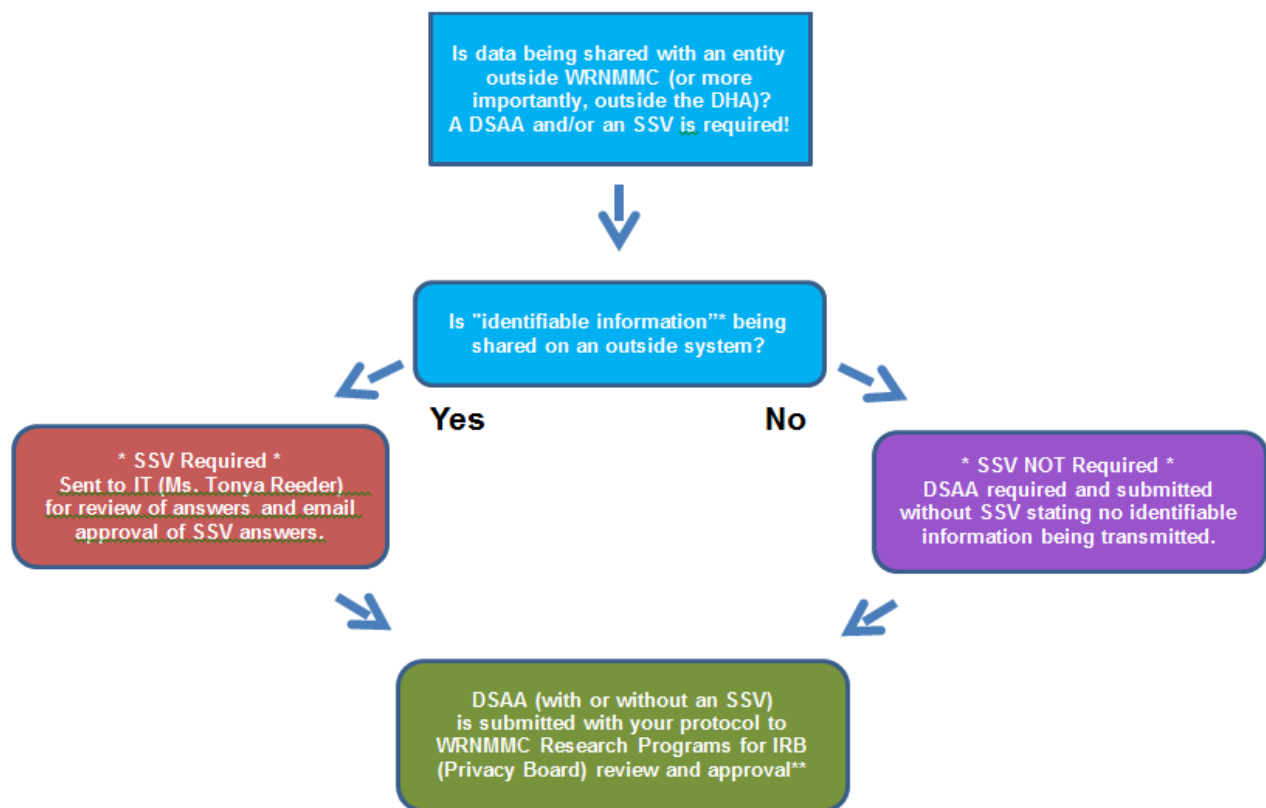




Military Medical Research Digest

POLICY PERISCOPE

System Security Verification and Data Sharing Agreement Application



* See page 3 for the 18 PHI identifiers.

** DHA Administrative Instruction (#083) states that IRBs, HIPAA Privacy Boards and/or Departments of Research Programs within the National Capital Region–Maryland Military Treatment Facilities will conduct appropriate HIPAA Privacy Rule reviews of research studies and DSAA's.

Flow chart courtesy of COL Peter Weina, director of the Department of Research Programs

Find forms at <http://www.dha.mil/Reference-Center/Forms?query=DSAA>



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.

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, 21 June 2016, 1200-1300
- ◆ Tuesday, 19 July 2016, 1200-1300
- ◆ Tuesday, 23 August 2016, 1200-1300

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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.

- ◆ 005 - Research Project Cover Sheet_dib ver 3 (1/5/2016)
- ◆ 02 TEMPLATE - Signature Page Template (1/13/2016)
- ◆ 02 TEMPLATE - Site Specific Addendum Template (2/2/16)
- ◆ 06 GENERAL INFORMATION - WRNMMC IRB Statement of Compliance_Jan 2016
- ◆ 03 INSTRUCTIONS - Combination Products Algorithm Feb 2015
- ◆ IRB Meetings Policy_Final_02March2016



POLICY PERISCOPE

The Big 18 Data Points to Watch For Safeguarding Protected Health Information

1. Names
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes. You may use the first three digits of a zip code, if according to the current publicly available data from the U.S. Census Bureau: (a) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people and (b) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) directly related to an individual, including birth date, admission date, discharge date, date of death and all ages over 89 and all elements of dates (including year) indicative of such age, except that you may aggregate such ages and elements into a single category of age 90 or older
4. Phone numbers
5. Fax numbers
6. Email addresses
7. Social Security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic or code (please note this does not mean the unique code assigned by the investigator to code the data)
18. Any other unique identifying number, characteristic or code (please note this does not mean the unique code assigned by the investigator to code the data)

Please see the following U.S. Department of Defense links for details:

- ◆ [DODI 3216.02](#)
- ◆ [DOD 6025.18-R](#) (HIPAA Privacy)
- ◆ [DOD 8580.2-R](#) (HIPAA Security)
- ◆ [DODI 6000.08](#)
- ◆ [Title 32 CFR Part 219.](#)



RESEARCH COMPETITION FINALISTS

2016 Research and Innovation Month - 8th Annual National Capital Region

Poster Display Week: Oral Poster Presentations Case Reports Fellow and Staff - 11 May 2016

Elizabeth Husson: The Effectiveness of Real Time Biofeedback Training in Reducing Vertical Impact Peaks During Running in a Service member with Unilateral Trans-tibial Limb Loss

LaGuinn Sherlock: Extended-Wear Hearing Aid Use in Operational Environments: Experiences from Two Deployments by a Combat Arms Commander

LT Sebastian Lara, MC: Desmoid Type Fibromatosis (DTF) in a Patient with Very Long-Chain-Acyl-CoA Dehydrogenase Deficiency (VLCADD)

Joshua Bernstein, Ph.D.: Optimizing the Frequency Map for a Cochlear-Implant Patient with Normal-Hearing in the Other Ear

Case Reports Intern and Resident

CPT Michael A Donohue, MC: Extensor Carpi Radialis Brevis Avulsion Fracture: A Novel Fixation Technique Using a Modified Hook Plate

CPT Christopher Lowe, MC: Primary Cutaneous Zygomycosis in an Extremely Preterm Infant Successfully Treated With Liposomal Amphotericin B

CPT Jennifer Windsor, MC: Radiofrequency Ablation of Amputation Related Neuromas

LT Samantha Mikals, MC: Hypoglossal Nerve Stimulator Use for Obstructive Sleep Apnea in the Military

CPT Meagan Simpson, MC: Routine Vaccines? Live Virus Vaccines in an Infant With DiGeorges Syndrome

CPT Shane Sweeney, MC: Spontaneous Regression of a Primary Clear Cell Renal Cell Carcinoma

CPT Timothy Blood, MC: Trans-nasal Endoscopic Eustachian Tube Closure for Recalcitrant CSF Leak Following Translabyrinthine Acoustic Neuroma Resection

LT Alana Connell, MC: Cardiac MRI for Noninvasive Differentiation of AL and ATTR Amyloidosis

Poster Display Week: Oral Poster Presentations - Evidence-Based Practice (EBP) - May 11, 2016

CAPT Lisa Osborne, NC: Implementation and Evaluation of the Patient Safety Obstetric Hemorrhage Bundle

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 1 Diabetes Are Associated With Decreased Admissions for Diabetic Ketoacidosis

CPT Matthew Holtkamp, MC: Implementation of the Neurology Resident Handbook Application Improves Patient Care Hematology Oncology Setting

Travis Combest: An Exercise and Nutrition Digital Message and Appointment Reminder In Relay Health on Preventive Health Measures

MAJ Heather Mascio, MC: A QI project: Improvement in Interdialytic Weight Gain in the Walter Reed Hemodialysis Unit with Individualized Adjustment of Dialysate Sodium Concentrations

MAJ Todd Simon, MC: A Quality Improvement Project to Improve IVC Filter Retrieval

LT Philip Rothberg, MC: Analysis Of Pelvic Binder Placement Among Casualties in Afghanistan: A Process-Improvement Initiative

Capt. Patrick Saas, MC: Ages and Stages Questionnaire Quality Improvement

Jeannie Williams, R.N.: Using Performance Improvement (PI) methods to Standardize and Improve Nursing Documentation in an Outpatient

Research Symposium I: Laboratory Presentations

Robert A. Phillips Fellow and Staff Laboratory Finalists - May 18, 2016

MAJ Luis Lozada, MC: Omega 3 PUFA Deficient Diet during Pregnancy and Lactation Has Long Term Effects on Learning and Memory in Mice

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

Anshu Rastogi, Ph.D.: Immunobiomarkers Novel Autoantibody Panel Containing Oncogenic ERG, C-Myc, AMACR and HERV-K Gag for the Detection of Prostate Cancer from Patient Sera

MAJ Kristen Bunch, MC: Upregulation of the Extrinsic Apoptosis Pathway by Docetaxel, Panobinostat, and Volasertib May Potentiate Synergy with Birinapant in High-Risk Serous Ovarian Cancer



Robert A. Phillips Resident Laboratory Finalists

LCDR Jonathan Seavey, MC: Vancomycin Powder Decreases Persistent Infection and Significantly Attenuates Ectopic Bone Formation in a Rat Model of Trauma-induced Heterotopic Ossification

CPT John Andersen, MC: Development of a Novel Cell-Line-Based Immunohistochemical tp53 Expression Control Panel at Walter Reed National Military Medical Center

LT Daniel Griffin, MC: Epigenetic Control and Fibrosis in Combat Blast-Related Heterotopic Ossification

LT Daniel Griffin, MC: Genetic Markers Correlating With Reoperation for Combat Blast-Related Heterotopic Ossification

Bailey K. Ashford (BKA) Laboratory Finalists

CPT Eric Scofield, MC: Up Regulation and Targeting Of Cancer Testis Antigens in Leukemic Blasts Using Epigenetic Therapy

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

LTC Greene Donald Royster, MC: Rapamycin Expands T-Regulatory Cells and Improves Implantation and Live Birth Rates in A Murine Model

Bethany Cunningham, M.D.: Elucidating the Mechanism of 6-Mercaptopurine Induced Hepatotoxicity and How Combination with Allopurinol Eliminates the Hepatotoxicity

Research Symposium II: Clinical Presentations (19 May 2016)

Robert A. Phillips (RAP) Fellow and Staff Clinical Finalists

Benjamin M. Sheffield: Evaluating the Operational Impact of Hearing Impairment on Dismounted Combat Using the Home Station Instrumentation Training System (HITS)

Jo Manette Nousak, Ph.D.: Aural Rehabilitation Outcomes Measures from Service Members (SMs) With Mild Traumatic Brain Injury (mTBI) and Psychological Health (PH) Conditions

MAJ Elizabeth M Polfer, MC: The Effect of Skin Pigmentation on Clinical Exam for Determination of Limb Ischemia in Healthy Controls

Marie Onakomaiya, Ph.D.: Multitasking in the Computer-Assisted Rehabilitation Environment (CAREN) Distinguishes Service Members with Mild Traumatic Brain Injury Alone From Those with Comorbid Post-Traumatic Stress Disorder

Robert A. Phillips (RAP) Resident Clinical Finalists

Capt Katrina Fernandez, MC: Suspected or Known Neonatal Sepsis and Neurodevelopmental Outcomes at Five Years

CPT Stephanie Berdy, MC: Neonatal Hypoglycemia and Developmental Outcomes in the First Five Years: A Retrospective Cohort Study

LT Theodora Dworak, MC: Epidemiology of Symptomatic Dorsal Wrist Ganglia in Active Duty Military and Civilian Populations

CPT Sarah B. Placek, MC: Outcomes of Fundamentals of Laparoscopic Surgery (FLS) Mastery Training Standards Applied to an Ergonomically Different, Lower-Cost Platform

Bailey K. Ashford (BKA) Clinical Finalists

MAJ Elizabeth Polfer, MC: The Effect of Skin Pigmentation on Clinical Exam for Determination of Limb Ischemia in Healthy Controls

MAJ Ruth Faircloth, MC: Talking about Childhood Obesity: What Parents Want

MAJ Torie Plowden, MC: Subclinical Hypothyroidism and Thyroid Autoimmunity Are Not Associated With Adverse Pregnancy Outcomes or Live Birth Rates

LT Scott Wagner, MC: Distal Ulnar Hounsfield Units Accurately Predict Forearm Bone Mineral Density and Future Fragility Fracture Risk



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 (OUSD[P&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, June 14, 2016, 1400-1500**
- **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

Managing Reference Citations with EndNote (Web version)

This workshop will help you to develop basic skills in bibliographic management using EndNote Web citation manager. In this hands-on class, attendees will create an online account via the Darnall Medical Library and will learn how to create a reference library accessible anywhere/anytime, collect citations from various biomedical literature databases, organize references, generate and format bibliographies, share your library electronically with peers, and insert references into a Word document. Attendees will also be briefly introduced to EndNote Desktop/Standalone

Session 3

Tuesday, 7 June 2016, 1300-1400; Building 6, Room 1369

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. Wednesday, 29 June 2016, 1200-1300; Building 6, Room 1369

PubMed Basics

Discover the secrets of effectively searching PubMed (MEDLINE), the world's leading biomedical literature database! In this introductory workshop, you will learn the best practices of keyword searching, how PubMed interprets your searches, and how to craft an advanced search. Additionally, we will explore how to filter and refine search results, locate related citations, and find the full-text article. We will use the MyNCBI feature for saving searches and results.

Session 2

Thursday, 9, June 2016, 1300 – 1400; Building 6, Room 1369

PubMed: Intermediate to Advanced

Maximize your existing PubMed (MEDLINE) search skills and become a more-efficient researcher. In this workshop, you will advance your understanding of Medical Subject Headings (MeSH), the MeSH search builder, and PubMed's Topic-Specific Queries. Not only will we teach you how to effectively search for information about drugs and diseases, but also how to craft more-complex searches for clinical and biomedical research. This class is perfect for individuals who are embarking on a literature review or for those who have complex clinical or research questions. Intended for individuals who have a basic foundation in searching PubMed.

Session 2

Thursday, 16 June 2016, 1300 – 1400; Building 6, Room 1369

PubMed for Nurses—Earn 1CNE!

Enhance your research and clinical assessment skills and abilities by using PubMed, the world's leading biomedical literature database, to obtain evidence-based nursing information relevant to your practices. 1 CNE will be awarded to nurses who attend. Thursday, 2 June 2016, 1200 – 1300; Building 6, Room 1369

**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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