

RESEARCH PROTECTIONS



UPDATE



News and Comment on the Protection of Human Subjects in Navy and Marine Corps Research

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HRPO Training Hosted by DON HRPP

The Department of the Navy Human Research Protection Program (DON HRPP) staff conducted a Human Research Protection Official (HRPO) training, broadcasted via video teleconference (VTC) and phone, on October 22, 2015. This training was held at the Office of Naval Research (ONR) headquarters in Arlington, Virginia and broadcasted to DON commands and offices. Attendees included DON HRPP staff, HRPOs, Command Human Research Protection Program (HRPP) and Institutional Review Board (IRB) staff, and respective contracting office staff members.

The HRPO is an essential member of a command's HRPP who is responsible for reviewing for compliance, DoD/DON-supported contracts and agreements that include or may include research involving human subjects. As outlined in the Department of Defense Instruction (DoDI) 3216.02 and title 48, Code of Federal Regulations, parts 207.172, 235.072, and 252.235.7004, this administrative review must be conducted BEFORE the research activity can begin. In addition, Secretary of the Navy Instruction (SECNAVINST) 3900.39D requires submission of human research protection documentation prior to award.

CAPT William Deniston, Director, DON HRPP, gave a presentation outlining the requirement for HRPO reviews and the role and responsibilities of the HRPO.

Following the presentation, the DON HRPP staff provided answers to questions that were solicited from Navy and Marine Corps HRPP and IRB offices prior to the training session. In addition, DON HRPP staff also answered live questions from attendees. These questions and their respective responses were sent to DON commands in the form of a "DON HRPP e-Gram" on December 4, 2015. A few of these questions and answers are included below.

"Who is responsible to determine if a contract or agreement needs HRPO review? We have several different contracts and agreements with one of them being a service contract. That service contract is a one year contract with up to 5 option years. Each option year can have over 50 Technical Direction Letters; some with Human Subject Research tasks, and some without. Again, we don't have a Contracting Officer (KO) at our command. We rely on a KO at NAVMEDLOGCOM for that contract. We have a local Contract Officer Representative (COR). Are the KO and COR required to do training sufficient to determine if the contract/agreement/or modification contains an element of human subject research?"

The IO of any institution supporting non-DoD conducted research is responsible for establishing a process

to meet the requirements of the DoDI 3216.02 and SECNAVINST 3900.39D There is no DON requirement to make the KO or COR responsible for making those determinations. The Program Officer (PO), Program Manager (PM) or equivalent person sponsoring the activities outlined in the contract or agreement is responsible for determining whether the contract or agreement may need HRPO review because this is part of the acquisition planning process. Proceeding without proper HRPO coordination/review adds an element of execution risk, that can be mitigated through good communication between HRPOs, POs/PMs, and the contracting personnel as to what elements "may include research involving human subjects" triggering requirements under DoDI 3216.02 (Enclosure 3, section 4). In addition, under the acquisition process, the [potential] awardee must be made aware of the HRPO review and contractor requirements as outlined in 48 CFR 252.235-7004, DFARS clause and DoDI 3216.02.

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Also in this Issue:

DON Addendum Phase-Out

PRIM&R Conference

DON HRPP Staff Changes

DON FWA Addendums Being Phased Out

Effective February 1, 2016, the Department of the Navy (DON) no longer requires non-DoD institutions to hold a DON Addendum to their Federalwide Assurance (FWA), when engaged in DON-supported human subject research (HSR).

As mentioned in the September 18, 2015 “DON HRPP e-Gram” sent to DON commands, DON will stop processing Addendum applications on January 31, 2016. After the effective date, non-DoD institutions with an active DON-Addendum to their FWA will remain on file through the expiration date listed on the Addendum certificate.

DON institutions supporting HSR conducted by non-DoD institutions will continue to be responsible for ensuring that these institutions comply with all applicable HSR protection requirements and applicable requirements are incorporated into relevant contracts, grants, Cooperative Research and

Development Agreements (CRADAs), and other agreements.

As mentioned in the cover article, the Human Research Protection Official (HRPO) review is vital to the HSR review process and is mandated in accordance with DoDI 3216.02 and title 48, Code of Federal Regulations, parts 207, 235, and 252. Commands will be asked to submit to DON HRPP (Human Research Protection Program) the HRPO approval letter issued for each HRPO review conducted. In addition to these submissions, DON HRPP will continue to maintain visibility through a comprehensive quality assurance review of command HRPO programs during Command Site Inspections and Assist Visits. Any questions and concerns regarding the addendum phase out can be sent to DON HRPP, usn.ncr.bumedfchva.mbx.don-hrpp@mail.mil.

DON Staff Attend Annual Ethics Conference

Department of the Navy (DON) staff attended the Public Responsibility In Medicine and Research (PRIM&R) Advancing Ethical Research (AER) Conference on November 2015 in Boston, Massachusetts. DON staff were among the more than 2,000 attendees, including active duty military, government personnel and contract support staff from Naval and Marine Corps commands domestically and internationally. DON staff (active duty and government personnel only) were required to submit their conference attendance requests through a lengthy approval process and receive approval from the DON Assistant for Administration prior to attending the PRIM&R conference.

The PRIM&R conference is an annual forum that is focused on human subject research protections, with research ethics serving as the primary foundation. The conference included a one day conference with workshops focusing on social, behavioral and

educational research (SBER) and three days of over 300 conference programs and workshops that focused on human subject research in both the SBER and biomedical arena. Representatives from the various DoD component level offices (Assistant Secretary of Defense for Research and Engineering, Under Secretary of Defense for Personnel and Readiness, Army, Navy, Marine Corps, Air Force, and DARPA) served on a DoD session panel and presented their respective component-specific requirements for conducting human subject research.

[PRIM&R](#) is a not for profit organization with over 4,000 members worldwide, whose mission is to support ethical standards in the conduct of biomedical, behavioral, and social science research through education, membership services, professional certification, public policy initiatives, and community building.

Fried and Khanna Join DON HRPP

Mr. Eric L. Fried came aboard on September 2015 as the legal advisor to the Department of the Navy Human Research Protection Program (DON HRPP)



within the Office of Naval Research (ONR). He advises the program which includes staff from both ONR and Navy Bureau of Medicine and Surgery (BUMED). He is the senior legal expert on human research protection in the DON, and advises on human subject research related matters related to

contract and grant award execution, policy development, and compliance. Prior to joining the ONR Office of General Counsel, Mr. Fried served as Counsel to the Air Force Surgeon General and Air Force Medical Support Agency Commander where he provided advice to the Air Force on human research issues and medical/research related topics involving the Air Force Medical Service. Mr. Fried received his Bachelor of Science Degree in Management Systems, from Rensselaer Polytechnic Institute, Troy, New York in 1988. He received his Juris Doctorate Degree from Albany Law School of Union University, Albany, New York in 1991.

Ashwani Khanna, PhD, a biomedical scientist and IRB Professional, joined DON HRPP on August 2015 as Education and Training Specialist

(contractor support) after serving as the Human Subject Protection Specialist at Brooke Army Medical Center at Fort Sam Houston, Texas and IRB Analyst at the University of Maryland. In these roles, he provided oversight of the human subjects' research studies conducted in these



institutes, ensuring compliance with all applicable federal, DoD regulations, and local laws. Dr. Khanna is also a regular reviewer providing scientific support to NIH study sections as well as providing manuscript review for scientific journals. He will provide education and training support in collaboration with Ms. Tamika Brown for the DON HRPP. Dr. Khanna holds a PhD in Immunology from the Postgraduate Institute of Medical Education and Research at Chandigarh, India.

HRPO Training Session Questions & Answers (continued from cover)

“Does the HRPO review requirement apply to all collaborative research that involves a non-DoD collaborator, including those in which Navy personnel are involved and the research is subject for review and oversight by a Navy IRB?”

Yes, HRPO review is still required of all the non-DoD collaborator's activities. A member of the Navy IRB can be nominated to be a HRPO to promote efficiency in the review process. See DON HRPP e-gram of 21 October 2015.

“I was asked by HR whether the requirements for the inclusion of DFARS clause in contracts applies to personal as well as to non-personal contracts. Request clarification on this. And whether there is abbreviated DFARS equivalent language that need to be included in the personal contracts”

There is no exception in DoDI 3216.02 for personal services contracts; therefore, the DFARS clause must be used.

“If a service support contractor conducts research involving human subjects under research that is led by a DON Principal Investigator and approved by a DON IRB, is HRPO review still required?”

Yes, HRPO review is still required for research activities conducted by non-DoD institutions if they are involved in activities that “may include research with human subjects,” even if the research is led by a DON PI, and the research is approved by the DON IRB. The DoDI does not provide for an exception applicable to service support contractors, or distinguish between roles as PI or AI.