RESEARCH PROTECTIONS UPDATE

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

Volume 10, Number 2 *June 2020*

Together We Create, Grow, Achieve & Thrive

The Department of the Navy Human Research Protection Program (DON HRPP) is against racism, discrimination, and disrespect for human life and dignity. We must have courage to stand up for what is right, and the commitment to create a workspace that is free for all people to be their unique, and best, selves. All people, regardless of race or other attributes, deserve equality and respect. The future of the Navy and Marine Corps, and the diverse community it serves, deserve no less.

Sadly, the history of human research is fraught with examples of abuse, from the use of unwilling participants, to unethical research, to unreasonable harm. This abuse has had a disproportionate impact on historically marginalized communities. For example, as part of the Tuskegee syphilis study (1932-1972), disadvantaged black men were deprived of a treatment for syphilis so researchers could study the untreated course of the disease. Without proper treatment many participants died from the disease or from complications related to the disease. It is the lessons from this and other abuses, and recognition that respect for human life is critical to success of any endeavor that contributed to modern human research protection. Not long after Tuskegee syphilis study was publicized Congress created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1974. After years of deliberations the Commission released the Belmont Report, which established Respect for Persons, Beneficence, and Justice as the basic ethical principles that should govern human research.

Even with its ugly past, it is important to note that human research contains an enormous potential for good, with the capacity to foster increased communication, community, and healing. Research enhances readiness, and the Navy and Marine Corps invests in research with human subjects to advance its mission while safeguarding to the utmost the participants' safety, dignity, and self-worth. Thankfully, there are many examples of cutting-edge research that have accomplished the pursuit of knowledge in this manner.

As we move forward into the future through unprecedented times, we must always err on the side of caution when evaluating potential harm to human research subjects', and the communities they come from, with physical and psychological well-being. At the same time, and to make this possible, we must treat one another at all times with the highest honor and respect due to a fellow human being. As we work through the many challenges ahead, protecting both human subjects and those who are conducting research, it is paramount that we incorporate multiple perspectives and considerations to strive, together, to create, to grow, to achieve, and to thrive.

-DON HRPP

1. The Belmont Report, 18 April 1979
2. Kim, Oliver J.; Magner, Lois N. (2018). A History of Medicine. Taylor & Francis Group, LLC. Page 138.
3. The Belmont Report, 18 April 1979

Also in this Issue:

Commentary

Conducting Human Subject Research During Disasters; Key Strategies to Consider

By Chidima Ioanou & Derek Englis

The coronavirus disease 2019 (COVID-19) pandemic and resulting public health emergency has caused immense human suffering and has changed the daily life of most. The pandemic has necessitated that many stay at home to prevent further spread of the virus. It has also profoundly affected research that relies on person-to-person interactions, due to concerns of spreading the virus. The COVID-19 public health emergency has brought to our attention the difficulties of conducting human subjects research (HSR) during an unexpected pandemic. Lessons learned from COVID-19 can help researchers, Institutional Review Boards (IRBs), human research protection programs (HRPPs) and institutions prepare for disasters.

Whether a local, regional or national disaster, the impact and challenges that arise can affect the subjects, researchers and their staff, IRBs, HRPPs, and the institutions. Although guidance[1] and resources are available to provide helpful assistance in the development and implementation of a disaster management plan, at best, only a generalized plan could prospectively be established. This is because each disaster situation might be different, thus requiring a unique response/management strategy. Following the declaration of a national emergency due to COVID-19[2] on 19 March 2020, the Food and Drug Administration (FDA) released a guidance document titled, "Conduct of Clinical Trials of Medical Products During the COVID-19 Pandemic[3]." The information in the guidance document (which has been updated multiple times since its original release) may be applicable to other types of disaster situations, as it may serve as a framework IRBs, investigators, and HRPPs can utilize to guide decision-making to assure the safety and welfare of human subjects involved in research. So, in light of the current global COVID-19 health emergency, in this commentary, we will attempt to identify and highlight some underlying key strategies from the FDA guidance document for conducting HSR during other disaster situations.

> The FDA guidance emphasizes the importance of protecting subjects during the current pandemic, stating that, "ensuring the safety of trial participants is paramount."

The FDA guidance highlights the importance of communication as a key strategy to be employed during the COVID-19 pandemic which could also be applied in any type of disaster situation. Good communication is an underlying tool that facilitates effective implementation of any disaster management plan. For instance, the guidance describes the importance of communication between investigators and subjects, such as communicating to research subjects protocol-related changes that may affect them. Communication between researchers and the IRB is also discussed. Researchers are encouraged to engage and communicate early on with the IRB when urgent or emergent changes to the protocol are warranted. Documentation (an effective communication tool), relating to rationale regarding contingency measures implemented, missing protocol-specific information due to protocol deviations, and revisions in policies and procedures, is also encouraged in the FDA guidance. Clear and timely communication between key stakeholders is an important aspect in conducting and managing HSR during disaster situations.

Another underlying key strategy that can be gleaned from the FDA guidance document for conducting research during a disaster is flexibility. The importance of maintaining flexibility in decision-making and research operations may be gathered from the many discussion points presented throughout the guidance document. For example, related to ongoing trials, the guidance discusses that deciding whether to maintain subjects on a study drug will depend on the nature of the study drug, the ability to conduct safety monitoring of the subject, and the nature of the specific disease under study. Also, there is discussion of the need to

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CDR Svec Assumes Director, DON HRPP Position

Commander Leedjia Svec takes on the Director, DON HRPP position. CDR Svec studied Psychology and Engineering Technology at the University of the Pacific, studied abroad at the University of Melbourne Australia, obtained her MA/PhD in Experimental Psychology from the University of Nevada, Reno, and a MA in International Relations from Saint Mary's University with distinction. She holds certifications in Human Systems Integration from Naval Post Graduate School, Innovation Thinking from Solve Next, data visualization from UC Berkeley, and Lean Six Sigma (green belt).

She has most recently served as the Director of Research for the Department of the Navy Sexual Assault Prevention and Response Office (DON SAPRO). At SAPRO, she was responsible for analyzing policy, data, facilitating research, maintaining communication, and providing subject matter expertise. She led the Women in Combat working group, Cadet Internship program, and was appointed a Technical Team member of the NATO working group on military sexual violence in addition to representing DON SAPRO in DoD meetings. While serving as an augmentee to the Naval Inspector General, Bahrain Area Assessment, she assisted in inspections, focus group management, data analysis, and reporting results to leadership. Previously, she directed military programs at NASA Ames and served as a liaison, leading collaborations within (and between) NASA, DoD, and other entities, locally and across the globe, for mutually beneficial partnerships resulting in knowledge, resource, and technology sharing. As part of this role, she implemented the State Department's TechWomen program for emerging leaders from Africa, Central Asia, and the Middle East, merging established guidance with new procedures for a first of its kind program. Additionally, she spearheaded multi-service Cadet Internship programs resulting in tools and products that continue to serve NASA Ames.

As senior scientist for the Defense Equal Opportunity Management Institute (DEOMI), she applied research in subject areas such as cultural heritage preservation, diversity and inclusion, anti-hazing, bias, and more. She served as the Research Approval Authority where she was responsible for the review and approval of all institute research. As a member of the Office of the Secretary of Defense Hazing Review Team, she was responsible for data collection with direct influence on DoD policy as well as training and assessment of 400 service members annually. Additionally, she founded and directed DEOMI's Science Technology Engineering and Math (STEM) Student Program. As Principle Investigator at the Naval Medical Research Unit San Antonio, she developed mathematical models for predicting color vision performance in aviators wearing Laser Eye Protection (LEP) while supporting research in non-lethal weapons and directed energy. As Vice Chair for the Institutional Review Board (IRB), she was responsible for aiding in the review and approval of all institute research. As Chair of the Air Force Technical Review Board, she led and managed a 10-person technical review team for feasibility determination of AF science and technology research projects. As Team Lead for the LEP Source Selection Team, she led the evaluation of LEP procurement contracts for Naval Air Systems Command. At the Center for Information Dominance, she served as a human performance technologist, initiating multidisciplinary research and statistical assessment to include introducing a course of academic improvement skills for over 6,000 sailors, which significantly decreased student attrition. As a member of the Human Performance Center Command Climate improvement team, she assessed climate and identified gaps in performance across multiple commands, providing recommendations and briefings to leadership.

CDR Leedjia Svec

CDR Svec's achievements include; STEM Influencer of the Year, Silicon Valley Women of Influence Award, NASA Silver Achievement Medal, NASA Equal Opportunity Medal, Aerospace Medical Association International Young Investigator award, national Engaged Leader award, Officer of the

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DIRECTOR'S CORNER

Hello! I am incredibly pleased to be taking the helm of the Department of the Navy Human Research Protection Program (DON HRPP). I am re-initiating this column to periodically share my vision, objectives, and thoughts for the way ahead. The mission of DON HRPP is to "ensure the ethical treatment of human subjects in DON-conducted or -supported research by promoting adherence to the ethical principles, laws, regulations and policies that protect human subjects." While my immediate objective is for DON HRPP to continue the established services to serve its constituency of Commanding Officers, Directors, Officers in Charge, IRB professionals, researchers, and human subjects, there is room for innovation. In the short time I have been at DON HRPP, I have witnessed a diverse team of talented individuals with ideas and energy to build the HRPP community, increase efficiency, revitalize education, and more. Moving forward, I intend to enable these valuable efforts, and I welcome your input as we take this journey together. Your feedback is critical to developing a robust and inclusive community that reflects your needs, where we share best practices, learn from each other, and navigate the always changing seas of organizational change and global crisis. As we face unprecedented times, I believe we can go beyond the important role of ensuring compliance. We can foster a community that exceeds the needs of safeguarding the rights, human dignity and respect for human subjects. I appreciate all the outstanding research done throughout the Navy and Marine Corps and look forward to serving you as DON HRPP Director!

-CDR Leedjia Svec

CDR Leedjia Svec

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Quarter, and student fellow of Norwich University Institute of Culture and Language. CDR Svec has served as adjunct professor at the University of West Florida, University of Texas, San Antonio and Saint Mary's University. As a TechWomen delegation team member to Kyrgyzstan, South Africa, Nigeria, Rwanda, and Washington D.C., she engaged in international science education and advocacy. She is a volunteer Chair on the board of directors for the University of the Pacific Alumni Association and is a member of the Naval X innovation unit for the US Navy.

Under the leadership of CDR Svec, DON HRPP will continue to ensure you are successful in meeting the requirements of human subjects research as outlined by applicable instructions and regulations. CDR Svec invites you to reach out, seeks to increase communication, and looks forward to the opportunity to speak with Command staff in the future.

DON HRPP will be updating the RPU content, for example, in future editions look for a new column aimed at highlighting challenges and celebrations of inclusion and diversity in human research protections. What else would you like to see? Please feel free to share any feedback, suggestions, or requests at usn.ncr.bumedfchva.mbx.don-hrpp@mail.mil.

Thank you!

Conducting Human Subject Research During Disasters

(Continued from page 2)

put new processes in place or to modify existing processes, and that such processes may differ by protocol during disaster situations. Such variability in implementing crisis management strategies on a protocol-by-protocol basis requires flexibility on the part of the researchers, IRB, and institution. Another consideration discussed in the guidance is flexibility in how study visits are carried out. During the COVID-19 public health emergency, investigators have had to consider whether they can adjust study procedures so that study visits can be done by phone or video conferencing. This would especially be a concern for visits designed to protect subject safety. While some follow-up visits must be conducted in person, having the ability to conduct these visits over the phone or virtually would prove to be helpful given the concern of exposing subjects to COVID-19. Developing the ability to be flexible is a key strategy in conducting HSR during times of disasters.

The FDA guidance emphasizes the importance of protecting subjects during the current pandemic, stating that, "ensuring the safety of trial participants is paramount."[3, p.5] Researchers, IRBs, HRPPs, and institutions have had to make many decisions related to ongoing research in an environment with the COVID-19 virus. They have had to consider how to manage research budgets, research staff, study visits, IRB approvals, subject safety, and numerous other factors. Of these factors, the question of subject safety is the most important. The FDA guidance encourages sponsors to consider "each circumstance, focusing on the potential impact on the safety of trial participants, and modify study conduct accordingly."[3, p.5] There are some studies that needed to be put on hold because the benefit of participation in the study (or lack thereof) would not justify the additional risk of potentially exposing subjects to COVID-19. For other trials, subjects may benefit the most by continuing study participation, such as in cases where an investigational treatment is involved. As researchers, IRBs, HRPPs and institutions carry out research during the current pandemic, and develop procedures for handling disasters, protecting human subjects is the highest priority.

References:

1. Office of Human Research Protections (OHRP). (May, 2018). Effects of Disasters on Human Research Protections Programs Guidance. Retrieved from https://www.hhs.gov/ohrp/regulations-and-policy/guidance/effects-of-disasters-on-human-research-protections-programs-guidance/index.html
2. Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (March, 2020), Retrieved from https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/
3. The Food and Drug Administration (FDA). (March, 2020). Conduct of Clinical Trials of Medical Products During the COVID-19 Pandemic. Retrieved from https://www.fda.gov/media/136238/download

Resources

Conducting Human Subject Research During the COVID-19 Pandemic

The Department of the Navy Human Research Protection Program (DON HRPP) recognizes the potential impact of the Coronavirus Disease 2019 (COVID-19) pandemic on research and Command mission. DON HRPP supports each HRPP (in coordination with its IRB or staff, as deemed appropriate) in the development of guidance or processes that best ensure compliance during and immediately following the COVID-19 pandemic while continuing to maintain compliance with all applicable human subjects research regulations. Please see below hyperlinks for resources on this topic:

- ◊ FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency
- ◊ OHRP Guidance on COVID-19

Naval Medical Research Center (NMRC) History Panel 2

This is part of a series of historical Navy medical R&D panels prepared by Mr. André B. Sobocinski, BUMED Historian. The mission of the BUMED History Office is to promote, preserve, and document the history and heritage of the Navy Medical Department, past and present. This mission is accomplished through management of the Navy's commemoration/ historical outreach program, oral history program, command operations report program, reference desk, publication program and archives/ historical collection.

Naval Medical Research Center (NMRC)

Established on 27 October 1942

WORLD WAR II

THE RESEARCH COMMAND IS BORN

Today's Naval Medical Research Center was established in 1942 as the Naval Medical Research Institute (NMRI) on the campus of the National Naval Medical Center Bethesda, MD

CAPT WILLIAM MANN FIRST COMMANDING OFFICER

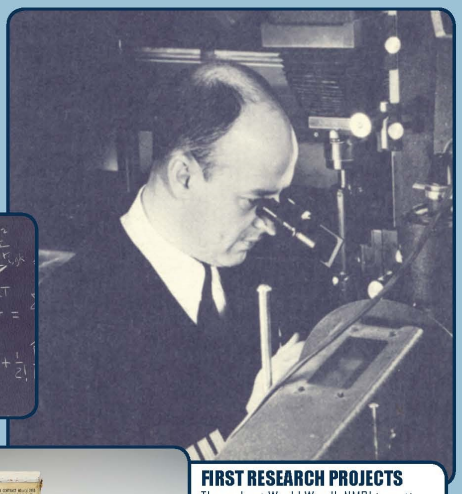
CAPT William Mann , MC, USN, took the helm of NMRI on 27 October 1942 becoming the first commanding officer of the research headquarters. In 1942, Mann was a 34-year veteran whose career was highlighted by deployments to China, Haiti, and the Philippines and for introducing field sanitation techniques to expeditionary units

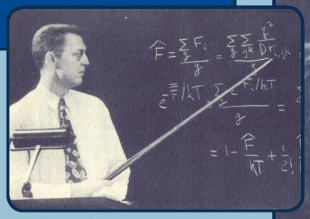
WHO WERE THE PLANKOWNERS?

In October 1942, NMRI was comprised of 13 Officers, 50 enlisted technicians and one civilian scientist.

FIRST SCIENTIFIC DIRECTOR

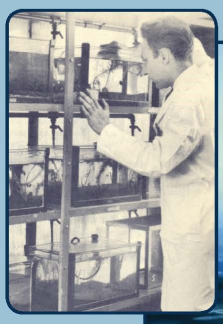
In the inaugural year of NMRI, Dr. Andrew C. Ivy served as the institute's first scientific director (1942-1943). Ivy, a Northwestern University professor of physiology, later earned renown as one of the developers of the Nuremburg Medical Code, a set of research principles on human use experimentation.





5 CATEGORIES OF RESEARCH

- -General
- -Surface Medicine
- -Sub and Dive Medicine
- -Aviation Medicine
- -Field Medicine



FIRST RESEARCH PROJECTS

Throughout World War II, NMRI investigated practically every problem relating to the health of Navy and Marine Corps. NMRI scientists researched and developed everything from first aid kits for aviators, resuscitation devices, protective creams for flashburns, sun burn protection, protective clothing and armor, to developing insect repellents, fungistatic agents, and special kits for desalinating seawater. NMRI also explored prevention of general effects of cold water immersion, new treatments for seasickness, transportation methods for whole blood, and researched tropical diseases (including treatments for malaria, scrub typhus and schistosomiasis).

NMRI RESEARCH DEPARTMENTS IN JULY 1943

Animal Laboratories. Aviation. Bacteriology. Biochemistry. Biophysics. Chemistry and Assay Analysis. Experimental Dentistry. Diving and Underwater Physiology. Heating, Air Conditioning and Ventilation. Industrial Hygiene. Library. Nutrition. Pathology. Personal Equipment Design. Pharmacology and Toxicology. Physiology. Psychology and Statistics. Psychometric and Metabolism. Hematology. Technical Shops. Experimental Surgery. Virology.

DON HRPP News!!

- DON HRPP is pleased to announce a new milSuite site for the DON research protections community. The DON HRPP milSuite site can be visited by milSuite users who request access. Anyone with a Department of Defense (DoD) Common Access Card (CAC) can create a milSuite account. Follow the link below and subsequent prompts to request access: https://www.milsuite.mil/book/groups/don-hrpp

- The Office of the Under Secretary of Defense for Research and Engineering (OUSD(R&E)) released the Department of Defense Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research" (DoDI 3216.02) dated 15 April 2020, cancelling the previous instruction of 8 November 2011.

- Commander Leedjia Svec assumes the role of Director, DON HRPP.

We Need Your Help!

Get a BZ from RPU

Have a "Good News" story or picture from your Research Protection Program? Don't keep it to yourself! Why not share it with the DON Research Protection community? We're looking for material to publish in the *Research Protections Update* newsletter. Send your research news, success stories, tips, pictures, lessons learned, or other material related to the ethical conduct of human research to usn.ncr.bumedfchva.mbx.don-hrpp@mail.mil.

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