DEPARTMENT OF RESEARCH PROGRAMS
Walter Reed National Military Medical Center

Military Medical Research News

Vol. 4, Issue 8 ▪ August 2017

Researchers probe low back pain after limb loss

Studies of body mechanics and other factors hold promise for relief

by Paula Amann

In the Biomechanics Laboratory at Walter Reed National Military Medical Center, a team of researchers is on a quest for clues. A set of 18 infrared cameras mounted along the top of the walls track the movements of service members with limb loss, pulling data from electrodes placed on their abdominal and spinal muscles.

Living with amputation is challenging, so the researchers are striving to understand, and ultimately ease, some of its secondary effects. Service members who have come home with limb loss in recent years are in their 30s, on average, noted Brad Hendershot, a senior research biomedical engineer with the DoD-VA Extremity Trauma and Amputation Center of Excellence, and director of the Biomechanics Laboratory.

"Basically, they're going to be living with this limb loss for several decades," Hendershot said. "We need to identify [problems] and intervene now to stem secondary effects."

The secondary effects of lower limb amputation include cardiovascular disease, osteoarthritis and low back pain.

It might be a surprise to learn that low back pain is foremost among these complaints. Yet, several U.S. studies suggest that the incidence of low back pain among adults with limb loss is roughly double (52-76 percent) that among adults in the general population (33 percent).

Meanwhile, low back pain costs the country close to $100 billion annually, most of it linked to lost wages and reduced productivity, according to a 2006 study by J. N. Katz.

Around the globe, other medical research points to low back pain as a condition both common and impactful among patients with limb loss. A 2012 study from a New Zealand team led by Devan Hemakumar found 64.1 percent of 322 people with transfemoral, or above the knee, amputation reported low back pain and 39.1 percent reported that it curbed their physical activity.

Earlier, a 2009 study of 141 Iranian veterans with a single lower limb amputation found 76.6 percent suffering from low back pain, two decades and more after the Iran-Iraq

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Researchers at the DoD-VA Extremity Trauma and Amputation Center of Excellence at Walter Reed National Military Medical Center are working to keep service members and veterans with lower limb loss active and healthy for longer. Here a wounded warrior warms up before the Amputee Softball Team exhibition game at Nationals Stadium in Washington, D.C., April 3, 2012. (Archival photo/Defense Department)

Department of Research Programs

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

The Department of Research Programs at Walter Reed National Military Medical Center supports research in the National Capital Region.

This monthly newsletter covers events, research and administrative policies and procedures, research studies and collaborations, department operations, workshops and other programs across our region.

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Supervising editor
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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.

Not on our email list? Don't miss an issue! Please drop us an email, and we will add you to our distribution list.

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, August 22, 1200-1300
  "Strong Words: Power Tools for Research Writing"
- Tuesday, September 19, 1200-1300
  "Introduction to the Henry Jackson Foundation"
- Tuesday, October 17, 1200-1300
  Topic to be announced

EIRB Tip of the Month

The Details That Ensure Success

The secret of success in navigating the Electronic Institutional Review Board often lies in the details. For starters, make sure when you are completing an EIRB submission form that you answer every question. Do not leave blanks.

If you are uploading documents, either remove the version numbers and version dates from the headers of the document or ensure they are the same as the version numbers and dates in EIRB.

Please make sure there is a clean copy of the consent form in your submission if you need a stamped consent form. The IRB approval stamp will always be in the top left corner of the document. Make sure there is room in the top left corner for the stamp.

In addition, please avoid submitting recruitment materials in PowerPoint, as content may change when the EIRB turns the document into a PDF. Try whenever possible to submit documents in PDF or Word formats, if they need to be stamped. Kindly leave room in the top left corner of the recruitment material, as on the consent form. Thanks for your patience, and best of luck in your research.

Robert Roogow
Director, Institutional Review Board Operations

ANNOUNCEMENTS

Oversight for survey approvals changed

Planning a survey, focus group or interviews of 10 people or more across any Defense Department components? The approval process has changed slightly. Oversight has shifted from the Defense Manpower Data Center to the Office of People Analytics (OPA), following an update of DoD Instruction 1100.13.

Generally, DoDI 1100.13 requires approval for surveys of staff from more than one component of DoD or the Office of the Secretary of Defense, including service members, their spouses, family members eligible for DoD benefits, DoD civilians, service academy students and survivors of deceased service members. After approval, these surveys receive a Report Control Symbol (RCS), which is valid for 1 to 5 years. Clearance takes 4 to 6 months

The instruction also covers surveys of DoD staff requested by outside groups – from local governments to public organizations – as well as surveys of the public by any DoD or OSD component. The clearance process to collect data from the public may take 8 to 10 months or longer. At the end of the process, the Office of Management and Budget issues a number, with approval granted for up to 3 years.

Overall, the approval program seeks to reduce the cost of surveys, the burden on respondents and duplication while boosting the quality of results. The OPA will pinpoint any duplication with current collections and any issues related to DoD's Survey Burden Action Plan that might require changes to the planned collection. The information management control officer will help you decide if your collection requires licensure and guide you through the process.

Questions? Contact Kim Frazier, an information management control officer, at kim.l.frazier2.civ@dha.mil or 703-681-3636. Please note that the survey instruction is not a factor in approval of protocols by the Institutional Review Board of the Department of Research Programs.

September speakers to spotlight biomedical research

Brian S. Mittman, Ph.D., a research scientist at the Kaiser Permanente Department of Research and Evaluation, Division of Health Services Research and Implementation Science is visiting Walter Reed National Military Medical Center. Mittman will talk on implementation science and making research meaningful to policy makers from 12:30 to 1:30 p.m. on Sept. 7 in Memorial Auditorium at Walter Reed National Military Medical Center. His intended audience includes researchers, residents and staff associated with the Quality and Safety Working Group.

Mittman co-leads the UCLA Clinical and Translational Science Institute's Implementation and Improvement Science Initiative, and works with the U.S. Department of Veterans Affairs (voluntary role) and RAND Health Program. He chaired the planning committee that launched the journal, Implementation Science, and is now co-editor in chief emeritus.

He was a founding member of the Institute of Medicine Forum on the Science of Health Care Quality Improvement and Implementation, and past chair of the Special Emphasis Panel on Dissemination and Implementation Research in Health at the National Institutes of Health. He serves on the Association of American Medical Colleges Advisory Panel on Research, and on other advisory committees for research programs, projects and training institutes.

Later next month, **Shai D. Silberberg,** will speak on the topic, "Assuring a Bright Future for Biomedical Research." The lecture and discussion will take place from 2 to 3:30 p.m. on Sept. 25 in the Great Lakes Rooms 2525 A, B and C of Building 19, on the hospital's second floor.

Shai Silberberg (Photo courtesy of subject)

As the director of research quality at the National Institute of Neurological Disorders and Stroke, Silberberg leads the institute's efforts to increase the excellence of science and the completeness of research reporting. In addition, he is a program director at the institute with a focus on the molecular structure, function and regulation of ion channels and transporters.

Silberberg earned his doctorate in neurophysiology from the Hebrew University in Jerusalem. Before joining NINDS, he was an associate professor at Ben-Gurion University of the Negev in Israel, investigating the biophysical functions and physiological roles of various ion channels. ⊡

Balancing privacy, free flow of research data

Department issues new rules on sharing data outside hospital

by Paula Amann

With a quick click of a Send icon, any researcher at the Walter Reed National Military Medical Center can pass data to partners anywhere in the world, right? Not so fast.

Officials at the Department of Research Programs want to ensure that investigators first safeguard the interests of their research participants.

"You can't just send it [personal health data] via email," said Sanjur Brooks, the program manager for human research protections**.** "You have to handle it like a fragile baby."

Brooks pointed to encrypted email and secure databases as potential tools for safe sharing of personal health data.

The Health Insurance Portability and Accountability Act (HIPAA), passed in 1996, mandates the confidential, secure handling of protected health information, whether in paper, oral or electronic form. Moreover, only the minimum data needed to conduct business can be used or shared.

> 'You can't just send it [personal health data] via email. You have to handle it like a fragile baby.'
>
> — *Sanjur Brooks, program manager for human research protections*

"It essentially is a privacy issue, insuring that data collected at Walter Reed [Bethesda] is shared with collaborators according to HIPAA privacy rules," said Brooks.

With those concerns in mind, the department released an Aug. 1 policy memorandum on data-sharing agreements that will promote research and also protect its human subjects.

The memorandum sets forth four general rules on this area of research policy. First, researchers or their partners must submit a data-sharing agreement to the Department of Research Programs through the Electronic Institutional Review Board (EIRB). They can submit the agreement with their initial protocol application or with a modification form.

In the second phase of the process, a privacy board manager will conduct an administrative review of the data-sharing agreement. As part of this review, the manager will give the agreement a tracking number (the EIRB project number); verify the data flow, data-sharing procedures and storage described in the agreement; and verify the agreement's signers.

After the administrative review, the privacy board or designee for Walter Reed Bethesda will conduct a privacy review and approve submitted data-sharing agreements. Finally, after approval, the human protection administrator or designee will sign the data-sharing agreement on behalf of Walter Reed Bethesda.

Before executing such an agreement, researchers must hammer out a cooperative research and development agreement, or CRADA, with their outside partners. The Business Cell of the Department of Research Programs can help with that process.

As for the data-sharing agreement, it is not a "speed bump" on the road to research but rather a tool for "transparency," said Army Col. Peter J. Weina, chief of the Department of Research Programs.

Crafting such an agreement might seem like one more administrative chore, but it actually protects not just human subjects, but researchers as well, suggested Weina. In an era rife with fears of data theft, he said, the agreement can serve to assuage such fears and shine a bright light on medical research, so that all concerned parties grasp its intent.

"It assures the subject, the institution and any outside group that may be looking behind the curtain that we're doing this on the up and up, for the stated purpose," Weina explained. ▣

Danko, Gada move up leadership ladder, amid plaudits

by Paula Amann

In her two years as deputy director of Education, Training and Research (ETR), Navy Cmdr. (Dr.) Janine Danko built a reputation for making the best of every situation, said the directorate's director, Navy Cmdr. (Dr.) Robert Liotta.

Liotta presented Danko with that tribute, along with a commemorative paddle, at a Hail and Farewell observance on July 20.

At the observance, Liotta also bade adieu to Cmdr. Satyen Gada, former assistant chief in the Simulation Department who recently became chair of the Executive Committee of the Medical Staff. Liotta welcomed several other new staff members to the directorate.

As for Danko, her gift for wresting something good out of a challenge and building cordial bonds with her colleagues along the way likely helped win her a new job last month as deputy director of the Medicine Directorate.

"A true measure of success is when your coworkers truly miss you when you are gone, and I can honestly say that CDR Danko excels far beyond that level of accomplishment with me and our entire ETR Team," said Liotta, in a June 15 email announcing her departure.

Although they overlapped briefly at the ETR directorate, Liotta and Danko have been colleagues for many years. They both did their clinical internship in 2001 at what was then the National Naval Medical Center.

While Liotta was honing his skills in radiology, Danko was deepening her knowledge of infectious diseases, her chosen field of medicine.

Upon her arrival at Walter Reed Bethesda, Danko spent two years as chief of the Biomedical Research Laboratory (BRL) at the Department of Research Programs (DRP). Now after service in the research, training and education areas, she will turn to a new role, directorate in the hospital, with some 1,400 staff members. In an interview, Danko seemed to relish the chance to explore a new aspect of hospital administration.

"I'm going to be totally shifting gears, focusing on quality and patient safety initiatives, clinical productivity, access to care metrics, and helping the director execute the mission of meeting the medical needs of our beneficiaries," Danko said.

For his part, Army Col. Peter Weina, the chief of the Department of Research Programs, hailed her leadership, past and present.

"Cmdr. Danko was a valued and important member of the DRP team while working here in the BRL, and continued her support of DRP while deputy for ETR," Weina wrote. "We will miss her direct advocacy for DRP, but look forward to her continued support for DRP's mission and wish her well as she steps into the role as deputy for medicine." ⊡

From right, Navy Cmdr. Janine Danko, the new deputy director of the Medicine Directorate; Cmdr. Satyen Gada, the new president of the Medical Staff; Cmdr. Robert Liotta, director of Education, Training and Research; and Army Col. Clifton Yu, chief of Graduate Medical Education, chat after a Hail and Farewell observance on July 20. (Photo by John Fadoju)

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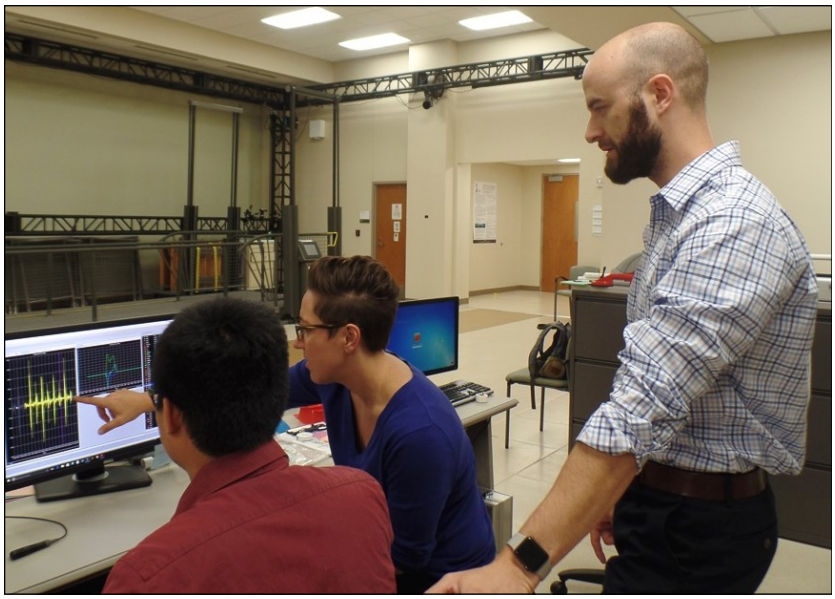
War that caused their injuries. Low back pain also played a role in poor health-related quality of life for these veterans.

Against this backdrop of research, Hendershot's team is probing the body mechanics that could provide insights into the physical causes and potential cures for the low back pain that attends lower limb loss.

"Postural control strategies differ among those with and without lower limb loss," said Hendershot. "Elevated or altered trunk muscular activity is correlated with risk for lower back pain."

In a 2015 study he coauthored with Erik J. Wolf, Hendershot found that people with transfemoral amputations walk with more mediolateral, or side-to-side, trunk movement than people without amputation. This movement pattern may raise the risk of low back pain.



In the Biomechanics Laboratory at Walter Reed National Military Medical Center, Courtney Butowicz, a postdoctoral researcher, points out data on electromyography, a measure of the electrical current passing through active muscles, as Julian Acasio, a biomedical engineer, left, and Bradford Hendershot, a senior research biomedical engineer and the lab's director, look on. (Photo by Paula Amann)

That combination of asymmetrical trunk movement with repetitive movement could be a key to the development of low back pain in people with amputation, suggested Hendershot.

"Back pain is such a multifactorial disorder," Hendershot said.

His team's work is taking place as military medical providers, like their civilian counterparts, are also seeking to stem the tide of opioid overuse.

"We want to avoid pharmacologic interventions," said Hendershot, explaining his emphasis on body mechanics.

> 'Basically, they're going to be living with this limb loss for several decades. We need to identify [problems] and intervene now to stem secondary effects.'
>
> *— Bradford Hendershot, senior research biomedical engineer and director of the Biomechanics Laboratory, DoD-VA Extremity Trauma and Amputation Center of Excellence*

In partnership with Shawn Farrokhi, the facility director of research at the DoD-VA Extremity Trauma and Amputation Center of Excellence in Greater San Diego, Hendershot is looking at psychosocial factors that may play a role in low back pain after limb loss.

Such factors might include marriage, divorce, unemployment and what Hendershot calls a mental habit of "catastrophizing," which might affect physical health. This effort might in time lead to "psychologically informed physical therapy," Hendershot said.

This is only one example of medical interventions that might one day ease the low back pain that plagues service members with amputations, suggested Christopher Dearth, Ph.D., research director of the DoD-VA Extremity Trauma and Amputation Center of Excellence at Walter Reed Bethesda.

"Ultimately, we want to intervene earlier and have a robust interactive paradigm that could mitigate these issues," said Dearth. "Only once we understand the pathology of diseases can [we] plan to treat them."

What's more, the partnership on psychosocial factors illustrates what it takes to do high-level medical research today, Dearth believes.

"It's really about going out to build that collaborative effort," said Dearth. "No one can do it in isolation." ⊡

RESEARCH ROUNDTABLE

A Message from the Host of the Research Roundtable

by Lisa Thompson

Lisa Thompson, academic research education specialist (Photo by subject)

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), and information on required Collaborative Institutional Training Initiative (CITI) training. We would like to join you 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 most months. Please rejoin us for the next roundtable on August 22, as **Paula Amann**, our News editor, shares "**Keeping It Clear: A Plain-Language Primer for Medical Researchers**."

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.

Researchers raise questions, get answers on compliance

Question-and-answer session revives original roundtable format

The room was full of questions when the post-approval compliance team presented at the Research Roundtable on July 18. How does a researcher write a note to file? When do you need a new Delegation of Authority Log? What patterns are emerging in research compliance?

Lea Olverson, a research compliance monitor, briefly shared "tools and tips" that can make a compliance audit go more smoothly. She spotlighted the Note to File (NTF), a document designed to explain an irregularity, give another document's location, or record a change of procedure.

After Olverson spoke, the format turned to discussion as research compliance officer, Diane Beaner, fielded questions from research coordinators present.

Diane Beaner, research compliance officer (Photo by subject)

Beaner flagged two areas that produce common mistakes during audits: disorganized regulatory binders and slips in the informed consent process. For instance, research teams sometimes have human subjects sign on the wrong line or use expired consent forms.

Beaner offered a simple fix for the binders that resonated for audience member Judith Travis, a research nurse coordinator at the Center for Prostate Disease Research. A simple table of contents can help auditors make sense of a research protocol, the compliance officer suggested.

The discussion also turned to handling the arrival of a new principal investigator in the Delegation of Authority Log. Such a change in leadership does not mean a brand-new log, Beaner stressed. However, it does require that the new investigator initial the existing log to note approval of the current research staff.

July's Research Roundtable represented a trial run for a new format for the series. Along with one formal presentation on a specific topic each month, the roundtable will host a question-and-answer session, or focus group, to address concerns among researchers at Walter Reed National Military Medical Center.

Travis applauded the new discussion format, a throwback to the original roundtable series she helped launch at Walter Reed Army Hospital several years ago. "How to do research and how to make our research better: That's how I see the purpose of the roundtable," Travis said. ⊡

—Paula Amann

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

Find it in Heroes Building (Building 5), fourth floor:

- Aug. 14, 2 p.m., Computer Classroom 1 (Room 4010)
- Sept. 13, 3 p.m., Computer Classroom 4 (Room 4031)
- Oct. 10, 2 p.m., Computer Classroom 1 (Room 4010)
- Nov. 14, 3 p.m., Computer Classroom 2 (Room 4011)

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

You belong in the CITI. Start training today!

Interested in data analysis?

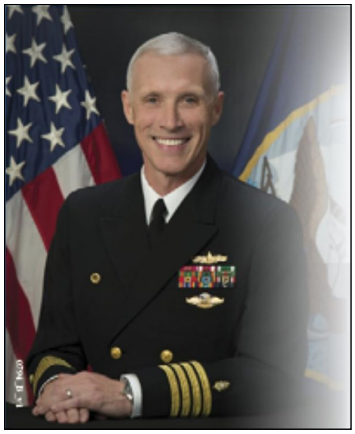
Let the biostatistics team at the Department of Research Programs help.
With two weeks' notice, we can lecture on many topics for you and five or more people:

- *Introduction to statistics (including types of variables, hypothesis testing)*
- *Sample size estimation*
- *Multiple comparisons between groups*
- *Confidence intervals*
- *Randomized clinical trials – the Consolidated Standards of Reporting Trials (CONSORT) checklist*
- *Clinical research design (including retrospective, prospective and case control)*
- *Diagnostic tests for sensitivity and specificity*
- *Estimating reliability between raters*
- *Odds ratios and relative risks*
- *Regression analysis*
- *Principal component analysis and factor analysis*
- *Introduction to Statistical Package for Social Sciences (SPSS)*
- *Analyzing with Excel (including pivot tables, row and column calculations, and graphing)*
- *New this year: Introduction to R (a statistical programming language)*

Got questions? Suggestions? Ready to schedule a class?

Contact Mr. Francois Tuamokumo at francois.tuamokumo.civ@mail.mil

DEPARTMENT DOWNLOAD
NEWS FROM THE DEPARTMENT OF RESEARCH PROGRAMS



Navy Capt. Mark Kobelja, the new director of Walter Reed National Military Medical Center (official photograph)

Army Col. Peter J. Weina used the monthly staff meeting on July 6 to hail the arrival of Navy Capt. Mark Kobelja, the new director of Walter Reed National Military Medical Center. Meanwhile, Weina is assuming the role of research integrity officer (RIO) for the hospital. Every research institution must now have its own RIO, who handles such issues as funding ethics and plagiarism.

Weina also noted the pending adoption of the Electronic Institutional Review Board (EIRB) across the Defense Department. On a local level, he also signaled a desire to move toward a single IRB with four panels for Naval Support Activity Bethesda. Currently, there are three IRBs at the hospital and one at the Uniformed Services University of the Health Sciences.

Weina has set new goals for the department. Its IRB is completing 350-400 protocol lifecycle actions a month in an average of 154 days to IRB approval for new protocols, with 90 days as the goal.

As for determinations, exempt determination officials are now turning them around in an average of department staff is now turning them around in an average of 36 days, with a goal for the coming year of three days, though two determinations officials will be departing soon. The department has training scheduled for September to train additional staff. Thirdly, Weina would like to see better marketing of the department.

> 'You're not supposed to have non-DEERS eligible people in military studies,'
>
> *— Army Col. Peter J. Weina, chief, Department of Research Programs*

Meanwhile, Martin Hindel, the department's research attorney, is working to clarify explanation of the policy on Defense Enrollment Eligibility Reporting System (DEERS), the database of people who are eligible for health care and other military benefits, as it relates to research participants.

As a rule, it is not permitted to provide military medical care to people outside DEERS, Weina stressed. Only service members, their family members and members of military reserve forces are eligible for such care, as may be provided in the course of research.

"You're not supposed to have non-DEERS eligible people in military studies," Weina said.

However, researchers may expand their pool of participants by partnering with outside hospitals, where non-DEERS patients can receive care, Weina suggested.

Meanwhile, Hindel is also working to better explain the 27 percent overhead for the hospital from industry-sponsored medical research at Walter Reed. Fort Belvoir Community Hospital will be following a similar course.

Within the department, policies on telework are in flux. Weina emphasized that staff members who are in leadership roles should limit their telework to one day a week. All those who do work from home must produce a list of tasks accomplished that day, Weina said.

Planning for the fiscal year 2018 is now underway. Weina lauded the work of research finance analyst, Patricia Asah, for revamping the accounting system so as to make the crafting of a new budget easier and more straightforward.

"You've done a wonderful job for us," Weina said. ⊡

Faces of Research

Arrival Gate

Freda Krosnick joins the Department of Research Programs as the new chief of the Business Cell, which oversees research funding, technology transfer, and related legal agreements with research partners outside Walter Reed National Military Medical Center. Krosnick brings over two decades of experience with government and technology transfer. In addition, Krosnick is a licensed patent attorney, and though she will not be serving in this capacity, she offers that perspective and knowledge.

Freda Krosnick, the new chief of the Business Cell (Photos by Paula Amann)

Krosnick earned her bachelor's degree in chemistry at the University of Maryland in College Park and her law degree at Catholic University of America in Washington, D.C. Most recently, Krosnick served as senior technology transfer officer at Walter Reed Army Institute of Research in Silver Spring. Before that, she briefly worked as a technology transfer specialist at Walter Reed Bethesda.

Earlier, Krosnick was a patent attorney and chief of the Intellectual Property Branch at the U.S. Army Research Laboratory. For some 16 years, she ran a solo practice in patent law. Krosnick said she is looking forward to working with everyone here and helping to support the important mission of military medical research.

Goodbye and Good Luck

Barbara "Bonnie" Bloomquist

Barbara "Bonnie" Bloomquist left the department on July 24, while voicing regret at missing the chance to see it blossom into a full directorate over the next year. Bloomquist, a quality assurance and research compliance auditor, will be working remotely for a specialty pharmaceutical sponsor headquartered in the United Kingdom, with the largest pipeline of addiction drugs in the world. This is a permanent position, and she expressed hope it would be her last one before setting her sights on retirement in ten years.

Bloomquist's new position will tap her education in neurology and behavioral health sciences and her experience working in all aspects of drug development, from the "bench to the bedside." As a certified quality auditor, she will oversee the U.S. audit program, work on cross-functional laboratory and manufacturing teams to support the quality management system, contribute to Six Sigma improvements, and evaluate compliance trends for management and stakeholder reporting. She invites her colleagues at Walter Reed Bethesda to keep in touch via LinkedIn. ⊡

DARNALL MEDICAL LIBRARY
Research and Scholarly Communication Support

Sarah Cantrell, Michele Mason-Coles, and Lyubov Tmanova, librarians, offer research support to Walter Reed Bethesda's biomedical community They lead research-oriented classes on a quarterly basis. Individual and group consultations are available upon request.

Research and Scholarly Communication Classes ▪ Building 5, Room 4011

Managing Reference Citations with EndNote (Web version)
Thursday, Aug. 10, 1 p.m. ▪ Building 1, Room 209
Instructor: Michele Mason-Coles

Develop basic skills in bibliographic management using EndNote Web citation manager. In this hands-on class, you will create an online account via the Darnall Medical Library and will create a reference library accessible anywhere, anytime. You will also collect citations from biomedical literature databases, organize references, generate and format bibliographies, share your library electronically with peers, and insert references into a Word document. You will also be briefly introduced to EndNote Desktop.

Writing Systematic Reviews
Wednesday, Aug. 16, 12 p.m. ▪ Building 1, Room 209
Instructor: Dr. Lyubov Tmanova

This lecture provides an overview of the purpose, structure, components, and writing process of systematic reviews. Attendees will become familiar with systematic review standards and guidelines and will explore opportunities for collaboration with librarians. Please see the Systematic Review Service page for details on collaboration opportunities with Darnall Medical Library librarians.

Research Data Management
Wednesday, Aug. 30, 12 p.m. ▪ Building 1, Room 209
Instructor: Dr. Lyubov Tmanova

This lecture 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, 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.

Designing a Compelling Scientific Presentation
Monday, Sept. 11, 12 p.m. ▪ Building 1, Room 209
Instructor: Dr. Lyubov Tmanova

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

Managing Reference Citations
Tuesday, Sept. 12, 12 p.m. ▪ Building 1, Room 209
Instructor: Dr. Lyubov Tmanova

This lecture will help you to develop basic skills in bibliographic management using EndNote standalone citation manager. Attendees will learn how to create a reference library, collect reference citations from various biomedical literature databases, organize references, generate and format bibliographies, share a library with peers, and connect with researchers.

PubMed
Thursday, Sept. 21, 1 p.m. ▪ Building 6, Room 1369
Instructor: Michele Mason-Coles

Discover the secrets of effectively searching PubMed (MEDLINE), the world's leading biomedical literature database! In this workshop, you will learn best practices of keyword searching, how PubMed interprets your searches, the role of Medical Subject Headings (MeSH), and how to craft an advanced search. Additionally, we will explore how to filter and refine search results, locate related citations, and find the full-text article.

Keeping Up with the Literature
Thursday, Sept. 28, 1 p.m. ▪ Building 6, Room 1369
Instructor: Sarah Cantrell

Keeping up with current biomedical research can be overwhelming. Imagine having one single list of articles from your favorite journals, newspapers, web sites, and blogs which you could peruse at your leisure. We will show you ways you can keep current by setting up search alerts and browsing your top journals in a mobile-friendly way. In just 45 minutes, you will learn all you need to know to get started!

RESEARCH POLICY RESOURCES

The appearance of external hyperlinks does not constitute endorsement by the U.S. Department of Defense of the linked websites, 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 Defense Department does not exercise any editorial control over the information you may find at these locations.

- 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 Trails 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.

- 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.***

- Vulnerable Populations

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

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)
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- Financial Disclosure by Clinical Investigators (21 CFR Part 54)[8]
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