

# RESEARCH PROTECTIONS UPDATE

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

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## *Comment*

### **DON HRPP: The Ultimate Mission**

This month, DON Human Research Protection Program Compliance Specialists Derek Englis and Sandy Sanford will visit the Naval Health Clinic at the U.S. Naval Academy in Annapolis, Md., and the Naval Hospital at Camp Lejeune, N.C., respectively, to provide assistance and support to the human research protection staffs at those facilities. Sanford's visit will be the 19th this year by DON HRPP specialists to Navy and Marine Corps commands that conduct research involving human subjects.

In recent months, Englis visited the Naval Medical Research Unit and Naval Health Clinic in Hawaii. DON HRPP Specialists Kristin Jones and Terrence Clemmons conducted a site inspection at the Naval Air Warfare Center, Patuxent River, Md., and Kathryn Reitz and Christy Borders visited the Naval Undersea Warfare Center in Newport, R.I. Jones, Clemmons, Reitz, and Borders shortly will be on the road again for visits to other Commands.

These inspection and "assist" visits are the most important and most effective way the DON HRPP carries out its baseline mission of providing oversight of research with human subject at DON Commands. But oversight, beyond ensuring

compliance by Commands with DON and DoD policies, also means helping Command HRPP staff members cope with the complex litany of regulations and directives that continues to evolve in the field of human subject protections, in both government and the private research sector.

The requirements aren't new. DON Commands, especially in the Navy medical community, long have recognized and met their obligations to protect research subjects.

DoD direction to all the Services in late 2004 to strengthen their research protections programs led to the standup of the DON HRPP the next year and approval of SECNAVINST 3900.39D by Navy Secretary Donald Winter in November 2006.

Since then, the DON HRPP has responded to the new urgency assigned to the protection of human subjects. Specialists assigned to the DON HRPP's Bureau of Medicine and Surgery (BUMED) Office, including Englis and Sanford, are responsible for HRPP support for the Navy's medical commands.

Jones, Clemmons, Reitz, and Borders are on the staff of the DON HRPP's Research Protections Division, Office of Naval Research which, in accordance with the SECNAVINST, supports the DON's

Systems Commands, operational forces, and the training commands.

Their mission on site visits isn't to reinforce the complexity of often-inscrutable policy directives, nor to find fault with the work of often understaffed and underfunded Command HRPPs.

They aim to support Command HRPPs in their efforts to protect men and women who, by participating in DON research, help to strengthen the operational and medical capabilities of Navy and Marine Corps units.

The DON HRPP seeks to give life to the principles of the Belmont Report of 1978: justice, beneficence, and respect for persons. Those ideals guide the work of the DON HRPP specialists as they prepare for their next visits—to help Commands comply with the letter of policy, but beyond that, to protect human lives.

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Director's Page

## A Focus on Excellence for Research Protections

By CAPT Alan F. Nordholm, Director, DON HRPP

*CAPT Nordholm, a native of Columbus, Ohio, enlisted in the Navy in 1976 and served as a Hospital Corpsman. He left the Navy and earned his B.S. in mathematics at California State University, Long Beach. After earning his M.S. in clinical psychology at Pepperdine University, he enlisted in the Navy Reserve and served in Operations Desert Shield and Desert Storm. He completed his Ph.D. at the University of Southern California in 1993 and was commissioned a lieutenant in the Navy Medical Service Corps as a research psychologist in 1995. Following joint-service and OPNAV tours, he served at the Human Performance Center, Dam Neck, Va., and later as the Defense Health Program analyst at OPNAV's Programming Division. He then was named Chief, Joint Medical Education and Training at Joint Forces Command, responsible for all joint medical training. He served at NASA Ames Research Center in 2010 as OIC, Navy Detachment, acting as OIC of the Mobile Care Team in Afghanistan. He joined DON HRPP in March 2012.*

This initial issue of **RESEARCH PROTECTIONS UPDATE** for the year features a couple of articles that define what I consider baseline values for the Department of the Navy's Human Research Protection Program: excellence in knowledge and performance. Terrence Clemmons, who leads the DON HRPP Guidance Working Group, lays out on page 3 the approach the group has used to produce clear and unambiguous direction to the research community on every aspect of our mission.

Our guidance and education/training components will be integrated to serve as a reservoir of policy and technical expertise to foster excellence in performance by the DON human research protections community. That community, at Navy hospitals, clinics, and the operational Commands, encompasses administrators, researchers, IRB Chairs, members and staffers, and the Commanding Officers who serve as Institutional Officials responsible for making the final go/no-go decisions on research.

At all those levels, they are the executors of research—the principals in the labs and in the field who do the work and those who oversee it.

Their ultimate product is added value, and at times, authentic and far-reaching scientific achievement that enables decisive advances in mission capability and operational impact. Yet it remains that when human subjects are involved, the DON HRPP mission is critical and non-negotiable. Research can't be conducted without accounting for the HRPP body of knowledge and expertise.



B. ARWINE

*CAPT Nordholm, (center) with RADM David J. Smith, Director, Medical Resources, Plans, and Policy (left), and Deputy Surgeon General RADM Michael Mittelman at Nordholm's promotion signing ceremony, 31 August*

Looked at another way, research that uses human subjects without obtaining their informed consent or without taking the steps necessary to ensure their safety is, in a word, fraudulent. That's not only because the mandated requirements aren't met, but also because research findings obtained by taking shortcuts compromise the integrity of research and research performers.

The DON HRPP mission embodies a substantive and positive hierarchy of values for Navy and Marine Corps research. We don't haul around the weighty ethical idealism of the 1970s that, to be sure, started

*(Continued on page 3)*

## Guidance Group Aims at Handbook Release in 2013

Terrence Clemmons, DON HRPP Guidance Working Group Chair, says that the group expects to publish a long-awaited DON HRPP *Guidance Handbook* in mid-2013, following final chop by Director CAPT Alan F. Nordholm.

Clemmons leads a team that is developing a unique series of DON HRPP guidance papers that will be adopted and published as the *Handbook*. The group, he says, completed its initial discussions of the selected topics in late September.

The working group members are Clemmons and Kathryn Reitz, both with the DON HRPP's Research Protections Division of the Office of Naval Research, and Derek Englis and Sandy Sanford of the Bureau of Medicine and Surgery's DON HRPP Office.

Clemmons says that beginning last fall, the team met to discuss and debate a considerable range of perspectives on about 20 topics that DON HRPP has found to be especially important to Commands that conduct research with human subjects. Among them: IRB quorum and attendance; scientific review; DoD personnel as subjects; and IRB meeting minutes and records.

Clemmons sought volunteers among the members to develop draft guidance documents on the proposed topics for discussion.

"Some topics, including conflict of interest, DoD-supported research involving human subjects, and

scientific review elicited extended and sometimes intense debate," he said. "All the team members are well-versed in the field and have a strong grasp of current DON and DoD policy.

"Many of these topics are open to a variety of interpretations. But we've had great dialogue, and sought consensus throughout the sessions."

Clemmons says that he emphasized to the team the importance of grounding new positions in current policy references. "We'll need to document our positions when we defend them during the adjudication of the documents," he adds.

The completed drafts will be reviewed by a DON HRPP leadership subcommittee made up of Dr. Tim Singer, Director of the Research Protections Division, DON HRPP Deputy Dr. Andy Jones and Counsel Ivana Sustersic.

The Working Group will defend the positions, but modify them as required.

The documents then will be compiled as a draft *Handbook* for review by the BUMED Secretariat. That review, Clemmons says, will identify any inconsistencies with established DON policy.

Following Secretariat approval, the near-final *Handbook* will go to Nordholm for his approval.

That won't be the end of the Working Group's job, Clemmons says. The team will start a second round of reviews, aiming at future amendments as they emerge.

### *A Focus on Excellence for Research Protections*

*(Continued from page 2)*

the evolution of the federal laws and DoD policies on protecting human subjects.

Our focus tends to be pragmatic and in the moment: supporting the efforts of researchers whose work in turn supports Navy physicians and nurses at hospitals and clinics, as well as fleet units deployed worldwide.

Navy researchers aim at developing new processes and technologies to enhance the quality of medical care for Navy and Marine Corps families and combat casualties, and to produce innovations for the broad

range of fleet operations. Those are their missions—they are ours as well.

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## PROMIS HRPP IT System Gains Acceptance Throughout DoD

DON HRPP Deputy Dr. Andy Jones and officials of the Department of Veterans Affairs are exploring the prospect of the VA deploying the Protections in Research, Oversight and Management Information System (PROMIS) for its HRPP.

The system was developed by the DON HRPP staff affiliated with the Research Protections Division of the Office of Naval Research for management of Navy and Marine Corps human research protections programs. PROMIS now is used by 17 DON Commands that conduct human subject research. Several Army Commands also are planning to use the system, Jones says.

In July, Navy Deputy Surgeon General RADM Michael Mittelman and then-Deputy Assistant Secretary of Defense for Force Health Protection and Readiness Dr. George Peach Taylor Jr., in a Memorandum for the Record, stated that PROMIS would serve as the technology baseline for a future DoD-wide human research protections IT system to be used by all the Components.

Jones and DoD officials now are developing a strategy for adding new capabilities, including workflow management, to the PROMIS architecture.

DON HRPP officials say that a key advantage of PROMIS is that it is government-owned.

DON HRPP-ONR started development of a DON HRPP IT system in 2006, when Research Protections Division Director Dr. Tim Singer and then-DON HRPP Director CAPT Eileen Villasante recognized a need to replace the obsolete Human Research Knowledge System, or HRKS.

Singer says the DON HRPP required in a new system an automated web-based capability to track human research protections data and provide DON HRPP staffers with an up-to-the moment understanding of the status of DON research with human subjects. The system also must help HRPP staffs at Commands to manage research and communicate more efficiently with DON HRPP.

"It's critical that we have real-time situational awareness of what is going on in the field," Singer

says. "PROMIS will enable us to respond rapidly in the event of unanticipated problems in research that affect human subjects, and help us keep DON leadership informed as necessary."

DON HRPP conducted a market study of systems used by government and university laboratories before selecting SharePoint, now widely used in government and industry, as the PROMIS database architecture.

The development team then surveyed prospective users at Naval Commands to define the full range of functionality needed to provide rapid access to research information, including protocols, data on Principal Investigators, subjects, IRB meeting minutes, and other information required for a comprehensive profile of Commands' HRPPs.



*PROMIS is in service at the Naval Research Laboratory in Washington, D.C.*

Following a demonstration of PROMIS capability for HRPP officials of all the Services late last year, Ms. Patty Decot, then-Associate Director of Human & Animal RDT&E Protection Programs for ASD (R&E), said that "PROMIS may be useful for those Components and DoD institutions that ... have not found a commercial product to meet their needs."

Planning continues for introducing the system to as many as 30 Navy and Marine Corps Commands, and eventually for the other DoD Components and non-defense federal agencies.

Staff Focus***Patti Yasenchak: On Point for Extramural Research***

*Patti Yasenchak, a native of Oceanside, N.Y., earned her B.A. (psychology) and M.Ed. (education) at the University of Virginia. After completing her graduate education, she served as a rehabilitation counselor at Workshops V, which supports five Virginia counties and the city of Charlottesville, Va. She then joined the UVA School of Medicine faculty as research project coordinator for UVA's Spinal Cord Injury Project, and later was named director of education for the American Academy of Orthotists and Prosthetists in Alexandria, Va. After serving as clinical data coordinator and clinical research associate for PRA International in Charlottesville, she was appointed case manager at UVA-HealthSouth Rehabilitation Hospital then clinical research coordinator at the Clinical Trials Office of the UVA Cancer Center. She joined DON HRPP's Research Protections Division at ONR in 2007.*

Research Compliance Specialist Patti Yasenchak, as DON HRPP's coordinator for extramural research, is undoubtedly the best-known member of the DON



HRPP staff nationwide—at universities, private research laboratories, and contractors who seek DON funding to conduct research with human subjects. As DON HRPP's primary contact with non-federal

“extramural” research performers, it's her job to explain to research officials at many levels of institutional governance that the Department of the Navy's requirements for extramural research are more stringent than those of the Office of Research Protections of the Department of Health and Human

Services. In many cases she works with senior executives of nationally prestigious research centers who assure her they know all about compliance with federal law, which requires them to hold a Federalwide Assurance, granted by OHRP.

“In most cases, they do—but sometimes don't understand that the DON has different standards to ensure that subjects in work supported by the Navy and Marine Corps are protected,” Yasenchak says.

The Navy requires non-federal performers of DON-sponsored research with human subjects to apply for a “DoD-Navy Addendum” to the FWA. The Addendum requires, among other things, provision for a research monitor for greater-than-minimal risk work; scientific review prior to IRB review; and protections for vulnerable subjects, including military subjects.

Proposals for international research get extra scrutiny. The Navy Surgeon General approves all Addendum applications.

Without the Addendum, performers cannot be funded. If an institution fails to renew before the Addendum expires, the research must cease. And Yasenchak is on point to explain why.

Despite the demanding process, Yasenchak has closed out nearly 300 Addendum applications and more than 200 renewals, many for elite research institutions, including MIT, Johns Hopkins, Carnegie Mellon, Stanford, Caltech, and Batelle; major state universities; corporations (Boeing, , Northrop Grumman, General Dynamics); hospitals (Brigham and Women's, Massachusetts General, Duke Health System); as well as many specialized smaller institutions.

Yasenchak says that when she meets her contacts from extramural institutions, she's “surprised that they actually act happy to see me.”

DON HRPP says that the Navy/Marine Corps will continue to maintain high standards for extramural performers. “We're aiming at getting work done—at the same time, we're doing all we can to ensure the safety of our subjects,” Yasenchak says.

Education and Training**DON HRPP Moving to Adopt DoD Training Guidance**

DON HRPP staff members are collaborating with their counterparts in the Army, Air Force, and other DoD Components to explore approaches to implementing new human research protection training requirements defined in a memorandum released August 16 by Dr. Patrick Mason, Director, Human Performance, Training and BioSystems in the Office of the Assistant Secretary of Defense (Research and Engineering).

Training and Education Coordinator Sandy Sanford says that the memorandum, referred to as the minimum education requirements framework or MERF, will require the DON HRPP and the human research protection programs of the other Services and defense agencies to modify the training they provide to their personnel to reflect a number of provisions of DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," which was released in October 2011.

On August 23 DON HRPP distributed an E-gram advising DON Commands of the release of the new requirements.

Sanford points out that DON HRPP currently offers training provided by the Collaborative Institutional Training Initiative (CITI) in many areas of research protections, although Commands are not required to use the training.

"We have a few Navy-specific modules, but the majority of the CITI content is generic to the human research world," she says.

The Army also uses the CITI modules for its HRPP training. Air Force Commands select their own training programs.

DON HRPP Training and Education Specialist Christy Borders is working with the Components to create a closely integrated training approach.

"The MERF requires us to modify the CITI modules taken by DON personnel to add references to the DoDI requirements," Sanford says.

She says, for example, that the CITI module that addresses the area of vulnerable populations cites the Common Rule [federal policy on protection of human subjects codified separately for 15 federal agencies]. However the DoDI has some specific differences with the Common Rule; the module must be tweaked to reflect the DoDI position.

Sanford explains that the MERF also will require DON HRPP to develop two entirely new training modules for CITI, one that addresses the applicability of 10 U.S.C. 980, which defines limitations on the use of humans as experimental subjects, and a second module covering the role of a research monitor.

ASD (R&E) officials have said that DoD HRPP personnel who already have gone through required training are to be "grandfathered" for compliance with the MERF until their training expires, unless they move to HRPP positions that require additional training.

New personnel will be required to undergo training that complies with the MERF requirements.

## **PRIM&R**

### **Public Responsibility in Medicine and Research**

*Advancing Ethical Research Conference*

*Guided by Principles in an Era of Change*

**December 4-6**

**San Diego CA**

**DoD Networking Luncheon Dec. 4, 12:00-1:45 PM**

**Navy Breakout Session Dec. 5, 3:30-5:00 PM**

**Pre-Conference Programs December 3**

**Registration: <http://www.primr.org/aer12/>**

## DON HRPP Specialist Clemmons Honored by ASN (M&RA)

The Hon. Juan M. Garcia, Assistant Secretary of the Navy for Manpower & Research Affairs, forwarded to Chief of Naval Research RADM Matthew Klunder a letter of appreciation for DON HRPP Research Protections Specialist Terrence Clemmons regarding his performance as a member of the Board for Correction of Naval Records.

The Board is responsible for reviewing and, when necessary, correcting the military records of current and former Navy and Marine Corps personnel.

Clemmons, a member of the DON HRPP staff of the Research Protections Division at the Office of Naval Research, serves as DON HRPP point of contact for the Naval Sea Systems Command as well as NAVSEA labs at Dahlgren, Va., Carderock, Md., and Panama City, Fla., SPAWAR Systems Centers Atlantic (Charleston, S.C.) and Pacific (San Diego), and the Naval Postgraduate School.

Secretary Garcia said in his letter that "Mr. Clemmons has performed his duties in a thoroughly competent and professional manner. He has

conscientiously attended scheduled meetings and consistently displayed keen analytical ability and sound judgment. As a result of his efforts and the efforts of his colleagues, 3,899 cases were finally resolved during the period from October 2011 through the end of June 2012."

He noted that the Board "deals with highly complex and sensitive issues that cannot be disposed of by normal administrative action. ... I wish to offer my sincere appreciation for the very important work Mr. Clemmons is performing in this assignment."

Mr. Clemmons, a native of Baltimore, has served on the Board of Corrections since 2009. A retired Navy Chief Hospital Corpsman, he served with the Marine Corps 3rd Force Service Support Group on Okinawa, Japan, and deployed to participate in Operations Desert Shield and Desert Storm.

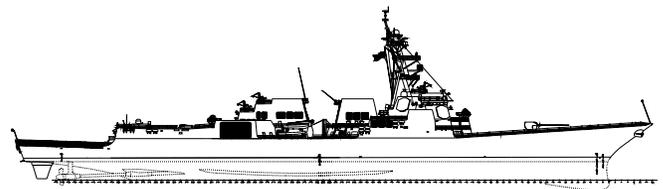
Clemmons came to DON HRPP's ONR office in 2007 from the Human Research Protection Program at the University of Maryland School of Medicine.

### *Extramural Research Picks Up Steam*

The DON HRPP office experienced a significant increase in recent months in applications for the DoD-Navy Addendum to the Federalwide Assurance from non-government "extramural" institutions that seek to conduct DON-sponsored research involving human subjects. The Addendum imposes standards in addition to those of the Office of Human Research Protections of DHHS on non-government research performers wishing to obtain DON funding (see page 5). The Addendum requires approval by the Navy Surgeon General.

Institutions seeking a new Addendum included Columbia University Medical Center, New York Presbyterian Hospital, Boston Children's Hospital,

Walden University, Gettysburg College, OncBioMune LLC, University of Tennessee Health



Science Center, University of Utah, West Health Institute, and Gettysburg College.

BAE Systems, George Washington University, and Creare Inc. submitted applications for renewal of previously awarded Addendums.

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