

# RESEARCH PROTECTIONS UPDATE

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

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## Comment

### **DON HRPP: “Getting the Word Out”**

DON HRPP director Capt. Eileen Villasante and Dr. Tim Singer, director of the Research Protections Division at the Office of Naval Research, briefed public affairs officers of the Navy’s regional medical commands in late January on the DON Human Research Protections Program. With the brief, the directors took another step in a continuing campaign to inform personnel of both the medical and operational communities on the background to the standup of the DON HRPP.

Villasante and Singer stressed the importance of human subject research in support of the Navy and Marine Corps warfighter for development of weapon systems and protective equipment, for disease prevention, and combat casualty care, among other USN/USMC missions. The DON HRPP team still faces the challenge of explaining how requirements to protect human research subjects apply to the diverse types of research done in the Navy.

For the PAOs, Villasante and Singer also discussed the provision of the Navy’s new policy on protecting human subjects, SECNAV-INST 3900.39D, on the public release of information: “To foster public trust in research and human subject protections, information is made available to the public, the

news media, and Congress.”

They noted that release of information regarding human research still must comply with other applicable DoD and Navy policies.

Public affairs practices that permit the prudent release of information represent a critical element of DON HRPP efforts to inform the Navy and the public on the human research protection mission.

Communication among the CO, the PAO, and the Institutional Review Board (IRB) will help the command identify research that might attract significant media attention or that might invite challenge by interest groups. Communication can be accomplished through periodic meetings and providing PAO with relevant excerpts from, or a copy of, IRB meeting minutes after official signature. PAOs may wish to attend an IRB meeting as a guest to learn about the IRB process and the many important and sensitive considerations that guide IRB decisions. IRB decisions are only recommendations to COs – the CO decides what research is approved.

Typically, releasing information about research with human subjects requires meticulous coordination and consultation among command officials, sponsors, and researchers.

In addition, investigators wishing to present or publish their research must adhere to Navy clearance procedures, including verification of IRB and institutional approval and appropriate disclaimers.

“Getting the word out” on the DON HRPP’s work will be a key element of completing the mission of enhancing and extending compliance with federal, DoD, and DON policy. Media coverage, publications, and presentations of Navy research projects to widespread audiences helps tell the story of the DON HRPP: to maintain the highest standards of research conduct and to provide for the ethical treatment and well-being of human subjects in research that’s critical to Navy missions.

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## CITI—An Intensive Education in Human Research Protection

The DON HRPP online training course in Human Research Protections, available at the website of the non-profit Collaborative Institutional Training Initiative (CITI) ([www.citiprogram.org](http://www.citiprogram.org)), offers a comprehensive yet concise education in the history, procedures and processes, and regulatory and legal foundation that is essential to effective management of a Navy HRPP program.

More than 30 training modules, written by recognized authorities in the field, are offered in an easy-to-follow format that enables all individuals involved in human subject research to complete required initial and continuing training, while making the training both challenging and interesting.

DON HRPP officials say that a number of human research protection training programs meet DON HRPP requirements. The CITI course, though, provides training required for all levels of HRPP responsibility: commanding officer and Institutional Signatory Official, Institutional Review Board (IRB) member, principal investigator, and administrative support personnel. The modules are organized into Biomedical and Socio-Behavioral “learner groups” that emphasize lessons unique to those fields.

The CITI training program provides a valuable opportunity for HRPP staffers to gain a solid understanding of the policies that form the foundation for human research protections.

The initial module, “The Belmont Report and CITI Course Introduction” directs students to read the Belmont Report which, when released in April 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, became the basis for human research protections policy in the United States.

The initial modules in the series aim at providing basic familiarization with human research protections.

“Students in Research,” by Maristela Cho and Susan Rose of USC, is a wide-ranging primer on all elements of HRP: key policy documents and events, federal policy, ethical values, types of research, IRB responsibilities, and definitions of important terms.

### History, Policy, Ethics

“History and Ethics” by Jeffrey Cohen of HRP As-

sociates, Elizabeth Bankert of Dartmouth, and Jeffrey Cooper of AAHRP Inc., is a detailed account of the decisive points in the evolution of current policy, including the Nuremberg Code, Declaration of Helsinki, the Public Health Service Syphilis Study of 1932 through 1971, and discusses how those and more recent events have influenced the development of ethics for research protections.

History and ethics are the basis for subsequent modules that offer more specialized training. “Defining Research with Human Subjects” by Lorna Hicks of Duke University defines such critical terms as “human subject” and “living individual,” and provides invaluable insights on the meaning of “observing” and “recording” private behavior, and the handling of private information.

Hicks also contributes a module entitled “The Regulations Applied to Social and Behavioral Sciences,” which gives technical guidance on the federal HRPP policies.

“Basic Institutional Review Board Regulations and Review Process” by Ada Sue Selwitz of the University of Kentucky, Norma Epley of the University of South Florida, and Janell Erickson of the Group Health Cooperative provides authoritative background on the role, authority, composition, and responsibilities of IRBs.

The CITI training also provides perspective on evaluating research with human subjects. Tracy Arwood of Clemson and Sangeeta Panicker of the American Psychological Association, in a module entitled “Assessing Risk in Social and Behavioral Sciences,” discuss the meaning of risk, how it occurs, for example, through invasion of privacy and breach of confidentiality, and ways of identifying degrees of risk.

### Consent and Confidentiality

In “Informed Consent,” Hicks of Duke University addresses such critical aspects of the informed consent process as waivers of the elements of consent, ensuring that potential subjects understand the meaning of consent, free choice, informed consent in exempt research, and the documentation required to validate consent. Subsequent modules provide important background on

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*Spotlight on Research*

## SYRUS - Understanding Individual Differences in Multitasking Performance

### Decision-Making for the Battle Space

Decision-making in an increasingly complex and uncertain battle space requires a comprehensive knowledge of the talents, traits, and skills of available human resources. This mandates an awareness of individuals' strengths and weaknesses and an ability to draw on individual talents with speed, agility, and accuracy. The plug and play capabilities of the Littoral Combat Ship and other emerging technologies make rapid individual adaptation to multifaceted environments more important than ever. One of the ways future leaders can maximize the effectiveness of these new hybrid sailors is through well-established and well-understood measures of multitasking performance.

### Developing Tomorrow's Sailors Today

Named for the Roman philosopher Publilius Syrus, this effort seeks to develop individual multitasking performance constructs that are reflective of his progressive vision. SYRUS joins scientists from Navy Personnel Research, Studies, and Technology (NPRST) and Michigan State University in rigorous academic research that is designed to provide a technology-based system capable of accurately determining individual multitasking abilities across a broad spectrum of operational demands. SYRUS leverages previous work in the fields of psychology, sociology, physiology, demography, education, and computer science to provide a multidisciplinary vantage point from which a comprehensive multitasking assessment pro-



*Dr. Andy Jones, SYRUS PI from NPRST, reviews computer-based multi-tasking performance evaluation tool*

gram can emerge. Cognitive and non-cognitive traits are joined with individual demographic and physiological characteristics to examine how they relate to individual performance in a dynamic, evolving, and multifaceted environment.

*"To do two things at once is to do neither"*

Roman philosopher  
Publilius Syrus, ca. 50 BC

### SynWin® Multitasking Software

Synthetic Work Program for Windows® (SynWin) is used as a test instrument to assess individual performance in a multitasking environment. In the SynWin program, a game-like environment requires participants to perform four separate tasks concurrently: (a) memory task, (b) arithmetic task, (c) visual monitoring, and (d) auditory monitoring. Performance of these tasks is possible because of several advantages through the use of the SynWin simulation. SynWin: (a) offers concurrent performance of multiple tasks, (b) is highly configurable (e.g., for interruptions), (c) is complex yet tractable for research, (d) is rich in data collection, (e) has no need for special populations, and (f) is used in relevant published research.

### SYRUS

SYRUS maps individual's cognitive, non-cognitive, demographic, and physiological traits using SynWin output measures derived in the memory task, arithmetic task, visual monitoring test, and the auditory monitoring test to establish individual multitasking performance constructs. The goal of SYRUS is to provide a legally defensible job classification tool that assesses individual Sailor's multitasking performance.

The test population for SYRUS thus far has included undergraduate students at Michigan State University and Sailors from across the Navy. Employing a physiological assessment component in an otherwise social/behavioral research effort created challenges that the NPRST IRB had not experienced before. A Medical Service Corps officer and a corpsman were

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## SYRUS—Understanding Individual Differences in Multitasking Performance

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called on to help ensure compliance with standards of medical practice and they helped inform IRB deliberations.

### Selection and Classification Research

NPRST's Institute for Selection and Classification

(PERS-13) is the Navy's primary resource and technical authority for selection and classification research. Ongoing efforts include the development of tools designed to assess Sailor's job qualification, career preference, personality, retention / attrition behavior, and an integrated Whole Person Assessment (WPA).

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## CITI—An Intensive Education in Human Research Protection

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privacy and confidentiality, records-based research, and on such sensitive and potentially controversial subjects as research with protected populations: prisons, children, minors, and pregnant women.

"Research in Public Elementary and Secondary Schools" also by Hicks, discusses the many complexities of conducting research in schools, including the body of regulation governing research in schools and such key areas as activities that may qualify for exemption, parental permission and child assent, research-related harms to children, and child abuse.

E. Dawn Fitzgibbons and Wenjin Li of the Fred Hutchinson Cancer Research Center, in a module entitled "International Research," cover the application of ethics to human subject research conducted overseas, U.S. and foreign government guidelines for research, and research review in host countries.

Helen McGough of the University of Washington, in "Group Harms: Research with Culturally or Medically Vulnerable Groups," provides valuable insight on the risks of injury to ethnic, religious, or tribal groups that can result from poorly designed research that inadvertently attributes negative characteristics to the group.

Several modules provide specific guidance on working with federal agencies. "FDA Regulated Research" by Susan Kornetsky of Children's Hospital, Boston, David G. Forster of the Western IRB, and Gary L. Chadwick of the University of Rochester, discusses research with the FDA and the complexities of participation of human subjects in such research.

Joan Porter, Karen Smith, and David Miller of the Department of Veterans Affairs and McGough of the University of Washington comment on the sensitivities inherent to research with military veterans.

The DON HRPP CITI training offers additional background information and orientation for IRB members in "The IRB Member Module: What Every IRB Member Should Know," by Cheryl Savini of the DON HRPP staff, Judy Matuk, Stony Brook University, State University of New York, and Allison Handler and Lawrence Rosenfeld of the University of North Carolina at Chapel Hill. The module provides the indispensable basics on IRB roles, membership, and responsibilities.

### HIPAA and Conflicts of Interest

The Health Insurance Portability and Accountability Act (HIPAA) regulates many aspects of human research, including privacy and disclosure of information concerning subjects. Anita Cava, Reid Cushman, and Kenneth Goodman of the University of Miami offer valuable guidance on dealing with HIPAA.

Robin Fiore of Florida Atlantic University, in "Financial Conflicts of Interest in Research with Human Subjects," provides insights on the pitfalls and risks of conflicts of interest.

The DON HRPP still is working on Navy-specific modules for the CITI program. The goal, staffers say, is to add modules that are informative, interesting, and relevant to the work of Navy HRPP professionals.

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DON Animal Research Protection

## An Important Year in Animal Care

By Col. Mark Gold

Completing fiscal year 2006 was not an occasion to celebrate accomplishments, but to start working even harder to execute the new budget and supporting the research and training mission. It also represents an opportunity to report on last year's animal use achievements, and to start gathering information for next year's reports.

Along with the USDA and other required reports, some of our labs updated their program descriptions in anticipation of upcoming site visits, and all completed their annual animal-use data calls. These were significant efforts—and all a part of ensuring the high quality of Navy intramural animal care and use programs.

While these efforts often seemed arduous, the results show real payoffs. The summarized FY 2002-2003 animal-use data-call report documents animal use in enough different ways to make even the most persnickety bean counter ecstatic. It cross-references species, USDA pain/distress categories, research uses, and efforts devoted to finding and using alternatives. By any interpretation it's a grand effort.

***Care is not the only thing that we are about. Well cared-for, content animals make the best models for our research programs, and help make Navy medicine programs examples that others emulate.***

***Good animal care and use go hand-in-glove with quality research***

What the report doesn't do well is to capture the tremendous efforts that the facilities put into their animal care and use programs. It doesn't capture the long hours working with researchers developing and supporting research. Nor does it reflect the many late-night vigils devoted to caring for animals and the dedicated personal connection that our people put into

every single animal in their care.

Having been to all but one of the DON animal research facilities in the last year, I can describe these great efforts first hand: with the hourly observations, recorded in medical records, through the night at some of our facilities, and the world-class enrichment at so many others.

But care is not the only thing that we are about. Well cared-for, content animals make the best models for our research programs, and help make Navy medicine programs examples that others emulate.

Good animal care and use go hand-in-glove with quality research. Our researchers turn out results that find their way to many important applications.

It is easy to see how our sailors and Marines benefit every day from these essential findings. More than that, these findings have direct benefit for animals. I can't help but think that veterinarians are reading these results and applying them to improve the care of animals serving in harms way with our brave people or to animals in our daily lives.

Through our site visits to the labs, we were tasked to ensure compliance with our instructions and policy guidance on animal care. More importantly, we tried to leave behind some tidbits to make your jobs easier or to improve the care for the animals.

Throughout the site visits, we carried your "best practices" from place to place and shared your ideas. We'll continue on in this vein through the next round of site visits to see how you implemented these suggestions, and how else you are setting the bar for quality of animal care.

*Col. Mark Gold, USA, is Director of Veterinary Affairs in the Office of Research Protections at the Bureau of Medicine and Surgery.*

*Research Protection on the Web*

## Web Sites of Interest to the International Researcher

International researchers face the added challenge of having their protocols approved by host country ethics committees. Three web sites try to fill the gaps, offering diverse resources:

**Harvard School of Public Health's Global Research Ethics Map** (<https://webapps.sph.harvard.edu/live/gremap>).

This site offers a clickable map and a drop-down country selection menu. Clicking on a country opens a resource page which includes a map marking the major cities and questions (with answers). This map is still under construction.

**The U.S. Office of Human Research Protection** annually updates its International Compilation of Hu-

man Subject Research Protections (<http://www.hhs.gov/ohrp/international/HSPCompilation.pdf>).

This guide lists and, where possible, links to the key research-governing organizations of most countries. For many countries, it also lists and links to legislation, and to regulations and guidelines on drugs and genetic research.

**World Health Organization's (WHO) page on National Bioethics Committees** (<http://www.who.int/ethics/committees/en/index.html>).

This site also features a clickable map, divided into WHO regions.

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*DON HRPP Site Visit*

## DON HRPP Visits NAWC-AD

The DON HRPP team, on a site visit to the Naval Air Warfare Center-Aircraft Division in Patuxent River, Md., in late-February, discussed the HRPP program goals and mission with key NAWC-AD human research protection officials, and got a glimpse of the fascinating research underway for Naval aviation.

NAWC-AD has pioneered the development of many critical systems for Navy and Marine Corps aircraft, including guidance and cockpit systems and devices, sensors and aircraft control systems, night vision goggles, and crew safety equipment and systems.

NAWC-AD recently conducted flight testing for such top-line aircraft as the F/A-18E/F Hornet fighter /

attack aircraft, V-22 Osprey tiltrotor aircraft, and the carrier-based and vertical-short takeoff/landing F-35 Joint Strike Fighter.

As with all DON HRPP site visits, the team met with key HRP staff and the commanding officer, Rear Adm. Steven Eastburg, to discuss the Navy program, as well as such topics as record-keeping and IRB roles and responsibilities.

The team also visited NAWC-AD facilities and systems used in research, including a horizontal accelerator, advanced life-support systems, and chemical-biological protective gear.

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## Education Coordinator Seeking Your Input on Research Ethics Training

DON HRPP's Education Coordinator, Dr. Christine Smith, wants to hear from YOU! Recently, Dr. Smith emailed a short, web-based questionnaire to many members of the DON HRPP community. To better support individuals in the Navy's human research protection program who conduct, review, approve, sup-

port, oversee, and manage human research, Dr. Smith wants your input about training topics and preferred methods of instruction. Please complete the survey, as well as forwarding it to others at your command. Your support is appreciated. (For regulatory reasons, the survey is limited to DoD personnel only.)

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