Department of RESEARCH PROGRAMS at Walter Reed National Military Medical Center

VOLUME 1, ISSUE 10 *Excellence in Military Medical Research* DECEMBER 2014

Marcus Morgan
Administrative Assistant

Greetings Research Community! I am humbled to have been given the opportunity to speak to all of you through the Department of Research Programs Monthly Newsletter December issue. What an honor! First and foremost, I want to start off by thanking our military members and their families. Without you, research wouldn't be possible. Thank you for all you do!

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Believe it or not, 2014 was a busy year for the Department of Research Programs. Join me as I take you back into the early months of DRP in 2014. DRP started off the year with a bang, successfully completing the largest audit ever conducted at a military treatment facility clinical investigation program. Way to go! In addition to the audit, DRP kicked off WRNMMC Research and Innovation Month, which consisted of several research-based events over the course of a one-month timespan, highlighting WRNMMC's robust clinical research portfolio. Following another wave of successful events, the summer months brought us new leadership. DRP welcomed COL Weina as our new Department Chief and bid farewell to LTC Nayback-Beebe.

The fall and winter months were a bit more challenging, yet monumental. Offering changes such as CAC-only access and establishing a new entity referred to as the "Business Cell." Conducting process improvement within the Department of Research Programs will make the organization as a whole more efficient and make your job as a researcher hopefully easier and more rewarding. Reestablishing better processes to do business can only make DRP better at what we do. Furthermore, helping to make your job as a researcher easier and more rewarding.

Thanks to the hard work and dedication of each and every one of our research staff, we were able to end the year as strong as we began. As we close the book on 2014, it is essential that we associate the challenges we faced as an indicator for the positive direction DRP is headed in. Please look forward to what the New Year has to bring.

From the DRP family to yours, Happy Holidays!

Center for Nursing Science & Clinical Inquiry (CNSCI)

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

Team, I want to make it known: CDR Jason McGuire is now the Chief of CNSCI. An underappreciated aspect of good leadership is the process of transitioning leaders in a way that reinforces stability and sustains that which is working while bringing a new set of eyes to the existing product to focus on continuous improvement. At the twilight of my career as an ANC Officer, it seemed "the right thing to do" to pass the torch now and let CDR McGuire blossom in his new responsibilities.

I will fill the role of Senior Nurse Scientist until my retirement in 2015. This transitional process will support CDR McGuire in his new role as leader and transition in a controlled manner versus a rushed process upon my retirement. I will assume the role of Village Elder and be available to teach, guide, coach and mentor.

I'd like everyone to know about the outstanding work Ms. Caitlin Jones has been doing and what an asset she is for us! Caitlin has been in the department longer than any of us currently here. She brings a great wealth of knowledge and history to our day-to-day operations.

Ms. Caitlin Jones
Project Director (Contractor)
Electromyostimulation and Strength Walking for Knee Injuries Study

I have been working on the Electromyostimulation and Strength Walking for Knee Injuries study since January 2014. Dr. Laura Talbot, Col (Ret) USAF NC, Professor, University of Tennessee Health Science Center, is the Lead PI. This is the second study I have worked on with Dr. Talbot (the first was titled "Strength, pain and function in OIF/OEF Amputees: A Nurse Managed Program" and was also conducted here at WRNMMC). I have been working in CNSCI with MAJ Hyatt for approximately the last two-and-a-half years. I serve as the Project Director and Intervention Manager.

My background includes a B.S. in Kinesiological Sciences from University of Maryland College Park, and an M.S. from The George Washington University in Clinical Exercise Physiology, and I am recognized by the American College of Sports Medicine as a certified clinical exercise specialist, ACSM-CES.

Please see Appendix 1, which provides more information on this study; we are collaborating closely with the WRNMMC PT department staff who have provided us with many referrals thanks to both LTC Shannon Lynch, Chief of PT, and physical therapist LT Lisa Romanzo. We recently expanded this study to Joint Base Andrews (JBA) and I helped facilitate this expansion and will be responsible for getting things up and running at JBA and managing day-to-day operations at both sites!

Research Protocol Development

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

Closure Reports

The completion of a study is a change in activity that needs to be reported to the IRB for review and approval. A final report is then issued, which allows the IRB to close its files. Investigators are required to submit their closure report for their IRB-approved research for IRB review using the electronic submission management system (IRBNet). Closures to exempt or "research not involving human subjects" will be reviewed and acknowledged by the Determinations Officer. A study is defined as completed if it is closed voluntarily by the PI, is closed to subject enrollment, subjects have completed research-related interventions and follow-up, data collection is completed, and at least one objective has been met or an abstract was published. (The information about the objects met and abstract is from the closure report.)

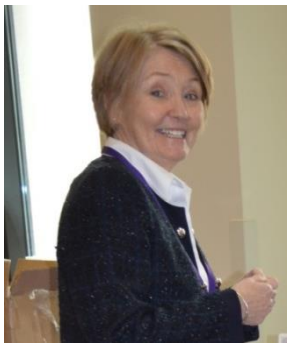
The PI needs to use IRBNet to submit a closure submission package for IRB review. The Closure Report Form can be found under "Forms and Templates" in IRBNet. The closure report should include information such as, but not limited to, the reason for closure and rationale for a result other than completion; summary of subject enrollment; summary of any unreported deviations, AEs, and UPs involving risks to subjects or others; publications and presentations that have resulted from the study; plans for retention, disposal or future use of any research materials generated in the course of the study (e.g., data collected for the study, biologic, or chemical samples, etc.).

An important thing to note is that if the closure report is being submitted more than two months after the last CR approval or if the study was still open for enrollment at the time of the last CR approval then the DMRN CR report accounting for protocol activity since the last CR approval is to be included. Once submitted, the package will be administratively reviewed for completeness then forwarded to the IRB. The submission will be approved through the expedited review pathway.

Monthly Research Roundtable

In response to last month's request by attendees for a "more robust" Research Roundtable, COL Weina (left) talked about initiating start letters, which will include checklists, so that researchers will be fully aware of when they may start research, and the dissolution of collaboration letters. COL Weina's goal is to create a culture of mentorship. Ms. Lisa Potts, Grant Writer (right) presented on the Agreements Review Committee (ARC) and the ARC Working Group; Ms Diane Beaner and Mr. Robert Roogow of PACM later presented on how to respond to audit findings by creating Corrective and Preventive Actions (CAPAs).

IRB Operations Office



Mary Kelleher
Acting Director, IRB Operations Office

IRB Approval Letter (below) for Review and Discussion

Dr. K. Kringle, Principal Investigator
IRBNet # 122520- 14
Adjunct Professor of Child Psychology
Far Northern University

Dear Dr. Kringle:

At the regularly scheduled December 24 meeting, the IRB reviewed your protocol, "A Global Observational Study of Behavior in Children." While we believe it has many good features, it could not be approved as submitted. If you choose to revise your study, please address the following concerns:

1. You propose to study "children of all ages." Please provide an exact lower and upper age limit as well as the precise number of subjects. Provide a statistically valid power calculation to justify this large of a study.
2. Your only inclusion criterion is "belief in Santa Claus." Please provide a copy of the screening questionnaire that determines such a belief. Provide a Waiver of Authorization under HIPAA in order to record these beliefs prior to enrollment in your study. The Board recommends that you obtain a Certificate of Confidentiality as beliefs are sensitive and personal information.
3. You propose to "know when they are sleeping and know when they are awake." How will this be done? Will children undergo video monitoring in their beds? Will they have sleep EEGs? You list 100 elves as research assistants. Are any of them a sleep physiologist?
4. Your primary outcome measure is to "know when they've been bad or good." What standard is being used to determine "goodness?" Do children have to be good all year or just most of the time? What if they have been really, really good except for one time when they hit their little brother?
5. You propose to conduct your research by entering the subjects' homes through the chimney. Have you considered the damage to the roof, carpeting, etc. that this will cause? Moreover, children are likely to be startled by your appearance late at night. Please revise your protocol to conduct your home visits between 9 am and 5 pm Monday through Friday with at least one parent being present.
6. You state that compensation for participation will be "sugarplums, candy, and toys" for the good little girls and boys. This may not be appropriate for the children with obesity, dental caries, and hyperactivity. Also, your proposal to leave a lump of coal in the stockings of the bad children will be unfairly stigmatizing to them individually and as a group. In general, the Board suggests a small token of appreciation for all participants. Perhaps a $5 Toys-R-Us gift card would be better.
7. The database of good and bad children will be kept "on a scroll at the North Pole." Please describe the security provisions you have in place to protect the research data. Is the scroll kept in a locked cabinet in a locked room? Who has access to the scroll? Are there backup copies of the scroll and how often are they compared to the original?
8. You mention the participation of "eight tiny reindeer" in your protocol. Please provide the Board with documentation of Institutional Animal Care and Use Committee approval.
9. Please provide the Human Subjects Protection training dates for Mrs. Claus and the elves.
10. As this study involves prospective data collection and is more than minimal risk without prospect of direct benefit to the subjects, informed consent signed by both parents will be required. Please have the consent form translated into every language spoken by children.

Please submit your revised protocol into IRBNet; however, it may take us a while to review since we are on holiday hours through 31 December. If approved, you will be able to conduct your study sometime in January.

Sincerely,

Dr. E Scrooge
E. Scrooge, MD - Chair, Institutional Review Board

HAPPY HOLIDAYS FROM THE IRB OFFICE!!
Here's to a safe, happy, healthy and prosperous 2015!

Research Compliance Office

Debarati Dasgupta, MS, CHRC, CIP
Research Compliance Officer

Diane Beaner
Research Compliance Specialist

This month's input was provided by Diane Beaner, Research Compliance Specialist.

HOT TOPIC OF THE MONTH
Is a Delegation Log Required?

Answer: Not really but…

Although a delegation log is not required per federal regulations, Good Clinical Practice suggests documentation when the Principal Investigator has delegated tasks to other members of the research team. For example:

- Screening of subjects
- Interpreting screening results/admitting to the study
- Informed Consent of subjects
- Receipt of test article; handling; administration
- Reporting (including safety reporting) /transcribing data
- Clinical laboratory /Data entry
- Archiving study data

See HRPP Policy Memorandum 1.9, Effective: March 2014

The purpose of this policy is to establish the requirements for documentation of delegation of authority by the Principal Investigator (PI) to research personnel.

What Is Appropriate Delegation of Study-Related Tasks?

The principal investigator is ultimately responsible for the conduct of the study, but it is common for the PI to delegate certain study-related tasks to other members of the research team (associate investigators, research nurses, coordinators, lab personnel, etc.).

When delegating study-related tasks the PI must ensure that:
- The delegated individual is appropriately qualified by education, training, and experience to perform the delegated task.
- The individual has the relevant formal medical training and, when appropriate, licensing and/or certification.
- The PI can adequately supervise the individual's activities and involvement in the ongoing conduct of the study.

NOTE: Individuals who perform only standard-of-care procedures and not part of the research team (e.g., EKG technicians, hospital nursing staff) are not required to be listed on the Delegation of Authority Documentation log.

When conducting an FDA-regulated research study, no matter who has been delegated tasks, the PI will assume full responsibility for the clinical investigation.
- This is documented by the PI's signature on the FDA Form 1572 for investigational drug research, or on the Investigator's Agreement for research using an investigational device.
- PI may select additional Investigators to assist with an investigation. Investigators may conduct the procedures and activities as required by the protocol under the supervision of the PI. Investigators are to be listed on the FDA Form 1572 or Investigator's Agreement, but are not required to sign the Form FDA 1572 or Investigator's Agreement.

Examples of inappropriate delegation of PI responsibilities include:
- Over-delegation to non-physicians (e.g., Screening evaluations, including obtaining medical histories and assessment of inclusion/exclusion criteria, conducted by individuals with inadequate medical training).
- Delegating to individuals who are already overloaded.
- Assigning an individual to assess crisis situations when they are looking to you for leadership (e.g., assessment of adverse events, and knowledge of the investigational product).
- Delegating the task of obtaining the Informed consent by an individual who lack the medical training, knowledge of the clinical protocol, or unfamiliarity with the investigational product.

Investigative Research

Marjan Ghahramanlou Holloway, Ph.D.
Uniformed Services University of the Health Sciences
(left)

Laura L. Neely, Psy.D.
Uniformed Services University of the Health Sciences
(right)

Laboratory for the Treatment of Suicide-Related Ideation and Behavior

Director: Dr. Marjan G. Holloway
Associate Director: Dr. Laura L. Neely
Interviewer: LT Ryan M. Kim, MC, USN

Dr. Holloway: The primary mission of our research lab is to design, evaluate, and deliver psychotherapy interventions for service members who are suicidal. We believe that by providing a timely and targeted intervention, we can improve the quality of life of a service member and help him or her understand that suicide is not the only option.

What do the psychotherapy interventions consist of?

Dr. Neely: Mostly, the interventions consist of cognitive behavioral strategies that aim to change a service member's suicidal thoughts and behaviors. One type of cognitive behavioral intervention that we have designed is for individuals who are psychiatrically hospitalized at a military treatment facility following a suicide-related event. This intervention is called Post Admission Cognitive Therapy (PACT).

Is suicide a prevalent issue in the military?

Dr. Holloway: Suicide continues to be a significant public health problem in the military. Suicide has been the second leading of cause of death in the military since 2009 and the first leading cause of death since 2012.

It's unfortunate, but I'm glad there's some research going on and I hope that we can make some progress.

Dr. Holloway: We are also hopeful that progress can be made. The research conducted in our lab is heavily focused on helping individuals who have attempted suicide and individuals who have struggled with suicidal thoughts. Our colleagues with expertise in epidemiology and studies such as ARMY STARRS are helping us understand suicide risk and protective factors unique to military personnel and families. Organizations such as the Tragedy Assistance Program for Survivors (TAPS) are helping survivors – those left behind after a suicide – to cope with the aftermath of a suicide. Our lab is making a contribution to DoD suicide prevention efforts by specifically treating service members who have attempted suicide or who have been hospitalized for suicide-related reasons. These individuals are at an elevated risk for eventual death by suicide. It is important for everyone to know that a history of suicidal behaviors is strongly predictive of future suicide risk. Our interventions help suicidal individuals cope with the emotional pain they experience as a result of a multitude of life stressors such as a relationship breakup. We're trying to make a change in their future behavior, such that if they find themselves in a situation where they're really stressed out, experiencing a lot of emotional pain, and at times physical pain, that they don't follow through with the decision to kill themselves—that they use other ways of coping and look at other solutions for the life problems they have.

When you mention other ways to view other solutions away from suicide, what exactly are you referring to?

Dr. Neely: In terms of treating suicidal individuals, we understand that many of these patients view suicide as the only option to solving their life problems. Let me explain briefly how our intervention PACT addresses this way of thinking. Our PACT clinicians first listen carefully to each research participant's suicide story. This involves understanding the circumstances, thoughts, emotions, and behaviors that went into the decision to harm oneself. The information from the suicide narrative helps our clinicians understand how to best intervene given each patient's life situation. Second, we focus on skill-building. Once we understand the unique triggers for suicidal thoughts and behaviors for one individual, we can then personalize the treatment to target these specific triggers. For example, a suicidal service member may be struggling with regulating his emotions, planning for his safety, delaying impulsive acts such as drinking, and problem solving a relationship stressor effectively. Our clinicians would teach this service member skills needed in each of these domains to prevent and even to manage a future suicidal crisis. Third, our clinicians focus on preventing relapse. This means that we continue to practice learned skills such that a future suicidal crisis can be prevented.

So I understand that judging from the nature of your work, that it has been ongoing, for years?

Dr. Holloway: I have been a faculty member at Uniformed Services University for the past eight years. When I was hired, the goal for my lab's programmatic research was to design interventions for suicidal service members. We first started with two pilot clinical trials at the old Walter Reed hospital. These trials were funded by the Congressionally Directed Medical Research Programs (CDMRP) and the National Alliance for Research on Schizophrenia and Depression (NARSAD). Dr. Neely coordinated these trials for our team and served as a study therapist. These pilot trials allowed us to set the infrastructure for psychotherapy research at the new Walter Reed. We subsequently initiated a randomized controlled trial at the inpatient psychiatric unit of Walter Reed to test a Safety Planning Intervention for the prevention of suicide among military service members and their beneficiaries. Currently, we are conducting a multi-site randomized controlled trial to test the efficacy of Post Admission Cognitive Therapy. A randomized controlled trial, as you may know, is considered the gold standard for testing an intervention. We are expecting that the study is going to continue over the next three to four years. We're recruiting patients from Walter Reed and the Fort Belvoir Community Hospital. This year, we are hoping to add the DC VA as a third recruitment site.

I also wanted to add to Dr. Neely's earlier point about treating suicidal individuals. What we're trying to do with our psychotherapy interventions is to help the suicidal service member think about their suicidal thoughts – sometimes distancing themselves from the thoughts and examining these thoughts based on facts, not emotions, helps build hope. We also try to teach our patients that having thoughts does not necessarily mean that you have to act on these thoughts. One can have thoughts about suicide but having the thoughts does not mean that one has to carry out the act.

Very good idea. It's interesting to step back and reflect on our thinking. In other words, thinking about what we're thinking. How has the interaction been between the service members whom you have been working with so far?

Dr. Holloway: The first issue to keep in mind is that we want to be incredibly respectful of service members and their family members. We understand that it is very challenging to be hospitalized following a suicide-related event. For those hospitalized, research participation is understandably not at the top of their list. Our research team is very sensitive to making sure that we're not causing harm and that we're approaching the service members at a time that is acceptable and in a manner that is respectful to them. For example, one of the strategies for showing this respect is to only approach a hospitalized suicidal patient after his or her physician has obtained oral permission for us to do so. One of our trained staff members then arranges a private meeting with the patient at the hospital to discuss the study objectives, ways in which the research participation of the patient can help with our intervention work, and to review the study's informed consent form. The research participation is, of course, voluntary, meaning that the individual has the right to say "yes" or "no." If the patient says "no," we collect data on the reason for refusal. We think that the reason for not participating in research is important for us to know. We thank the patient for considering our request during this challenging time.

We are always incredibly grateful when a patient decides to participate in one of research studies. For one of our inpatient treatment studies, participants have a 50% chance of being randomized to receive the PACT intervention. This means that the patient receives up to 8 sessions of individual psychotherapy during their inpatient stay, in addition to 2 self-help books, an initial psychological evaluation, and 12-months of research case management. After the patient leaves the hospital, he or she will also receive up to 4 telephone psychotherapy sessions to promote linkage to aftercare during this high vulnerability period. Participants also have a 50% chance of being randomized to receive enhanced usual care. This means that the patient receives the usual care provided at the hospital, in addition to 2 self-help books, an initial psychological evaluation, and 12 months of research case management. By the way, the 2 self-help books are *Choosing to Live* (which focuses on strategies to prevent suicide) and *Courage After Fire* (which focuses on coping with posttraumatic stress disorder).

Many of our study participants openly acknowledge that one of the most important reasons for their participation is to help fellow service members. Our research participants are playing a significant role in helping us design helpful talk therapy interventions to address suicide risk.

I would imagine that participating in the study would make a significant contribution to their views on living as well.

Dr. Neely: Yes. We certainly hope to change a suicidal service member's views on the value of his or her life.

Monthly Meeting

Employee of the Month Award

Ms. Angela Drago Quispe del Pino, Research Support Specialist, receives Employee of the Month award for taking on numerous additional responsibilities to help keep the IRB Operations Office running. She stepped up to the challenge to manage the expedited review process allowing the IRB managers time to catch up on the IRB minutes that needed to be finalized. Angela did this in addition to her ongoing responsibilities related to the convened board and IRBNet training duties.

New Employee

Kysha Watson, Financial Analyst, brings 14 years' experience in the financial market. She considers herself an experienced analyst in government acquisition, contracting, budgeting, financial analysis, and client services. Ms. Watson has worked as a Contract and Acquisitions Specialist, Resource Advisor, and Budget and Program Management Analyst conducing quantitative analysis managing environmental funds. She looks forward to utilizing her financial skills in the Department of Research Programs.

Holiday Party 2014

The food was catered after everyone chipped in. Entertainment included two games hosted by Venetta Jones. The first game was pairing two sets of people who could only use one hand each to wrap a present using their one hand each only. The second game was a singing game where everyone picked a song randomly from a ticket box then had to hymn that song and find their fellow song group. What a good time!

Behind the Scenes – Keeping the Ball Rolling

Dina Bernstein, Esq.
WRNMMC Staff Judge Advocate's Office –

This month we are pleased to invite one of the attorneys from the WRNMMC legal office who gets involved in a lot of the military medical research issues here – *Fiat Justitia Ruat Caelum.*

What role do you play in human subjects' research?

I attend IRB meetings and advise the Agreements Review Committee. Occasionally I assist IRB members who conduct expedited reviews. [Concerning IRB meetings], when I get involved in a particular project, I start my review by first looking at the informed consent document as a lay person, because I don't have a scientific background. I approach my review by asking, "Is this a project I would want to participate in" in an effort to ensure that a possible research subject has sufficient information and a decent understanding to make an informed decision about participating Because my job requires me to interact with a multitude of different people, and I have had a variety of experiences as a result, I'll ask questions and raise discussion points from a different perspective than others around the table. I next review and compare the informed consent document with the protocol. I do that to understand how they are going to recruit, how they will protect and share the data, how they've identified selection criteria and risks/benefits, and have they been consistent with their documents. This is designed to minimize protocol deviation problems. I'll look to see if there are legal issues with the project. For instance, have they complied with the DODI's provisions on compensating participants? I review advertisements and questionnaires. I also review agreements that set out the parties' roles and responsibilities. I'll compare the protocol, consent document and agreement to make certain they are in sync (for instance, if the researcher is asking to waive getting a HIPAA authorization, the agreement shouldn't say we are getting one). For agreements, I also want to ensure Government liability and fiscal sections are appropriately addressed, among other things. I try to approach all my reviews by asking myself if the project or agreements makes sense.

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

Communicate, communicate, communicate. Get assistance from folks who have experience before they start working on things. Ask questions. Circle back as necessary. Course correct if needed. Communication is fundamental. It doesn't matter if you're talking about clinical care or research. Additionally, I hear COL Weina say at every Research Roundtable, "Staff here at DRP is willing, ready, and able to assist researchers. They just need to be approached." Communicating entails a real dialogue between individuals—what are we really trying to accomplish? By doing that, perhaps we can dig further and figure out a pathway that is still acceptable, sound and not problematic. Meaning, if we can sit down and really discuss what the researcher want to do, perhaps we can still meet those objectives, but it may be done by heading down a different pathway than originally contemplated. I've seen this dialogue repeatedly at IRB meetings because what is written up in the project didn't really convey what the researcher wanted. It's so refreshing to see issues get resolve just by talking things through with others.

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

I think it would really be good if they had someone who is experienced as a coordinator who could keep them track and help them with paperwork. And maybe project a few weeks in advance so that suspenses are met and they get things accomplished. For instance, if they know they have something due within 30 days, they get a reminder 45 days out so they can build in some time. There are a lot of good people out there who can help get things through. It would also be good if they had a mentor or more experienced researcher who could help assist them in the process. Again, staff at DRP is there to help.

Induction Ceremony

SSG Hodges, DRP SEL, receives the Creed of the Non-Commissioned Officer, Charge of the Non-Commissioned Officer, and Army regulations on leadership during the 14 November 2014 NCO Induction Ceremony.

After reciting *Boots of the NCO*, four Non-Commissioned Officers wearing period dress and battle uniforms march up the isle way symbolizing that an NCO has always been there, wearing boots.

Office of Research and Technology Applications

"Men at work"

COL Weina and SSG Hodges discuss Office of Research and Technology Applications (ORTA) matters with Mr. Steve Ross, ORTA Manager.

ORTA is set up to offer advice and assist with technology transfer agreements, especially Cooperative Research and Development Agreements (CRADAs), intellectual property agreements, patent-licensing agreements, and personnel exchange.

Development of DRP's CRADAs is very high on COL Weina's agenda for the future of DRP. Mr. Ross is pivotal to this effort.

Feedback on the Newsletter

Please send feedback on the newsletter to:

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

November 2014 WRNMMC Publications

(Provided by the Darnall Medical Library)
WRNMMC authors are in bold.

1. Al-Rakan M, Shores JT, Bonawitz S, et al. Ancillary procedures necessary for translational research in experimental craniomaxillofacial surgery. *J Craniofac Surg*. 2014;25(6):2043-50.
   WRNMMC Authors: **Santiago G, Grant G**
2. **Andersen RC**, **Wilson KW**, Bojescul JA, **Mickel TJ**, **Gordon WT**, **Potter BK**. Open, combat-related loss, or disruption of the knee extensor mechanism: treatment strategies, classification, and outcomes. *J Orthop Trauma*. 2014;28(11):e250-7.
3. **Balazs GC**, **Polfer EM**, **Brelin AM**, **Gordon WT**. High seas to high explosives: the evolution of calcaneus fracture management in the military. *Mil Med*. 2014;179(11):1228-1235.
4. 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;119(5):1094-101.
5. **Byrd K**, Seay R, Bechert CJ, Maxwell GL, Bicher A. Metastatic choriocarcinoma presenting in a gravid woman. *Gynecol Obstet Invest*. 2014 Nov 19. [Epub ahead of print]
6. **Carter CA**, **Nations JA**, **Lazarus A**. Molecular targets in the treatment of non-small-cell lung cancer: is there hope on the horizon? *Postgrad Med*. 2014;126(7):139-148.
7. **Cohen SP**. Precision targeting for neuroablative therapies: the future of interventional pain medicine. *Reg Anesth Pain Med*. 2014;39(6):447-9.
8. **Cohen SP**, Hayek S, Semenov Y, et al. Epidural steroid injections, conservative treatment, or combination treatment for cervical radicular pain: a multicenter, randomized, comparative-effectiveness study. *Anesthesiology*. 2014;121(5):1045-55.
   Additional WRNMMC Authors: **Kurihara C**, **Griffith SR**, **Verdun AV**
9. Dickens JF, Owens BD, Cameron KL, et al. Return to play and recurrent instability after in-season anterior shoulder instability: a prospective multicenter study. *Am J Sports Med*. 2014 Nov 5. pii: [Epub ahead of print]
   Walter Reed Author: **Kilcoyne K**
10. **Erbele ID**, **Bernstein JG**, **Schuchman GI**, **Brungart DS**, **Rivera A**. An initial experience of cochlear implantation for patients with single-sided deafness after prior osseointegrated hearing device. *Otol Neurotol*. 2014 Nov 18. [Epub ahead of print]
11. **Farrell J**, Young D, Chen Y, et al. Predominance of ERG-negative high-grade prostate cancers in African American men. *Mol Clin Oncol*. 2014;2(6):982-986.
    Additional WRNMMC Authors: **Rosner IL**, **McLeod DG**
12. **Hartzell JD**. Q fever reporting: tip of the iceberg? *Am J Trop Med Hyg*. 2014 Nov 17. pii: 14-0636. [Epub ahead of print]
13. **Holley LA**, **Sobieszczyk CM**, **Sherner LJ**, **Perkins MM**. Respiratory symptoms in service members returning from Afghanistan and Iraq. *Am J Respir Crit Care Med*. 2014;190(9):1076-7.
14. **Hyatt KS**. CE: Mild traumatic brain injury. *Am J Nurs*. 2014;114(11):36-42.
15. **Landau ME, Faillace WJ, Nesti LJ, Grimes JB.** Neuralgic amyotrophy manifested by severe axillary mononeuropathy limited only to the anterior branch. *Muscle Nerve*. 2014 Nov 22. [Epub ahead of print]
16. **Lange RT**, Panenka WJ, Shewchuk JR, et al. Diffusion tensor imaging findings and postconcussion symptom reporting six weeks following mild traumatic brain injury. *Arch Clin Neuropsychol*. 2014 Nov 21.[Epub ahead of print]

    Nugent J, Edmonds A, Lusiama J, Thompson D, Behets F, Pediatric HIV Care and Treatment Group. Predicting mortality in HIV-infected children initiating highly active antiretroviral therapy in a resource-deprived setting. *Pediatr Infect Dis J*. 2014;33(11):1148-55.
17. Okulicz JF, Le TD, Agan BK, et al. Influence of the timing of antiretroviral therapy on the potential for normalization of immune status in human immunodeficiency virus 1-infected individuals. *JAMA Intern Med.* 2014 Nov 24. [Epub ahead of print]
    Walter Reed Author: **Ganesan A**
18. **Sabino J**, **Polfer E**, **Tintle S**, et al. A decade of conflict: flap coverage options and outcomes in traumatic war-related extremity reconstruction. *Plast Reconstr Surg*. 2014 Nov 20. [Epub ahead of print]
    Additional WRNMMC Authors: **Jessie E**, **Fleming M**, **Martin B**, **Valerio I**
19. Starmer AJ, Spector ND, Srivastava R, et al. Changes in medical errors after implementation of a handoff program. *N Engl J Med*. 2014;371(19):1803-1812.
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Appendix 1 – Electromyostimulation and Strength Walking for Knee Injuries Study

Is This Research Study For You?

- Do you have a knee injury that does not require surgery?
- Are you between the ages of age 18 and 50 years?

If you answered "yes" to any of the above questions, the knee injury research study may be for you.

For more information about the study, please contact

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This research study is being conducted at Walter Reed National Military Medical Center
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The Knee Injury Research Study

A Strengthening Program For Knee Injuries

What is the Knee Injury Research Study?

The Knee Injury Study is a muscle strengthening program for active duty military with a knee injury.

The purpose of this research study is to test four different approaches to knee injury rehabilitation as potential treatments for improving muscle strength, fitness level, movement, injury symptoms/knee pain, and quality of life.

Are you eligible?

- Military service member at the time of injury (Including active duty, Reserve/ NG in AD status)
- Age ≥18 and <50 years
- A diagnosis of knee injury or knee pain

How Much Time Do You Need To Devote To This?

Once eligibility is determined for the Knee Injury Study, participants are randomly assigned into four groups.

- All groups will continue to participate in the WRNMMC Knee Injury Rehabilitation Protocol.
- One group will receive neuromuscular electrical stimulation (NMES) with WRNMMC PT, a 2nd group will receive walking with a weighted vest plus WRNMMC PT, a 3rd group will receive NMES, walking with a weighted vest and WRNMMC PT, a 4th group will receive WRNMMC PT.
- You will be asked to come in to Physical Therapy (America Building) during an 18-week period.
- Each visit will last 20-90 minutes depending on the measurement tools schedule for that phase of the research project.

What General Information Do You Need to Know?

- All testing is provided at no cost to you.
- Your participation is completely voluntary
  All information will be kept confidential.
- This study may increase your thigh muscle strength, reduce knee pain, increase your movement and improve your quality of life.