DEPARTMENT OF RESEARCH PROGRAMS
Walter Reed National Military Medical Center

Military Medical Research News

Vol. 4, Issue 7 ▪ July 2017

Webinar series previews changes to Common Rule

First amendments to landmark regulation in a quarter century will alter 'exempt' categories, reporting and use of biospecimens

by Paula Amann

Policy makers have fine-tuned the federal rules on research, enshrined in a longstanding document called the Common Rule. On Jan. 19, 2018, the Department of Defense, the U.S. Department of Health and Human Services, and a dozen other federal agencies will start pivoting to new regulations on protecting human subjects.

"It was a needed revision," said Dr. Sanjur Brooks, program manager for human research protections at the Department of Research Programs at Walter Reed National Military Medical Center. She played an advisory role on the Notice of Proposed Rule Making for Title 45 Code of Federal Regulations, the official name of the Common Rule.

"You have to realize the landscape of research has changed, especially with the introduction of technology," Brooks explained.

More than a quarter century of use has led to the accretion of research and regulatory practices that are due for an update, suggested Army Col. Peter J. Weina, the department's chief and a veteran researcher on tropical infectious diseases.

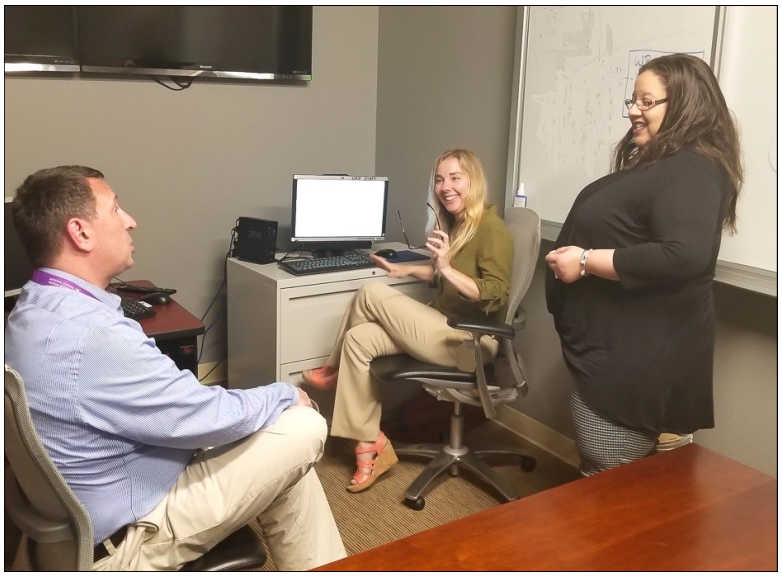
The changes in the Common Rule, Weina said, are designed to "challenge the cumulative complexities."

At Walter Reed Bethesda, the Department of Research Programs is preparing for the change. The Defense Health Agency, which is the oversight authority on research for Walter Reed Bethesda, will eventually provide detailed guidance on the new rule.

"It's all well and good to anticipate these changes, but not to jump the gun until our assuring agency develops the guidance to implement it," Weina said.

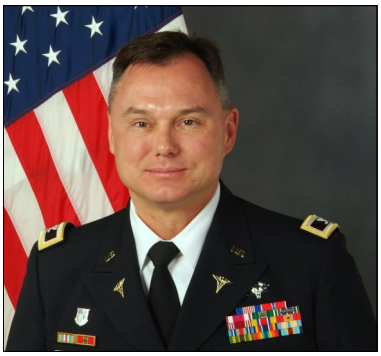
A recent series of webinars on the Revised Common Rule hosted by the department underscored shifting rules in areas

See CHANGES, page 6



Robert Roogow, director of Institutional Review Board operations, and Anmarie Widener, L.C.S.W.-C., Ph.D., a contracting officer representative at the National Intrepid Center of Excellence, discuss pending changes in the Common Rule with Sanjur Brooks, program manager for human research protections, at right, on July 5. The regulation governs how to protect human participants in medical research. (Photo by John Fadoju)

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.

Contents

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.

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, July 18, 1200-1300
  "Compliance Tips and Tricks for Your Research Records"
- Tuesday, August 22, 1200-1300
  "Keeping It Clear: A Plain-Language Primer"
- Tuesday, September 19, 1200-1300

EIRB Tip of the Month

Advice on Consent

Revised your consent form recently? Please check to make sure you upload a clean version of your consent form when making a submission with an updated consent form or when uploading your consent form to a continuing review submission.

In addition, make sure that you upload the consent form in the Informed Consent link, under Protocol Items. Please steer clear of the Other Protocol Documents link, which we use for other forms.

Try to avoid putting version numbers and dates in the header of your consent forms, so they match your EIRB version. Thank you for your care and for your efforts to advance military medicine.

Robert Roogow
Director, Institutional Review Board Operations

Correction

Departing research compliance auditor, Barbara "Bonnie" Bloomquist, took the wonderful picture of Navy Petty Officer 2nd Class Rhesa Cantu singing "The Star-Spangled Banner" on May 16 during Aware for All for our June issue (page 12).

Going the distance in Portsmouth

Navy-wide competitors from Walter Reed Bethesda win big

by Paula Amann

When four finalists from Walter Reed National Military Medical Center made the trek to Portsmouth, Virginia for the Navy-wide Academic Research Competitions, all came home with awards. Details of the wins reached the hospital three weeks after the May 25 event, but for one of the four judges, the strength of the contestants remained vivid.

"It was the top of the pyramid, basically," said retired Navy Capt. (Dr.) Eric Gessler, one of four judges for this competition. He called the contenders "the winners of the winners, the best of the best."

From Walter Reed Bethesda, this elite group included Capt. Christopher Daniels, who won the first-place award for trainees in the basic science category, and Lt. Col. (Dr.) E. Matthew Ritter, who took home the top clinical award for staff.

Maj. (Dr.) Kristen Zeligs finished second in basic science for the staff award, and Lt. Luke Johnston earned second place for clinical projects by trainees. In addition, Zeligs earned the special award for partnerships, while Johnston received the special award for health.

The judges for this round brought their own military medical experience to the task. Now an otolaryngologist in private practice, Gessler drew on 25 years in Navy medicine for his decisions as a Navy-wide judge. He retired in 2015 as residency program director at Naval Medical Center Portsmouth.

Rear Adm. (ret.) Thomas Cullison built on a 38-year Navy military career, which closed with his service as deputy surgeon general. Before his 2010 retirement, Cullison held leadership roles as commanding officer at Naval Hospital Camp Lejeune, fleet surgeon of the U.S. Pacific Fleet and command surgeon of the U.S. Pacific Command.

Cullison lauded Ritter's award-winning project on teaching endoscopy to future surgeons, "Development of a Proficiency-Based Skills Curriculum for the Fundamentals of Endoscopic Surgery."

"He had a well-designed study asking a practical question that applies to military surgeons and presented it exceedingly well," said Cullison, who is now a senior advisor at the Center for Global Health Engagement at the Uniformed Services University of the Health Sciences.

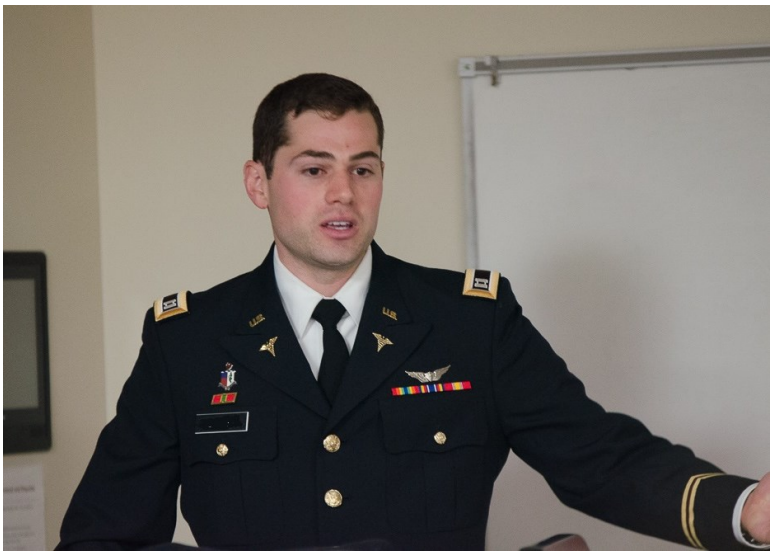
In an earlier interview, Ritter himself was modest about his curricular project, pointing to the pedagogical method he adapted to the task of training surgeons to pass a required endoscopy examination.

"The power of this comes from applying the mastery learning theory," Ritter said of his system.

Answering medicine's unsettled questions

All of the research projects that did well this year identified and addressed an unsolved medical problem, Gessler noted. In particular, he pointed to the award-winning work by Daniels, who probed the biochemistry of nerve regeneration in "Validation of Nuclear Translocationof an Epigenetic Regulator Peptidomimetic in Trauma-Induced Mesenchymal Progenitor Cells."

See PORTSMOUTH, page 4



Capt. Christopher Daniels took his Robert A. Phillips Award in the laboratory category on to the Navy-wide Research Competitions in Portsmouth, Virginia. There he won the first-place award for trainees in the basic science category for his project on the epigenetics of nerve regeneration. (Photo by John Fadoju)

PORTSMOUTH, from page 3

Cullison also praised Daniels' research, calling it "a very elegant study" with strong relevance to military medicine.

"Nerve regeneration is a big area of study within the Department of Defense because of [the need for] limb regeneration and limb replant surgery," Cullison said.

As to the project brought to Portsmouth by Johnston, "Reducing Complications Following Reversal of Combat-Associated Ostomies," both judges cited the strengths that helped it win the special award for health.

Noting the common use of a "diverting colostomy" in the care of service members with abdominal wounds, Gessler affirmed the need to reevaluate the practice and its aftermath.

Calling Johnston's study "very forward-thinking," Gessler noted its tremendous potential impact in changing practices so as to "get our soldiers, sailors and marines back to health quicker."

Cullison pointed to the way this study addressed a gap in the research literature since Vietnam War Era on this medical problem, and called Johnston's oral presentation "very eloquent."

Commenting on the close contest for the staff award in basic science, Gessler hailed the quality of the study by Zeligs, "Preclinical Characterization of a Novel Monoclonal Antibody Targeting a Neo-Antigen Expressed in Ovarian and Gastrointestinal Malignancies."

"Her study, presentation and slides were all phenomenal," Gessler said. "It was upper-level research."

For his part, Cullison pointed out the contrast in the two competing research projects in basic science. Zeligs presented a laboratory study of a potential cancer medication.

In the Navy-wide competition, Zeligs faced a rival project limited in scope and focused on a safe way to handle intra-osseous (within bone) blood transfusion, a critical problem in combat care.

"You had two really elegant studies – one very simple, the other very complicated – so it was a very tough decision," Cullison said, adding, "I hope we have the same problem every year."

Although the study of post-combat transfusion edged out Zeligs' cancer study, the judges paid tribute to her research by giving her the special award for partnership.

Lt. Luke Johnston, a surgical resident at Walter Reed Bethesda, presents his research at Research Symposium II on May 10. His study on reducing complications after ostomy reversal won a Robert A. Phillips Award that day. At the Navy-wide Research Competition two weeks later, Johnston finished in second place for clinical projects by trainees and brought home the special award for health. (Photo by John Fadoju)

"Her study definitely deserved special recognition," Gessler said, noting her collaboration with the National Cancer Institute, the Uniformed Services University of the Health Sciences and Precision Biologics, Inc. "It was a perfect example of partnership between military medicine and civilian research."

The caliber of today's research

Reflecting on the past decade, Cullison said he has observed a surge of sophisticated, original research coming to the competition. This trend marks a departure from past years, in which Cullison noted more "recycling" of research projects carried out during civilian fellowships.

"More and more, we're seeing original research generated at the [military] medical centers," Cullison said. "We're very excited about that."

See PORTSMOUTH, page 5

PORTSMOUTH, from page 4

He expressed hope that in future years the judges would see more work not only from Walter Reed Bethesda but from family medicine residents working in the naval hospitals at Camp Lejeune in Jacksonville, North Carolina; Camp Pendleton in Southern California; and Jacksonville, Florida.

> 'More and more, we're seeing original research generated at the [military] medical centers.... We're very excited about that.'
>
> *— Retired Rear Adm. Thomas Cullison, former deputy surgeon general; judge, Navy-wide Research Competition*

Appraising the field of research projects, Gessler, a first-time judge for the competition, was struck by their overall caliber.

"It was a proud moment because you realized that research in residencies in the Navy [and other armed

The benefits of the research shared at the competition, Gessler suggested, could ultimately reach well beyond the armed services and its medical treatment facilities.

For example, he noted, the nerve regeneration research pioneered by Daniels could one day help civilian survivors with neural damage from car accidents, shootings and surgeries.

"Usually, out of war come some enhancements in all trauma care," Gessler said. ◘

◘ ◘

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CHANGES, from page 1

such as exemption categories, types of review, bio-specimens and identifiable private information.

(To view any of the five webinars, click on the light green button labeled, "Track news and events," on the intranet page of the Department of Research Programs.)

Medical science has burgeoned amid the swift growth of new knowledge and computer technologies since the last major version of the Common Rule emerged in 1991.

"The sheer volume of data that can be generated in research, the ease with which it can be shared, and the ways in which it can be used to identify individuals were simply not possible, or even imaginable, when the Common Rule was first adopted," note the authors of this year's revision, explaining the need for changes.

> 'We have two purposes here: promoting research and protecting subjects. When they come into conflict, what wins is protecting the subject.'
>
> *— Army Col. Peter J. Weina, Chief, Department of Research Programs Walter Reed Bethesda*

To deal with the increase in personal data, the revised Common Rule broadens the definition of "human subject" in research. Under the new rule, a subject is viewed as a living person about whom an investigator gathers data or biospecimens through interaction or intervention; or "obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens."

With the avalanche of data can come more potential privacy concerns, warned Weina.

"The fact that we have access to all that data and all these samples may mean there's greater risk to individuals," Weina said. "We have two purposes here: promoting research and protecting subjects. When they come into conflict, what wins is protecting the subject."

Meanwhile, as the Common Rule expands the definition of research participants, it also widens the options for informed consent. Researchers now can obtain "broad consent" to store and use identifiable biospecimens or private information instead of getting "study-specific informed consent," the revised regulation reads.

"The concept of broad consent is not new in the research community," said Brooks. However, the new language, she explained, "will allow oversight agencies to have a regulatory foundation."

Also in the revised Common Rule is a new definition of research that omits four sets of activities. Now removed from research and its oversight are tasks linked to scholarship and journalism (such as oral history and legal research), public health surveillance approved by a relevant authority, criminal justice work and authorized national security missions.

Government authorities such as the FBI sometimes collect biospecimens in the course of criminal investigations, for instance. This work does not count as research, which is subject to rules on confidentiality and privacy, the new Common Rule makes clear.

Some kinds of research will now be "exempt," that is, needing only limited review by an Institutional Review Board (IRB), given safeguarding of privacy and confidentiality for identifiable data. These changes, Brooks said, generally mean shifting some kinds of research from expedited review to exempt status.

In essence, the Common Rule changes on exemptions are "taking routine practice and turning it into regulatory provisions," Brooks said.

For instance, the revised Common Rule clarifies the exempt research categories that specifically govern research with human research interactions involving educational tests, surveys or interviews, or observation of public behavior.

"The real challenge becomes: Do we track those things [exempt research projects] and how do we track them," Weina said. "Because of that [uncertainty], there's a potential for greater risk to subjects."

In another update, research involving benign behavioral interventions and collection of data from an adult subject who agrees to the study in advance may be exempt if one

See CHANGES, page 7

CHANGES, from page 6

of three criteria is met. One criterion for exemption is this: The human subjects' identities cannot readily be determined through identifiers linked to them.

An alternate criterion is that any disclosure of the human subjects' responses outside the research would not put subjects at likely risk of criminal or civil liability, or hurt subjects' financial standing, employability, educational advancement or reputation.

In a third kind of exemption, subjects' identities can be determined but an expedited IRB review ensures provisions for privacy and confidentiality.

Given broad consent by human subjects, research may also be exempt from full IRB review, if investigators store or maintain identifiable private information or biospecimens for potential secondary research use.

Continuing review can sometimes add another layer of process and paperwork for a research team. In another change, all studies that have expedited review by an IRB can skip continuing review.

The revised regulations also contain special provisions for clinical trials. The final rule does not cover non-federally funded clinical trials. For all clinical trials covered by the Common Rule, researchers now have to post a copy of a consent form approved by the relevant IRB on a federal website, after trials are closed to recruitment and no later than 60 days after the last study visit by any participant.

A posted consent form "gives you a snapshot of the study, which people couldn't previously see until they were recruited [as participants]," said Brooks, who said it is part of "an effort to have transparency between researchers and the larger community."

As the Common Rule evolves, so too in time will guidance from the Defense Health Agency, which is the assuring authority on research for Walter Reed Bethesda. For now, regulators will be developing new policy much like the Supreme Court elucidates law, based on the cases the justices hear.

Likewise, said Brooks, regulators like her will craft their responses to the revised Common Rule in part "driven by the research that is appearing."

For his part, Weina says the Department of Research Programs will observe and enforce the existing regulations.

"If our assuring agency hasn't provided us guidance, we have to follow things as they are," Weina said. ⊡

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 at noon. Please rejoin us for the next roundtable on July 18, as **Lea Olverson**, a research compliance monitor, shares "**Compliance Tips and Tricks for Your Research Records**."

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.

Research Roundtable zooms in on funding

Geneva Foundation touts 'matchmaker' role for researchers, grants

by Paula Amann

For nearly two and a half decades, the Geneva Foundation has worked to link military medical researchers with the funds they need, and sometimes, the collaborators they seek.

Kelly Lehner, regional director in the foundation's Grants and Contracts Department, joined Kelli Blaize-Wise, client relationship manager at the Geneva Foundation, for a presentation on June 20 at the Research Roundtable.

Kelly Lehner, regional director at the Geneva Foundation's Grants and Contracts Department, briefs the Research Roundtable on June 20. (Photo by John Fadoju)

The foundation, which is based in Tacoma, Washington but has offices nationwide and in seven countries abroad, provides grant money for some research at Walter Reed National Military Medical Center.

The foundation's core services are threefold, Lehner indicated: managing federal contract awards, conducting industry-sponsored clinical trials and planning educational conferences. However, the heart of its work is

See GENEVA, page 9

GENEVA, from page 8

connecting military medical research with potential grant makers.

For its part, Geneva Foundation collects an overhead of 19.8 percent, she noted.

The institution welcomes military medical research in diverse fields, ranging from behavioral and mental health,

Kelli Blaize-Wise, client relationship manager at the Geneva Foundation, describes funding options for military medical research. (Photo by John Fadoju)

cardiology and critical care to rehabilitation and urology. Worldwide, it supports 73 researchers, both novice and experienced, and underwrites 191 clinical trials.

The foundation offers services ranging from proposal development to study conduct and closeout. It has its own business cell that handles legal contracts between research partners and the like.

"For everything federal, we will guide the investigator through the steps," Blaize-Wise said. ⊡

TRAINING FOR RESEARCHERS

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- 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!

Department Download
News from the Department of Research Programs

In major news, the new 2017 Strategic Plan calls for the Department of Research Programs (DRP) to become its own directorate within Walter Reed National Military Medical Center. Army Col. Peter J. Weina, DRP chief, made the announcement at the monthly meeting of the department on June 8.

Impetus for the new structure came from the board of directors of Walter Reed Bethesda, Weina said. The new research directorate will have its own budget and hiring power; it will retain its business cell.

"I think in the end it'll be good for the department and good for the institution to give research the visibility it deserves," Weina said.

According to the strategic plan recently released by the hospital, the structural overhaul could come as soon as September 2018.

In another development, Robert Roogow announced that he would be scaling back question and answer sessions on the electronic Institutional Review Board from weekly to twice a month.

"EIRB is working a little better than when it started," Roogow said, adding that he expects upgrades in the system will result in "a new pipeline with bigger bandwidth."

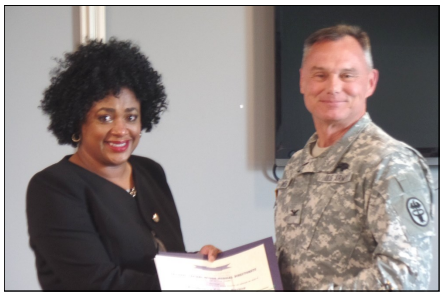
Meanwhile, the department will be seeing some staff departures over the coming weeks and months. Army Col. Michael Schlicher, heretofore a nurse scientist in the department, will be moving to a new post in Seattle later this summer.

For his part, Army Capt. Franz Frye, who has led the Biomedical Research Laboratory, will be heading to a new assignment in late September. Finally, Dr. Wendy Bernstein, chair of scientific review, is set to retire on Sept. 2. ⊡

Faces of Research

Honoring our own

June was a banner month for staff awards. Notably, Lisa Thompson, the supervisory medical education specialist for the Department of Research Programs, received the Outstanding Civilian Service Award.



Lisa Thompson, supervisory medical education specialist, accepts the Outstanding Civilian Service Award, from Army Col. Peter J. Weina, chief of the Department of Research Programs. (Photo by John Fadoju)

The award recognized Thompson's role in assisting in training more than 2,800 military and civilian staff members on the new Performance Management and Appraisal Program. Thompson undertook this challenge over a six-month period ending in May of this year.

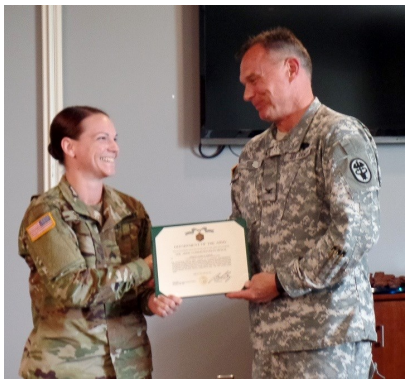
Martin Hindel, a research attorney, was recognized for his role as interim chief of

Meanwhile, research attorney Martin Hindel was recognized in the "I Save Lives" Campaign, a quarterly recognition, for his service of some six months as interim chief of the Business Cell, in the absence of a permanent chief for this unit.

"Marty really stepped up to the plate," said Army Col. Peter J. Weina, department chief, noting Hindel's leadership of the only such office in the military medical system. Weina underscored the value of this work, in that the cell serves "to recoup the costs of research, so it doesn't take dollars away from patient care."

See HONORING, p. 11

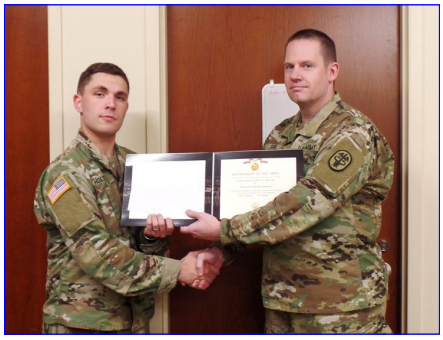
HONORING, from page 10



Army Sgt. Alisha Kohler receives an Army Commendation Service Medal from Weina at the June 8 department meeting. (Photo by John Fadoju)

At the June meeting, Weina also recognized a department staff member for 20 years of service: medical technologist Brian Reinhardt, who works in the Biomedical Research Laboratory.

For her part, Army Sgt. Alisha Kohler, who has served the department as non-commissioned officer in charge, received an Army Commendation Service Medal from Weina in front of department staff. In a separate ceremony the following week, Army Spc. Dakotah Holtman received a good conduct medal from the chief of the Biomedical Research Laboratory, Army Capt. Franz Frye.



Army Capt. Franz Frye presents Spc. Dakotah Holtman with a Good Conduct Medal on June 15 near the Biomedical Research Laboratory, of which Holtman is the manager. (Photo by Paula Amann

ARRIVAL GATE

Stephanie Lyn Marquez is a new face on the team of protocol analysts at the Department of Research Programs. Earlier, she served as a clinical research assistant conducting gastroenterology pharmaceutical trials for Capital Digestive Care – Chevy Chase Clinical Research, where she helped ensure the rights, safety and welfare of participants.

Stephanie Marquez, a new protocol analyst (Photo by Paula Amann)

Previously, Marquez worked for nearly four years as a laboratory research assistant for the Cengiz Laboratory at the University of Wisconsin – Madison. In addition, she was a research assistant on cancer studies with the National Institutes of Health and a laboratory research assistant with the Applied Physics Laboratory at Johns Hopkins University.

Marquez earned a bachelor's degree in biology from the University of Wisconsin – Madison. Her college years included a semester abroad at Leeds University in England and a global health field experience on the Chinese diaspora in Indonesia. As a child immigrant from the Philippines, Marquez speaks fluent Tagalog and takes pride in cooking traditional Filipino food. She is excited to be here at Walter Reed Bethesda and learn from all the great mentors in the Department of Research Programs.

Umber Shafique, a quality assurance and research compliance auditor (Photo by Paula Amann)

Umber Shafique recently joined the staff as a quality assurance and research compliance auditor. She earned her bachelor's degree in medicine and surgery from a medical college in Pakistan, Fatimah Jinnah Medical College Lahore, and moved to the United States in 2005. She received her certification from the Educational Commission for Foreign Medical Graduates after passing the United States Medical Licensing Examination and went on to pursue a career in clinical research.

For the past seven years, Shafique worked with the Sidney Kimmel Comprehensive Cancer Research Center at Johns Hopkins University in Baltimore. Besides coordinating several clinical trials over their entire life span, she assisted in electronic Institutional Review Board (IRB) submissions and correspondence to both local and central IRBs. She was a coauthor for a clinical trial published in March 2013, "A dose-finding study of temsirolimus and liposomal doxorubicin for patients with recurrent and refractory bone and soft tissue sarcoma."

Outside the research arena, Shafique enjoys doing home improvement projects and recently installed her kitchen backsplash by herself.

See ARRIVAL, p. 11

ARRIVAL, from p. 11

Svetlana "Veta" Smith is a new technology transfer specialist with the department. Smith earned her master's degree in genetics and biological sciences, with a concentration in biochemistry from Novosibirsk State University in Russia. She went on to get her doctorate in cell biology from the Institute of Cytology and Genetics in Russia. She is also registered with the U.S. Patent and Trademark Office as a patent agent.

Svetlana Smith recently joined the department as a technology transfer specialist (Photo by John Fadoju)

Smith gained experience in cancer research working as a postdoctoral fellow at The Johns Hopkins University and studied molecular mechanisms of neurodegenerative diseases as postdoctoral and research fellow at the National Institute of Neurological Disorders and Stroke within the National Institutes of Health. As she became increasingly interested in promoting basic science research into biomedical technologies, she switched career paths and graduated from the Technology Transfer Program supported by FAES at the National Institutes of Health.

Prior to joining Walter Reed Bethesda, Svetlana worked as a technology transfer specialist at the United States Army Medical Research Institute of Infectious Diseases, where she executed multiple research agreements dealing with infectious diseases. In her free time, Svetlana enjoys Pilates, painting with acrylics and the sport of curling.

Chia-Wei Tsai recently brought her skills as a research chemist to the Biomedical Research Laboratory. Wei earned her bachelor's degree in chemistry from the University of Florida. Upon graduation, she stayed at the university to complete her doctorate in chemistry with a focus on analytical chemistry.

Half way through her graduate education, Wei joined the Visiting Scientist Program and finished a couple of projects included in her dissertation at the Counterterrorism and Forensic Science Research Unit of the FBI. Her research work focused on explosives analysis by mass spectrometry, which includes plastic explosives analysis using gas chromatography and mass spectrometry and the integration of paper spray ionization to high-field asymmetric waveform ion mobility spectrometry.

Wei is a native speaker of both Taiwanese and Mandarin. She has worked part-time translating journal articles from one language to another. She is also learning Korean and, upon receiving her graduate degree, went to the Korean Immersion Program at Sogang University, South Korea. ⊡

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

Conducting Research: Process, Methods and Design
Tuesday, July 18 12 p.m. ▪ Building 6, Room 1369
Instructor: Dr. Lyubov Tmanova

This lecture explores the process of conducting research, particularly on the development of the research question and hypothesis, literature analysis, research methods, study designs, data management, research integrity, and research management.

Preparing Your Manuscript for Publication
Tuesday, July 25, 12 p.m. ▪ Building 6, Room 1369
Instructor: Dr. Lyubov Tmanova

This lecture centers on planning, writing, and submitting manuscripts for publication in biomedical journals — the publication process, journal selection, and authorship guidelines and standards. The writing section of the workshop focuses on writing a compelling manuscript.

See DARNALL , page 13

DARNALL , from page 12

PubMed
Thursday, Aug. 3, 1 p.m. · Building 1, Room 209
Instructor: Sarah Cantrell

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.

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 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.

See RESOURCES, p. 14

RESOURCES, from p. 13

● 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)
- 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.

Back DA, Waldmann K, Hauer T, et al. Concept and evaluation of the German War Surgery Course - Einsatzchirurgie-Kurs der Bundeswehr. *J R Army Med Corps.* 2017;163(3):206-210. Walter Reed Bethesda author: **Bowyer MW**

Balazs GC, Hanley MG, Pavey GJ, Rue JP. Military personnel sustaining Lisfranc injuries have high rates of disability separation. *J R Army Med Corps.* 2017;163(3):215-219.

Bateman NW, Dubil EA, Wang G, et al. Race-specific molecular alterations correlate with differential outcomes for black and white endometrioid endometrial cancer patients. *Cancer.* 2017 Jun 27. [Epub ahead of print] Other Walter Reed Bethesda authors: **Hood BL, Oliver JM, Gist GD, Mitchell DA, Blanton B, Phippen NT, Tian C, Shriver CD, Darcy KM, Hamilton CA, Conrads TP, Maxwell G**L

Beigel JH, Tebas P, Elie-Turenne MC, et al. Immune plasma for the treatment of severe influenza: an open-label, multicentre, phase 2 randomised study. *Lancet Respir Med.* 2017;5(6):500-511. Walter Reed Bethesda author: **Danko J**

Bhatia A, Nelson A, **Cohen SP**. Breaking bad (tissue): epidural adhesiolysis and Its outcomes. *Anesth Analg.* 2017;124(6):1755-1757.

Bradley M, Nealiegh M, Oh JS, Rothberg P, Elster EA, **Rich NM**. Combat casualty care and lessons learned from the past 100 years of war. *Curr Probl Surg.* 2017;54(6):315-351.

Brandenburg WE, Levandowski W, Califf T, **Manly C**, Levandowski CB. Animal, microbial, and fungal borne skin pathology in the mountain wilderness: a review. *Wilderness Environ Med.* 2017;28(2):127-138.

Brungart DS, Walden B, Cord M, et al. Development and validation of the Speech Reception in Noise (SPRINT) Test. *Hear Res.* 2017;349:90-97. Other Walter Reed Bethesda authors: **Phatak S, Grant KW**

Cervenka PD, Perez L Jr, Perez DE, **Jones B**. Melanoma metastasis to the mandible-case report and comprehensive literature review. *J Oral Maxillofac Surg.* 2017 Jun 1. [Epub ahead of print]

Chou E, Liu J, Seaworth C, et al. Comparison of revision rates of anterior- and posterior-approach ptosis surgery: a retrospective review of 1519 cases. *Ophthal Plast Reconstr Surg.* 2017 Jun 2. [Epub ahead of print]

Dey D, **Wheatley BM**, Cholok D, et al. The traumatic bone: trauma-induced heterotopic ossification. *Transl Res.* 2017 Jun 15. [Epub ahead of print]

Dickens JF, Rue JP, Cameron KL, et al. Successful return to sport after Arthroscopic shoulder stabilization versus nonoperative management in contact athletes with anterior shoulder instability:a Prospective multicenter study. *Am J Sports Med.* 2017 Jun 1: [Epub ahead of print]

Dumas EK, Garman L, Cuthbertson H, et al. Lethal factor antibodies contribute to lethal toxin neutralization in recipients of anthrax vaccine precipitated. *Vaccine.* 2017;35(26):3416-3422. Walter Reed Bethesda author: **Engler RJM**

Feuerstein M, **Gehrke AK, McMahon BT, McMahon MC**. Challenges persist under Americans with Disabilities Act Amendments Act: how can oncology providers help? *J Oncol Pract.* 2017;13(6):e543-e551.

Fischer J, Ohmer M, **Petersen M**. The weekday wheezer. *Clin Pediatr (Phila).* 2017 Jun 1:9922817715940.[Epub ahead of print]

Giwa S, Lewis JK, **Alvarez L**, et al. The promise of organ and tissue preservation to transform medicine. *Nat Biotechnol.* 2017;35(6):530-542.

Han JJ, **Tarney CM**, Song J. Variation in genital human papillomavirus infection prevalence and vaccination coverage among men and women in the USA. *Future Oncol.* 2017 Jun 7. [Epub ahead of print]

Han JJ, **Tarney CM**, Song J. Variation in genital human papillomavirus infection prevalence and vaccination coverage among men and women in the USA. *Future Oncol.* 2017 Jun 7. [Epub ahead of print]

Howard JT, Stockinger ZT, Cap AP, **Bailey JA**, Gross KR. Military use of TXA in combat trauma: does it matter? *J Trauma Acute Care Surg.* 2017 Jun 9. [Epub ahead of print]

Howe EG 3rd. How should physicians respond when the best treatment for an individual patient conflicts with practice guidelines about the use of a limited resource? *AMA J Ethics.* 2017;19(6):550-557.

Jones TA, Chin J, **Mcleod D**, Barkin J, Pantuck A, Marks LS. High-intensity focused ultrasound for radio-recurrent prostate cancer: a North American clinical trial. *J Urol.* 2017 Jun 23. [Epub ahead of print]

Kawoos U, **McCarron RM**, Chavko M. Protective effect of N-acetylcysteine amide on blast-induced increase in intracranial pressure in rats. *Front Neurol.* 2017;8:219.

Keller MD, Ziriax JM, Barns W, et al. Performance in noise: impact of reduced speech intelligibility on Sailor performance in a Navy command and control environment. *Hear Res.* 2017;349:55-66. Walter Reed Bethesda authors: **Sheffield B, Brungart D**

See PUBLICATIONS, page 14

PUBLICATIONS, from page 13

Kwok RM, Tran TT. Management of cirrhotic patients after successful HCV eradication. *Curr Treat Options Gastroenterol.* 2017;15(2):305-315.

Lange RT, Lippa SM. Sensitivity and specificity should never be interpreted in isolation without consideration of other clinical utility metrics. *Clin Neuropsychol.* 2017 Jun 8:1-14. [Epub ahead of print]

Larkin TM, **Cohen SP**. Drug marketing and prescribing patterns: challenges facing physicians entering the new Trump era of health care: are there parallels with the Canadian experience? *Pain Med.* 2017;18(6):1001-1003.

Lettieri CJ, Collen JF, Williams SG. Challenges in the management of sleep apnea and PTSD: is the low arousal threshold an unrealized target? *J Clin Sleep Med.* 2017 ;13(6):845-846.

Luangphakdy V, Elizabeth Pluhar G, Piuzzi NS, et al. The effect of surgical technique and spacer texture on bone regeneration: a caprine study using the masquelet technique. *Clin Orthop Relat Res.* 2017 Jun 20. [Epub ahead of print] Walter Reed Bethesda author: **D'Alleyrand JC**

Lynall RC, Pietrosimone B, Kerr ZY, **Mauntel TC**, Mihalik JP, Guskiewicz KM. Osteoarthritis prevalence in retired National Football League players with a history of concussion and lower extremity injury. *J Athl Train.* 2017;52(6):518-525.

Michalowicz M, Ramanathan M Jr. Clival osteomyelitis presenting as a skull base mass. *J Neurol Surg Rep.* 2017;78(2):e93-e95.

Mohamed AA, Tan SH, Xavier CP, et al. Synergistic activity with NOTCH inhibition and androgen ablation in ERG-positive prostate cancer cells. *Mol Cancer Res.* 2017 Jun 12. [Epub ahead of print] Other Walter Reed Bethesda authors: **Katta S, Huang W, Ravindranath L, Jamal M, Li H, Sreenath TL, McLeod DG, Srinivasan A, Petrovics G, Dobi A, Srivastava S**

Morgan EN, Means KR Jr, Paez AG, Parks BG, Innis PC. Suture-button device stabilization following ring finger ray amputation: a comparative cadaver study. *Hand (N Y).* 2017 Jun 1. [Epub ahead of print]

Morgan M, McGann P, Gierhart S, et al. Consumption of chlorhexidine and mupirocin across the Health System of the US Department of Defense (DOD) and the incidence of the qacA/B and mupA Genes in the DOD facilities of the National Capital Region. *Clin Infect Dis.* 2017;64(12):1801-1802.

Nakanishi R, Baskaran L, Gransar H, et al. Relationship of hypertension to coronary atherosclerosis and cardiac events in patients with coronary computed tomographic angiography. *Hypertension.* 2017 Jun 12. [Epub ahead of print]Walter Reed Bethesda author: **Villines TC**

O'Boyle AL, Mulla BM, **Lamb SV, Greer JA, Shippey SH, Rollene NL.** Urinary symptoms after bladder flap at the time of primary cesarean delivery: a randomized controlled trial (RTC). *Int Urogynecol J.* 2017 Jun 2. [Epub ahead of print]

Oronsky B, Ray CM, Spira AI, Trepel JB, **Carter CA**, Cottrill HM. A brief review of the management of platinum-resistant-platinum-refractory ovarian cancer. *Med Oncol.* 2017;34(6):103.

Pavey AR, Bodian DL, Vilboux T, et al. Utilization of genomic sequencing for population screening of immunodeficiencies in the newborn. *Genet Med.* 2017 Jun 15. [Epub ahead of print]

Pintauro M, Duffy A, Vahedi P, **Rymarczuk G**, Heller J. Interspinous implants: are the new implants better than the last generation? A review. *Curr Rev Musculoskelet Med.* 2017;10(2):189-198.

Pisano A, Helgeson M. Cervical disc replacement surgery: biomechanical properties, postoperative motion, and postoperative activity levels. *Curr Rev Musculoskelet Med.* 2017;10(2):177-181.

Potter BK. CORR insights®: prolotherapy induces an inflammatory response in human tenocytes in vitro. *Clin Orthop Relat Res.* 2017 Jun 9. [Epub ahead of print]

Quintero DG, Taylor RB, Miller MB, Merchant KR, Pasieta SA. Air-abrasive disinfection of implant surfaces in a simulated model of periimplantitis. *Implant Dent.* 2017;26(3):423-428.

Rivard SC, Wallace SA, **Marquart JD**. In a pinch? Rocker-slide punch biopsy technique. *Dermatol Surg.* 2017 Jun 28. [Epub ahead of print]

Sainato R, Flores M, Malloy A, et al. Health maintenance deficits in a fully insured population of adolescents with chronic medical conditions. *Clin Pediatr (Phila).* 2017;56(6):512-518.
Other Walter Reed Bethesda authors: **Geaney C, Weisse M**

Stokes TA, Kukora SK, Boss RD. Caring for families at the limits of viability: the education of Dr Green. *Clin Perinatol.* 2017;44(2):447-459.

Williams SG, Collen JF, Lettieri CJ. The continued search for optimal therapy in patients with OSA and PTSD. *J Clin Sleep Med.* 2017;13(6):849.

Xydakis MS, Belluscio L. Detection of neurodegenerative disease using olfaction. *Lancet Neurol.* 2017;16(6):415-416.

Zhu K, Manjelievskaia J, Shriver CD. Use of adjuvant chemotherapy after surgery in patients with colon cancer-reply. *JAMA Surg.* 2017 Jun 14. [Epub ahead of print] ▣

Walter Reed National Military Medical Center
Department of Research Programs

TRAINING FOR ELECTRONIC INSTITUTIONAL REVIEW BOARD (EIRB)

QUESTION AND ANSWER SESSIONS

Time slot: First & Third Mondays 1200–1300

Month	Dates *Radiology Conference Room B015, Building 19, Basement*
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August	7 | 21
September	18
October	2 | 16
November	6 | 20
December	4

The Department of Research Programs
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Where investigators learn the rules of the road on policy, funding and more

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Third Tuesdays, noon to 1300 ⊙ Brown bag lunches welcome
Desert Conference Room 2301
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⊙ **July 18 – Compliance Tips and Tricks for Your Research Records**
Lea Olverson, Research Compliance Monitor

⊙ **Aug. 22 – Keeping It Clear: A Plain-Language Primer for Medical Researchers**
Paula Amann, Editor, Military Medical Research News

Got a research-related topic to share? We're seeking fall presenters. Please contact Lisa Thompson at lisa.p.thompson5.civ@mail.mil.