



Department of RESEARCH PROGRAMS

at Walter Reed National Military Medical Center



Volume 2, Issue 4

Excellence in Military Medical Research

May 2015



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Overview

Research plays a significant role in the medical field in many different ways. Its findings help explain the pathophysiology, epidemiology, risk factors, and causes of diseases. Research findings may be used to optimize healthcare guidelines and provide much needed knowledge for future healthcare providers. Moreover, clinical research studies can help providers learn about and attempt new treatment protocols that could help save lives and improve patients' quality of life. To show our appreciation to those who participate in research at Walter Reed National Military Medical Center (WRNMMC), the Department of Research Programs (DRP) organized numerous events including the Aware for All, Poster Display Competition, Symposium I and Symposium II Competitions, 30th Annual Navy-Wide Academic Research Competition, and the 2015 Spring Research Summit, to recognize and celebrate the positive impact research has on the medical field during the month of May 2015. The DRP coordinated these events with graduate medical education trainees, staff and faculty throughout the National Capital Region. Talks, lectures, and posters were presented to patients, visitors and employees. DRP invites all to take advantage the services it provides for those who want to start research projects.

The DRP offers services to help researchers overcome many obstacles that may prevent them from starting a project. Some novice researchers may not have the knowledge about how to get started or find collaborators. The DRP's Protocol Navigators are available to help novice researchers develop research protocols and can provide them with important information to get started with their research projects. Ms. Patricia Titi (patricia.l.titi.civ@mail.mil) is the point of contact (POC) who can connect you with DRP's Protocol Navigators.

Some novice researchers may not start research due to the belief that extensive funding and equipment is needed to conduct a successful investigation. The DRP can help you find funding opportunities through its Business Cell. Ms. Lisa Potts (lisa.m.potts6.ctr@mail.mil), Grant Writer, is the POC who can get you started. Additional, she can assist research investigators and prevent negative perceptions from hindering attempts to start a research endeavor.

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Overview

Starting a research project can be easy. Anyone can begin on a research project and make contributions to the medical field by taking the time and effort to observe trends and review literature—only a library is needed. Literature reviews can create footholds for further studies by providing evidence-based knowledge to optimize decision making. The DRP’s Center for Nursing Science and Clinical Inquiry can assist you with developing a research project with evidence-based practices. LTC Terri Yost is the point of contact (terri.l.yost.mil@mail.mil).

Laboratory studies can help you visualize cells or tissues at the microscopic level in clinical settings. The information and data gathered can be useful for understanding disease processes and treatments. With the state-of-the-art laboratory equipment, the DRP’s Biomedical Laboratory may help you collect data and conduct laboratory studies to meet your research needs. CPT Franz Frye is the point of contact (franz.a.frye.mil@mail.mil) for Biomedical Research Laboratory studies.

This year’s events continued a long tradition and were a tremendous success. Patients, staff, and military personnel from the National Capital Region came together to learn and to exchange new knowledge in the field of medicine.

Newsletter authors: LT Ryan Kim and Ms. Lisa Thompson

3rd Annual Aware for All a Success



**Ms. Lisa Thompson
provide opening
remarks for the event**

The 3rd annual Aware for All was held on 06MAY2015. Ms. Lisa Thompson, Supervisory Medical Education Specialist from the Department of Research Program opened the Aware for All by speaking to the event’s purpose, which is to recognize and thank volunteers who have or will participate in clinical research at WRNMMC. Ms. Thompson explained that their contributions help “clinical researchers make significant advancements in military medicine and improve the health of the beneficiaries locally and throughout the Military Health System.” She invited the guests to visit the researchers’ booths and learn “how society needs clinical research” to “understand the safety benefits and risks of clinical research” and to “hear stories from patients who have participated in clinical research” at both WRNMMC and USUHS.

Seventeen organizations participated by decorating booths, introducing themselves to the public, passing out brochures and takeaways, and speaking with others about research participation. Groups included the Department of Research Programs, the Henry Jackson Foundation, the Center for Rehabilitation Sciences Research, the WRNMMC Pulmonary Clinic, the Diabetes Institute, the Center for Prostate Disease Research, the Uniformed Services University and Warrior Canine Connection, the Center for Neuroscience and Regenerative Medicine, the WRNMMC Breast Care Center–Murtha Cancer Center Clinical, Breast Care Project, the Audiology and Speech Center, the Department of Rehabilitation, the National Intrepid Center of Excellence–Department of Research, the Defense and Veterans Center for Integrative Pain Management, the Immunization Healthcare Branch of the Defense Health Agency –Walter Reed Bethesda, the Vision Center of Excellence, the Infectious Disease Clinical Research Program, and the Center for Nursing Science and Clinical Inquiry.



3rd Annual Aware for All a Success



COL Roop provide a brief history of the event

COL Stuart Roop, Director for Medicine, thanked participants for their support and provided a brief history of the event. The Aware for All started with an idea from the Center for Information and Study on Clinical Research Participation (CISCRP), an independent nonprofit organization focused on educating and empowering people to make informed decisions about participating in clinical research. Responding to the public's lack of knowledge about and trust in clinical research, the organization achieves its goal by increasing awareness, ongoing engagement, and advertising the value of participation. This simple but powerful CISCRP idea spread to other medical centers with research activities including WRNMMC.



COL Weina, COL Belson, and Ms. Thompson pose for the cake-cutting ceremony.

Later in the event, COL Peter Weina, Chief of the Department of Research Programs; COL Brian Belson, Chief of the Education, Training, and Research Directorate; and Ms. Thompson initiated the cake-cutting ceremony. Cake and refreshments were offered to the guests and speakers as a token of appreciation for their support. COL Weina provided closing remarks to the attendees. He stated that the Department of Research Program's "job is to make sure that we facilitate research here!" COL Weina encouraged the audience to attend the other events of the 2015 Research and Innovation Month including the Poster Display Week and Research Symposiums I and II.

With the successful turnout, the Department of Research Programs plans on hosting the 4th Annual Aware for All next year, keeping to its purpose: To recognize and thank participants while encouraging the public to support clinical research.



Research organizations introduce themselves to the attendees at the 3rd Annual Aware for All Event.



Poster Display Week Shines with Bright Research Findings



A civilian reads over the research poster

Poster Display Week was held on 11MAY2015 to 15MAY2015 in the lobby of Building 9 and nearby mezzanines. To increase public awareness at WRNMMC, the posters and their authors presented research findings and case studies performed in the National Capital Region. Graduate Medical Education trainees, staff, and faculty displayed their posters and provided a diverse array of research clinical findings and strategies for the public.

As part of the 7th Annual National Capital Region Research Competitions, participants in the Bailey K. Ashford, the Robert A. Phillips, the Case Report and the Evidence Based Practice–Quality Improvement categories publically presented their findings as poster displays. Noncompeting researchers, consisting of Lean Six Sigma and investigators from research institutes also provided posters for the event.

Many people visited the exhibition to learn of ongoing behind-the-scenes work that affects the practice of medicine. Healthcare providers and researchers were presented with learning opportunities from their peers. While waiting for their appointments, patients read the posters to learn about research in the National Capital Area.

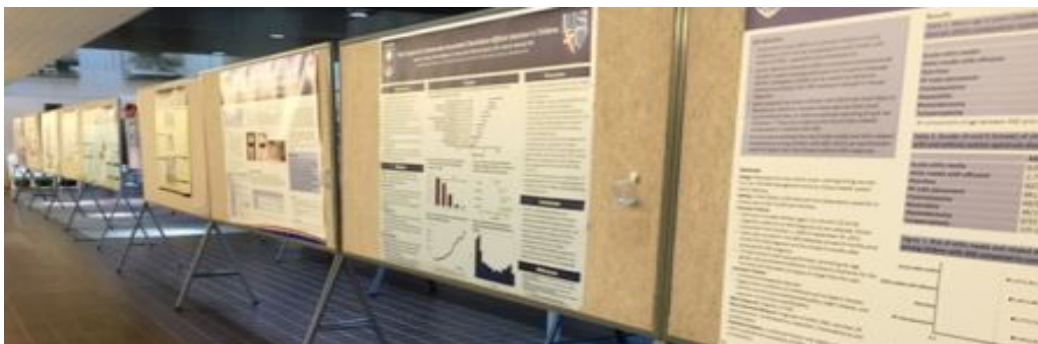
COL Brian Belson, chief of the Education, Training, and Research Directorate, and COL Clifton Yu, Chief of the Graduate Medical Education program at WRNMMC, were impressed by the research posters displayed inside the flagship military medical center. COL Brian Belson said, “I am impressed as always, with how this turns out. There is so much behind-the-scenes work that often goes unappreciated. To pull this off every year with everything else going on, is simply amazing.” COL Yu, stated “I had a visiting colleague from an outside academic institution here yesterday who saw the poster display, and he was so impressed with the quantity and quality of the research output here at this command.”



Active Duty Service Members read and discuss a laboratory research poster

Poster Display Week proved to be beneficial for everyone at WRNMMC. Investigators had an opportunity to present their research projects and shared their knowledge with the public. Visitors and patients learned about ongoing studies that could improve medical care for patients.

With numerous positive comments provided about the event, the Department of Research Programs wishes to provide another opportunity for researchers to publically display their work. All are encouraged to learn more about it by emailing Ms. Lisa Thompson (lisa.p.thompson5.civ@mail.mil) or by visiting the [DRP's Website](#).



Posters displayed at the Poster Display Week



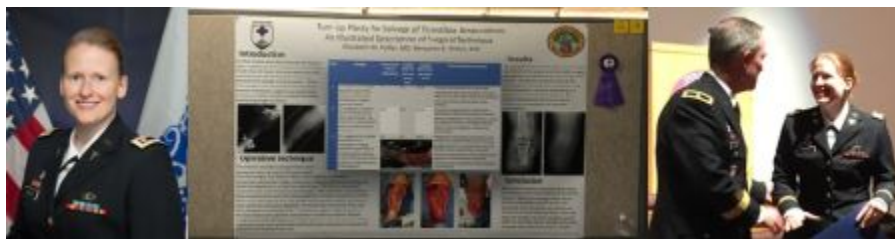
Poster Competitions

Poster Competitions was held on 13MAY2015, in the lobby of Building 9, as part of the 7th Annual National Capital Region Research Competitions to determine the winners of two competition categories. Case Report and Evidence Based Practice–Quality Improvement finalists presented their research studies as posters for the judges while patients and WRNMMC personnel observed the proceedings.

Speakers in the Case Report category presented findings from direct patient interactions. The entire category was split into two different subcategories: intern/resident and fellow/staff. Nine speakers presented in the former and four in the latter. Topics ranged from clinical to surgical cases. Each speaker had ten minutes to present their case followed by ten minutes to answer questions from the audience. Judges evaluated each presentation based on certain criteria including the clarity of the presentation, intervention methods used, the results shown, the conclusion, and the poster presentation itself. Dr. Wendy Bernstein of DRP was the judge coordinator. She led the judging with LTC Matthew Goldman, LTC Thomas Newton, CAPT(r) Laurie Balagurchik, and COL (r) Paul Pasquina.

Speakers for the Evidence Based Practice–Quality Improvement (EBP-QI) category presented a case on applying the best medical practice available with clinical expertise and the targeted patient’s preferences to provide the best patient experience at the medical center. In years past, Evidence Based Practice and Quality Improvement were two separate categories. Now combined into one, speakers had a greater variety of topics to present. The judging criteria remained the same. CDR Jason McGuire, Chief of Center for Nursing Science and Clinical Inquiry was the judge coordinator. He led the judging with LTC Cheryl Creamer, Ms. Laura Taylor, and LTC Terri Yost.

Winners were determined at the end of the day, and a category-customized purple ribbon was pinned beside the winners. A total of three purple ribbons were pinned: one for the Case Report intern/resident category, another for the Case Report fellow/staff category, and the last for the EBP-QI category. All the winners were invited to an awards ceremony, along with runners-up to receive certificates from BG Jeffery Clark, Hospital Director for WRNMMC, for their hard work. In addition, the winner of the EBP-QI category was invited to be the first presenter at Research Symposium I on 18May2015.



Winner of Case Report – Intern/Resident Category

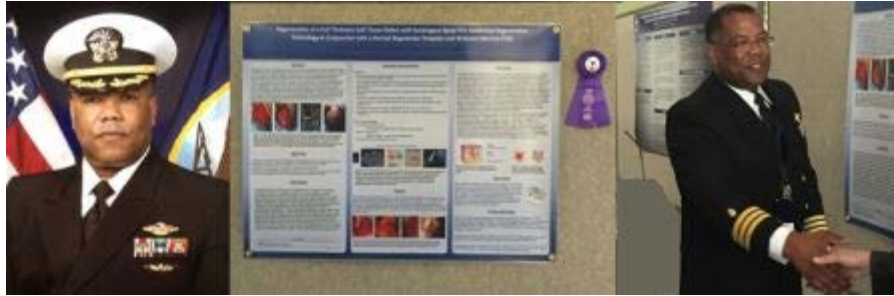
MAJ Elizabeth Polfer, MC

Turn-Up Plasty for Salvage of Transtibial Amputations: An Illustrated Description of Surgical Technique

Summary: A case series of three patients who sustained IIIB tibia fractures due to combat related trauma to describe the operative technique for a transtibial amputation turn-up plasty stabilized with modern compression plating to salvage functional transtibial amputations. Two remained on active duty, while one underwent subsequent amputation for recurrent osteomyelitis.



Poster Competitions



Winner of Case Report – Staff/Fellow Category

CDR Mark Fleming, MC

Regeneration of a Full Thickness Soft Tissue Defect with Autologous Spray Skin Epidermal Regenerative Technology in Conjunction with a Dermal Regenerate Template and Widened Meshed STSG

Summary: A report outlining a military trauma treated successfully by a combination of regenerative modalities: A dermal regenerate matrix and spray skin regenerative therapy. Through a compassionate care protocol, this case report describes the successful treatment of full-thickness wounds using aerosolized autologous skin cell in combination with a dermal regenerative template. Using this method, a small patch of the patient's skin, cells are denatured with enzymes and sprayed onto the wound, achieving soft tissue overage of a large defect, later resulting in tissue regeneration.



Winner of Evidence Based Practice – Quality Improvement

Capt Shannon Pierce, NC

The MICU Spotlight Journal: Initiating a Peer Feedback Nurse-Lead Critical Care Journal at Walter Reed National Military Medical Center

Summary: The purpose was to provide a multidisciplinary, evidenced-based, and easily distributable scholarly journal that contains varied Critical Care review topics, case studies, and certification of critical care nurses (CCRN) review questions to staff and adjunct services in a Medical Intensive Care Unit. Findings showed that the MSJ; increased the critical-care knowledge base of new critical-care nurses and provided ongoing education and reflection in others; improved critical thinking skills in complex cases and re-established patient focused care; and improved successful CCRN completion and nurses preparing for the exam by more than 20% since journal initiation.



Poster Competitions

COL Weina, chief of the Department of Research Programs, expressed his gratitude to everyone who participated in the event. He gave tremendous credit to Dr. Wendy Bernstein "...for the Herculean effort and valuable time she put into the planning, execution, and management of the entire post competition for this year. It is not in the least bit an overstatement to claim that we could not have done this without her pivotal role in the process." He also provided grateful acknowledgements to all of the category judges, the researchers, and their colleagues and mentors for their support.

Investigators got an opportunity to present their research projects and share their knowledge with the public while readers learned about ongoing studies that might improve medical care for the patients. Those participating in next year's research competitions will follow a high standard.

Highlights of the Poster Competitions



This collage depicts activities taking place during Poster Display Week. Posters were displayed for public exhibition. Finalists for the Case Report and Evidence Based Practice – Quality Improvement categories presented at the Poster Competitions.

Symposiums I and II

Finalists for the Bailey K. Ashford (BKA) and the Robert A. Phillips (RAP) categories gathered to compete for their respective awards at Research Symposiums I and II on 18May2015 and 19May2015. After LT Ryan Kim, the master of ceremonies for the event, and COL Stuart Roop, the Director for Medicine, opened the event. The speakers conducted slide presentations of their research projects. Details from presentations included background information, hypotheses, procedures, data, and interpretations. Judges asked questions and provided feedback after each speaker's presentation.



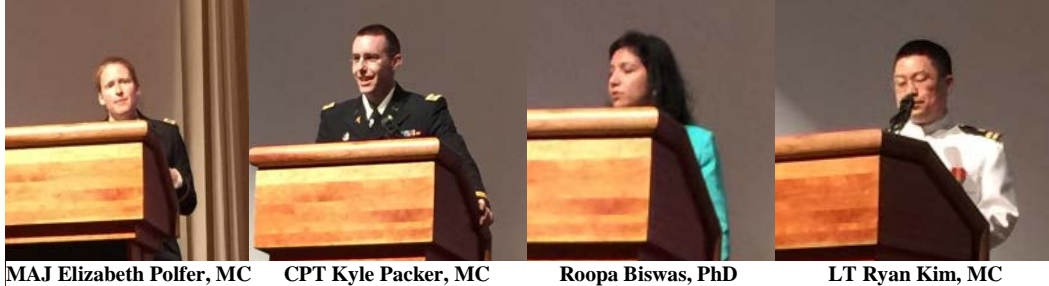
Capt Katherine Shedlock, MC LT Donald Lucas, MC MAJ David Hostler, MC COL Stuart Roop



BG Jeffery Clark

Research competition participants gathered for a group photo

COL Peter Weina



MAJ Elizabeth Polfer, MC

CPT Kyle Packer, MC

Roopa Biswas, PhD

LT Ryan Kim, MC

To accommodate the many presentations, the overall Research Symposium was split into a two-day event. Laboratory subcategories were presented on 18MAY2015. These focused on gathering objective data from subjects to determine physiologic, anatomic, or pathologic changes. These observations allow investigators to make conclusions on the applicability of a medical observation. Judges who participated that day were of CAPT Charmagne Beckett, LTC David Osborn, Dr. Silvia Ratto-Kim, COL Craig Shriver, and LCDR Scott Tintle.

Clinical subcategories were the focus in Research Symposium II on 19MAY2015. These studies focused on the application of medical practices with patient interactions to determine its effectiveness in treatment. COL Michael Nelson, COL Stuart Roop, and Dr. Nancy Solomon were judges.



Symposiums I and II

Both the Bailey K. Ashford (BKA) and the Robert A Phillips (RAP) Awards are traditionally held research competitions in recognition of researchers' contributions to military medicine.

The Bailey K. Ashford Clinical Research Award was established through the efforts of Colonel Marcel E. Conrad, the first Chief of Clinical Investigation at the Walter Reed Army Medical Center in Washington DC. At his retirement in 1974, Dr. Conrad dedicated the award to Colonel Bailey K. Ashford, honoring Dr. Ashford's work during the early 1900s solving the problem of hookworm-induced anemia in Puerto Rico. The Department of Clinical Investigations, now known as the Department of Research Programs, added the laboratory component to the BKA Research Awards in 1996. During the same year, the Army, Navy, and Air Force GME programs within the National Capital Region began integrating, and any trainee who belonged to a program for which WRAMMC was an active teaching center became eligible to compete for the awards. Following the 2011 Base Realignment and Closure-integration of institutions within National Capital Region, the BKA Awards are presented annually to graduating trainees who contribute the most significant research effort to the clinical or laboratory program during training in a GME program that is based in the Joint Task Force National Capital Region Medical (JTF CapMed) Institutions.

The Robert A. Phillips award honors Captain Robert Allan Phillips (1906-1976) who established effective evidence-based rehydration methods for the treatment of cholera. As a Navy Lieutenant at the Rockefeller Institute for Medical Research (New York, New York) during World War II, Phillips developed a field method for the rapid assessment of fluid loss in wounded servicemen. After the war, he championed the establishment of United States Naval Medical Research Unit (NAMRU)-3 (Cairo; 1946) and NAMRU-2 (Taipei; 1955), serving at the helm of both units. Phillips embarked on cholera studies during the 1947 Egyptian cholera epidemic and brought them to maturity at NAMRU-2 (1958-1965). He elucidated the pathophysiologic derangements induced by cholera and developed efficacious methods of intravenous rehydration. His conception of a simpler cholera treatment was realized in the late 1960s with the development of glucose-based oral rehydration therapy, a monumental breakthrough based on the work of many. Today, these advances have been integrated into everyday medical practice across the globe, saving millions of lives annually.



Mientka, Matt. COL Bailey K. Ashford. Digital image. Dcmilitary.com. Web. 15 May 2015.



Robert Allan Phillips. Digital image. Albert Lasker Clinical Medical Research Award. The Lasker Foundation. Web. 15 May 2015.



Symposiums I and II

Winners were determined at the end of Research Symposium II. This year the Department of Research Programs also gave special recognition to the runners up. A total of 20 awardees, nine of them winners, were given special recognition for their hard work and efforts.

Winners of Robert A. Phillips – Laboratory, Resident Category



CPT Kyle Packer, MC

Novel Anterior Chamber Tube Shunt with Tissue Autograft

Summary: This project explored a new design of tube shunt construction using a tissue autograft vs. standard operating procedures. While histologic analysis of tissue samples is pending, the study did demonstrate a significant reduction in intraocular pressure.

Winners of Robert A. Phillips – Laboratory, Staff Category



Roopa Biswas, PhD

Role of microRNAs in the Development of Prostate Cancer

Summary: This project identified ERG-associated microRNAs (miRNA) that can serve as prognostic markers as well as therapeutic targets for ETS-related gene-associated tumors using Taqman miRNA low-density arrays in 6 human prostate tumor tissue samples. The project identified biomarkers miR-449a and miR-874 as potential candidate therapeutic targets because their modulation could suppress the cancer phenotype that creates ERG-associated prostate cancer cells.

Winners of Robert A. Phillips – Clinical, Resident Category



Capt Katherine Shedlock, MC

Autism Spectrum Disorder Increases the Risk of Obesity and Metabolic Comorbidities

Summary: This retrospective case-cohort study evaluated children with autism spectrum disorder to see if they were more likely to have a diagnosis of obesity and other metabolic comorbidities, such as diabetes mellitus type II (T2DM), hypertension (HTN), hyperlipidemia, and nonalcoholic fatty liver disease/nonalcoholic steatohepatitis. Data revealed an odds ratio of at least 1.84, compared to the control groups.

Winners of Robert A. Phillips – Clinical, Staff Category



MAJ David Hostler, MC

Feasibility of Intercostal Artery Doppler Ultrasound Exam Prior to Thoracentesis

Summary: A prospective pilot study demonstrated the feasibility of routinely performing a Doppler arterial exam prior to thoracentesis. It also showed minimal time and perceived burden, increased perceptions of safety, and some instances of averted arterial injury.



Symposiums I and II

Winners of Bailey K. Ashford – Laboratory



MAJ Elizabeth Polfer, MC

Development of a Rat Model for Blast-Related Post-Traumatic Heterotopic Ossification (HO)

Summary: By reproducing the phenotype of combat-related heterotopic ossification in rats, this study attempted to address clinical studies, evaluate novel therapeutic approaches, and determine if the presence of bioburden (*Acinetobacter baumannii* or methicillin-resistant *Staphylococcus aureus*) affects the magnitude of HO formation.

Brigadier General Jeffery Clark, the Hospital Director for WRNMMC, concluded Research Symposium II. He emphasized, “Every good or great academic medical center excels in research. Therefore, the flagship of the military health system must excel in research. So what you’ve done is incredible.” In recognition of those who participated, he said “I think everybody who did research, who brought forth research, who made an effort to make things better for our patients should be very, very proud of them and should feel very good about them... we owe you a debt for the time you spent often running around doing all of the other things we ask you to do and we owe you a gratitude for the time you spent in order to make things better for our patients.” As COL Weina announced the names winners, BG Clark handed gave them certificates. In addition, BG Clark provided a newly-minted BKA/RAP medallion to each category winner for this year’s competition.



BG Clark poses with the DRP Chief COL Peter Weina (Far Right) and the event coordinators: Lisa Thompson (Far Left), LT Ryan Kim (Left of BG Clark).

Winners of Bailey K. Ashford – Clinical



LT Donald Lucas, MC

Assessing Readmission after General, Vascular, and Thoracic Surgery using ACS-NSQIP

Summary: This study sought to define the incidence and risk factors associated with readmission after surgery. A multivariate analysis revealed that ASA class and the patient’s length-of-stay were most strongly associated with readmission.



CAPT Sarah Martin, Chief of Staff shakes hands with the winners and alternate winners of the 7th Annual National Capital Region Research Competitions.



30th Annual Navy-Wide Academic Research Competitions

The 30th Annual Navy-Wide Academic Research Competitions were held in the Clark Auditorium at Walter Reed National Military Medical Center on 26MAY2015. The Navy-wide Academic Research Competition (NWARC) is a proud naval tradition that spans distance and time. When the event first started at the National Naval Medical Center in Bethesda, MD, winners of the Robert A. Phillips awards competed with those from Naval Medical Center–San Diego and Naval Medical Center–Portsmouth by conducting slide presentations of their research projects. Later, when the three medical centers took turns as hosts for the event, speakers were invited to travel across the nation to participate. Following the tradition, four speakers from WRNMMC, three from Portsmouth, and two from San Diego presented this year.

This year's NWARC was conducted differently than in previous years. Walter Reed National Military Medical Center became the first joint service military medical center to host this traditionally held naval event. Speakers and judges from Army, Navy, Air Force, and civilian backgrounds attended to support joint service efforts. CAPT(r) Joseph Pellegrini, a judge from previous NWARC events, presented opening remarks. Other judges included MAJ Jason Hawksworth, CDR Randy Bell, CAPT(r) Patricia Kelley, and Lt Col Wade Gordon.

Brigadier General Jeffery Clark, the Hospital Director of WRNMMC, helped conclude the Naval Competition. During the award ceremony, winners were announced by COL Weina as BG Clark provided a certificate, a BKA/RAP medallion, and a hospital director challenge medallion to each category winner.

Winner of Clinical Category – Resident (Category 1A):



Capt Katherine Shedlock, MC
Bethesda, MD

Autism Spectrum Disorder Increases the Risk of Obesity and Metabolic Comorbidities

Summary: This retrospective case-cohort study evaluated children with autism spectrum disorder to see if they were more likely to have a diagnosis of obesity and other metabolic comorbidities, such as diabetes mellitus Type II (T2DM), hypertension (HTN), hyperlipidemia, and nonalcoholic fatty liver disease/nonalcoholic steatohepatitis. Data revealed an odds ratio of at least 1.84.

Winner of Clinical Category – Staff (Category 1A):



CDR Jeffery Millegan, MC
San Diego, CA

Recent Sexual Trauma and Adverse Health and Occupational Outcomes among Men Serving in the US Military

Summary: This prospective cohort study examined the associations of recent sexual trauma on health with functioning and occupational outcomes among male US service members. The results concluded that sexual trauma has a significant negative association with health and functionality that may extend into post-military life.



30th Annual Navy-Wide Academic Research Competitions

Winner of Laboratory Category – Resident (Category 1B):



CPT Kyle Packer, MC

Bethesda, MD

Novel Anterior Chamber Tube Shunt with Autograft Tissue

Summary: This project explored a new design of tube shunt construction using a tissue autograft vs. standard operating procedures. While histologic analysis of tissue samples is pending, the study demonstrated a significant reduction in intraocular pressure.

After the award ceremony, BG Clark gave closing remarks by first emphasizing the hospital's mission statement: An extraordinary patient experience for every patient, every time. Then, he explained why research is a significant supporting pillar for the patient's experience, "The only reason we do research is for the next patient. If it wasn't going to improve patient outcomes, if it wasn't going to make things better for the next patient, then we should be spending our time and energy on something else." Finally, he thanked all of the event speakers for their time and effort by saying, "I also know we don't do this on the hop. You find the time, and you figure it out, and you get it done, and you make your contributions that improve, give, and provide for our patients." At the event's conclusion, the attendees were invited to a cake-cutting ceremony to share the sweet rewards of their project involvement.

No matter where the event is located, speakers for the Navy-Wide Academic Research Competition have a rare opportunity to present alongside participants from other medical centers. This annually held naval tradition continues to invite winners of the Robert A. Phillips award to participate, no matter what their military or civilian background is. The research investigator's presence confirms that their research studies are appreciated and have made a significant contribution to the military medical field.

Winner of Laboratory Category – Staff (Category 1B):



Roopa Biswas, PhD

Bethesda, MD

Role of microRNAs in the Development of Prostate Cancer

Summary: This project identified ERG-associated microRNAs (miRNA) that could serve as prognostic markers as well as therapeutic targets for ETS Related Gene-associated tumors using Taqman miRNA low density arrays in six tissue samples from human prostate tumors. The project identified biomarkers miR-449a and miR-874 as potential candidate therapeutic targets because their modulation could suppress the cancer phenotype that creates ERG-associated prostate cancer cells.



BG Clark, along with LCDR Wallace and CPT Packer, initiate the cake-cutting ceremony



2015 Spring Research Summit: Many Prestigious Speakers



Collage of speakers who presented at the 2015 Spring Research Summit

Left: CDR Jason McGuire, CAPT Robert Browning, LCDR Alicia Warnock, LTC Aaron Holley, CAPT Timothy Burgess; Center: Lisa Thompson; Right: Ms. Keli Blaize-Wise, Mr. Travis Combest, Dr. Jin Lie, Dr. Erik Wolf, Dr. Limone Collins, COL Peter Weina

The 2015 Spring Research Summit was held on 27MAY2015 in the Clark Auditorium. Research investigators from different clinics and organizations gathered together for this networking opportunity. Ms. Lisa Thompson, the Department of Research Program's Supervisory Medical Education Specialist, opened the event as the master of ceremonies. Referring to the hospital's icon at the front of the auditorium, she emphasized how "patient-centered care is our priority," and how "research plays a supporting role in providing an extraordinary patient experience at WRNMMC." She encouraged all leaders to provide support for the hospital's mission statement and for those who set aside time to conduct research. Ms. Thompson encouraged the flagship of the military health center to continue to excel in research. She concluded by thanking all participants for their support and by expressing gratitude for the time they "spent in research to make life better for our patients."

The first speaker was CAPT Timothy Burgess from the Infectious Disease Clinical Research Program (IDCRP) at the Uniformed Services University of the Health Sciences. Facilitated by the Henry Jackson Foundation, the IDCRP is a federal program for military-relevant multi-center collaborative infectious disease research. Its mission is to conduct research of importance to the military through a unique, adaptive, and collaborative network to inform health policy, clinical practice and disseminate findings throughout the scientific community. Some of the organization's projects include "The Role of Gut Microbial Translocation in the Pathogenesis of HIV" and "A Study Examining HIV Associated Neurocognitive Disorders (HAND)."

The next speaker was Ms. Kelli Blaize-Wise who introduced the Geneva Foundation to the audience. This nonprofit organization supports and advances innovative medical research and excellence in education within the U.S. military. It also builds enduring partnerships dedicated to the health and well-being of service members, their families, and the global community. It achieves its goal by conducting industry-sponsored Phase I to Phase IV studies; proposing and managing federally funded service contract awards; coordinating educational conferences; grants and gifting; and proposing and managing federally funded PI-driven grant and contract awards.

CAPT Robert Browning represented the WRNMMC Pulmonary Clinic. He introduced the clinic's four areas of research focus: lung cancer, COPD, asthma, and sarcoidosis. Then he talked about pulmonary clinic bronchoscopic evaluation procedures and how they can identify abnormal tissues including tumors. Finally, he talked about an ongoing, multi-site trial to detect lung cancer before it can be detected by a CT procedure.



2015 Spring Research Summit: Many Prestigious Speakers

Mr. Travis Combest represented the Department of Nutrition Services–Outpatient Nutrition Services to the audience. He presented his current study “Comparison of Three Weight Loss Approaches for Improvement of Body Composition in Overweight Department of Defense (DoD) Beneficiaries.” His goal is to determine if patients defined as overweight or obese would have greater decreases in weight and body fat if utilizing an accelerometer device with multidisciplinary intervention for weight loss rather than either the device or intervention alone. Preliminary data from the study looks promising and suggests additional research studies using other devices, such as the Fitbit®.

Dr. Erik Wolf represented for the Department of Defense–Veterans Affairs, Extremity Trauma and Amputation Center of Excellence. He explained the institute’s research initiatives; including returning patients with extremity trauma and amputation to high-level function; defining optimal intervention strategies; the sequences of care to improve outcomes; pain management for patients with extremity trauma and amputation; and facility optimal reintegration into the military and civilian communities. He listed some of their ongoing studies, including “Evaluation of Spine Health and Spine Mechanics in Service Members with Lower Trauma,” “Evaluation of Knee Joint Health in Service Members with Unilateral Lower-Extremity Trauma,” and “Assessing Risk Factors for Cardiovascular Disease in Individuals with Traumatic Amputations.”

LCDR Alicia Warnock from the Diabetes Institute presented the institute’s latest research study. She explained how the institute’s primary goals include expert clinical care, patient and professional education, and cutting edge research to improve the understanding and treatment of patients with T1DM and T2DM as well as obesity. Along with research studies, she listed some of the clinic’s challenges, solutions, and opportunities for collaboration.

Dr. Jie Lin from the Murtha Cancer Center presented one of their pilot studies “Smokeless Tobacco in the US Military.” This study’s short-term goals consists of evaluating the use of tobacco products in the military, investigating factors that may be associated with smokeless use of tobacco in the study populations, and assessing the feasibility of conducting a large-scale cohort study among active-duty service members. Along with background information, she listed the study’s specific aims, its study design, locations, data-collection methods, and long-term goals.

CDR Jason McGuire represented the Center for Nursing Science and Clinical Inquiry (CNS&CI). He introduced the CNS&CI’s other members: COL Jeffrey Ashley, LTC Terri Yost, and CDR Virginia Blackman. To give the audience an example of what they do, he presented a research project he is working on called “The Effectiveness of Dexmedetomidine as a Prophylactic Treatment for Emergence Delirium among Combat Veterans with High Anxiety: A Randomized-controlled Trial.” This ongoing study seeks to determine if dexmedetomidine is an effective prophylactic treatment for emergence delirium among combat veterans that present to surgery with high state-anxiety.

Dr. Limone C. Collins, Jr. presented the DHA Immunization Healthcare Branch’s vision to audience members at the event. Their vision is a responsive patient-centered healthcare organization promoting excellence in immunization policy and practice for service members and beneficiaries. Dr. Collins listed some of their current protocols; its accession screening and immunization program; its post-marketing safety surveillance studies; and its immunization healthcare branch grant program.



2015 Spring Research Summit: Many Prestigious Speakers

LTC Aaron Holley, from the Sleep Clinic was the last presenter. He presented “The Study of Active Duty Military for Pulmonary Disease Related to Environmental Deployment Exposures (STAMPEDE).” He explained how the Sleep Clinic work alongside those involved with research involving airway diseases. He also highlighted another study about the Airflow Perturbation Device, to help objectively evaluate airway disease for service members coming back from deployment. Finally, LTC Holley described the sleep laboratory and how the Sleep Clinic could help others in their sleep studies.

COL Peter Weina, Chief of the Department of Research Programs, concluded the event with closing remarks. He thanked Ms. Thompson “for all of her heroic work...” He also gave recognition to LT Ryan Kim and Mr. John Fadoju for their phenomenal work and emphasized how the event’s setup involved a big collaboration with numerous people.

Ms. Lisa Thompson, the event’s Master of Ceremonies, hopes to create the 2015 Fall Research Summit to attract incoming trainees, staff, and faculty to learn about the research institutes and opportunities available at WRNMMC.

Residents’ Research Day

LTC Joshua Hartzell, Assistant Chief of Graduate Medical Education (GME) opened Residents’ Research Day on 12MAY2015, at WRNMMC. This event introduced new and interested GME trainees about how to conduct research studies at WRNMMC. LTC Hartzell invited staff from the Department of Research Programs to speak about their services and how to begin on a research project.

COL Peter Weina, Chief of the Department of Research Programs, started his presentation by introducing Ms. Lisa Thompson, the department’s Supervisory Medical Education Specialist, as the “face of the department” who would reach out and communicate its services with the medical center’s training programs. Next, he described the DRP’s job in a simple phrase, “to try to make life easier for the researcher.” He described how the DRP successfully provided funding for ten GME protocols without using any of the hospital’s funds for patient care. After giving brief descriptions of the department’s services, including its Business Office and Biomedical Research Laboratory, he emphasized two things that interested researchers need to know when starting a research project at WRNMMC:

1. “If you want to do research, walk over to Building 17B, and see the Department of Research Programs on the third floor. Get hooked up with a protocol navigator.”
2. “You can’t start enrolling patients until you get a start letter from me. If you can remember those two things, that’s all you would need to remember.”

Understanding how busy trainees and clinicians are, COL Weina arranged for Protocol Navigators to guide researchers on setting up a research protocol and getting it through the approval process. He said they know what material is required, how to create and submit the proper paper work, and who the research investigators need to meet (such as biostatisticians). Their services can help researchers obtain a start letter indicating that the review process is complete and they may start on their research project.



Resident Research Day



A collage of speakers presenting at the May Resident Research Day
 Top Left to Right: LTC Joshua Hartzell, Ms. Courtney Pitts, Dr. Jasleen Shant
 Bottom Left to Right: CPT Franz Frye, COL Peter Weina and CDR Ruben Acosta

To help investigators create a research protocol, CDR Ruben Acosta, Deputy Chief of the Department of Research Programs, presented the department's protocol development services. He introduced the biostatisticians and navigators as available sources that advise on the setup of a research project. In addition, CDR Acosta listed factors to consider when creating a protocol. Such factors include the type of research, time available to do research, and the feasibility of obtaining the target population. Finally, he encouraged researchers to take advantage of the DRP services not just to set up a research protocol, but to find the resources needed to get the project started.

Dr. Jasleen Shant came up next to talk about the department's Business Office. She introduced herself as the point of contact for researchers who have business needs related to their research such as funding and outside collaborations. She listed ways the office could help researchers obtain grants for research protocols, including intramural funding. She pointed out that the DRP can also help investigators write grant applications for funding from outside institutions. Finally, she encouraged researchers to see her if they plan to do a study collaboration with an outside institute to ensure the parties' roles are clearly understood.

CPT Franz Frye represented the Biomedical Research Laboratory (BRL). He advised researchers planning to conduct biomedical laboratory research studies to visit his department. The laboratory can help design their research protocol and determine their optimal laboratory methodology. In addition, the laboratory's microbiologist, biochemist, and three experienced medical technologists all can help provide subject matter expertise; assist with their laboratory procedures; and teach researchers how to conduct the research experiments. With the BRL state-of-the-art equipment, researchers have opportunities to perform a wide variety of experiments using gel electrophoresis, ELISA, real-time PCR, trace metal analysis, and mass spectrometry.



Resident Research Day

Ms. Courtney Pitts, the Institutional Review Board (IRB) Manager, was the last speaker. The WRNMMC IRB reviews protocols involving human subjects and ensures that patients are not exposed to unnecessary and dangerous risks. Ms. Pitts described IRB “as the liaisons between the IRB members and the research community.” The IRB assigns its members to review protocols and advise the principle investigators about human protections. In addition, they help familiarize researchers with IRBNet, the institution’s electronic research protocol system, and establish accounts with the Collaborative Institutional Training Initiative (CITI) for training related to their research.

The Department of Research Programs provided a wide variety of speakers for GME trainees wishing to start a research project. Understanding how complicated it can be, the DRP is set up to assist or improve research protocols no matter what stage they are in. The department wants not only to help researchers create research protocols but ensure they have resources and services available to conduct the studies successfully at WRNMMC.

COL Michael Nelson’s Farewell Party

Jeremy Nelson, the Education, Training, and Research (ETR) Directorate Administrator, organized a farewell party for COL Michael Nelson, Chief of the ETR, on 20APRIL2015. COL Nelson was recently given Permanent Change of Station orders assigning him to a new area in May. Before his departure, the ETR took the opportunity to show appreciation for his leadership and service.

COL Nelson’s impact has resonated throughout the ETR. COL Clifton Yu, Chief of the Graduate Medical Education (GME) training program at WRNMMC, praised his support saying, “Any opportunity to improve the GME environment here at this hospital... he really helped get things through to the next level.” COL Tammie Morton, Chief of the Hospital Education and Training program, remembered him, “every time I always learn something when I go to a meeting with him.” She also mentioned about how he helped provide insight about education and how he supported their department. Ms. Ann Holman, from the Darnell Medical Center gave thanks and good wishes to COL Nelson.

Numerous awards were provided to COL Nelson to recognize his involvement. COL Belson provided a department-signed picture. COL Yu and COL Morton provided elaborately decorated paddles as a metaphor for his experience “paddling upstream” to obtain the required help for tasks needed to improve the ETR. In addition, COL Morton provided a hospital director challenge coin to acknowledge his services. Moreover, flowers were given to COL Nelson’s wife for providing family support.



COL Belson

COL Nelson and Mrs. Nelson

COL Yu

COL Morton

Ms. Holman



COL Michael Nelson's Farewell Party

COL Michael Nelson provided final remarks to summarize his involvement with WRNMMC. He was proud of how the staff worked together to help create a better directorate to train future healthcare providers. He thanked the department Chiefs for their ideas and leadership that helped move the ETR forward. COL Nelson introduced COL Brian Belson as the new Chief of the ETR. COL Nelson expressed confidence in COL Belson's abilities and said: "I couldn't be more proud than to turn this over to COL Belson. He is a strong, visionary leader who will execute and, most importantly, he knows the mission. He won't forget the mission. He won't forget the people because he knows you...I know you are in good hands."



COL Michael Nelson

Noting the team's unity and ability to work together, COL Nelson maintained confidence that the ETR would continue to provide even better services to the patients and trainees at the medical facility. At the conclusion, staff and faculty gave their personal wishes to COL Nelson while enjoying cake and punch as a team.



Staff and faculty with the Education, Training, and Research Directorate gather to share their memories with COL Michael Nelson during his farewell party.



The Operations Office Operates Well



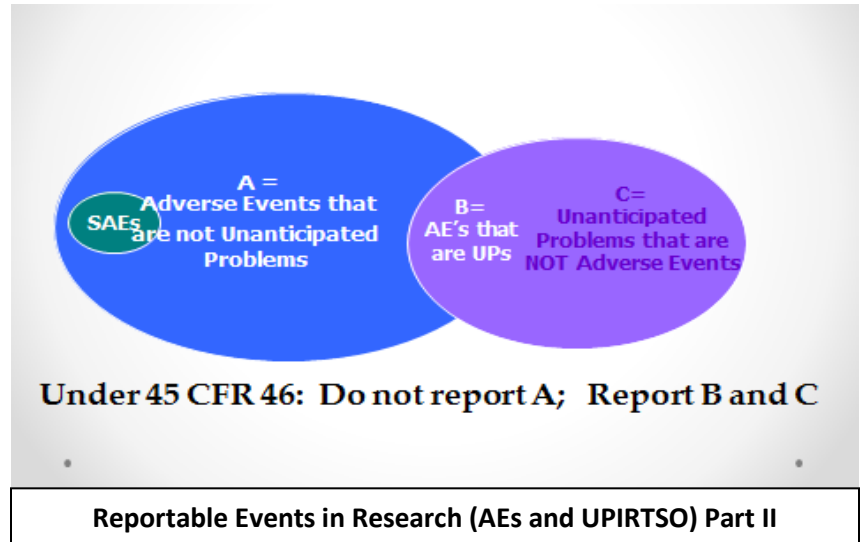
Ms. Lorna Moore
Clinical Trials Auditor
Research Compliance Officer

REPORTABLE EVENTS IN RESEARCH (AES AND UPIRTSO) PART II

The general relationship between Adverse Events and Unanticipated Problems are as follows:

Unanticipated Problems (UP) should be reported to the IRB and Sponsor (for IND studies) as soon as the principal investigator becomes aware of the event. To help determine if an adverse event is a UP, three questions should be considered:

1. Is the event unexpected?
2. Is the event related or possibly related to the subject's participation in the study?
3. Does the event suggest the research places subjects or others at greater risk of harm than was previously planned for or known?



If the response is yes to all three questions, then the adverse event is a UP and must be reported to the IRB immediately in accordance with the IRB Handbook and Investigator's Guidebook. To meet the criteria for prompt reporting of a UP the following must be adhered to:

- Within 24 hours of the investigator becoming aware of the UP (unexpected adverse event), it should be reported to the IRB by telephone or email and followed up with a written report within 5 days. For sponsor-related clinical trials, follow the direction of the Sponsor.

Remember

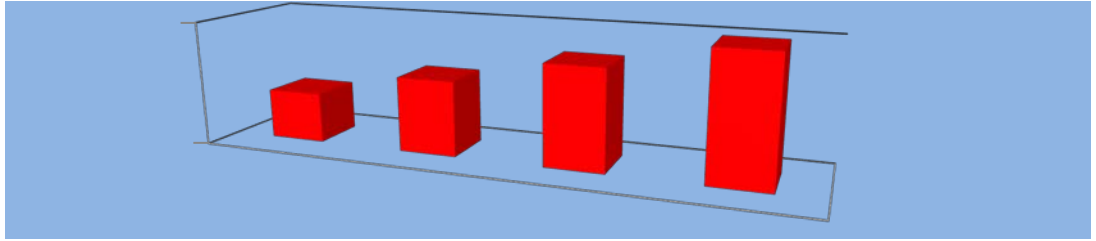
All adverse events, including events that are not related to or caused by the subject's study participation, should be collected, reviewed and tracked by the investigator. Events which are to be reported should be defined in the protocol for both routine and unexpected events. Adverse Events that have been described in the protocol, Informed Consent Form, Investigator's Brochure, or package inserts and which are not related to subject participation in the study or do not meet the prompt reporting criteria can be reported in the studies Continuing Review Report. Reporting criteria can be found in WRNMMC IRB Handbook.



All You Ever Wanted To Know About Statistics

**Robin Howard, MA,
Chief Biostatistician**

**Minoo Rouhanian,
MS, Biostatistician**



LEARNING MORE ABOUT STATISTICS

There are numerous resources to begin or advance your knowledge of statistics:

1. WRNMMC Department of Research Programs:

a. **SPSS Training:** Classes in the use of the statistical software SPSS will be offered every quarter **by reservation only:**

i. **Introductory Level:** Hands-on "Introduction to SPSS" training:

1. Tuesday and Wednesday May 12 and 13 Completed
2. Tuesday and Wednesday Sept 29 and 30 1330 - 1630
3. Tuesday and Wednesday Jan 26 and 27 1330 - 1630

ii. **Intermediate Level:** Hands-on training of more advanced statistical methods:

1. Pre-requisite: The introductory level training course
2. Classes to begin 2016 on annual basis

iii. **Advanced Level:** Hands-on training of multivariate methods:

1. Pre-requisite: Intermediate level training course
2. Classes to begin 2016 on an annual basis

ALL SPSS classes require a reservation so that students can access the software. The number of hands-on attendees is limited to a maximum of 15 per session.

POC is Minoo Rouhanian, MS (301-295-8219) or via Outlook

b. **Help from a DRP Biostatistician:** DRP biostatisticians will help design your research, estimate sample size and provide a data analysis plan, as well as edit/write the relevant sections of your protocol

i. For an appointment for help with all aspects of writing a protocol at the hospital (known as: PROTOCOL OUTREACH PROGRAM):

1. Bldg 19, Allergy Clinic, 4th Floor, rm #4113; Mon or Thu mornings
2. POC is Ms. Patricia Titi (301-295-8239) or via Outlook

ii. One-on-One Consulting with a biostatistician at the DRP:

1. Bldg 17B, Department of Research Program, 3th Floor
2. POCs are Francois Tuamokumo, PhD (301-319-8788) or Minoo Rouhanian, MS (301-295-8219)

Due to limited staff availability, assistance is provided as workload permits with resources focused on supporting GME. Randomization, data analysis, and reporting will only be provided to investigators with WRNMMC IRB-approved protocols.

2. **Learn Statistics at your own pace when you have time:**

a. SPSS guidance online:

- i. From UCLA: <http://www.ats.ucla.edu/stat/spss/modules/>
- ii. From U Central Michigan: <http://calcnet.mth.cmich.edu/org/spss/toc.htm>

b. General statistical theory/software/applications: Very Basic through Advanced Statistics: FREE Online courses through www.edX.org and www.coursera.org



The Business Office is all Business



Ms. Venetta Jones
Contract Manager

CONTRACTS MANAGEMENT SUPPORT GUIDANCE

Contracts Management is an essential component of WRNMMC. Within WRNMMC, the DRP has erected a fully functioning Business Office to help with all research-related business needs. One of the services the Business Office provides is a dedicated Contracts Management Support Liaison for procurement guidance, contract administrative and management support, by interpreting contracting opportunity guidelines for principal investigators and a large network of organizations within WRNMMC.

A DRP milestone has been reached within the Business Office, which now helps WRNMMC to facilitate the contract submission process for our investigators by offering assistance in administration, submission, and award processes by utilizing Research Development Test and Evaluation (RDTandE) funds (aka DoD research dollars). Big thanks to the capabilities of the General Fund Enterprise Business System (GFEBS), the DoD's accounting system, that was migrated here at WRNMMC. During a U.S. Army-wide implementation, WRNMMC accomplished a base-wide kick-off during the summer of 2014. GFEBS is a robust Web-based enterprise resource planning system that replaces or absorbs more than 80 legacy accounting and asset management systems. One major function of GFEBS is the Work Breakdown Structure (WBS) element that allows for decomposition of funding allotments for detailed cost accounting and visibility of various colors of money, to include research (RDTandE) dollars. Whereas, previously WRNMMC/DRP was unable to receive research dollars it can now do so thanks to GFEBS.

With the dynamic collaboration of the experience and expertise of the Business Office, The Department of Research Programs can now submit, annually, hundreds of purchase requests and receive funds for sponsored research for our principal investigators that range in dollar value. The Contract Management Support Liaison specializes in the management and support of the DRP contracting program. In an effort to ensure effective, efficient, and timely completion of the WRNMMC research mission, the Contract Management Support Liaison provides significant expertise and depth in advanced concepts, principles, and practices within the acquisition management and general medical logistics management functional areas, to include: program management, Integrated Logistics Support (ILS) concepts, wholesale supply system, cataloging, and contracting administration/procurement.

The DRP offers the services of a dedicated Contract Management Support Specialist, who also focuses on the management and support of acquisition strategy, purchasing, and contracts from contract planning through award, post-award administration, and contract closeout. The Contract Management Support Liaison will assist the Principal Investigator and/or DRP staff to:

- Define their contract requirements: who, what, what, when, where, how.
- Conduct Market Research
- Obtain Funding document from Resource Management
- Obtain required signatures
- Submit Procurement package to Acquisitions Division, to include: GFEBS Purchase Requisition, Statement of Work if applicable, Sole Source Justification if applicable, and quotes

The DRP Business Office and the Contracts Management Support Liaison look forward to supporting and working closely with our principal investigators as we continue to move forward with the establishment of WRNMMC as a leading DoD research institution. For contracting requirements, please contact the DRP Contracts Management Support Liaison, Venetta Jones, at venetta.s.jones.ctr@mail.mil or (301) 295-8272.



IRB Operations Office: When You Work with Human Subjects



Ms. Elizabeth Narvaez
IRB Manager

SUBMITTING ADVERTISEMENTS FOR HUMAN SUBJECTS RESEARCH

A RESEARCH ADVERTISEMENT is any information given or presented to potential research subjects using radio, television, printed, electronic or World Wide Web media or other means with the intent to recruit into a research study. Examples of advertisements are flyers, postcards, brochures, newspaper advertisements, radio advertisements, press releases, or postings on the Internet.

Investigators should design their own advertisements following the requirements listed in Guidelines for Use of Advertisements and Instructions Policy is found in IRBNet in Forms and Templates in WRNMMC Department of Research Programs (DRP) – Documents for Research Library.

Advertisements for research being conducted at other institutions that will be displayed at WRNMMC must also be reviewed and approved by DRP to ensure compliance with institutional policy.

The content of advertisement should clearly state the following:

- Advertisement is being used for recruiting for research.
- Purpose of the study
- Eligibility criteria used to enroll subjects
- Time or other commitment required for subject participation
- Potential benefits
- Name and affiliation (department or service) of the principal investigator
- Location of the study
- Point of contact including the phone number and e-mail

There is no prohibition against stating the compensation and the amount; however, inappropriate statements highlighting financial compensation are prohibited.

All advertisements for research conducted at WRNMMC require review by the Department of Research Programs (DRP) and approval by the IRB WRNMMC IRB Department of Research Programs. The advertisement should be submitted to IRB as part of the package for initial review. If, at a later date, the investigator decides to advertise for subject recruitment for an ongoing approved research protocol, an addendum for the advertisement needs to be submitted for review and approval by the IRB. If the content of an advertisement requires changes (even at the level of contact information), an addendum with the proposed content change(s) needs to be submitted to IRB for approval.

Only IRB-Stamped printed materials may be displayed, disseminated, or presented at WRNMMC.



DRP Monthly Research Roundtable



Ms. Lisa Thompson
Host of Research Round Tables

The May Research Roundtable, held on 12MAY2015, provided information for the research community at WRNMMC to share with their colleagues. Lisa Thompson (left), host of the Research Roundtable, started the event by giving a short history about the Research Roundtable, the purpose behind the meeting, and how the DRP uses the Research Roundtable to assist the Research Committee at WRNMMC.

She explained how the Research Roundtable was established and hosted by a group of research coordinators over 5 years ago at Walter Reed National Medical Military Center. As the word spread about the research coordinators' hosting research roundtables, physicians, residents, scientist, and others began attending and using this platform to address research issues, ask questions, and provide answers. Research roundtables met monthly and became an established town hall meeting that grew out of necessity.

Today, the Department of Research Programs hosts the Research Roundtable and invites anyone interested in research to attend. Although it is intended to be an informal occasion, anyone interested in providing a research-related presentation is welcome to do so. The Research Roundtable is held once a month (see schedule below) at WRNMMC. We have staff readily available to answer research questions.

Ms. Thompson said, "Whenever you are ready to get started with a research project, please remember to walk over to 17B and speak to our Protocol Navigators. The Protocol Navigator will assist you in developing your protocol. Also remember not to start any research project until you receive a start letter from COL Weina, Chief of Department of Research Programs."

Additionally, Ms. Thompson informed the audience of changes regarding scientific reviews.

Scientific review will no longer be conducted by DRP. New protocols needing scientific review will now be reviewed by its appropriate service chief's designee. This policy change ensures subject matter experts review the protocols to improve the scientific review process. Dr. Wendy Bernstein will provide assistance. COL Weina will serve as the point of contact. If you have any questions please contact COL Weina 301-400-1239.



Lisa Potts presents "Research Funding" at the Monthly Research Roundtable

Ms. Lisa Potts (left), Grant Writer from Department of Research Programs presented, "Research Funding," an overview about how she can help the research community at WRNMMC review grant guidelines, find grant opportunities and submit grants from within WRNMMC. Ms. Potts' goal is to locate grant funding, and assist WRNMMC investigators in submitting grants directly to funding agencies. Ms. Potts explained that "As part of the new DRP infrastructure, the Comptroller's Office has added a Budget Officer who will set up cost centers in the General Fund Enterprise Business System so that research funding can now flow directly into WRNMMC. The Budget Officer will add line items into the established cost centers which will assist investigators in managing their award funding here at WRNMMC."



DRP Monthly Research Roundtable

Ms. Potts encourages all researchers to go to the DRP's Website to find grant opportunities. In addition, she will help you find grant opportunities online and she will ensure you apply for correct funding opportunity including congressionally directed medical research program opportunities and links to affiliates of WRNMMC. Ms. Potts emphasized the need for investigators to come to her before they miss out on grant opportunities because their studies may not qualify according to stringent criteria. She will translate their protocols into proposals, optimizing their abilities to obtain their targeted awards.

RESEARCH ROUNDTABLE SCHEDULE

**America Building (Bldg. 19), 2nd Floor,
Desert Conference Room 2301**

Tuesday, June 23, 1200-1300

Tuesday, July 21, 1200-1300

Tuesday, August 18, 1200-1300

Tuesday, September 22, 1200-1300

Tuesday, October 20, 1200 – 1300

Tuesday, November 17, 1200 – 1300

Tuesday, December 22, 1200 – 1300

Moving forward, the DRP will be inviting participants to offer requests for topics to be included and members from each of DRP's sections will be providing representatives to discuss hot topics related to their sections.



Clinical Research



Dr. John Moore, Jr.
Allergy and Immunology Service

WRNMMC MEDICAL MONITORS IN CLINICAL RESEARCH

Continuing Need for Medical Monitors:

There is always a critical need for thorough and careful monitoring of all clinical studies by a Medical Monitor (MM) at all institutions that conduct clinical research. Walter Reed National Military Medical Center continues to be the foremost leader of military medical research in the world. All clinical studies at WRNMMC comply with current laws and regulations. The compliance of every clinical study is always carefully monitored by a MM. The MM is the guardian of patient safety.

No Bias:

The MM on any study is a subject matter expert in that particular area. Importantly, however, the medical monitor must be free of any bias.

No Academic Bias:

The MM may not receive any academic credit for his or her efforts.

No Financial Bias:

The MM must be free of any financial ties to any drug or medical device companies. The MM must disclose any and all of his associations.

Patient Safety:

The MM must guarantee the medical safety of each and every subject in the study including patients in the placebo or control arm as well. The MM must ensure prompt reporting of any and all complications. All complications must be reviewed even if seemingly unrelated.

Responsibilities:

Termination of the Clinical Study:

The MM may have to terminate the study if a clear benefit is found early.

The MM may have to terminate the study if one Rx is clearly superior and is found early in the study.

The MM may have to terminate the study if no benefit is clearly found.

The MM may have to immediately shut down any study as soon as any injury to any patient is discovered and this can include psychosocial adverse events as well as medical adverse events.

Data Safety Monitoring Boards (DSMB):

Certain studies have multiple sites. In this case, a Data Safety Monitoring Board (DSMB) is required to monitor all sites. This includes all military sites, all civilian sites, and all foreign sites.

Reporting Complications Encountered in a Clinical Study:

Reporting complications to the Food and Drug Administration as well as the Institutional Review Board (IRB) is required. There are usually several brilliant research administrators and research nurses who are experienced in these requirements and assist in prompt notification procedures.

The DSMB is required to monitor all subjects at every site including all military sites, all civilian sites and any participating foreign sites.



Volunteer:

Never hesitate to volunteer for this important duty for clinical research.

References:

1. Principles and Practice of Clinical Studies; Third Edition 2013; Edited by John I. Gallin and Frederick P. Ognibene, John Wiley; 2013, pp. 96-97.
2. Clinical Trials Handbook–Design and Conduct by Curtis L Meinert, Wiley 2013.
3. Writing Clinical Research Studies–Ethical Considerations by Evan Derenzo and Joel Moses, Elsevier Academic Press; 2006. pages 107-108.

Publications Clearance Office



Mr. James Simms
Medical Librarian

SUBMITTING A PUBLICATION CLEARANCE REQUEST

All publication clearance requests are submitted through IRBNet and obtain an ID number. Publication clearance of an abstract is required before it may be submitted to the publisher. Once the abstract is accepted, you should resubmit the full manuscript. See the document "Introduction to Publication Clearance."

Please submit the DMRN Publication Clearance Coversheet

Your package will be unlocked in order to facilitate the completion of this document. To obtain the coversheet: go to **Designer**, add new document and in the on-line document section, click on the DMRN Publication Clearance coversheet. Once it's completed, click on **Save** and **Exit**, and then **Mark Revisions Complete**. (PLEASE DO NOT RESUBMIT).

Please submit your publication material.

To add publication material, go to **Designer**, add new document and document type section upload your material for review. After uploading all necessary documents, please click on **Mark Revisions Complete** (PLEASE DO NOT RESUBMIT).

Supervisor Signature

Your request for publication must be signed by your department chief, service chief or supervisor in order for our committee to grant an approval letter. If you happen to be the PI/author and hold one of these positions as well, you only need to sign the package once.

If you intend to add the department head signature or when there is an absence of the department head signature, have him fax a script authorizing you to sign for him. Then you can scan the authorization into the Document Type area or Signed By area.

Both Signatures

If the author has not signed this Package, it requires the author's signature. If he does not have the ability to log into IRBNet, you can have him sign a statement and upload this into the package.

Note: that the signature of the author in the "**Author Information**" of the cover sheet must match that of the signature in the "this package has been signed by" area of the submission. The "**Requested Clearance Date**" is needed to process this document. The reason is to match it with the submission date to determine if the document had been published or presented before the submission was received.



DRP Monthly Meeting

HIGHLIGHTS

- Ms. Courtney Pitts, IRB Manager, was announced as the most recent employee to be recognized as Employee of the Month for taking the initiative in a leadership role. Yaling Zhou, Biomedical Scientist, was recognized in the previous month as the Employee of the Month. However, COL Weina recognized all employees who “lead from behind” and he thanked them for doing good job. SGT Robert Martinez received a Letter of Appreciation from the Commander for achieving over 270 on his physical fitness test. In addition, SGT Martinez received a Good Conduct Medical for exemplary conduct.



Left: Ms. Courtney Pitts

Left: Mr. Yaling Zhou

Left: SGT Robert Martinez

- COL Peter Weina announced that the “Aware for All” event went exceedingly well thanks to Mrs. Thompson, LT Kim and Mr. Fadoju.
- LCDR Ruben Acosta was promoted to CDR. He will be leaving the Department of Research Programs in June.



Left: CDR Ruben Acosta

- Scientific Review will be conducted by the Chief of Service designee. A Scientific review template will be provided to guide all those conducting scientific review. COL Weina will serve as the point of contact. Dr. Wendy Bernstein will offer scientific review guidance.

DRP Monthly Meeting

- COL Weina explained how DoD allocates money through Major Force Programs from congress. He explained the differences between Patient Care Program 6 (P6) Money for Research Development and Technology Evaluation M and Program 8 Money for Training and Medical Reasons or better known as Operations and Maintenances (OM) money which includes Patient Care (OM) and GME Training. In addition he explained misappropriation of P6 and P8 money and reimbursable money that is tied to the fiscal year. He also, discussed solicitations from a prohibited source and research start letters.



May 2015 WRNMMC Publications

(Provided by the Darnall Medical Library)

1. **Aita-Holmes C, Liacouras P, Wilson WO Jr, Grant GT.** Digital capture, design, and manufacturing of an extraoral device for a clarinet player with Bell's palsy. *J Prosthet Dent.* 2015 May 16.[Epub ahead of print]
2. Allen K, Mesner O, **Ganesan A**, O'Bryan TA, Deiss RG, Agan BK, Okulicz JF. Association between hepatitis B vaccine antibody response and CD4 reconstitution after initiation of combination antiretroviral therapy in HIV-infected persons. *BMC Infect Dis.* 2015;15(1):203.
3. Bernstock JD, **Caples CM, Wagner SC, Kang DG, Lehman RA Jr.** Characteristics of combat-related spine injuries: a review of recent literature. *Mil Med.* 2015;180(5):503-12.
4. **Calais CJ, Banks TA.** Resolution of alcohol-induced respiratory symptoms following aspirin desensitization in aspirin-exacerbated respiratory disease. *Ann Allergy Asthma Immunol.* 2015. pii: S1081-1206(15)00118-0.
5. Cha EK, **Donahue TF**, Bochner BH. Radical transurethral resection alone, robotic or partial cystectomy, or extended lymphadenectomy: can we select patients with muscle invasion for less or more surgery? *Urol Clin North Am.* 2015;42(2):189-199.
6. **Cheng FK, Albert DM, Maydonovitch CL, Wong RK, Moawad FJ.** Categorization of patients with reflux symptoms referred for pH and impedance testing while off therapy. *Clin Gastroenterol Hepatol.* 2015;13(5):867-73.
7. **Dretsch MN**, Silverberg ND, Iverson GL. Multiple past concussions are associated with ongoing post-concussive symptoms but not cognitive impairment in active-duty army soldiers. *J Neurotrauma.* 2015 May 14. [Epub ahead of print]
8. Ellsworth DL, Mamula KA, Blackburn HL, et al. Importance of substantial weight loss for altering gene expression during cardiovascular lifestyle modification. *Obesity* (Silver Spring). 2015 May 9. [Epub ahead of print]
WRNMMC Authors: **Engler RJ, Vernalis MN**
9. **Formby PM, Wagner SC, Pisano AJ, Van Blarcum GS, Kang DG**, Lehman RA Jr. Outcomes after operative management of combat-related low lumbar burst fractures. *Spine* (Phila Pa 1976). 2015 May 27. [Epub ahead of print]
10. **Ganesan A**, Mesner O, Agan B. Reply to Yang et al. *Clin Infect Dis.* 2015;60(9):1444-5.
11. **Goodman J.** Reflections: service to our nation. *Otolaryngol Head Neck Surg.* 2015 May 27. [Epub ahead of print]
12. **Hyatt KS**, Davis LL, Barroso J. Finding the new normal: accepting changes after combat-related mild traumatic brain injury. *J Nurs Scholarsh.* 2015 May 14. [Epub ahead of print]
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