Department of RESEARCH PROGRAMS at Walter Reed National Military Medical Center

Military Medical Research News

Vol. 3, Issue 8 ▪ September 2016

Research Program Moves to Limit Protocol Load
Concerns for human subject safety drive 'proactive' measure

by Paula Amann

A new policy from the Department of Research Programs (DRP) that puts a ceiling on the number of studies principal investigators (PIs) can oversee popped into inboxes across Walter Reed National Military Medical Center on Aug. 15.

The three-page issuance, "General Responsibilities of Principal Investigators," limits each PI reliant on the hospital Institutional Review Board (IRB) to a portfolio of five greater-than -minimal risk or 10 minimal-risk, non-exempt human research studies.

Alternatively, a PI can oversee a combination of protocols, in a 2-to-1 ratio of minimal risk to greater than minimal risk.

If PIs currently exceed this cap, or would like to open an additional study that would place them over this limit, they must request a waiver from the IRB and demonstrate they have adequate resources and protected research time to provide sufficient oversight to protect the rights and welfare of potential study participants.

"We're willing to dialogue with PIs to ensure both subject safety and high-quality research," said Robert Roogow, IRB operations director. In explaining the impetus for the move, DRP leaders cited their concern about investigators taking on a growing load of research studies, without adequate oversight or resources to adequately protect human subjects from harm.

Human subjects safety is a mandate for all research institutions. Research Research suggests that "investigators with an excessive amount of protocols are unable to have the appropriate oversight, or underestimate the resources required to manage the studies," said Sanjur Brooks, DRP's

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If diagnosed with breast cancer, these African-American and white service members would have about the same chance for a cancer-free interval, new research suggests. Indeed, the African-American women in uniform would likely have an edge over their civilian peers. The key, researchers believe, may be equal access to health care in the armed forces. See story on page 3. In this archival photo, guests attend a wreath-laying ceremony at the Women in Military Service for America Memorial in Arlington, Va., May 20, 2014. (Photo by U.S. Marine Corps Lance Cpl. Alejandro Sierras)

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.

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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.

Research Roundtable Schedule

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

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

EIRB Tip of the Month

Double-check your dates

See a looming – or recent – expiration date or date for continuing review on your screen in the new Electronic Institutional Review Board (EIRB)?

If the dates don't match your records, don't panic. What you see may be wrong, as a result of a data dump from the old IRBNet.

Please refer to your last continuing review or IRB approval letter to find the right date for your protocol expiration, as well as the due date for your next continuing review.

The Department of Research Programs is working with the EIRB Executive Steering Committee to correct the "doubtful date" issue as soon as possible.

Meanwhile, thank you for your patience during this technical transition. And, most important, best wishes for success in your research.

Research illuminates breast cancer in African-American women

by Paula Amann

Studies of patients at the Murtha Cancer Center of Walter Reed National Military Medical Center could shed new light on breast cancer in African-American women – and one day even help replace the mammogram as the premier diagnostic tool.

Meera Srivastava, a professor in the Department of Anatomy, Physiology and Genetics at the Uniformed Services University of the Health Sciences (USUHS), is leading a team in search of biomarkers for breast cancer. Found in blood, biomarkers are special proteins that can signal the presence, even the extent, of such tumors.

The researchers, which also include staff from the Chan Soon-Shiong Institute of Molecular Medicine in Windber, Pa. and the Murtha Cancer Center at Walter Reed Bethesda, have a special focus. They hope to find a set of 20 to 50 biomarkers that will spot breast cancer in one, often underserved population: African American women.

Meera Srivastava, foreground, and Ofer Eidelman examine slides of patient serum in their search for biomarkers that might help diagnose breast cancer in African-American women. Srivastava, a research professor at the Uniformed Services University of the Health Sciences, leads a research team that has found race-linked biomarkers such as ICAM-1 and two forms of JunB. Eidelman is a research associate professor and bioinformatician at USUHS (Photo by Paula Amann)

"I am most excited about developing this into a liquid mammogram, so it could be used in hospitals," said Srivastava in a recent interview. With blood draws common in hospital settings, she said, this new kind of diagnostic tool would be "easy, inexpensive and noninvasive."

Meanwhile, researchers from the Chan Soon-Shiong Institute; the Clinical Breast Care Project at the Henry M. Jackson Foundation in Rockville, Md.; and the Murtha Center have their sights on a related medical problem. For years, clinicians have wondered why African American women are more likely to die of invasive breast cancer than their Caucasian counterparts.

A recent study suggests that equality of health care might be the key. Jianfang Liu, a statistical analyst at the Soon-Shiong Institute, was lead author for the study. He and a team led by Hai Hu, vice president for research at the institute, compared the breast cancer-free interval (BCFI) for 112 African-American and 372 Caucasian women.

The study cohort was drawn from the Clinical Breast Care Project (CBCP), headed by Army Col. Craig D. Shriver, director of the Murtha Cancer Center. Other coauthors included Albert J. Kovatich, Jeffrey A. Hooke, J. Leigh Campbell-Fantacone of CBCP–Henry Jackson Foundation, and Leonid Kvecher and Lori A. Sturtz of the Soon-Shiong Institute.

Their research problem was harder to solve than it might look. First, African-American women are more prone to highly aggressive subtypes, or strains, of cancer.

"In general, African American patients have a lower breast cancer incidence rate," said Hu. "However, once they have the cancer, their cancers are typically more aggressive."

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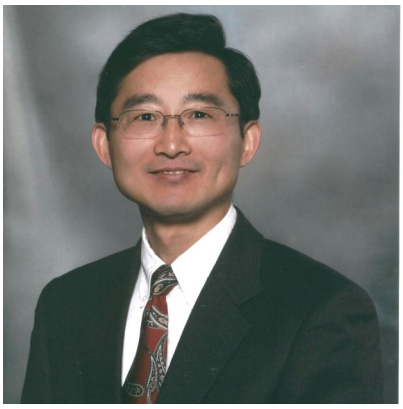

Hai Hu, vice president for research at the Chan Soon-Shiong Institute (Photo courtesy of Hai Hu)

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Knowing this, the research team controlled for subtypes of cancer and after following patient outcomes over five years, found some intriguing results.

"For the two races, the rate for the subtypes may be different, but once you control for that, the BCFI is the same," Hu said.

Yet, similar studies found that African American women in cohorts outside the military medical system had worse outcomes for breast cancer than their Caucasian peers. Why the difference?

"We think one of the main reasons is that Walter Reed [Bethesda] patients have equal access to health care" regardless of race, Hu said.

Hu cautioned that it would take more than one study to prove this point. In fact, he hopes to take part in other studies that would probe differences in BCFIs over a longer time, along with differences in cancer treatment.

Given more research evidence, more studies with similar results could have ripple effects not only for patients and their families, but for health care policy, he suggested.

"If the conclusion is that equal access to health care removes the racial disparity, then that's something that the politicians will want to look at," Hu said.

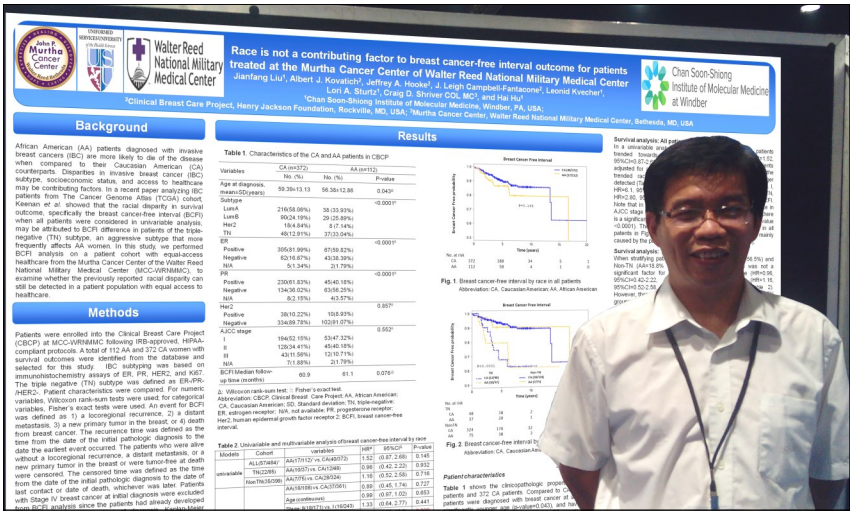
Hu and Liu presented the team's early findings on race and BCFI on Aug. 16 at the Military Health System Research Symposium in Orlando, Fla.

For their part, Srivastava and her colleagues have a dream. Imagine a quick needle stick and a simple blood test, as opposed to the mammogram — the painful, lengthy and costly set of X-rays of the breast that is now the gold standard for cancer detection. Their vision of another kind of cancer diagnosis is no mirage, based on early research.

The research team has already found three phosphorylated proteins – proteins altered in shape and function by the addition of a phosphate group – in a significant percentage of African-American cancer patients, but in a much smaller proportion of their Caucasian peers.

The USUHS scholar also presented findings about the proteins, ICAM-1 and two forms of JunB, at the Military Health System Research Symposium on Aug. 16.

The serum samples used for the study were also drawn from the Clinical Breast Care Project led by Col. Shriver. Ofer Eidelman and Joshua Starr in Srivastava's lab conducted the experiments. James Craig, Leonid Kvecher, Liu and Hu of the Soon-Shiong Institute analyzed the data. Other coauthors included Army Ltc. Matthew Hueman of the Murtha Cancer Center and Harvey Pollard of USUHS.



Jianfang Liu, of the Chan Soon-Shiong Institute, presents a study comparing breast cancer-free intervals among African-American and Caucasian service members at the Military Health System Research Symposium on Aug. 16. When they controlled for cancer subtype, researchers found no significant difference between the two groups. (Photo courtesy of Jianfang Liu)

The right biomarkers could serve a triple function, stressed Srivastava: detecting breast cancer early, helping doctors track patient progress and guiding treatment choices.

"You have to monitor the patients regularly, and doing a biopsy regularly is not feasible," she explained.

While the potential benefits are clear, the research remains challenging. The phosphorylated proteins that could signal breast cancer are few in number and appear in minute concentrations in the bloodstream, said Srivastava.

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Murtha Center Helps Fuel Cancer Moonshot

One team, one fight: It's a motto that conveys the shared mission of health care providers at Walter Reed National Military Medical Center.

Those four words could also sum up the Cancer Moonshot, a $1 billion research effort that includes the John P. Murtha Cancer Center at Walter Reed Bethesda and a host of partners nationwide.

Army Col. Craig Shriver, director of the John P. Murtha Cancer Center at Walter Reed National Military Medical Center. (Photo courtesy of Murtha Cancer Center)

Launched by President Barack Obama at his final State of the Union Address on Jan. 12 of this year, the Cancer Moonshot aims to achieve a decade of progress in half the time, explains Army Col. Craig Shriver.

He attended a June 30 national summit on the project at Howard University, in Washington, D.C., with Vice President Joe Biden and Dr. Jill Biden hosting the event. It took place simultaneously with 260 local summits across the country.

The moonshot's goal is "to accelerate progress," Shriver said in an interview last month, through better data sharing, collaboration between federal and nonfederal partners, regulatory relief and patient involvement.

One partnership emerging from the moonshot is the Applied Proteogenomics Organizational, Learning, and Outcomes (APOLLO) consortium. The effort would seek to better target therapies for cancer patients by examining both the genetic and protein makeup of their tumors.

APOLLO would pool the research of three big players: the National Cancer Institute, the Veteran's Administration, and the Department of Defense, which includes the Murtha Cancer Center.

"What we're doing is examining DNA and RNA, and protein expressions of a unique set of patient samples, which has never been done before,"

Shriver said, referring to the helical molecules that, respectively, code for the body's proteins and carry that code to the ribosomes, cellular structures where proteins are made. "Our hope is to perform those analyses on up to 8,000 samples over four to five years."

Each year, Shriver noted, about 1,000 active-duty service members get a cancer diagnosis. He voiced his hope that a large number of them would take part in the APOLLO studies.

In his remarks to the June 30 summit, Vice President Joe Biden, who helms the moonshot, underscored the need to accelerate cancer research.

"Time matters, days matter, minutes matter," said Biden, who lost his adult son, Beau Biden to brain cancer last year, learning much about recent medical research in the process.

"There is a consensus that we've reached an inflection point," Biden said.

The vice president pointed to new partnerships among oncologists, immunologists, microbiologists, virologists, chemical engineers and biological engineers that augur growing progress in understanding and treating cancer. ▣

– Paula Amann

CANCER, from page 4

What's more, in a diverse America, not all African American women have the same genetic heritage. Clinicians will likely need to adapt diagnostic biomarkers to each patient who walks into their office.

"We have the capacity to 'subgroup' within the African American population or the Caucasian population," Srivastava said, noting that her current task is "to find biomarkers for the whole group."

As they work toward a liquid mammogram, the medical researchers from USUHS, the Murtha Center and the Soon-Shiong Institute face two friendly rivals, Srivastava noted.

Research teams from the Center for Applied Proteomics and Molecular Medicine at George Mason University in Manassas, Va. and the MD Anderson Cancer Center at the University of Texas in Houston are also hunting for similar biomarkers.

The research race is on. ▣

Laying the Groundwork for Postgraduate Research

by Lisa Thompson

The Department of Research Programs (DRP) can help Graduate Medical Education (GME) trainees meet milestones outlined in their course curriculum, while they conduct research here at Walter Reed National Military Medical Center.

The center has some 62 GME programs, including the Navy Postgraduate Dental Service, each with its own curriculum and program requirements based on accreditation standards for research. To help meet these requirements, the DRP provides trainees with guidelines to help them launch their research project.

The Dental Service offers a prime example on how to follow a schedule and curriculum for meeting the milestones in order to complete a research project during the calendar year.

In July, postgraduate trainees may be required to form a research committee to monitor the research project and adverse events, and conduct scientific review. Trainees must take Collaborative Institutional Training Initiative (CITI) courses and earn a certification to conduct research at Walter Reed Bethesda.

DRP's Research Education Services can assist trainees with identifying their roles and with polices and procedure for adhering to the Human Research Protection Program. They must register on the Electronic Institutional Review Board (EIRB) system, and upload their CITI certificate and curriculum vitae.

Program directors or their designees may provide suggestions on gathering information and making research queries, designing a research topic, and submitting protocols online.

In addition, the trainee may seek help from DRP's Institutional Review Board (IRB) and the Tiger Team, which provides EIRB training and can help transfer and submit research protocols into the EIRB system.

In August, trainees may contact Darnall Library for aid with literature searches that can help shape their research questions.

In September, trainees should have identified a mentor to assist them with developing and writing literature reviews and creating bibliographies. Mentors can help trainees formulate their research questions and hypothesis that will be submitted to the department's research committee for approval.

If the trainee needs further guidance in developing materials and methods to test the research hypothesis or question they can reach out to the DRP biostatisticians. Also, the biostatisticians are available to provide free statistical reviews and training for GME trainees.

In October, the trainee should establish their research design and research proposal. The DRP biostatisticians can review the trainees' research design and ensure that their primary and secondary objectives are met.

In November, trainees should submit their research proposal to the research committee. They will go on to write the proposal and send it for scientific review by the chief of the department or designee.

Once the literature review, materials and methods, bibliography and scientific review conditions are met in the research paper, the trainee can contact the DRP to submit their research proposal for protocol development and for IRB Committee review.

This serves as a rough guide for trainees startng their research project. To ensure the trainees are aware of the research resources available to them, DRP invites trainees to attend Research Residents Day, Nov. 14, 2016, at the National Intrepid Center of Excellence (see page 18).

Trainees are also invited to participate in the Poster Display Week, Poster Competition and Symposia I and II during the 2017 Research and Innovation Month in May 2017. All participants must submit their research protocol abstracts and other required documents to DRP's Research Education Services.

Upcoming newsletters will provide more information on the 2017 Research and Innovation Month events. ▣

RESEARCH ROUNDTABLE

Photo by Lisa Thompson

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 every third Tuesday of every month. Next month, we're pleased to welcome Albert Churilla, J.D., Ph.D., a counsel with the Naval Medical Research Center, who will speak about patents.

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.

Online Research Resources Detailed at Roundtable

Department chief also warns about expired protocols

Although in existence for some 70 years, the Defense Technical Information Center (DTIC) has expanded rapidly over the past two and has refined its online collaborative tools for researchers, free of charge.

"If you have Internet, you can be using these tools 24/7 across the globe," said Carolyn Fota, M.H.R., a member on the Training Team of the Customer Support Division in the User Services Directorate of DTIC, who presented via remote access at the Research Roundtable on Aug. 23.

In addition, Army Col. Peter Weina, chief of the Department of Research Programs (DRP), which hosts the roundtable, used this platform to flag several problems related to protocols at Walter Reed National Military Medical Center.

For one, the regulation known as 45 CFR part 46 requires an annual continuing review of protocols previously approved by the Institutional Review Board, or IRB. Without that review, the protocol approval automatically expires.

"There are a number of protocols in our system that have been expired for 120 days or more," Weina told the roundtable audience.

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Army Col. Peter Weina, chief of the Department of Research Programs, makes a point at the Research Roundtable (Photo by John Fadoju)

ROUNDTABLE, from page 5

In light of technical challenges that have plagued the new electronic IRB (EIRB), the DRP chief called on principal investigators and their staff to keep a paper copy of their protocols for reference."Your file is the protocol you print out and put in a folder," Weina said.

As for DTIC, Fota told the Roundtable attendees about a set of resources especially relevant to researchers. Armed with just a Common Access Card, or CAC, active duty service members, Defense Department civilians and contractors, and other federal employees and contractors can register to enter what's known as the center's R & E Gateway.

In particular, Fota touted the advantages of DoDTechSpace, a networking platform similar to Facebook and DoDTechipedia, an informational wiki similar to Wikipedia. Interactive by design, DoDTechSpace offers a platform for status updates, conversations, blogs, and news, for starters. The tool permits users to search, browse, filter and bookmark items. Scheduled searches of research data take place weekly in such fields as audiology and pain management.

As for DoDTechipedia, this tool permits browsing a wide array of topics from blogs and defense technology to science and strategy. It offers the option to expand, rate and moderate pages and calendars, and to comment on material. While often used individually, the tool can also help build communities of people with shared interests.

Fota added one note of warning about networking and pooling information inside the R & E Gateway: DTIC online tools are not designed for sharing outside of federal government circles. "Share within the gateway," Fota cautioned. ▣

PROTOCOL LOAD, from page 1

suggests that "investigators with an excessive amount of protocols are unable to have the appropriate oversight or underestimate the resources required to manage the studies," said Sanjur Brooks, DRP's program manager of human research protections. She cited the need to implement the informed consent process and simply oversee the daily work of research.

Lack of proper oversight for studies involving human participants raises the odds that someone will suffer harm, suggest DRP leaders. "We're taking a precautionary approach," explained Brooks. "We don't want to be reactive; we want to be proactive."

Researchers have six months from the release date of the policy to meet the new limits on studies with greater than minimal risks. To do so, in most cases, takes submitting an amendment to the protocol for a change of PI. If PIs would like to remain involved in a large number of projects, they can do so as associate investigators and recruit well-qualified alternates to serve as PIs.

"With this transition period, it gives the investigators time to assess their research portfolios and make a determination [about] which studies they want to be PIs on and which studies they want to transition to their colleagues – or even narrow their research focus," said Brooks.

Principal investigators and their department chiefs must consider many factors such as the PIs clinical obligations, upcoming deployments or Permanent Change of Station moves, and resource limitations that may prohibit them from effectively overseeing the non-exempt human subject research in their portfolio.

Besides curbing protocol loads, the new policy reaffirms several principles related to human subject safety in medical research. For example, the measure enjoins PIs to protect subjects from needless risk, use procedures already being performed on subjects for diagnosis or treatment, select subjects in an equitable manner, and gain informed consent prior to research participation.

See PROTOCOL LOAD, page 9

DEPARTMENT DOWNLOAD

NEWS FROM THE DEPARTMENT OF RESEARCH PROGRAMS

The Aug. 4 meeting of the Department of Research Programs, or DRP, touched on a broad range of topics from research oversight to leadership styles, and from the Zika outbreak to an unexpected transition.

Navy Cmdr. Virginia Blackman, who has been with the department for some two years, most recently as chief of the Center for Nursing Science and Clinical Inquiry, announced her departure this November. She will be taking a new job on the faculty of the Daniel K. Inouye Graduate School of Nursing at the Uniformed Services University of the Health Sciences.

"It's very exciting for me," said Blackman, who said she hopes to continue serving on the Institutional Review Board, or IRB. Blackman arrived in the department in December 2014, upon completing her doctorate. She has played a leadership role in the annual Research and Innovation Month.

Army Col. Michael Schlicher, A.N., is now serving as a senior nurse scientist at the center, while Navy Cmdr. Bill Danchanko, NC, USN, will be joining as a full -time nurse researcher and the new chief of the Center for Nursing Science.

Navy Cmdr. Virginia Blackman, now chief of the Center for Nursing Science and Clinical Inquiry, leaves in November for a faculty job with the Uniformed Services University of the Health Sciences. (Photo by Paula Amann)

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PROTOCOL LOAD, from page 6

In remarks at the Aug. 23 Research Roundtable, the DRP chief, Army Col. Peter Weina, said he, his staff and hospital leaders had been discussing limits long before release of the new policy a week earlier. He pointed to strong support for the move by both the current and former directors of Walter Reed Bethesda.

Principal investigators who exceed the cap will be notified in writing and asked pursue a waiver from the IRB or close study protocols in their portfolio. The new policy calls for sanctions on PIs who, after the six-month transition period, exceed the maximum number of studies. In such cases, the IRB can enact administrative closure of contested protocols.

"The key is to know your research portfolio, assess and report your availability of resources and provide assurances to the IRB that study oversight is maintainable and proactive," said Col. Ann Nayback-Beebe, DRP's deputy chief and protocol development chief in an interview.

In a gesture of support for PIs, Weina acknowledged the amount of time that research oversight can take for doctors already carrying a full load of patient care. He pledged to renew efforts to establish relative value units (RVUs) for doing research and mentoring other investigators. The units now provide credit for the number of patients seen, but do not yet reflect the hours many physicians also devote to medical research.

Weina and Brooks both underscored their support for medical investigation at Walter Reed Bethesda.

"My job is to promote research here, but my overriding job is to protect human subjects," Weina said. "We're here to help."

For her part, Brooks sees a scientific silver lining to the stronger, hands-on role for PIs called for by the new policy. "As we reduce the excessive quantity of protocols per PI, it will, I think, produce higher quality research," Brooks said. ▣

DOWNLOAD, from page 7

Meanwhile, Army Col. Peter Weina, the DRP chief, asked all department staff – military, civilian and contractor – to complete a couple of job duties as soon as feasible. First, employees of all stripes should complete required training, including the Collaborative Institutional Training Initiative, or CITI, modules.

Army Col. Ann Nayback-Beebe, the department's deputy chief, noted that completion of CITI is expected for both evaluation and employment. "It's an expectation of your job," she said.

Secondly, DRP staff must respond to messages from the Everbridge emergency system. "These are exercises we're doing, but what if it was the real thing?" asked Weina.

In case of multiple forms of outreach, such as calls to both land lines and cellular phones, employees need only reply to one, to comply with the requirement to respond, he said.

Nayback-Beebe reminded staff that these messages are used to notify them of snow days, base shutdowns and other emergencies. "The purpose is to keep you informed as employees of the federal government, to keep you safe," she said.

To further strengthen the department culture, Weina touted the concept of leading from below, noting that he depends on the initiative of staff throughout the department.

"It means providing alternatives, providing information to help all of us do things better than we do," Weina said.

He emphasized that success does not mean being indispensable, but ensuring that a given job gets done, no matter who does it. "Make sure you are not a single point of failure," Weina said.

In the spirit of leading from below, the DRP chief urged staff to feel empowered to share their views on any research projects that do not pass muster for protection of human subjects. "Our primary job is the protection of people in human studies here," Weina said. "Just because it [a study] was approved doesn't mean it will always be approved."

In an effort to help researchers get credit for the time they give to investigations, meanwhile, the DRP chief is working to adapt relative value units (RVUs) that would reflect time spent by doctors on such activities as research and mentoring.

Weina also noted that Dr. Wendy Bernstein will offer training on scientific reviews with individual researchers.

For her part, Nayback-Beebe voiced her appreciation for staff members who are serving on the Tiger Team and working on outreach about the new electronic Institutional Review Board (EIRB), in addition to their regular duties.

Significantly, she flagged a cutoff on accepting continuing review (CR) submissions to the IRB using the old CR template as of Sept. 30. All CR submissions beyond that date need to be submitted using the new CR template within EIRB and should have a completed protocol application reflecting the legacy protocol in order to be processed.

"We're looking at those studies that are open," Nayback-Beebe said, noting the need to close certain protocols, such as those that have not recruited participants over subsequent years, protocols that have lapsed in IRB approval, or those that show evidence of PI non-compliance with reporting requirements.

The deputy chief also paid tribute to Robert Roogow, the director of IRB operations, for all his work. "He has been so very responsive to the needs of the investigators," Nayback-Beebe said.▣

Update from the Zika Front

Myths about the Zika virus abound, noted Col. Peter Weina, reporting to department staff on his experience seeing service members who are concerned about the illness. The DRP chief is a national expert on tropical infectious diseases.

One key misconception is the idea that if a mother has Zika, her baby will inevitably have birth defects. Despite alarming accounts in the news media, Weina said, most pregnant women with Zika do not give birth to infants with microcephaly, a condition in which they have abnormally small heads. In one case of twins, he noted, one baby was born normal and the other emerged with microcephaly.

Second, staying indoors at night is unlikely to reduce the risk of Zika transmission, Weina said, as the Aedes mosquitos that carry the virus are day-biting mosquitos.

And contrary to some reports, Zika has little impact on most individuals infected with it. "The vast majority of people exposed to Zika have zero symptoms," Weina said, who described the virus as much less virulent than Dengue fever.

However, he noted, in addition to the risk of microcephaly for a small proportion of infants, Zika infection can occasionally lead to Guillain-Barré syndrome, a serious immune disorder that produces weakness and ascending paralysis. ▣

FACES OF RESEARCH

HONORING OUR OWN

At the August meeting of the Department of Research Programs, Col. Peter Weina, chief of the Department of Research Programs (DRP) presented the I Save Lives honor to Michele McGee-Guthrie, a manager for the Institutional Review Board, who received the honor in absentia.

Col. Peter Weina, chief of the Department of Research Programs, honors Michele McGee-Guthrie, a manager for the Institutional Review Board, as part of the I Save Lives campaign. (Photo by John Fadoju)

"Thank you very much for this award," McGee-Guthrie wrote of the recognition in a later email. "More importantly, I would like to thank the members of my team who assisted with my training and helped me acclimate to a new environment."

At the DRP departmental meeting, Weina underscored the reasons for the campaign that monthly honors a member of the staff. He emphasized the essential role each of his staff members plays in promoting military medical research, protecting the safety of patients, and thereby saving lives.

The DRP chief pointed to the huge advances that modern medicine has achieved in treating hepatitis C, which was close to a death sentence when he trained as a doctor.

"The difference between then and now is that there are drugs" to treat the illness, noted Weina. "It's because of the work that's done here. Things you do every day make a difference."

ARRIVAL GATE

Army Col. **Michael Lee Schlicher,** Ph.D., R.N., just arrived from his previous position as the executive director for the military's TriService Nursing Research Program at the Uniformed Services University of the Health Sciences in Bethesda, Md. In that role, he oversaw 68 research programs totaling more than $45 million. Schlicher was also a member of the Research Advisory Council of the National Institute of Nursing Research within the National Institutes of Health.

Army Col. Michael Lee Schlicher. (Photo by Paula Amann)

His prior leadership positions have included regional chief of nursing research for both the Pacific Regional Medical Command in Honolulu and the Southern Regional Medical Command in San Antonio. Schlicher was recently selected to serve as the nursing research consultant to the Army Surgeon General – Office of the Surgeon General.

Schlicher's program of research seeks to use aspects of nanotechnology to develop new nursing therapeutics for wound healing, pain control and disease prevention. He will be serving as senior nurse scientist at the Center for Nursing Science and Clinical Inquiry. ▣

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.

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))

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, MHA, MBA, will share the latest policy guidance from the Research Regulatory Oversight Office within the Office of the Under Secretary of Defense for Personnel and Readiness (OUSD [P&R]). The workshop will cover the following vital areas:

- OUSD (P&R) Assurance for the Protection of Human Subjects
- Minimum Education Requirements Framework (MERF) for DoD Personnel involved In Human Subjects Research
- Collaborative Institutional Training Initiative (CITI) role-based training instructions for researchers who conduct, review or approve research with human subjects in compliance with the MERF standards set forth by the Assistant Secretary of Defense for Research and Engineering

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

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

RECENT PUBLICATIONS

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

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Department of Research Programs

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