



Military Medical Research News

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Driving the diagnostic frontier Researchers tap high tech, simple insight to detect injury and illness

by Paula Amann

A service member is wheeled into the emergency room with complex arm wounds, due to a blast. Doctors may readily detect injuries to bone and muscle, but how best to find nerve damage without hurting soft tissue or shaking loose embedded shrapnel?

It's one of several diagnostic puzzles – from such disparate fields as neurology, orthopedics and physical medicine – that researchers at Walter Reed National Military Medical Center are working to solve. As investigators mull their choices, they must weigh patient safety, ease of use and data quality.

This kind of challenge led a team of doctors to look deeply at four cases of multiple arm wounds, including peripheral nerve injuries, among patients at Walter Reed Bethesda. Their study appeared in the December 2016 issue of *Muscle and Nerve*.

“Where there’s a blast injury, there may be multiple, penetrating traumas, making the nerve lesion hard to locate,” said the study’s second author, Army Maj. Dr. Matthew E. Miller, a physical medicine and rehabilitation provider, explaining the diagnostic dilemma in an interview.

On their own, Miller and the study’s first author, Army Maj. Dr. Jonathan K. Smith, a clinical neurophysiologist at Walter Reed Bethesda, began turning to ultrasound for answers.



Army Maj. Dr. Jonathan K. Smith, a clinical neurophysiologist at Walter Reed Bethesda, observes a nerve through the use of ultrasound, as his “patient,” Navy Lt. Andrew R. Garrett, a neurology resident, follows the results on screen. In real cases of trauma, ultrasound can help specialists like Smith diagnose injuries. The method offers a quick, high-resolution and painless way to probe damage to peripheral nerves. (Photo by Paula Amann)

In the past, diagnosis in trauma cases involved only a clinical examination and electrodiagnostic tests, tiny electroshocks that record nerve and muscle function, Smith explained.

Dating back to World War I, electrodiagnosis has a shadow side: pain for the patient, especially in the case of severe injuries. In addition, these exams sometimes fail to fully locate nerve injuries and gauge their gravity, Miller adds.

**See DIAGNOSTIC FRONTIER, page 5,
and related story on the enduring
power of the clinical exam, page 6**



DEPARTMENT OF RESEARCH PROGRAMS



Army Col. Peter Weina, director of Department of Research Programs (official photo)

The Department of Research Programs (DRP) at Walter Reed National Military Medical Center supports research activities in the National Capital Region (NCR) through regular news.

This monthly newsletter covers events, research and administrative policies and procedures, research studies and collaborations, department operations, workshops and other NCR initiatives.

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MILITARY MEDICAL RESEARCH NEWS

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This newsletter appears monthly. We welcome your story ideas, comments, corrections and photographs (action shots are best). Please send any timely information by the 15th day of the prior month for the following month's issue. Send your ideas, pictures or infographics to paula.m.amann.ctr@mail.mil.

RESEARCH FIRST STEPS

Our protocol navigators are available to help you start the process and assist you with your submission. To make an appointment with a protocol navigator, please call the Department of Research Programs (DRP) office at 301-295-8239. DRP is located in Building 17B, on the third floor, to the left of the elevators.

RESEARCH ROUNDTABLE SCHEDULE

**Walter Reed National Military Medical Center
America Building (Building 19), Second floor, Room 2301**

- ◆ Tuesday, Feb. 21, 1200-1300
- ◆ Tuesday, March 21, 1200-1300
- ◆ Tuesday, April 18, 1200-1300

Did you miss the last roundtable on responsible conduct of research? Please see story and a preview of our next presentation about research ethics by chemist David Evers on page 6.

EIRB TIP OF THE MONTH Sorting Roles and Regulations

Wondering how to expand your research team and stay within the letter of Defense Department regulations? Add a new team member – such as an associate investigator or research coordinator – by submitting a Modification Submission Form to the Institutional Review Board (IRB) through its electronic system, EIRB. The IRB must approve this change, before the team member can participate in study-related procedures.

However, it's easier to add a study contact, who has read-only access to the protocol. You may fold a contact into your team at any point, without making a submission to the IRB in the EIRB. Please note that the study contact cannot make submissions on behalf of the principal investigator.

If you have found a great shortcut for working in EIRB, we'd love to hear about it. Please send your solution to paula.m.amann.ctr@mail.mil. We will route it to your friendly, local IRB office.

Thanks again for your patience during the transition to EIRB. Meanwhile, our best wishes for a great month of research.



DEPARTMENT ANNOUNCEMENTS

Kick-start set for research projects

Starting March 1, investigators will no longer have to wait for a separate start letter from the command. The start letter from the Institutional Review Board will clearly state what needs to be done and verified before the launch of a new research project.

Poster orders due Feb. 27, Florentino deadline held till Feb. 21

Sent your abstract for Research and Innovation Month? Share your findings with colleagues and patients: Plan a poster. And if patient- and family-centered care is your passion, you can still submit an abstract for the Paul Florentino Award till Feb. 21 at noon.

For posters, please send the Medical Graphic Arts Department (MGAD) four items by Feb. 27: a poster draft, a work order form for MGAD, the Instructions for Permission form for the Bureau of Medicine and Surgery (BUMED), and a Health Insurance Portability and Accountability Act (HIPAA) Privacy Release form. Points of contact are Mary-Ann Ayrandjian (mary-ann.ayrandjian.civ@mail.mil) and Shane Stiefel (shane.m.stiefel.civ@mail.mil).

To find forms or apply, visit <https://www.wrmmmc.capmed.mil/ResearchEducation/ResearchPrograms/SitePages/Home.aspx>. Next May 1-5, the Arrowhead Zone will be bursting with posters Will one be yours? And might you win the Florentino Award this year?

Symposium calls for abstracts

Each year, military medical care providers, scientists, scholars, and industry professionals swap information on research and health care at the Military Health Systems Research Symposium. Organizers are still determining time and place of this year's meeting, but they are accepting abstracts through March 6.

The 2017 symposium will offer more than 60 scientific breakout sessions, including new topics such as prolonged field care and knowledge translation. In-depth "tract sessions" will cover issues such as global health and environmental exposure monitoring. In addition, an entire plenary session will spotlight research by young investigators.

Details appear on the event's website: <https://mhsrs.amedd.army.mil/SitePages/Home.aspx>.

Proposals sought for telemedicine, high-tech projects

The Telemedicine and Advanced Technology Research Center (TATRC), at Fort Detrick, Md., is seeking proposals for its Advanced Medical Technology Initiative (AAMTI) for fiscal year 2018. Proposals must seek to identify, explore or demonstrate innovative technologies and processes required to overcome technological barriers unique to military medicine.

Preproposal submissions are due between now and April 12, with full proposals accepted June 21-July 28 and awards announced Sept. 30. All projects require local Commander and Information Management Division concurrence to confirm support. Projects may also require Institutional Review Board approval if they require human or animal use.

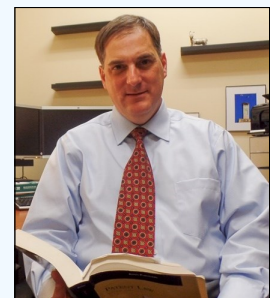
Questions? Contact Holly Pavliscsak, program manager, AAMTI, Telemedicine and Advanced Technology Research Center, 240-566-2378, holly.h.pavliscsak.ctr@mail.mil. Or visit <http://www.tatrc.org/www/labs-and-programs/aamti/>

Business Cell gets new leader

There's a familiar face in a novel role in the Department of Research Programs. Martin J. Hindel, who joined the department last spring as medical research attorney, is now serving as interim chief of the Business Cell.

When a researcher finds a prospective partner, this office drafts a contract known as a cooperative research and development agreement (CRADA) or a material transfer agreement (MTA). To start the process, the researcher fills out an Agreement Request Form. Find this form on the department's intranet (EIRB forms and Templates/ Documents for Researchers). Email completed forms to Hindel: martin.j.hindel.civ@mail.mil.

The business staff initiates and negotiates all agreements with outside parties. Both parties then sign the final negotiated agreement. Signature authority rests with the director of Education, Training and Research or the chief of staff for the medical center.



Martin J. Hindel,
interim chief of the
Business Cell (Photo
by Paula Amann)



POST-APPROVAL COMPLIANCE MONITORING: HOT TOPIC

Regulatory Binders for Clinical Research: Frequently Asked Questions

by Diane Beaner

1. What is a regulatory binder, and why do I need one?

The term “regulatory binder” refers to the place where regulatory documentation on your study is stored and updated. *It's not necessarily one place or even a binder.* A physical binder containing regulatory information is ideal and preferred. However there is no requirement to have all of your regulatory information in any specific order or organized in a binder.

A key point: Documentation showing appropriate study conduct is required for any study. Please note: Studies conducted under regulations of the U.S. Food and Drug Administration (FDA) may have other requirements.

A comprehensive regulatory binder displays evidence that researchers adhered to their responsibilities under federal laws and guidance for conduct of human subjects research. When it comes to documenting your research, keep this saying in mind: “If it’s not documented, it didn’t happen.”

2. If my study is not a drug or device study, or if my study is not conducted under regulations for an investigational new drug (IND) or investigational device exemption (IDE), do I still need to have a regulatory binder?

If your study is not a drug or device study, it will still be useful to pick and choose those components of the regulatory files that do pertain to your study. Much of the documentation required by FDA and International Conference on Harmonisation Good Clinical Practice (ICH GCP), are similar. Examples include all approved versions of informed consent documents and protocols, case report forms, study staff logs and enrollment logs.

Walter Reed Bethesda expects you to conduct your clinical research to the highest ethical and clinical standards. Compliance with ICH GCP helps ensure compliance with regulations from the Office of Human Research Protection and FDA, as well as ethical standards guiding clinical research. Your documentation provides validation that you are conducting the study to these standards.

3. Do I have to keep documentation of all previous approved versions of sponsor protocols, site protocols, investigator brochures, etc.? This binder could get pretty large!

Yes, you should maintain these materials, which demonstrate how the study was conducted. However, you may decide to file certain older documents outside of the main regulatory binder, in secondary binders. Also, you might scan and archive some documents in an electronic file folder for access as needed. (Be sure the study sponsor approves this process.)

If you keep any materials outside of the binder, it is helpful to document where they are and how to find them. You can use an Essential Documents Log to do this. Likewise, you may maintain centrally some information, such as investigator and staff curricula vitae and CITI training information, especially when staff members are working on more than one study. As stated before, be sure the sponsor approves this process in advance.

4. Where can I find a list of all the required essential documentation for a research study?

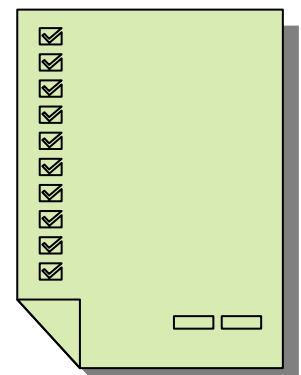
The ICH GCP guidelines provide a more specific list of documents that will help you meet FDA requirements. You can also contact DRP’s research compliance staff, who can provide a list of essential study documents.

5. Should any documentation be maintained outside of the regulatory binder?

Yes. Per ICH GCP 8.3.21, you should keep a confidential list of all participants who are enrolled in a trial, including names of the individuals linked to participant ID numbers. This type of document should not be kept in the regulatory binder. Separate it from participant-specific files by putting it in another secure location, such as in a locked file in a locked office.

Keep participant-specific source documents and case report forms in participant files. Keep signed consent forms in the participant files or collectively in a separate location. Store financial documents separately. □

In case of questions about regulatory binders, researchers may contact Diane Beaner, quality assurance and research compliance officer in the Department of Research Programs, at Diane.M.Beaner.civ@mail.mil or 301-295-8226.



DIAGNOSTIC FRONTIER, from page 1

Meanwhile, magnetic resonance imaging (MRI) also carries downsides for patients and health care providers.

“MRIs are slow, time-consuming and costly,” noted Smith, “and there’s a subset of people who cannot get them, due to new or prior injuries with metallic fragments.”

In fact, the machine’s magnetism can dislodge metal such as shrapnel inside the human body, potentially causing further injury, note the doctors.

But Miller and Smith believe they have found a tool that can supplement, even surpass other diagnostic methods: high-resolution ultrasound.

Ultrasound’s potential has emerged in just the past five to 10 years, Miller says. As makers of ultrasound machines have refined them, these advances have helped clinicians see vastly more than before.

“I can look at the entire course of the nerve, from hand to shoulder, in 15 to 30 seconds,” Smith said, contrasting these results with the 30 to 60 minutes needed for an MRI exam, which the patient might need to repeat several times to capture all segments of the nerve.

With increased resolution in recent years, ultrasound can not only deliver diagnosis, but also assess long-term chances of recovery.

“Ultrasound is so good now that we can look at the internal architecture of nerves and predict how they may recover,” Miller said. He noted that doctors now can use the tests not only to locate damage, but to gauge outcomes of surgery.

Meanwhile, early detection and treatment of nerve injuries can have a big impact on overall healing. Ideally, neurologists have a six-month window in which to best repair the damage.

“Once the nerve is injured, the muscle can atrophy,” Miller said. “You’re racing the clock.”

As ultrasound emerges as a tool for detecting combat damage to peripheral nerves, the technology can also diagnose another common yet sometimes crippling impairment: carpal tunnel syndrome.

To that end, investigators from Walter Reed Bethesda and Stanford University are developing a systematic way of using ultrasound to discern the syndrome.



Army Maj. Dr. Yin-Ting Chen, a sports medicine specialist in rehabilitation and physical medicine at Walter Reed Bethesda, led creation of an ultrasound protocol for diagnosing carpal tunnel syndrome. The syndrome is to blame for 9 in 10 cases of compressive, peripheral nerve damage. (Official photo)

Last year, the team published “Review of Ultrasonography in the Diagnosis of Carpal Tunnel Syndrome and a Proposed Scanning Protocol” in the *Journal of Ultrasound Medicine*.

Army Maj. Dr. Yin-Ting Chen, a sports medicine specialist in physical medicine and rehabilitation at Walter Reed Bethesda and the study’s lead author, says an ultrasound protocol for carpal tunnel syndrome is overdue. Although ultrasound works well for diagnosing the syndrome, he said, its use varies widely and requires much practice by clinicians.

The formal protocol for this technology developed by his team, Chen believes, would help doctors detect this syndrome among their patients.

Another traditional tool, electrodiagnosis, entails shocks and needle sticks, which are “time-consuming, invasive and uncomfortable” for patients, he says.

This older form of assessment also misses the 1 in 10 cases of carpal tunnel syndrome due to causes besides

See DIAGNOSTIC FRONTIER, page 7



The art of observation

How clinical exams can still help spot disease

by Paula Amann

Even as technology speeds diagnosis, the old-fashioned clinical examination is still yielding insights into disease. Take the tell-tale triceps.

Fresh fodder for the clinical approach comes in a December 2016 letter to the editor of the *Journal of Clinical Neuromuscular Disease*. In it, Carmina Domingo, a past resident at Walter Reed Bethesda; Dr. Mark Landau, a clinical neurophysiologist at the hospital; and Dr. William Campbell detail an observational study of myasthenia gravis, a chronic autoimmune disease.

The Myasthenia Gravis Foundation of America estimates that 20 out of 100,000 people in the United States have been diagnosed with the condition. However, the foundation suggests myasthenia is underdiagnosed and may actually be more prevalent.

“It can be a young person’s disease, especially among younger women,” said Landau, the study’s second author.

However, he notes that myasthenia gravis also targets people of both genders at all stages of life – from infancy to old age.

The condition commonly causes weakness in the muscles controlling the eyes, speech, swallowing, and the body core, notes the National Institute of Neurological Disorders and Stroke. Classic symptoms include a drooping eyelid, blurred vision, slurred speech, and trouble swallowing, according to the Myasthenia Gravis Foundation of America.

The group estimates that 20 out of 100,000 people in the United States have been diagnosed with the condition. However, the foundation suggests myasthenia is underdiagnosed and may actually be more prevalent.

Meanwhile, neurologists at Walter Reed Bethesda have found another warning sign of the disease: a weak triceps, despite an often otherwise fit body.

“People can assume that the weakness is due to stress or being out of shape, rather than recognizing it as a medical condition,” Landau said.

He and his colleagues think the triceps weakness could be a tipoff for neurologists and other clinicians as they examine patients.

“People can assume that the weakness is due to stress or being out of shape, rather than recognizing it as a medical condition.”

— Dr. Mark Landau

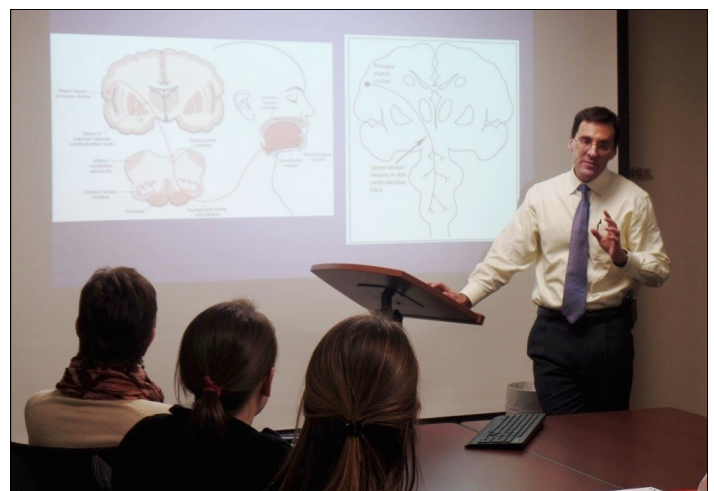
Triceps weakness among service members who are otherwise physically fit can signal myasthenia gravis, Landau notes.

“Make sure that you carefully examine this muscle and make sure it’s normal,” Landau said of the triceps. “If this muscle is weaker than other muscles, it raises the suspicion of this condition.”

It all goes back to the sometimes neglected roots of modern medicine, suggests

Landau: listening to patients and checking their symptoms for clues to disease.

Looking forward, he would like to see laboratory researchers explore the reasons why myasthenia gravis attacks certain muscles. And their efforts, in turn, could further stretch the limits of diagnosis. □



Dr. Mark Landau, a clinical neurophysiologist at Walter Reed Bethesda, describes dysphagia, a swallowing disorder, to the hospital’s speech pathologists on Feb. 2. Landau was second author on an observational study spotlighting how triceps weakness can signal myasthenia gravis, an autoimmune disorder. (Photo by Paula Amann)



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repetitive stress. These rarer cases may involve a ganglion cyst, intrusive muscle or tendonitis, for instance.

But as in cases of combat trauma, newer technologies offer a better picture of the wrist joint, without adding the pain of electrodiagnosis to an already inflamed area.

“Ultrasound always allows us to look for unconventional cases of carpal tunnel syndrome,” Chen said.

Now, Chen and his colleagues seek to help their field use ultrasound in a more accurate, consistent way. The key to their protocol is the delta, or change, between the cross-sectional area of a nerve that runs through the carpal tunnel to the thickness of that nerve higher in the arm.

“In carpal tunnel syndrome, the median nerve is swollen in the carpal tunnel and not in the forearm,” Chen explained, “and by subtracting the difference in cross-section, we can estimate the swelling and determine if the person has carpal tunnel syndrome.”

His team’s protocol recommends a cross-sectional area of greater than 14 square millimeters to “rule in” carpal tunnel syndrome.

Yet, that seemingly simple measurement is easier said than done. In fact, Chen cautioned that accurate use of ultrasound takes practice.

“The acceptance of this new technology really hinges on training,” Chen said. “Ultrasound can require a fairly steep learning curve. Our hope is that we will provide a tool to help clinicians with this.”

Over in orthopedics, other researchers are using a different diagnostic tool to screen back surgery patients for weak bones. The team has included orthopedist, Navy Lt. Cmdr. Dr. Scott C. Wagner; Army Capt. Dr. Peter M. Formby, an orthopedic resident, along with two orthopedic surgeons, Dr. Melvin Helgeson, now of Reston, Va., and, Dr. Daniel G. Kang, who works at the Madigan Army Medical Center in Tacoma, Wash.

Their study, “Diagnosing the Undiagnosed: Osteoporosis in Patients Undergoing Lumbar Fusion,” appeared in a 2016 issue of Spine.

This research builds on work by lead author Wagner suggesting that computed tomography (CT) scans can predict osteoporosis. Osteoporosis, or porous bones, and osteopenia, low-density bones, afflict some 55 percent of people over the age of 50 in the United States, according

to the International Osteoporosis Foundation. These conditions are especially prevalent among post-menopausal women.

Wagner, an orthopedist, won a Bailey K. Ashford Award at Walter Reed

Bethesda last May for his discovered use of CT scans to screen for osteoporosis. He is now a Spine Fellow with the Rothman Institute at Jefferson and an instructor at Sidney Kimmel Medical College at Thomas Jefferson University, both in Philadelphia.

CT uses X-ray images taken from different angles, plus computer programming, to fashion cross-sections of body tissues, including bone.

Meanwhile, it’s still unclear if and how osteoporosis might affect the risks of lumbar fusion surgery. One study, says Formby, suggested increased rates of “nonunion” among patients with the condition. That preliminary result drove

‘Ultrasound can require a fairly steep learning curve.’

— Army Maj. Dr. Yin-Ting Chen

See **DIAGNOSTIC FRONTIER**, page 8



Bailey K. Ashford winner, Dr. Scott Wagner, now a Navy lieutenant commander, speaks on May 19, 2016 at Research Symposium II during Research and Innovation Month. His discovered use of computed tomography scans to screen for osteoporosis helped launch a study of undiagnosed osteoporosis in lumbar fusion patients. (Archival photo by John Fadoju)



RESEARCH ROUNDTABLE

A MESSAGE FROM THE HOST OF THE RESEARCH ROUNDTABLE

by Lisa Thompson

The Department of Research Programs (DRP) would like to offer a 10-15 minute presentation to your staff. Our talk ranges from DRP services to upcoming events and policy updates from the Office of the Under Secretary of Defense [(Personnel & Readiness and Research Regulatory Oversight Office (R202)], a review of the Minimum Education Requirements Framework (MERF) issued by the Office of the Assistant Secretary of Defense for Research and Engineering, and information on required Collaborative Institutional Training Initiative (CITI) training. We would like to join you once annually or every six months, before or after your program meets for didactic or lecture hall sessions.

Our goal is to promote research. We want to help familiarize your Graduate Medical Education (GME) trainees, faculty, and staff with DRP services to help them meet their research and scholarly project program requirements.

Our services include assistance with protocol development, courses on research methods, statistics, and grant writing, GME trainee research project funding opportunities, collaborative agreements development, manuscript editing, publication clearance, and bench research space through our Biomedical Research Laboratory.

DRP invites you to join us at the Research Roundtable on the third Tuesday of every month at noon. On Feb. 21, chemist David Evers will spotlight the values behind scientific inquiry, with an informal talk entitled, "Research Ethics: Great Moments in Military Human Subject Research Protections."

We invite you to present as well. If there is a pressing concern you would like addressed or if you would like to present material on a topic of your choice, please talk to me at the Research Roundtable or send an email to lisa.p.thompson5.civ@mail.mil. □



Lisa Thompson,
supervisory medical
education specialist
(Photo by subject)

DIAGNOSTIC FRONTIER, from page 7

Wagner, Formby and their team to explore this surgical question further. "That's why we wanted to look into this," Formby said.

Next on the research frontier for this team: Testing the predictive value of CT scans by other scanners at other hospitals.

In addition, Wagner, Formby and their team want to examine if patients with diagnosed osteoporosis and osteopenia have different surgical outcomes from others.

As they seek to learn more, Formby and his orthopedic colleagues at Walter Reed Bethesda have launched a new practice to improve patient safety.

"Anyone who comes in with a fragility fracture gets a CT scan of that extremity, and from that, we determine whether they need to be worked up further for osteoporosis," Formby said.

And computed tomography may have value in screening for weak bones prior to other surgeries besides lumbar fusion, Formby suggested.

"It's not just the spine you can use CT scans in; it's potentially other parts of the body," Formby said. □



HOMAGE TO A HOUSEKEEPER – Staff members of the Department of Research Programs pitched in to give a New Year's gift to Imelda Valdovinos. Every day, this housekeeper works hard to make the bathrooms shine in Building 17B. Army Sgt. Alisha Kohler, the noncommissioned officer in charge for the department, presented the gift to Valdovinos on Jan. 3 in front of the still-decorated holiday tree. Valdovinos expressed her thanks for the appreciation. (Photo by Paula Amann)



Training made plain Thompson takes the mystery out of online research modules

by Paula Amann

Among the many missions of the U.S. Defense Department, one has special relevance for the Walter Reed National Military Medical Center: the commitment to high-quality, ethical research.

That pledge, in turn, drives the training Walter Reed Bethesda asks of its researchers, stressed Lisa Thompson, the speaker at the Jan. 24 Research Roundtable.

Thompson serves as the academic research education coordinator for the Department of Research Programs. In this role, she directs training through the Collaborative Institutional Training Initiative, or CITI, as well as supplementary training mandated through the Minimum Education Requirements Framework (MERF).

Training starts with online modules through the Collaborative Institutional Training Initiative, or CITI. Successful passage of a course requires a score of 80 percent



Lisa Thompson clarifies training mandates at the Research Roundtable on Jan. 21. Thompson, the academic research education coordinator for the Department of Research Programs, manages training for the research community at Walter Reed Bethesda. (Photo by Paula Amann)

or more on the final quiz. The set of courses members of a research team must take depends on the roles they play, Thompson explained.

Staff involved with research must retake the appropriate CITI course sequence every three years, Thompson added.

Also, to meet the MERF, staff members must complete a four-hour interim training within the second year of being CITI certified.

Another form of training, the course of study to be a Certified Institutional Review Board Professional (CIP), exempts a research team member from CITI requirements.

For the principal investigator, CITI or CIP training is crucial not only for critical knowledge but for the legal conduct of a study.

‘The PI should never allow CITI training to lapse because their protocol can be suspended until they are CITI or CIP certified.’

—Lisa Thompson

“The PI should never allow CITI training to lapse because their protocol can be suspended until they are CITI or CIP certified,” Thompson said, adding that “the study can go on as long as the PI is compliant.”

If other research team members fail to meet CITI requirements, the study may still continue, Thompson explained. However, they will be suspended from the study until they are CITI or CIP certified again.

Of course, some research teams at Walter Reed Bethesda may be exempt from training requirements altogether, if they do not work with human subjects or if they partner with another institution that is exempt from training.

Since August 2014, training mandates come from the Office of the Under Secretary of Defense for Personnel and Readiness [OUSD (P & R)], through the Research Regulatory Oversight Office.

In turn, R2O2, as it’s dubbed, oversees the Human Research Protection Program not only at Walter Reed Bethesda, but also at Fort Belvoir Community Hospital and the Uniformed Services University of the Health Sciences, or USUHS.

That oversight, Thompson emphasized, mandates the same research training across all three institutions.

See ROUNDTABLE, page 10



ROUNDTABLE, from page 9

Common training means “you can go to USUHS and you won’t be doing something different than what we do here,” Thompson said.

Notably, researchers who have taken CITI courses at another federal agency will only take any other required courses here at Walter Reed Bethesda, but will not have to repeat training modules, Thompson stated in an email after her talk.

As for MERF, it also follows requirements set forth by OUSD (P & R), which tailors the kind and amount of training to one of 10 research roles played. These roles range from institutional officials and Institutional Review Board members to investigators, research support personnel, research monitors and coordinators.

For its part, the Institutional Review Board monitors MERF training when a principal investigator submits a protocol for determination and review.

At Walter Reed Bethesda, training oversight goes right to the top. Indeed, the hospital’s director, Army Col. Michael Heimall, serves as the institutional official who signs an assurance, a legal document affirming his staff has complied with relevant statutes, regulations and policies on protecting human subjects.

At Walter Reed Bethesda, training oversight goes right to the top.

Training is just one way in which OUSD (P & R) is harmonizing work across the military health systems it oversees, Thompson noted.

This office also manages the conduct of multisite studies, protocols, business processes and use of the electronic Institutional Review Board.

Looking ahead, Thompson said she expects to see new policy guidance on training for a key element of required training – responsible conduct of research – emerge early this year. □



TRAINING FOR RESEARCHERS

Ready for research? The Department of Research Programs has the right training for your role. We offer workshops for researchers working with human subjects:

- Collaborative Institutional Training Initiative (CITI)
- Minimum Educational Requirement Framework (MERF)

Arrange training for your department. Or join our monthly classes. We have only eight spaces per class, so sign up today!

Your Monthly Class Options

Find them all in Heroes Building (Building 5), fourth floor:

- February 13, 2-3 p.m., Computer Classroom 1 (4010)
- March 13, 2-3 p.m., Computer Classroom 2 (4011)
- April 10, 2-3 p.m., Computer Classroom 2 (4011)
- May 8, 2-3 p.m., Computer Classroom 2 (4011)

Questions? Please contact Ms. Lisa Thompson, supervisory research education specialist, at 301-295-8231 or lisa.p.thompson5.civ@mail.mil.



FACES OF RESEARCH

GOODBYE AND GOOD LUCK

January saw three staff departures from the Department of Research Programs, and another is set for this month. Jasleen Shant, the former chief of the Business Cell, left to do similar work at the Walter Reed Army Institute of Research.

“Dr. Shant has been integral to the creation of our Research Business Cell,” said Army Col. Ann Nayback-Beebe, the department’s deputy chief and chief of protocol development.

Nayback-Beebe credited Shant for establishing the Agreements Review Committee, which permits command-level review of all research-related agreements. The deputy chief also pointed to Shant’s tracking and invoicing of agreements and services from the Institutional Review Board. This system brings in funds to support Graduate Medical Education at Walter Reed Bethesda, Nayback-Beebe pointed out.

Michele McGee-Guthrie, a manager for the Institutional Review Board (IRB), also departed for a new job with the Veterans’ Affairs Administration after just over a year in the department.

“During the implementation of EIRB, she was forward-thinking and provided valuable insight and support as the Department of Research Programs underwent two recent audits,” Nayback-Beebe said. “We wish her the best of luck in her new position.”



Army Col. Ann Nayback-Beebe, the department’s deputy chief; Jasleen Shant; and Michele McGee-Guthrie share a light moment at the monthly staff meeting on Jan. 5. Nayback-Beebe paid tribute to the two veteran staff members as they prepared to leave for new jobs. (Photo by John Fadoju)



Elena Morris poses with Army Col. Peter Weina, chief of the Department of Research Programs, marking her four decades of service last October 6. (Archival photo by John Fadoju)

Without fanfare but with much appreciation, Elena Morris, a medical technologist with the Biomedical Research Laboratory, retired after more than 40 years of service. Back in October, Chief Peter Weina paid tribute to her long tenure with the military.

Elena Morris has been a quiet force within the Biomedical Research Lab,” Nayback-Beebe said. “She is a skilled medical laboratory technician who left her imprint on numerous research projects at Walter Reed Army Medical Center and Walter Reed Bethesda.”

Nayback-Beebe also lauded Morris’ “steadfast dedication to quality biomedical research and the education of staff and scientists alike.”

Laboratory to put his skills to work for the Smithsonian Institution in the District.

“Dr. Asher Newsome has shared his mass spectrometry expertise with the Biomedical Research Laboratory and Walter Reed Bethesda,” said Army Capt. Franz Frye. “We wish to thank him for the many contributions he has made.”



Asher Newsome (Photo by John Fadoju)



DARNALL MEDICAL LIBRARY

Research and Scholarly Communication Support

Lyubov Tmanova, DVM, MLIS, MS, informationist/biomedical research librarian, offers research support to Walter Reed Bethesda's biomedical community and helps integrate biomedical information into medicine to advance research and scholarly communication. She offers research-oriented classes on a quarterly basis. Individual and group consultations are available upon request.

Research and Scholarly Communication Classes ■ Building 5, Room 4011

FEBRUARY

Conducting Research: Process, Methods, and Design

Tuesday, Feb. 21, 12-1 p.m.

This workshop is centered on conducting research, particularly on developing the research question and hypothesis, literature analysis, research methods, study designs, data management, research integrity, and research management.

Research Data Management

Tuesday, Feb. 28, 12-1 p.m.

This workshop introduces data-driven research, research data management, and data management planning for grant proposals. The research data life cycle, including data collection, processing methods, and analysis of qualitative and quantitative data will be discussed.

MARCH

Writing Systematic Reviews

Thursday, March 16, 12-1 p.m.

This workshop provides an overview of the purpose, structure, components, and writing process of systematic reviews. Attendees will learn systematic reviews standards and guidelines, and explore working with librarians (details on Systematic Review Service page).

Preparing Your Manuscript for Publication

Tuesday, March 21, 12-1 p.m.

This workshop focuses on planning, writing, and submitting manuscripts for publication in biomedical journals. We take students through the publication process, journal selection, and authorship guidelines and standards. The workshop's writing section is centered on steps and tips for writing a compelling manuscript.

Designing a Compelling Scientific Presentation

Tuesday, March 28, 12-1 p.m.

This workshop will help you to structure and design your research presentation using the key elements of scientific presentation to communicate your research findings to your audience.

Contact: Lyubov Tmanova, DVM, MLIS, MS
Informationist / Biomedical Research Librarian
Darnall Medical Library, Building 1, Room 3458
Phone: 301-319-2475 ■ Email: lyubov.tmanova.civ@mail.mil



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WEB RESOURCES

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Education Materials

- [Belmont Report](#)

The Belmont Report provides "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" that is found in Code of Federal Regulations, 45 CFR part 46.

- [Comparison of FDA and HHS Regulations](#)

The FDA provides a chart comparing FDA's regulations for human subject protection with those of the Department of Health and Human Services.

- [The President's Council on Bioethics](#)

This web site provides useful references on ethical issues that arise from advances in biotechnology and biomedical sciences.

- [Clinical Trials.gov](#)

Clinical Trials is a service of the National Institutes of Health, provides free public access to a database of Federal and private studies taking place nationwide and provides information on clinical studies for a wide range of diseases and conditions.

- [HHS Office for Human Research Protections](#)

HHS OHRP provides assurances and IRB registration, education, policy guidance, and workshops.

- [HHS Office of Civil Rights](#)

HHS Office of Civil Rights provides guidance on the Health Insurance Portability and Accountability Act (HIPAA) and Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule).

- [MedlinePlus](#)

MedlinePlus provides medical research literature including full-text drug information and an illustrated medical encyclopedia.

- [Office for Human Research Protections \(OHRP\)](#)

OHRP Guidebook (1993) provides current and historical materials about human subject protection. Caution: this serve as a guide and some information is obsolete; however, some portions remain valid.

- [Federal Policy for the Protection of Human Subjects \('Common Rule'\)](#)

HHS provides information about HHS regulations, 45 CFR part 46 and four subparts a, b, c, and d.

- [Protocol Review](#)

HHS provides guidance for protocol development, use of IRB, and Expedited Review procedures and exemptions.

- [Informed Consent](#)

HHS provides informed consent requirements, guidance on the use of exculpatory language, legal obligation and penalties, documentation and changes to documentation.

- [Investigators](#)

HHS provides investigators guidance about emergency medical care and research.

- [Biological Material and Data](#)

HHS provides guidance and the law about research involving the use of biological material and data.

- [Vulnerable Populations](#)

HHS provides guidance for populations including prisoners, children, and HIV human subjects.

See RESOURCES, page 14



RESOURCES, from page 13

FDA Regulations

- [CFR – Code of Federal Regulations Title 21](#)
- [FDA Regulations Relating to Good Clinical Practice and Clinical Trials](#)
- [Preambles to GCP Regulations](#)
- [Electronic Records; Electronic Signatures \(21 CFR Part 11\)](#)
- [Regulatory Hearing Before the Food and Drug Administration \(21 CFR Part 16\)](#)
- [Protection of Human Subjects \(Informed Consent\) \(21 CFR Part 50\)](#)
- [Additional Safeguards for Children in Clinical Investigations of Food and Drug Administration-Regulated Products \(21 CFR Parts 50 and 56\)](#)
- [Informed Consent Elements \(21 CFR 50.25\(c\)\)](#)
- [Exception From General Requirements for Informed Consent \(21 CFR 50.23\(e\)\)](#)
- [Financial Disclosure by Clinical Investigators \(21 CFR Part 54\)⁸](#)
- [Institutional Review Boards \(21 CFR Part 56\)⁹](#)
- [FDA IRB Registration Rule \(21 CFR 56.106\)](#)
- [FDA IRB Registration Rule \(21 CFR 56.106\) \(printable PDF version\)](#)
- [Good Laboratory Practice for Nonclinical Laboratory Studies \(21 CFR Part 58\)](#)
- [Investigational New Drug Application \(21 CFR Part 312\)](#)
- [Foreign Clinical Trials not conducted under an IND \(21 CFR 312.120\)](#)
- [Expanded Access to Investigational Drugs for Treatment Use \(PDF - 216KB\)](#)
- [Charging for Investigational Drugs \(PDF - 204KB\)](#)
- [Form 1571 \(Investigational New Drug Application\)](#)
- [Form 1572 \(Statement of Investigator\)](#)
- [Applications for FDA Approval to Market a New Drug \(21 CFR Part 314\)](#)
- [Bioavailability and Bioequivalence Requirements \(21 CFR Part 320\)](#)
- [Applications for FDA Approval of a Biologic License \(21 CFR Part 601\)](#)
- [Investigational Device Exemptions \(21 CFR Part 812\)](#)
- [Premarket Approval of Medical Devices \(21 CFR Part 814\)](#)
- [Exception From General Requirements for Informed Consent \(21 CFR 50.23\(e\)\)](#)

Reporting Problems to the FDA

- [Reporting Complaints Related to FDA-Regulated Clinical Trials](#)
- [Mandatory IRB Reporting: FDA Contacts](#)
- [Clinical Trial Forms](#)



RECENT PUBLICATIONS

Courtesy of Darnall Medical Library

Find articles by authors at Walter Reed Bethesda in bold.

Alarcón A, **Morgan M**, Montgomery SP, et al. [Diagnosis and treatment of congenital chagas disease in a premature infant](#). *J Pediatric Infect Dis Soc*. 2016;5(4):e28-e31.

Aronson N, Herwaldt BL, Libman M, et al. [Diagnosis and treatment of leishmaniasis: clinical practice guidelines by the Infectious Diseases Society of America \(IDSA\) and the American Society of Tropical Medicine and Hygiene \(ASTMH\)](#). *Clin Infect Dis*. 2016;63(12):e202-e264. Walter Reed Bethesda author: **Weina P**

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Balazs GC, Hanley MG, Pavey GJ, Rue JP. [Military personnel sustaining Lisfranc injuries have high rates of disability separation](#). *J R Army Med Corps*. 2016 Dec 9. [Epub ahead of print]

Becker-Weidman DJ, Malhotra N, **Reilly DF**, Selvam N, Parker L, Nazarian LN. [Imaging surveillance in patients after a benign fine-needle aspiration biopsy of the thyroid: associated cost and incidence of subsequent cancer](#). *AJR Am J Roentgenol*. 2016 Dec 8:1-4. [Epub ahead of print]
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Davila CJ, Schmidt AH. [Extremity war injuries XI: maintaining force readiness during an era of military transition](#). *J Am Acad Orthop Surg*. 2016;24(12):e202-e214.

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Healy MW, Yamasaki M, Patounakis G, et al. [The slow growing embryo and premature progesterone elevation: compounding factors for embryo-uterine asynchrony](#). *Hum Reprod*. 2016 Dec 16. [Epub ahead of print] Additional Walter Reed Bethesda author: **Hill MJ**

See PUBLICATIONS, page 16



PUBLICATIONS, from page 15

- Hendershot BD, Mahon CE, Pruziner AL. [A comparison of kinematic-based gait event detection methods in a self-paced treadmill application](#). *J Biomech*. 2016;49(16):4146-4149.
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*Walter Reed National Military Medical Center
Department of Research Programs*

TRAINING FOR ELECTRONIC INSTITUTIONAL REVIEW BOARD (EIRB)

QUESTION AND ANSWER SESSIONS

Time slot: Mondays 1200–1300

Month	Dates <i>Radiology Conference Room B015, Building 19, Basement</i>
February	13 27
March	6 13 20 27
April	3 10 17 24
May	1 8 15 22



*The Department of Research Programs at
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2017 RESEARCH AND INNOVATION MONTH

Be a research hero — and more.

IMPORTANT DATES

Call for Abstracts

☐ **01–30 January (abstract submission deadline: 30 January)**

All staff, faculty and trainees in all disciplines register for a research or non-research competition by sending their abstracts and related forms in a single email to dha.bethesda.wrnmcc.mbx.researchandinnovationmonth@mail.mil.

Poster Production

☐ **01–27 February (poster draft submission deadline: 27 February)**

All participants must submit a poster draft to the Medical Graphic Arts Department (MGAD). Points of contact are Mary-Ann Ayrandjian (mary-ann.ayrandjian.civ@mail.mil) and Shane Stiefel (shane.m.stiefel.civ@mail.mil).

Poster Display Week

☐ **01–05 May**

All competition participants display their research posters in the Mezzanine Center, East, and West Wings of Building 9. Posters based on Unity of Effort will carry its logo in the upper right corner. Unity of Effort reflects the partnerships among Walter Reed National Military Medical Center (Walter Reed Bethesda) and its neighbors, the Uniformed Services University of the Health Sciences and the National Institutes of Health.

☐ **03 May – Poster Competition I (Case Reports, Evidence-Based Practice, and Quality Improvement)**

Finalists from non-research competition categories present their posters to judges in Building 9, East Wing. Award ribbons will be pinned next to the winning posters of each research competition category.

☐ **04 May – Poster Competition II (Paul Florentino Patient and Family-Centered Care)**

Quality improvement participants in this category will present their project posters for first, second, and third prizes in Building 9.

Research Symposia I and II

☐ **09–10 May**

Finalists for the Bailey K. Ashford and Robert A. Phillips research awards present slides on their work before judges in Memorial Auditorium, Building 2, third floor. Winners receive certificates and medallions. Also, winners of Poster Competitions I and II will present.

5th Annual Aware for All

☐ **16 May**

Aware for All aims to help the public make informed decisions about clinical research participation through speakers and display tables. Research teams at Walter Reed Bethesda and groups from the National Capital Region showcase their work in the lobby of Building 19.

Spring Research Summit

☐ **24 May**

Research-related groups present slides, share information, and network about their work at Memorial Auditorium, Building 2, third floor.

***For details on Research and Innovation Month, contact the Department of Research Programs:
dha.bethesda.wrnmcc.mbx.researchandinnovationmonth@mail.mil***

