Department of RESEARCH PROGRAMS at Walter Reed National Military Medical Center

Vol. 3, Issue 6 ▪ July 2016

Military Medical Research News

Improving medicine through science
Lessons of Research and Innovation Month

by Paula Amann

When servicemembers suffer severe trauma and lose tissue from an improvised explosive device, gunshot or accident, they may need a tissue transfer from another body part, such as the forearm or thigh, to cover the wound.

As this surgery heals, doctors and nurses check for danger signs, such as pale skin, that signal ischemia – lack of blood flow to the transfer area, or flap. If medical staff detect and treat it fast, they can restore blood flow and save the flap. After some 12 hours of ischemia, though, the flap can die, leaving a patient with an untreated injury and lost tissue, says Army Maj. Elizabeth Polfer, MC, a young hand surgery fellow at Walter Reed National Military Medical Center.

For years, anecdotal evidence has suggested that dark-skinned patients were harder to monitor for ischemia after flap transfers, but the standard of care has been to visually check all patients. Yet, until Polfer could prove it, the research was silent on this score.

Army Maj. Elizabeth Polfer, MC, a 2016 finalist for the Bailey K. Ashford and Robert A. Phillips Awards, has shown that clinical exams may miss ischemia in darker-skinned patients. (Photo by John Fadoju).

Anshu Rastogi, Ph.D., a fellow at the Center for Prostate Disease Research at the Uniformed Services University of the Health Sciences, works to devise new and better tests for prostate cancer. (Photo by Paula Amann)

A new study by Polfer was one of several shared during 2016 Research and Innovation Month that could help propel progress in medical care across the armed forces and the society at large.

Other such projects emerging from Walter Reed and its partners, in research and evidence-based practice, augur new ways to diagnose prostate cancer and gauge skill levels in an emerging mode of anesthesia.

Polfer, a 2016 finalist for the Bailey K. Ashford and Robert A. Phillips Awards, devised a study to show how skin color might shade the clinical examination of flaps. A teaching fellow in surgery since 2011 at the Uniformed Services University of the Health Sciences, a 2015 winner of the Ashford award and a 2013 winner of the Phillips award, she recruited 29 volunteers of varied racial backgrounds.

See LESSONS, page 4

Department of Research Programs

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

The Department of Research Programs (DRP) at Walter Reed National Military Medical Center (WRNMMC) 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.

Military Medical Research News

Supervising Editor
Lisa Thompson, M.H.A., M.B.A.

Contributing photographer
John Fadoju

Editor
Paula Amann

Contributing editor
Sanjur Brooks, Ph.D.

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

Contents

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.

Research Roundtable Schedule

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

- Tuesday, 23 August 2016, 1200-1300
- Tuesday, 20 September 1016, 1200-1300

Big Data brings pitfalls, promise to medical research

by Paula Amann

Big data is flooding the medical field. With the advent of electronic health records (EHRs) and data sets from the National Institutes of Health, for example, a growing harvest of data points on more and more patients appear ripe for use by researchers.

However, not all such data has value for improving public health, and pitfalls await investigators, say observers. As recently as May 6 of this year, an annual conference at Harvard University explored the nuances of "Big Data, Health Law, and Bioethics." Amid the promise of this brave new research world lie pitfalls such as patient privacy, conflicts of interest among researchers or a lack of clear protocols to define the work at hand.

First and foremost, researchers need to keep their eye on the ball of medical ethics, say observers in the field.

Back in April 2013, in a piece for the American Journal of Bioethics (AJOB), Stanford University professor, John Ioannidis, worried that some big data researchers are neglecting the cornerstone ethic of informed consent.

Ioannidis suggested that self-interest is pushing researchers to sideline informed consent. Says this critic, "the pressure is mostly due to the large number of emerging studies that use big data that were (or are) not primarily collected for research purposes."

Writing in the AJOB a year later, Turkay Dereli and his colleagues cited the risks of "creative destruction," an idea first described by Austrian economist and political scientist Joseph Schumpeter. With the impact of big data still unknown, they warned, countries need to set up systems for ethical review of the new research emerging today.

What's more, in the big picture of big data, researchers should not confuse data quantity with quality, commentators say.

"Most of [the increasing quantity of information] is just noise, and the noise is increasing faster than the signal," writes Nate Silver in "The Signal and the Noise," as cited and paraphrased by Bruce Psaty, M.D., Ph.D., and Alasdair Breckenridge, M.D. in the June, 5, 2014 New England Journal of Medicine (NEJM).

Sounding a harsher critique, Ioannidis shares Silver's concerns about data quality, as well as broader worries about ethics.

Federal Policy Pointers for Big Data

Within the U.S. Department of Health and Human Services, the Secretary's Advisory Committee on Human Research Protections **(SACHRP)** has produced a raft of recommendations on protecting human research participants. Here are a few of those with special relevance for big data work:

♦ **Attachment A: Recommended Guidance on Minimal Risk Research and Informed Consent.** Appended to a letter of Sept. 28, 2015, this attachment spells out ethical issues around informed consent and minimal risk. http://www.hhs.gov/ohrp/sachrp-committee/recommendations/2015-september-28-attachment-a/index.html

♦ **Attachment A: Human Subjects Research Implications of "Big Data" Studies.** Appended to a letter of April 24, 2015, this attachment presents the problems that may be posed by big data research. http://www.hhs.gov/ohrp/sachrp-committee/recommendations/2015-april-24-attachment-a/index.html

♦ **Attachment D: Informed Consent and Waiver of Consent.** Appended to a letter of Jan. 10, 2013, this document examines the scope of informed consent by human research participants. http://www.hhs.gov/ohrp/sachrp-committee/recommendations/2013-january-10-letter-attachment-d/index.html

♦ **Attachment D: FAQs, Terms, and Recommendations on Informed Consent and Research Use of Biospecimens.** Appended to a letter of Oct. 13, 2011, this document focuses on research use of such biospecimens such as blood and other body fluids. http://www.hhs.gov/ohrp/sachrp-committee/recommendations/2011-october-13-letter-attachment-d/index.html

"In all, the hype about non-research-committed big data is enthusiasm about fools' gold," Ioannidis wrote in AJOB. "There is no serious justification why ethical standards of research should be compromised to facilitate more researchers performing more spurious analyses with junk."

For one thing, not all data sets are ready for comparison with others. To make sure researchers are weighing the medical counterpart of apples and apples, the field needs standard data and metadata (data that describes other data) formats, suggested Rebecca Kush, Ph.D., and Michel Goldman, M.D., Ph.D., in the NEJM's June, 5, 2014 issue.

Standards are a must, argue Kush and Goldman, for melding large amounts of patient data, analyzing it and

See DATA, page 4

DATA, from page 3

making sound clinical decisions based on results. For instance, they point to varying use of the Alzheimer's Disease Assessment Scale "preventing accurate comparisons among studies or among patients unless data are later translated into a common format."

Yet, big data, used wisely, has great potential for growing medical knowledge, say other observers.

For their part, Psaty and Breckenridge point to the Mini-Sentinel, a pilot project of the Sentinel Initiative within the U.S. Food and Drug Administration (FDA). Mini-Sentinel, a pilot program that later flowed into the larger initiative, examined electronic data to gauge the safety of drugs, medical devices, and biologics on the market.

Despite such data roadblocks as 68 different terms used to count platelets, the program saw some public health successes. In 2013, the FDA mined data from a query about links between the high blood-pressure drug, olmesartan, and sprue-like enteropathy – a severe, prolonged diarrhea coupled with major weight loss – to add a warning to the drug's label.

The Mini-Sentinel approach had key advantages not always found in other big data research, note Psaty and Breckenridge: It fully protected patient privacy, posted protocols for public comment and tapped researchers free of conflicts of interest.

As a result, Mini-Sentinel turned big data not only into a "national research resource fit for the purpose of evaluating adverse drug reactions," say Psaty and Breckenridge, but one that can help build strong research partnerships to study the use and effect of drugs among specific groups of people.

All things considered, big data offers tremendous potential for broadening and enriching medical research. Yet, with all its promise, say ethicists, this new research tool shares with older methods the need to safeguard patient privacy, avoid conflicts of interest and maintain the kind of transparency that advances medicine.

References:

Dereli, T. et al. (2014). Big data and ethics review for health systems research in LMICs: Understanding risk, uncertainty and ignorance—And catching the black swans? Amer. J. Bioethics. 14(2):48–50.

Ioannidis, J. P. A. (2013) Informed consent, big data, and the oxymoron of research that is not research. Amer. J. Bioethics. 13(4):40–41.

Kush, R. and Goldman, M. (2014). Fostering responsible data sharing through standards. New Engl. J. Med.. 370(23):2163-65.

Psaty, B. and Breckenridge, A. (2014). Mini-Sentinel and regulatory science—Big data rendered fit and functional. 370(23):2165-67.

LESSONS, from page 1

In one "flap," 10 minutes out, the surgeons correctly found "ischemia" in less than a quarter (23.3 percent) of African-American volunteers, while the doctors found the "ischemic" limbs in most (92.9 percent) of the Caucasians. Other simulation results showed similar racial gaps.

"Even if we were experienced observers, we really weren't able to tell," said Dr. Ken Means, an attending physician and research director at the Curtis National Hand Center, and a coauthor of Polfer's study. "This project is proving to us that we need better monitoring options, especially for people with darker skin."

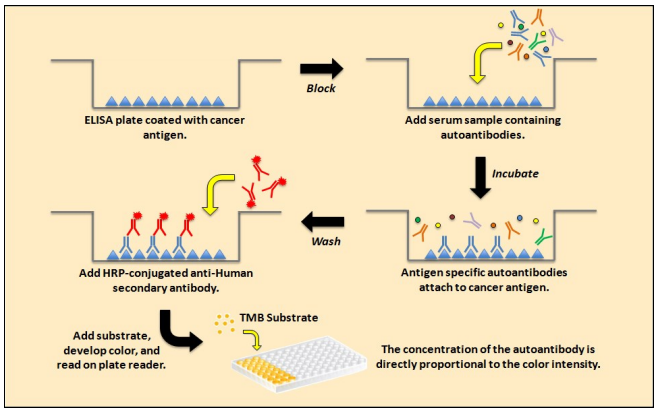
Means points to other diagnostic tools, such as near-infrared spectroscopy, which is used at his hospital and can signal ischemia in patients of all skin tones. Meanwhile, he lauds Polfer's research into an issue he says bears further study.

"Her organizational skills were off the charts," Means said. "It was a pretty ambitious project, but she hit it out of the park."

Polfer's work, if replicated, could spur changes in standards of care. "In certain patient populations, there's concern that the clinical exam isn't sufficient to detect ischemia," Polfer said in a June 22 interview, "and in that case, alternative methods of monitoring should be employed."

Meanwhile, at the Center for Prostate Disease Research of the Uniformed Services University of the Health Sciences, Anshu Rastogi, Ph.D., and her colleagues are racing to develop tests that can reveal the presence – and the stage – of prostate cancer. Rastogi, a fellow at the center, was a finalist for this year's Phillips Award.

See LESSONS, p. 5



This diagram of an enzyme-linked immunosorbent assay (ELISA) shows how Rastogi and her team test for autoantibodies as biomarkers for prostate cancer. In time, the team hopes to produce a '"liquid biopsy" to detect this common cancer. (Image courtesy of Anshu Rastogi, Center for Prostate Disease Research)

LESSONS, from page 4

The prostate-specific antigen, or PSA, test commonly used to diagnose this disease has its drawbacks, as it can indicate benign conditions as well as prostate cancer. "There's been a lot of controversy in terms of the PSA, because it can lead to overdiagnosis and overtreatment in patients," said Rastogi in a June 27 interview.

The "false positives" for cancer that sometimes result from the PSA test can lead to intrusive biopsies for the patient, said her mentor, Alargarsamy Srinivasan, Ph.D., in a June 29 interview.

What if there was a better way to detect prostate cancer? Rastogi and Srinivasan see an answer in autoantibodies, proteins that the human immune system builds against antigens that surface when cancer is present.

These autoantibodies include ERG, a protein that is normally dormant in prostate cells. But when fused to TMPRSS 2, another gene, ERG turns into a cancer-related oncogene, which directs the production of cancer cells in the tissue.

The CPDR team is aiming to create a "liquid biopsy," say Rastogi and Srinivasan. "The idea of our study is to take a blood sample, separate out the serum and see what we're dealing with – in a relatively quick test, without the invasive procedures," Rastogi said.

Next steps in the research, she noted, include devising a more diverse panel of biomarkers to reflect the ethnic mix of servicemembers. For instance, the oncogene ERG crops up in 50-60 percent of Caucasian Americans with prostate cancer and just 25-30 percent of African Americans.

The team's ultimate goal: A panel of biomarkers that not only detects prostate cancer but can predict its course and help guide a treatment strategy. These researchers want to provide a test that answers some crucial questions, said Rastogi: "How will this progress? How aggressively should this be treated?"

For Srinivasan, doing medical research at Walter Reed National Military Medical Center and the CPDR is the perfect fit.

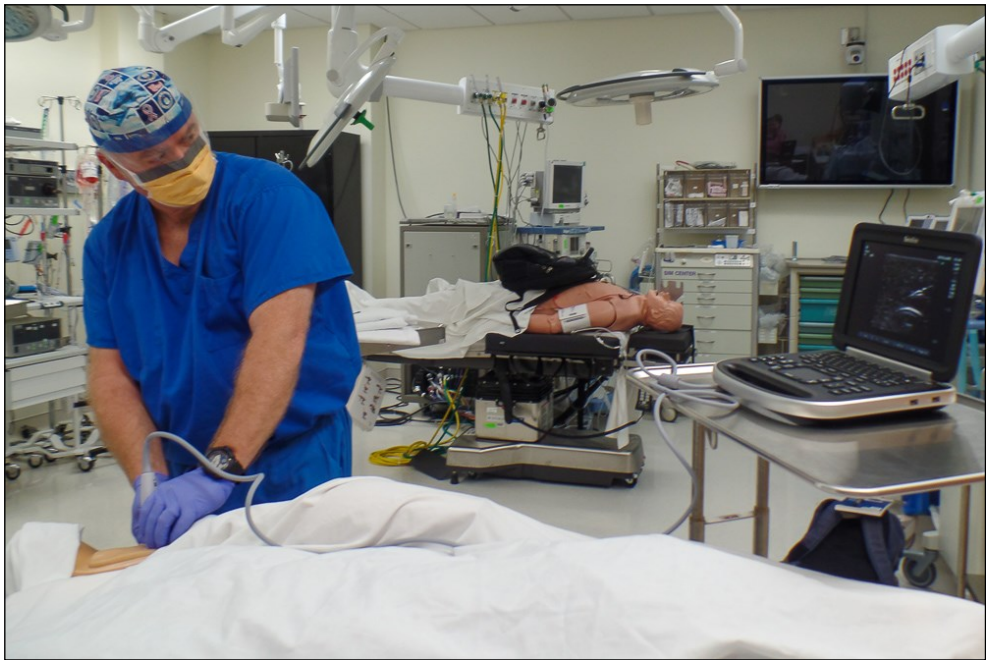
"We have the patience population, the right technology and the right person," said Srinivasan, noting the intelligence and "perseverance" that his younger colleague, Rastogi, brings to the task of finding a better test for prostate cancer.

Over at the Uniformed Services University of the Health Sciences, another medical team is gauging skill levels in a popular anesthetic method, with an eye to patient safety.

Ultrasound guided regional anesthesia, commonly known as UGRA, is a technique that blocks selected nerves – and pain – with a boost from an ultrasound screen at the patient's bedside to guide the anesthetist.

UGRA has gained wide use in the past decade, but the field is just starting to pinpoint the right metrics to assess the skills of its practitioners. CDR Darren Couture, Ph.D., CRNA, NC, advised a team of nurse anesthetists as they tested a new tool to gauge UGRA competency.

LESSONS, see page 6



In a simulation laboratory used for training nurse anesthetists, Air Force Maj. Lonnie Hodges, assistant clinical site director for the Registered Nurse Anesthetist Program at Walter Reed National Military Medical Center and instructor in the Graduate School of Nursing at the Uniformed Services University of the Health Sciences, models a popliteal nerve block. At right, an ultrasound screen guides Hodges as he inserts the needle into the leg of a sheet-draped mannequin. Anesthetists use this procedure to block pain during and after foot and ankle surgeries. Hodges and Navy Cmdr. Darren Couture advised a team of nurse anesthetists in a evidence-based practice project that seeks to gauge the skills of their peers in ultrasound guided regional anesthesia. (Photo by Paula Amann)

LESSONS, from p. 5

UGRA offers many advantages for practitioner and patient alike. "The benefits of using UGRA is that you get real-time imaging to avoid structures you want to avoid, and to direct the needle exactly where you want it to go," said Couture in a June 20 interview.

And, as compared with older methods, UGRA eases the aftermath of such procedures as a knee replacement, notes LT Thomas Diggs, who played a major role in the project.

"For patient comfort and safety, it's really the way to go," said Diggs in a June 29 interview, noting that UGRA can relieve pain for as long as eight to 12 hours after surgery and reduce use of painkillers.

Yet, with all its benefits, UGRA takes practice and precision, and a slip can damage surrounding tissue. "It's a much steeper learning curve" for anesthetists, said Couture.

The early results from the project, suggesting a highly effective assessment, are already making ripples in the field.

In fact, they produced not only a Poster Display Week prize for evidence-based practice in May of this year, but a poster presentation at the American Association of Nurse Anesthetists last August, and also a poster and podium talk that same month by team member, Capt Adam Garrison, NC, at the Tri-Service Nursing Research Program.

"Today, we want to ensure we have competent nurse anesthetists to get the results we want: patient comfort and safety," Diggs said from his car, as he drove to a new job in North Carolina. Once settled into his position, he hopes to suggest use of the assessment tool just tested locally.

As Diggs takes what he learned at Walter Reed to a new hospital, Rastogi and her team keep probing the biomarkers of prostate cancer. And, at press time, Polfer was submitting a study to a journal in her field on the way skin color can shape the perceptions of even the most seasoned hand surgeons. Together, these clinicians and researchers could affect the practice of medicine in the military system and beyond.

RESEARCH ROUNDTABLE

A Message from the Host of the Research Roundtable

by Lisa Thompson

The Department of Research Programs (DRP) would like to request time for a 10-15 minute presentation about DRP's 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 request to meet one day a year or once every six months, either before or after your program meets for didactic or lecture hall sessions.

Our goal is to facilitate research. We want to help familiarize your Graduate Medical Education (GME) trainees and staff with DRP services to help them start their research projects. Our services include, but are not limited to the following areas: protocol development, research methods, SPSS (Statistical Package for the Social Sciences) statistics courses, grants writing, GME Trainee Funding for Research, collaborative agreements, 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 August, see schedule on page 2). In June, Lisa Buchanan, compliance officer with the Division of Compliance Oversight, spoke about "Unanticipated Problems Reporting to the IRB."

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 communicate your requests at the Research Roundtable or send an email to lisa.p.thompson5.civ@mail.mil.

Taking the Fear out of Research Problems, EIRB
Buchanan, Roogow present at Roundtable

by Paula Amann

Don't be afraid to report a problem that crops up in your research project: That was the message brought to June's Research Roundtable by Lisa Buchanan, compliance officer with the Division of Compliance Oversight of the Office for Human Research Protections, or OHRP.

Also speaking at the June 21 event was Robert Roogow, director of operations for the Institutional Review Board with the Department of Research Programs at Walter Reed National Military Medical Center. Roogow fielded questions on the recently introduced EIRB, or Electronic Institutional Review Board.

With an eye to taking the dread out of compliance, Buchanan spoke on "Reporting Unanticipated Problems and Serious or Continuing Non-Compliance: What's Necessary, What's Not."

"Reporting to OHRP is a good thing," Buchanan told the roundtable audience, adding that if a principal investigator has a large portfolio of projects and reports no problems in any, "That's a red flag for us."

OHRP, a Rockville-based agency within the U.S. Department of Health and Human Services, does not define continuing non-compliance, Buchanan noted. However, she cited a telling example: "a researcher who routinely fails to obtain consent" from research participants.

Lisa Buchanan, compliance officer with the Division of Compliance Oversight of the Office for Human Research Protections, or OHRP, urged researchers to report unexpected issues that arise during the course of a project. (Photo by Paula Amann)

Standard Operating Procedures can guide researchers in this area, suggested Buchanan. Meanwhile, she flagged four items of concern in determining "serious non-compliance."

These include lack of review and approval by the institutional review board (IRB) for non-exempt research with human subjects, major changes to IRB-approved research without IRB sanction, a serious non-compliance incident as determined by the IRB, and as noted earlier, lack of informed consent – unless it can be waived.

Buchanan spent some time exploring the nuances of unanticipated problems and adverse events. Most adverse events, she stressed, are not unanticipated problems and need not be reported to OHRP.

As for unanticipated problems that require reporting, Buchanan underscored the need for prompt action. Researchers should report serious problems of this kind to the IRB within one week and other unanticipated problems within two weeks. A month out or less, researchers should report all such problems to institutional leaders, the supporting agency head and OHRP, she advised.

Later in the roundtable, Roogow led a freewheeling discussion of how best to use the EIRB. The system requires use of the email associated with a researcher's common access card, or CAC, he said.

If needed, Roogow noted, staff can arrange to have military emails send to an alternative government email. He stressed that research teams should provide correct emails for all of their key members, so they can receive crucial updates.

Meanwhile, the IRB leader reminded researchers with multi-site projects within the U.S. Department of Defense that the EIRB will track them all. "Anything you had opened anywhere else, you'll have access to," Roogow said.

Researchers sending reports to OHRP should email them to IRPT.OS@hhs.gov.

Helping Researchers Navigate Online Review System
Department hosts briefings for research community

by Paula Amann

As the Electronic Institutional Review Board (EIRB) rolls into use, the Department of Research Programs (DRP) is hosting a series of question-and-answer sessions for researchers. One such event on June 27 drew 22 people to a meeting hall at the National Intrepid Center of Excellence at Walter Reed National Military Medical Center.

As of August, the series moves to the Executive Conference Room (Room 0301) in the basement of Building 9 at Walter Reed National Military Medical Center. The series, consisting of one-hour sessions at noon on Mondays, will continue two to four times monthly through 2016.

Robert Roogow, IRB director of operations with the DRP at Walter Reed, fielded questions.

The June 27 session brought a spontaneous praise for the Help Desk of the EIRB from Mary McDuffie, who works with researchers under the auspices of the Henry M. Jackson Foundation. She reported same-day help for a "stuck screen" that was impeding her work.

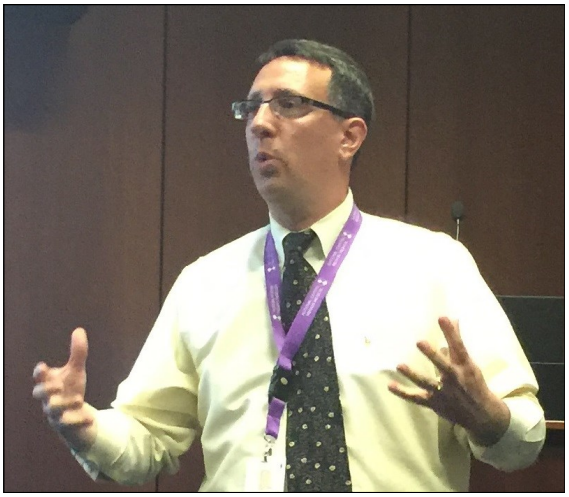
The Help Desk staffer took care of the problem fast, McDuffie told those gathered. "He did it while I was running around the block," McDuffie said.

As to staffing changes at the Department of Research Programs, Roogow noted the arrival of a new deputy chief, Col. Ann Nayback-Beebe. With the July departure of MAJ Scott Baumgartner, Sanjur Brooks, Ph.D., will move into the role of determinations officer and James Simms will handle publication clearance.

Early in the June 27 session, an attendee asked about listing of staff as associate investigators. Roogow underscored that anyone listed as an associate investigator must have the requisite education. The DRP will be releasing new guidance on this shortly.

Once a research project wins won IRB approval, researchers themselves cannot change the associated staff lineup online.

"You can't backfill the application with new people," Roogow said, but he noted that he can adjust the staff list for existing, approved studies. "You can make modifications, going forward."



Robert Roogow , Institutional Review Board director of operations, makes a point at a June 20 question and answer session for researchers on the new EIRB, hosted by the Department of Research Programs. (Photo by Lisa Thompson).

Meanwhile, the IRB can handle four to five points of contact for a given project. In the case of an expected departure by the principal investigator, such as retirement or maternity leave, Roogow suggested removing that person's name from the protocol months beforehand.

A new protocol needs prior vetting for its science. "Scientific review should happen before it comes to us," said Roogow. In a later conversation, he noted that radiation safety review can occur before or after IRB approval.

As to protocol numbers, research projects launched prior to EIRB keep their old IRBNet or DRPNet numbers. New protocols, however, will get a new number like this example, WRNMMC-2016-0001, at the time of approval.

Meanwhile, a question arose about the use of surveys and questionnaires in research projects. According to Roogow, any survey given to ten people or more requires approval by the Defense Health Agency in the U.S. Department of Defense, which takes some four to six months or longer. (Please see story with details on page 9.)

In the meantime, research teams can win approval from the IRB and gain a start letter, stressed Roogow.

Please see p. 19 for a full schedule of EIRB sessions for the remainder of the year.

Handling Surveys and Questionnaires

Getting Your U.S. Department of Defense Internal Information Collection and Report Control Symbol Approval

by Army Maj. Scott Baumgartner

Why is this important to me? If you are using a survey, questionnaire, focus groups or similar instruments as a data collection tool for your research protocol, you will need to obtain information collection approval and a report control symbol from the Defense Health Agency in the U.S. Department of Defense (DoD) prior to use.

Wait! What? In accordance with DoD Instructions 1100.13 and 8910.13, all DoD internal information collections ***must be licensed*** with a report control symbol. This Report Control Symbol (RCS) is given through a DoD-level review and approval process.

What is an "information collection"? It is a systematic collection of data or information (hard copy or electronic) for a specific purpose using a specified format or instrument. The information is solicited from respondents (individuals, groups, businesses, organizations, etc.); collections have an associated frequency (one time, quarterly, annually, biannual, etc.) and the results are "owned" by the requester.

What "specific format/instruments" are included? This may include DoD or Office of the Secretary of Defense (OSD) forms and applications; primary data collections such as surveys and questionnaires, focus groups, or structured interviews; and written reports, requested input for reporting or record keeping requirements, or related activities.

Are there are any exceptions/exclusions? Yes, there are a few. The most notable are the following:

1. Information collection with less than 10 respondents in a 12-month period
2. Open-ended questions
3. Information collection from a single component (e.g., only the U.S. Army)

It should be noted, however, that your request for exemption must be approved.

Is this an IRB thing? No. This is not a research regulation or Common Rule requirement. This is tied to the Paperwork Reduction Act of 1995, Department of Defense Instruction (DODI) 1100.13 (DOD Surveys), and DODI 8910.01 (Information Collection and Reporting).

Do I have to have my survey approved prior to getting IRB Approval? No. Survey approval will not prevent the IRB from approving your protocol or issuing a start letter. You will, however, want to work these two processes in parallel. The survey approval process can take four to six months.

Where can I go for more information? Start with http://www.dtic.mil/whs/directives/collections/internal_process.html for definitions, process overview, and forms, etc. The DHA points of contact are Ms. Kim L. Frazier (DHA IMCO) at 703-681-3636 or Kim.L.Frazier2.civ@dha.mil and Ms. Sandra E. Dennis (Contractor, Altarum Institute), at 703-681-8818 or Sandra.E.Dennis4.ctr@dha.mil.

DEPARTMENT DOWNLOAD

NEWS FROM THE DEPARTMENT OF RESEARCH PROGRAMS

Robert Roogow led the business side of the June 16 meeting of the Department of Research Programs (DRP), which also included a farewell party for Army Lt. Col. Terri Yost, who officially retired from the military on June 29 (see Goodbye and Good Luck, on page 11). The department, noted Roogow, has been spearheading use of the new electronic institutional review board, known as EIRB.

"DRP is outshining everyone using the system right now," Roogow said. In case of problems with EIRB, he advised users to call the Help Desk and provide as much information as possible.

DOWNLOAD, see page 10

DOWNLOAD, from page 9

A recent fire drill spotlighted the need to review procedures. Roogow underscored the need to take the following steps, when the alarm sounds:

1. Leave your office, taking your Common Access Card, or CAC, and key belongings.
2. Lock your door.
3. Proceed to the nearest stairs and exit the building.
4. Walk across the street from Building 17A to the department meeting area in front of Building 27, to the left of the circular drive.
5. Stay with the group until the fire drill or alarm is over. If you must leave, tell a colleague.

— John Fadoju provided reporting for this story, which was complied by Paula Amann

FACES OF RESEARCH

HONORING OUR OWN

Angela Drago (Photo by John Fadogu)

At June's departmental meeting, Robert Roogow, director of operations of the Institutional Review Board (IRB) at the Department of Research Programs, stood in for DRP Chief Col. Peter Weina, to deliver the I Save Lives award. The winner this year was Angela Drago, research support specialist.

The I Save Lives award recognizes a different staff member each month, for his or her "behind the scenes" contributions to medical research at Walter Reed National Military Medical Center.

"I was flabbergasted," Drago said of receiving the honor. In her job, she supports the IRB, and says she takes special pride in using her computer skills to help researchers navigate through the new electronic review system.

ARRIVAL GATE

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

Army Col. Ann M. Nayback-Beebe joins the Department of Research Programs (DRP) as both deputy chief of DRP and chief of the Protocol Development Section. She earned her bachelor's degree in nursing from The University of Texas at Austin; a master's degree in nursing, family nurse practitioner, from Uniformed Services University of Health Sciences; and in 2010, graduated summa cum laude with her doctorate in nursing from The University of Texas at Austin.

Later, Nayback-Beebe served as deputy chief of the Centers for Nursing Science and Clinical Inquiry at both Brooke Army Medical Center and Walter Reed National Military Medical Center before becoming DRP's interim chief. In May 2014, she was selected as director for Education, Training and Research at Fort Belvoir Community Hospital.

In addition to her leadership roles in research and education, Nayback-Beebe has been a principal investigator on over $1.5 million in federally funded research, including three ongoing studies at Brooke Army Medical Center investigating the use of electroanalgesia in the treatment of servicemembers with chronic pain.

Sgt. Alisha M. Kohler joins the Department of Research Programs (DRP) as the non-commissioned officer in charge (NCOIC) and a medical laboratory technician in the U.S. Army. Kohler is pursuing her degree in medical laboratory science at George Washington University.

Prior to joining DRP, Kohler worked in Operations for Troop Command, United States Army Element North, as a medical laboratory technician for the Armed Services Blood Bank and in Client Services at Walter Reed, Bethesda.

She is passionate about volunteering with therapy animals, and on top of her regular duties, can be found at work with the Walter Reed Hospital Dog Program providing therapy to patients, their families and staff.

G. Asher Newsome (Photo by John Fadoju)

Originally from Georgia, **G. Asher Newsome** majored in chemistry at the University of Georgia. He earned a doctorate in analytical chemistry from the University of North Carolina-Chapel Hill, where he studied ion trap mass spectrometry with Gary Glish.

Seeking to learn practical chromatography – how the other 99 percent of mass spectrometry users live – he took a postdoctoral job with the FDA Center for Food Safety and Applied Nutrition in College Park, Md. There he created an assay for dairy milk allergens in baked goods. Later, Newsome joined the Center for Safety and Survivability in the chemistry division of the U.S. Naval Research Laboratory in Washington, D.C. There he served as the resident mass spectrometry expert, developing innovative methods for explosives and ambient analysis.

Active in the mass spectrometry field, Newsome serves on the board for a local discussion group and publishes research. He looks forward to working on new applications and with new people in the Department of Research Programs.

GOODBYE AND GOOD LUCK

Lt. Col. Terri Yost, former deputy chief of the Center for Nursing Science and Clinical Inquiry, retired from military service at the end of June. On June 16, Yost threw a luncheon "thank you party" for her colleagues and drew a host of accolades.

"This is a party for you," Yost told the assembled staff. "It's so much easier to come to work when you work with great people."

In the absence of Col. Peter Weina, chief of the Department of Research Programs (DRP), Col. Joy Napper, deputy director of nursing at the Walter Reed National Military Medical Center presented Yost with a Meritorious Service Medal for exemplary service over the past decade. The two women served together in Korea in 1996.

Recalling a colleague determined to serve, "working tirelessly on our wards, taking care of patients," Napper saw the seeds of the nurse leader she would become. "Even then, she was driven as a provider," Napper said.

Col. Joy Napper, deputy director of nursing at Walter Reed, pays tribute to her old friend, then Lt. Col. Terri Yost, at a June 16 farewell party for Yost, who retired from the Army last month. (Photo by Paula Amann)

The deputy director of nursing also cited her colleague's ability to balance her family commitments not only with work but with higher education. Yost earned a doctorate with distinction from the University of Virginia in Charlottesville in 2011.

"I can't believe how you balanced [family] and this complex world of nursing," Napper said, noting Yost's path to an advanced degree in only three years. "That just speaks to the caliber of person, the caliber of professional you are."

Cmdr. Virginia Blackman shares a light moment with Lt. Col.. Terri Yost, before presenting her with a paddle inscribed with farewell wishes from colleagues. Before her retirement June 29, Yost served as the deputy chief of the Center for Nursing Science and Clinical Inquiry. (Photo by Lisa Thompson)

Earlier, Cmdr. Virginia Blackman presented Yost with other tributes, including a medallion for her service on the Institutional Review Board (IRB), where she was a "highly regarded reviewer" of research projects, Blackman said. Yost also received a poster featuring the tower of Walter Reed, Bethesda, and a miniature paddle signed by many colleagues.

Days later, on June 28, another gathering marked the departure for a new assignment of **Staff Sgt. Jullian Hodges**, DRP's non-commissioned officer in charge for the past 2 and 1/2 years. Col. Brian Belson, director of Education, Training and Researcher joined DRP staff and members of Hodges' family at the celebration.

Col. Ann Nayback-Beebe, deputy chief of the Department of Research Programs (DRP), gives Staff Sgt. Jullian Hodges a paddle signed by his colleagues. Last month, Hodges marked the end of his stint as DRP's non-commissioned officer in charge. (Photo by Paula Amann)

"It's been great working with all of you, even with those who are new," Hodges said to a crowd assembled for a midday picnic, featuring homemade baked goods. "You've really broadened my career, my way of looking at things."

The newly arrived deputy chief of the Department of Research Programs, Col. Ann Nayback-Beebe, lauded Hodges, calling him the "rock" of the department.

She presented him with a citation and an IRB medallion, along with a poster of the base tower and an ornamental paddle, both signed by a host of well-wishers.

Spc. Dakotah Holtman chuckles, at left, as Col. Ann Nayback-Beebe, banters with Staff Sgt. Jullian Hodges and gives him a signed photo of Building 1 at Walter Reed National Military Medical Center. (Photo by Paula Amann)

"You can take this with you," said Nayback-Beebe, pointing to the medallion and then to the poster full of signed farewells, "but it's this that you'll appreciate more."

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 U.S. Department of Defense does not exercise any editorial control over the information you may find at these locations.

Education Materials

• Belmont Report

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

• Comparison of FDA and HHS Regulations

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

• The President's Council on Bioethics

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

• Clinical Trials.gov

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

• HHS Office for Human Research Protections

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

• HHS Office of Civil Rights

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

• MedlinePlus

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

• Office for Human Research Protections (OHRP)

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

• Federal Policy for the Protection of Human Subjects ('Common Rule')

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

• Protocol Review

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

• Informed Consent

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

• 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

Research Education Services (RES)
Offers Instructional Workshop:
MERF and CITI Training for Researchers

The mission of the DRP is to facilitate research and help researchers work with the protocol submission and the sign-off process. To this end, the RES offers the MERF & CITI training for Researchers workshop. This workshop will help researchers learn policy guidelines, requirements for meeting the Minimum Educational Requirement Framework (MERF) and training modules needed for their investigative roles.

MERF and CITI Training for Researchers
Workshop Schedule

MERF and CITI Training for Researchers workshop will be offered monthly. Ms. Lisa Thompson, MHA, MBA, will provide attendees with policy guidance promulgated by 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:

- 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 involving human subjects in compliance with the MERF standards set forth by the Assistant Secretary of Defense for Research and Engineering

The training will be provided upon request for groups at their department or facility, and at the designated location below during the scheduled times.* Eight seats are available. Please send an email or call to reserve a seat. If you have any questions, please contact Ms. Lisa Thompson at 301-295-8231or (lisa.p.thompson5.civ@mail.mil).

***Heroes Building, Fourth Floor, Room 4011**

- **Tuesday, August 9, 2016, 1400-1500**
- **Tuesday, September 13, 2016, 1400-1500**

MONTHLY PUBLICATION CLEARANCE

Courtesy of Darnall Medical Library

Authors based at Walter Reed National Military Medical Center are in bold.

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DARNALL MEDICAL LIBRARY
Research and Scholarly Communication Support

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

2016 Research and Scholarly Communication Classes

Managing Reference Citations with EndNote
July 13, 1300-1400
This workshop will help you to develop basic skills in bibliographic management using EndNote standalone citation manager. Attendees will learn how to create a reference library, collect reference citations from various biomedical literature databases, organize references, generate and format bibliographies, share a library with peers, connect with researchers, and insert references into a Word document. Attendees will also be briefly introduced to the web-based version of EndNote.

Writing Systematic Reviews
July 18, 1300-1400
This workshop 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.

Preparing Your Manuscript for Publication
August 12, 1300-1400
This workshop covers planning, writing, and submitting manuscripts for publication in biomedical journals. Students will be guided through publication , journal selection, and authorship guidelines and standards. The writing section of the workshop is centered on steps and tips for writing a compelling manuscript (title, abstract, introduction, methods/materials, results, and discussion). The manuscript submission and review processes, copyright, research integrity, and public access policy compliance will also be discussed.

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
Phone: 301-319-2475
Email: lyubov.tmanova.civ@mail.mil
Website: www.wrnmmc.libguides.com/home/researchsupport

Walter Reed National Military Medical Center
Department of Research Programs

2016 EIRB TRAINING
QUESTION AND ANSWER SESSION

Time for all sessions: 1200 – 1300

Location: National Intrepid Center of Excellence (NICoE)
Main Auditorium, Building 51, First Floor
July 18 | 25

Location: Executive Conference Room 0301, Building 9 Basement
August 1 | 8 | 22 |29
September 5 | 12 | 26
October 3 | 10 | 24 | 31
November 7 | 14 | 28
December 5 | 12 | 26

Office for Human Research Protections (OHRP) and
Department of Research Programs, Research Education Services,
Walter Reed National Military Medical Center

Present

GETTING THROUGH HUMAN RESEARCH REVIEWS WITH SKILL

A HALF-DAY WORKSHOP ON HUMAN RESEARCH PROTECTIONS

This workshop aims to provide you with the knowledge and information you need to get your protocol approved for human research protections. It will focus on reducing confusion and give you practical tips and solutions to problems commonly encountered during IRB review.

Earn a certificate for attending!

This certificate will satisfy the required four-hour interim training to meet the Minimum Education Requirement Framework (MERF) by the Research Regulatory Oversight Office within the Office of the Under Secretary of Defense for Personnel and Readiness (OUSD[P&R]).

MONDAY, 29 AUGUST 2016
TIME: 0830–1230

LOCATION: MEMORIAL AUDITORIUM, BUILDING 2, THIRD FLOOR, WALTER REED NATIONAL MILITARY MEDICAL CENTER

REGISTRATION DEADLINE: 22 AUGUST 2016

To register, please contact
dha.bethesda.wrnmmc.list.research-education-services@mail.mil