

VOLUME 1, ISSUE 8

Excellence in Military Medical Research

OCTOBER 2014

The Greek philosopher Heraclitus stated, "The only thing that is constant is change." Those who have been watching the Department of Research Programs (DRP) have noticed, and dare I say, felt the pain, of this quote.

One of the biggest agents of change and issues that we face doing research here at WRNMMC is IRBNet. IRBNet is the communications system we have grown accustomed to. This is how we currently handle the literally thousands of protocols, agreements, and publications processed every year. One issue with IRBNet has been keeping our network secure by addressing inherent weaknesses with this commercially available data management program. This has been accomplished diligently as issues have arisen; however, due to increasing Department of Defense computer security requirements, we are now transitioning to CAC-only access for all users. We know this creates challenges for some of our users. We have no choice as our only other option would be shutting IRBNet down completely. Also, like any contracted product, IRBNet must be re-competed every five years to comply with acquisition laws. The competition and final selection will be made outside of WRNMMC, so we are not certain which electronic IRB management tool (eIRB) we will be working with in the near future. Rest assured that we will do our utmost to minimize disruption to everyone's research when and if the transition

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to another eIRB occurs and as we transition to CAC-only access for IRBNet now.

Another significant change in DRP is with the agreements process. We are examining our agreements processes at WRNMMC and will be reexamining all of our agreements with our partners. Potential improvements in our processes have been identified with the review of some of our agreements. The current agreement process is less than user-friendly for researchers and we want to improve this. Our goal is to have a process in place where the clinical researcher outlines a statement of work with his or her partners, and then DRP handles the rest (i.e., paperwork, negotiations, etc.).

This may seem like a daunting and perhaps impossible task to new researchers who may have limited time to do research. We plan on addressing this as well; soon we will be implementing protocol navigators to DRP. The protocol navigators



will be single points of contact for investigators to help investigators navigate necessary administrative change. We hope that this will help build a trust relationship with DRP and speed up protocol approvals.

Yes, the only constant is change, but we are confident that this change will translate into better research executed in a responsible manner with minimal disruption of administrative burden. My team and I look forward to working through these and likely many other changes in the years to come.

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

Biomedical Research Laboratory (BRL)



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

This month and again next January, the staff of the BRL opens its doors to U.S Army soldiers learning how to become medical laboratory technologists (MLTs). Each of them already completed a didactic classroom portion of the 12-month course, and is now applying their knowledge at the laboratory bench. The instructor for this course is Elias Paz Alonzo and it is under the leadership of LTC Robert Pell. LTC Pell approached the BRL leadership for assistance because the Dept. of Pathology and Anatomic Laboratory (DPALs) had limited space to accommodate this portion of the course. While in the BRL, the MLT students are learning how to perform blood typing, blood compatibility tests for transfusion services and day-to-day blood-banking procedures.



BRL staff members PFC Brandon Thompson and SGT Robert Martinez are assisting them as needed. BRL scientists are talking with the students about the research conducted in the BRL and career opportunities available in laboratory science. The BRL team is happy to support the needs of education efforts such as these and expose the students to some of the capabilities our laboratory has to offer!



Elias Paz Alonzo (far right) and the students



Center for Nursing Science & Clinical Inquiry (CNSCI)



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

LTC Yost and MAJ Hyatt participate in:

TriService Nursing Research Program (TSNRP) Research and Evidence-Based Practice Dissemination Course – San Antonio, Texas

Last month, LTC Terri Yost and MAJ Kyong Hyatt presented at this three-and-a-half day course, which combined the previously long-standing dissemination events for military nursing (i.e., the Army's Phyllis J. Nursing Research Course, and the AMSUS-associated Karen Rieder Poster Session).

The theme for the 2014 maiden TSNRP course – "Creating the Science, Advancing the Practice" – articulated the importance of both research and EBP in improving the delivery of health care services. During the week, over 200 nurse attendees representing active, retired, reserve, and guard of all three major branches of service, Army, Navy and Air Force as well as Department of Defense civilian nurses heard stimulating lectures on research and EBP projects within our military nursing communities as well as education presentations from military nursing leaders and nationally-known clinical experts.

Keynote lecturers included MG Jimmie O. Keenan, Commanding General, Southern Regional Medical Command and Chief, U.S. Army Nurse Corps; Joan Walter, JD, PA, of the Samueli Institute; Bonnie Jennings, PhD, RN, FAAN, Visiting Professor, Emory University, Atlanta, GA; and author and nurse



historian Elizabeth Norman, PhD, RN, FAAN, Professor of Humanities at NYU's Steinhardt School of Culture, Education, and Human Development.



LTC Yost's presentation titled "Recovery in Service Members with Traumatic Brain Injury" explored the concept of recovery as viewed by those affected by a brain injury. This discussion, based on qualitative interview findings with service members who had been undergoing neuro-rehabilitation after sustaining a brain injury, sought to educate the medical and nursing communities on the patient's perspective on "what constitutes recovery." Since everyone has varying ideas about what recovery means to them, LTC Yost's research suggests that health care team members should seek and use that information as a framework for establishing individualized treatment goals and priorities in an effort to promote patient-centered health care.

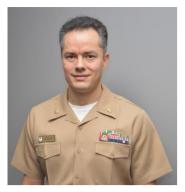
MAJ Hyatt's presentation titled "Family Reintegration Experiences of Soldiers with Combat-Related Mild Traumatic Brain Injury (mTBI)" examined post-injury family reintegration experiences of Soldiers and their civilian spouses. MAJ Hyatt's briefing included discussion of post-mTBI rehabilitation challenges, management strategies, and rehabilitation process. MAJ Hyatt's research findings suggest that "finding the new normal" is the

overarching theme of the post-injury family reintegration experiences. MAJ Hyatt suggests that future studies that examine post-mTBI family reintegration as they evolve over time may provide a deeper understanding and provide a basis for creating effective rehabilitation and support programs for this population.

The TSNRP Research and Evidence-Based Practice Dissemination Course provided an invaluable opportunity for military and civilian nurses representing military health care to network, share ideas and plant the seeds for future research and collaborative partnerships. Due to the overwhelming success of this course, the goal of TSNRP is to seek support from the Executive Board to continue offering this course on an annual basis. This is one step towards becoming the exemplar for the entire professional nursing community on implementing best nursing practice based on scientific research findings.



Research Protocol Development



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

On a bimonthly basis, a statistical contribution is provided by one of our staff biostatisticians. This month's section was provided by **Robin Howard, Biostatistician.**

Writing a Manuscript? How about a Checklist!

"The good news is that the ... editorial board has asked us to submit revisions and responses to the comments and to carefully address the STROBE checklist."

-- WRNMMC Investigator, August 2014

Journals provide specific checklists for presenting different types of research. Authors are often asked to highlight sections of their manuscript that correspond to each item on the checklist. The CONSORT checklist for randomized controlled trials is the most well-known checklist. Other checklists for many different types of studies are presented in **Table 1**. Always check your journal's "Authors Guidelines" for other possible checklists before writing your manuscript. DRP statisticians also recommend using these checklists when writing your protocol.

Table 1 – Sample Checklists for Trials, Studies, and Protocols

TRIAL/STUDY	CHECKLIST	LINK
Cluster Randomized Controlled Trials (RCTs)	No name; see link.	http://www.ncbi.nlm.nih.gov/pmc/art icles/PMC381234/
Controlled Trials • RCTs	CONSORT	http://www.consort-statement.org/
 Non-RCTs 	TREND	http://www.cdc.gov/trendstatement/
Diagnostic Test	STARD	http://www.stard-statement.org/
Health-Related Quality of Life Studies	No name; see link.	http://www.sciencedirect.com/scienc e/article/pii/S0140673611612567
Non-inferiority and Equivalence RCTs	No name; see link.	http://jama.jamanetwork.com/article. aspx?articleid=202506
Non-Pharmacological Treatment Interventions	No name; see link.	http://annals.org/article.aspx?articleid =739590
Observational (cohort, case-control, and cross- sectional)	STROBE	http://www.strobe-statement.org/
RCTs with Patient-Reported Outcomes	No name; see link.	http://jama.jamanetwork.com/article. aspx?articleid=1656259
Reliability and Agreement	GRRAS	http://www.sciencedirect.com/scienc e/article/pii/S0895435610000971
Systematic Reviews and Meta- Analyses	PRISMA	http://www.prisma-statement.org/



IRB Operations Office



(left to right) Wendy R. Gilbert Mary Kelleher Chief, IRB Operations Office

The IRB Operations Office provides support to our hard-working IRB Chairs and IRB members to ensure the efficient and effective review of research. The IRB Ops team is also your primary point of contact once a package has been submitted for IRB review. Wendy Gilbert and Beth Narvaez manage submissions being reviewed by expedited procedures and Angela Quispe and Dee Groover coordinate the activities of the convened panels on the 2^{nd} and 4^{th} Thursday each month.

Transparency, reliability, and outstanding customer service are the cornerstones of the IRB Operations Office. We look forward to working with you to support the responsible conduct of research.

Meet the IRB Operations Office Team



IRB Manager wendy.r.gilbert.civ@mail.mil 301-295-8221 Wendy brings 18 years' experience in the area of research administration, 7 years as a research data manager at WRAMC, and 11 years' experience in human subjects' protection as a research protocol reviewer and as an IRB manager at WRNMMC.

Elizabeth D. Narvaez IRB Manager elizabeth.d.narvaez.civ@mail.mil 301-295-8216 Beth brings 13 years' experience in

the area of research administration in human subjects' protection as a research protocol reviewer and as an IRB Manager at WRNMMC.

Angela Drago Quispe del Pino

Research Support Specialist angela.d.quispedelpino.civ@mail.mil 301-295-6512

Angela has 6 years' experience in the area of human subjects protection. She developed her skills by serving as a Continuing Review Coordinator at WRAMC, then as a Protocol Reviewer, IRB Manager and Research Support Specialist at WRNMMC. Her strong computer skills have allowed her to become the go-to person for the eIRB system. Angela brings a strong base of institutional and regulatory knowledge.

Beatrice D. Groover (aka "Dee")

Research Support Specialist beatrice.d.groover.civ@mail.mil

(301) 295-8225

Beatrice has over 21 years of experience in research administration. Prior to joining the IRB staff as a Research Support Specialist, she gained a wealth of knowledge at the WRAMC Nursing Research Service and WRNMMC Center

for Nursing Science and Clinical Inquiry. Her background in the research administration and strong organizational skills has been essential in adapting to the human protections environment.

And special congratulations to our own Dee Groover who was selected as the DRP Employee of the Month!



Research Compliance Office



Debarati Dasgupta, MS, CHRC, CIP Research Compliance Officer

> Robert Roogow Auditor

Human Subjects Research Compliance

– Tip Sheet #1

The Post-Approval Compliance Monitoring (PACM) Program within the Research Compliance Office has been conducting compliance monitoring visits to ensure the protection of human subjects in research, to provide education to research community members, and to identify the strengths and weaknesses of research practices at WRNMMC. The team of auditors has come up with a few tips to help increase your compliance with Federal and DoD regulations, human research protection (HRP) policies and good clinical practices. We will provide similar tip sheets on an ongoing basis.



- 1) The Investigator's Guide lists the following PI responsibility: "The study will be conducted as it is outlined in the research protocol and all research procedures that involve human subjects have been fully disclosed in the research protocol." Remember that evaluating the protocol is an ongoing process. A research protocol should be constantly evaluated to ensure the ability of the research team and the subjects to comply with protocol requirements. The most common example of a protocol that should be re-evaluated is a protocol that requires subjects to attend frequent visits at specific time intervals. It is important to schedule the subjects according to the protocol specific dates, for instance 2 weeks or 3 months after the first visit. If it is a problem seeing subjects exactly 2 weeks or 3 months after the initial visit, it would be appropriate to re-evaluate the protocol and consider adding visit windows (for example, visit at 2 weeks ±3 days or 3 months ±2 weeks).
- 2) Review the WRNMMC IRB Handbook Chapter 10 for reporting requirements of reportable events such as protocol deviations, Adverse Events (AE) (both expected and unexpected), and Unanticipated Problems (UP) Involving Risks To Subjects or Others (UPIRTSO). Use a Protocol Deviation Log and an Adverse Event Log to capture all deviations and AEs and submit the logs with your Continuing Review submission.
- 3) When information linked to subjects will be recorded as part of the research design, the IRB requires that adequate precautions be taken to safeguard the confidentiality of the information. Ensure confidentiality is protected and that PHI and PII are filed appropriately. If your protocol specifies that PHI/PII and coded data will be kept separate, then file PHI/PII separately from the coded data. Always comply with your protocol.
- 4) The WRNMMC IRB Handbook Chapter 3 states, "It is the responsibility of the Principal Investigator to submit the continuing review submission at least 45 days before the expiration date of IRB approval to allow sufficient time for IRB review." Frequently check IRBNet for unlocked packages requesting additional information from the protocol reviewers and the IRB Operations staff.
- 5) Visit the Forms and Templates section of IRBNet frequently (choose WRNMMC Department of Research Programs (DRP) – Documents for Researchers in the Select a Library dropdown) for the most up to date versions of DRP forms and templates. Make sure you are using current template versions when you make changes to study documents.
- 6) Correct errors on case report forms (CRF) (and/or any data collection forms/source documentation) with a single line strike through, initial and date. Scribbling out data or using correctional fluid is not acceptable.
- 7) Do not leave blank spaces on case report forms. Document "N/A" if the data point is "Not Applicable" or "N/D" if the data point is applicable, but not collected (or not done). If the data point is not required by the protocol or it is determined to be no longer significant consider revising your CRF and submit the changes to the IRB.
- 8) Do not use an expired consent form to consent subjects. If you are expecting subjects to be consented for a planned visit and you have not received the current IRB approved ICF from your last submission, call the IRB Operations Office. It is important to make certain the most recent IRB-approved stamped consent form is being used to consent subjects.



Investigative Research



Gerald T. Grant, DMD, MS, CAPT, DC, USN Service Chief, 3D Medical Applications Center, Radiology Department

The 3D Medical Applications Center (3DMAC) provides digital design and additive manufacturing support to military medicine throughout the world; services include virtual surgery, fabrication of surgical guides, medical models, custom implants, custom prosthetic accessories, and research. The Center's staff comprises a maxillofacial prosthodontist, a PhD biomedical engineer, two CT technicians, and a metals engineer who coordinate the use of six different additive manufacturing processes. Fabrication materials range from paper to resins and titanium. Additive manufacturing technologies are well suited for medical applications, including medical images ranging from CT scans to MRI or even ultrasound can be used to fabricate a 3D model. Individual anatomical

areas can be segmented out using contrast or hounsfield units; a model is developed and sliced into layers to fabricate the model. Each slice contains all of the anatomy segmented; therefore, internal features such as nerves, vessels, tumors, etc. can be "printed" within the model.

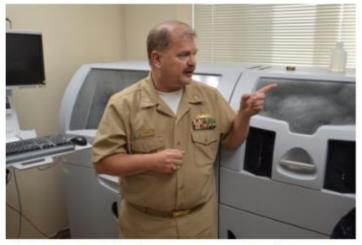


Figure 1 Powder binding printers produce color pre-surgical models often used in neurosurgery to show vessels and tumors



Figure 2 A materials jetting technique machine produces plastic models for dental implants and surgical guides

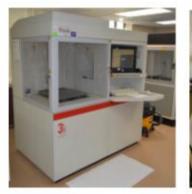


Figure 3 Stereolithography machines (SLA) are the workhorse of 3DMAC; they can produce large models often used by orthopedics for pre-surgical planning



Figure 4 The electron beam melting process is used to fabricate titanium implants and prosthetic parts



Figure 5 3DMAC has the only hospital on-location ability to print titanium parts in the USA



Figure 6 A larger recovery system allow for recycling of titanium powder



DEPARTMENT OF RESEARCH PROGRAMS NEWSLETTER

3DMAC fabricates models, guides, devices, and implants using additive manufacturing technologies, commonly known as 3D printing. The largest machines are the SLAs (Stereo Lithography Apparatus); there are three machines, two of which can produce models on a platform that is approximately 2x2 feet. The machines work by building a model, layer-by-layer. A laser beam traces the layer on a vat of a photopolymer, curing the layer, that layer is then lowered and another layer is traced and fused to the previous layer until the entire model or device is fabricated. This is one of the more common ways to fabricate medical models; however, once the models are completed, they need to be washed, supports need to be removed, and the models need to be cured in a light oven. These models are generally white, clear, or amber. Orthopedic surgeons request many models prior to surgical procedures. A smaller SLA machine, the Viper Pro, has a 10-inch platform, and is very accurate (custom hearing aids are made commercially from these machines, for example).

Color models are fabricated on the ProJet 460 and 660, previously known as Zprinters. A layer of gypsum powder is laid across a platform and a print head moves across the powder, adding a binder and color to the powder in a layer-bylayer manner. Similar to other printing methods the internal anatomy is printed; however, the powder is trapped within the model making the model more useful if you don't need to see any structures within the model. The great feature of this machine is that the powder provides support for the model so when the model is completed the powder is vacuumed from the chamber; however, the resulting model is fragile with the consistency of chalk, and the model needs to be sealed. Usually, the models are sealed with super glue, which provides a hard surface exterior; however, we can infuse models with wax or resin. The finished models are used extensively by neurosurgeons to define vessels and tumors in the head prior to any surgical procedure, since we can color each feature a different color. Furthermore, this is probably the fastest method currently available to fabricate a model. In many cases we can load a file of the model on the machines in the morning and have the printed model available by the afternoon.



Figure 7 3DMAC models

Multiple materials printing via our materials jetting printers is also available. This printing technology allows 3DMAC to build models using two different materials. The two different materials can be two hard materials of different color, or a hard and a soft material. Our printers allow us to determine properties of specific materials for a device that has both hard and soft elements or produce a clear model with an internal feature in another color, such as a tooth, nerve, tumor, etc. These machines are used for printing surgical guides for dental implants, craniofacial surgery, and orthopedics.

For the most part there are two ways you can use powders to fabricate metal parts: with a laser and with an electron beam. At 3DMAC, we use an electron beam melting device to fabricate titanium devices and implants. A layer of titanium is raked across a metal plate and an electron beam, guided by a magnetic coil, traces out the layer to be produced. In this case the chamber where the powder is located is heated in an oxygen-free environment, under a vacuum. This produces parts that are free of residual stress, so there is no need for any post-processing to ensure the fit of the device. Devices are made for prosthetics and research, as well as implants for non-stress-bearing areas, such as cranial plates or craniofacial fixation devices.



Monthly Meeting

Employee of the Month Award



Beatrice Groover is awarded **Employee of the Month** for going above and beyond her stated duties.

In addition to her day-to-day responsibilities supporting the short-staffed IRB office, during August/September "Dee" provided extraordinary administrative support to COL Ashley.

Dee organized, copied, collated, tracked, revised, and reorganized a significant amount of data collected over the course of a multi-week period.

COL Ashley stated, "I could not have produced my work this month without Ms. Groover's assistance."

As needed to meet deadlines, Dee came in early or stayed late to support COL Ashley while still keeping up with her regular duties.

Money Talk

COL Weina uses the zero sign to describe the amount DRP received from three research agreements.

This was a major focus of this month's meeting, DRP's goal:

Becoming Better Financial Stewards, Which Benefits All

The function of DRP's new Agreements Review Committee (ARC), which meets every Wednesday from 11:00 to 12:00, will be to review all of the roughly 1,000 current research agreements in place with DRP and its partners.



Behind the Scenes – Keeping the Ball Rolling

This month we highlight Ken Harvey, our Research Financial Analyst in our newly formed Business Cell. Our Business Cell will be taking on COL Weina's agenda of **bringing money into research**: in particular, bringing money into the Department of Research Programs.



Kenneth Harvey Research Financial Analyst Business Cell

What role do you play in human subjects' research?

None. Instead, I'm the comptrolling liaison. I capture budget and expense reporting and ensure that the budget execution as well as reimbursables for DRP are recouped and that the budget execution is executed in a timely manner. I'm also part of two groups. One is the business cell, in which I report all of the work breakdown structure (WBS), a line-item structure, which includes all of the programs, maintenance, operations, etc. that are currently within the new system GFEBS (General Fund Enterprise Business System). This system helps capture all of the expenses, budget and financial transactions for all of WRNMMC, including the Department of Research Programs. WBS is currently being formed.

GFEBS is not currently fully functional. And the other group that I belong to is the Agreements Review Committee (ARC), in which we look at CRADAs, Memorandums of Understandings/Cooperative Agreements to ensure that for one they make practical business sense and second the Department of Research Programs is getting a fair deal.

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

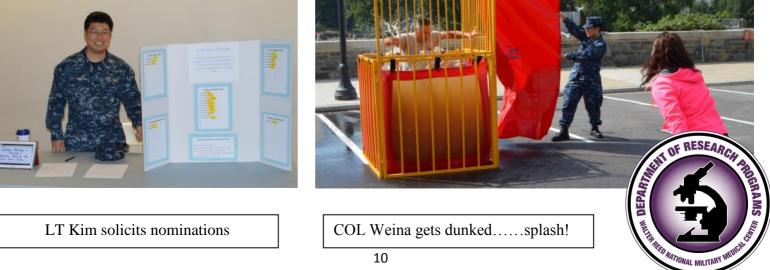
The more research you can do and the more diverse you are as a researcher, which means that you are not limited to only certain things – or even just one thing – in the Department. You have to explore different opportunities. On the training side for the researchers it is important for them to have available to them different trainings in different areas in order for them to be well-versed researchers. Research is not just research *per se*. Research involves **MONEY**. You need to get a business sense separate from strict research only. You cannot be myopic. The more protocols we produce as a Department, the more money we bring in. It's not all about research, and it's not all about money, it's a combination of the two. And within our Agreements Review Committee we intend to ensure that the protocols that we put out to non-Federal organizations, such as the Henry Jackson Foundation or Geneva, for example, have Walter Reed's best interests included.

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

The researchers seem to be doing a good job; however, the more research a researcher can do the more money that can be generated on all sides. Diverse training is integral to broadening anyone's scope of operations, including our growing and expanding Department. Seek out training as much as possible. The more you are known in your community the more likely you are to encounter new opportunities, including research opportunities that you might not even have known existed. I would encourage you to "think out of the box."

Junior Officers Dunk

Junior Officers Dunk held to raise funds for the Winter Ball. The live Dunk Tank was held on Thursday, September 18th at 1500 in front of the Tower by the flag pole, Building 1.



Education, Training & Research (ETR) End of Summer Picnic/Potluck Held in USO Building

On September 19th, COL Nelson hosted the ET&R End of Summer Team building, Meet & Greet, Picnic/Potluck held in the new USO Building. This event was designed to bring all ET&R staff together to; participate in team building exercises, share challenges and solutions, and provide updates and discussion. Everyone pitched in and provided delicious food and drinks. Hails and farewells were offered with COL Nelson thanking members of ET&R for all their hard work. This was another successful end of summer ET&R team-building gathering.



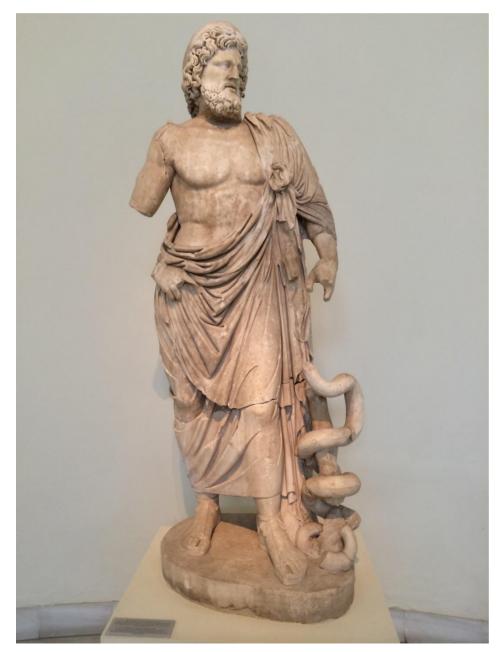
Feedback on September Newsletter

Comments included the following:

I am writing with appreciation for my recently being featured in the DRP newsletter as a new team member. As a result of this publication, I have been contacted by a colleague within WRNMMC who shares similar research interests and is interested in collaborating on a new study with me. The newsletter is a wonderful way to market what we do here as well and help establish professional connections. Thank you very much for doing this!

Please send feedback on the newsletter to:

dha. be the sda.ncr-medical. list. wrnm-drp-newsletter-feedback@mail.mil



End of Summer Image

DRP employee Robin Howard enjoyed vacationing in Greece this summer.

This was taken in the National Archaeological Museum in Athens, Greece. It is a statue of the Greek god of medicine, Asklepius. The snake coiled around the staff is still used as a symbol of medicine.

In the original Hippocratic Oath, one would invoke "Asklepius." The oath began as, "I swear by Apollo Physician and Asklepius and Hygieia and Panaceia and all the gods and goddesses, making them my witnesses, that I will fulfill according to my ability and judgment this oath and this covenant..."

-- Robin Howard, Biostatistician

(Photo taken by Robin Howard on September 25, 2014)



September 2014 WRNMMC Publications

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

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Appendix 1 – Updated Publications Clearance "Slim Jim"



Now Clear This

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Please see Principal Investigator Requirements in DRP's Investigator's Guide; and Instructions regarding Publication Clearance in IRBNet, under Forms and Templates.

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Now Clear This

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Protocol-Related Publication Clearance in DRP is not a censoring process; it is a matching process. The reviewers check to see that the content matches the study's objectives, confidentiality and privacy protections, and legal copyright requirements.

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Clearance usually takes investigators 14 days. In the submission process, investigators provide a specific date (for conference presentations for example, or journal submission), and if feasible, reviewers attempt to provide clearance prior to that date.

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