

DEPARTMENT OF RESEARCH PROGRAMS NEWS

Why Research?

Clinical research is one of the pillars of Walter Reed National Military Medical Center (WRNMMC). Research provides a foundation for discovery aimed at improving patient care downrange and in-hospital. Research seeks to elucidate the mechanisms of morbidity and mortality as well as to devise medical strategies for treatment and support. Additionally, research enhances the education, teaching, and readiness of our servicewomen and men.



COL Peter Weina

Contents	
Why Research?	1
Clinical Breast Care Project	2
Research: Coffee and Butter	4
Red Cross Summer Interns Assist and Learn	5
Research Resident's Day, July 2015	5
R2O2 Townhall Meeting	8
What's New in RES?	11
I Save Lives	12
Research Roundtable	12
Award for DRP Staff Sergeant	17
ReUp	18
Farewell COL Ashley	18
Onboarding	19
Useful Information Sources	20
Paper and Pencil	20
Save the Dates	21
Darnall Library	23
Quarterly Newsletter	33
Credits	33

Warfighters of the future will depend upon clinical research and resultant discoveries made today to help them prepare for the battlefield, for ever-improving treatment and aftercare of combat injuries and other health needs and for rehabilitation. Research will help patients move back into civilian society with confidence and self-reliance.

The mission of the Department of Research Programs (DRP) is to facilitate clinical research at WRNMMC. The department provides multiple services for researchers including help starting research, applying for grants, developing proper design of projects, and writing documents for regulatory purposes or publication (see [page 6](#)).

As we move further into the 21st Century, it is important that WRNMMC conducts robust research to continue supporting clinical advancement for military members and their families. The DRP is proud to be a part of that effort.



Clinical Breast Care Project

Introduction

In a recent interview, COL Craig Shriver (MD, FACS, U.S. Army, Director of the Murtha Cancer Center) described the Clinical Breast Care Project (CBCP) at WRNMMC.

The CBCP is a congressionally mandated and funded program designed to understand, treat, and prevent breast cancer. The CBCP employs a multidisciplinary approach to study breast cancer. Prevention, screening, diagnosis, and treatment/continuing care are all part of the CBCP's efforts. The CBCP uses high-throughput molecular biology-based methods and discovery to augment clinical care.

Mission and Goals

The overall mission of the CBCP is to decrease morbidity and mortality due to breast diseases among military members and their families.

Long-term goals include:



- Decrease morbidity and mortality of breast cancer among American women.
- Continue to develop a comprehensive breast care center/system with a multidisciplinary team approach.
- Empower women afflicted with breast cancer and other breast disorders, with the decision-making tools to enhance their quality of life.
- Develop research facilities that drive world-class high-throughput translational research.
- Develop an integrated computational and biomedical informatics infrastructure with an integrated data warehouse related to diseases of the breast.
- Empower the clinical staff with a physician decision-support system.

Need

There are over 200,000 women in the Department of Defense who are on active duty and over 450,000 women in the National Guard. Moreover, there are over 5,000,000 military personnel and family members. Readiness to go to war is an important consideration for the military forces and breast cancer is a debilitating disease that can have a strong impact on military readiness as well as on the families of military personnel.

Women make up 20% to 25% of the armed services, and breast cancer is observed at younger ages than ever before. Women in military are at the same risk of breast cancer as civilians. African Americans are represented in the military services a rate double that of the general population, and certain subtypes of breast cancer occur disproportionately in African American women.



Approach

As a major component of the Murtha Cancer Center, the Clinical Breast Care Project (CBCP) at WRNMMC has been helping patients, conducting research, and teaching residents and interns for 15 years. The CBCP is a congressionally mandated program involving civilian and military scientists, clinicians, and their collaborators. It has five pillars of excellence.

- Center of excellence in clinical care
- Tissue banking to develop and maintain one of the world's finest repository of human biospecimens of breast diseases
- Risk reduction for women at risk for developing breast cancer,
- Targeted translational research into the molecular signatures of breast diseases and cancer
- Biomedical informatics

These pillars of excellence have helped make the CBCP internationally known and a major player in the ongoing fight against breast cancer. With such a reputation, the CBCP is a magnet for talented physicians and researchers from around the world. Excellence begets excellence.

As a translational research center the CBCP seeks to apply its research findings to patient care as smoothly as possible. One way to achieve this is through the study of biorepository samples.

Biorepository



Tissue Biorepository at Windber Research Institute (collaborating institution) in Windber, PA, COL Shriver (L)

The CBCP works with a unique biorepository at the Windber Research Institute in Windber, Pennsylvania. The biorepository holds breast tissues, lymph nodes and blood samples from diseased and nondiseased (e.g., benign tumors) tissues as well as samples from many different types of cancers. All of the samples are rigorously acquired and stored. For instance, labile RNAs can even be studied intact. In the past 15 years the CBCP has collected over 60,000 tissue samples from over 7,000 patients. The biorepository is a worldwide resource that has spawned collaborations with Vanderbilt University, the Anne

Arundel Medical Center, the National Cancer Institute (including the Cancer Genome Atlas), the Susan G. Komen Breast Cancer Project, Thomas Jefferson University, and the NCCP Cancer Drug Management Programme.

Moreover, collaborative studies have been developed with the Pacific Northwest National Laboratory (Department of Energy), which assists the CBCP in panomics (the interaction of all biological functions within a cell



and with other body functions, combining data collected by targeted tests and global assays with other patient-specific information) studies. Recently, scientists at Thomas Jefferson University, in collaboration with the CBCP, characterized the expression of 250 markers from 5,000 patients. Other partners, along with the CBCP, have studied the genomes of 1,000 cancers for DNA copy number, DNA methylation, exome sequences, messenger RNAs, microRNAs, and protein expression.

Conclusion

The CBCP continues to generate new knowledge about breast cancer. Overall, about 100 peer-reviewed publications have resulted from the CBCP efforts, including some published in PLOS One, Nature, Cancer, and The Lancet. Multiple collaborations have been spawned by the CBCP with numerous institutions that employ multiple state-of-the-art molecular methods to find and integrate data. Finally, the CBCP has created one of the world's largest breast tissue banks.

Research: Coffee and Butter

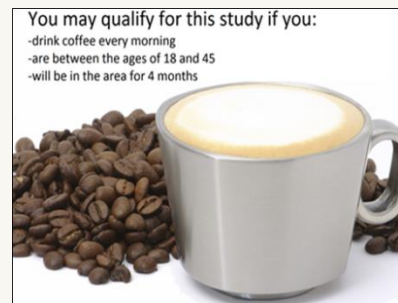
When LCDR Karl Nadolsky offers you a cup of coffee, you could be in for a surprise; he might serve you coffee with butter. LCDR Nadolsky is an endocrinologist with a special interest in metabolism. The effects of drinking the newest diet craze are the subject of LCDR Nadolsky's current clinical trial.



LCDR Carl Nadolsky

You might drink your regular coffee with cream and sugar, but coffee with butter is something altogether different. It is made with grass-fed cow butter and medium-chain triglyceride oil derived from coconuts. Although this may seem unconventional to the modern American, it traces its roots back to a traditional Tibetan tea made with yak butter and called *po cha*.

Coffee with butter is sweeping pop culture for its purported benefits: enhancing energy levels, boosting focus and cognition, and even supporting weight loss. It is allegedly super coffee that wakes you up ready for anything—but these claims have not been scientifically demonstrated.



You may qualify for this study if you:
-drink coffee every morning
-are between the ages of 18 and 45
-will be in the area for 4 months

LCDR Nadolsky was intrigued by the claims and decided to test them, hence a clinical trial. LCDR Nadolsky is conducting a prospective randomized controlled interventional study to explore the effects of coffee with butter. The primary outcome will be change in apolipoprotein B levels between groups. Secondary outcomes include changes in lipids, waist circumference, blood pressure, glycated hemoglobin,



and fibrinogen B beta. Exploratory analyses will include changes in dietary macronutrient load and subgroup analysis of effects related to dietary patterns. Anecdotal reports suggest that coffee with butter has actually caused an increase in apolipoprotein B in a patient, but perhaps this study will reveal some truth in this fad diet.

Red Cross Summer Interns Assist and Learn

This summer the DRP hosted seven participants from the Red Cross VolunTeen Program. Interns represented 10th to 12th grades at seven different high schools: Northwest High School, St. Albans School, Walt Whitman High School, Peddie School, Poolesville High School, Thomas S. Wootton High School, and Churchill High School. The students were selected by the Red Cross based on their academic performances, a short application essay, and a teacher recommendation letter.

After receiving health and base clearances, the interns attended an orientation where they were learned about HIPPA regulations and hospital procedures. During the program the interns read protocols submitted by WRNMMC researchers, attended various meetings (including IRB meetings and the



DRP Research Roundtable), and assisted in the Biomedical Research Laboratory.

Special visits were arranged for the students including a visit to KAREN, an apparatus that simulates different landscapes to help patients with PTSD and physical disabilities. Interns also saw the Brain Fitness Center where they saw the ORBB, a device used to help patients with PTSD.

Although not all of the interns were interested in pursuing a career in the medical field, every one of them had an enjoyable and important learning experience. They all recommend the program to

anyone looking for a productive and positive way to spend their summer break. According to the students, the internship experience provided many great memories.

VolunTeen program: [American Red Cross](http://AmericanRedCross.org), (mary.leggit@redcross.org)

Research Resident's Day, July 2015

The Graduate Medical Education (GME) Department hosted the July, 2015 Research Residents Day at the National Intrepid Center of Excellence Auditorium. The event was introduced by LTC Hartzell (Assistant Director for the GME Department). Onboarding interns, residents, fellows, and staff were invited to learn about conducting research at the WRNMMC.

Department of Research Programs

The DRP staff provided information about the DRP and how it can facilitate research at WRNMMC. The goal was to explain how to begin a research



project. DRP speakers included Ms. Lisa Thompson, Ms. Deborah Kessler, Ms. Lisa Potts, Mr. Robert Roogow, and CPT Franz Frye.

The DRP provides assistance in multiple areas including:

- Protocol navigation and development
- Scientific writing and editing
- Biostatistics
- Institutional start letters
- Intra- and extramural funding
- Institutional Review Board review
- Biomedical Research Laboratory services
- Business agreements



Resident's Research Day Speakers from the Department of Research Programs; (left to right) Ms. Lisa Thompson, CPT Franz Frye, Mr. Robert Roogow, Ms. Lisa Potts

Protocol Navigation and Development

The protocol is the most important element in a research plan. Protocol navigators are experts in protocol development and provide guidance and assistance to researchers throughout the process, from writing to execution. Simultaneously, protocol navigators will ensure collaborative agreements are guided through the DRP Business Cell.

During the development process, protocol navigators help researchers define and prepare various protocol components such as:

- Targeted patient population
- Laboratory or clinical procedures
- Type of research
- Informed consent

When obstacles arise during the planning phase, protocol navigators advise the researchers on other resources or approaches. Protocol navigators also provide the proper paperwork and advice required to gain needed signatures. No matter what the questions may be, protocol navigators follow along and offer guidance to researchers as they develop protocols and start their research. Contact the Protocol Navigators Group (c/o patricia.l.titi.civ@mail.mil).



**Ms. Deborah Kessler,
Protocol Navigator**

Writing and Editing

The DRP senior technical editor provides writing/editing help for researchers developing protocols, writing grants, or preparing manuscripts. Contact the editor (joseph.j.shaw19.ctr@mail.mil).



Biostatistics

DRP Biostatisticians serve as consultants for investigators whose protocols involve human subjects. Biostatisticians help determine if a study design will allow a researcher to reach her objectives and ensure that objectives reflect the data that will be captured. Biostatisticians provide advice about the appropriate statistical methods and the appropriate sample size for the study. Thus, the Biostatisticians can help you write the objectives clearly, collect the data, establish p values, sample size and power, offer statistical software training, guarantee scientific merit, and ensure that departments monitor for adverse effects. Contact the Biostatistics Group (robin.s.howard.civ@mail.mil).



Mr. Roogow speaking to audience

Institutional Review Board

The mission of the Institutional Review Board (IRB) is to protect human subjects. The IRB reviews and approves nonexempt research involving human subjects. Advice and input from the protocol navigators and the DRP's designated staff are paramount for preparing the IRB materials and for obtaining approval. Once the entire protocol is completed and its required documents provided, IRB operations assigns reviewers to inspect the submission's contents for completeness, scientific merit, and purpose. Afterwards, the IRB reviewers determine if adequate protections are in place to maximize benefits and minimize harm to human subjects. Contact the IRB staff (robert.roodow.civ@mail.mil).

Funding

Intramural funding for research is provided by the GME through the DRP. Applicants may be granted up to \$7,500 per year for up to two years for their research project. Funding is competitive and depends on the merits of their research protocol. Extensions may be offered to researchers.

Intramural funds may be used to assist in publication of results, and researchers are encouraged to publish. However, researchers are also encouraged to avoid publishers that charge large publication fees. Intramural funds cannot be used for travel. Contact the grants writer (lisa.m.potts6.ctr@mail.mil).

Biomedical Research Laboratory

The Biomedical Research Laboratory offers sophisticated equipment and experienced staff to help researchers with projects utilizing human tissues and samples. Covering 12,000 square feet, this facility has state-of-the-art equipment to assist in many techniques, including real-time PCR, 2D-gel electrophoresis, mass spectrometry, trace metal analysis, and high pressure liquid chromatography. Laboratory staff is available to assist



researchers and can even help design projects. Contact CPT Frye at the Biomedical Research Laboratory (franz.a.frye.mil@mail.mil).

Final Thoughts

Approval for a protocol package that is complete and clear can be quick. Turnaround time decreased recently, going from 200 days to 100 days. The current goal is to decrease approval time to 90 days. If the project does not involve human subjects, it might take as little as 30 days to gain approval. However, the approval process will likely be delayed if the package is not complete and clear. If the science is unclear or inadequate, a protocol can be rejected. Also, use of outdated forms or missing electronic signatures can hinder a project's approval.

When a protocol is approved an institutional start letter will be provided by the department Chief, COL Weina. Do not start your research until you receive the letter. It will be provided via email with electronic signature within 24 hours of approval.

While many resources are available from the DRP, there are two important take-home messages for anyone starting a research project.

- 1. Go to building 17B (DRP, third floor), and make an appointment with a protocol navigator.**
- 2. Do not enroll patients until you get a start letter from COL Weina.**

Contact the DRP: 301-295-8239 (patricia.l.titi.civ@mail.mil).

R2O2 Townhall Meeting

The Office of the Under Secretary of Defense Personnel and Readiness (OUSDP&R), Research Regulatory Oversight Office (R2O2) convened a Town Hall Meeting on August 25, 2015. An expert panel presented R2O2-related information, explained recent memorandums, and answered questions from the audience.

Panel members

- Dr. Patrice Robinson-Haley (ScD, Director R2O2)
- Maj Brandi Ritter (Deputy Director R2O2)
- Ms. Francine Jones (CIP, Health Science Administrator, R2O2)
- Ms. Kendra Orjada (MPH CIP, Health Science Administrator, R2O2)
- Ms. Jill Conover (Health Science Administrator, R2O2)



Policy Guidances

1. Duplicate Reviews

In order to streamline multi-site research, only one DoD regulatory/ethical review, excluding administrative reviews, is required. OUSD(P&R) institutions seeking additional regulatory/ethical reviews require prior authorization from R2O2.

2. DoD-Supported Research

DoD-supported research is defined as providing resources in support of a research study (including personnel). This is compared to DoD-conducted, which refers to when DoD personnel are actively involved in the conduct of the study. There is overlap between the two definitions, especially when it comes to DoD personnel implementing tasks identified in the protocol. The distinction is that when the DoD is engaged in the conduct of the study, then it is DoD-conducted. If not, then it is DoD-supported. Recruitment that is conducted by DoD personnel means that they are engaged in the conduct of the study. Prior to DoD staff contacting or recruiting patients for research, they are required to obtain appropriate approvals, as necessary.

Update

Modernization of the eIRB (Electronic IRB) will occur soon. The new contract has not been awarded, but the solicitation phase has closed. A new contract is expected to be awarded within the next two months. All IRBNet documents will be downloaded and placed in a SharePoint installation so they will be available during the transition. (*Editor's note: Please see the next article for updated information.*)

Assurance

The Assurance consolidating NCR-MD, WRNMMC, Ft. Belvoir Community Hospital, and the Joint Pathology Center, has been approved. There is now one Assurance for National Capital Region Medical Directorate.

Although these institutions share a single DoD assurance, they will maintain their individual federal-wide assurance. The federal-wide assurance is the assurance required when receiving HHS funding to conduct human research. DoD assurances only cover DoD-funded research.

Question from the audience: Is DoD “supported” the same as DoD “engagement”?

Answer: No. DoD supported refers to research that might be funded by the DoD or where DoD is providing access to resources/personnel. Engagement means that that DoD facility is actively doing the research and there is a DoD investigator. However, even though a DoD institution might not be “engaged” in the research does not mean that the DoD should not be aware what activities are occurring and that appropriate DoD approval to do said activities is obtained.



Question from the audience: Do investigators have to complete the interim training outlined in the Minimum Education Requirements Framework (MERF)?

Answer: No. Although the MERF states that interim training is required, the only required training for OUSD(P&R) institutions is the triennial CITI training. This is because there is no functional way of tracking this training at this time. R2O2 hopes to have a way to track this training in the future, at which point the interim training will be reconsidered.



Maj Brandi Ritter, Ms. Jill Conover, Ms. Kendra Orjada, Ms. Francine Jones (L to R)

Goodbye IRBNet, Hello iRIS

COL Peter Weina (Chief, DRP), spoke at an informational meeting about the changeover from IRBNet to a new software database. The IRBNet is a central repository for research-related documents at WRNMMC. Movement of protocols and monitoring of human subjects research at WRNMMC are the responsibilities of DRP, and DRP stored these documents in IRBNet. However, a contract has been awarded to a new vendor for storing the information.



COL Peter Weina

In the future, WRNMMC will use iRIS (Integrated Research Information Software) from iMedRIS Data Corporation. For now, however, while iRIS is implemented (projected start date: June 1, 2016), researchers are encouraged to interact with DRP via email (dha.bethesda.ncr-med.mbx.wrn-drp@mail.mil). Protocols will be accepted at that email address, protocol navigators can be contacted at that email address, and questions about the changeover, etc. can be sent to that email address.

Chief of Staff, COL Michael Heimall, encouraged IRBNet users to be confident during the period of change. IRBNet has provided Defense Health Agency with copies of all our data that is stored in their system. He encouraged the audience not to make paper copies of all IRBNet historical documents because they will be online as soon as iRIS is up and running. He apologized for the loss of IRBNet and said that it



was a “distraction,” and he encouraged the audience to use the interim system.

Researchers will still submit protocols to the DRP; the DRP will still issue a protocol number; and the system will work much the same as before. The protocol navigators will continue to move protocols to the IRB manager’s office for authorization. However, document movement will be via email. As before, researchers may not start their project until they receive a start letter from COL Weina.

IRBNet was already completely backed up through May of this year, and the DRP is currently making backups of data generated from May until now. Researchers were encouraged to back up their own files as well. COL Weina said that Dr. Dan Brooks (Biostatistician) has been our knight in shining armor during this transition, and he wrote routines to help back up files faster. He did “really good work.”

Access to forms and templates can be found on the intranet, in the Education Training & Research Directorate, Department of Research Programs, in the Library under "IRB Forms and Templates", WRNMMC DRP Documents for Researchers ([direct link](#)).

All concerns during this transition should be directed to COL Peter J. Weina c/o Ms. Patricia Titi, 301-295-8239, (patricia.l.titi.civ@mail.mil) or the new email address (dha.bethesda.ncr-med.mbx.wrnm-drp@mail.mil).

What’s New in RES?

Research Education Services (RES) will be presenting a new course this fall and winter to help researchers work with the protocol submission and the sign-off process.

MERF & CITI Classes

MERF & CITI Training for Investigators will be offered monthly beginning in November. Ms. Thompson will provide attendees with policy guidance promulgated by the Research Regulatory Oversight Office within the Office of the Under Secretary of Defense for Personnel and Readiness (OUSD[P&R]). The course will cover:

- OUSD(P&R) Assurance for the Protection of Human Subjects.
- Minimum Education Requirements Framework (MERF) for DoD Personnel Involved In Human Subjects Research.
- Collaborative Institutional Training Initiative (CITI) role-based training instructions for researchers who conduct, review, or approve research involving human subjects in compliance with the MERF standards set forth by the Assistant Secretary of Defense for Research and Engineering

The training will be provided on demand for groups as well as at scheduled times. The classes listed in the schedule are small. Please RSVP to reserve a seat. If you have a question please contact Ms. Lisa Thompson (lisa.p.thompson5.civ@mail.mil).



Heroes Building, Room 4011

- Tuesday, November 10, 2015, 1400–1500
- Tuesday, December 8, 2015, 1400–1500
- Tuesday, January 12, 2016, 1400–1500
- Tuesday, February 9, 2016, 1400–1500
- Tuesday, March 8, 2016, 1400–1500
- Tuesday, April 12, 2016, 1400–1500

I Save Lives

The “I Save Lives Campaign” features a DRP employee each month. That employee makes it possible for research to carry on discovering new and better ways to care for our nation’s heroes and their families. Research generates new knowledge that is directed to provide better care for patients. First and foremost, research is intended to save lives.



SGT Martinez (left), Ms. Verna Parchment (right)

Recipients of the honor are featured in a poster at the entry of the DRP. Additionally, they receive a framed photo and WRNMMC coin.

The following employees were recognized for their service by the “I Save Lives Campaign.”

- SGT Robert Martinez (NCOIC BRL and Lab Manager), July
- Ms. Verna Parchment (RN, Senior Protocol Development Specialist), August
- Ms. Deborah Kessler (RN CIP, Senior Protocol Development Specialist), September

Research Roundtable

July

Ms. Lisa Thompson (Supervisory Medical Education Specialist, DRP) hosted the roundtable. Ms. Thompson explained that there are seven lines of effort where implementation of Research Unity of Effort between WRNMMC and USUHS is underway.

Unity of Effort is two or more groups working together to achieve a common goal, even when the two groups are under different commands. Unity of Effort might include the following areas:



Ms. Lisa Thompson



- Research
- Simulation
- Pathology
- Traumatic Brain Injury
- Leadership and Readiness
- Library
- Murtha Cancer Center

She also stated that Dr. Maddox (Vice President of Research, USUHS) had been appointed by MG Clark and Dean Kellermann (USUHS) to lead a small group to explore Unity of Effort in Research between WRNMMC and USUHS and to provide recommendations. Dr. Maddox was newly appointed as vice-president after more than 25 years of distinguished service at NIH.



From left to right: CAP Franz Frye, Dr. Joseph Shaw and Research Roundtable Participants

Dr. Shaw (PhD, Senior Technical Editor) introduced himself and described his background in science. He explained that he can help researchers in the writing/editing process for protocols and grants.

CPT Franz Fry (Acting Chief, Biomedical Research Laboratory) described the laboratory facilities and explained how the Biomedical Research Laboratory can help investigators answer research questions.

August

Dr. Lyubov Tmanova (MLIS MS VV [DVM], Biomedical Research Librarian) from the Darnall Medical Library presented information about biomedical research support services.

Services include help in

- Biomedical literature informatics
- Bibliographic management
- Publication visibility
- Systematic review collaboration
- Data management planning
- NCBI molecular database searches



Mr. Greg Rose (left), Research Roundtable Audience (right)

Additionally, Dr. Tmanova described classes for the National Capital Region that she will be presenting in the upcoming months at Darnall Library.

Thus, if you need help with a literature review or are looking for a new way to manage



citations, contact Dr. Tmanova (301-319-2475, lyubov.tmanova.civ@mail.mil).

September

Ms. Rita DeShields (Data Sharing Compliance Manager), Ms. Liz Tutwiler (JD, DHA Privacy Office Support), and Ms. Stormy Clevenger (Senior Data Sharing Analyst) from the Defense Health Agency Privacy and Civil Liberties Office (Privacy Office) attended the Research Roundtable.

Data Sharing Agreements: Overview

Ms. DeShields presented an overview of the Data Sharing Program as it relates to research.

A data sharing agreement (DSA) is an administrative control measure to:

- Confirm that Defense Health Agency (DHA) data will be used as permitted or required.
- Exercise administrative, technical and physical safeguards to protect the privacy of PHI as required by HIPAA.
- Determine the HIPAA-defined category of data intended for use.
- Maintain records to confirm compliance in case of an investigation.



Ms. Rita DeShields

The DSA process allows the Privacy Office to confirm that Defense Health Agency (DHA) data will be used or disclosed in compliance with multiple programs, regulations, and instructions. DHA data is personally identifying information (PII) including protected health information (PHI) maintained on a DHA managed system. DHA managed systems include, but are not limited to AHLTA, TMDS, CHCS, DMHRSi, and PDTs.

DSAs are executed to share data for a number of purposes including a) PHI, b) PII, c) de-identified information, and d) a data use agreement for a limited data set (LDS). The DSA process includes the DHA Privacy Office, the DHA Privacy Board, the System Program Office, and the DSA requesting partners.

A DHA government sponsor is required and is the point of contact from within a sponsoring organization. The government sponsor assumes overall responsibility, on behalf of the government for the projected data use and protection. The government sponsor also confirms that the information provided in the Data Sharing Agreement Application (DSAA) is accurate.

The DSAA applicant is the individual who has primary responsibility for safeguarding the DHA data during its expected use. The applicant is the recipient of the executed DSA.



September Attendees at Research Roundtable



The DSAA is an application to prompt data requestors to accomplish the following:

- Make reasonable efforts to verify that DHA data are limited to the minimum necessary uses.
- Obtain satisfactory assurance that the DHA data will be appropriately safeguarded.
- Verify that the use of DHA data is permitted by the responsible DHA system program office.

The DSAA also allows the Privacy Office to confirm key compliance points:

- DHA data will be used according to the permitted uses defined in the applicable System of Records Notice.
- Information system(s) and networks intended for data processing and/or storage have appropriate safeguards.
- Research-related data uses have been reviewed by the applicable compliance offices and have obtained the required determinations.

Research-related DSAs may require the following information:

- The DHA HRPP determination reference number and expiration date.
- The survey license number and expiration date, if the data will be used for survey purposes
- Also, a DSA submitted for research involving the use of PHI, greater than an LDS, will be forwarded to the DHA Privacy Board for review.

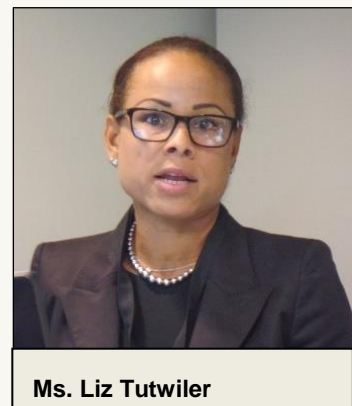
The Privacy Office created three separate data request templates to help DSA Applicants and government sponsors list the data elements needed for the project or study, which are:

- The DRT for MHS Data Repository (MDR) extractions.
- The General DRT (extractions from all other DHA systems).
- The DRT for Access by Login (directly accessing data in a DHA System).

Overview: DHA Privacy Board

Ms. Tutwiler spoke about the HIPAA Privacy Board. The purpose of the presentation was to provide an overview of the DHA Privacy and Civil Liberties Office's (DHA Privacy Office) DHA Privacy Board's function and operations. The establishment of the DHA Privacy Board and regulatory requirements, the difference between the common rule and the HIPAA privacy rule, and the types of privacy rule reviews were all discussed.

- DHA does not have an IRB; therefore, the DHA Privacy Office established a HIPAA Privacy Board, the DHA Privacy Board.
- HIPAA compliance reviews and documentation are required by an IRB or privacy board set up in accordance with the HIPAA regulations when PHI is used or disclosed for research purposes.



Ms. Liz Tutwiler



- The DHA Privacy Board accepts and relies on HIPAA reviews conducted by DoD or outside IRBs that meet regulatory standards.

There are four types of Privacy Board Reviews

- Required representations for research on decedent's information.
- Required representations for review preparatory to research.
- Studies that must obtain HIPAA authorizations.
- Studies that require a waiver of authorization or an altered authorizations.

HIPAA authorizations are presumed by HIPAA to be complete.

- Researchers are required to obtain a written and signed HIPAA authorization from every participant in the research study.
- Authorizations must contain all core elements and required statements set forth in the HIPAA Privacy Rule and DoD 6025.18-R.
- PIs are required to initial and sign a certification.

HIPAA authorizations may be waived (full or partial waivers)

- Where it is impossible or impracticable to obtain a written Authorization from each and every research participant.
- Partial waivers should be obtained when PHI will only be necessary for part of the study or if the PI will be able to obtain Authorizations from the research participants in the future.
- Documentation by an IRB or Privacy Board of approval of a waiver must contain all required criteria set forth in the HIPAA Privacy Rule, 45 CFR 164.512(i)(2) and DoD 6025.18-R, C.7.9.2.

Altered authorizations

- Altered authorizations may be allowed when a research study requires a modification or removal of some, but not all, required elements from an authorization.
- An approved alteration only applies to the study for which it is requested and cannot be used for any subsequent use or disclosure of PHI in a different project.

Data Sharing Agreement (DSA) Modifications, Extensions, Renewals, and Terminations

- DHA Privacy Board approvals are DSA-specific.
- Modifications, extensions, and renewals may be granted for DSAs under certain specific conditions.
- When a DSA is modified, the DSA will be sent to the DHA Privacy Board to determine whether the approval is still appropriate or whether additional review is necessary.
- When a DSA is extended or renewed, the PI certifies that there have been no changes to the study, so DHA Privacy Board review is not required.
- When a research-related DSA expires or is otherwise terminated, any related Privacy Board approvals will also expire or be terminated.



Additionally, when a new DSAA is submitted, the PI is required to complete a new submission to the Board.

Additional Privacy Office-related Information

Email the Data Sharing Agreements Manager (dha.ncr.health-it.mbx.dsa-mail@mail.mil)

Email for information about HIPAA in research (dha.ncr.pcl.mbx.privacyboard@mail.mil)

[DHA Health Information Technology](#)

[Contract language & Privacy clauses](#)

[Systems of Record Notices \(SORNs\)](#)

[Department of Health & Human Services \(HHS\) HIPAA De-identification Guidance](#)

[DoD 6025.18-R, DoD Health Information Privacy Regulation](#)

[DoD 8580.02-R, DoD Health Information Security Regulation](#)

Research Roundtable Schedule, America Building, Room 2301

- Tuesday, October 20, 2015, 12:00–13:00
- Tuesday, November 17, 2015, 12:00–13:00
- Tuesday, December 22, 2015, 12:00–13:00
- Tuesday, January 26, 2016, 12:00–13:00
- Tuesday, February 16, 2016, 12:00–13:00
- Tuesday, March 15, 2016, 12:00–13:00
- Tuesday, April 19, 2016, 12:00–13:00
- Tuesday, May 24, 2016, 12:00–13:00
- Tuesday, June 21, 2016, 12:00–13:00
- Tuesday, July 19, 2016, 12:00–13:00
- Tuesday, August 2016, 12:00–13:00

Award for DRP Staff Sergeant

SSG Jullian Hodges received a letter of appreciation from WRNMMC. The letter thanked him for his work with the combined federal campaign, which supports multiple charities. SSG Hodges has been a key worker for the past two years. He said, “The work is rewarding; I look forward to doing again.”



COL Michael Heimall (Chief of Staff, left) presenting letter to SSG Hodges (right)





COL Peter Weina (left) and SGT Robert Martinez (right)

ReUp

SGT Robert Martinez re-enlisted in the Army for three years this past summer. He will soon be working in the Martin Army Community Hospital at Ft. Benning, GA. At a re-enlistment ceremony, SGT Martinez reaffirmed his commitment to duty and selfless service for the protection of our nation. Friends and supporters of SGT Martinez attended.

Farewell COL Ashley

COL Jeffrey Ashley (Senior Nurse Scientist) is retiring this fall, and an awards ceremony was held in his honor in the atrium of Building 17. He was honored for 30 years' years of service (1985-2015). MG Clark presented COL Ashley with the Legion of Merit award and the Defense Meritorious award. Participants in the ceremony included CDR Jason McGuire, CDR Virginia Blackman, MAJ Patricia Schmidt, and Ms. Josephine Saunders. At the end of the awards ceremony, SFC Daniel White concluded the ceremony with the Army Song and the crowd joined in. Afterwards a reception was held in the lobby.



Friends and Supporters of COL Ashley; COL Ashley (center photo and bottom right photos)



Onboarding

Six people joined the DRP over the summer. COL Weina and the DRP staff welcome them aboard.



(top to bottom)
Guanglie Yu
Adama Guyton
Michael Grippaldi
Daniel Brooks
Erica Reid

MAJ Andrew Senchak, (MS, DO) is the new Deputy Chief of the DRP. MAJ Senchak is a general otolaryngologist practicing at WRNMMC since 2012 and is also an assistant professor of surgery at Uniformed Services University of the Health Sciences. MAJ Senchak completed his otolaryngology residency at Tripler Army Medical Center (Honolulu, HI) in 2008. He was then assigned as Chief of Otolaryngology at Bayne Jones Army Community Hospital (Fort Polk, LA) until 2010. From 2010 to 2012 MAJ Senchak was a general otolaryngologist at San Antonio Military Medical Center (Fort Sam Houston, TX) where he also completed a fellowship in Clinical Research. He also received a master's degree in Clinical Investigation from the University of Texas Health Science Center at San Antonio.



MAJ Andrew Senchak

Dr. Guanglie (Julie) Yu, (MS MS MD, Research Biologist) received her first MS degree in Harbin, PRC. She received her medical degree also at Harbin Medical University, and she practiced medicine for about 10 years in Harbin. She received her second MS in Biomedical Sciences from Eastern Virginia Medical School, Norfolk, VA. Dr. Yu has worked in the biotechnology field since leaving Norfolk. Her expertise includes cell biology, immunohistochemistry, and molecular biology.

Ms. Adama Guyton (Administrative Support Assistant) went to Austin Peay University in Tennessee where she studied Philosophy. She began working for the federal government in Germany and later worked in several government positions in Hawaii and California. Prior to her arrival at WRNMMC, Ms. Guyton worked at Uniformed Services University of the Health Sciences where she provided administrative support in the Department of Epidemiology and Biostatistics. Earlier in her career she studied animal husbandry and worked in that field in Gambia.

Mr. Michael Grippaldi Esq. (MA JD, Quality Assurance and Research Compliance Monitor) studied Biology at Boston College in Chestnut Hill, Massachusetts. He received his MA degree in Bioethics at Wake Forest University in Winston-Salem, NC. He also received his law degree from Wake Forest University. He is licensed to practice law in Virginia, and he has worked in human subjects protection since coming to Maryland.



Dr. Daniel I. Brooks (PhD, Biostatistician) studied Psychology and Classics at Tufts University in Medford, MA. He received a PhD in Psychology from the University of Iowa in Iowa City, IA where he studied comparative cognition and behavioral neuroscience. After completing postdoctoral fellowships at Brown University (Providence, RI) and Tufts University, he moved to the capital region with his wife and dog.

Ms. Erica Reid (BA CIP, Protocol Development Specialist) went to Christopher Newport University in Newport News, Virginia, where she received a BA in psychology. She spent a year at Old Dominion University to study experimental psychology. She received CIP certification in 2013. Her previous employers include the American Psychological Association and the Armed Forces Institute of Pathology.

Useful Information Sources

ClinicalTrials.gov (registry and results database of clinical trials around the world)

PubMed (National Center for Biotechnology Information, Medline search)

US National Library of Medicine (all NLM resources)

Online Mendelian Inheritance in Man (OMIM, catalog of human genetic disorders)

Preventing Chronic Disease Journal (public health, research, and policy)

World Health Organization (WHO home page)

WebMD (clinical conditions and health information)

Mayo Clinic (email newsletters for medical professionals)

Cancer.gov (cancer clinical trials)

Paper and Pencil

Editorial

Daniel Brooks (PhD, Biostatistician)

Excessive use of paper forms in research settings is a common data-related issue that I have seen during my short time at Walter Reed National Military Medical Center. Use of paper forms to record data poses a number of problems that make this method inferior to electronic data capture.

Use of paper forms can introduce errors

Data quality is paramount in all research, but especially so when doing research involving patients. Using pencil and paper to record research data creates multiple steps where errors may be created and propagated.



Use of paper forms creates additional work.

Transcribing paper records into an electronic dataset is often seen as a rite of passage for students before they start a real project. But, the truth is that this unnecessary work is usually done by well-qualified individuals who could be treating our nation's wounded.

Use of paper forms creates a time lag between data collection and analyses

A hidden problem created by paper coding and subsequent transcription is delayed analysis. Forms sometimes sit in filing cabinets or folders for months or years. But, these surveys and records might contain critical information about patient conditions or wellbeing. Data already in electronic format is more easily and quickly analyzed.

There are resources to help

The solution to this problem is to concurrently collect and digitize records. We can either create surveys electronically in a way that will be self-digitizing (e.g., through Survey Monkey), or we can create simple software to assist in data entry.

Contact Us

Call or visit the biostatisticians at the Department of Research Programs (301-319-8709).

Save the Dates

- **4th Annual Aware for All, May 4, 2016**
 - Table display kick-off for 2016 Research and Innovation Month in the Building 19 Lobby
 - Members of the WRNMMC and National Capital Region will showcase their research, hand out brochures, flyers, takeaways, and perhaps show video presentations and provide demos
- **8th Annual National Capital Region Research Competitions**
 - Protocol Submission Deadline, Jan. 1 31, 2015
Medical trainees, staff, and faculty register for participation in a research competition category by electronically submitting their research protocols for the first part of the judging process
 - Poster Display Week, May 9 13, 2016
Research Competition participants will display their research posters in the Mezzanine Center, East, and West Wings of Bldg. 9 featuring their state-of-the-art military medical research efforts
 - Poster Competitions (Judged Oral Presentations), May 11, 2016
Finalists from several research competition categories will present in front of their posters to a committee of walking judges in the East Wing of Bldg. 9



Award ribbons will be pinned next to the winning posters of each research competition category

- Research Symposiums I and II, May 18-19, 2016

Finalists for the Bailey K. Ashford and Robert A. Phillips research competitions will deliver slide presentations of their medical research with judges present in the Memorial Auditorium

Certificate awards will be given to the research competition category winners

- **2016 Spring Research Summit, May 25, 2016**

- The final gathering for 2016 Research and Innovation Month
 - Various Walter Reed National Military Medical research groups introduce their organizations via slide presentations (questions and answers are welcomed throughout the summit) at the Clark Auditorium
-



Darnall Library

Darnall Library Classes (Biomedical Research Support Services, [Classes for National Capital Region](#), Building 5, 4th Floor

- PubMed Basics, Wednesday, October 28, 2015 12:00 pm
- EndNote, Friday, November 20, 2015 12:00 pm
- Writing Systematic Reviews, Thursday, December 3, 2015 12:00 pm
- EndNote, Wednesday, December 16, 2015, 12:00 pm

Publications (Courtesy of [Darnall Library](#))

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Quarterly Newsletter

This newsletter covers events that occurred in July, August, and September.

Credits

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