



Department of **RESEARCH PROGRAMS** at Walter Reed National Military Medical Center



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Military Medical Research Digest

**Walter Reed, partner groups stretch the knowledge frontier
Research and Innovation Month spotlights emerging medicine***

Saluting Our Top Winners

RESEARCH SYMPOSIA WINNERS (BETHESDA, MD., MAY 19)

Bailey K. Ashford Laboratory Award: LCDR Gabe Santiago, MC

Establishing Cephalometric Landmarks for the Translational Study of Le Fort-Based Facial Transplantation in Swine: Enhanced Applications Using Computer-Assisted Surgery and Custom Cutting Guides

Bailey K. Ashford Clinical Award: LT Scott Wagner, MC

Distal Ulnar Hounsfield Units Accurately Predict Forearm Bone Mineral Density and Future Fragility Fracture Risk

Robert A. Phillips Fellow/Staff Laboratory Award: Charles Xavier, Ph.D.

Identification of the ERGi-USU, A Novel Inhibitor for the ERG Oncogene-Positive Cancers

31ST NAVY-WIDE ACADEMIC RESEARCH COMPETITION WINNER (SAN DIEGO, MAY 23)

Charles Xavier, Ph.D. – Identification of the ERGi-USU, A Novel Inhibitor for the ERG Oncogene-Positive Cancers

A Walter Reed salute to all who gave of their time, thought, and grit to take part in this year's research competitions. Look for another opportunity to compete next spring!

- ***Please see the full set of stories on Research and Innovation Month events at Walter Reed National Military Medical Center in the June issue of Military Medical Research News on the intranet of the Department of Research Programs.***

See WINNERS, p. 3



DEPARTMENT OF RESEARCH PROGRAMS



COL. Peter Weina, chief of the Department of Research Programs

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

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

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MILITARY MEDICAL RESEARCH DIGEST

Editor

Paula Amann

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

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, 19 July 2016, 1200-1300
- ◆ Tuesday, 23 August 2016, 1200-1300
- ◆ Tuesday, 20 September 2016, 1200-1300
- ◆ Tuesday, 18 October, 2016, 1200-1300

WHAT'S NEW: FORMS, TEMPLATES AND POLICIES

Find all forms in "IRB Forms and Templates" on the DRP Intranet Site, in the "01 - WRNMMC DRP - Documents for Researchers" folder.

- ◆ 06 GENERAL INFORMATION - WRNMMC IRB Statement of Compliance_ Jan 2016
- ◆ 03 INSTRUCTIONS - Combination Products Algorithm Feb 2015
- ◆ IRB Meetings Policy_Final _02March2016



RESEARCH ROUNDTABLE

A MESSAGE FROM THE HOST OF THE RESEARCH ROUNDTABLE

by Lisa Thompson



Photo by Lisa Thompson

The Department of Research Programs (DRP) would like to request time for a five-minute presentation about DRP's services, upcoming events and policy updates from the Office of the Under Secretary of Defense (Personnel & Readiness), Research Regulatory Oversight (R202) policy guidelines, and MERF and CITI Training. We request to meet one day a year or once every six months, either before or after your program meets for didactic or lecture hall sessions.

Our goal is to facilitate research. We want to help familiarize your Graduate Medical Education (GME) trainees and staff with DRP services to help them start their research projects. Our services include, but are not limited to protocol development, research methods, SPSS (Statistical Package for the Social Sciences) statistics courses, grants writing, GME Trainee Funding for Research, collaborative agreements, publication clearance and the Biomedical Research Laboratory.

DRP invites you to join us at the Research Roundtable every third Tuesday of every month (except for August, see schedule on page 2). In June, Lisa Buchanan, compliance officer with the Division of Compliance Oversight, will speak about "Unanticipated Problems Reporting to the IRB."

We invite you to present as well. If there is a pressing issue you would like addressed or if you would like to present material on a topic of your choice, please communicate your requests at the Research Roundtable or send an email to lisa.p.thompson5.civ@mail.mil. Your inquiries will be answered by either Thompson or someone else from DRP.

WINNERS, from p. 1

RESEARCH SYMPOSIA WINNERS (CONT.)

Robert A. Phillips Fellow/Staff Laboratory Award: LT Daniel Griffin, MC

Genetic Markers Correlating With Reoperation for Combat Blast-Related Heterotopic Ossification

Robert A. Phillips Fellow/Staff Clinical Award: Benjamin Sheffield

Evaluating the Operational Impact of Hearing Impairment on Dismounted Combat Using the Home Station Instrumentation Training System (HITS)

Robert A. Phillips Resident Award: CPT Sarah Placek, MC

Outcomes of Fundamentals of Laparoscopic Surgery (FLS) Mastery Training Standards Applied to an Ergonomically Different, Lower-Cost Platform

POSTER WEEK WINNERS (BETHESDA, MD., MAY 11)

Case Report (Fellow/Staff): Joshua Bernstein

Optimizing the Frequency Map for a Cochlear Implant in a Patient With Normal Hearing in the Other Ear

Case Report (Intern/Resident): Jennifer Windsor

Radiofrequency Ablation of Amputation-Related Neuromas

Evidence-Based Practice: CDR Darren J. Couture, NC

Measuring Competency in the Provision of Ultrasound-Guided Regional Anesthesia

Quality Improvement: Traci Carter, R.N.

Written Insulin Pump Backup Plans for Pediatric Patients With Type I Diabetes Are Associated With Decreased Admissions for Diabetic Ketoacidosis



WEB RESOURCES

The appearance of external hyperlinks does not constitute endorsement by the U.S. Department of Defense of the linked web sites, or the information, products or services contained therein. For other than authorized activities such as military exchanges and Morale, Welfare and Recreation (MWR) sites, the U.S. Department of Defense does not exercise any editorial control over the information you may find at these locations.

Education Materials

- [Belmont Report](#)

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

- [Comparison of FDA and HHS Regulations](#)

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

- [The President's Council on Bioethics](#)

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

- [Clinical Trials.gov](#)

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

- [HHS Office for Human Research Protections](#)

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

- [HHS Office of Civil Rights](#)

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

- [MedlinePlus](#)

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

- [Office for Human Research Protections \(OHRP\)](#)

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

- [Federal Policy for the Protection of Human Subjects \('Common Rule'\)](#)

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

- [Protocol Review](#)

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

- [Informed Consent](#)

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

- [Investigators](#)

HHS provides investigators guidance about emergency medical care and research.

- [Biological Material and Data](#)

HHS provides guidance and the law about research involving the use of biological material and data.

- [Vulnerable Populations](#)

HHS provides guidance for populations including prisoners, children, and HIV human subjects.



FDA Regulations

- [CFR – Code of Federal Regulations Title 21](#)
- [FDA Regulations Relating to Good Clinical Practice and Clinical Trials](#)
- [Preambles to GCP Regulations](#)
- [Electronic Records; Electronic Signatures \(21 CFR Part 11\)](#)
- [Regulatory Hearing Before the Food and Drug Administration \(21 CFR Part 16\)](#)
- [Protection of Human Subjects \(Informed Consent\) \(21 CFR Part 50\)](#)
- [Additional Safeguards for Children in Clinical Investigations of Food and Drug Administration-Regulated Products \(21 CFR Parts 50 and 56\)](#)
- [Informed Consent Elements \(21 CFR 50.25\(c\)\)](#)
- [Exception From General Requirements for Informed Consent \(21 CFR 50.23\(e\)\)](#)
- [Financial Disclosure by Clinical Investigators \(21 CFR Part 54\)⁸](#)
- [Institutional Review Boards \(21 CFR Part 56\)⁹](#)
- [FDA IRB Registration Rule \(21 CFR 56.106\)](#)
- [FDA IRB Registration Rule \(21 CFR 56.106\) \(printable PDF version\)](#)
- [Good Laboratory Practice for Nonclinical Laboratory Studies \(21 CFR Part 58\)](#)
- [Investigational New Drug Application \(21 CFR Part 312\)](#)
- [Foreign Clinical Trials not conducted under an IND \(21 CFR 312.120\)](#)
- [Expanded Access to Investigational Drugs for Treatment Use \(PDF - 216KB\)](#)
- [Charging for Investigational Drugs \(PDF - 204KB\)](#)
- [Form 1571 \(Investigational New Drug Application\)](#)
- [Form 1572 \(Statement of Investigator\)](#)
- [Applications for FDA Approval to Market a New Drug \(21 CFR Part 314\)](#)
- [Bioavailability and Bioequivalence Requirements \(21 CFR Part 320\)](#)
- [Applications for FDA Approval of a Biologic License \(21 CFR Part 601\)](#)
- [Investigational Device Exemptions \(21 CFR Part 812\)](#)
- [Premarket Approval of Medical Devices \(21 CFR Part 814\)](#)
- [Exception From General Requirements for Informed Consent \(21 CFR 50.23\(e\)\)](#)

Reporting Problems to the FDA

- [Reporting Complaints Related to FDA-Regulated Clinical Trials](#)
- [Mandatory IRB Reporting: FDA Contacts](#)
- [Clinical Trial Forms](#)



MERF AND CITI CLASSES

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

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

MERF and CITI Training for Researchers Workshop Schedule

MERF and CITI Training for Researchers workshop will be offered monthly. Ms. Lisa Thompson, MHA, MBA, will provide attendees with policy guidance promulgated by the Research Regulatory Oversight Office within the Office of the Under Secretary of Defense for Personnel and Readiness (OUSDP&R). The workshop will cover:

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

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

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

- **Tuesday, July 12, 2016, 1400-1500**
- **Tuesday, August 9, 2016, 1400-1500**
- **Tuesday, September 13, 2016, 1400-1500**



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 Darnall Medical Library, Building 1, Third Floor, Room 3458

Biomedical Data Discovery, Visualization, and Management

This workshop introduces a concept of data-driven research, data sharing, data reuse, research data management, and data management planning for grant proposals. The research data life cycle, including data collection, and processing methods of qualitative and quantitative data will be discussed. Attendees will become familiar with sources of biomedical data sets and statistics, data submission standards, data visualization tools, and DoD and NIH biomedical research and data policy.

One session: Wednesday, 29 June 2016, 1200-1300;
Building 6, Room 1369

Promoting Your Research

Take advantage of a government-wide initiative to foster access to journal articles and data from federally funded research (policies DoDI 3200.12 and DoDM 3200.14).

Published journal articles generated from all DoD-funded research require submission to the Defense Technical Information Center (DTIC).

https://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf

Submit your final peer-reviewed manuscript to DTIC at

<http://www.dtic.mil/dtic/submit/submit.html>

These policies are intended to make your research easier to find, help colleagues build on existing research funding by the federal government, and to advance science.

<https://www.dtic.mil/REGateway/docs/DOC-15371>

<https://www.dtic.mil/REGateway/docs/DOC-15372>

Contact: Ms. Lyubov Tmanova, DVM, MLIS, MS

Darnall Medical Library, Bldg. 1, Rm 3458

Phone: 301-319-2475

Email: lyubov.tmanova.civ@mail.mil

Website: wrnmmc.libguides.com/home/researchsupport



PUBLICATION CLEARANCE

Courtesy of Darnall Medical Library

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

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- Garvey WT, Mechanick JI, Brett EM, et al. [American association of clinical endocrinologists and American College of Endocrinology clinical practice guidelines for comprehensive medical care of patients with obesity - executive summary.](#) *Endocr Pract.* 2016 May 24. [Epub ahead of print]
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- Haran FJ, Dretsch MN, **Bleiberg J.** [Performance on the defense automated neurobehavioral assessment across controlled environmental conditions.](#) *Appl Neuropsychol Adult.* 2016 May 16:1-7. [Epub ahead of print]
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Additional WRNMMC Authors: **Csokmay JM, Yauger BJ, Hill MJ**



PUBLICATION, from p. 8

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ELECTRONIC INSTITUTIONAL REVIEW BOARD

Tips for Your Help Desk Ticket

Need help getting help?

If you need a hand navigating the Electronic Institutional Review Board, please contact the Help Desk. To submit your help ticket, you may reach the **DHA Global Service Center Help Desk (DHAGSC)** by email or telephone:

Email: dhagsc@mail.mil

Telephone: 800-600-9332; Select Option 5 for EIRB

Have the following information ready:

- **Product Name:** EIRB
- **User's Name:**
- **Telephone number where you can be reached:**
- **Name of institution where problem occurred:**
- **Description Title:** e.g., Create an account
- **Detailed description of the issue:**
- **Sequence of events leading to the issue, include screen title:**
- **Full Computer Name:**
- **Attachments (Error messages, screen shots):**

Note: Depending on the issue reported, some fields will not apply.

A Help Desk staff member will try to resolve your problem as soon as possible!

