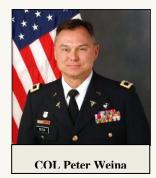


Volume 3, Issue 1a January 2016

DEPARTMENT OF RESEARCH PROGRAMS NEWS



The Walter Reed National Military Medical Center (WRNMMC), Department of Research Programs (DRP) strives to provide support for research activities within the National Capital Region (NCR) with continued exciting news. The DRP is pleased to provide news about events, research and administrative policies and procedures, research studies and collaborations, the departments' operations, workshops and other new and ongoing initiatives in the NCR for the month of January 2016. Please join us at our Research Roundtables and pick up a copy of DRP's internal newsletter. The DRP's public newsletter outlines a portion of our efforts.

STARTING RESEARCH: WHAT TO DO

While many resources are available from the DRP, there are two important take-home messages for anyone starting a research project.

- 1. Go to building 17B (DRP, third floor), and make an appointment with a protocol navigator.
- 2. Do <u>not</u> enroll patients until you get a start letter from COL Weina.

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FORMS AND TEMPLATES FOR RESEARCH

The Department of Research Programs (DRP) has revised the current Protocol Template. The new template is version OCT 2015. The following templates have been in effect since OCT 2015. It has been uploaded to the Documents for Researchers on the <u>DRP intranet web page</u>.

There are two new forms.

- Researcher's Responsibility Form
- Conflict of Interest (COI) Form

WEB RESOURCES

Education Materials

• Belmont Report

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



• Comparison of FDA and HHS Regulations

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

• The President's Council on Bioethics

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

Clinical Trials.gov

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

• HHS Office for Human Research Protections

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



HHS Office of Civil Rights

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



MedlinePlus

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

Office for Human Research Protections (OHRP)

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

Federal Policy for the Protection of Human Subjects ('Common Rule')

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

Protocol Review

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

Informed Consent

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

Investigators

HHS provides investigators guidance about emergency medical care and research, financial conflict of interest, investigator responsibility, review and reporting unanticipated problems and adverse events and the withdrawal of humans subjects form research studies.

Biological Material & 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))



Report Problems to the FDA

- Reporting Complaints Related to FDA-Regulated Clinical Trials
- Mandatory IRB Reporting: FDA Contacts²
- Clinical Trial Forms

RESEARCH ROUNDTABLE SCHEDULE

Research Roundtable Schedule

WRNMMC, America Building, 2nd Floor, Room 2301

- Tuesday, 15 March 2016, 1200–1300
- Tuesday, 19 April 2016, 1200–1300
- Tuesday, 24 May 2016, 1200–1300
- Tuesday, 21 June 2016, 1200–1300
- Tuesday, 19 July 2016, 1200–1300
- Tuesday, 23 August 2016, 1200–1300



2016 RESEARCH & INNOVATION MONTH SAVE THE DATES

4th Annual Aware for All, May 4, 2016

Table display kick-off for 2016 Research and Innovation Month in the Building 19 Lobby. Members of the WRNMMC and National Capital Region will showcase their research, hand out brochures, flyers, takeaways, and perhaps show video presentations and provide demos.

8th Annual National Capital Region Research Competitions

- O Poster Production Submission to Medial Graphic Arts Department (MGAD), Closeout Date: March 1, 2016. MGAD produces posters for use with National Capital Region Poster Competitions, to be displayed only within WRNMMC. You must ensure that you have permission to use any photos/images/brands and any copyright information for your poster before you send it for production. The posters must also comply with all applicable regulations. Should researchers wish to use these posters outside WRNMMC, they must get appropriate approval (i.e., clearance through the Department of Research Programs and Public Affairs Office) to display.
- o **Judging of Abstracts:** Competitors abstracts will be judged and finalist will be notified between the months of March through April 2016.
- o **Poster Display Week, May 9 13, 2016.** Research Competition participants will display their research posters in the Mezzanine Center, East, and West Wings of Bldg. 9 featuring their state-of-the art military medical research efforts.
- Poster Competitions (Judged Oral Presentations), May 11, 2016. Finalists from several research
 competition categories will present in front of their posters to a committee of walking judges in the East
 Wing of Bldg. 9. Award ribbons will be pinned next to the winning posters of each research competition
 category.
- o **Research Symposiums I and II, May 18-19, 2016.** Finalists for the Bailey K. Ashford and Robert A. Phillips research competitions will deliver slide presentations of their medical research with judges present in the Memorial Auditorium, Bldg. 2, and 3rd Floor.

Certificate awards will be given to the research competition category winners.

2016 Spring Research Summit, May 25, 2016

- o The final gathering for 2016 Research and Innovation Month.
- Various Walter Reed National Military Medical Center research groups introduce their organizations via slide presentations (questions and answers are welcomed throughout the summit) at the Memorial Auditorium, Bldg. 2, 3rd Floor.

Questions regarding the 2016 Research and Innovation Month should be forwarded to the following link:

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

BIOSTATISTICS SECTION

Department of Research Programs Biostatistics Section Course Offerings: 2016

The Department of Research Programs (DRP) biostatisticians are available to assist WRNMMC investigators in all aspects of research from planning to publication. Our services include assistance with:

- Initial study design
- Sample size determination
- Writing a data analysis plan for the protocol/grant
- Guidance and assistance with data collection methods/instruments
- Database planning
- Randomization tables
- Analysis of data
- Writing abstracts, presentations, manuscripts

'Statistics - On Demand'

Training directors can select from a list of lectures (~45 minutes in length) to be presented at a date/time/place of their choice. Please give at least 2 weeks' notice. Topics currently include:

- Introduction to the DRP Biostatistics Section: How we can help you and what information we need
- Sample size estimation Comparing proportions between two groups
- Sample size estimation Comparing means between two groups
- Multiple comparisons How to compare many groups and/or many outcomes
- Confidence Intervals What are they and how to compute them
- Randomized Clinical Trials The CONSORT checklist
- Study Designs: Retrospective Cohort v. Prospective Cohort v. Case Control
- Diagnostic Tests Calculating Sensitivity, Specificity, Predictive Values
- Comparing two devices or raters: Estimating Reliability
- Odds Ratios and Relative Risks

We also take requests for new topics and will make every effort to tailor lectures to your department or service.

Data Management and Exploration in Spreadsheet Software

This bimonthly class will quickly review basic topics spreadsheet software before transitioning to more advanced functionality such as Pivot Tables, Data Validation, Formulas, and Filters. By the end of the class, students should feel comfortable managing and exploring their own datasets using these tools.

SPSS is On the Network!

Each quarter we will offer a short hands-on course, "Introduction to SPSS." These two afternoon classes will introduce the software, and participants will analyze a simple data set to include computing descriptive statistics (means, medians, standard deviations), compare outcomes between two groups or between pre and post time periods (t-tests, Wilcoxon tests) and calculate correlations. No prerequisites required.

POC for all courses: Ms. Sorana Raiciulescu 301-319-2813 or sorana.raiciulescu.ctr@mail.mil



MERF & CITI CLASSES

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

The mission of the DRP is to facilitate research and its goal is to help researchers work with the protocol submission and the sign-off process. To help researchers with this process, 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 to be taken for their investigative roles.

MERF & CITI Training for Researchers Workshop Schedule

MERF & 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.* 8 Seats are available. Please send an email or call to reserve a seat. If you have any questions, please contact Ms. Lisa Thompson at 301-295-8231or (lisa.p.thompson5.civ@mail.mil).

*Heroes Building, $\mathbf{4}^{\text{th}}$ Floor, Room 4011

- Tuesday, March 8, 2016, 1400–1500
- Tuesday, April 12, 2016, 1400–1500



DARNALL LIBRARY

Manuscript Writing & Scientific Communication Classes

Writing Systematic Reviews

This workshop provides an overview of the purpose, structure, components, and writing process of systematic reviews. Attendees will become familiar with systematic reviews standards and guidelines and explore opportunities of collaboration with librarians.

Preparing Your Manuscript for Publication

This workshop is focused on planning, writing, and submitting manuscripts for publication in biomedical journals. Students will be guided through the publication process, journal selection, and authorship guidelines and standards. The writing section of the workshop is centered on steps and tips for writing a compelling manuscript (title, abstract, introduction, methods/materials, results, and discussion). The manuscript submission process and review, copyright issues, research integrity, and public access policy compliance will also be discussed.

America Building (Bldg. 19), 2 nd Floor	Desert Conference, Room 2301
PREPARING YOUR MANUSCRIPT FOR PUBLICATION	DESIGNING A COMPELLING SCIENTIFIC PRESENTATION
Tuesday, March 8	Wednesday, March 9
1000 – 1100	1000 – 1100
Tuesday, April 12	Wednesday, April 13
1000 – 1100	1000 – 1100

For more information, please contact Dr. Tmanova at lyubov.tmanova.civ@mail.mil.



Research & Scholarly Communication Support Darnall Medical Library

Dr. Lyubov Tmanova, 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 & Scholarly Communication Classes

Darnall Medical Library, Bldg. 1, 3rd Floor, Room 3458

Designing a Compelling Presentation

March 9, 2016, 1000-1100, America Building, 2nd Floor Desert Conference, Room 2301. This workshop will help you to structure and design your research presentation using the key components and elements of scientific presentation to communicate your research findings to your audience.

Preparing Your Manuscript for **Publication**

March 8, 2016, 1000-1100, America Building, 2nd Floor Desert Conference, Room 2301. This workshop is focused on planning, writing, and submitting manuscripts for publication in biomedical journals. Students will be guided through the publication process, journal selection, and authorship guidelines and standards. The writing section of the workshop is centered on steps and tips for writing a compelling manuscript (title, abstract, introduction, methods/materials, results, and discussion). The manuscript submission and review processes, copyright, research integrity, and public access policy compliance will also be discussed.

Genetic Medicine

March 1, 1200-1300, Darnall Medical Library, Bldg. 1, 3rd Floor, Room 3458.

This workshop focuses on information resources and molecular databases centered on human medical genetics, genetic tests and laboratories, and genetic disease and human variation resources. The workshop consists of a brief introduction and guided walkthrough search that is based on a clinical case scenario in the databases.

Biomedical Data Discovery, Visualization & Management

March 29, 1200-1300, Darnall Medical Library, Bldg. 1, 3rd Floor, Room 3458.

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.

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

December 2015 Citations (WRNMMC Authors in BOLD)



Publications (Courtesy of Darnall Library)

WRNMMC Authors are in bold.

- 1. Adams DJ, Susi A, Erdie-Lalena CR, et al. Otitis media and related complications among children with autism spectrum disorders. J Autism Dev Disord. 2016 Jan 6. [Epub ahead of print]
 - Additional WRNMMC Authors: Gorman G, Rajnik M, Nylund CM
- 2. Adams S, Lin J, Brown D, Shriver CD, Zhu K. Ultraviolet radiation exposure and the incidence of oral, pharyngeal and cervical cancer and melanoma: an analysis of the SEER data. Anticancer Res. 2016;36(1):233-7.
- 3. Bailie JM, Kennedy JE, French LM, et al. Profile analysis of the neurobehavioral and psychiatric symptoms following combat-related mild traumatic brain injury: identification of subtypes. J Head Trauma Rehabil. 2016;31(1):2-12. Additional WRNMMC Authors: Brickell TA, Lange RT
- 4. Balazs GC, Brelin AM, Grimm PD, Dickens JF, Keblish DJ, Rue JH. Hybrid tibia fixation of soft tissue grafts in anterior cruciate ligament reconstruction: a systematic review. Am J Sports Med. 2016 Jan 22. [Epub ahead of print]
- 5. Bartalena L, Burch HB, Burman KD, Kahaly GJ. A 2013 European survey of clinical practice patterns in the management of Graves' disease. Clin Endocrinol (Oxf). 2016;84(1):115-20.
- 6. Bateman NW, Shoji Y, Conrads KA, et al. Identification and functional characterization of a novel bipartite nuclear localization sequence in ARID1A. Biochem Biophys Res Commun. 2016;469(1):114-9. Additional WRNMMC Authors: Hamilton CA, Darcy KM, Maxwell GL, Conrads TP

- 7. Carter CA, Rajan A, Keen C, et al. Selumetinib with and without erlotinib in KRAS mutant and KRAS wild-type advanced non-small cell lung cancer. Ann Oncol. 2016 Jan 22. [Epub ahead of Additional WRNMMC Author:

 - Brzezniak C
- 8. Crothers BA, Darragh TM, Tambouret RH, et al. Trends in cervical cytology screening and reporting practices: results from the College of American Pathologists 2011 PAP education supplemental questionnaire. Arch Pathol Lab Med. 2016;140(1):13-21.
- 9. **Dearth CL**, Keane TJ, Carruthers CA, et al. The effect of terminal sterilization on the material properties and in-vivo remodeling of a porcine dermal biologic scaffold. Acta Biomater. 2016 Jan 27. [Epub ahead of print]
- 10. Dretsch M, Bleiberg J, Williams K, Caban J, Kelly J, Grammer G, **DeGraba T.** Three scoring approaches to the neurobehavioral symptom inventory for measuring clinical change in service members receiving intensive treatment for combat-related mTBI. J Head Trauma Rehabil. 2016;31(1):23-9.
- 11. Gatti-Mays ME, Venzon D, Galbo CE, et al. Exemestane use in postmenopausal women at high risk for invasive breast cancer: evaluating biomarkers of efficacy and safety. Cancer Prev Res (Phila). 2016 Jan 12. [Epub ahead of
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- 13. Gilder TR, **Hawley JS, Theeler BJ.**Association of reversible splenial lesion
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 Neurol Sci. 2016 Jan 7. [Epub ahead of print]
- 14. Groomes CL, Gianferante DM,
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 Lieuw K. Reduction of factor VIII
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 VIII-Fc fusion protein. Pediatr Blood
 Cancer. 2016 Jan 6. [Epub ahead of
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- 15. Hill MJ, **Suzuki S**, Segars JH, Kino T. <u>CRTC2 Is a coactivator of GR and couples GR and CREB in the regulation of hepatic gluconeogenesis.</u> *Mol Endocrinol.* 2016;30(1):104-17.
- Ibrahim Z, Santiago GF, Huang J, Manson PN, Gordon CR. <u>Algorithmic</u> <u>approach to overcome scalp deficiency</u> <u>in the setting of secondary cranial</u> <u>reconstruction</u>. *J Craniofac Surg*. 2016;27(1):229-33.
- 17. **Kim DJ**, Hawksworth DJ, Hurwitz LM, Cullen J, **Rosner IL**, Lue TF, **Dean RC**. A prospective, randomized, placebocontrolled trial of on-Demand vs. nightly sildenafil citrate as assessed by Rigiscan and the international index of erectile function. *Andrology*. 2016;4(1):27-32.
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- Lewis CJ, Li P, Stewart L, et al.
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 <u>military injury and the associated risk of infectious complications.</u> Br J Surg.
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- 20. **Little DJ, Yuan CM**, Thurlow JS, et al. Effects of traumatic amputation on β-trace protein and β2-microglobulin concentrations in male soldiers. *Am J Nephrol.* 2016;42(6):436-442.

- Additional WRNMMC Authors: Theeler BJ, Olson SW
- 21. Littlefield PD, Pinto RL, Burrows HL, Brungart DS. The vestibular effects of repeated low-level blasts. *J Neurotrauma*. 2016;33(1):71-81.
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 lenalidomide, and prednisone in patients
 with metastatic castration-resistant
 prostate cancer. BJU Int. 2016 Jan 18.
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 Rosner I
- 24. **Mallory R**, Jackson JL, Mondragon D, Hatzigeorgiou C, DeZee KJ, Greenburg D, **O'Malley PG**. <u>Characteristics of highly rated internal medicine attendings before and after the 2004 work-hour restrictions</u>. *Mil Med*. 2016;181(1):76-81.
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- 27. **Moawad FJ**, Dellon ES, Achem SR, et al. Effects of race and sex on features of eosinophilic esophagitis. *Clin Gastroenterol Hepatol*. 2016;14(1):23-30.

Additional WRNMMC Author: **Maydonovitch CL**



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 military cohort. Diagn Microbiol Infect
 Dis. 2016;84(1):34-5.
- 29. Onakomaiya MM, Henderson LP. Mad men, women and steroid cocktails: a review of the impact of sex and other factors on anabolic androgenic steroids effects on affective behaviors.

 Psychopharmacology (Berl). 2016 Jan 12. [Epub ahead of print]
- 30. Oronsky B, Carter C, Scicinska A, Oronsky A, Oronsky N, Lybeck M, Scicinski J. Medical Machiavellianism: the tradeoff between benefit and harm with targeted chemotherapy.

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- 33. Powers JH, Guerrero ML, Leidy NK, et al. <u>Development of the Flu-PRO: a patient-reported outcome (PRO) instrument to evaluate symptoms of influenza.</u> *BMC Infect Dis.* 2016;16(1):1.

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- 34. Riojas CM, Dodge A, Gallo DR, White PW. Aortic dissection as a cause of pulsus bisferiens: a case report and review. Ann Vasc Surg. 2016;30:305.e1-5.
- 35. Seavey JG, Masters ZA, Balazs GC, Tintle SM, Sabino J, Fleming ME,

- Valerio IL. <u>Use of a bioartificial dermal regeneration template for skin restoration in combat casualty injuries.</u> *Regen Med.* 2016;11(1):81-90.
- 36. Segal MW, Smith DG, Segal DR, Canuso AA. The role of leadership and peer behaviors in the performance and well-being of women in combat: historical perspectives, unit integration, and family issues. *Mil Med*. 2016;181(1S):28-39.
- 37. Singman EL, Daphalapurkar N, White H, Nguyen TD, Panghat L, Chang J, McCulley T. <u>Indirect traumatic optic neuropathy</u>. *Mil Med Res*. 2016;3:2.
- 38. Strilka RJ, Stull MC, Clemens MS, McCaver SC, Armen SB. Simulation and qualitative analysis of glucose variability, mean glucose, and hypoglycemia after subcutaneous insulin therapy for stress hyperglyc Theor Biol Med Model. 2016;13(1):3.
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- 40. **Syed V**. <u>TGF-β signaling in cancer</u>. *J Cell Biochem*. 2016 Jan 16. [Epub ahead of print]
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Credits

List of publications provided by Darnall Library

DRP's Workshops provided by Lisa Thompson

Darnall Library Workshops provide by Lyubov Tmanova, DVM, MLIS, MS

DRP's Internal Newsletter will be provided at the Research Roundtables

