

Department of RESEARCH PROGRAMS

at Walter Reed National Military Medical Center



VOLUME 1, ISSUE 5

What I Do Matters!

JULY 2014

Welcome to the Department of Research Programs July 2014 newsletter!

This month our new Chief, COL Peter Weina, provides his first Message from the Chief. Another first in this issue is feedback provided on last month's issue. Thank you everyone for providing feedback—keep it coming! Yet another first this month is Useful Links for Researchers on page 11, which provides potentially useful U.S. Food and Drug Administration web links for researchers.

Our usual section updates are featured, and special features are presented, including *Research Day* and *Research Roundtable*. Also included is a CNSCI flyer titled GOT EBP? The final first this month is an article contributed from the Defense Health Agency: *New DHA Web Tool Streamlines Research Oversight Compliance*.

Folks, I would like to personally remind everyone that my technical editing skills are here for you to use. It is hard for me to edit my own written work, as it is likely hard for you to edit yours, since we are all too close to our own work. My second set of eyes is here for you to use. Please feel free to send me your documents for review and I will be happy to return them to you with my recommended track changes for your consideration. I'm here to help finesse your final documents. Please email me your editing requests to me at gregory.g.greer.ctr@health.mil.

Thank you.

Gregory Greer, Technical Editor, DRP

Building 17 hosts an Olympic-size pool, basketball court, and workout gym

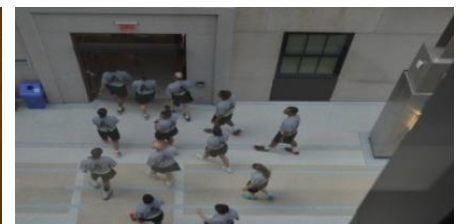
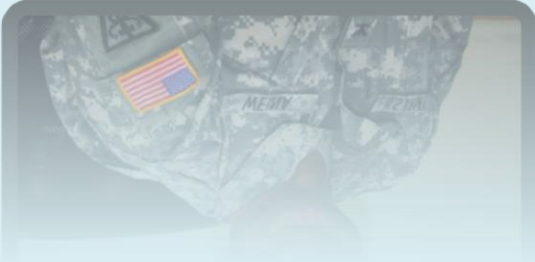


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Message from the Chief



This is my first opportunity as your new Chief to speak through the newsletter. I am humbled by this great privilege and look forward to the opportunity to serve as your Chief. In this role, I will daily communicate on your behalf to the wider Walter Reed Bethesda and National Capital Region community. First and foremost, I want to convey my deep appreciation and gratitude for the professionalism and dedication I have witnessed every day in the short time I have had here. Second, I want to reiterate to the team in the Department and the entire Institution that the tone and direction of the Department of Research Programs will be one of service, partnership, and professionalism in every encounter.

The services we provide have too often been viewed as one of policing and my goal is that it be of partnership and cooperation. We have a dual responsibility to promote and encourage research at this Institution, as well as safeguard the rights and safety of those who might become research subjects. Rather than accomplish this through regulating and monitoring actions, we can assure protection of the patient who might volunteer as a research subject by connecting and functioning side-by-side with the researcher at Walter Reed Bethesda, assuring that the research done is scientifically sound, achievable, and ethically performed.

This world class patient care facility deserves and has every right to expect world class research to improve the care of those who serve in in harm's way. We must and will earn the trust of the research community at Walter Reed Bethesda through exceptional listening, service, and teamwork to lead that world class research effort. I have faith that we can and will achieve this every day and with every encounter.

Peter J. Weina, PhD, MD, FACP, FIDSA
COL, MC, USA
Chief, Department of Research Programs



The Gargoyle - **Hat on:**
COL Weina is in or nearby; **Hat off:**
COL Weina is out

Biomedical Research Laboratory (BRL)



CDR Janine R. Danko, MD, MPH
Chief, Biomedical Research Lab

Our science staff has been busy working with WRNMMC investigators on new protocols this spring that will soon be submitted for IRB/Institutional review. New collaborations are being formed with investigators in the Naval Postgraduate Dental Program, the Department of Pathology, and in the Integrative Cardiac Health Project (ICHP). The lab continues to support several ongoing bench projects from the Defense & Veterans Center for Integrative Pain Management (DVCIPM), too. As always, any investigator interested in our services is asked to contact CDR Danko (301-295-8279) or Dr. Zhou.

Enjoy the coming 4th of July holidays.

Dr. Yaling Zhou is a supervisor and Science Director of the Biomedical Research Laboratory in DRP. He received his PhD in immunology from the University of Minnesota in 1994 and completed his postdoctoral fellowship in 1997 at Dana-Farber Cancer Institute, Harvard Medical School. He started his career as a research virologist and conducted a number of studies on pathogenesis, vaccine development, antigenic relationships, and immune responses of a number of human and animal viruses such as human hepatitis C virus (HCV), murine acquired immunodeficiency syndrome (MAIDS, the mouse model of human AIDS) virus, chicken Newcastle disease virus (NDV), bovine viral diarrhea virus (BVDV), hog cholera virus (HCV), and porcine epidemic diarrhea virus (PEDV) in several universities and institutes around the world including Nanjing Agricultural University in China, University of Hannover in West Germany, Institut für Virologie in West Germany, University of Utrecht in The Netherlands, and Harvard Medical School in the United States.



Upon receiving his PhD, his primary research interest shifted to molecular and cellular immunology. He is now interested and experienced in application of molecular biology and immunology techniques for analysis of immune cell functions and immune regulations for all disease conditions including viral infectious diseases, cancers, autoimmune diseases, inflammatory diseases, etc.

Before he joined the former Water Reed Army Medical Center (WRAMC), he worked as a Senior Scientist in Northwest Biotherapeutics, Inc. developing cancer vaccines for immunotherapy of solid cancers such as prostate, lung, and brain cancers. He has 20 peer-reviewed publications, including research papers, a book chapter, and review articles.

Dr. Zhou joined the former WRAMC in 2003 and is now overseeing the development and implementation of all research protocols presented to and conducted at the Biomedical Research Laboratory. He serves as a scientific and technical consultant and provides assistance to WRNMMC Principal Investigators for their research protocol preparation and submission. He can assist in all scientific aspects of protocol development and preparation including discussion with investigators for their study and experiment design, method selection, literature search and review, budget preparation, and grant writing. He can also assist in protocol implementation by performing lab experiment procedures that require the use of standard and advanced immunology and molecular biology techniques including various immunoassays such as ELISA, flow cytometry analysis, Luminex multiplex cytokine assays, and conventional and real-time PCR for gene expression analysis, etc. If you need assistance in any aspect of your protocol preparation and implementation, please feel free to contact him at 301-295-8287 or yaling.zhou.civ@health.mil.

Center for Nursing Science & Clinical Inquiry (CNSCI)



COL Jeffrey S. Ashley, AN, PhD
Chief & Senior Nurse Scientist

Updates

Please see CNSCI Informational “GOT EBP?” on pages 12 and 13.

Everything else remains *status quo* for CNSCI this month.

Institutional Review Board (IRB) Operations Office



Debarati Dasgupta
Director of IRB Operations

This month let's continue our discussion of Reportable Events. The following is from Chapter 10 of the WRNMMC IRB Handbook-Reportable Events:

The WRNMMC IRB requires that the PI report certain occurrences and events to the IRB. The events may be separate or inter-related. The timing of the report is directly tied to the nature and severity of the event. The reporting requirements are outlined in the WRNMMC Adverse Event (AE) and Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) Reporting workflow diagram dated 31 January 2014. (This document is posted in IRBNet, under “Forms and Templates,” under the library “WRNMMC DRP-Documents for Researchers” (03 INSTRUCTIONS-WRNMMC Adverse Events and UPIRTSO)).

Prompt Reporting: The PI shall promptly report the following to the IRB within 24 hours of learning of the incident by calling or emailing the WRNMMC IRB Operations Office as outlined in the Reportable Event Submission form followed by a written submission through IRBNet within 5 working days. (This document is posted in IRBNet, under “Forms and Templates,” under the library “WRNMMC DRP - Documents for Researchers” (04 FORM-Reportable Event Form)).

Adverse Events - All adverse events not reported under prompt reporting requirements must be tracked by the PI using the Adverse Event Tracking Log and reported to the IRB at the time of continuing review. These include AEs (even SAEs) deemed not related to the research and any adverse events occurring in one or more subjects participating in a research protocol with the nature, severity, or frequency of which is consistent with these issues:

- A. Known risks or side effects of the research procedures or interventions;
- B. Expected natural progression of subjects' underlying diseases, disorders, and conditions;
- C. Subjects' predisposing risk factor profiles for the adverse events.

UPIRTSOs and major protocol deviations previously reported to the IRB for prompt review should also be tracked using the log.

Research Administration



Jeremy Nelson
Administrator
Directorate of Education, Training, & Research

Research team members are encouraged to stop by to meet our subject matter experts and learn how we can assist you in all areas of research and address any concerns you may have moving forward.

Q&A

Q: How can I benefit from the expertise of a Grants Writer, Grants Manager, or a Technical Editor?

A **Grants Writer** can assist you with managing pre-award grants and contracts submission processes to include: locating funding opportunities, assisting in the grant writing, research issues related to submission guidelines, final review of the completed grant submission package to ensure all guidelines and requirements are met prior to submission.

A **Grants Manager** provides investigators with administrative, mathematical and content accuracy assistance based on protocol documentation to ensure the regulatory requirements for legal review are in compliance with the Code of Federal Regulations (CFR).

A **Technical Editor** rewrites your final written work product checking for inconsistencies, grammatical errors, typos, logical flow of information, overall presentation, and that the document is ready for receipt by its intended audience. This is the last step prior to submission; a second set of eyes reviewing your final written work is always helpful.

Q: Who can I contact to schedule an appointment with one of your subject matter experts?

Please contact Marcus Morgan (301-400-3529 or marcus.t.morgan@health.mil) to set up an appointment with one of our subject matter experts.

Research Protocol Development



LCDR Ruben D. Acosta, MC
Chief, Research Protocol Development

Research Monitors

A **Research Monitor** is required for studies involving greater than minimal risk or any study where the IRB decides that an additional monitor will add to subject safety. Research Monitors must be independent of the investigative team (i.e., should not fall under the direct chain of command of the Investigator) and possess sufficient educational and professional experience to serve as the subject advocate.

The Research Monitor:

- 1) Will ensure that the enrollment of subjects is in compliance with the protocol's inclusion and exclusion criteria.
- 2) May assess one or more of the following phases of a research project: subject recruitment, subject enrollment, data collection, data storage and analysis.
- 3) Shall provide a current Curriculum Vitae (CV) and Human Subjects Protections (HSP) training certificate.
- 4) Will review all Adverse Events (AEs), reporting Unanticipated Problems Involving Risks to Subjects (UPIRTSOs) and Principal Investigator's (PI) recommendations (e.g., no change in the consent form) prior to submission to WRNMMC's IRB per institutional AE-reporting policy.
- 5) May, at the discretion of the IRB, be assigned to discuss research progress with the PI, interview subjects, consult on individual cases, or other duties as assigned.
- 6) Shall promptly report research concerns or problems to the IRB.
- 7) Shall have the authority to stop a research study in progress, remove individual subjects from a study, and take whatever steps are necessary to protect the safety and well-being of research subjects until the IRB can assess the Research Monitor's report.

Research Oversight and Compliance Office (ROCO)



Mary Kelleher
Chief, ROCO

This month ROCO is pleased to provide an article from a contributing author.

New DHA Web Tool Streamlines Research Oversight Compliance

by Michael A. Parker

Senior Strategic Communications Analyst

Contractor Support to Force Health Protection and Readiness

DHA, Defense Health Headquarters

Whether it's how to best prevent sexual assault, suicide or substance abuse, Department of Defense (DoD) researchers are pushing the boundaries in the fields of behavioral and social science, conducting groundbreaking studies and surveys that benefit U.S. and Global citizens every day. Though the public may only see the final product of this hard work, there are important checks and balances behind the scenes that must occur before research and studies involving human subjects can be initiated.

The Defense Health Agency, located in Falls Church, Virginia, houses a Research Regulatory Oversight Office (R2O2) to ensure compliance with DoD's ethical and regulatory requirements for research activities involving humans and animals. Military researchers and investigators in the areas of behavioral and social science work with the Research Regulatory Oversight Office to check off every component of compliance – a long and complicated process.

The Research Regulatory Oversight Office, along with the Defense Health Agency Privacy and Civil Liberties Office, has launched a new web tool to standardize the way military researchers and investigators obtain the information and documents needed to ensure that their studies are compliant with regulatory and policy requirements. The innovation is part of the Defense Health Agency's efforts to modernize and streamline Military Health System capabilities.

The Privacy, Information Collection, Human Research (PICHR) tool aggregates all relevant compliance information and data necessary for conducting research into one platform, and is being hailed as a large step forward in simplifying navigation of the approval pathways for researchers, investigators and DoD.

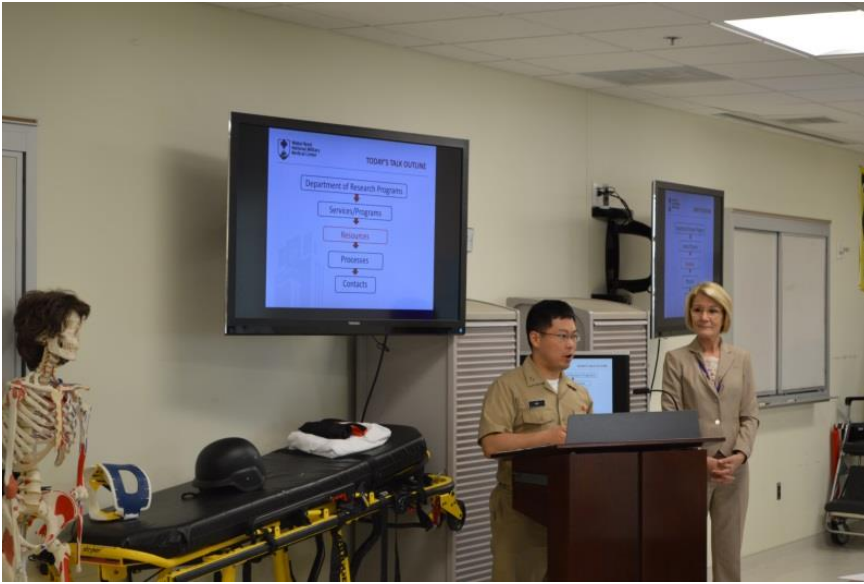
“Before PICHR was created, researchers would have to make three or more separate phone calls and visit multiple websites,” said Public Health Service Capt. John Eckert, acting director of R2O2. “Now we have a one-stop shop with general guidance that will answer over 90 percent of the questions researchers would ever have on regulatory matters.”

PICHR functions as a drop-down tree to lead researchers through a series of questions, which vary at each step depending on the response to particular questions. Once all of the questions are answered researchers are redirected to a page with an organized list of the information, documents and all other applicable materials needed to ensure DoD regulatory requirements are met. On average this process can be completed in less than 10 minutes. These are vital checks to ensure standards are being satisfied for their particular activities related to privacy, information collection and human research protection.

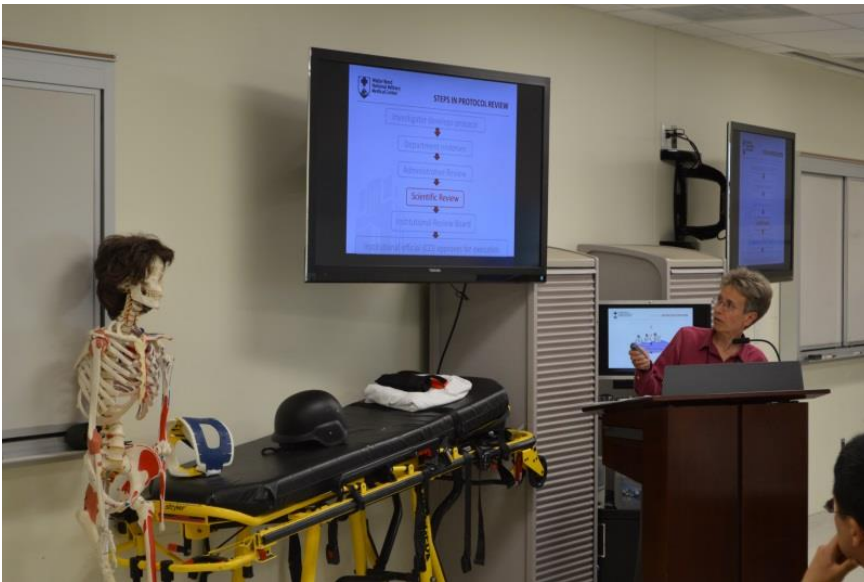
“It's common for investigators to overlook some research compliance checks without even realizing it – a misstep which can bar them from publishing or presenting their findings,” said Capt. Eckert. “The PICHR tool lends researchers an ease of mind so they can focus on the work at hand, not the red tape.”

This new tool is available and can be accessed at <http://www.health.mil/pichr>.

Research Day



LT Ryan Kim explains the differences between IRBNet and IRB to GME trainees during their Research Day 13 JUNE 2014

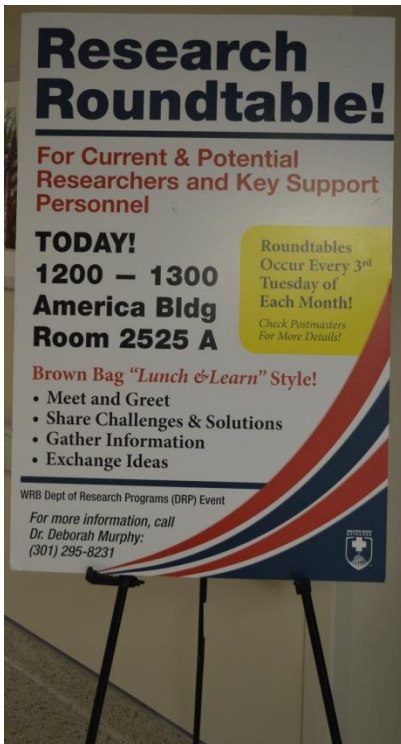


Dr. Wendy Bernstein, Chair of the Central Scientific Review Committee (SRC), walks trainees through the steps of a scientific review



Ms. Lisa Potts, Grants Writer, indicates what kinds of funding are available to investigators, and where to find sources

Research Roundtable



Deborah Murphy, PhD
Academic Research Education Coordinator

The Department of Research Programs (DRP) hosts a monthly *meet and greet* from 1200-1330 in Conference Room 2525A, 2nd Floor, Building 19 (America) for Researchers and Key Research personnel.

All are Welcome.

Participants share challenges and solutions, welcome newcomers, and hear updates from the Department. Typically, 15-25 people join the session to *lunch and learn*.



At the June meeting COL Weina, new DRP Chief, introduced himself to the group and talked about his experience with and support of research. He reiterated his open door policy, and invited participants to feel comfortable and welcome to request DRP support for issues at any level.

Among the topics discussed at the June meeting were CITI Training and Certification, DRP's *Meet the MERF Campaign* (DoD Minimum Education Requirements Framework), a joint educational session about Biomedical and Behavioral Research requirements that will be held in August at Uniformed Services University of Health Sciences (USU), and the Research Infrastructure team who support grant writing, technical writing, biomedical research, statistical modeling, grant management, audits, and business agreements.

Several participants brought up particular research study challenges for discussion, and the group offered practical solutions.

This monthly event is a forum for community-building, inter-departmental information exchange, and informal learning. DRP personnel contribute updates and news; regular participants bring their stories and experiences; and guests are introduced and welcomed. We encourage you to spark conversation with questions, observations, recent learning experiences, and anecdotes.

We invite you to join us, bring colleagues, meet other Researchers and key Research Personnel, and get your name on our Research Roundtable mailing list.

We meet on the 3rd Tuesday of every month - our next meeting is 15 JULY 2014. See you then!

Research Roundtable
3rd Tuesday of the month
1200-1330
Conf Rm 2525A
2nd Floor Building 19 (America) – above the piano!



June Research Roundtable

CNSCI Flyer

GOT EBP?

Patient Caring Touch System



Points of Contact

If you have any questions, feel free to call or email CNSCI and ask to speak with a Nurse Scientist:

COL Jeffrey S. Ashley, PhD, RN
Senior Nurse Scientist
Jeffrey.S.Ashley@health.mil
(301) 400-1238

MAJ Kyong S. Hyatt, PhD, RN
Nurse Scientist
Kyong.S.Hyatt.mil@health.mil
(301) 400-1241

CNSCI Location: Building 17B, 3rd floor, Room 3314

Darnall Biomedical Library: <http://wrnmmc.libguides.com/home>



What is EBP?

EBP = Evidence Based Practice

EBP is the integration of:

1. The best evidence
2. Clinical expertise
3. Patient Values
4. The context

EBP Process *EBP is a 5 step process:*

1. **Ask** the question
2. **Acquire** the existing knowledge
3. **Appraise** the literature
4. **Apply** the findings as appropriate
5. **Analyze & Adjust** to improve outcomes (evaluate)



Triggers for Implementing EBP

Problem Focused Triggers:

- Risk Management Data
- Process Improvement Data
- Internal/External Benchmarking Data
- Identification of clinical problems

Knowledge Focused Triggers:

- New research or evidence
- National agency or specialty organization guidelines
- New philosophies of care

What is a PICO Question?

P = Patient population or problem

- Age, gender, symptoms, setting, etc.

I = Intervention

- Treatment, medication, education, assessment, etc.

C = Comparison

- Different units, before and after change, etc.

O = Outcome

- Anticipated outcome from the intervention
- What metrics will be tracked to determine change from baseline?

Example of a PICO Question

“For adult surgical inpatients on SE with peripheral intravenous (IV) catheters, does the use of saline to flush the peripheral IV maintain patency & decrease phlebitis when compared to the use of heparin flushes?”

Useful Links for Researchers

Researchers might be interested in the following U.S. Food and Drug Administration (FDA) web links.

FDA Clinical Investigator Training

<http://www.fda.gov/training/clinicalinvestigatortrainingcourse/default.htm>

Investigator-Initiated Investigational New Drug (IND) Applications

<http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/ucm343349.htm>

Small Business Assistance

<http://www.fda.gov/drugs/developmentapprovalprocess/smallbusinessassistance/default.htm>

Feedback on June Newsletter

Comments included the following:

- *“Great newsletter!”*
- *“Thanks so much for the recent newsletter publication. It is so enlightening to read these”*
- *“General info helpful but too long; blurry photos shouldn't be included in the final cut.”*
- *“I thought it was nice!!! There were two items that could be tweaked and a few of the photos were a little blurry and the folks who slung their badge strings around their necks appeared to be choking – just ask them to remove their badge.”*
- *“Excellent informative newsletter. Thank you”*

We welcome your feedback to improve our newsletter by providing the most state-of-the-art information regarding military medical research at WRNMMC.

Please send feedback on the newsletter to **WRNM-DRPNewsletterFeedback@health.mil**.

WRNMMC authors are in bold.

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