

# Military Medical Research News

Vol. 3, Issue 11 • December 2016

## Research Day orients more than residents Daylong educational immersion draws varied crowd

by Paula Amann



**Audience members at Residents' Research Day on Nov. 14 take in one of 15 short sessions during the daylong event, hosted by the Department of Research Programs. Participants earned 7.5 continuing education credits.**

Research starts with a question. How can medical teams better predict risk for wrist fractures? Are surgeons missing ischemia, or lack of blood flow, in tissue transplant patients with dark brown skin? How does hearing loss affect the way service members perform in ground combat?

Questions like these have launched investigations by hospital residents and others at Walter Reed National Military Medical Center. In fact, questions are the spark that ignites research, and with it, new knowledge, suggested Lyubov Tmanova, an informationist and biomedical research librarian at Darnell Medical Library, in remarks at Residents' Research Day on Nov. 14.

“Curiosity will drive you to develop a good question, which will help you get funding and publication,” said Tmanova.

The librarian was among 15 speakers who gave “mini-workshops” to some 50 people who attended at least part of

the day's program. Participants walked away with 7.5 credits of continuing education.

Beyond the urge to explore knowledge, research can help build a career in medicine and related fields. “It really does create opportunities,” said Army Lt. Col. Joshua D. Hartzell, a hospital internist, in the program's opening session, dubbed Research 101.

**See RESEARCH DAY, page 4**



**TROPICAL TRIBUTE – Army Col. Peter Weina, chief of the Department of Research Programs and a specialist in tropical infectious diseases, admires a plaque given to him by department leaders in honor of his 40 years of Army service. The department's non-commissioned officer in charge, Army Sgt. Alisha Kohler, presented him with the plaque before assembled staff on Nov. 22. Army Sgt. 1st Class Michael Moe and others crafted the memento out of Honduran wood. (Photos by Paula Amann)**



# 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](mailto: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, third floor, to the left of elevators.

## RESEARCH ROUNDTABLE SCHEDULE

### Walter Reed National Military Medical Center

**America Building (Building 19), Second floor, Room 2301**

- ◆ Tuesday, Dec. 20, 1200-1300
- ◆ Tuesday, Jan. 24, 1200-1300
- ◆ Tuesday, Feb. 21, 1200-1300
- ◆ Tuesday, March 21, 1200-1300

Did you miss the last roundtable on second-level review by the Defense Health Agency? Please see story and a preview of our next presentation on page 8.

## EIRB TIP OF THE MONTH

### Addition Made Easy

Found a hitch when adding data to a form in the electronic Institutional Review Board (EIRB)? Let's say you need to update the number of human subjects you enrolled, with separate figures for your control and experimental groups. Yet, the EIRB seems to lack a place for that laudable level of detail.

Here's our fix: Add a separate document. Go to section 9.0, labeled "Attach Documents." Add a New Document, filling in the title, description and any relevant comments. Then, presto, upload that document with your new totals for subjects recruited.

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](mailto: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 success in your research.

## CORRECTIONS

In the photo caption on page 3 of November's issue, we omitted the name of Lt. Gen. Nadja Y. West, surgeon general of the United States Army and commanding general, U.S. Army Medical Command.



## Review board plugs broader literature searches IRB leaders: Researchers should cast a wide net for continuing review

Gearing up for continuing review of your research protocol? You will need to do a thorough literature search in advance, say members and staff of the Institutional Review Board (IRB) at Walter Reed National Military Medical Center.

A cursory check of related research may not turn up a crucial development in the field that could have a bearing on continuing review, stresses Robert Roogow, IRB director of operations.

In an interview, he presented three potential scenarios, among many that could arise in the course of a multi-year investigation. First, another research team could have completed the same project at another institution. Also of concern, other investigators could have unearthed more risks to human subjects that were unknown before.

**'PubMed ... only covers a small amount of the biomedical literature'**

*— Kimberly Adams, director of the Darnall Medical Library*

Finally, new data could suggest the need for changes in the protocol and the consent form.

To capture these scenarios and more, researchers should check the full range of databases available at the Darnall Medical Library, contends its director, Kimberly Adams, who also serves on the IRB.

“While PubMed is the most popular search tool, it only covers a small amount of the biomedical literature, and it does not cover conference proceedings, meeting abstracts or poster sessions, where many new research findings are presented,” she wrote in an email to Roogow.

Adams counsels researchers to consult with a Darnall librarian, who can guide them to other online tools such as Web of Science, Embase and many more resources. □

*— Paula Amann, adapted from material by Kimberly Adams*

*The mention in this newsletter of products or services does not constitute an intended or implied endorsement by the U.S. Department of Defense .*

## DEPARTMENT OF RESEARCH PROGRAMS ANNOUNCEMENTS

### Competition deadlines near

It's time to start planning for 2017 Research and Innovation Month. This year the Department of Research Programs (DRP) is sponsoring six different competitions. Abstracts are due by January 30.

Next May 1-5, the Arrowhead Zone will be bursting with posters – from research and case reports to quality improvement, evidence-based practice, and family- and patient- centered care. Will one of those posters be yours? And will you be a finalist or winner in an expanded field of competitions?

Be a research hero – and more. Please join us for all the events of Research and Innovation Month. For more on key dates, competition rules, categories and application, please see back cover or go to DRP's SharePoint site (see details below).

### SharePoint secrets

Have you visited the DRP Intranet site recently? This SharePoint site is your one-stop shop for the latest research announcements and more. Check out our rotating banner, staff directory, calendar, competition details, past newsletters and more.

On the Walter Reed Intranet Site Homepage, under Quick Links, click Education Training and Research under Directorates. Then click on Research. Or click on this link: <https://www.wrnmcc.intranet.capmed.mil/EducationTrainingResearch/ResearchProgramsDepartment/SitePages/Home.aspx>.





## RESEARCH DAY, from page 1

Getting one's name on a study can yield invitations to review the work of others, speaking slots at conferences and, ultimately, national recognition, Hartzell explained.

Although Residents' Research Day takes its name from medical trainees, the annual event is open to staff, fellows, and interns – as well as nurses, dentists, and those in allied health fields (physical therapy, social work, and the like). This year's audience ranged from residents to medical students and nurses.

Traci Carter, a diabetes nurse educator, sat near the front of the auditorium for the entire program. In her job, Carter said, she works with endocrinology fellows on both quality improvement and research projects.

"Sometimes, I admit, it feels like we're speaking different languages," said Carter, who won a quality improvement award in last May's poster competitions at Walter Reed Bethesda. "I thought this would be a good way to understand the terminology of research."

Carter and the other attendees heard from presenters on a broad array of topics, from the basics of research and statistics, to opportunities for funding and use of the Biomedical Research Laboratory.

### Groundwork for research

At Walter Reed Bethesda, research starts with training to ensure protection of human subjects through the Collaborative Institutional Training Initiative.



**Traci Carter, a diabetes nurse educator at Walter Reed Bethesda, opted to attend Residents' Research Day. On May 11 of this year, she presented an award-winning poster on quality improvement at Poster Display Week (Archival photo)**



**Lt. Col. Joshua Hartzell, an internist at Walter Reed Bethesda, led three of 15 sessions at this year's Residents' Research Day, including one on writing for publication. See highlights in sidebar on page 5. (Official photo)**

Also known as CITI, this online learning system offers modules on such topics as assessing risk, mentoring and plagiarism.

"You have to take the required courses" before starting any research, stressed Lisa Thompson, the supervisory medical education specialist at the Department of Research Programs and lead organizer of the day's program.

Speaking to the values and regulations that underpin research at Walter Reed Bethesda was Dr. Sanjur Brooks, program manager for human research protection. The Defense Department is one of 15 federal departments and agencies that subscribe to 45 CFR, subpart A, better known as the Common Rule, which governs the ethical treatment of human subjects in research.

Enforcement of these research ethics is the job of the Institutional Review Board, represented at the Research Day by Robert Roogow, director of IRB operations. IRB staff and researchers alike have been facing challenges as they seek to maneuver within the EIRB, a new online tracking system.

**See RESEARCH DAY, page 5**



# Landing a Journal Publication: Tips for the Novice Research Writer

In a session called “How to Get Published” at Residents’ Research Day, Army Lt. Col. Joshua D. Hartzell shared a host of tips on writing for research. His presentation drew from one prepared by a colleague, Dr. Fouad J. Moawad.

## **Pick the right place.**

In his session, Hartzell stressed the importance of finding a quiet place, free from interruptions, for writing up a research project. “Shut off your email, shut off your cell phone,” Hartzell said. “Find a place where you can work without interruption.”

## **Seek critique.**

Mentoring, suggested Hartzell, can keep researchers from repeating mistakes in their writing. “Find someone who’s a good writer and have them critique your work,” said Hartzell.

## **Gather in groups.**

Hartzell encourages novice research writers to meet with peers who share their interest in writing for journals. Reviewing someone else’s manuscript, he suggested, can help writers sharpen their own.

## **Time it right.**

Writing a journal article immediately after a presentation at a conference can be a winning approach, suggests Hartzell. Knowledge in biomedical fields is growing fast. A delay in publication could mean another researcher with similar findings lands their journal acceptance before yours, he suggested.

## **Aim for your audience.**

Would-be authors should keep their desired audience in mind, Hartzell counseled, and pitch their research to the readers of the journal targeted. “If you’re writing for an endoscopy journal, that’s a little different from writing for a general medical journal,” Hartzell said, illustrating his point.

## **Write to the field.**

Of all the sections of a research manuscript, from the abstract to the conclusion, one makes the biggest difference, suggested Hartzell: methods. Why this section? In science, knowledge advances when researchers can replicate the results of others, by following a similar or identical process. “You want someone to be able to read it, understand it, and duplicate it,” Hartzell said.

## **Hone your skills.**

Like other skills, writing takes practice, and plenty of practice can produce improvement. “This is really an acquired skill,” Hartzell said in his remarks. “You have to do it over and over, and you’ll get better over time.”

— *Paula Amann*

## **RESEARCH DAY, from page 4**

Both Brooks and Roogow acknowledged these limitations but encouraged investigators to stick with the system while problems are ironed out.

“The DHA [Defense Health Agency] is relying on Walter Reed, the flagship of the military medical system, to make sure EIRB works,” Roogow said.

For her part, Brooks urged researchers to contact the Tiger Team, a group of staff members from the Department of Research Programs, for help with EIRB glitches.

### **Numbers can shape design**

Beyond this high-tech platform, Robin Howard, the supervisory biostatistician and civilian deputy chief in the

Department of Research Programs, showed how statistics can shape research design.

Whether investigators are planning clinical trials, retrospective research or pilot studies, among a host of options, they will need to turn their results into numerical data, noted the veteran biostatistician.

“The moral of the story is: Call the statistician,” Howard suggested.

Howard flagged several pitfalls that sideline some novice or returning investigators. First among pitfalls is attrition:

## **RESEARCH DAY, page 6**



## RESEARCH DAY, from page 5

As many as 10 to 20 percent of the people recruited for a study might drop out. This potential falloff suggests researchers should draft a higher number of subjects than actually needed, Howard said.

Echoing the need to vet research numbers of all kinds was biostatistician Sorana Raiciulescu in a session on data sets. She noted that she and her colleagues can assist in planning sample size, data analysis, data collection methods, and even the data in manuscripts or presentations.

When meeting a biostatistician, she suggested, it's helpful for researchers to bring – or better, email in advance – the research protocol, early data, or articles on similar studies. “The earlier in the process, the better,” Raiciulescu said.

Outlining how to plan a research project was Deborah Kessler, a protocol development specialist. She pointed to a crucial step – after identifying a study population, a study site or sites, and methods: finding a set of other researchers with complementary skills.

Research is a team sport, Kessler emphasized.

Turning to scientific review, Wendy Bernstein, M.D., noted that problems tend to crop up in three sections of a research protocol: objectives, methods, and statistical analysis.

The endpoints and objectives are where a lot of people have a misfire,” Bernstein said.

She explained that primary endpoint is the measure used (e.g., hemoglobin levels after use of a new drug) to meet the primary objective.

Common snags in research include overly ambitious objectives, and primary endpoints that do not align with primary objectives, Bernstein noted. Other challenges arise when the methods section of

or when the methods fail to address the research question or objectives.

“It’s important when you design your methods that you set yourself up for success,” Bernstein said.

## The business side of research

On a practical note, Lisa Potts, the grant writer for the business office at the Department of Research Programs, counseled would-be researchers to persevere in their pursuit of financial support.



**Lisa Potts, grant writer for the Department of Research Programs, talks about funding opportunities. (Photos by Paula Amann)**

“Continue to apply if you’re not fortunate enough to receive funding the first time,” Potts said.

Potts emphasized that Graduate Medical Education trainees can receive up to \$7,500 a year for up to two years. A host of funding opportunities, she noted, regularly appear on the intranet of the Department of Research Programs.

Another staffer from the business office, technology transfer specialist Jelena Gvozdenovic-Jeremic briefed the audience on how to bring new devices and methods developed at Walter Reed Bethesda to the market.



**Dr. Wendy Bernstein, an expert on scientific review, points out pitfalls in the design of research projects.**

**See RESEARCH DAY, page 7**





## RESEARCH DAY, from page 6

In a bid to spur economic growth, Congress passed no less than 12 laws over 1980-86 to foster this kind of transfer. Collaborations may involve partners from business and academia, to the nonprofit sector and state and local government, Gvozdenovic noted.

Underlying all these partnerships is a legal tool known as a cooperative research and development agreement, commonly known as a CRADA. This kind of deal permits federal laboratories to exchange services, staff, materials or information with a nonfederal party – or to collaborate with such a party. Funding may or may not be part of the package, Gvozdenovic underscored.

### Research on the rise

Despite all the challenges of research, from the ethical and scientific to the practical and administrative, the number of studies conducted at Walter Reed Bethesda has more than doubled over the past five years, noted Howard in her own remarks.

In fiscal year 2011, researchers from the hospital's naval and army precursors authored just 214 scientific papers in the medical journals listed in PubMed, a leading database. Five years later, 476 such papers had been published, Howard said.

**'There wasn't one session that I didn't think was essential.'**

— *Traci Carter, a diabetes nurse educator at Walter Reed Bethesda who took part in Residents' Research Day on Nov. 14*

As a short course in research, Residents' Research Day worked well for many attendees, according to online evaluations.

In an interview a few days later, Carter, the diabetes nurse educator, reported that she was planning a staff in-service for her team to share what she had learned.

"I thought it was fabulous; it was just at the level I needed," Carter said of the program. "There wasn't one session that I didn't think was essential." □

## The (literature) reviews are in Using reviews to power your project

Before your research project is in full swing, consider a trip to the library, urged Sarah Cantrell, a clinical librarian at the Darnall Medical Library, a speaker at last month's Residents' Research Day.

"You want to start reviewing the literature as early in your research as possible," Cantrell said in her remarks.

A literature review can serve the investigator in several ways, Cantrell said. First, the review can help pinpoint existing gaps in knowledge worth exploring. On the other hand, it can locate landmark studies from the field under scrutiny. It can suggest promising techniques and methods that researcher can adapt for their own projects. And, importantly, it can identify other leading researchers.

Investigators can visit Darnall Library by simply going online to the website, but for the best results, Cantrell suggests enlisting the skills of a professional on staff.

"A librarian is your best friend in this process," Cantrell told the audience.

One trick is to develop a suite of related terms about the area in question. For example, a person delving into Lou Gehrig's disease might "harvest" a list of terms including amyotrophic lateral sclerosis, the medical name for the illness.

Cantrell advises avoiding acronyms – such as ALS, in this example – in favor of full references when using such databases as PubMed.

"PubMed hates acronyms," Cantrell said. "Spell them out."

Finally, this librarian recommends revisiting the literature review shortly before submitting a research paper for publication. That last check, she says, can alert an investigator to new findings in the field. □



# 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 on DRP services, 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.



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

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. On Dec. 20, we'll hear from Ann Hardy and Petrice Brown-Longenecker, human research protection officers with the National Institutes of Health (NIH). They'll discuss how to handle human subjects protection when applying for research grants at NIH.

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](mailto:lisa.p.thompson5.civ@mail.mil).



## Building a good defense Planning to meet Defense Department standards for research

by Paula Amann

Has your research vaulted the hurdle of approval by the Institutional Review Board, or IRB? If so, you might be looking toward second-level review by the Defense Health Agency.

Through its office of Human Research Protections Program (HRPP), the agency keeps an eye on research safety, gauging compliance with the so-called "Common Rule," as well as a host of regulations particular to the U.S. Department of Defense.

The Common Rule is the federal regulation for human research protections adopted by most federal departments and agencies that support and conduct research with human subjects.

At the Nov. 29 Research Roundtable, Erin Loos, a contractor with the Defense Health Agency Human Research Protections Program, at the Office of the Assistant Secretary of Defense for Health Affairs,

provided a road map for second-level review.

DoD Instruction 3216.02 mandates such reviews in certain circumstances. Most commonly, they are required when an investigator relies upon an IRB outside the military system for regulatory review and oversight.

In those cases, "Anything you would submit to your IRB, you should submit to your HRPP" for the second-level review, Loos said.

**See DEFENSE, page 8**



**Erin Loos, with the Defense Health Agency Human Research Protections Program, at the Office of the Assistant Secretary of Defense for Health Affairs, coaches researchers on regulations at November's Research Roundtable. (Photo by Paula Amann)**





## DAY, from page 8

These reviews serve to ensure the research complies with requirements unique to the Defense Department, and which IRBs outside the department might not know.

At Walter Reed National Military Medical Center, investigators should start with the Department of Research Programs.

“We are here to help you, not just to add another layer of paperwork,” Loos added.

Still, as noted earlier, the Defense Department has some specific rules for research. For example, the department requires that a research monitor be assigned to oversee any project of greater than minimal risk. □

## Making a list, checking it twice What belongs in your regulatory binder?

Consider collecting the documents listed here, as they apply to your clinical study, advises Erin Loos, a contractor with the Defense Health Agency Human Research Protection Program Support at the Office of the Assistant Secretary of Defense for Health Affairs. “Don’t just rely on your electronic records,” Loos said. “Make a binder.”

Army Col. Peter Weina, chief of the Department of Research Programs, reinforced her emphasis on keeping a binder. Over his career, Weina noted, he has seen the value of an easy-to-access, paper record of a research project to share with short-term staff or important visitors.

### Protocol and Amendments

- Log of protocol changes
- Institutional Review Board (IRB)-approved protocol, with signed principal investigator (PI) signature page
- IRB-approved blank Case Report Forms
- IRB-approved advertisements
- IRB-approved Participant Information Sheets
- IRB-approved protocol amendments

### Informed Consent Documents

- Log of Informed Consent versions
- IRB-approved Informed Consents

### IRB Documentation

- IRB Federal Assurance Number
- Updated IRB Roster
- IRB registration (optional)

### IRB Approvals and Correspondence

- IRB approval letters (e.g., protocol, protocol amendments, consent and assent documents, continuing review, advertisement or recruitment materials, investigator’s brochure, package insert)
- Original IRB application/submission
- Correspondence related to contingent approvals or stipulations
- IRB correspondence
- IRB annual renewals
- Interim and annual progress reports to the IRB

### Investigator Qualification Documentation

- Updated investigator and sub-investigator CVs (signed/dated within 2 years)
- A clinical (dental, medical, etc.) license for the PI and co-investigators, if licensed

### Clinical Investigator’s Brochure

- Clinical investigator’s brochure or
- Package insert; include labeling for approved medications

*Checklist from the Defense Health Agency*



# DEPARTMENT DOWNLOAD

## NEWS FROM THE DEPARTMENT OF RESEARCH PROGRAMS

November's monthly meeting of the Department of Research Programs (DRP) saw a staff departure. Navy Cmdr. Virginia Blackman, who served as chief of the Center for Nursing Science and Clinical Inquiry, said her farewells before moving to her new post on the faculty of the Daniel K. Inouye Graduate School of Nursing at the Uniformed Services University of the Health Sciences.

Army Col. Peter Weina, the DRP chief, presented Blackman with his congratulations and a photograph of the vaunted "Tower," the administrative building at Walter Reed Bethesda, signed by well-wishers.

The larger DRP family saw a pair of new arrivals this fall. Biostatistician Dan Brooks and his wife welcomed the birth of a baby, as did research education and events coordinator, John Fadoju and his wife.

For a different kind of passage, Weina marked his 40th anniversary of Army service, and Robin Howard, civilian deputy chief, presented him with a cake. The DRP chief also noted that he had been tapped to serve in the military for another two years. He took the helm of the department in June 2014.

In other news, Weina announced that DRP's campaign for staff recognition, I Save Lives, now moves from a monthly to a quarterly schedule.



**Army Col. Peter Weina, chief of the Department of Research Programs, congratulates Navy Cmdr. Virginia Blackman, who was chief of the Center for Nursing Science and Clinical Inquiry for close to two years. She has joined the graduate nursing faculty at the Uniformed Services University of the Health Sciences. (Photo by Paula Amann)**

### *Writing Rx*

### **Editorial Services**

### *Department of Research Programs*

- ★ *Got questions on usage, style or grammar?*
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# ▣ TRAINING FOR RESEARCHERS ▣

The Department of Research Programs works to promote research and protect human participants. We offer training workshops for researchers in two key areas:

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

The MERF workshop will help you and your research team learn policy guidelines, requirements for meeting the MERF, and training modules needed for your investigative roles.

## ▣ MERF AND CITI TRAINING ▣ WORKSHOP SCHEDULE

Join monthly workshops on MERF and CITI. Ms. Lisa Thompson, M.S.H.A., M.B.A., will share the latest policy guidance from the Research Regulatory Oversight Office within the Office of the Under Secretary of Defense for Personnel and Readiness (OUSD [P&R]). The workshop will cover the following vital areas:

- ▣ OUSD (P&R) Assurance for the Protection of Human Subjects
- ▣ Minimum Education Requirements Framework (MERF) for DoD Personnel involved In Human Subjects Research
- ▣ Collaborative Institutional Training Initiative (CITI): Role-based training for researchers who conduct, review or approve research with human subjects in compliance with the MERF standards set forth by the Assistant Secretary of Defense for Research and Engineering

You can arrange training in your department. Or join our monthly classes in the location listed below (eight seats are available).\* Please email or call to reserve your seat. Questions? Please contact Ms. Lisa Thompson at 301-295-8231 or [lisa.p.thompson5.civ@mail.mil](mailto:lisa.p.thompson5.civ@mail.mil).

### \* HEROES BUILDING, FOURTH FLOOR, ROOM 4011

- ▣ Tuesday, Dec. 13, 1400-1500

▣ YOU BELONG IN THE CITI. START TRAINING TODAY! ▣





# DARNALL MEDICAL LIBRARY

## Research and Scholarly Communication Support

Lyubov Tmanova, DVM, MLIS, MS, the informationist/biomedical research librarian, offers research support to the WRNMMC biomedical community and helps integrate biomedical information into medicine in order to advance research and scholarly communication. Research-oriented classes are offered on a quarterly basis. Individual and group consultations are available upon request.

### 2016 Research and Scholarly Communication Classes

#### DECEMBER

##### Research Data Management

Library: Darnall Medical Library

Location: Building 6, Room 1369

Instructor: Dr. Tmanova

When: Monday, 12-12-2016 at 13:00:00

This workshop introduces a concept of data-driven research, research data management, and data management planning for grant proposals. The research data life cycle, including data collection, data processing methods, and analysis of qualitative and quantitative data will be discussed. Attendees will become familiar with data submission standards and DoD biomedical research and data policy.

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](mailto:lyubov.tmanova.civ@mail.mil)

Website: [www.wrnmmlibguides.com/home/researchsupport](http://www.wrnmmlibguides.com/home/researchsupport)

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## RECENT PUBLICATIONS

### Courtesy of Darnall Medical Library

Find articles by authors at Walter Reed Bethesda in bold.

Abbara S, Blanke P, Maroules CD, et al. [SCCT guidelines for the performance and acquisition of coronary computed tomographic angiography: a report of the society of Cardiovascular Computed Tomography Guidelines Committee: Endorsed by the North American Society for Cardiovascular Imaging \(NASCI\)](#). *J Cardiovasc Comput Tomogr*. 2016;10(6):435-449. Walter Reed Bethesda author:

**Villines T**

**Andrews AM**, Deehl C, Rogers RL, **Pruziner AL**. [Core temperature in service members with and without traumatic amputations during a prolonged endurance event](#). *Mil Med*. 2016;181(S4):61-65.

**Balazs GC**, **Dworak TC**, Tropf J, **Nanos GP 3rd**, **Tintle SM**. [Incidence and risk factors for volar wrist ganglia in the U.S. military and civilian populations](#). *J Hand Surg Am*. 2016;41(11):1064-1070.

**Bernstein JG**, Danielsson H, Hällgren M, Stenfelt S, Rönnerberg J, Lunner T. [Spectrotemporal modulation sensitivity as a predictor of speech-reception performance in noise with hearing aids](#). *Trends Hear*. 2016 Nov 4;20.?

See PUBLICATIONS, page 13



## PUBLICATIONS, from page 12

- Blakely WF, Romanyukha A, Hayes SM, et al. [U.S. Department of Defense multiple-parameter biodosimetry network](#). *Radiat Prot Dosimetry*. 2016 Nov 24. [Epub ahead of print] WALTER REED BETHESDA Author: **Reyes RA**
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# REGULATORY RESOURCES

*The appearance of external hyperlinks does not constitute endorsement by the U.S. Department of Defense of the linked web sites, or the information, products or services contained therein. For other than authorized activities such as military exchanges and Morale, Welfare and Recreation (MWR) sites, the U.S. Department of Defense does not exercise any editorial control over the information you may find at these locations.*

## 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](#)

*HHC 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.*

- [Protection of Human Subjects and Adherence to Ethical Standards](#)

*This instruction sets policy and responsibilities for the protection of human subjects in DoD-supported programs to implement part 219 of title 32, Code of Federal Regulations (the Common Rule) .*

- [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 16**



## RESOURCES, from page 15

### 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 \(21 CFR Part 54\)<sup>8</sup>](#)
- [Institutional Review Boards \(21 CFR Part 56\)<sup>9</sup>](#)
- [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](#)



*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***

<b>Month</b>	<b>Dates</b> <i>Radiology Conference Room B015, Building 19, Basement</i>
<b>December</b>	5   12   19
<b>January</b>	9   23   30
<b>February</b>	6   13   27
<b>March</b>	6   13   20   27





*The Department of Research Programs at  
Walter Reed National Military Medical Center presents*

## **2017 RESEARCH AND INNOVATION MONTH** *Be a research hero — and more.*

### **IMPORTANT DATES**

#### **Call for Abstracts**

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

Medical trainees, staff, and faculty 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](mailto: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](mailto:mary-ann.ayrandjian.civ@mail.mil)) and Shane Stiefel ([shane.m.stiefel.civ@mail.mil](mailto: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](mailto:dha.bethesda.wrnmcc.mbx.researchandinnovationmonth@mail.mil)**

