



Department of RESEARCH PROGRAMS

at Walter Reed National Military Medical Center



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Excellence in Military Medical Research

SEPTEMBER 2014

Introspective looks at ourselves, especially brutally honest ones, can be useful and help us to improve both our own selves and the world immediately around us in ways we could never have predicted. This introspection can also be quite uncomfortable and forces all of us to admit first that we are not always right. It also potentially opens us to sometimes painful criticism from those who delight in pointing out the flaws of others. This should not prevent us from being thoughtful about what we can do to improve research so the Department of Research Programs has done this analysis.

Walter Reed National Military Medical Center and the organizations that this Institution sprung from produced some of the most remarkable clinicians, scientists, and researchers found anywhere in the world. To maintain that exceptional quality, we need to prepare our GME trainees and young investigators who will go out and eventually work with civilian and Federal academic partners for the business of research. This aspect of research is often underappreciated but is as critical to the success of research as the science and the partnerships.

The Department of Research Programs is chartering two new process teams within our department. One of them we are calling the “Business Cell” and the other is the “Agreements Review Committee” (ARC). The Business Cell will examine our business practices and how we pay the bills, and the ARC will examine thoroughly all agreements with external partners. We need to make sure that all the responsibility and risk associated with clinical research is properly balanced between partners and that the costs associated with minimizing risk to our research volunteers is appropriately resourced.



We envision the Business Cell as being the bedrock we ground our operational strategic vision to, and the ARC as the interdepartmental execution arm of that strategic vision for continual improvement of the research we perform.

The ARC is an open and transparent committee that I invite you to talk to us about and join us in our discussions to improve the research experience for all of us.

Peter J. Weina, PhD, MD, FACP, FIDSA
COL, MC, USA
Chief, Department of Research Programs

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Biomedical Research Laboratory (BRL)



CDR Janine R. Danko, MD, MPH FACP
Chief, Biomedical Research Lab

The BRL would like to welcome its newest member, SPC Thompson.

Welcome aboard!



SPC Brandon Thompson
Medical Laboratory Specialist (ASCP), Biomedical Research Lab

SPC Thompson comes to us from the Pentagon. SPC Thompson grew up in Springfield, Ohio, north of Dayton, Ohio. He began his military career with basic training at Fort Jackson, South Carolina, where he earned the Soldier of the Cycle award. His Advanced Individual Training (AIT) began at Fort Sam Houston, Texas, and ended at Fort Bragg, North Carolina. His first assignment out of AIT was at the Pentagon. At the Pentagon, SPC Thompson was sent on a White House mission, and frequently drew blood from numerous general officers. SPC Thompson now works with SGT Martinez, his first line leader. SPC Thompson looks forward to enhancing the Biomedical Research Laboratory.

Center for Nursing Science & Clinical Inquiry (CNSCI)



COL Jeffrey S. Ashley, AN, PhD
Chief & Senior Nurse Scientist

This month we offer congratulations to MAJ Hyatt and welcome our newest member, LTC Yost.

MAJ Hyatt recently published (as the lead author) her paper titled, *Chasing the Care: Soldiers Experiencing Combat-Related Mild Traumatic Brain Injury*, in *Military Medicine*.



Kyong S. Hyatt, PhD, FNP, RN
Nurse Scientist

MAJ Hyatt also presented her paper, *Family Reintegration Experiences of Soldiers with Combat-Related Mild Traumatic Brain Injury*, at the 25th International Nursing Research Congress in Hong Kong. This event was sponsored by Sigma Theta Tau International Foundation for Nursing and served as a platform for researchers, clinicians, students, and nurse leaders to collaborate, learn, and share information on topics affecting research and evidence-based practice in nursing.





LTC Terri L. Yost, PhD, FNP-BC
Nurse Scientist

LTC Yost comes to WRNMMC from the Center for Nursing Science and Clinical Inquiry at Tripler Army Medical Center, Honolulu, Hawaii, where she also served on both the Scientific Review Board and Human Use Committee for the Department of Clinical Investigations. She is a board-certified family nurse practitioner and research scientist. LTC Yost hails from the city of Pittsburgh, Pennsylvania, and is an avid sports fan, crafter and gardener. She earned her BSN from Clarion University of Pennsylvania in 1995 and her MSN from the University of Pennsylvania in 2001.

She earned her PhD from the University of Virginia in 2011 under the mentorship of Dr. Ann Gill Taylor at the University's Center for the Study of Complementary and Alternative Medicine.

As a principal investigator, LTC Yost has received funding for two TSNRP research studies: "Qigong as a Novel Intervention for Service Members with Mild Traumatic Brain Injury" and more recently "Cranial Electrotherapy for Military Beneficiaries with Restless Legs Syndrome." She loves teaching and mentoring in both research and evidence-based practice and has a special interest in lecturing on nursing and medical history. She has also served as a peer reviewer for the *Journal of the American Academy of Nurse Practitioners*.

Research Administration



Jeremy Nelson
Administrator
Directorate of Education, Training, & Research

Training Folders Compliance Audit

In the month of September, the Department of Research Programs will be involved in a Department-wide Training Folders Compliance Audit. The purpose of this audit is to ensure each National Capital Region staff member is in compliance with the Hospital training requirements. SSG Hodges and Marcus Morgan have been working diligently to ensure all training folders are up-to-date and all staff are compliant with annual training. Marcus will keep the staff up to date on the results of the audit.

Annual Training

All required training for all staff can be found on the shared drive under the Admin Section: DRP Training Compliance.



Research Protocol Development



LCDR Ruben D. Acosta, MC, USN
Chief, Research Protocol Development
Deputy Chief, DRP

Inevitably, at some point or another, research teams can find that recruitment of subjects can hit a lull. There can be many reasons for this and it can be challenging for investigators to overcome these hurdles. One new resource to help overcome these challenges is a presentation at our monthly Research Roundtable.

The audience for these roundtables are seasoned research coordinators and investigators who collectively have years of experience recruiting subjects for a variety of research studies here at WRNMMC. The format for this presentation is very low key and is meant to brainstorm ideas for increasing enrollment.

If this sounds like an opportunity you would like to take advantage of, please email me and I will add you to the schedule.

LCDR Ruben D. Acosta
 ruben.d.acosta.mil@mail.mil

IRB Operations Office



Mary Kelleher
Chief, IRB Operations Office

No one in the IRB Operations Office is a document control expert, but it is important that documents submitted for IRB review are organized to make them easy to access and ensure that the correct versions are being reviewed, approved and then used throughout the study. Otherwise, data integrity and study management could be compromised.

The suggestions below are based on resources found on the Internet and our own experience. If you'd like additional information or assistance developing a naming convention for your study documents, please contact DRP and we will be happy to assist you.

BE CONSISTENT

Develop a naming convention and have everyone use it. (It makes no sense to have everyone on the study team develop their own personal naming convention.)

- Use underscores instead of periods or spaces. (Periods have a specific electronic file name function [e.g., “.pdf”], and spaces may be read as something else.)
- Keep the name short but sufficiently descriptive so it is easy to find among a list of documents. (When using dates, choose a clear standard. In our experience, it's easiest to read DDMonYY. Example: 26Mar14.)
- Use version numbers to manage drafts and revisions (e.g., “v1, v2_1”).
- Include the document control name in small font in the header or footer of the document, not just in the electronic name of the document.
- **BE SURE TO UPDATE BOTH THE DOCUMENT TITLE AND THE HEADER/FOOTER OF THE DOCUMENT.**

We appreciate your assistance and support helping to facilitate a more efficient and effective way to track documents through the IRB review and approval process. Also, please see **Appendix 1** on how to update your email address in IRBNet.



Research Compliance Office



Debarati Dasgupta, MS, CHRC, CIP
Research Compliance Officer

The Food and Drug Administration (FDA) issued guidance “Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring” in August 2013

(<http://www.fda.gov/downloads/Drugs/.../Guidances/UCM269919.pdf>), which is having an impact on the clinical operations process. It is important for all research teams to become familiar with the growing trend of risk-based approach to monitoring, which (as stated in the guidance) “focuses sponsor oversight activities

on preventing or mitigating important and likely risks to data quality and to processes critical to human subjects protection and trial integrity.” It is imperative that all stakeholders (i.e., sponsors, clinical investigators) focus on building in quality into the clinical trial enterprise.

While the guidance focuses on the sponsor role in quality risk management, it is clear that investigators play a key role in risk management. Investigator sites have significant risks to manage during study conduct. Studies have shown that there is value for sites to integrate a quality systems approach to running clinical trials. A component of risk management is the conduct of a risk assessment. Generally, risk assessment involves the following components/questions:

- What are the critical data to be collected/processes to be followed?
- What are some potential threats to these data/processes?
- How likely is the threat to occur?
- If the threat occurred, how significant would it be?
- Would this risk be something to control? If so, how?
- Are there detection mechanisms for tracking breaks in risk control?

The critical collected data and processes are to be linked to subject protection and data integrity. Possible risks should be reassessed on an ongoing basis throughout the duration of the study.

This guidance provides much food for thought and is a step towards fostering a positive culture change in the clinical trials enterprise.

Please remember that the PACM team provides many services to the research community, including directed educational sessions on various aspects of the conduct of quality human subjects research, assistance with self-assessments, and not-for-cause evaluations of research files and investigator SOPs. We invite you to send your post-approval compliance questions and ideas on how we can better serve YOU to:

dha.bethesda.ncr-medical.list.wrnm-pacm-info@mail.mil (NOTE NEW EMAIL ADDRESS)

We’re here to help!

The FDA provides many valuable resources that may be used for self-study activities.

Please visit the FDA Training and Continuing Education website <http://www.fda.gov/Training/default.htm> for up-to-date information on training opportunities.

Following is an upcoming training opportunity:

Clinical Investigator Training Course

The Sixth Annual Clinical Investigator Training Course, co-sponsored by the Food and Drug Administration’s Office of Medical Policy and the Duke University School of Medicine is now open for registration. The agenda can be accessed here:

<http://www.fda.gov/downloads/Drugs/NewsEvents/UCM405436.pdf>



Date(s) November 4 – 6, 2014
 Location: The Holiday Inn Washington - College Park (I-95)
 10000 Baltimore Avenue
 College Park, MD 20740

This extensive three-day course focuses on nonclinical, early clinical, and phase-3 studies; issues in the design and analysis of trials; safety and ethical considerations; and FDA's regulatory requirements related to the performance and evaluation of clinical studies. Attendees will have the unique opportunity of hearing directly from FDA's nationally renowned experts on issues critical to successful clinical research. The course is designed for physicians, nurses, pharmacists, and other health care professionals involved in clinical trials.

For more information on the course and how to register, click here:

<http://continuingeducation.dcri.duke.edu/CITC2>

You will need to create a profile prior to registering for this course. Instructions are included on the registration page. The course fee is \$150.00. Visa and MasterCard are accepted. Continuing Medical Education (CME) credits are available. If you have questions, please contact Tomeka Arnett at ClinicalInvestigator@fda.hhs.gov or (301) 796-8486.

Behind the Scenes – Keeping the Ball Rolling



Marcus Morgan (Contractor)
Personal Assistant to the Chief

This month we go behind the scenes and interview Personal Assistant to COL Weina, **Mr. Marcus Morgan**. Marcus sits directly across the hall from COL Weina and receives all visitors to DRP, so he has a perfect vantage point that few have.

Let's see what Marcus has to say.

What role do you play in human subjects' research?

I'm the gatekeeper. When the protocols come in, I distinguish what protocol goes where. I answer researchers' questions regarding forms, templates and any general question they may have. I also coordinate with IRBNet Support in fixing issues, such as log-in issues and other logistics.

What can researchers do to make your role more effective and efficient?

Researchers should take advantage of the plethora of services we offer in the Department of Research Programs. One particular service that we offer that I would highly recommend to all researchers is our Outreach Program.

Our Outreach Program was established to help researchers better understand the steps in submitting a protocol through IRBNet, developing a protocol, maneuvering through IRBNet and submitting the correct forms, just to name a few. Too often the correct forms needed are missing. There are particular documents that need to be included in a submission to move a protocol forward, which are often missing. That slows the submission process.

What tips would you offer researchers to get their protocols approved faster or to improve their research?

Take advantage of our Outreach Program. This is the researchers' system for getting their protocols approved faster. Making sure packages have the proper forms before being submitted is key. This step prevents packages from getting kicked back or withdrawn.



Investigative Research



Chester 'Trip' Buckenmaier III, MD
COL, MC, USA

Program Director, Defense and Veterans Center for Integrative Pain Management (DVCIPM.org)

DVCIPM is an organization that evolved during the last 13 years of combat. I've never known medicine without war. Military medicine has changed dramatically for the better: we now have a less than 10% died-of-wounds rate. No land army in the history of warfare has ever achieved that statistic. One of the things that played into this was a very rapid evacuation system, but that system resulted in issues with warrior pain management.

We started out with what was called the Army Regional Anesthesia and Analgesia organization and a white paper to then-Congressman Murtha. We had this idea of how we could improve anesthesia.

A soldier can be shot in Iraq or Afghanistan and be in Landstuhl, Germany, in less than 24 hours passing through many providers from all services. We started opening the aperture from a very myopic view of pain, which was that pain was the symptom of the disease and if you threw morphine at it, it would fix it, to recognizing that pain could become chronic pain, a disease process in its own right, and everything about pain inhibits rehabilitation and recovery.

It's not just about drugs or catheters or local anesthetics, it's about the pantheon of treatment options that can be brought to bear, and people that have issues or can help with managing pain: physical therapists, integrative medicine providers, such as acupuncturists, yoga providers, psychologists, psychiatrists, anesthesiologists, etc.

We are now called the Defense and Veterans Center for Integrative Pain is obvious and then Management (DVCIPM.org). There's a real reason we didn't say "medicine." It's not just about anesthesiologists or doctors. We're in the process of creating acute pain medicine as a specific anesthesiologist sub-specialty. It's not just anesthesiologists. Psychologists, psychiatrists, physical medicine and rehabilitation physicians are involved in pain medicine. That's where DVCIPM came from.

In regional anesthesia, we're dealing with the peripheral nervous system as opposed to the central nervous system, and we turn off areas of the body. I can turn off your arm to pain. I can turn off your leg or various regions on your body wall. When you lose an arm, that is a very abnormal state. All those pain signals are flooding the body. I can stop those pain signals in the peripheral nerve with local anesthetics like you get at the dentist. They're still being transmitted, but I stop them from being received by the spinal cord or the brain. When you lose a foot, that's a condition your body wasn't designed to deal with. The information that's coming from that injury floods your nervous system and literally puts your nervous system on fire. That's a phenomenon we call "wind-up."

If we aggressively treat pain throughout recovery and rehabilitation, we're either attenuating the development of chronic pain or possibly avoiding it. Chronic pain is a devastating disease. It's a national health care problem. We just had the Institute of Medicine report and we had our own report in the DoD, the Pain Management Task Force Report, recognizing the toll that this disease takes on number of work hours lost, quality of people's lives, and the ability of people to participate in their recovery. For example, someone who has complex regional pain syndrome in his or her stump isn't going to be doing very well with his prosthetic to become ambulatory again.

With DVCIPM right now, one of the things we're charged with doing is trying to operationalize Pain Management Task Force, based on *The Pain Management Task Force Report* of May 2010, which has 109 recommendations. One project is a new DoD pain scale called the Defense and Veterans Pain Rating Scale.¹

Another project we have is called PASTOR, which is Patient Assessment Screening Tool and Outcomes Registry. PASTOR works on a PROMIS engine, which is an NIH project, a hundred million dollars of investment that the tax payers have made for question banks. Pain is beyond just a zero-to-ten number. It has physical and psychological aspects. It has issues of depression. Sleep disturbances. The list goes on.



¹ See Appendix 2

Monthly Meeting

Highlights



SGT Martinez, NCOIC, BRL, receives Army Achievement Medal for highest enlisted male PT score in his Company



MAJ Baumgartner is awarded Employee of the Month for exemplary work on writing Standard Operating Procedures (SOPs) for the Determinations Workspace and for finalizing a Memorandum that will serve as a planning document for the next Research Competition

Feedback on July Newsletter

Comments included the following:

- *Please number the WRNMMC publications list.*
- *Really like the intro by COL Weina.*
- *The part on biostats is a nice educational touch.*
- *A little on the long side; would consider not having so much each month or spreading out issues otherwise people will not read it.*
- *Very impressive and really like the increased morale related to research.*

Please send feedback on the newsletter to:

dha.bethesda.ncr-medical.list.wrnm-drp-newsletter-feedback@mail.mil



AUGUST 2014 WRNMMC Publications

(Provided by the Darnall Medical Library)

WRNMMC authors are in bold.

1. **Balazs GC, Pavey GJ, Brelin AM, Pickett A**, Keblish DJ, Rue JP. Risk of anterior cruciate ligament injury in athletes on synthetic playing surfaces: a systematic review. *Am J Sports Med.* 2014 Aug 27.[Epub ahead of print]
2. **Banks T, Savitz J, Nelson MR**. Practice parameters and strength of recommendation data: a variable compass. *Ann Allergy Asthma Immunol.* 2014;113(2):193-7.
3. Bedocs P, Capacchione J, **Potts L**, Chugani R, Weiszhar Z, Szebeni J, Buckenmaier CC. Hypersensitivity reactions to intravenous lipid emulsion in swine: relevance for lipid resuscitation studies. *Anesth Analg.* 2014 Aug 14. [Epub ahead of print]
4. **Blaylock JM, Hartzell JD**. A major cause of pertussis resurgence: gaps in vaccination coverage. *Clin Infect Dis.* 2014;59(4):611-2.
5. **Brungart DS, Sheffield BM, Kubli LR**. Development of a test battery for evaluating speech perception in complex listening environments. *J Acoust Soc Am.* 2014;136(2):777.
6. **Caruso AM**, Meyer TK, Allen CT. Hoarseness after metastatic colon cancer treatment. *JAMA Otolaryngol Head Neck Surg.* 2014 Aug 21. [Epub ahead of print]
7. Clark RA, Marler AT, Lin CK, et al. A review of anomalous origination of a coronary artery from an opposite sinus of Valsalva (ACAOS) impact on major adverse cardiovascular events based on coronary computerized tomography angiography: a 6-year single center review. *Ther Adv Cardiovasc Dis.* 2014 Aug 10.[Epub ahead of print] (WRNMMC authors: **Villines TC, Hulten EA**)
8. Collins JD, Markham A, Service K, Reini LS, **Wolf E**, Sessoms P. A systematic literature review of the use and effectiveness of the computer assisted rehabilitation environment for research and rehabilitation as it relates to the wounded warrior. *Work.* 2014 Aug 28. [Epub ahead of print]
9. Cook MB, Wood SN, **Cash BD**, et al. Association between circulating levels of sex steroid hormones and Barrett's esophagus in men: a case-control analysis. *Clin Gastroenterol Hepatol.* 2014 Aug 23.[Epub ahead of print] (Additional WRNMMC authors: **Young P, Acosta RD, Dykes C**)
10. Enewold L, Horner MJ, **Shriver CD**, Zhu K. Socioeconomic disparities in colorectal cancer mortality in the United States, 1990-2007. *J Community Health.* 2014;39(4):760-6.
11. **Fleming ME, O'Daniel A, Bharmal H, Valerio I**. Application of the orthoplastic reconstructive ladder to preserve lower extremity amputation length. *Ann Plast Surg.* 2014;73(2):183-9.
12. Garman L, Smith K, Farris AD, **Nelson MR, Engler RJ**, James JA. Protective antigen-specific memory B cells persist years after anthrax vaccination and correlate with humoral immunity. *Toxins (Basel).* 2014;6(8):2424-31.
13. Garman L, Vineyard AJ, Crowe SR, et al. Humoral responses to independent vaccinations are correlated in healthy boosted adults. *Vaccine.* 2014 Aug 17.[Epub ahead of print] (WRNMMC Authors: **Spooner CE, Collins LC, Nelson MR, Engler RJ**)
14. **Hendershot BD, Wolf EJ**. Mediolateral joint powers at the low back among persons with unilateral transfemoral amputation. *Arch Phys Med Rehabil.* 2014 Aug 4.[Epub ahead of print]
15. **Hyatt K**, Davis LL, Barroso J. Chasing the care: soldiers experience following combat-related mild traumatic brain injury. *Mil Med.* 2014;179(8):849-855.
16. **Lange RT**, Shewchuk J, Rauscher A, Jarrett M, Heran MK, Brubacher JR, Iverson GL. A prospective study of the influence of acute alcohol intoxication versus chronic alcohol consumption on outcome following traumatic brain injury. *Arch Clin Neuropsychol.* 2014;29(5):478-95.
17. Lanigan A, Tompkins AJ, **Rivera A**. Unilateral ear and temporomandibular joint discomfort. *JAMA Otolaryngol Head Neck Surg.* 2014 Aug 14. [Epub ahead of print]
18. **Levin SW**, Baker EH, Zein WM3, et al. Oral cysteamine bitartrate and N-acetylcysteine for patients with infantile neuronal ceroid lipofuscinosis: a pilot study. *Lancet Neurol.* 2014;13(8):777-87.
19. **Little DJ**, Reese JA, Vesely SK, George JN. Increased urinary albumin excretion following recovery from thrombotic thrombocytopenic purpura due to acquired ADAMTS13 deficiency. *Am J Kidney Dis.* 2014;64(2):317-8.
20. Liu Y, Jesus AA, Marrero B, et al. Activated STING in a vascular and pulmonary syndrome. *N Engl J Med.* 2014 Aug 7;371(6):507-18. (WRNMMC Authors: **Jones OY, Horkayne-Szakaly I**)
21. Mac Donald CL, Johnson AM, Wierzechowski L, et al. Prospectively assessed clinical outcomes in concussive blast vs nonblast traumatic brain injury among evacuated US military personnel. *JAMA Neurol.* 2014;71(8):994-1002. (WRNMMC Author: **Oh, J**)
22. McNeil MM, Cano M, R Miller E, Petersen BW, **Engler RJ**, Bryant-Genevier MG. Ischemic cardiac events and other adverse events following ACAM2000(®) smallpox vaccine in the Vaccine Adverse Event Reporting System. *Vaccine.* 2014;32(37):4758-65.
23. Maxwell GL, Shoji Y, Darcy K, et al. Micro RNAs in endometrial cancers from black and white patients. *Am J Obstet Gynecol.* 2014 Aug 28.[Epub ahead of print] (WRNMMC Author: **Hamilton CA**)
24. Mende K, Beckius ML, Zera WC, et al. Phenotypic and genotypic changes over time and across facilities of serial colonizing and infecting escherichia coli isolates recovered from injured service members. *J Clin Microbiol.* 2014 Aug 20.[Epub ahead of print] (WRNMMC Author: **Weintrob AC**)
25. Nicholas L, **Bingham J, Marquart J**. Percutaneous buried modification of the purse-string closure. *Dermatol Surg.* 2014 Aug 5. [Epub ahead of print]
26. Okulicz JF, Mesner O, **Ganesan A**, O'Bryan TA, Deiss RG, Agan BK. Hepatitis B vaccine responsiveness and clinical outcomes in HIV controllers. *PLoS One.* 2014 Aug;9(8).
27. **Paik H, Kang DG**, Lehman RA Jr, Cardoso MJ, **Gaume RE, Ambati DV, Dmitriev AE**. Do stand-alone interbody spacers with integrated screws provide adequate segmental stability for multilevel cervical arthrodesis? *Spine J.* 2014;14(8):1740-7.
28. **Pasquina PF**, Evangelista M, **Carvalho AJ**, et al. First-in-man demonstration of fully implanted myoelectric sensors for control of an advanced electromechanical arm by transradial amputees. *J Neurosci Methods.* 2014 Aug 4.[Epub ahead of print] (Additional WRNMMC Authors: **Griffin S, Nanos G, McKay P, Ipsen D, Butkus J, Miller M, Murphy I**)
29. **Pavey AR, Gorman GH**, Kuehn D, **Stokes TA**, Hisle-Gorman E. Intimate partner violence Increases adverse outcomes at birth and in early infancy. *J Pediatr.* 2014 Aug 12.[Epub ahead of print]
30. **Perry BN**, Mercier C, Pettifer SR, Cole J, **Tsao JW**. Virtual reality therapies for phantom limb pain. *Eur J Pain.* 2014;18(7):897-9.
31. **Phatak SA, Grant KW**. Phoneme recognition in vocoded maskers by normal-hearing and aided hearing-impaired listeners. *J Acoust Soc Am.* 2014;136(2):859.
32. **Pickett CA, Villines TC, Ferguson MA, Hulten EA**. Percutaneous closure versus medical therapy alone for cryptogenic stroke Patients with a Patent Foramen Ovale: Meta-Analysis of Randomized Controlled Trials. *Tex Heart Inst J.* 2014;41(4):357-367.
33. **Savitz J, Geaney C, Banks TA**. A case of anaphylaxis to palivizumab. *Ann Allergy Asthma Immunol.* 2014;113(2):236-7.
34. Schinkel JK, Zahm SH, Jatoi I, et al. Racial/ethnic differences in breast cancer survival by inflammatory status and hormonal receptor status: an analysis of the Surveillance, Epidemiology, and End Results data. *Cancer Causes Control.* 2014;25(8):959-68. (WRNMMC Authors: **Shiver CD, Zhu K**)
35. Schoepfer AM, Straumann A, Panczak R, et al. Development and validation of a symptom-based activity index for adults with eosinophilic esophagitis. *Gastroenterology.* 2014 Aug 23.[Epub ahead of print] (WRNMMC Author: **Moawad FJ**)
36. **Stanley AY**, Conner BT. Implementing a clinical practice guideline to manage postpartum urinary retention. *J Nurs Care Qual.* 2014 Aug 27. [Epub ahead of print]
37. **Theeler BJ**, Ellezam B, Yust-Katz S, Slopis JM, Loghini ME, de Groot JF. Prolonged survival in adult neurofibromatosis type I patients with recurrent high-grade gliomas treated with bevacizumab. *J Neurol.* 2014;261(8):1559-64.
38. Thomas D, Anderson D, **Hulten E**, et al. Open versus endovascular repair of abdominal aortic aneurysm: Incidence of cardiovascular events in 632 patients in a department of defense cohort over 6-year follow-up. *Vascular.* 2014 Aug 18.[Epub ahead of print] (Additional WRNMMC Author: **Villines TC**)
39. **Valerio I, Sabino J, Thomas S, Tintle S, Fleming M**, Shashikant M, Kumar A. Multiple limbs salvaged using tissue transfers in the same casualty: a cohort comparison study chronicling a decade of war-injured patients. *Plast Reconstr Surg.* 2014;134(2):333-8.
40. Winn AE, **Pace S, Adams EG**. Localized erythema multiforme-like contact dermatitis from a knee brace. *Clin J Sport Med.* 2014 Aug 5. [Epub ahead of print]
41. **Yuan CM, Prince LK, Zwettler AJ, Nee R, Oliver JD 3rd, Abbott KC**. Assessing achievement in nephrology training: using clinic chart audits to quantitatively screen competency. *Am J Kidney Dis.* 2014 Aug 23. [Epub ahead of print]



Appendix 1 – Update Your Email Address in IRBNet

Update your Email Address in IRBNet!

health.mil to mail.mil

We have now transitioned to the DoD Enterprise Email (DEE) service and it is necessary to update your email address for all your affiliations in IRBNet to ensure you continue to receive IRBNet messages and alerts. Please go to

<http://fhpr.dhhq.health.mil/resources/research-regulatory-oversight/DMRN.aspx>

and follow the steps below:

1. Go to your **User Profile**

The screenshot shows the IRBNet User Profile page. In the top right corner, the 'USER PROFILE' link is circled in red. The page title is 'User Profile' and the user is identified as 'Angela Quispe'. The main content area is titled 'Manage Your User Profile' and contains sections for 'User Account Information and Password', 'Affiliations', and a list of active affiliations.

2. Click **Edit** to update your information for each active affiliation

The screenshot shows a list of affiliations with the following details:

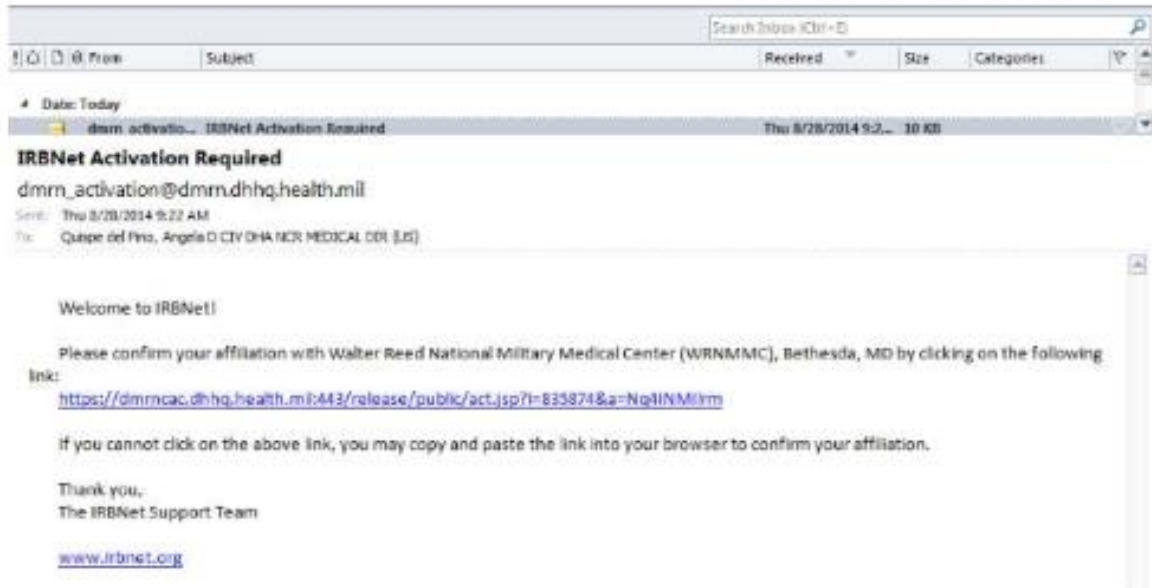
Affiliation	Status	Action
Researcher at William Beaumont Army Medical Center (WBAMC), Fort Bliss, TX	(inactive)	(Edit)
Researcher at Wills Eye Institute, Philadelphia, PA	(inactive)	(Edit)
WRNMMC Scientific Review, Bethesda, MD	(Edit) (Deactivate)	
Researcher at Walter Reed National Military Medical Center (WRNMMC), Bethesda, MD	(Edit) (Deactivate)	

The 'Edit' link for the 'Researcher at Walter Reed National Military Medical Center (WRNMMC), Bethesda, MD' affiliation is circled in red.

3. Update your information then click **Save**. An activation email will be sent to your Outlook account. **Note: If this email does not show up in your inbox, check the Junk Mail inbox for it. If necessary move this email to your inbox.**

The screenshot shows the IRBNet User Profile page. The page title is "User Profile" and it includes a "USER PROFILE" and "LOGOUT" link in the top right. The main heading is "Your Contact Information". Below this, there is a text box explaining that the user should specify their contact information at Walter Reed National Military Medical Center (WRNMMC), Bethesda, MD, and that the email address will be used for communications related to WRNMMC projects. There are three input fields: "Telephone Number" (with a red asterisk), "Fax Number", and "Email" (with a red asterisk). The "Telephone Number" field contains "301-295-6512" and the "Email" field contains "j.spodoligno.civ@mail.mil". A red asterisk and the text "required fields" are visible at the bottom left of the form. A small dialog box is overlaid on the form, displaying a warning icon and the message: "An activation email will be sent to the email address shown on this affiliation." with an "OK" button.

4. Open the email and click the link to Activate your Affiliation



5. You will be taken back to the IRBNet homepage. Click on your **User Profile** to check if your affiliations are activated.

Activated

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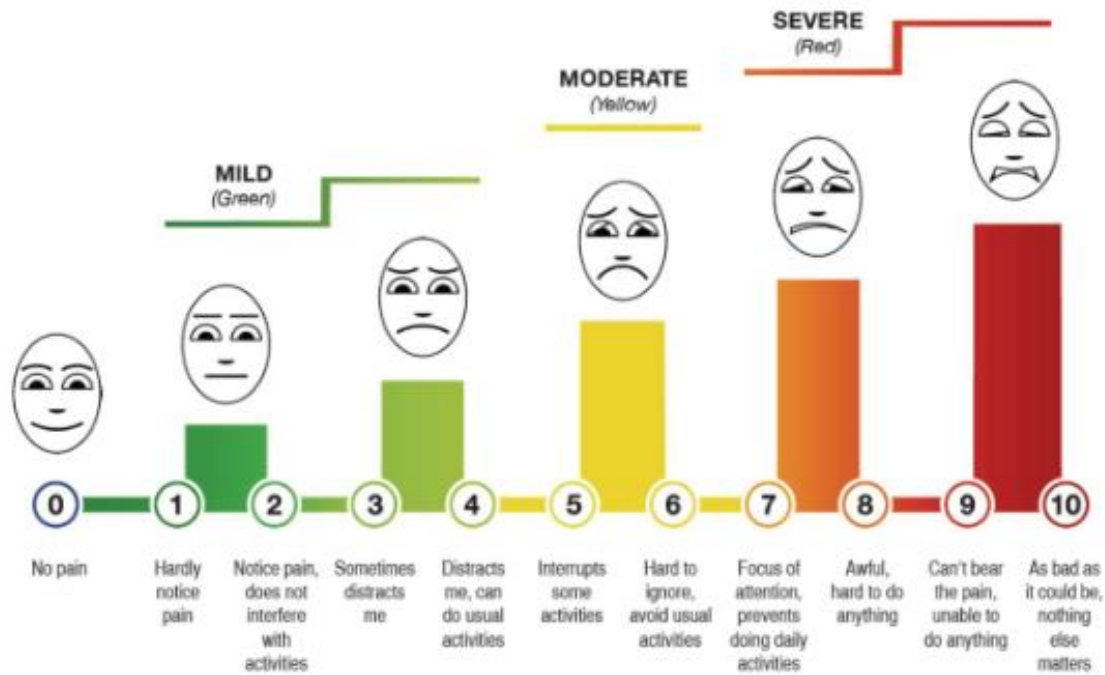
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Appendix 2 – The Defense and Veterans Pain Rating Scale

Defense and Veterans Pain Rating Scale



DoD/VA PAIN SUPPLEMENTAL QUESTIONS

For clinicians to evaluate the biopsychosocial impact of pain

1. Circle the one number that describes how, during the past 24 hours, pain has interfered with your usual **ACTIVITY**:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
 Does not interfere Completely interferes

2. Circle the one number that describes how, during the past 24 hours, pain has interfered with your **SLEEP**:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
 Does not interfere Completely interferes

3. Circle the one number that describes how, during the past 24 hours, pain has affected your **MOOD**:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
 Does not affect Completely affects

4. Circle the one number that describes how, during the past 24 hours, pain has contributed to your **STRESS**:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
 Does not contribute Contributes a great deal

*Reference for pain interference: Cleeland CS, Ryan KM. Pain assessment: global use of the Brief Pain Inventory. Ann Acad Med Singapore 23(2): 129-138, 1994.