DEPARTMENT OF RESEARCH PROGRAMS
Walter Reed National Military Medical Center

Military Medical Research News

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Hospital inquiry projects transform care, cut costs

Poster competitions offer broad range of topics, potential impact

by Paula Amann

Tally visits to a typical U.S. emergency room, and chest pain is one of the top two reasons for arrival. Yet, a deeper dive into these figures from the National Center for Health Statistics suggest that only a small share (15 to 30 percent) of ER patients have acute coronary syndrome, and only about 1 in 10 of these are at risk of dying from it, notes Army Maj. Jason Reese.

A cardiologist who served as a cardiovascular fellow at Walter Reed National Military Medical Center, Reese won the award for evidence-based practice during Poster Week at the hospital last May. This competition is one of six that takes place during Research and Innovation Month, held annually by the Department of Research Programs.

Besides evidence-based practice, the inquiry poster competitions include quality or performance improvement, case reports, and patient- and family-centered care.

Also in May are two sets of research competitions for military service members: the Bailey K. Ashford and the Robert A. Phillips Awards. Both offer laboratory and clinical categories for staff and fellows, as well as for interns and residents.

Phillips winners go on to vie against peers from Naval Medical Center Portsmouth and Naval Medical Center San Diego in the Navy-wide Academic Research Competition. Walter Reed Bethesda will host in 2018.

Health providers of all stripes – military, civilian and contractor – can also vie for an award in the category of case reports. These projects lift up unusual patient cases and therapies that may stretch the boundaries of medical knowledge.

For his evidence-based practice project, Reese zoomed in on the laboratory tests that help doctors discern cardiac from non-cardiac causes of chest pain. Choosing the best tests for the job was at the core of his winning project.

The project was also on track to save the hospital up to $213,412 in costs and more than 2,100 hours of laboratory staff time over three years. “Collaboration between the laboratory and the clinic can save time and money,” said Reese, summing up his project in remarks at Research Symposium I on May 9.

Traci Carter, a diabetes nurse educator, took home the quality improvement award in 2016 for a project training families on use of insulin pumps. Based on her experience, she encourages other health care providers pondering entry in a Poster Week competition to give it a try.

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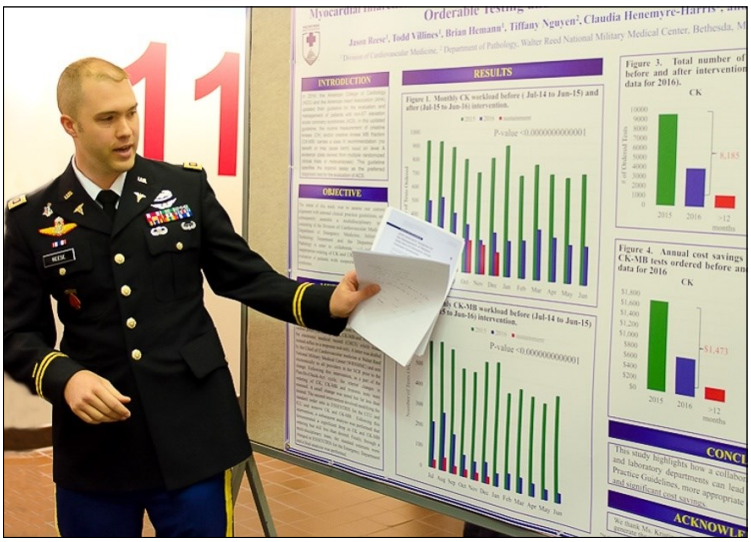

Army Maj. Jason Reese, a cardiologist who was a cardiovascular medicine fellow at Walter Reed Bethesda, details May 3 how his team’s project saved costs and staff time by reducing needless cardiac tests. His poster won the award for evidence-based practice during 2017 Research and Innovation Month. (Archival photo by John Fadoju)

Department of Research Programs

Army Col. Peter Weina, chief of the Department of Research Programs

The Department of Research Programs at Walter Reed National Military Medical Center supports research in the National Capital Region.

This monthly newsletter covers events, research and administrative policies and procedures, research studies, department operations, workshops and other programs across our region.

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This newsletter appears monthly. We welcome your comments and story ideas. ***Please email material by the 15th day of the prior month for the following month's issue to paula.m.amann.ctr@mail.mil.*** Not on our email list? Please drop us an email, and we would be glad to add your name.

Research First Steps

Our research protocol analysts are here to help you start your project. To make an appointment, please call the Department of Research Programs at 301-295-8239. We are in Building 17B, Suite 3C, on the third floor by the elevators.

Research Roundtable Schedule

Walter Reed Bethesda, America Building (Building 19), Room 2301

- Tuesday, Dec. 19, 1200-1300
  "Just the Facts, Ma'am: Advertisements for Research"
  Vicki Miskovsky, protocol analyst
- Tuesday, Jan. 23, 1200-1300
  "Training for Research: Role of DRP, MERF and CITI," Lisa Thompson, medical education specialist

Lunch & Learn Schedule

- Wednesday, Dec. 13, 1200-1300
  Introduction to Research Misconduct
  (Webinar by PRIM&R)
- Wednesday, Jan. 10, 1200-1300
  "Guarding Our Intellectual Property: What You Need to Know About Invention Disclosure"

EIRB Tips of the Month

Cutting and pasting into text boxes.

When copying text from Microsoft Word, please change the font to Arial or Times New Roman first. This will prevent unwanted changes and weird formatting. It also works best to use the tool bar in the text boxes for cut and pasting, instead of Control C and Control V.

Getting guidance

Lost in the electronic Institutional Review Board? Get oriented with the "User Guide (Humans)" in EIRB's Resource Centers. The "humans" term refers to your research subjects. (Our staff does not question your personhood.) The document provides an overview of the EIRB system; and step-by-step guidelines for performing routine and special tasks in EIRB.

When all else fails, consider picking up the phone or shooting an email to a staff member at the Department of Research Programs. It would help our staff help you if you send screen shots of the troublesome EIRB step that seems to be holding up your submission.

— compiled by Robert Roogow, Institutional Review Board director of operations and Wendy Gilbert, Institutional Review Board manager

Correction

Air Force Lt. Col. (Dr.) Peter Learn was misidentified as an Army officer in a front-page caption (upper right) of our November issue and again on page 6. Our apologies, Lt. Col. Learn.

The Department of Research Programs presents

2018 Research & Innovation Month

Important Dates

Call for Abstracts

☐ **December–January (final abstract submission deadline: 31 January)**

Register for a research or inquiry poster competition by sending your abstracts and required forms in a single email to dha.bethesda.wrnmmc.mbx.researchandinnovationmonth@mail.mil.

Poster Production

☐ **February (poster draft submission deadline: 28 February)**

All participants must submit a poster draft to the Medical Graphic Arts Department (MGAD). Points of contact are Mary-Ann Ayrandjian (mary-ann.ayrandjian.civ@mail.mil) and Shane Stiefel (shane.m.stiefel.civ@mail.mil).

Poster Display Week

☐ **30 April–04 May**

All participants display their research posters in the Mezzanine Center, East, and West Wings of Building 9. Posters based on Unity of Effort must carry its logo in the upper right corner. Unity of Effort reflects the partnerships among Walter Reed National Military Medical Center, the Uniformed Services University of the Health Sciences and the National Institutes of Health.

☐ **02 May – Poster Competition I (Case Reports, Evidence-Based Practice, Performance Improvement, Quality Improvement)**

Finalists from inquiry poster competitions present their posters to judges in Building 9, East Wing. Winning posters get award ribbons.

☐ **03 May – Poster Competition II (Paul Florentino Patient and Family-Centered Care)**

Contenders present their project posters by the Paul Florentino plaque in Building 9. Judges will award first, second, and third prizes.

Research Symposia I and II

☐ **09–10 May**

Finalists for the Bailey K. Ashford and Robert A. Phillips research awards present slide talks before judges in Main Auditorium at the National Intrepid Center for Excellence. Also, winners of Poster Competitions I and II will present.

Navy-Wide Academic Research Competition

☐ **16 May**

Winners of the Phillips competition at Walter Reed Bethesda compete with peers from Naval Medical Center Portsmouth, Naval Medical Center San Diego in the conference room of the National Intrepid Center for Excellence.

6th Annual Aware for All

☐ **23 May**

Aware for All aims to help the public make informed decisions about clinical research participation through speakers and display tables. Research teams at Walter Reed Bethesda and groups from the National Capital Region showcase their work in the lobby of Building 19.

Spring Research Summit

☐ **30 May**

Research-related groups present slides, share information, and network in the Main Auditorium, National Intrepid Center for Excellence.

Questions? Contact the Research Education Services team.

dha.bethesda.wrnmmc.mbx.researchandinnovationmonth@mail.mil

ANNOUNCEMENTS

Window opens for submissions to spring competitions

Throwing your hat into the ring for Research and Innovation Month? The submission window for abstracts to six different competitions opened Dec. 1, with a final deadline of January 31. Staff, fellows, interns and residents from the National Capital Region can vie for awards in research, case reports, patient- and family-centered care, evidence-based practice, and quality or performance improvement.

During Poster Display Week, from April 30 to May 4, Building 9 will be brimming with posters. Will one be yours? And will you be a finalist or winner? Find background and application forms in the first e-blast for competitions, which went out on Nov. 20. You may also click here for needed documents. Early submissions are encouraged.

Biosafety and biosecurity training now available

The Department of Research Programs is proud to announce new online training modules on biosafety and biosecurity. The modules are designed for Institutional Biosafety Committee (IBC) members, who review human gene transfer protocols. These protocols involve such elements as recombinant DNA, oncogenes, synthetic nucleic acid, select agents, pathogens requiring high biosafety-level containment and toxins.

The training seeks to ensure that human gene transfer protocols meet guidelines from the U.S. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research and the National Institutes of Health.

Available through the Collaborative Institutional Training Initiative (CITI), the new training covers IBC review processes that prevent harm to human subjects, public health and the environment. To learn more, please contact Lisa Thompson at lisa.p.thompson5.civ@mail.mil.

Events spell out rules on research misconduct, advertisements

Lunch and Learn: Research 2.0 launches this month on Dec. 13, in Room 1369 of Building 8, with a webinar from Public Responsibility in Medicine and Research on research misconduct. The training is aimed at professionals with the Institutional Animal Care and Use Committee, Institutional Review Board and Institutional Biosafety Committee. Participants can earn credits for the Minimum Education Requirements Framework for this session.

On Dec. 19 at noon in Desert Conference Room 2301 of Building 19, the Research Roundtable presents Vicki Miskovsky with the talk, “Just the Facts, Ma’am: Advertising for Research Recruitment.” A veteran protocol analyst, Miskovsky will clarify federal rules on use of advertising in research studies. Audience questions about ads and research policy will follow the presentation. ▣

GETTING STARTED WITH THE INSTITUTIONAL REVIEW BOARD AT WALTER REED BETHESDA

A convened panel of the Institutional Review Board (IRB) meets twice a month, with actions assigned based on submission deadlines.

Submission deadlines are the dates that the IRB receives a submission with all administrative, scientific and any other required pre-reviews already done. Please work with a research protocol specialist and refine your project in time to make these deadlines.

Expedited actions have no submission deadlines, because the IRB reviews them independently of the convened meeting schedule. However, please follow these deadlines to help build our IRB agenda for this month and early 2018. Thank you for your cooperation.

Submission Deadlines (Time: 1600)	Convened IRB Meetings
December 7	December 21
December 28	January 11
January 4	January 18
January 11	January 25
January 18	February 1

Kibbe: Gender bias in research can hurt science, patients

by Paula Amann

When it comes to medical drugs, risks can differ by gender. Consider this: Of all the drugs yanked off the U.S. market in recent years, 4 in 5 were pulled off pharmacy shelves due to adverse risks for women. How could that happen?

Questions like these were at the heart of a Nov. 8 talk at Walter Reed National Military Medical Center by Melina R. Kibbe, Zack D. Owens professor and chair of the department of surgery at the University of North Carolina – Chapel Hill.

"Why do we study males when developing therapies for both sexes?" Kibbe asked her audience of some 35 surgeons and other hospital staff.

Kibbe, who also is a professor in the department of biomedical engineering, delivered the Oliver H. Beahrs Distinguished Surgical Lecture on "Sex Bias in Surgical, Biomedical and Clinical Research." The Uniformed Services University – Walter Reed Bethesda Department of Surgery hosted the event.

The winner of the 2009 Early Career Award for Scientists and Engineers, Kibbe holds six patents or provisional patents. Her insights on gender bias turned into a segment on the CBS news show, "60 Minutes," in 2014.

"It was really my first foray into advocacy," Kibbe said of her work as a champion for medical research that better includes women.

It all goes back to an experiment Kibbe carried out with laboratory rats while working at Northwestern University in Evanston, Illinois. In her group of exclusively male rats, she found nitric oxide worked to reduce postsurgical stenosis, the narrowing of blood vessels, which can limit blood flow after balloon procedures for vascular blockage.

When a woman mentor asked about the compound's impact on female rats, Kibbe had no answer.

"That was my light-bulb moment," Kibbe recalled during her remarks at Walter Reed Bethesda. "I had never asked the question."

The gender gap in research makes no sense, Kibbe said, given deep differences between the sexes in disease symptoms, response to drugs and even incidence of certain illnesses. For instance, more men than women get cardiovascular disease, yet more women than men actually die from the disease, Kibbe noted. Among common drugs, prophylactic aspirin benefits men more than women, and statins have greater adverse risks for women than men.

Melina Kibbe, Zack D. Owens professor and chair of the department of surgery at the University of North Carolina – Chapel Hill, fields a question at the Oliver H. Beahrs Distinguished Surgical Lecture Nov. 8. The Uniformed Services University – Walter Reed Bethesda Department of Surgery hosted the event, which shined a light on gender bias in medical research. (Photo by Paula Amann)

Yet, too often female patients get the same drug at the same dose as males, Kibbe said. The same may occur with implanted medical devices, she noted, which sometimes work differently in women than in men.

The problem pervades the "pipeline" for new medical therapies, Kibbe argued. It all starts with cellular or

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BIAS, from page 5

or basic research, which gives way to animal or translational research, and ultimately, human subjects or clinical research.

Kibbe was the corresponding author for a 2014 article by Dustin Y. Yoon et al. in the journal, Surgery, "Sex bias exists in basic science and translational surgical research." The research team surveyed 2,347 articles published over two years of studies in five top journals on general surgery.

Of the 618 studies based on animal or cells, 78 percent reported the sex involved, but of those, 80 percent involved all male animals. The team found a bigger gap in the actual number of animals used: 84 percent male versus 16 percent female. Among cell research studies, only 24 percent stated the sex of the donor, and 71 percent of those cases involved only males.

The gender gap in research makes no sense, Kibbe said, given deep differences between the sexes in disease symptoms, response to drugs and even incidence of certain illnesses. For instance, more men than women get cardiovascular disease, yet more women than men actually die from the disease . . .

Such disparities surfaced even in studies of diseases common to women, such as cardiovascular and thyroid disease, Kibbe said. She believes medical journals have a role to play in moving research beyond gender bias. For instance, she suggested that journals ask all authors to report the sex of animals used in research behind published studies.

"If only one sex is studied, justification should be required," Kibbe said.

The gender gap has a few sides, the speaker suggested. First, drug trials, both in animals and in humans, often fail to include females in significant numbers. Second, trials that do include females may not include a number comparable to the number of males studied. To top it off, researchers often do a poor job of reporting sex-based differences.

Sex bias in research has broad implications for medical drugs, Kibbe believes. First, drugs tested only or largely on men may not help women. Approved drugs also may have yet unidentified side effects for female patients. Lastly, drugs that do not work in men may fail to see further development, which might show their efficacy for women, as in the case of the human papilloma virus vaccine now used with young women and teenaged girls.

Federal law and policy have advanced in the past quarter century, Kibbe said. The National Institutes of Health Revitalization Act of 1993 mandates inclusion of women and minorities in clinical research funded or conducted by the NIH.

Yet, most drug trials today derive their funding from industry, Kibbe noted. Pharmaceutical firms, she urged, should follow the same rules for research as the federal government. ⊡

The Department of Research Programs presents

TRAINING FOR ELECTRONIC INSTITUTIONAL REVIEW BOARD (EIRB)

Question and Answer Sessions
Most first and third Mondays, 1200–1300
Radiology Conference Room B015, Building 19 Basement

Month	Days
December	4
January	8 | 22
February	5

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"I would say: Go for it," said Carter, who works in the Pediatric Subspecialty Clinic. "Even if [the project] seems minor, if it has big outcomes, it's worth reporting."

In her team's case, the outcomes were measurable. The family education program brought cases of ketoacidosis, a serious complication of diabetes, down from 4 in the first quarter of 2015 to zero over the following two years in the pediatric clinic where Carter works.

Joan Godich, a nurse consultant with the hospital's Infection Prevention & Control unit, won the top award in quality improvement this past spring. The impetus for her team's project came from three cases of septic arthritis in 2016 at the Physical Medicine and Rehabilitation unit.

No serious harm resulted, but Godich and her colleagues revamped patient care on the unit. New procedures, such as a separate medication room and use of multidose vials for only one patient, stopped the infections cold.

When the results were in, Godich wanted to spread the word. "I thought that entering the competition would be a way to get the information out there," Godich said.

A wide array of hospital staff members take part in Poster Week. They range from nurses like Carter and Godich, and doctors like Reese, to psychologists, social workers, physical therapists and nutritionists.

These competitions are "open to everyone who wants to present what they're doing at the hospital," said Navy Cmdr. William Danchanko, chief of the Center for Nursing Science and Clinical Inquiry.

He also coordinates the judges for evidence-based practice and quality or performance improvement projects.

As for Reese, his project drew on evidence from the field. Three years ago, guidelines from the American College of Cardiology and American Heart Association began urging use of cardiac troponins as the best biomarkers for acute coronary syndrome. Meanwhile, the American Board of Internal Medicine had started discouraging tests of creatine kinase and a related kinase, CK-MB, for this condition.

With a new troponin assay on the way, Reese and his project team went about persuading providers at Walter Reed Bethesda, Fort Belvoir Community Hospital and Malcolm Grow Medical Clinics at Andrews Air Force Base that it was time to reduce use of the older CK tests.

"We had to get everyone to agree that we needed to change the way we do cardiology," Reese, now a cardiologist at Madigan Army Medical Center, recalled in an interview last month.

Getting that "buy-in" was the toughest part of the project, he said, but over the long term, it helped drive the reductions in costs and staff time.

An evidence-based practice project like this can seem daunting in other ways, noted Danchanko. "You have to find the literature that matters and synthesize the material," Danchanko said. After the actual work is underway, competitors have the chance to put their project into a larger context.

A project "has to be grounded in theory, some kind of theoretical framework," Danchanko said.

From left, Navy Cmdrs. Brigette Ferguson, director of Pathway to Excellence, and William Danchanko, chief of the Center for Nursing Science and Clinical Inquiry, join Army Col. Ann Nayback-Beebe, assistant chief, Department of Research Programs, to judge posters May 3. This quality improvement event was among six competitions, from research to patient-centered care, during Research and Innovation Month. (Archival photo by John Fadoju)

Evidence-based practice projects start with a population, intervention, comparison, outcome and time (PICOT) question, followed by an intervention and outcome assessment plan.

Quality or performance improvement projects rely on the Plan-Do-Check-Act (PDCA), FOCUS-PDCA, or Lean Six Sigma models.

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INQUIRY, from page 7

The Paul Florentino Patient- and Family-Centered Care Award offers another avenue for inquiry. Travis Combest, a clinical exercise physiologist and diabetes educator, earned second place in May's competition for a three-day, call-ahead appointment reminder system he developed with Army Capt. Paul Rosbrook.

Patients were literally getting lost en route to the outpatient nutrition clinic where the pair works, so the staff devised a new system. With reminder calls, and emailed maps and directions, the clinic saw a drop in the no-show rate and an uptick in patient satisfaction.

"Measuring the voice of the customer" is crucial to care, said Combest, whose team used the no-show rate and patient surveys to monitor progress.

Joan Godich presents the poster that won first place for quality improvement May 3. (Archival photo by Paula Amann)

The varied projects of Poster Week reflect a big picture of ongoing improvements in health care, suggested Godich. Across Walter Reed Bethesda, health care providers can learn from and adapt projects going on in other clinics. Thus, Poster Week competitors contribute to their field and beyond.

"Everyone at the hospital is interested in giving our patients stellar care, and there are so many projects that people don't know about," Godich said.

For Carter, all the data analysis, writing and poster design that it took to win a quality improvement award was well worth the time.

"It was just a thrill to share what we had done and to get recognition for it," said Carter. "I still have the ribbon hanging in my office." ▣

Vying for Poster Week awards

Competition victors share tips

Talk with past winners of Poster Week competitions at Walter Reed National Military Medical Center, and they have definite ideas about what helped set them on the path to an award.

Find your finish line.

A prize-winning project starts with a health care problem and ends with some measure of progress in solving it. "Pick an endpoint that is tangible," said Army Maj. Jason Reese, a cardiologist who earned last year's evidence-based practice award. Behind recent inquiry awards are such metrics as reduced number of patients with a given condition, numbers of appointments kept, and amount of money saved for the hospital, actual and projected.

Involve your team.

Joan Godich, a nurse consultant who finished first for quality improvement in last May's competitions, asked her team members to provide feedback before submitting her poster. She credits their ideas and advice for the strength of the award-winning product.

Make your message graphic.

Helping the judges visualize the results of a project is one key to success, say past winners. Reese acknowledged his coauthor, Army Capt. Tiffany Nguyen, for her help designing their team's poster, which used vivid bar graphs to depict changes in cardiac tests and hospital costs.

Put passion in your presentation.

A winning poster talk not only presents data but also conveys drama. Past judges say they read the posters before the oral presentation. By that time, they may be seeking to grasp the motivation behind the inquiry. "For me, what's helpful is to convey the enthusiasm I have for the project," Reese said.

For Travis Combest, a clinical exercise physiologist and diabetes educator who placed second in last year's Paul Florentino Patient- and Family-Centered Care Awards, the poster talk is about "painting a picture, telling a story."

Connect with your audience.

With so many competitors in the mix, one key to an award may lie in building a bridge to the audience. "Make eye contact, engage the entire audience and have your poster memorized so you don't have to look away," advised Reese, who held a script for reference.

Stay centered and confident.

It might be hard for some presenters to keep their focus while judges are scrutinizing their poster and talking notes on every talking point. Yet, the contenders know their project best, reminded Combest. "You're the expert," Combest said. "Feel calm about it and just tell the story."

RESEARCH ROUNDTABLE

A MESSAGE FROM THE HOST OF THE RESEARCH ROUNDTABLE

by Lisa Thompson

Lisa Thompson, academic research education specialist (Photo by subject)

The Department of Research Programs (DRP) invites you to the Research Roundtable on the third Tuesday of most months. Our new program includes a 20-minute presentation on a "how to" research topic, followed by 40 minutes of questions and answers about challenges in conducting research, navigating the Electronic Institutional Review Board or submitting actions to the Institutional Review Board.

At the next roundtable on Dec. 19, **Vicki Miskovsky**, a program analyst in DRP, will speak on the topic, **"Just the Facts, Ma'am: Advertising for Research Recruitment."** We invite you to present as well. If there is a pressing concern you would like addressed or if you would like to lead a discussion on a research-related topic, please talk to me at the Research Roundtable or send an email to lisa.p.thompson5.civ@mail.mil.

Meanwhile, I would like to join your team to provide a 10-15 minute update on DRP services annually or every six months, before or after your program meets for didactic or lecture hall sessions. These remarks range from DRP services to upcoming events and policy updates from the Office of the Under Secretary of Defense [Personnel & Readiness and Research Regulatory Oversight Office (R202)], a review of the Minimum Education Requirements Framework (MERF), and information on required Collaborative Institutional Training Initiative (CITI) training.

Our goal is to promote research. We want to help familiarize your Graduate Medical Education (GME) trainees, faculty, and staff with DRP services to help them meet their research and scholarly project program requirements. Our services include assistance with protocol development; courses on research methods, statistics and writing; GME trainee research project funding; collaborative agreement development; manuscript editing; publication clearance and bench research space through our Biomedical Research Laboratory. I hope to see you soon at one of our events! ⊡

Roundtable delves into data-sharing agreements

On Sept. 1, the Department of Research Programs' Human Research Protections Program released a policy on research-related, data-sharing agreements at Walter Reed National Medical Center. The recent release of this document and the prevalence of research partnerships at the hospital might explain the standing-room-only crowd at a Nov. 21 talk on this topic.

Some 45 people crammed into the Desert Conference Room in Building 19 for "How to Craft a Data-Sharing Agreement," a Research Roundtable led by Sanjur Brooks, D.P.S., program manager for the Human Research Protections Program at Walter Reed Bethesda.

Sanjur Brooks, program manager for human research protections, listens to a question on data-sharing agreements at November's Research Roundtable. (Photo by John Fadoju)

"If you're sharing data externally to Walter Reed, you must have a data-sharing agreement," or DSA, Brooks told her audience, who plied her with questions during and after the formal slide talk.

A DSA serves to protect the privacy and security of personal health information and personal identifiable information shared with research partners outside the hospital. The Defense Health Agency, which oversees all military medical treatment centers, now requires such agreements.

A DSA brings its own requirements. For example, researchers must give online notice of a data breach within one hour of discovery. Within 24 hours of discovery, the applicant and government sponsor must also complete a Breach Report and email it to the Defense Health Agency.

A DSA differs from a cooperative research and development agreement (CRADA) in its focus on use of data. A CRADA is intended to speed up the commercialization of technology, optimize resources and protect the parties

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involved. If research partners are sharing samples or other research materials, they may need a material transfer agreement, rather than a DSA.

Martin Hindel, the research attorney with the Department of Research Programs, suggested a rough guide for distinguishing the right contract.

"Am I trying to share data or material?" asked Martin Hindel, the research attorney with the Department of Research Programs. "If it's the former, it's Dr. Brooks' lane with a DSA." Otherwise, he said, a material transfer agreement would likely be in order.

DSAs come in four flavors, as it were. One type deals with protected health information, another with personally identifiable information, and a third with de-identified information. The fourth is the limited data set, which omits 16 direct identifiers set forth in the Privacy Rule of the Health Insurance Portability and Accountability Act.

Taking the first step toward any of the four involves filling out a data-sharing agreement application. The application must be submitted to the Department of Research Programs for review, via the electronic Institutional Review Board. The privacy board or designee must approve the application prior to executing the DSA with the government sponsor and applicant.

"Keep in mind when filling out the application [that] there are elements that do not apply," cautioned Brooks. Meanwhile, she and the staff of the Department of Research Programs are available to help. ⊡

To learn more, find slides from the talk at this link.

Webinar tackles ethics of electronic informed consent

As a new research practice, electronic informed consent raises a host of questions. In fact, Public Responsibility in Medicine and Research drew on five presenters for its webinar, "Electronic Informed Consent: Ethical, Regulatory, and Practical Implications."

A group of 28 people attended the Nov. 29 training, which was part of Lunch and Learn: Research 2.0, hosted by the Department of Research Programs.

Cheryl Grandinetti, a health science policy analyst with the Office of Medical Policy of the U.S. Food and Drug Administration, laid out the latest guidance from her agency on electronic informed consent.

The rules for electronic consent resemble those for pen-and-paper forms. Electronic consent must include all elements required by the FDA, present content in understandable language and minimize the risk of coercion or undue influence on the person's choice to take part in a study.

Upsides to the electronic approach include innovation for clinical trials, convenience for the patient, and options to track patients in real time, Grandinetti said.

Yet, electronic vehicles can pose challenges for some patients, noted presenters Christian Simon, David Klein and Helen Schartz. Some patients find a paper form more portable; others lack computers and smartphones.

Kathleen Noel, left, and 27 others take in a Nov. 29 webinar on electronic informed consent. Attendees earned credits for the Minimum Educational Requirements Framework. (Photo by Paula Amann)

A slide show can help potential subjects understand a clinical trial, but it may take more time than a paper form. The presenters stressed that electronic informed consent does not work for everyone.

As noted by Grady in a 2017 study and quoted by Simon and his colleagues, "Informed consent is not … 'one size fits all' and should be tailored to context." ⊡

To learn more, find webinar slides at this link.

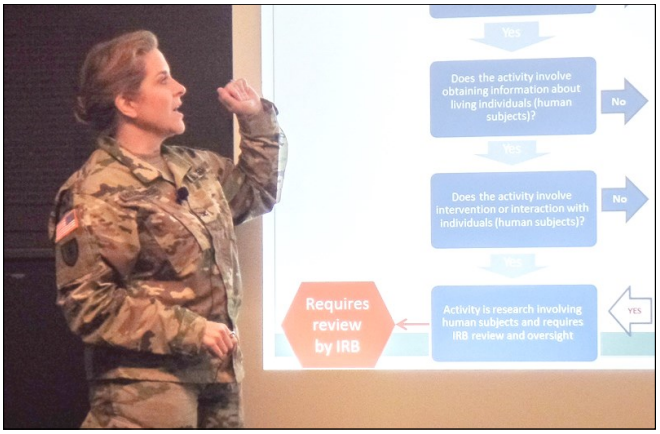
Risk drives regulatory oversight, says Nayback-Beebe

At Walter Reed National Military Medical Center, oversight of medical research and other inquiry boils down to four letters: R, I, S and K, says Army Col. Ann Nayback-Beebe, assistant chief of the Department of Research Programs.

In other words, regulatory requirements exist to assess and mitigate "risk" to human subjects. With expanded knowledge has come expanded risk oversight, noted Nayback-Beebe at a Lunch and Learn on Nov. 9.

"It's the speed of technology: Years ago we never could have imagined what's possible today," said Nayback-Beebe. "Being sensitive to how the data can be put together and affect someone's life and livelihood is really important."

Reducing risk takes a system of interlocking oversight structures, explained Nayback-Beebe, in a slide talk entitled, "The Many Facets of Scholarly Inquiry: A Review of Regulatory Oversight and Requirements." These structures and the professionals behind them range from the Institutional Official, the hospital's director, Navy Capt. Mark Kobelja; to the human protections administrator, Sanjur Brooks; the Institutional Review Board and its director of operations, Robert Roogow; and the post-approval compliance monitors, led by Diane Beaner.



Army Col. Ann Nayback-Beebe, assistant chief of the Department of Research Programs, offers a bird's eye view of research oversight at the Lunch and Learn on Nov. 9. (Photo by John Fadoju)

In her presentation, Nayback-Beebe also drew distinctions between pure research, defined by regulatory oversight entities as "a systematic investigation designed to develop or contribute to generalizable knowledge," and other forms of inquiry.

Non-research inquiry includes performance improvement, which focuses on changing the way a team works together, and quality improvement, which seeks to better processes for medical treatment and delivery of care.

Given potential staff and leadership turnover, these kinds of inquiry require periodic attention, Nayback-Beebe stressed, calling this an "ongoing process."

Others involved in inquiry choose evidence-based practice projects, which delve into existing research to find the evidence to support the adoption of practices and procedures for bettering patient care, reducing its healthcare costs, and improving efficiencies.

"These projects are critical," Nayback-Beebe stressed. "It's important that those performing them understand that their regulatory status as exempt from IRB oversight does not mean they are exempt from review."

It's essential that these projects are submitted to an exempt determinations official, so the organization knows we are adequately protecting the rights and welfare of patients and following the appropriate regulatory guidelines. ⊡

To learn more, find slides for the talk at this link.

Faces of Research

Arrival Gate

Anmarie Widener
(Photo by John Fadoju)

Anmarie Widener, LCSW-C, Ph.D., is the first full-time chair of the Institutional Review Board at Walter Reed Bethesda, holding the first such position in a military treatment facility. She comes from the National Intrepid Center of Excellence where she was regulatory officer and contracting officer representative, and managed research operations. Since 2013, she has worked at the hospital in research and as a credentialed clinical social worker.

Earlier, as a defense contractor, Widener supported the Defense and Veterans Brain Injury Center, the National Center for Disaster Medicine and Public Health, and the American Health Information Community. She also led research on the nation's Family and Medical Leave Act for the Johns Hopkins University Bloomberg School of Public Health, Child and Maternal Health Department. For the Peace Corps, she was a key member of the medical team in the Office of Medical Services, Washington, D.C.

Widener held a private practice in clinical social work. She taught graduate students at the University of Michigan and undergraduate students at Georgetown University. Widener earned her doctorate in social science from Leiden University, the Netherlands. She holds master's degrees in clinical social work from the University of Michigan and in literature from Michigan State University.

Goodbye and Good Luck

Army Sgt. **Alisha Kohler**, who served as non-commissioned officer in charge at the Department of Research Programs, moved on to a new assignment. Earlier this fall, Kohler won recognition as non-commissioned officer of the quarter for Charlie Company. In June, she won an Army Commendation Service Medal.

Army Sgt. Alisha Kohler receives an Army Commendation Service Medal from Col. Peter Weina, chief of the Department of Research Programs, at a June 8 staff meeting. (Archival photo by Paula Amann)

During more than one and one half years with the department, Kohler provided logistical support and coordination for Research and Innovation Month, and aided with other events. She secured crucial audiovisual equipment that will improve the quality of our outreach work for years to come.

Army Col. Peter J. Weina, the chief of the Department of Research Programs, lauded Kohler's contribution to the functioning of his department.

"I think it would not be an overstatement to say that the daily operations of DRP [the Department of Research Programs] would have been significantly more difficult without the presence and hard work of Sgt. Kohler," Weina stated in an email. "She did more than most people will ever realize and she will be sorely missed."

Deadlines are nearing for

2018 Research & Innovation Month,

from the Department of Research Programs.

Get a jump on the competitions. Choose among six.
Find all application packets in your mailbox or online!

Final deadline: Jan. 31. Prejudging starts now.

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- 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.***
- Vulnerable Populations
  HHS provides guidance for populations including prisoners, children, and HIV human subjects.

FDA Regulations

- CFR – Code of Federal Regulations Title 21
- FDA Regulations Relating to Good Clinical Practice and Clinical Trials
- Preambles to GCP Regulations
- Electronic Records; Electronic Signatures (21 CFR Part 11)
- Regulatory Hearing Before the Food and Drug Administration (21 CFR Part 16)
- Protection of Human Subjects (Informed Consent) (21 CFR Part 50)
- Additional Safeguards for Children in Clinical Investigations of Food and Drug Administration-Regulated Products (21 CFR Parts 50 and 56)
- Informed Consent Elements (21 CFR 50.25(c))
- Exception From General Requirements for Informed Consent (21 CFR 50.23(e))
- Financial Disclosure by Clinical Investigators (21 CFR Part 54)[8]
- Institutional Review Boards (21 CFR Part 56)[9] ⊡

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RECENT PUBLICATIONS

Courtesy of Darnall Medical Library

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PUBLICATIONS, from page 14

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