



Military Medical Research News

Vol. 3, Issue 7 • August 2016

The Ears Have It Audiologists at Walter Reed Bethesda probe scope of hearing loss

by Paula Amann

Imagine you're a service member back from a tour of duty in Afghanistan or Iraq. Your hearing tests fine, but you often have trouble "getting the message" when someone's talking to you.

And here's another clue: You were exposed to blasts on the battlefield.

Audiologists at Walter Reed National Military Medical Center are partnering with other military treatment facilities to unravel this medical mystery.

Their research shows that blast-exposed service members with normal to near-normal hearing thresholds are as much as 5.4 times more likely to perform poorly on functional hearing tests than peers with similar hearing thresholds, who were not exposed to blasts.

"We could be dealing with a form of 'hidden hearing loss,' or it could be due to an auditory processing or cognitive deficit," said Ken W. Grant, Ph.D., deputy director of the Audiology and Speech Center and chief of the Research Section at the National Military Audiology and Speech-Pathology Center.

Grant also is the principal investigator of a multisite study to probe the prevalence of speech communication and hearing deficits among service members with normal or near-normal hearing thresholds.

Lina Kubli, Ph.D., is the research audiologist who has been overseeing the work at Walter Reed Bethesda and elsewhere.



Soldiers plan their next move, after locating a target during a simulated dismounted combat. Earplugs mimic the impact of hearing loss on their battlefield performance. See related story on page 7. (Photo by Benjamin Sheffield)

See EARS, page 5



DEPARTMENT OF RESEARCH PROGRAMS



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

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

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

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MILITARY MEDICAL RESEARCH NEWS

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

RESEARCH FIRST STEPS

Our protocol navigators are available to help you start the process and assist you with your submission.

To make an appointment with a protocol navigator please call the Department of Research Programs (DRP) office at 301-295-8239. DRP is located in Building 17B, third floor.

EIRB TIP OF THE MONTH: UPDATING EMAILS

Don't miss a message.

1. Go to this URL for the electronic Institutional Review Board (EIRB): <https://dmrncac.dhhq.health.mil/>
2. Click on the icon at middle left: Update Your Enterprise Profile.
3. Enter your primary and secondary emails in the spaces provided.
4. Now, go into the EIRB via your CAC.
5. Go to My Assistant, then select My Account Information.
6. Update your email address once more.
7. Save changes, by clicking icon at upper right.

Meet the Tiger Team

Helping Transfer Your Old Protocols Into the New Online System



A Department of Research Programs team will be conducting face-to-face outreach and education with principal investigators and their research teams to help transfer of

existing research protocols into the new electronic IRB system.

The team includes Army Col. Ann Nayback-Beebe, chief of Protocol Development; Vicki Miskovsky, protocol navigator; Erica Reid, protocol navigator; Diane Beaner, research oversight and compliance officer; Rashida Redd, Institutional Review Board (IRB) manager; and Robert Roogow, director of IRB operations.

Principal investigators who have a large number of active protocols will be among the first contacted to receive these services. To schedule a face-to-face educational outreach session with a team member, or to ask any specific questions about transfer of protocols into the new system, please email Nayback-Beebe at ann.m.naybackbeebe.mil@mail.mil.

RESEARCH ROUNDTABLE SCHEDULE

Walter Reed National Military Medical Center

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

- ◆ Tuesday, Aug. 23 , 1200-1300
- ◆ Tuesday, Sept. 20, 1200-1300
- ◆ Tuesday, Oct. 18, 1200-1300
- ◆ Tuesday, Nov. 22, 1200-1300
- ◆ Tuesday, Dec. 20, 1200-1300



RESEARCH ROUNDTABLE

A MESSAGE FROM THE HOST OF THE RESEARCH ROUNDTABLE by Lisa Thompson



Photo 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), Research Regulatory Oversight (R202) policy guidelines, and MERF and CITI Training. We would like to join you once annually or every six months, before or after your program meets for didactic or lecture hall sessions.

Our goal is to promote research. We want to help familiarize your Graduate Medical Education (GME) trainees and staff with DRP services to help them start their research projects. Among our services are protocol development, research methods, SPSS (Statistical Package for the Social Sciences) statistics courses, grants writing, GME Trainee Funding for Research, collaborative agreements, manuscript editing, publication clearance, and the Biomedical Research Laboratory.

DRP invites you to join us at the Research Roundtable every third Tuesday of every month (except for this month). In July, we hosted a true “roundtable” of speakers on topics that ranged from vetting the risk of medical devices, to protecting research participants, transferring old protocols into the new electronic Institutional Review Board to improving writing skills.

Next month, we’re pleased to welcome staff of the Defense Technical Information Center, who will detail their tools and resources for researchers. Do you know the difference between DoDTechSpace and DoDTechipedia? Expect to find out.

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.



Institutional Review Board seeks new members Roundtable also touches on medical devices, writing, protocol transfers

The Institutional Review Board, or IRB, is recruiting a few good people to join its ranks. That was the message Sanjur Brooks, Ph.D. and program manager for human research protections at the Department of Research Programs (DRP), brought to the July 19 Research Roundtable.



Sanjur Brooks, Ph.D., program manager for human research protections (Photo by Paula Amann)

The IRB is a committee that reviews human subject research to ensure it meets ethical standards and regulatory requirements. In essence, its members serve as advocates for research subjects.

“We are looking for scientists and nonscientists,” Brooks said. “You don’t have to be a Ph.D. or M.D. to be on the IRB.”

Also on the roundtable roster was Navy Cmdr. Mark S. Miller, senior regulatory review officer for the Office of Compliance at the U.S. Food and Drug Administration (FDA), who parsed the differences between significant risk and nonsignificant risk for medical devices.

DRP’s research technical writer, Paula Amann, spoke briefly on plain language, a recent trend in the federal government, but one rooted in the best writing traditions.



In addition, Erica Reid, a protocol development specialist and a member of the Tiger Team (see page 2), fielded questions on transfer of old protocols into the new electronic IRB system (EIRB).

As for Brooks, she emphasized that researchers are required to take the CITI training once every three years. Others who conduct evidence-based practice and quality improvement projects are mandated to take Exempt Determinations Official (EDO) training.

She encouraged researchers to reach out to her with any questions about protecting human subjects. “I give a lot of leeway to people contacting me, because research is fluid,” Brooks said.

In his own remarks and a later email, Miller noted that the FDA is in the process of updating its policies on medical devices. He flagged a significant risk (SR) device as one that poses serious risk to the health, safety or welfare of a human research participant.

Such devices include implants, items used to support or sustain human life, and other things crucial to diagnosing, curing, mitigating, or treating disease or preventing impairment of human health.

FDA is increasing its focus on IRB inspections of research projects, including those using new regulatory mechanisms and those involving vulnerable populations, Miller indicated.

“The one thing I’ve been hearing is that they’re focusing on the IRB determination of whether devices are SR or NSR [nonsignificant risk],” Miller said.

Amann formally introduced herself for the first time at the Research Roundtable. With a degree in biology from the University of Michigan, she said she feels lucky to be working for DRP, because the job brings together two of her favorite things: “wordsmithing and science.” She edits DRP’s monthly newsletter and encouraged anyone to contact her with story ideas about exciting, new research.

Amann shared three important tips on how to simplify sentences:

- Start with key points.
- Split long sentences into shorter ones.
- Use the fewest, shortest words you can.

Amann stressed the importance of using plain language for practical reasons, as well as because it’s the law, since passage of the Plain Writing Act of 2010. To illustrate, she engaged the audience in a short exercise using the three tips to “unpack” an overstuffed sentence.

Amann is available to do training, coaching and editing for the research community, and can be reached at paula.m.amann.ctr@mail.mil.

For her part, Reid addressed questions about the transfer of existing, or legacy, protocols into the EIRB.

One researcher asked if she and her colleagues need to transfer a study they are phasing out. Reid emphasized they should do so, unless they plan to close the study in the near future. On the other hand, she stressed, “If you’re going to close a study, we suggest that closure come as soon as possible.”

Reid noted that many researchers are asking about how to handle a protocol application that contains a question or section that does not appear in the latest version of protocol approved by the IRB.

“Please don’t create any text or answer any questions that aren’t covered in the approved protocol,” Reid cautioned in a June 20 interview.

Asked about missing “shells,” or electronic folders, for protocols approved during the gap between the old IRBNet and the new EIRB (between about Sept. 29, 2015 and April 15, 2016), Reid affirmed that researchers would have to create their own, filling them with items already approved by IRB.

– Paula Amann and John Fadoju reported this story; Sanjur Brooks reviewed a draft; Michele McGee-Guthrie helped define IRB’s role; Erica Reid filled in gaps on the EIRB; and Daniel Brooks helped turn EIRB “shells” into plain English.



Paula Amann (Photo by John Fadoju)



Navy Cmdr. Mark Miller (Photo by Paula Amann)



EARS, from page 1

“We think people who have been blast exposed need to be examined more closely,” Kubli said. “Our current fitness for duty standards are determined by each branch of the military and are based mainly on pure-tone thresholds. When there is enough hearing loss then speech in noise measures are used. However, we are seeing blast exposed Service Members who have normal pure-tone thresholds and are experiencing difficulty understanding speech in complex environments. We are evaluating if other metrics may be beneficial to the current Auditory Fitness for Duty standards. These studies are funded through many resources including Army Public Health Command (Provisional), WRNMMC, Hearing Centers of Excellence, and U.S. Army Medical Research and Materiel Command.”

And the research suggests the problem may be widespread. In fact, Grant believes that “10 to 15 percent of our troops who deployed to Iraq and Afghanistan force may be asked to perform a variety of operational tasks in noisy, kinetic and stressful environments while having their hearing compromised.”

At the annual meeting of the American Auditory Society in March of this year, Walter Reed Bethesda researchers presented these results in a study, “Prevalence and Verification of Communication Deficits in Blast-Exposed Service Members.”

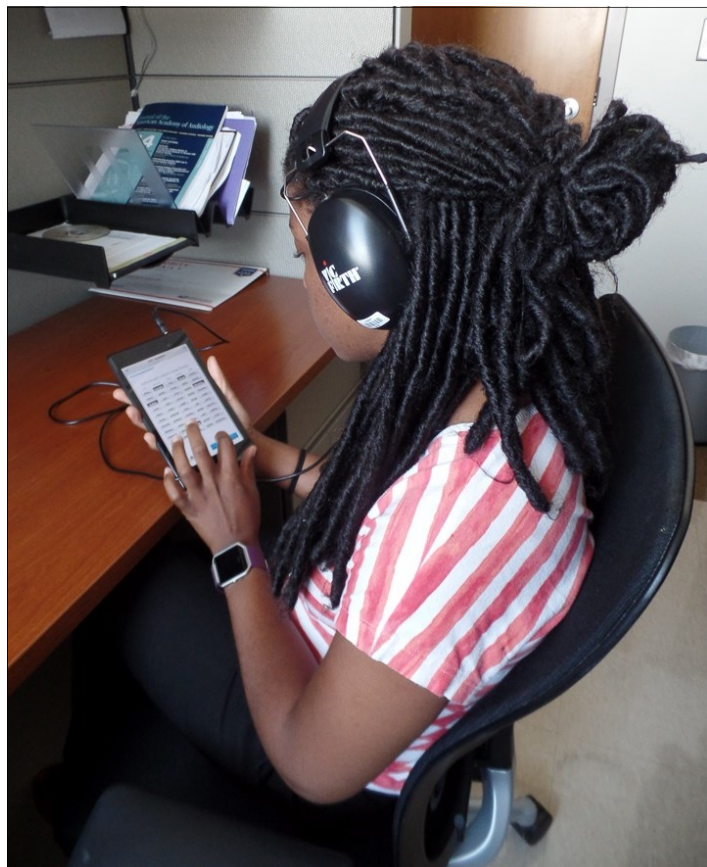
In its medical sleuthing, the Walter Reed Bethesda team has joined forces with Brook Army Medical Center and Wilford Hall Ambulatory Surgical Center.

Of the 1,654 participants studied so far, 12.3 percent showed poor hearing performance on either a short survey of their ability to hear and understand speech in noisy situations, or a brief functional hearing test developed for this study using speech and non-speech sounds, Grant said.

More than 1,000 other service members also have been studied at the Navy Medical Center San Diego, Grant added. Their data will join the rest after the signing of a memorandum of agreement that will permit data sharing across sites.

Meanwhile, hearing deficits can also have repercussions well beyond clear communication on the job and beyond, say professionals who counsel service members at Walter Reed Bethesda.

In the practical realm, hearing loss among service members can keep them from acquiring new skills and mastering new



A summer intern with the Audiology and Speech Center at Walter Reed National Military Medical Center tries out the tablet technology used to test for functional hearing loss after blast exposure. (Photo by Paula Amann)

tasks. “They can’t learn or follow directions,” noted Anne Molloy, Psy. D., a psychologist at Walter Reed Bethesda.

What’s more, reduced hearing can undermine family ties, as people with hearing loss misunderstand or entirely miss what’s going on with their spouse and children.

“There is a social impact when they mishear, and the whole family gets frustrated,” Molloy said. “They will isolate themselves, avoid activities they enjoy and they can become depressed.”

Army Lt. Col. John O’Grady, a Catholic chaplain who ministers to patients in the intensive care units and the emergency room, corroborates Molloy’s concerns. As chaplains like him make their rounds, he suggests, it’s easy to mistake hearing loss for indifference.

“If they’re not responding, it can be misinterpreted by us as lack of interest,” said O’Grady, who says he looks for nonverbal cues, such as eye movement, to determine if patients can hear his words of comfort.

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EARS, from page 5

Part of the problem for caregivers is that young soldiers, unlike older veterans, are often reluctant to admit they can no longer hear well, O’Grady noted.

“It’s a bigger problem than any of us realize,” O’Grady said. “It’s something that can be misread, even by family members.”

Both O’Grady and Molloy have observed the psychosocial impact of hearing loss among service members.

“They will isolate themselves, avoid activities they enjoy and they can become depressed,” Molloy said, who noted that anxiety also arises for many with hearing problems, as they worry about missing crucial information.

For audiologists, the challenge is to detect hearing deficits across a large population who present with apparently clinically normal hearing, in hopes of avoiding this chain of problems.

In this effort, Kubli and a team of other local audiologists – plus many more nationwide – have harnessed the latest technologies. In their study, participants use a tablet for both surveys and listening tests, Grant explained.

For example, they listen through headphones to a female voice speaking low-context sentences over the babble of four other speakers, and try to pinpoint the spoken words on the touch screen. Results are “de-identified” to protect patient privacy and stored in a secure cloud server.

Researchers have designed the self-administered tablet tests for use in war zones as well, Kubli stressed.

“We’re developing measures that can be used shortly after exposure to see if hearing is affected” by blasts, Kubli said. “If they’re affected, they could put themselves or others in harm’s way.”

What’s more, the study showed that damage to nerve cells progressed for as much as two years after the initial exposure to loud noise.

And here’s the startling outcome, which Grant believes is likely happening among people exposed to such high- pressure noises as

explosions on the battlefield. Hearing thresholds, measured clinically using standard audiometry, snapped back to normal levels. Yet, inside the ears of the mice, neurons were dying.

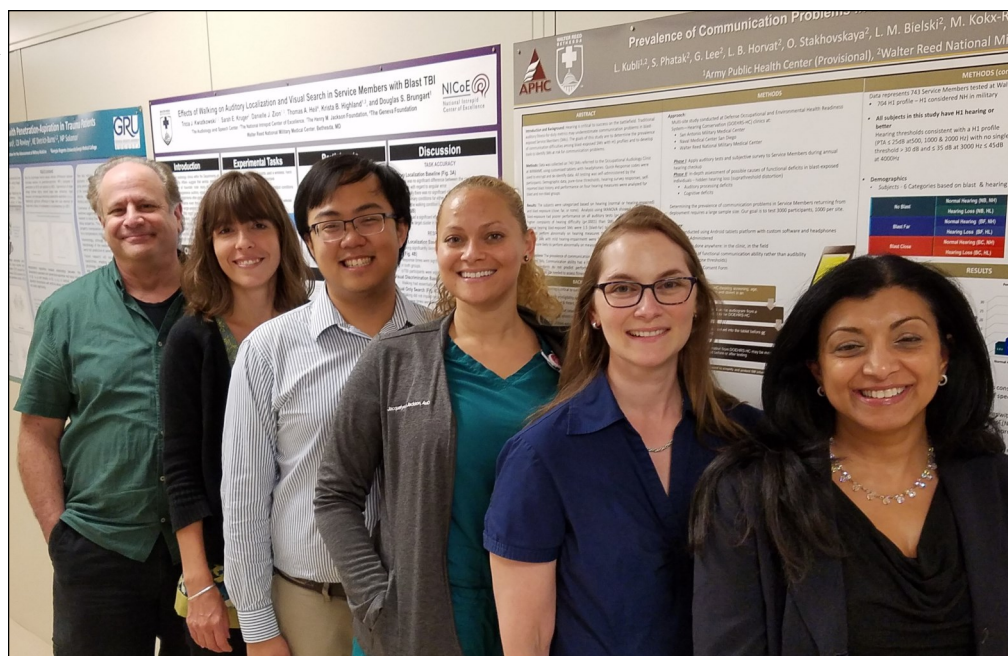
“It is sobering to consider that normal threshold sensitivity can mask ongoing and dramatic neural degeneration in noise-exposed ears,” Kujawa and Liberman concluded in their 2009 study, adding, “The clear conclusion is that noise exposure is more dangerous than has been assumed.”

Moving forward, Grant and his team hope to examine the physical reasons and potential remedies for these types of hearing deficits.

At this point, Grant believes the causes may involve both peripheral sound distortion – due to loss of synapses – and problems with central auditory and cognitive processing in the brain.

Meanwhile, Grant’s team is mapping the scope of hidden hearing loss and aiming to develop ways to rehabilitate service members who have it.

“Are you hearing-fit for duty?” Grant said. “And if you’re not, what can we do to improve hearing capability?”



It takes a team to get a handle on hearing loss among service members nationwide. From left, Ken W. Grant, deputy director of the Audiology and Speech Center and chief of the Research Section at the National Military Audiology and Speech-Pathology Center; Lee Ann Horvat, research assistant, audiologist; General Lee; Jacquelyn Jackson, A.U.D.; Lynn Bielski, Ph.D.; and Lina Kubli, Ph.D., the research audiologist who has overseen the study at Walter Reed and other sites. (Photo by Matthew Makashay)



Gauging How Hearing Loss Impacts Combat

by Paula Amann

For soldiers on combat patrol, hearing counts. Detecting a footfall, a kicked pebble or the sound of crunching leaves can help them locate the foe. What's more, when squad members can hear each other, they work better as a team.

The armed forces rates hearing on a scale from H1 (normal), to H2 (mild hearing loss), and H3 (enough hearing loss to trigger an audiology evaluation of fitness for duty).

For all these reasons, Benjamin Sheffield, an audiologist at Walter Reed National Military Medical Center, devised an ingenious research project that showed hearing loss can hurt battlefield performance.

On May 19, as part of Research and Innovation Month at Walter Reed Bethesda, Sheffield earned a Robert A. Phillips Award for the study, "The Effects of Hearing Impairment on Fire Team Performance in Dismounted Combat."

Colleagues Douglas Brungart, chief scientist with the Audiology and Speech Center, and Army Lt. Col. Amy Blank, the center's director, also worked on the project.

"What Ben's study does is it validates the existence of the H3 standard, the importance of the auditory fitness for duty standard, because it demonstrates that dismounted soldiers with a moderate amount of hearing loss are less combat effective than those with normal hearing," Brungart said in an interview.

They took audiology into the woods, with a simulated fire fight among four teams of male soldiers armed with M4 rifles, firing blank rounds, Sheffield explained. Their MILES gear (multiple integrated laser engagement system) sent off a laser each time they fired their weapon.

Meanwhile, each soldier's body-worn sensor information was fed back to a central trailer that received sensor data for each soldier, so researchers could record shots and targets. GPS transmitters tracked their movements.

Wearing special plugs that mimic different levels of hearing loss, the soldiers had to "hit" as many as 12 potential targets and gather at an end point. As in real combat, they also had to avoid getting hit by other teams.

The simulated hearing loss had a dramatic impact, the researchers found. Lethality, survivability, mission progress and overall mission success fell significantly. And in a curious twist, the strongest fighting teams seemed to suffer most from loss of hearing acuity.



Audiologist Benjamin Sheffield details the study that earned him a Robert A. Phillips Award at the May 19 Research Symposium at Walter Reed National Military Medical Center. (Photo by John Fadoju)

"The better they performed overall, the more hearing loss seemed to hurt them," Sheffield said in an interview.

The high-performing teams saw more of a drop in combat outcomes, he suggested, because hearing loss reduced their ability to talk with each other about the mission.

"They're communicating better when they can hear, which helps their performance," Sheffield speculated. "They become more like the low-performing teams, as they [the high performers] lose hearing."

Sheffield was set to present his research at a plenary of the Military Health Science Research Symposium in Kissimmee, Fla. on Aug. 17 and at the Human Factors and Ergonomics Society International Annual Meeting in Washington, D.C. on Sept. 19-23.

He hopes his research will trickle down to decisions on the battlefield. "If you can tell a commander his [hearing-impaired] soldier going to be half as lethal, it gives him something he can understand and care about," Sheffield said.

Meanwhile, Brungart credits his colleague for building the scientific case that hearing loss impacts combat performance. This in turn will help the audiology field update the fitness-for-duty standard.

"Prior to Ben's study, we had no objective evidence," Brungart said. Now, he said, "Nobody can deny the importance that hearing has for their operational tasks, and that's important for a standard that's acceptable for both the medical and operational communities."



DEPARTMENT DOWNLOAD

NEWS FROM THE DEPARTMENT OF RESEARCH PROGRAMS

Amid challenges posed by the new electronic Institutional Review Board (EIRB), the Department of Research Programs (DRP) has mustered a new customer service team, known as the Tiger Team.

“We’re going to be both proactive and reactive,” said the DRP’s new deputy chief, Army Col. Ann Nayback-Beebe in remarks to the July 7 department meeting.

Nayback-Beebe, who also serves as chief of the DRP Protocol Development Section, said she and Tiger Team members plan to reach out to researchers with protocols. The team will be helping to shift existing protocols into the EIRB.

In addition, Nayback-Beebe pledged to “streamline” processes of protocol development and the Office of the IRB in an effort to reduce submission to approval times for research protocols, continuing reviews and modifications. She will also seek to turn legacy processes from the former Walter Reed and Bethesda Naval Hospital Departments of Research into best practices for the current operating climate.



Col. Ann Nayback-Beebe (Photo by John Fadoju)

At the July meeting, Army Col. Peter Weina, chief of DRP, formally introduced his new deputy, noting that she will oversee not only protocol development, but also the biostatistics consultation, and research education and outreach teams.

Introducing herself as a “nurse scientist” by trade, Nayback-Beebe noted her penchant for a blend of harmony and teamwork in managing both a family and a staff like that of DRP. She promised an “open door policy” for staff questions and concerns.

The new deputy chief also previewed a series of face-to-face meetings with investigators on the EIRB at DRP, the Darnall Library annex or a location convenient to investigators. Internally, she noted, the DRP will be reassessing and potentially reassigning some office space, in an effort led by Army Sgt. Alisha Kohler. DRP staff should share their office preferences with her.

Also introduced at July’s meeting were IRB manager Rashida Redd and Navy Lt. Sierra Howell, who is doing a summer research residency with DRP, while pursuing her doctorate in nursing. During her residency, Howell is broadening

her knowledge of research regulations, human research protection and policy development.

For his part, Weina also previewed a new outreach project for July: the filming of a video on the launch of the new EIRB, with the help of “actors” from the various services. It was due for release this month, pending review.

Circling back from a July 28 sendoff for then-departing Army Staff Sgt. Jullian Hodges, Nayback-Beebe announced the winners of the bakeoff held that day. The anonymous panel of judges turned out to consist of Army Col. Brian Belson, director of the Education, Training and Research Directorate at Walter Reed National Military Medical Center; Hodges; and Nayback-Beebe herself.

The event’s organizer, Beth Narvaez, who is also an IRB manager, walked away with the third-place medal for her summery peach cobbler. In second place was biostatistician and veteran baker Robin Howard for her caramel-filled, chocolate-walnut cookies. Paula Amann, editor of this newsletter, garnered first place for a peach crisp with a cardamom- and coconut-flavored topping.

The next DRP celebration is slated for the September 1 meeting. Harvest dishes, anyone? These could range from stuffed squash and grilled corn to apple pie. The sky – or at least your local farmer’s market – is the limit.

– Paula Amann



FACES OF RESEARCH

HONORING OUR OWN

At July's departmental meeting, Col. Peter Weina, chief of the Department of Research Programs (DRP) presented the I Save Lives recognition to Erica Reid, a protocol development specialist.

"Even though this award was presented to me," Reid stated in an Aug. 28 email, "it should really be seen as a reflection of the hard work put in by the entire DRP navigator team."

Speaking of the campaign that monthly honors a member of the DRP staff, Weina said, "There's nobody here who's not in the business of saving lives."

As an infectious disease specialist, he recalled the enormous progress his field has made in treating AIDS – once a fatal diagnosis, now one managed by drugs. Work done at Walter Reed played a role in these advances, he said, noting that "the research that was done every day in these facilities allowed that to happen."



Col. Peter Weina, chief of the Department of Research Programs, presents Erica Reid, a protocol development specialist, with the I Save Lives poster on July 8. (Photo by John Fadoju)

ARRIVAL GATE

Rashida Redd joins the department as our new institutional review board (IRB) manager. She earned her bachelor's degree in biological sciences from the University of Maryland in Baltimore County, which she attended as a Meyerhoff scholar.

Redd came to the DRP from the National Institutes of Health, where she worked as a protocol navigator, assisting investigators and their staff with writing, reviewing and obtaining approval for their clinical research protocols. Prior to that, she worked as a senior quality assurance and regulatory affairs specialist at a biopharmaceutical company, where she oversaw clinical trials, assisted with regulatory submissions, conducted staff trainings, managed drug inventory and reviewed product manufacturing data. She also has worked as an IRB coordinator, as well as having carried out and supervised laboratory bench work.

Redd is excited to be here at Walter Reed Bethesda, and sees it as an honor to work alongside the country's military heroes. She's looking forward to learning about the various research projects happening around campus and to becoming an integral part of the DRP team.



Rashida Redd (Photo by Paula Amann)



WEB 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 Defense Department 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.

- [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.



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](#)



☐ 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:

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

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, MHA, MBA, 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 instructions 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

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- ☐ Tuesday, Sept.13, 2016, 1400-1500
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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

Designing a Compelling Presentation

September 9, 1300-1400

This workshop 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.

NCBI Medical Genetics Resources

September 20, 1200-1300

This workshop focuses on information resources and molecular databases centered on human medical genetics, genetic tests and laboratories, and genetic disease and human variation resources. The workshop consists of a brief introduction and guided walkthrough search that is based on a clinical case scenario in the NCBI molecular databases.

Research Data Management

September 27, 1200-1300

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, 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

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RECENT PUBLICATIONS

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Cleared articles by authors at Walter Reed National Military Medical Center are in bold.

Ahmadi A, Stone GW, Leipsic J, et al. [Prognostic determinants of coronary atherosclerosis in stable ischemic heart disease: anatomy, physiology, or morphology?](#) *Circ Res.* 2016;119(2):317-29. WRNMMC Author: **Villines TC**

Alarcón A, **Morgan M**, Montgomery SP, et al. [Diagnosis and treatment of congenital chagas disease in a premature infant.](#) *J Pediatric Infect Dis Soc.* 2016 Jul 27. [Epub ahead of print]

Albert D, Heifert TA, Min SB, et al. [Comparisons of fluticasone to budesonide in the treatment of eosinophilic esophagitis.](#) *Dig Dis Sci.* 2016;61(7):1996-2001. Additional WRNMMC Authors: **Maydonovitch CL, Baker TP, Chen YJ, Moawad FJ**

Balazs GC, Brelin AM, Donohue MA, et al. [Incidence rate and results of the surgical treatment of pectoralis major tendon ruptures in active-duty military personnel.](#) *Am J Sports Med.* 2016;44(7):1837-43. Additional WRNMMC Authors: **Dworak TC, Giuliani JR, Dickens JF**

Bardenheier BH, Duderstadt SK, **Engler RJ**, McNeil MM. [Adverse events following pandemic influenza A \(H1N1\) 2009 monovalent and seasonal influenza vaccinations during the 2009-2010 season in the active component U.S. military and civilians aged 17-44years reported to the Vaccine Adverse Event Reporting System.](#) *Vaccine.* 2016 Jul 19. [Epub ahead of print]

Bello KJ, Mesner O, O'Bryan TA, et al. [Factors associated with 10 years of continuous viral load suppression on HAART.](#) *BMC Infect Dis.* 2016;16:351. WRNMMC Author: **Ganesan A**

Bhatt NA, Lazarus A. [Obesity-related asthma in adults.](#) *Postgrad Med.* 2016 Jul 7:1-4. [Epub ahead of print]

Bittencourt MS, **Hulten E**, Polonsky TS, et al. [European Society of Cardiology recommended CAD consortium pre-test probability scores more accurately predict obstructive coronary disease and cardiovascular events than the Diamond and Forrester score: the partners registry.](#) *Circulation.* 2016 Jul 13. [Epub before print]

Bodanapally UK, Shanmuganathan K, Dreizin D, et al. [Penetrating aerodigestive injuries in the neck: a proposed CT-aided modified selective management algorithm.](#) *Eur Radiol.* 2016;26(7):2409-17. WRNMMC Authors: **Vasquez M, Cardarelli C**

Brickell TA, Lippa S, French LM, Kennedy J, Bailie J, **Lange RT.** [Female service members and symptom reporting following combat and non-combat related mild traumatic brain injury.](#) *J Neurotrauma.* 2016 Jul 1. [Epub ahead of print]

Burch HB, Burman KD, Cooper DS, Hennessey JV, **Viotor NO.** [A 2015 survey of clinical practice patterns in the management of thyroid nodules.](#) *J Clin Endocrinol Metab.* 2016;101(7):2853-62.

Cassler NM, Merrill D, Bichakjian CK, Brownell I. [Merkel cell carcinoma therapeutic update.](#) *Curr Treat Options Oncol.* 2016;17(7):36.

Chen D, Wang H, Sheng L, et al. [An algorithm for creating prognostic systems for cancer.](#) *J Med Syst.* 2016;40(7):160. WRNMMC authors: **Hueman MT, Patel JA**

Cheng FK, Moawad FJ. [Reply.](#) *Clin Gastroenterol Hepatol.* 2016;14(7):1061.

Davila CJ, Swiontkowski MF, **Andersen CR.** [Extremity war injuries X: return to health and function.](#) *J Am Acad Orthop Surg.* 2016 Jul 29. [Epub ahead of print]

Emmerich T, Abdullah L, Crynen G, et al. [Plasma lipidomic profiling in a military population of mild traumatic brain injury and post-traumatic stress disorder with apolipoprotein E ε4-dependent effect.](#) *J Neurotrauma.* 2016;33(14):1331-48. WRNMMC Author: **Dretsch M**

Fairbairn NG, Ng-Glazier J, Meppelink AM, et al. [Light-activated sealing of acellular nerve allografts following nerve gap injury.](#) *J Reconstr Microsurg.* 2016;32(6):421-30. WRNMMC Authors: **Valerio IL, Fleming ME**

Fonda SJ, Graham C, Munakata J, Powers JM, Price D, Vigersky RA. [The cost-effectiveness of Real-Time Continuous Glucose Monitoring \(RT-CGM\) in type 2 diabetes.](#) *J Diabetes Sci Technol.* 2016;10(4):898-904.

Greer MD, Brown AM, Shih JH, et al. [Accuracy and agreement of PIRADSV2 for prostate cancer mpMRI: a multireader study.](#) *J Magn Reson Imaging.* 2016 Jul 8. [Epub ahead of print] WRNMMC Author: **Marko J**

Hays M, Andrews M, Wilson R, Callender D, O'Malley PG, Douglas K. [Reporting quality of randomised controlled trial abstracts among high-impact general medical journals: a review and analysis.](#) *BMJ Open.* 2016;6(7):e011082.



Heaton SM, Weintrob AC, Downing K, et al. [Histopathological techniques for the diagnosis of combat-related invasive fungal wound infections.](#) *BMC Clin Pathol.* 2016;16:11. Additional WRNMMC Authors: **Keenan B, Wells J**

Heckendorn E, Auerbach A. [Pathology of extranodal lymphoma.](#) *Radiol Clin North Am.* 2016;54(4):639-48.

Jacobs MB, Cohen SP. [Duloxetine for subacute pain management after total knee arthroplasty: should we write it off or reevaluate?](#) *Anesthesiology.* 2016 Jul 7. [Epub ahead of print]

Kent ML, Hsia HJ, Van de Ven TJ, Buchheit TE. [Perioperative pain management strategies for amputation: a topical review.](#) *Pain Med.* 2016 Jul 8. [Epub ahead of print]

Knaus CM, Patronas NJ, Papadakis GZ, Short TK, Smimiotopoulos JG. [Multiple endocrine neoplasia, type 1: imaging solutions to clinical questions.](#) *Curr Probl Diagn Radiol.* 2016;45(4):278-83.

Koeller KK, Shih RY. [Extranodal lymphoma of the central nervous system and spine.](#) *Radiol Clin North Am.* 2016;54(4):649-71.

Lalani T, Yun H, Tribble D, et al. [A comparison of compliance rates with anti-vectorial protective measures during travel to regions with dengue or chikungunya activity, and regions endemic for Plasmodium falciparum malaria.](#) *J Travel Med.* 2016;23(5). WRNMMC Author: **Ganesan A**

Lindsay RW, George R, Herberg ME, Jackson P, Brietzke S. [Reliability of a standardized nasal anatomic worksheet and correlation with subjective nasal airway obstruction.](#) *JAMA Facial Plast Surg.* 2016 Jul 14. [Epub ahead of print]

Liu J, Balu N, Hippe DS, et al. [Semi-automatic carotid intraplaque hemorrhage detection and quantification on Magnetization-Prepared Rapid Acquisition Gradient-Echo \(MP-RAGE\) with optimized threshold selection.](#) *J Cardiovasc Magn Reson.* 2016;18(1):41. WRNMMC Author: **DeMarco JK**

Lucas DJ, Ejaz A, Spolverato G, et al. [Packed red blood cell transfusion after surgery: are we "overtransfusing" our patients?](#) *Am J Surg.* 2016;212(1):1-9.

McBee E, Ratcliffe T, Goldszmidt M, et al. [Clinical reasoning tasks and resident physicians: what do they reason about?](#) *Acad Med.* 2016;91(7):1022-8. WRNMMC Author: **Masel J**

McGann P, Snesrud E, Maybank R, et al. [Escherichia coli Harboring mcr-1 and blaCTX-M on a Novel IncF Plasmid: First Report of mcr-1 in the United States.](#) *Antimicrob Agents Chemother.* 2016;60(7):4420-1. WRNMMC Authors: **Whitman T, Schaecher KE**

McGann P, Snesrud E, Maybank R, et al. [Erratum for McGann et al., Escherichia coli Harboring mcr-1 and blaCTX-M on a Novel IncF Plasmid: first report of mcr-1 in the United States.](#) *Antimicrob Agents Chemother.* 2016;60(8):5107. WRNMMC Authors: **Whitman T, Schaecher KE**

Min SB, Nylund CM, Baker TP, et al. [Longitudinal evaluation of noninvasive biomarkers for eosinophilic esophagitis.](#) *J Clin Gastroenterol.* 2016 Jul 29. [Epub ahead of print]. Additional WRNMMC Authors: **Ally M, Reinhardt B, Chen YJ, Nazareno L, Moawad FJ**

Moawad FJ, Appleman HD. [Sloughing esophagitis: a spectacular histologic and endoscopic disease without a uniform clinical correlation.](#) *Ann N Y Acad Sci.* 2016 Jul 6. [Epub ahead of print]

Moawad FJ, Cheng E, Schoepfer A, et al. [Eosinophilic esophagitis: current perspectives from diagnosis to management.](#) *Ann N Y Acad Sci.* 2016 Jul 28. [Epub ahead of print]

Mula KN, Winston J, Pace S, Kentosh JB. [Use of a microwave device for treatment of amputation residual limb.](#) *Dermatol Surg.* 2016 Jul 8. [Epub ahead of print]

Murphey MD. [Imaging of extranodal lymphoma.](#) *Radiol Clin North Am.* 2016;54(4):xi.

Oronsky B, Scicinski J, Kim MM, et al. [Turning on the radio: epigenetic inhibitors as potential radiopriming agents.](#) *Biomolecules.* 2016;6(3). WRNMMC Author: **Carter CA**

Paris DH, Dumler JS. [State of the art of diagnosis of rickettsial diseases: the use of blood specimens for diagnosis of scrub typhus, spotted fever group rickettsiosis, and murine typhus.](#) *Curr Opin Infect Dis.* 2016 Jul 13. [Epub ahead of print]

Pinches H, Dobbins K, Cantrell S, May J, Lopreiato J. [Asymptomatic Kawasaki disease in a 3-month-old infant.](#) *Pediatrics.* 2016 Jul 1. [Epub ahead of print]

Potter BK. [Bench to bedside: platelet-rich plasma-how do we adequately "Untranslate" translational "Breakthroughs" in an after-market setting?](#) *Clin Orthop Relat Res.* 2016 Jul 22. [Epub ahead of print]

Potter BK. [From bench to bedside: how stiff is too stiff? Far-cortical locking or dynamic locked plating may obviate the question.](#) *Clin Orthop Relat Res.* 2016;474(7):1571-3.

Robbins RC, Edison JD. [Images in clinical medicine. Milk of urate bursa.](#) *N Engl J Med.* 2016;375(2):162.

Rohena-Quinquilla IR, Lattin GE Jr, Wolfman D. [Imaging of extranodal genitourinary lymphoma.](#) *Radiol Clin North Am.* 2016;54(4):747-64.

Scultetus AH, Haque A, Chun SJ, et al. [Brain hypoxia is exacerbated in hypobaria during aeromedical evacuation in swine with traumatic brain injury.](#) *J Trauma Acute Care Surg.* 2016;81(1):101-7. Additional WRNMMC Author: **Malone DL**

Vo KT, Edwards JV, Epling CL, et al. [Impact of two measures of micrometastatic disease on clinical outcomes in patients with newly diagnosed Ewing sarcoma: a report from the Children's Oncology Group.](#) *Clin Cancer Res.* 2016;22(14):3643-50.

Warren WA, Hagaman JT. [Endobronchial ultrasound guided transbronchial needle aspiration for mediastinal staging in a community medical center.](#) *Ann Am Thorac Soc.* 2016 Jul 13. [Epub ahead of print]



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