure (1) for a full listing of personnel included within each Research Role.
Modules completed through the CITI "IRB Reference Resource" will not transfer to the requirements for any individual Research Role

Research Role*	Initial Training	Continuing, Ongoing, and Refresher Training Options
4. Scientific Review Personnel Estimated Time: 1 hour Refer to Enclosure (1), Role 4	Each command or institution may determine its initial and continuing training requirements for these individuals. The DON HRPP recommends the following modules: 1. The Belmont Report and Introduction 2. History and Ethical Principles 3. Department of the Navy Introduction 4. Defining Research with Human Subjects 5. Department of the Navy HRPP Module 6. Department of the Navy Information & References	Command will (1) determine training requirements and (2) describe the requirements in its HRPP policies and procedures.

*See Enclosure (1) for a full listing of personnel included within each Research Role.
Modules completed through the CITI "IRB Reference Resource" will not transfer to the requirements for any individual Research Role

Research Role*	Initial Training	Continuing, Ongoing, and Refresher Training Options
5. IRB Chairs, Vice Chairs, and members Estimated Time: 4 – 6 hours Note: Current Certified IRB Professional (CIP) or Certified IRB Manager (CIM) **and** DON HRPP Module meet this requirement. Refer to Enclosure (1), Role 5	**BIOMEDICAL FOCUS** 1. The Belmont Report and Introduction 2. History & Ethics for Biomedical Researchers 3. Defining Research with Human Subjects – SBR 4. Department of the Navy Introduction 5. Basic IRB Regulations & Review Process 6. Informed Consent 7. SBR for Biomedical Researchers 8. Assessing Risk – SBR 9. Records-based Research 10. Genetic Research 11. Research with Protected Populations – Overview 12. Group Harms - Research with culturally or medically vulnerable groups 13. Internet Research – SBR 14. Research with Prisoners – SBR 15. Research Involving Pregnant Women 16. Research Involving Minors 17. Research Involving Children- SBR 18. Privacy & Confidentiality – SBR 19. Workers as Research Subjects 20. FDA-regulated research 21. Hot Topics 22. Conflicts of Interest 23. IRB Member 24. Department of the Navy HRPP Module 25. Department of the Navy Information & References *If conducting research with the VA, complete:* • Human Subjects Research at the VA	Requirement: 6 hours every 3 years • Repeat Initial Training – Biomedical or Social-Behavioral ***OR*** **BIOMEDICAL FOCUS** • CITI Biomedical 200 Refresher training, *and* • Four (4) hours of other continuing training **SOCIAL-BEHAVIORAL FOCUS** • CITI SBR 201 Refresher training, *and* • Five (5) hours of other continuing training ***OR*** Current Certified IRB Professional (CIP)or Certified IRB Manager (CIM) ***OR*** Six hours total of continuing education activities as described in Table 1

*See Enclosure (1) for a full listing of personnel included within each Research Role.
Modules completed through the CITI "IRB Reference Resource" will not transfer to the requirements for any individual Research Role

IRB Chairs, Vice Chairs, and members (cont'd) Refer to Enclosure (1), Role 5	**SOCIAL-BEHAVIORAL FOCUS (SBR)** 1. The Belmont Report and Introduction 2. History and Ethical Principles – SBR 3. The Regulations and SBR 4. Informed Consent - SBR 5. Defining Research with Human Subjects – SBR 6. Assessing Risks – SBR 7. Records-based Research 8. Research with Protected Populations – Overview 9. Group Harms - Research with culturally or medically vulnerable groups 10. Internet Research – SBR 11. Privacy and Confidentiality – SBR 12. Research with Prisoners – SBR 13. Research with Pregnant Women 14. Research with Children – SBR 15. Students in Research - SBR 16. Hot Topics 17. Conflicts of Interest 18. IRB Member 19. Department of Navy HRPP Module 20. Department of the Navy Information & References *If conducting research with the VA, complete:* • Human Subjects Research at the VA	

*See Enclosure (1) for a full listing of personnel included within each Research Role.
Modules completed through the CITI "IRB Reference Resource" will not transfer to the requirements for any individual Research Role

Research Role*	Initial Training	Continuing, Ongoing, and Refresher Training Options
6. DON HRPP and IRB Staff Estimated Time: 4 – 6 hours Note: Current Certified IRB Professional (CIP) or Certified IRB Manager (CIM) and DON HRPP Module meet this role's requirements. Refer to Enclosure (1), Role 6	**BIOMEDICAL FOCUS** 1. The Belmont Report and Introduction 2. History & Ethics for Biomedical Researchers 3. Defining Research with Human Subjects – SBR 4. Department of the Navy Introduction 5. Basic IRB Regulations & Review Process 6. Informed Consent 7. SBR for Biomedical Researchers 8. Assessing Risk – SBR 9. Records-based Research 10. Genetic Research 11. Research with Protected Populations – Overview 12. Group Harms - Research with culturally or medically vulnerable groups 13. Internet Research – SBR 14. Research with Prisoners – SBR 15. Research Involving Pregnant Women 16. Research Involving Minors 17. Research Involving Children- SBR 18. Privacy & Confidentiality – SBR 19. Workers as Research Subjects 20. FDA-regulated research 21. Hot Topics 22. Conflicts of Interest 23. IRB Member 24. Department of the Navy HRPP Module 25. Department of the Navy Information & References *If conducting research with the VA, complete:* • Human Subjects Research at the VA	Requirement: 6 hours every 3 years • Repeat Initial Training: Biomedical or Social-Behavioral ***OR*** **BIOMEDICAL FOCUS** • CITI Biomedical 200 Refresher training, *and* • Four (4) hours of other continuing training **SOCIAL-BEHAVIORAL FOCUS** • CITI SBR 201 Refresher training, *and* • Five (5) hours of other continuing training ***OR*** Current Certified IRB Professional (CIP) or Certified IRB Manager (CIM) ***OR*** Six hours total of continuing education activities as described in Table 1

*See Enclosure (1) for a full listing of personnel included within each Research Role.
Modules completed through the CITI "IRB Reference Resource" will not transfer to the requirements for any individual Research Role

DON HRPP and IRB Staff (cont'd) Refer to Enclosure (1), Role 6	**SOCIAL-BEHAVIORAL FOCUS** 1. The Belmont Report and Introduction 2. History and Ethical Principles – SBR 3. The Regulations and SBR 4. Department of the Navy Introduction 5. Informed Consent - SBR 6. Defining Research with Human Subjects – SBR 7. Assessing Risks – SBR 8. Records-based Research 9. Research with Protected Populations – Overview 10. Group Harms - Research with culturally or medically vulnerable groups 11. Internet Research – SBR 12. Privacy and Confidentiality – SBR 13. Research with Prisoners – SBR 14. Research with Pregnant Women 15. Research with Children – SBR 16. Hot Topics 17. Conflicts of Interest 18. IRB Member 19. Department of the Navy HRPP Module 20. Department of the Navy Information & References *If conducting research with the VA, complete:* • Human Subjects Research at the VA	

*See Enclosure (1) for a full listing of personnel included within each Research Role.
Modules completed through the CITI "IRB Reference Resource" will not transfer to the requirements for any individual Research Role

Research Role*	Initial Training	Continuing, Ongoing, and Refresher Training Options
7. Research Coordinators and Administrators Estimated Time: 4 – 6 hours Note: Current Certified Clinical Research Professional (CCRP), Clinical Research Associate (CRA), or Clinical Research Coordinators (CRCs) and DON HRPP Module meet this role's requirements. Refer to Enclosure (1), Role 7	**BIOMEDICAL FOCUS** 1. The Belmont Report and Introduction 2. History & Ethics for Biomedical Researchers 3. Defining Research with Human Subjects – SBR 4. Department of the Navy Introduction 5. Basic IRB Regulations & Review Process 6. Informed Consent 7. SBR for Biomedical Researchers 8. Assessing Risk – SBR 9. Records-based Research 10. Genetic Research 11. Research with Protected Populations – Overview 12. Group Harms - Research with culturally or medically vulnerable groups 13. Internet Research – SBR 14. Research Involving Pregnant Women 15. Research Involving Minors 16. Research Involving Children- SBR 17. Privacy & Confidentiality – SBR 18. Workers as Research Subjects 19. FDA-regulated research 20. Hot Topics 21. Conflicts of Interest 22. Department of the Navy HRPP Module 23. Department of the Navy Information & References *If conducting research with the VA, complete:* • Human Subjects Research at the VA	Requirement: 6 hours every 3 years • Repeat Initial Training: Biomedical or Social-Behavioral ***OR*** **BIOMEDICAL FOCUS** • CITI Biomedical 200 Refresher training, *and* • Four (4) hours of other continuing training **SOCIAL-BEHAVIORAL FOCUS** • CITI SBR 201 Refresher training, *and* • Five (5) hours of other continuing training ***OR*** Current Certified Clinical Research Professional (CCRP), Clinical Research Associate (CRA), or Clinical Research Coordinators (CRCs) ***OR*** Six hours total of continuing education activities as described in Table 1

*See Enclosure (1) for a full listing of personnel included within each Research Role.
Modules completed through the CITI "IRB Reference Resource" will not transfer to the requirements for any individual Research Role

Research Coordinators and Administrators (cont'd) Refer to Enclosure (1), Role 7	**SOCIAL-BEHAVIORAL FOCUS** 1. The Belmont Report and Introduction 2. History and Ethical Principles – SBR 3. The Regulations and SBR 4. Department of the Navy Introduction 5. Informed Consent - SBR 6. Defining Research with Human Subjects – SBR 7. Assessing Risks – SBR 8. Records-based Research 9. Research with Protected Populations – Overview 10. Group Harms - Research with culturally or medically vulnerable groups 11. Internet Research – SBR 12. Privacy and Confidentiality – SBR 13. Research with Pregnant Women 14. Research with Children – SBR 15. Hot Topics 16. Conflicts of Interest 17. Department of the Navy HRPP Module 18. Department of the Navy Information & References *If conducting research with the VA, complete:* • Human Subjects Research at the VA	

*See Enclosure (1) for a full listing of personnel included within each Research Role.
Modules completed through the CITI "IRB Reference Resource" will not transfer to the requirements for any individual Research Role

Research Role*	Initial Training	Continuing, Ongoing, and Refresher Training Options
8. Research Support Personnel Estimated Time: 1 hour Refer to Enclosure (1), Role 8	Each command or institution must (1) determine training requirements for the individuals in the role of "Research Support Personnel," and (2) describe the requirements in its HRPP policies and procedures. The DON HRPP recommends the following modules: **BIOMEDICAL FOCUS** 1. The Belmont Report and Introduction 2. History and Ethics for Biomedical Researchers 3. Defining Research with Human Subjects 4. Department of the Navy Introduction 5. Privacy and Confidentiality 6. Records-based Research 7. Department of the Navy HRPP Module 8. Department of the Navy Information & References **SOCIAL-BEHAVIORAL FOCUS** 1. The Belmont Report and Introduction 2. History and Ethics for Biomedical Researchers 3. Defining Research with Human Subjects 4. Department of the Navy Introduction 5. Department of the Navy HRPP Module 6. Department of the Navy Information & References	Requirement: 3 hours every 3 years • Repeat Initial Training: Biomedical or Social-Behavioral ***OR*** **BIOMEDICAL FOCUS** • CITI Biomedical 200 Refresher training, *and* • One (1) hour of other continuing training **SOCIAL-BEHAVIORAL FOCUS** • CITI SBR 201 Refresher training, *and* • Two (2) hours of other continuing training ***OR*** Three hours total of continuing education activities as described in Table 1

*See Enclosure (1) for a full listing of personnel included within each Research Role.
Modules completed through the CITI "IRB Reference Resource" will not transfer to the requirements for any individual Research Role

Research Role*	Initial Training	Continuing, Ongoing, and Refresher Training Options
9. Midshipman at the USNA Estimated Time: 1 hour Refer to Enclosure (1), Role 9	1. The Belmont Report and Introduction 2. Students in Research – SBR 3. Department of the Navy Introduction 4. Department of the Navy Information & References	Command will (1) determine training requirements and (2) describe the requirements in its HRPP policies and procedures.

Research Role*	Initial Training	Continuing, Ongoing, and Refresher Training Options
10. Ombudsman Estimated Time: 2-3 hours Refer to Enclosure (1), Role 10	1. The Belmont Report and Introduction 2. History and Ethics for Biomedical Investigators 3. Social and Behavioral Research for Biomedical Investigators 4. Department of the Navy Introduction 5. Informed Consent – SBR 6. Privacy and Confidentiality – SBR 7. Research with Protected Populations – Vulnerable Subjects: An Overview 8. Workers as Research Subjects 9. Department of the Navy Information & References	Commands, institutions, or IRBs will (1) determine training requirements and (2) describe the requirements in its HRPP policies and procedures. Recommend: Training as needed when individual serves in this role.

*See Enclosure (1) for a full listing of personnel included within each Research Role.
Modules completed through the CITI "IRB Reference Resource" will not transfer to the requirements for any individual Research Role

Research Role*	Initial Training	Continuing, Ongoing, and Refresher Training Options
11. DON Human Research Protection Officials (HRPO) Estimated Time: 1 hour Refer to Enclosure (1), Role 11	DON Human Research Protections Officials Module: 1. Belmont Report & CITI Introduction 2. History and Ethical Principles 3. Research with Protected Populations 4. Group Harms - Research with culturally or medically vulnerable groups 5. Department of the Navy HRPP Module 6. Department of the Navy Information & References 7. DON HRPO Module	Repeat initial training every year

Research Role*	Initial Training	Continuing, Ongoing, and Refresher Training Options
12. DON-supported Extramural Performers Estimated time: 1 hour Refer to Enclosure (1), Role 12	DON HRPP Extramural Performers Module: 1. Belmont Report & CITI Introduction 2. History and Ethical Principles 3. Defining Research with Human Subjects 4. Informed Consent 5. Privacy and Confidentiality 6. Research with Protected Populations 7. Workers as Research Subjects 8. Department of the Navy Introduction 9. Department of the Navy Information & References	Recommend Refresher training or repeat initial training every three years

*See Enclosure (1) for a full listing of personnel included within each Research Role.
Modules completed through the CITI "IRB Reference Resource" will not transfer to the requirements for any individual Research Role