

# RESEARCH PROTECTIONS UPDATE

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

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*Comment*

## HRPP: The Medical Research Side

The DON HRPP oversight and monitoring mission, addressing the full spectrum of research conducted by Navy Commands, is constituted in two broad domains: medical and non-medical. Recent issues of *RPU* have focused on three of the DON communities catalogued as “non-medical”: Navy diving; Marine Corps force planning; and systems engineering for surface warfare.

The distinction between the two domains isn’t clearcut, because as the Navy Experimental Diving Unit, Marine Corps Combat Development & Integration, and the Naval Surface Warfare Center’s Dahlgren Division focus on mission requirements, they also must address such medical needs as diver survivability and combat casualty care, among others.

At the top level, “medical” for the DON HRPP is represented by the major medical centers (Bethesda, Portsmouth, San Diego); hospitals; clinics; and the medical research centers and labs, including the Naval Medical Research Units in Lima, Peru, and Cairo, among others.

HRPP staff members Navywide are well aware that the “medical/non-medical” demarcation is represented by the assignment of DON HRPP compliance specialists to DON Commands. “Medical” Commands and labs are supported by specialists

at the Bureau of Medicine & Surgery (BUMED); non-medical Commands are assisted by the staff of the Research Protections Division at the Office of Naval Research.

This arrangement is based on direction in UNSECNAV Executive Decision Memorandum of 29 April 2005, which assigned sole authority for the program to the Navy Surgeon General, but authorized him to delegate to the Chief of Naval Research (CNR) responsibility for all non-medical research at DON-supported institutions.

The Surgeon General did exactly that in his memorandum of 4 August 2005, which assigned to CNR the HRPP responsibility for 14 non-medical Commands.

The lineup of Commands served by BUMED and ONR has changed since then, but the mission remains: supporting and assisting HRPP teams to ensure compliance with DON and DoD policies and with federal law.

To some degree, the BUMED and ONR compliance specialists face different challenges. Protection of human subjects in research long has been an integral component of medical research at Navy as well as civilian sites. Hospital, clinic, and medically oriented research staffs understand and appreciate the

urgency and complexity of HRPP requirements. Their recognition and acceptance of the obligation to safeguard subjects’ lives and welfare predates the formal standup of the DON HRPP.

Navy Commands—medical or non-medical—that conduct research involving human subjects sometimes struggle with the rigorous body of DoD and DON policy and federal law and regulation imposed to strengthen programs.

Yet as repeated inspections have demonstrated, understanding and endorsement of the urgency of the HRPP work in the Navy’s medical universe is indisputable.

DON HRPP applauds those institutions, and continues to support their dedication to carrying out the mission.

### *Also in this Issue:*

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*Director's Notes*

## A Clear Focus on People

By CDR William Deniston

This issue of *Research Protections Update* provides a close-up look at two Navy Commands that conduct research that falls on the “medical” side of the DON HRPP’s portfolio.

Research at the Naval Medical Center Portsmouth (page 3), one of the Navy’s flagship MCs, is concerned primarily with patient care, but NMCP protocols also address operational priorities. The Naval Medical Research Unit-Dayton (NAMRU-D page 6) addresses risks in many operational settings, including tactical aviation operations, the handling of hazardous materials, and potential effects of the submarine environment on women’s health.

Drs. Charles Morgan, just-retired Head of NMCP’s Research Subjects Protections Division and Thomas Rieg, Head of the Clinical Investigation Department at Portsmouth, describe the full spectrum of NMCP’s mission: providing IRB review of research proposed by principal investigators (P.I.s) at Commands throughout Navy Medicine East; forging collaborations with Army, Air Force, and international researchers; seeking proactive ways to support Portsmouth’s hardworking clinicians.

They cite some significant challenges, among them the uncertainties implicit in the strategic reorganization of the DoD health system, now underway. These will include a shift to centralized IRBs instead of local ones for research review.

At NAMRU-D, Dr. Richard Arnold, director of the Aeromedical Research Directorate, cites critical aviation-related dangers, such as hypoxia (oxygen deprivation), spatial disorientation, and fatigue, which will become more acute as the Navy and Marine Corps field new high-performance aircraft.

Arnold’s team is conducting wide-ranging research that seeks solutions for all of the above. The directorate also pursues cooperative engagements with the other Services to support the work.

Dr. Michael Gargas, director of NAMRU-D’s Environmental Health Effects Directorate, says his group conducts research primarily with animals. His team seeks to determine how the surroundings in which military personnel operate may pose risks to their health and ability to carry out missions.

“We worry about people who refuel aircraft, Marines in ground operations exposed to toxic gasses emitted by burn pits, and women serving on submarines,” he says.

This is groundbreaking work, that gets to the heart of the Navy’s research protections mission: safeguarding the lives and welfare of persons, in both medical and operational settings.

DON HRPP’s mission is to support both P.I.s who conduct research, and the professionals in the research protections community. Their goal is protecting human lives. It’s our goal as well.

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### New Leadership for ONR’s DON HRPP Team

Dr. Tim Singer, Director of the Research Protections Division at the Office of Naval Research (ONR) since the DON HRPP was established in 2006, has announced his retirement.

The Division, a component of the DON HRPP, is responsible for monitoring and oversight of DON non-medical research at the Navy’s Systems Commands, training Commands, and operational forces, and at non-government research institutions. CAPT John Schmidt, military deputy for ONR’s Warfighter Performance department, is serving as

acting Division Director. CAPT Schmidt chaired the IRB at the Naval Postgraduate School. CDR Katie Shobe (see page 9) has taken the assignment of Research Protections Division Deputy Director.

Terrence Clemmons, Compliance Specialist for the Division since 2007, now serves as Lead Compliance Specialist for the DON HRPP, following the departure of Andy Jones in November. Clemmons acts as POC for five Commands and plays a key role on the SECNAVINST 3900.39 “Echo” team.

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Naval Medical Center Portsmouth**Naval Medical Center Portsmouth: Innovative Leadership for Medical Research**

The research program of the Naval Medical Center Portsmouth (NMCP), one of the Navy's largest, is working to implement the Navy Surgeon General's three strategies of Navy medicine: jointness, readiness, and value, both in its extensive residency research program and in the protection of human subjects who participate in the Command's research.



**Dr. Charles Morgan**

NMCP, staffed by more than 5,000 Navy and civilian personnel, is the oldest continuously operating Navy hospital, dating from completion of a three-story hospital in 1827. Charles Morgan, Ph.D., Head of NMCP's Research Subject Protections Division, says that the Command's two Institutional Review Boards (IRBs) review protocols submitted by investigators at Commands representing most of Navy Medicine East: the Naval hospitals at Jacksonville and Pensacola, Fla.; Camp Lejeune, N.C.; Great Lakes, Ill.; Corpus Christi, Texas.; the Center for Security Forces Detachment/Kittery Survival, Evasion, Resistance and Escape School (SERE-East), Kittery, Maine; and the Navy Medicine Operational Training Center (NMOTC) in Pensacola.

Portsmouth also has conducted reviews for investigators at Guantanamo, Cuba; Rota, Spain; Naples and Sigonella, Italy; as well as those assigned to the hospital ship USNS *Comfort*. That portfolio, Morgan says, probably will in the future include the hospitals at the U.S. Naval Academy in Annapolis, Md., and at Marine Corps Base Quantico, Va.

Thomas Rieg, Ph.D., Head of the Clinical Investigation Department at NMCP, says that in

recent years the NMCP research staff has grown from five to 36 highly experienced personnel. The growth has included the addition of research assistants, research coordinators, research nurses, a biostatistician, a medical editor, a grants writer, and a grants manager. Addition of these staff members has strengthened the support for the research conducted by the resident and staff physicians.

The Command relies heavily on outside sources for funding of its research. Expansion of the research program, Morgan says, has enabled the Command to win some \$2 million to \$3 million in external funding each year, both from professional medical societies and government sources, such as Congressionally Directed Medical Research Programs.

Rieg says that "Previously we would have had to send patients with certain problems to local area hospitals. By being able to conduct the research here, we now can treat them at NMCP."



**Naval Medical Center Portsmouth**

He points out that much of the Command's research is conducted by NMCP residents, in compliance with a requirement by the Accreditation Council for Graduate Medical Education (ACGME)

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Naval Medical Center Portsmouth*“Conducting Research Fosters Readiness”**(Continued from page 3)*

that all medical residency programs conduct research, or “scholarly activity.” Such activity, Rieg says, consists of original research, from retrospective chart reviews, double-blind placebo-controlled crossover control group studies, to many others intended to contribute to medical knowledge.

The Command’s research encompasses all medical disciplines: obstetrics and gynecology; pediatrics; emergency medicine, and orthopedics (the four largest); internal medicine, otolaryngology (ear, nose, and throat), general surgery, anesthesiology, and psychiatry, as well as 34 other departments.

“In order to be at the forefront of medical knowledge, we have to conduct research,” Rieg says.

“What separates a good medical school from a not-so-well-known one is research. When you’re conducting research you’re producing new medical knowledge. So having people conduct research fosters readiness—they’ll be ready to deploy.”

Jointness, Morgan says, is an important feature of research at Portsmouth. The research staff and IRB membership include Army and Air Force professionals. The Command, he says, is planning new research initiatives in collaboration with the other Services, such as an OB/GYN project at nearby Langley Air Force Base.

Portsmouth also is engaged in joint programs with the Army through an agreement with Central Command that enables researchers in the CENTCOM area of responsibility (AOR) in the Middle East and Southwest Asia to propose and conduct research while deployed with CENTCOM units, and then continue the work when they return home.

Deployment overseas—a fact of life for most investigators—is a perennial challenge, especially for certain departments. A large proportion of the general surgeons assigned to Portsmouth usually are deployed, Rieg says. The deployments should wind

down as the U.S. presence in Afghanistan is reduced. Still, many deployed investigators have been able to conduct research, often in collaboration with Army, Air Force, or international partners.

The Command sponsors extensive research conducted by non-government research performers, including universities, and private contractors and laboratories. Morgan points out that for research that involves human subjects, private performers must have a Federalwide Assurance for the Protection of Human Subjects and then obtain a DoD-Navy Addendum approved by the Navy Surgeon General. He notes that the Addendum approval process—not required by the Army or the Air Force—is complicated and often time-consuming.



*Dr. Thomas Rieg*

centralized IRBs instead of by local IRBs. He points out that Portsmouth’s Infectious Disease Division sends most of its protocols not to the Portsmouth IRB but to an IRB at the Uniformed Services University of the Health Sciences (USUHS), which also reviews Army and Air Force protocols.

“It’s a good model, and they are successful doing the research.” He adds that the National Cancer Institute wants Portsmouth to submit its protocols concerning oncology research to its central IRB.

A critically important aspect of research is that it

*(Continued on page 5)*

Morgan says that, as the Services move toward consolidation of their medical programs in a joint Defense Health System, a critical challenge for the protection of human subjects in research will be the shift to the review of research by

## *NMC Portsmouth: Research Requires Long-Term Support*

*(Continued from page 4)*

is a long-term endeavor, Rieg points out. “Research takes years to complete—from the time the PI gets the protocol to the IRB, to IRB approval, to when it’s conducted, analyzed, and published. Drug production, or developing new drugs, takes 10 to 15 years, and the studies and collaborations with pharmaceutical companies are just one part of that process.

“What I’d like to see is a continuation of the process we’ve set up now” that in coming years would permit dedicated research coordinators to support the research in individual NMCP departments. Morgan adds that travel also is

important for professional development for CID staff members, not only for professional gatherings, but also to visit NMCP’s supported Commands to meet with Command staff members and conduct education and training sessions. Command staffers subsequently reported that their research personnel found those sessions highly effective.

Rieg notes that in 2013 a researcher from one of those Commands, the Naval Aerospace Medical Institute, was last year’s winner of the Navy’s research competition. “Those AORs for which we serve as the IRBs are doing the best research in the Navy,” he says.

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### **Handbook, Coming Soon, Aims to Provide Answers**

The DON HRPP is developing a comprehensive HRPP Handbook to serve as a practical, “how-to” user’s tool for DON HRPP staff members. The Handbook, scheduled for release in March, will be a kind of “source book” to assist Commands that conduct research with human subjects in complying with DoD and DON HRPP policies and federal law governing human subject protections.

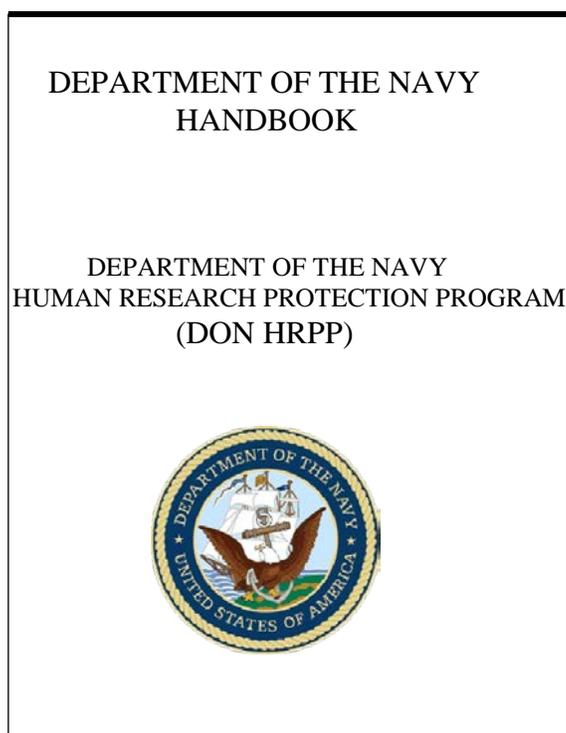
DON HRPP hopes that publication of the Handbook will help provide answers to many of the questions that arise among HRPP professionals in addressing HRPP requirements at both medically oriented Commands and “non-medical” Commands focused on research to provide technologies and tactical systems for Fleet/Force operations.

In its current draft form, the Handbook offers some 20 chapters that discuss such topics as determination of human subject research; IRB review of research; scientific review; use of humans as experimental subjects; IRB meeting minutes; and DoD/DON requirements for DoD-supported research with human subjects.

Other sections explain the use of the Institutional Agreement for IRB Review, Individual Investigator Agreement, and the DoD-DON Addendum to the Federalwide Assurance.

The Handbook team has asked a number of Commands that conduct research with human subjects to submit comments on the draft.

The team plans to continue to update the Handbook for periodic reissue. DON HRPP encourages Command HRPP staffers to offer input on potential topics—at any time—for consideration for inclusion in future editions. Send suggested topics to Terrence Clemmons ([Terrence.clemmons1@navy.mil](mailto:Terrence.clemmons1@navy.mil)).



NAMRU-Dayton

## NAMRU-D: Pioneering Aeromedical, Health Research

The Naval Medical Research Unit Dayton (NAMRU-D) is pursuing collaborations with Army and Air Force laboratories on cutting-edge research efforts, ranging from finding ways to overcome risks to Navy and Air Force aircraft crews to protecting military personnel from toxicological dangers.

NAMRU-D was established at Wright-Patterson Air Force Base in Dayton, Ohio, on Oct 6, 2010 as a result of a 2005 Base Realignment and Closures (BRAC) Commission decision to merge the Naval Aerospace Medical Research Laboratory with the Naval Environmental Health Effects Laboratory.



The Navy organized the new NAMRU-D in two directorates, Aeromedical Research and Environmental Health Effects Research, reflecting the missions of the original two Commands. NAMRU-D Commanding Officer CAPT Jeffrey

*CAPT Jeff Andrews* Andrews says that the Command “does the ‘bare-bones’ early-on R&D [in both directorates] ... the work we’re doing is innovative and operationally relevant.”

Dr. Richard Arnold, Director of NAMRU-D’s Aeromedical Research Directorate, says his group is pursuing research in five major areas: detection and prevention of hypoxia (oxygen deprivation); spatial disorientation; motion sickness countermeasures; fatigue mitigation; and vision science.

The directorate is collaborating with the Office of Naval Research and the Air Force to evaluate various cockpit sensors for detection of pilot hypoxia in order to cue preventive measures. Currently, naval aircraft do not have such sensors, he points out.

Arnold says that spatial disorientation is the

primary cause of flight mishaps, especially Class A mishaps, the most serious. The directorate has a “robust and growing” program to identify and counteract it. His group also has an active initiative to identify pharmaceutical countermeasures for motion sickness, which extends also to surface operations, and to alleviate crew fatigue.

In vision science, the team is investigating potential upgrades to the Navy’s color-vision tests, which have not been revised substantively since just after World War II.

NAMRU-D is collaborating extensively with the Air Force on many of these programs, Arnold says. He notes that as one outcome of the BRAC decision, NAMRU-D shares facilities with the Air Force’s 711th Human Performance Wing (HPW). At the site, NAMRU-D will operate a large multi-access disorientation research device (DRD) to support research on the effects of acceleration, motion, and spatial disorientation on the body.

The 711th HPW is acquiring a high-G human centrifuge and several hypobaric chambers, all of which, along with the DRD, are planned to be shared resources between the two Services.

Arnold says that the directorate works closely with the Naval Air Systems Command’s Aviation Training Systems program office on their hypoxia and spatial disorientation familiarization training systems.

The directorate developed a reduced oxygen breathing device (ROBD) sponsored by NAVAIR prior to fielding; the device now is used for hypoxia familiarization refresher training throughout the fleet.

NAMRU-D maintains a memorandum of understanding with the Naval Air Warfare Center Aircraft Division for joint work on human systems and human performance research. NAWCAD also participates in the ONR-sponsored hypoxia work.

Arnold’s group has supported the Commander, Naval Air Forces, based at Naval Air Station North Island, Calif., assisting in developing and priori-

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NAMRU-Dayton**“How Do We Integrate the Human with Technology?”**

*(Continued from page 6)*

tizing CNAF’s “top ten” aeromedical threats and devising ways to counter them. NAMRU-D then aligns its research initiatives with the threats to the maximum extent possible—although, Arnold adds, as a reimbursable laboratory, NAMRU-D must compete for research funding to address identified research gaps.

Andrews explains that an important challenge for the NAMRU-D lab is “cockpit workload—too much information” in the cockpit.

“Cognitive processing is a paradigm shift—a factor in the way we process information,” he says. We’re starting to incorporate that into our [warfighter] training.”

Arnold adds that helmet-mounted displays transfer cockpit symbology to the display. The orientation to the outside scene, while displays are projected on the helmet—whether “slaved” to the aircraft or to the pilot—raise questions about the impact on spatial orientation and disorientation. Night operations, he says, add to the problem, when pilots must view the scene outside the cockpit and then shift to scan their instruments inside the cockpit.

He says that “These issues fall under the ‘big umbrella’ of human systems integration. The question is how do we integrate the human with this technology and these systems in a way that maximizes performance while reducing risk?”

Arnold explains that his directorate, through its initiatives on hypoxia, spatial disorientation, and fatigue, among others, is working to answer this critical question.

Dr. Michael Gargas, director of NAMRU-D’s Environmental Health Effects Directorate, notes that his group is referred to informally as the toxicology directorate. The work focuses on research with animals in order to determine levels of risk to personnel of exposure to occupational chemicals and materials, and to propose solutions, such as health protective exposure limits.

“We worry about people refueling aircraft; aircraft carrier deck crews exposed to engine exhaust;

Marines conducting land operations; and submarine crews subjected to the submarine environment while on extended deployments.

In a recent major effort, the directorate studied the impact of the introduction of women aboard Navy submarines, as directed by Congress in November 2011. At that time, the Navy recognized that the data on the submarine environment and the



*At NAMRU-D: a bank of whole body inhalation exposure chambers in DoD’s largest toxicology inhalation research facility.*

standards established for it all were based on male effects only. NAMRU-D looked at the effects of gas mixtures aboard subs on women. It also studied the impact of chemical buildup aboard undersea rescue vehicles and deep-diving suits, working closely with the Naval Submarine Medical Research Laboratory in Groton, Conn. (See *Research Protections Update*, Spring 2013).

Gargas says his group has conducted extensive studies developing simulated burn pit emissions for exposure to in-vitro cell systems and for animal testing as a means of studying health effects.

Marine Corps and Army ground units have used open burn pits to incinerate trash in operational areas, some covering over 100 acres. The emissions may be carried by the wind to living areas, creating

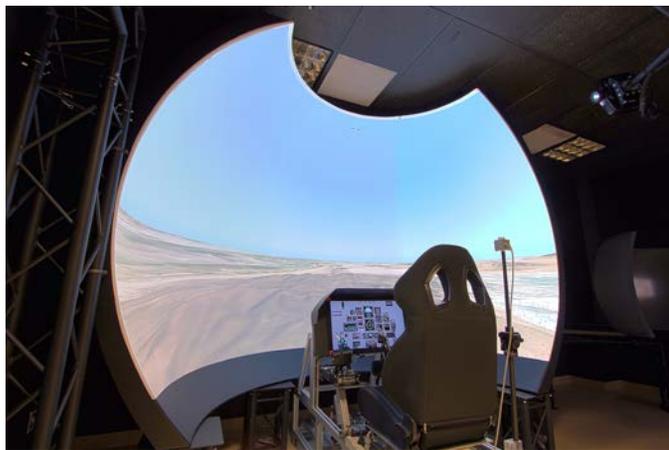
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NAMRU-Dayton**“Our Research is Aligned with Fleet Requirements”**

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serious health risks for personnel, particularly respiratory problems. In the same way, the directorate used rats to study the effects of inhaled sand from combat environments in Iraq and Afghanistan.

In a recently-approved study, the Gargas team will partner with the 711th HPW on a study of burn pit exposure alone, sand exposure alone and a combination of the two; the NAMRU-D group will examine the general toxicology and pathology while



*Research on spatial disorientation is a top NAMRU-D priority. Shown here: the Spatial Disorientation Dome at the Command's Spatial Disorientation Laboratory.*

the 711th will search for biomarkers of exposure and effect. If successful, the biomarkers identified will allow for screening of potentially exposed personnel as well as for the extent of injury, in addition to providing insights into the mechanism(s) of the toxic response.

Studies of this type, Gargas says, will allow us to better protect our personnel in the field.

Gargas says that the study of new fuels has become a major area of emphasis. Testing is needed to determine whether new fuels are less toxic; some components of Navy and Air Force jet fuels may cause hearing loss. Studies also may look at both the effects of jet fuel and noise-induced hearing loss,

which he notes is a major health concern for veterans.

Gargas is the Navy representative to the Tri-Service Toxicology Consortium, which arranges collaborative research programs by investigators from all the Services to take advantage of their unique skills, avoid duplication of effort, and maximize the impact of funding.

In one such effort, NAMRU-D teamed with the Army Public Health Command to evaluate the environmental effects of ammunition and other materials left on firing ranges that may leave the test range and enter the soil and water.

He points out that once such materials leave military installations, the Services, like private industrial concerns, must comply with Environmental Protection Agency standards. The NAMRU Dayton-Army team developed a health-based standard that, if accepted by the EPA, could save the Army as much as \$200 million by reducing the need for cleanups.

In another study, NAMRU-D teamed with the Army to study the effects of gases generated by a halon fire extinguisher used on Army tactical vehicles. The study used sheep to test the effects of the gases on personnel, and determined that they would have adequate time to escape a vehicle fire if the halon extinguishers were used.

Andrews says that both the NAMRU-D Aeromedical Research and Environmental Health Effects directorates “work for the fleet—our research is aligned with fleet requirements.” The extensive work of both directorates with the Army and Air Force, he adds, recognizes that “the future is joint.

“We’ve talked about ‘jointness’ for a long time—but we are living it now,” he says.

“The difficulties we see are with bureaucracy and funding, as decisions on the new structure for the DoD Health System are made. But at the level of the deckplate, and in the exchange of ideas, it’s happening now,” he says.

*Office of Naval Research*

## Shobe Takes Over Deputy Role for DON HRPP's ONR Team

CDR Katie Shobe, who assumed the role of Deputy Director for the Research Protections Division of the Office of Naval Research (ONR) in late 2013, says that thanks to her own experience as a researcher and IRB member, she “appreciates what it means to be on the receiving end” of DON HRPP policymaking.

*CDR Katie Shobe*

“I’m excited—working at ONR has been one of my goals as a research scientist.” Shobe, a native of Naperville, Ill., earned her B.S. in psychology at the University of Illinois Champaign-Urbana and her Ph.D. in cognitive psychology at Yale University. She then taught at Yale and at Barnard College in New York. “That’s when I realized that teaching wasn’t for me. Her experience as a graduate student fellow at the National Academy of Sciences, in which she worked on military embedded training issues, guided her towards more applied research opportunities, she says.

After earning her Navy commission in late 2000 she was assigned to the Naval Submarine Medical Research Laboratory, where she served as a deputy head of the Human Performance Department. She conducted research in such areas as skill development and submarine habitability. She also gained valuable experience as an IRB member. She then joined the staff of the Submarine Learning Center, overseeing studies in training effectiveness and program evaluation.

In early 2007 she reported to Space and Naval Warfare Center Pacific. “My research there was more ‘user-centric,’” she says. Some of her work

was funded by the Capable Manpower Future Naval Capability initiative managed at ONR. She conducted studies in human-systems integration, providing direct support to deployed Navy units.

“I love the operational work—my work was directly aligned to improving warfighter performance,” she says.

In August 2009 she was named Head of the Behavioral Sciences and Epidemiology Department at the Naval Health Research Center. While at NHRC she led the Navy’s Behavioral Health Needs Assessment Survey.

She deployed in May 2010 to Afghanistan for a six-month tour as Operations Officer for the BUMED Mobile Care Team, which evaluated the mental health of some 2,000 Navy personnel serving in the theater.

Shobe reported to ONR in October 2012 and, in



*Katie and therapy dog Sgt. Timmy* In March 2013 Navy Surgeon General VADM Matthew Nathan named her Research Psychology Specialty Leader.

Shobe, a distance runner, says that she plans to apply her operator’s perspective to the Division’s oversight work.

“I’ll focus on customer service—making our communications more understandable and useful for HRPP staff members at Commands,” she says.

addition to the Research Protections post, serves as Deputy Director for the Warfighter Protection and Applications Division, overseeing a wide range of research initiatives.

In March 2013

PRIM&R 2013

## DON HRPP Staffers Meet at PRIM&amp;R Conference

More than a dozen DON HRPP staff members, including representatives of several Commands, participated in the 2013 “Advancing Ethical Research” conference sponsored by Public Responsibility in Medicine & Research (PRIM&R) held in Boston in November.

The 4,000-member organization supports development of high ethical standards and education in the protection of human subjects in research. The PRIM&R conference also offers workshops and courses that enable HRP professionals to obtain and renew professional



*Nancy Dawood*

Marine Corps Combat Development Command, Naval Hospital Guam, Naval Medical Research Unit-San Antonio, and Space and Naval Warfare Systems Center Pacific (SSC Pacific) received SECNAV approval to attend PRIM&R.

DON HRPP officials note that HRPP training is difficult to obtain in the current fiscal environment, but the PRIM&R conference proved to be a valuable forum for the staffers who attended.

The conference offered five keynote addresses, 17 plenary sessions, and 125 workshops on research ethics, education, and other HRP-related topics.

Nancy Dawood, of DON HRPP headquarters, said that PRIM&R “gives attendees the opportunity to discuss challenges and share ideas.” She found several workshops especially useful, including one that explored whether consent documents provide

sufficient information about risks.

Compliance Specialist Patti Yasenchak, based at the Office of Naval Research (ONR), participated in sessions on education and identification of risk. She said the conference provided perspective on HRPP problems outside DoD.

Specialist Peter Marshall, also of DON HRPP headquarters, said that he obtained useful information at PRIM&R about review of research conducted using forums on the Internet.

Leah Watson, who serves both as IRB Chair and Administrator for the Marine Corps HRPP, says that the PRIM&R conference is “one of the most valuable things I do every year.”

She points out that Navy human research protections is oriented primarily to medical research rather than social, behavioral and educational (SBE) research, the focus of the Marine Corps program. PRIM&R, she says, enables her to meet with specialists from other organizations and institutions that conduct SBE research.

Terrence Clemmons, Lead Compliance Specialist at ONR found a session on determining whether a project is human subjects research and if research requires IRB review to be informative and helpful.

Compliance Specialist Derek Englis said that PRIM&R was “overall a very worthwhile conference,” and enabled him to earn continuing education credits to maintain his CIP status and strengthen relationships with his Commands.

Kathleen Bocker, HRPP/IRB Administrator at SSC Pacific, said that she found the conference informative, well organized, and well worth the trip.

SSC Pacific Assistant Counsel Diana King also attended PRIM&R. “The conference was extremely educational. The keynote addresses were interesting, the panels were thought-provoking, and the breakout sessions were hands-on,” she added.

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