



Military Medical Research News

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Passion Is Key, Say Research and Innovation Month Winners

by Paula Amann

Talk to past winners of competitions for Research and Innovation Month about how they made it to the top tier, and you will hear a common theme. It all comes down to heart.

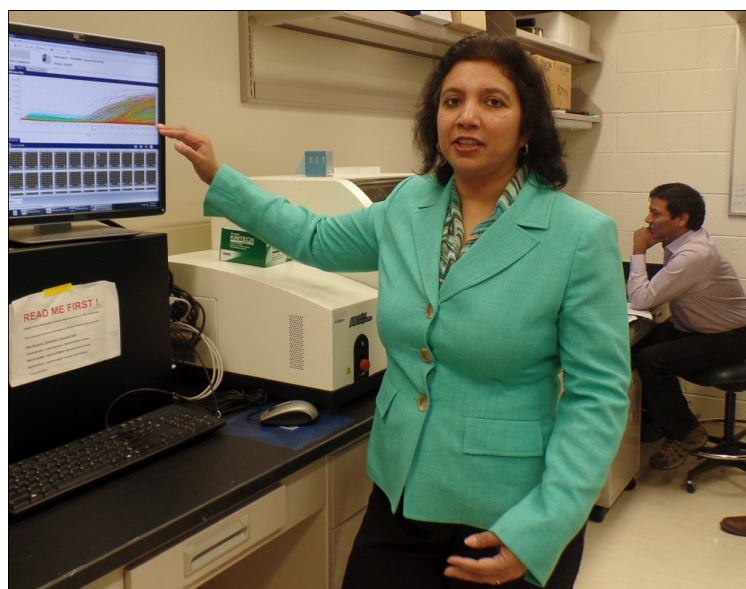
“My one piece of advice is [that] enthusiasm is infectious, and you need to be passionate about the work you submit,” said Army Maj. James League-Pascual, M.C.

Formerly a trainee at Walter Reed National Military Medical Center, he recently transferred to Ft. Belvoir Community Hospital as a staff general pediatrician.

The young pediatrician won a second-place Robert A. Phillips Award in 2015 for his laboratory study on delivering a chemotherapy drug for pediatric brain cancer through the nose. That same year, he finished in second place for a case report on using a novel drug to treat venolymphatic malformations – abnormally shaped veins and lymph vessels.

Each May, Walter Reed Bethesda hosts a series of events to showcase medical research and non-research projects. Poster Display Week offers a chance to prepare and talk about a poster on a medical case report, an idea for quality improvement in the hospital, or an evidence-based practice project. Awards are given in these three categories, and may be divided between staff and fellows, on the one hand, and interns and residents, on the other.

For those who relish a tougher competition, the annual Research Symposium allows researchers connected to Walter Reed Bethesda to vie for the Bailey K. Ashford Award or the Phillips Award mentioned earlier. The latter falls into four categories: two laboratory awards and two clinical awards (one each for staff and fellows, and for interns and



Roopa Biswas, Ph.D., a 2015 winner of the Robert A. Phillips Award and an associate professor in the Department of Anatomy, Physiology and Genetics at Uniformed Services University of the Health Sciences, points out brightly colored lines that represent microRNAs from the serum of patients. In the background, staff scientist, Parammeet Kumar, scans other laboratory results. (Photo by Paula Amann)

residents). Ashford Award contestants, who compete for laboratory or clinical honors, must win endorsement from a medical mentor.

Asked about her own advice for choosing a research topic for one of the competitions, Roopa Biswas, Ph.D., an associate professor at Uniformed Services University of the Health Sciences, echoed League-Pascual.

“The trick is to pick a project you’re passionate about, so you put your heart and soul into it,” said Biswas.

See **PASSION**, page 7



DEPARTMENT OF RESEARCH PROGRAMS



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

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

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

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, to the left of elevators.

RESEARCH ROUNDTABLE SCHEDULE

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

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

Contents

Profile: Capt. John Eckert.....	3
Pediatric Autoimmune Disorders	4-5
Waivers on Protocol Load Limits.....	6
Research or Not? (Determinations).....	7
Research Roundtable	8-9
Department Download	10
Honoring Our Own.....	10
Arrival Gate	11
Editorial Services	11
Web Resources	12-13
Research Funding	14-15
MERF and CITI Courses	16
Darnall Library Classes	17
Recent Publications	18-20
Training Calendar for EIRB	21
Research Residents' Day.....	22

EIRB TIP OF THE MONTH Passing on Your Legacy Getting Your Protocol Into the EIRB

When uploading your legacy protocol in the new EIRB, please submit by using a Modification Form. In section 2.2, finish this sentence: *This modification requires changes to...*

Be sure to check the boxes for Protocol and Other Study Documents. Further down in the form, in Section 3.1, the system will prompt you to attach the protocol application that you just completed.

Under Other Study Documents, please attach the last IRB-approved version of your protocol, your informed consent form, and any other IRB-stamped documents.

Again, thanks for your patience during our technical transition. And, meanwhile, our best wishes for success in your research.



FACES IN FOCUS: CAPT. JOHN ECKERT

Ground Zero forensics vet brings upbeat, long view to research

by Paula Amann

There's a new face around Walter Reed National Military Medical Center this season. Navy Capt. John Eckert, director of the Human Research Protection Program for the Office of the Assistant Secretary of Defense for Health Affairs and the Defense Health Agency (DHA), has briefly joined the team at the Department of Research Programs (DRP).

"My formal role really is as a conduit from Walter Reed to the DHA headquarters and also to get information flowing down the chain," Eckert explained in a Sept. 16 interview.

Eckert also will lead a December audit of research programs and human subject protection at Walter Reed Bethesda. He and his team will be checking programs, policies and business practices, such as standard operating procedures. The goal: to ensure the center meets all policy requirements for protecting human research subjects.

In the short term, Eckert is helping to roll out the electronic Institutional Review Board (EIRB) and fine-tune the research program in the Hematology-Oncology Department. Being on site, he notes, has given him a better sense of the obstacles faced by researchers and DRP staff as they cope with the new EIRB.

"There are major frustrations keeping staff at DRP from being able to interact with and assist investigators, because they're spending the majority of each day fixing data in EIRB," Eckert said.

Transferring massive amounts of data from the former system to the new one, he notes, produced a host of problems, such as expired protocols. Yet, Eckert takes the long view, and what he sees ahead is positive.

"Once the system is fixed, there are grand opportunities for people from the departments to come in [to DRP] and learn the system," Eckert said.

Meanwhile, he and the DRP leadership team are trying to whittle away EIRB's technical problems, one by one.

"It's satisfying to see even the littlest wins," Eckert said.

To his provisional post at Walter Reed Bethesda, the captain brings a long record of challenging assignments. Before his current job at DHA, he served as director of the Research Regulatory Oversight Office.



Navy Capt. John Eckert
(Photo by Paula Amann)

He also was deputy director of the U.S. Public Health Service Force Management Program, with a sea tour as medical executive team officer aboard the USS Boxer in the Pacific Ocean.

Over his career, Eckert has earned a host of awards, notably the Defense Meritorious Service Medal, the Surgeon General's Exemplary Service Medal, two Outstanding Service Medals, and a Joint Services Commendation Medal.

For his work to boost minority participation in the National Marrow Donor Program, he received awards from former President Bill Clinton, U.S. Sen. John Breaux and New Orleans municipal leaders.

Earlier, Eckert held tenured faculty appointments at Xavier University in New Orleans and State University of New York, College at Potsdam, where he chaired the biology department. He earned a doctorate in microbiology with a minor in biochemistry and a nuclear science concentration from Louisiana State University.

Eckert's postdoctoral work includes a fellowship in allergy and clinical immunology in the Department of Medicine at LSU's Medical Center. He received advanced training in forensic medicine and DNA typing through the Office of Chief Medical Examiner for New York City.

See FORENSICS, page 4



Pediatric immune, autoinflammatory disorders draw spotlight

Walter Reed Bethesda, National Institutes of Health cosponsor event

by Paula Amann



Col. Michael Heimall, director of Walter Reed Bethesda, welcomes people to a Sept. 19 symposium exploring recent research and potential partnerships on autoinflammatory and immune-dysregulatory diseases, cosponsored by the National Institutes of Health.

One small child suffered from blistering leg sores that kept her from walking till age 4. Another young girl would throw up in bed by night and require painful shots by day.

And one boy went from a family vacation to the Intensive Care Unit at Walter Reed National Military Medical Center, where Dr. Olcay Jones helped save his life.

Jones, who with Dr. Raphaela Goldbach-Mansky of NIH, organized the conference, voiced hope it would become an annual event. Their vision includes a joint clinic to care for such patients at Walter Reed Bethesda and partnerships with groups studying dysregulatory conditions.

Over the four-hour symposium, speakers linked patients and their stories with the genetic basis of their illnesses, and a host of new technologies that may help diagnose and treat them.

These tools include next-generation sequencing to decode individual genomes, flow cytometry to isolate and study diseased cells, and tissue banks to use for reference samples.

The conference heard from a pioneer in the field, Dr. Dan Kastner, scientific director of the National Human Genome Research Institute at NIH, director of the Division of Intramural Research and head of the Inflammatory Disease Section.

Kastner outlined how genetics and genomics have redefined immune dysregulation. His work and that of others have moved the field from a one-gene to a multi-gene model.

These snapshots of real patients emerged from a half-day symposium on autoinflammatory and immune-dysregulatory illnesses held at Walter Reed Bethesda on Sept. 19 and introduced by its director, Army Col. Michael Heimall. The Children's Center at the hospital cosponsored this first-time gathering with the National Institutes of Health.

See PEDIATRIC, page 5

FORENSICS, from page 3

A veteran of multiple deployments for both disasters and overseas operations, Eckert put his forensics to work at Ground Zero as a member of the Disaster Mortuary Operations Response Team.

"It was not a happy homecoming, but I was glad to contribute to the recovery," Eckert said of his return to New York.

His job was to identify the bodies emerging from the rubble of the Sept. 11, 2001 attack on the Twin Towers.

"They were long days, but there were uplifting events every day," Eckert recalled. "There were people lining the streets, thanking you."

During that nine-week detail, this forensics expert celebrated his birthday among strangers turned friends, the family members of people who perished in the attack. ▣



PEDIATRIC, from page 4

And Clifton Dalgard, of the Collaborative Health Information Research Program (CHIRP) at the Uniformed Services University of the Health Sciences, touted big data as a biomedical tool.

The idea behind CHIRP is moving from clinical studies to whole-genome sequencing, and ultimately, personalized medicine. Data machines, aided by robots, can help analyze patient genomes, decoding as many as 170 each week.

For her part, Goldbach-Mansky noted her own experience developing “targeted therapies” for children with autoinflammatory and immune-dysregulatory illnesses. Treating these rare diseases takes blocking the Interleukin 1 (IL-1) family of cytokines, proteins secreted by cells that play a role in inflammation and autoimmune disorders.

“Uncontrolled IL-1 causes these diseases,” said Goldbach-Mansky. She noted her successful use of anakinra, an IL-1 receptor antagonist to treat neonatal onset multisystem inflammatory disease, or NOMID.

At the cell level, pediatric dysregulatory disorders have “lots of manifestations,” said Dr. Steven Holland, scientific director at the National Institute of Allergy and Infectious Diseases and chief of its Immunopathogenesis Section.

Holland illustrated his point with vivid slides of infected cells, which may show incursions by mycobacteria, bacilli (rod bacteria) or fungi.

Col. Limone Collins (ret), a trained pediatrician who is chief of the Vaccine Safety and Evaluation Section of the Defense Health Agency, touted the value of adversomics.

This new field – the study of adverse vaccine reactions through immunogenomics and systems biology – could shed light on immune-dysregulatory medicine, Collins suggested.

Service at NIH, cited the growing toolbox for diagnosing immune disorders.

“Linking genomics, clinical testing and phenotype ... is really what this story is about,” Fleisher said. “We want to be linking the right diagnostics with the right disease.”

Standing in for all the military families with children who suffer from autoinflammatory and immune-dysregulatory illnesses were Air Force wife, Erin Wilson, and Navy Cmdr. Margaret Read, the executive assistant for the deputy chief for readiness and health of the Navy Bureau of Medicine and Surgery.

“Sixty of our own little warriors need your help,” Wilson, a board member, military family representative and patient advocate with the Autoinflammatory Alliance, told the audience, citing the number of children in U.S. military families with these rare conditions.

Wilson paid tribute to the “priceless” care her daughter received at Walter Reed Bethesda – the only military hospital with a full-time pediatric rheumatologist – but noted that many other families cannot easily tap its resources.

As for Read, she made her own plea to attendees to pursue research on dysregulatory disorders.

“As you move forward, please remember Davey’s face and the faces of the other children,” said Read, choking back tears as she stood beside her son. “We need your expertise, your voice.” ▣



This rash on a baby’s back is caused by Cryopyrin-Associated Periodic Syndrome, or CAPS, an autoinflammatory disorder. (Photo art, original photo courtesy of the Autoinflammatory Alliance)



Research Department Opens Door to Waivers Investigators Can Appeal Protocol Load Limits

by Paula Amann

Last month, the Department of Research Programs (DRP) issued a policy that limits principal investigators (PIs) to 10 minimal-risk protocols, five greater-than-minimal-research protocols or a proportional combination of the two. Yet, DRP leaders say this effort to draw a reasonable line has room for exceptions.

DRP's deputy chief, Army Col. Ann Nayback-Beebe, calls the new policy a reasonable point from which to begin assessing whether PIs possess the adequate resources and time to ensure the protection of human subjects.

"It's a benchmark: Those who have done research believe that beyond that, you're losing your ability to adequately oversee the protection of human subjects in research," Nayback-Beebe said in an interview.

"This, of course, may not be true in all cases," she added, "It depends on the researcher's experience, their available resources and dedicated research time, and the active involvement of other study team members."

Sanjur Brooks, D.P.S., the program manager for human research protections, frames the question in terms of what the IRB needs to know in order to approve a waiver. A few crucial facts, she suggested, would let the IRB "develop a view of the department, the investigator and their portfolio of research projects."

This information would include the number of support staff engaged and the amount of time the PI can devote to the research projects.



Sanjur Brooks, program manager for human research protections (Archival photo by Paula Amann)

"If, as a clinician, you work 60 hours a week, how many of those hours can you give to the conduct of your research?" Brooks said.

She noted that IRB members understand that the medical workload can fluctuate, but want to know what

percentage of effort, on average, PIs commit to overseeing their research.

What's more, researchers who are also service members reach out to the Department of Research Programs to assess possible options when these circumstances occur.

When an AI is taking over for a colleague, the IRB will want to know that replacement is fully conversant with the project, stressed Nayback-Beebe.

"For any PI who is over the maximum, what's important in transition planning is that the AI is knowledgeable about the studies and is already an integral part of the research team before the PI leaves," Nayback-Beebe said.

Those investigators at or over the limit, she said, should contact the Office of the Institutional Review Board (IRB) or Dr. Sandy Brooks, Human Protections Administrator, about their research portfolios as soon as possible.

"Sooner is better, when it comes to these discussions," suggested Nayback-Beebe.

PIs have to be in compliance with the protocol limits within six months, she noted, and they might need some lead time to take the steps required to file a request for waiver with the IRB.

Meanwhile, Robert Roogow, IRB operations director, stressed that PIs need to stay abreast of regulatory oversight as well. The job of the PI is not simply overseeing the subjects, he noted, but also keeping the IRB informed about continuing reviews, adverse events, amendments and the like.

"Accurate and timely submissions to the IRB is an important and overlooked part of keeping subjects safe and data collected, usable," Roogow stated in an email.

▣



PASSION, from page 1

The USUHS scholar scored the 2015 first-place Phillips Award for laboratory research on the role that microRNAs play in the growth of prostate cancer. MicroRNAs are short, one-stranded molecules that help messenger RNA govern gene expression.

“The cancer field was a new project for me,” said Biswas, who said she was drawn to the study because the disease affects so many people and still eludes a definitive cure.

For his part, League-Pascual banked his case report win on the unusual use of a drug known for its impact on a different health problem.

“Who would have thought a blood pressure medicine could solve a dermatologic, vascular condition?” said League-Pascual.

He counseled this year’s competitors to devise a project

that is “innovative” and “outside the box” of conventional thinking.

“Taking ordinary or known topics in the scientific or medical world and exploring a new story line are what people like the most,” League-Pascual said.

Beyond their shared enthusiasm and intellectual curiosity, former award winners are striking in their diversity. They are women and men, service members and civilians. Some, like League-Pascual, work as doctors, nurses and other health professionals.

Others, like Biswas, are full-time medical researchers and professors. Some enter the fray armed with a doctorate,

PASSION, see page 8

Research or Not? Shaping Your Research Project

Crafting a new research project? Aiming to compete for an award during Research and Innovation Month? Sanjur Brooks, Ph.D., the program manager for human research projections suggests you start with two simple ideas.

First, think back on the meaning of the word “research,” as defined by the U.S. federal government in such regulations as 45 CFR 46.102 (Protection of Human Subjects 2009). This landmark document defines the term as “a systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

A critical element, said Brooks, is generalizable knowledge. If you believe that the data or descriptions you produce are apt to apply to settings beyond the one studied, you might have a research project on your hands.

Another crucial concept is that of human subjects, which might seem straightforward, but also has its nuances. Again, 45 CFR 46.102 offers the working definition: “living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, (2) Identifiable private information.”

“Being comfortable with those two key definitions is always a good starting point,” Brooks said.

Sometimes a great idea turns into something other than traditional research: a case report, a quality improvement project or an evidence-based practice project.

Navy Cmdr. Virginia Blackman, chief of the Center for Nursing Science and Clinical Inquiry, has long had a hand in sorting out the latter two types of projects.

A case report is just what it says: a written description of an intriguing condition, procedure, treatment or other situation that might be of value to

other medical professionals. Take that award-winning case report by Maj. James League-Pascual (see page 1) about the successful use of a blood-pressure drug to treat malformed veins and lymph vessels.

Say you have a bright idea for a new vaccine schedule or a better routine for newborns that would boost the caliber of patient care. It could add up to a quality improvement project for Poster Display Week during Research and Innovation Month.

“The quality improvement project has local impact – that’s the key,” Blackman said. It does not contribute to generalizable information. Its intent is to improve the quality of the care given within the facility.

She distinguished between quality improvement and evidence-based practice, noting that the latter involves a literature search as its starting point followed by rating of the evidence for the question or problem that needs to be solved.

A project of this kind, she noted, revolves around a practice standard and its research basis. The implementation of a falls prevention program by nursing staff on the inpatient nursing units is one such EBP project that has taken traction at Walter Reed Bethesda.

Whatever the form a project takes, Blackman underscored the need to get it formally vetted before investing days, weeks and even months of effort. “The investigator must get a determination from a DRP determinations official,” Blackman said. “If you want to share it via poster or conferences, if you want to share it outside this command, then it must have a determination.” ■

—Paula Amann



RESEARCH ROUNDTABLE

A MESSAGE FROM THE HOST OF THE RESEARCH ROUNDTABLE

by Lisa Thompson

The Department of Research Programs (DRP) would like to offer a 10-15 minute presentation to your staff on DRP services, upcoming events and policy updates from the Office of the Under Secretary of Defense (Personnel & Readiness), Research Regulatory Oversight (R202) policy guidelines, and MERF and Collaborative Institutional Training Initiative (CITI) training. We would like to join you once annually or every six months, before or after your program meets for didactic or lecture hall sessions.

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 in the third Tuesday of every month. Next month, we're pleased to welcome Ning Yang, J.D., a counsel with the Naval Medical Research Center, who will continue our program on patents, with a focus on technology transfer.

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.



Lisa Thompson, M.S.H.A., M.B.A., supervisory medical education specialist (Photo by Lisa Thompson)

PASSION, from page 7

like Biswas, or a master's degree in biomedical engineering, like League-Pascual.

As to other tips for first-time award seekers, League-Pascual underscored the value of partnerships, the vaunted Unity of Effort among Walter Reed Bethesda, USUHS and the National Institutes of Health. The most powerful research projects, he said, have the "strongest assistance from all three institutions."

Biswas had been an independent researcher since 2005, but winning the Robert A. Phillips Award a decade later still was a thrill.

"It's a great honor to put on your CV [curriculum vitae]," said Biswas, noting it was "the start of obtaining more funds and taking that research further."

Beyond the Phillips Award itself, Biswas points to the benefit of attending the Research Symposium, where contestants present their findings, as something akin to a professional conference.

"You never know what you [will] learn or hear, and how you may end up using it," Biswas said. "There's a tremendous gain from any of these gatherings."

'Every May, when the posters come out, it makes you appreciate how innovative, creative and knowledgeable our colleagues and medical professionals are.'

— Army Maj. James League-Pascual

League-Pascual endorsed her view of Research and Innovation Month, noting that it gives him a sense of the intellectual growth in his own field and beyond.

"Every May, when the posters come out, it makes you appreciate how innovative, creative and knowledgeable our colleagues and

medical professionals are," League-Pascual said.

And Biswas has one final observation: Showing up counts. When mentors, friends and colleagues attend the Research Symposium, it energizes participants, much like the impact of a packed stadium on ball players or a crowded concert hall on the band stepping onto the stage.

"You are more stimulated to present when you have a full audience," Biswas said. ▣



Legal ace Churilla guides Roundtable through patent maze

by Paula Amann

It's long, detailed, research related and potentially lucrative. Stumped? Think: a patent for your medical invention from the U.S. Patent and Trademark Office.

At the Research Roundtable on Sept. 20, Al Churilla, J.D., Ph.D., a counsel and intellectual property counsel with the Naval Medical Research Center (NMRC), walked the audience through this often misunderstood area of federal law. In essence, he suggested, a patent is a contract between an inventor and the government.



Al Churilla, J.D., Ph.D., counsel and intellectual property counsel with the Naval Medical Research Center (NMRC), briefs the Research Roundtable on Sept. 20. (Photo by Paula Amann)

“The government; the person gets exclusivity,” Churilla said, summing up the terms of the deal.

The process, though legally valuable, is time consuming, he stressed, pointing to waits from three to five years, with biotechnology at the longer end of that time span.

For anyone interested in pursuing a patent, the NMRC counsel urged a simple first step: Contact a patent lawyer like him or one of his colleagues.

As for patents, Churilla cited three major benefits they can bring the inventor. First, a patent safeguards federal rights to use the product in question, such as a new medical device. What's more, it can help researchers secure more funds for further development of their invention. And in practical terms, the patent permits income for federal inventors.

Although simple in concept, patents can be cumbersome in execution, observed the NMRC counsel.

“Because of the importance of patents in commerce, the patent process is fairly arduous,” Churilla told the Roundtable, calling it “akin to writing a manuscript.”

Binder Reminder

At last month's roundtable, Army Col. Peter Weina, chief of the Department of Research Programs, had a housekeeping reminder for researchers.

Citing the ups and downs of the new electronic Institutional Review Board, Weina cautioned attendees to create a paper trail. Specifically, he urged researchers to keep a hard-copy binder with such crucial documents as the protocol and approval letters, in case the electronic system should stall.

“The electronic system is there to help us process these things,” Weina said, “but you still need a paper backup.”

He ticked off the trio of research products protected by patents: methods (such as the enzyme-linked immunosorbent assay, or ELISA, a chemical technique that helps find certain substances), devices (such as an electronic stethoscope), and “compositions” (such as a new drug).

Off the table for patents are such things as living organisms and algorithms. To fall under patent law, said the NMRC counsel, an item must be useful (such as a prosthetic arm), novel (different than anything now on the market) and non-obvious, or, as European patent law prefers to state, inventive.

A U.S. patent protects the inventor, but only up to a point, cautioned Churilla. It safeguards a method, device or composition in the United States, but not abroad. Inventors must apply for separate patent approval in other countries, if needed.

In addition, a patent does not give an inventor rights to use an invention. Yet, it can keep other people from using the device or other item for 20 years from the date of filing.

The sheer time and effort it takes to secure a patent can pay off in time for those involved, the speaker emphasized.

“If you do invent a device, there's a big market for that,” Churilla said. ▣



DEPARTMENT DOWNLOAD

NEWS FROM THE DEPARTMENT OF RESEARCH PROGRAMS

Resilience training took center stage at the Sept. 1 meeting of the Department of Research Programs (DRP). Army Spc. Gilbert Sampson walked staff members through exercises on the links between an “activating event” (A) and the thoughts (T) that follow, producing a chain of consequences (C): emotions and reactions.

“Sometimes we think an event causes a reaction, but it’s the thought that causes the reaction,” Sampson said during his slide presentation on the ATC training, based on research conducted at the University of Pennsylvania and adopted by the U.S. Army.

Thanking Sampson, Army Col. Ann Nayback-Beebe, DRP’s deputy chief, flagged the relevance of ATC as staff members cope with the technical challenges of the electronic Institutional Review Board (EIRB).

“We’re coming upon a stressful time,” she said. “We know that the challenges of the EIRB system will be an activating event for our staff, our investigators, and our IRB members who are reviewing protocols. Keeping it in perspective will help frame our emotions and reactions to these challenges.”

As for the training, Sampson said, one of its goals is to help people pinpoint their “heat-of-the-moment thoughts” (T) about an event, so as to gain more control over emotions and reactions. Staff members broke into groups to list their positive and negative feelings.

Although negative emotions such as anger and fear can move us to action, positive emotions are key to developing resilience, Sampson stressed. Broadening our range of “feeling words,” he suggested, can help tilt our emotional responses in a positive direction.

“Knowing how vocabulary affects your emotion is a very important self-awareness tool,” Sampson said.

Similarly, he added, people often shift from a simple thought to a “thought theme,” such as loss, danger, trespass and negative comparisons with others. From those negative thought themes, people often move to emotions such as sadness and withdrawal, or reactions such as embarrassment and hiding.

On the plus side of the ledger, positive thought themes can build resilience, through a focus on such things as appreciation and a sense of contribution, the ATC training showed. These feelings tend to produce, in turn, more positive reactions, such as helping others and planning for future achievement.



FACES OF RESEARCH

HONORING OUR OWN

At September’s meeting of the Department of Research Programs, Army Col. Ann Nayback-Beebe, deputy chief of the Department of Research Programs (DRP) presented the I Save Lives honor to Paula Amann, DRP’s research technical writer and the editor of this newsletter.

Thanking DRP leaders for the tribute, Amann also voiced appreciation to her department colleagues for their “encouragement, support and sheer camaraderie” over her first six months on the job.

“Ms. Amann has been integral to the DRP team,” Nayback-Beebe recalled.

Amann shares the successes of our investigators at Walter Reed Bethesda with the research community at large. “Her words paint the picture of our successes and soften the news of our challenges,” said the deputy chief.



Army Col. Ann Nayback-Beebe, Paula Amann celebrate Amann’s I Save Lives Award Sept. 1. (Photo by G. Asher Newsome)



ARRIVAL GATE



Navy Cmdr. William G. Danchanko (Photo by Paula Amann)

Navy Cmdr. William G. Danchanko joins the Department of Research Programs (DRP) as a new scientist and will become chief of the Center for Nursing Science and Clinical Inquiry upon Cmdr. Virginia Blackman's departure.

Danchanko enlisted in the Navy as a hospital corpsman in 1994 and received a Naval Reserve Officers Training Corps scholarship while on active duty. He earned his bachelor's degree in nursing from The Pennsylvania State University; a master's degree in nursing (adult/advanced oncology nurse practitioner) from the University of Pennsylvania; and a doctorate in nursing science from the Uniformed Services University of the Health Sciences in 2016.

Over many years in oncology, Danchanko has specialized in bone marrow transplants as well as palliative and end-of-life care. He worked at the Naval Medical Center San Diego as a clinical educator and inpatient nurse practitioner, while serving as a consultant for palliative care for all inpatient services.

Shortly after returning from Kandahar, Afghanistan, he was the service chief of Inpatient Oncology for the integration of the Walter Reed Army Medical Center and the National Naval Medical Center. In the Afghan theater, he served as a nurse practitioner and department head for urgent care on NATO Role 3, Multinational Medical Unit.

Danchanko's most recent research focuses on how embedded metal shrapnel impacts bone physiology in an animal model. ▣

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Email paula.m.amann.ctr@mail.mil.***



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 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.

See RESOURCES, page 13



RESOURCES, from page 12

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 FUNDING SOURCES

The following list of research funding sources is provided as a service by the Department of Research Programs.

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McKnight Endowment Fund for Neuroscience - 2017 McKnight Technological Innovations in Neuroscience Awards

A goal of the Technology Awards is to foster collaboration between the neurosciences and other disciplines; therefore, collaborative and cross-disciplinary applications are explicitly invited. Investigators who are conducting research at institutions within the United States are invited to apply. Applicants must be in tenured or tenure-track faculty positions, and may not be employees of the Howard Hughes Medical Institute or scientists within the Intramural Research Program of the National Institutes of Health. Funds may be used toward a variety of research activities, but not the recipient's salary. Applicants may not hold another type of McKnight Endowment Fund for Neuroscience award that would overlap with the Technological Innovations Award. For an application form, please visit our website: [Caution-https://www.neuroscience.mcknight.org/newsroom/upcoming-deadlines/2017-tech-awards](https://www.neuroscience.mcknight.org/newsroom/upcoming-deadlines/2017-tech-awards)

National Institute of Arthritis and Musculoskeletal and Skin Diseases

* Notice of NCCIH's Participation in PA-16-414 "Innovation Corps (I-Corps) at NIH Program for NIH and CDC Phase I Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Grantees (Admin Supp)" (NOT-AT-16-003) <
[Caution-http://grants.nih.gov/grants/guide/notice-files/NOT-AT-16-003.html](http://grants.nih.gov/grants/guide/notice-files/NOT-AT-16-003.html) >

National Center for Complementary and Integrative Health

Notice of Change in Key Dates for PAR-16-176 "NCI Clinical and Translational Exploratory/Developmental Studies (R21)" (NOT-CA-16-065) <
[Caution-http://grants.nih.gov/grants/guide/notice-files/NOT-CA-16-065.html](http://grants.nih.gov/grants/guide/notice-files/NOT-CA-16-065.html) >

National Cancer Institute

* Notice of Change in Application Due Dates for PAR-16-166
" Integrating Biospecimen Approaches into Clinical Assay Development (U01)"
(NOT-CA-16-068) <
[Caution-http://grants.nih.gov/grants/guide/notice-files/NOT-CA-16-068.html](http://grants.nih.gov/grants/guide/notice-files/NOT-CA-16-068.html) >

National Cancer Institute

* Notice of Change in Application Due and Other Key Dates for PAR-16-416 "NCI Small Grants Program for Cancer Research (NCI Omnibus R03)" (NOT-CA-16-069) <
[Caution-http://grants.nih.gov/grants/guide/notice-files/NOT-CA-16-069.html](http://grants.nih.gov/grants/guide/notice-files/NOT-CA-16-069.html) >

National Cancer Institute

* Notice of Change to RFA-ES-15-016 "NIEHS SBIR Phase IIB Awards for Validation and Commercialization of Approaches to Reduce Animal Use in Toxicology Testing (U44)" (NOT-ES-16-010) <
[Caution-http://grants.nih.gov/grants/guide/notice-files/NOT-ES-16-010.html](http://grants.nih.gov/grants/guide/notice-files/NOT-ES-16-010.html) >

National Institute of Environmental Health Sciences

Notice of Clarification to NHLBI's Policy Regarding Total Years of Support for K24 Funding (NOT-HL-16-442) <
[Caution-http://grants.nih.gov/grants/guide/notice-files/NOT-HL-16-442.html](http://grants.nih.gov/grants/guide/notice-files/NOT-HL-16-442.html) >

National Heart, Lung, and Blood Institute

AHRQ Announces Interest in Innovative Methods Research to Increase the Utility of Systematic Reviews (NOT-HS-16-016) <
[Caution-http://grants.nih.gov/grants/guide/notice-files/NOT-HS-16-016.html](http://grants.nih.gov/grants/guide/notice-files/NOT-HS-16-016.html) >

See FUNDING, page 15



FUNDING, from page 13

Agency for Healthcare Research and Quality

Notice of Change to Key Dates in PAR-16-398 "Engineering Next-Generation Human Nervous System Microphysiological Systems (R01)" (NOT-MH-16-019) <

Caution-<http://grants.nih.gov/grants/guide/notice-files/NOT-MH-16-019.html> >

National Institute of Mental Health

Notice of Change to Key Dates in PAR-16-397 "Engineering Next-Generation Human Nervous System Microphysiological Systems (R21)" (NOT-MH-16-020) <

Caution-<http://grants.nih.gov/grants/guide/notice-files/NOT-MH-16-020.html> >

National Institute of Mental Health

Notice of Technical Assistance Webinars for Human Heredity and Health in Africa (H3Africa) FOAs: RFA-RM-011, RFA-RM-012, RFA-RM-013, RFA-RM-014, RFA-RM-16-015, RFA-RM-016, and RFA-RM-017 (NOT-RM-16-028) <

Caution-<http://grants.nih.gov/grants/guide/notice-files/NOT-RM-16-028.html> >

National Institutes of Health Roadmap Initiatives

Notice of New Expiration Date for RFA-RM-16-013 "Human Heredity and Health in Africa (H3Africa): Ethical, Legal, and Societal Issues (ELSI) Research Program (U01)" (NOT-RM-16-029) <

Caution-<http://grants.nih.gov/grants/guide/notice-files/NOT-RM-16-029.html>

NIH Center for Scientific Review Hosts Webinars on Peer Review

Posted on September 30, 2016 < Caution-<https://nexus.od.nih.gov/all/2016/09/30/nih-csr-webinars/> > by NIH Staff < Caution-<https://nexus.od.nih.gov/all/author/nih-staff/> >

The NIH Center for Scientific Review < Caution-<http://www.csr.nih.gov/> > (CSR) is the portal for receipt and referral of NIH grant applications, and, for the majority of those applications, carries out the peer review process for assessing scientific and technical merit. In November and December, CSR will host three different "online briefings" on peer review for: fellowship grant applicants; R01 applicants; and researchers who are proposing and/or reviewing basic science applications. All of the briefings will be approximately one hour long, including a 30 minute question and answer period.

For more information and to register for each webinar, visit the CSR event website < Caution-<http://public.csr.nih.gov/Pages/csrwebinar.aspx> > .

Nov. 2, 2016 - 8 Ways to Successfully Navigate NIH Peer Review and Get an R01 Grant – covering things applicants need to know about the submission and review of an R01 grant

Dec. 1, 2016 - NIH Peer Review Briefing for Basic Research Applicants and Reviewers – covering NIH's commitment to basic research and helping applicants and reviewers do their part in proposing and reviewing basic research



☐ TRAINING FOR RESEARCHERS ☐

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

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

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

☐ MERF AND CITI TRAINING ☐ WORKSHOP SCHEDULE

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

- ☐ OUSD (P&R) Assurance for the Protection of Human Subjects
- ☐ Minimum Education Requirements Framework (MERF) for DoD Personnel involved In Human Subjects Research
- ☐ Collaborative Institutional Training Initiative (CITI) role-based training 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

You can arrange training in your department. Or join our monthly classes in the location listed below (eight seats are available).* Please email or call to reserve your seat.

Questions? Please contact Ms. Lisa Thompson at 301-295-8231 or

lisa.p.thompson5.civ@mail.mil.

* HEROES BUILDING, FOURTH FLOOR, ROOM 4011

- ☐ Tuesday, Sept.13, 2016, 1400-1500
- ☐ Tuesday, Oct. 11, 1400-1500
- ☐ Tuesday, Nov. 8, 1400-1500
- ☐ Tuesday, Dec. 13, 1400-1500

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



DARNALL MEDICAL LIBRARY

Research and Scholarly Communication Support

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

2016 Research and Scholarly Communication Classes

Preparing Your Manuscript for Publication

Tuesday, October 11, 2016, 1300-1400

Darnall Medical Library, Building 6, Room 1369

This workshop focuses on planning, writing and submitting manuscripts for publication in biomedical journals. Students will be guided through the publication process, 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 process and review, copyright issues, research integrity, and public access policy compliance will also be discussed.

Designing a Compelling Scientific Presentation

Monday, October 24, 1300-1400

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

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

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RECENT PUBLICATIONS

Courtesy of Darnall Medical Library

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

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See PUBLICATIONS, page 17



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**Walter Reed National Military Medical Center
Department of Research Programs**



TRAINING FOR ELECTRONIC INSTITUTIONAL REVIEW BOARD (EIRB)

2016 QUESTION AND ANSWER SESSIONS

Time for all sessions: Mondays 1200–1300

Month	Executive Conference Room 0301, Building 9 Basement	Radiology Conference Room B015, Building 19 Basement
October	24 31	17
November	7 14	21 28
December	5 12	19



*Coming soon,
the Department of Research Programs
presents*



RESIDENTS' RESEARCH DAY

**14 November 2016, 0800–1430, Auditorium
National Intrepid Center of Excellence, Building 51
Walter Reed National Military Medical Center**

Research at Walter Reed Bethesda

Databases

How to Get Published

Developing Research Questions

Statistics for Researchers

Literature Reviews

DRP Services, MERF & CITI

Human Research Protection Policies

The Common Rule and the Belmont Report

Protocol Development

Editorial Services

Scientific Review

Funding Resources

Institutional Review Board (IRB)

Biomedical Research Laboratory

Compliance



*Launch your research.
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