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Military Medical Research Digest

DEPARTMENT OF RESEARCH PROGRAMS



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

This 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-in-Chief

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This digest appears monthly, along with Military Medical Research News, a longer newsletter containing stories and news items. We welcome your story ideas, comments, corrections and research photographs (action shots preferred). Any timely information must arrive by the 15th of the prior month for the following month's issue. Send your ideas, pictures or infographics to paula.m.amann.ctr.@mail.mil.

Contents

DRP Chili Cook-Off	2
Research Roundtable Schedule	2
Web Sources	3
Research and Innovation Month	5
Biostatistics Training	6
MERF and CITI Training	7
Darnall Library	8
Publications Clearance	10
Town Hall on iRIS	12

RESEARCH FIRST STEPS

Starting a research project? Please take these two steps before proceeding:

- 1. Go to building 17B (DRP, third floor), and make an appointment with a protocol navigator.
- 2. Wait to enroll patients until you get a start letter from COL Weina.

WHAT'S NEW: POLICIES, FORMS AND TEMPLATES

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



RESEARCH ROUNDTABLE SCHEDULE



WRNMMC, America Building, Second Floor, Room 2301

- 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



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))

Reporting Problems to the FDA

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



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

- Poster Display Week, May 9-13, 2016. Research Competition participants will display their research
 posters in the Mezzanine Center, East, and West Wings of Building 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 Building 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, Building 2, and third 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, Building 2, third floor.

Please forward any questions on Research and Innovation Month to this link: dha.bethesda.wrnmmc.mbx.researchandinnovationmonth@mail.mil,



BIOSTATISTICS TRAINING

Department of Research Programs Biostatistics Course Offerings

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 or grant
- Guidance and assistance with data collection methods and instruments
- Database planning
- Randomization tables
- Analysis of data
- Writing abstracts, presentations and manuscripts

'Statistics - On Demand'

Training directors can select from a list of lectures (about 45 minutes in length) to be presented at a date, time and place of their choice. Please give at least two 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 or Outcomes
- Confidence Intervals: What Are They and How to Compute Them
- Randomized Clinical Trials: The CONSORT checklist
- Study Designs: Retrospective Cohort Versus Prospective Cohort Versus Case Control
- Diagnostic Tests: Calculating Sensitivity, Specificity and 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.

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



MERF AND 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 and 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.

Researchers Workshop Schedule

MERF and CITI Training for Researchers workshop will be offered monthly. 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, April 12, 2016, 1400-1500

Tuesday, May 3, 2016, 1400-1500

Tuesday, June 14, 2016, 1400-1500

Tuesday, July 12, 2016, 1400-1500

Tuesday, August 9, 2016, 1400-1500

Tuesday, September 13, 2016, 1400-1500

Tuesday, October 11, 2016, 1400-1500

Tuesday, July 12, 2016, 1400-1500



DARNALL LIBRARY

Research and 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 and Scholarly Communication Classes
Darnall Medical Library, Building 1, Third Floor, Room 3458

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 review standards and guidelines and will explore opportunities for collaboration with librarians. Wednesday, 20 April 2016, 1200-1300; Building 6, Room 1369

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. Wednesday, 25 May 2016, 1200-1300; Building 6, Room 1369

Designing a Compelling Scientific Presentation

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

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 1

Friday, 8 April 8 2016, 1300-1400; Building 6, Room 1369

Session 2

Friday, 13 May 2016, 1300-1400; Building 6, Room 1369

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

Getting the Most Out of ClinicalKey

Participants will become familiar with the sources available in ClinicalKey through hands on activities. ClinicalKey information resources include journals, eTextbooks, drug monographs, guidelines, patient education, multimedia, and video procedures. Participants will also learn how to quickly add ClinicalKey images with citations to their presentations. Tuesday, 24 May 2016, 1300-1400; Building 6, Room 1369

Searching the Nursing Literature with CINAHL + JBI

CINAHL (Cumulative Index to Nursing & Allied Health Literature) and the Joanna Briggs Institute (JBI) databases are two of the premier evidence-based nursing literature resources. Learn how to effectively search for pertinent journal articles in CINAHL as well as systematic reviews, evidence summaries, and recommended practices in JBI. Tuesday, 26 April 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 1

Thursday, 12 May, 2016, 1300-1400; Building 6, Room 1369

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 1

Thursday, 26 May 2016, 1300-1400; Building 6, Room 1369

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, Building1, Rm 3458

Phone: 301-319-2475.

Email: lyubov.tmanova.civ@mail.mil Website:wrnmmc.libguides.com/home/researchsupport



PUBLICATIONS CLEARANCE

Courtesy of <u>Darnall Library</u> February 2016 Citations (WRNMMC Authors in Bold)

- 1. Haran FJ, **Dretsch MN**, Slaboda JC, Johnson DE, Adam OR, Tsao JW. <u>Comparison of baseline-referenced versus norm-referenced analytical approaches for in-theatre assessment of mild traumatic brain injury neurocognitive impairment. *Brain Inj.* 2016 Feb 24:1-7. [Epub ahead of print]</u>
- 2. **Hawkins JM, Schmidt JE, Hargitai IA, Johnson JF, Howard RS, Bertrand PM**. <u>Multimodal assessment of body pain in orofacial pain patients</u>. *Pain Med*. 2016 Feb 10. [Epub ahead of print]
- 3. **Hefner JN, Howard RS, Massey R, Valencia M, Stocker DJ, Philla KQ**, et al. <u>A randomized controlled comparison of esophageal clearance times of oral budesonide preparations.</u> *Dig Dis Sci.* 2016 Feb 26. [Epub ahead of print] Additional WRNMMC Authors: **Goldman MD, Nyund C, Min SB**
- 4. **Hostler DC, Marx ES,** Moores LK, **Petteys SK**, **Hostler JM**, **Mitchell JD**, et al. <u>Validation of the international medical prevention registry on venous thromboembolism bleeding risk score.</u> *Chest.* 2016;149(2):372-9. Epub 2016 Jan 12.
 - Additional WRNMMC Authors: Holley AB, Foster BE
- 5. **Hulten E, Aslam S,** Osborne M, Abbasi S, Bittencourt MS, Blankstein R. <u>Cardiac sarcoidosis-state of the art review.</u> *Cardiovasc Diagn Ther.* 2016;6(1):50-63.
- 6. Iida J, Bell-Loncella ET, Purazo ML, Lu Y, Dorchak J, Clancy R, et al. <u>Inhibition of cancer cell growth by ruthenium complexes</u>. *J Transl Med*. 2016 Feb 12;14(1):48. WRNMMC Authors: **Cutler ML**. **Shriver CD**
- 7. Jutel M, Agache I, Bonini S, Burks AW, Calderon M, Canonica W, et al. <u>International consensus on allergen immunotherapy II: mechanisms, standardization, and pharmacoeconomics.</u> *J Allergy Clin Immunol.* 2016;137(2):358-68.
 - WRNMMC Author: Martin BL
- 8. Kentosh JB, Marquart JD. Purse-string anchor. Dermatol Surg. 2016 Feb 8. [Epub ahead of print]
- 9. **Lane JD**, Friedberg MW, Bennett CL. <u>Associations between industry sponsorship and results of cost-effectiveness</u> analyses of drugs used in breast cancer treatment. *JAMA Oncol.* 2016 Feb 1;2(2):274-6.
- 10. **Lincoln M, Royer M**. <u>Uncommon tumor, uncommon location: a dermal-based spindle cell/pleomorphic lipoma</u>. *Am J Dermatopathol*. 2016 Feb 24. [Epub ahead of print]
- 11. Liu W, Soderlund K, Senseney JS, Joy D, Yeh PH, Ollinger J, et al. <u>Imaging cerebral microhemorrhages in military service members with chronic traumatic brain injury</u>. *Radiology*. 2016;278(2):536-45. Epub 2015 Sep 15. Additional WRNMMC Authors: **Sham EB, Oakes TR, Riedy G**
- 12. Mitsouras D, Lee TC, Liacouras P, Ionita CN, Pietilla T, Maier SE, et al. <u>Three-dimensional printing of MRI-visible phantoms and MR image-guided therapy simulation</u>. *Magn Reson Med*. 2016 Feb 11. [Epub ahead of print]
- 13. Noonan AM, **Bunch KP**, Chen JQ, Herrmann MA, Lee JM, Kohn EC, et al. <u>Pharmacodynamic markers and clinical results from the phase 2 study of the SMAC mimetic birinapant in women with relapsed platinum-resistant or refractory epithelial ovarian cancer. *Cancer.* 2016 Feb 15;122(4):588-97. Epub 2015 Nov 13.</u>
- 14. **Onakomaiya MM**, Henderson LP. <u>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;233(4):549-69. Epub 2016 Jan 12.</u>
- 15. **Potter BK.** From bench to bedside: targeted therapy, denosumab, and 21st century orthopaedics: targets abound, but where are the therapies? *Clin Orthop Relat Res.* 2016 Feb 12. [Epub ahead of print]
- 16. **Potter BK**. CORR insights: how much clinical and functional impairment do children treated with knee rotationplasty experience in adulthood? Clin Orthop Relat Res. 2016 Feb 12. [Epub ahead of print]
- 17. Ravindra VM, **Wallace SA**, Vaidya R, Fox WC, Klugh AR 3rd, Puskas D, et al. <u>Spinal stabilization using orthopedic extremity instrumentation sets during Operation Enduring Freedom-Afghanistan</u>. *World Neurosurg*. 2016;86:503-9. Epub 2015 Sep 21.
- 18. **Ressner RA, Gada SM, Banks TA**. Antimicrobial stewardship and the allergist: reclaiming our antibiotic armamentarium. *Clin Infect Dis.* 2016 Feb 1;62(3):400-1. Epub 2015 Oct 20.
- 19. **Ritter EM**, Brissman IC. <u>Systematic development of a proctor certification examination for the fundamentals of laparoscopic surgery testing program. *Am J Surg.* 2016;211(2):458-63. Epub 2015 Nov 10.</u>

- 20. **Shin EH, Drake ML**, Parks BG, Means KR Jr. <u>Hook plate versus suture anchor fixation for thumb ulnar collateral ligament fracture-avulsions: a cadaver study. *J Hand Surg Am*. 2016;41(2):192-5. Epub 2015 Dec 22.</u>
- 21. Thurlow JS, **Yuan CM.** Dialysate-induced hypocalcemia presenting as acute intradialytic hypotension: A case report, safety review, and recommendations. *Hemodial Int.* 2016 Feb 28. [Epub ahead of print]
- 22. Vo KT, **Edwards JV**, Epling CL, Sinclair E, Hawkins DS, Grier HE, et al. <u>Impact of two measures of micrometastatic disease on clinical outcomes in patients with newly diagnosed Ewing sarcoma: a report from the Children's Oncology <u>Group. Clin Cancer Res.</u> 2016 Feb 9. [Epub ahead of print]</u>
- 23. **Wagner SC, Kang DG, Helgeson MD**. <u>Traumatic migration of the Bryan cervical disc arthroplasty.</u> *Global Spine J*. 2016;6(1):e15-20. Epub 2015 Apr 23.
- 24. White BK, Mende K, Weintrob AC, Beckius ML, Zera WC, Lu D, et al. <u>Epidemiology and antimicrobial susceptibilities of wound isolates of obligate anaerobes from combat casualties</u>. *Diagn Microbiol Infect Dis*. 2016;84(2):144-50. Epub 2015 Oct 23.
- 25. **Wolfe HL, Wu Healy M, Yauger BJ, Csokmay JM.** Cobblestone fallopian tubes on hysterosalpingogram followed by bilateral tubal abscesses and sepsis. *Am J Obstet Gynecol.* 2016 Feb 6. [Epub ahead of print]



Department of Research Programs (DRP)



TOWN HALL

Attend one of the following town halls to learn more about the new electronic IRB Submission Tracking System (iRIS).

April 12, 0900–1000 April 18, 1300–1400 in Clark Auditorium

The iRIS is coming. Don't be left behind.

Learn about the improved features of the new iRIS tracking system:

- ☐ It's the same across the whole Department of Defense (DoD).

 The iRIS uses standard language and templates that work for all research institutions in the DoD.
- The iRIS keeps your submissions simple.
 Now, all researchers across the Defense Department can submit their research projects the same way.
- You can make iRIS work for you and your team.Each institution can program its systems to produce customized metric reports.

See you at the Town Hall on April 12 or 18!

