Department of RESEARCH PROGAMS at Walter Reed National Military Medical Center

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Welcome to the Department of Research Programs' first monthly newsletter!

The Department of Research Programs (DRP) comprises five sections, including the Biomedical Research Laboratory (BRL), Center for Nursing Science & Clinical Inquiry (CNSCI), Research Protocol Development, Research Administration, and Research Oversight and Compliance Office (ROCO).

The overall mission of DRP is to facilitate research education and protocol development and to implement the Walter Reed National Military Medical Center (WRNMMC) Human Research Protection Program (HRPP). DRP offices are located in Building 17B (above the Fitness Center) on the 3rd floor, Suite 3C.

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In January, DRP received submissions for Research and Innovation Competitions 2014. Winners in several categories will present their work at the annual Poster Display and Research Symposium in April – dates and locations to be announced. The competitions include Bailey K. Ashford (BKA); Robert A. Phillips (RAP); Case Reports (CR); and Evidence-Based Practice (EBP). This year, under CDR Michelle Kane's direction, DRP's Center for Nursing Science & Clinical Inquiry has spearheaded a National Capital Region outreach campaign to include nurses and others in the EBP Competition. See next month's DRP newsletter to learn of competition finalists (April) and winners (May and June newsletters). A collaborative team is organizing and managing the numerous activities that will combine to make spring 2014 an exciting time for WRNMMC research and innovation recognition and celebration. Sign-up to help organize and support poster displays, judging, and publicity. The point of contact is Dr. Deborah Murphy at **deborah.murphy2@us.army.mil**.

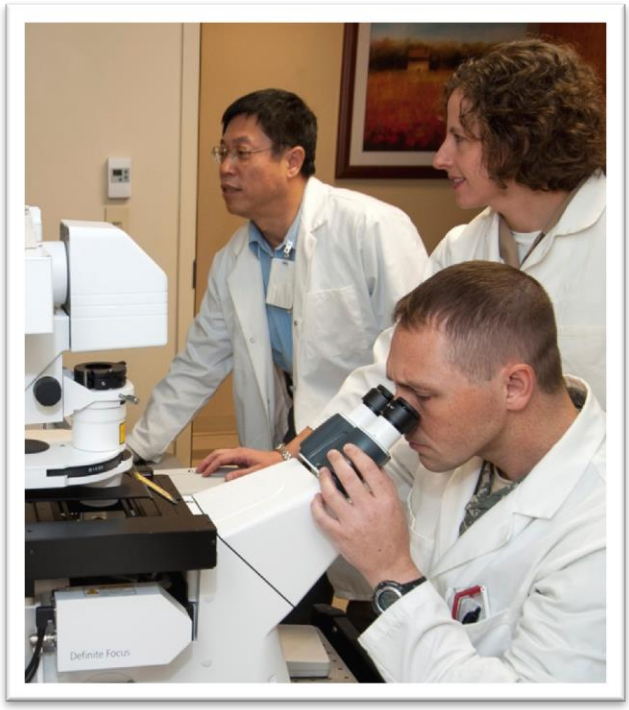
Message from the Chief

I'm happy to have the opportunity as the Acting Chief of the Department of Research Programs to welcome WRNMMC investigators and members of the research community to DRP's first monthly newsletter. Our goal is to keep investigators and members of the research community updated on any changes to the Department of Defense, Federal, and local policies that affect how research is conducted at WRNMMC and other institutions that fall under the WRNMMC Assurance. We would like to introduce you to the many services available through DRP and encourage you to attend our outreach events or schedule one-on-one assistance as you develop your research protocol, seek a research determination or Institutional Review Board approval, and conduct your research. Every month, our newsletter will also provide answers to frequently asked questions (FAQs) from investigators and research study team members. We hope to build a bridge between investigators and DRP services by fostering open communication and a mutual understanding of each other's roles and responsibilities in the conduct and oversight of ethical human subjects' research. We hope you enjoy our February issue and welcome your input for future topics of discussion. Please contact Gregory Greer, Technical Editor, at **gregory.g.greer.ctr@health.mil** with your ideas.

Biomedical Research Laboratory (BRL)

Our Mission

The Biomedical Research Laboratory (BRL) was created to support the research mission of Walter Reed National Military Medical Center. We help physicians, nurses, PhDs, therapists, Graduate Medical Education (GME) students, and other interested staff find answers to clinical questions. We provide lab research protocol development and assistance with generating data.



I missed the recent Biomedical Research Lab Open House and am wondering if the team can perform assays to help me answer my clinical research question before I write my protocol. Whom should I call to find out?

The two main POCs for this type of question are CDR Janine Danko, Chief of the Lab, and Dr. Yaling Zhou, the Lab's Science Director. Both can be reached by phone or email. CDR Danko: 301-295-8279; Dr. Zhou: 301-295-8287.

Our Services

We have over 12,000 square feet of lab space full of advanced instrumentation, including both MALDI-TOF/TOF and LCMS-IT-TOF, a Zeiss confocal microscope, and gel documentation equipment. We offer technical guidance and support on how to execute lab protocols in the following areas:

- Immunology
- Molecular and Cell Biology
- Biochemistry

We also teach a course on basic lab techniques, which includes didactic and laboratory components.

If I have lab bench skills and am interested in doing some of my own assays for the conduct of my research project, is this possible?

Yes! The Biomedical Research Laboratory team encourages investigators to seek out such opportunities. Basic lab safety training is required annually for all approved projects. Coordination of the space and use of the equipment may be necessary and is managed by the Science Director and Deputy Director (CPT Raymond Casteline). Fees may be assessed. Investigators are urged to schedule an appointment with the Science Director to discuss options.

Center for Nursing Science & Clinical Inquiry (CNSCI)

The Center for Nursing Science & Clinical Inquiry (CNSCI) consists of PhD-level nurse scientists who facilitate and conduct military-relevant funded and unfunded research studies in support of the Army Nurse Corps and Navy Nurse Corps research priorities. The nurse scientists work closely with other nurses on developing multidisciplinary research protocols aimed at improving the provision of nursing care and with Clinical Nurse Specialists to develop evidence-based practice (EBP) projects for implementation at the bedside and in the outpatient clinical areas to improve nursing care and quality.

CNSCI staff members provide the following services in support of the DRP mission:

- Nursing Research and EBP subject matter expertise in support of unit, facility, and Corps-level Nurse Practice Councils.
- Grant, protocol, presentation, and professional writing assistance.
- Nursing research and EBP educational offerings.
- Extramural funding protocol writing assistance.
- Data analysis and interpretation for research and/or decision support.
- Mentoring novice PhD-level nurse scientists.
- Review of scientific research protocols.
- Appointed membership on the Institutional Review Board.
- Mentoring of novice PhD- and DNP-level nurses, Army nurse Long Term Health Education and Training (LTHET) master's and PhD students, and WRNMMC staff nurses in research-related activities.
- Review and translation of evidence for nursing practice at the bedside (bench to bedside).
- Estimation and management of impact of research and EBP project implementation on WRNMMC nursing services.

Alphabet Soup Anyone???

"EBP," "QI," and "Research." Do these terms seem like a bowl of alphabet soup? Ever wonder what the difference is among them?

Here is a simple way of distinguishing their subtle differences:

Evidence Based Practice: Evaluates evidence along a continuum to identify strongest or best evidence out there in the literature that can guide our practice at WRNMMC. An example of this is developing evidence-based clinical practice guidelines based upon the latest research and evidence found in the literature.

Remember: EBP **translates** knowledge into practice.

Quality Improvement: Improves Internal Process within an organization. Focus is within the organization. Specific quality indicators at WRNMMC include medication error tracking and falls tracking.

Remember: QI **incorporates** data-driven knowledge

Research: Produces generalizable knowledge that benefits the broader scientific community. An example of this is a strict protocol that is researching new treatments for traumatic brain injury (TBI) patients.

Remember: Research **generates** knowledge.

Who is responsible for application of EBP, QI, and research to practice?

We all are!

Research Administration

Research Administration coordinates the collection of all costs above the standard of care incurred in the conduct of research, maintains a foundation account for the management of collected funds in accordance with applicable regulations, provides a biannual itemized list of the status of current Office of the Institutional Review Board accounts, and acts as the liaison for the disbursement of collected funds.

Research Protocol Development

The Research Protocol Development section includes biostatisticians, administrative reviewers, and central Scientific Review Committee (SRC) Administrators and the Office of Research Technology Applications (ORTA). The section's mission is to:

> ***Encourage clinical investigation and maintain an atmosphere of inquiry throughout the organization that is consistent with the dynamic nature of the health sciences;***
>
> ***Support WRNMMC staff members who are interested in conducting research that contributes to their professional career growth and academic excellence and support WRNMMC's strategic research priorities.***

Staff from the Research Protocol Development section advise and educate investigators and other members of the research study team on protocol development and the protection of human subjects; map out a research project, from conception through development, funding, and securing necessary agreements; provide administrative, technical, and policy guidance relevant to the investigator's proposal; identify and resolve potential problems associated with the investigator's research, including fiscal and legal implications; and assist the investigator with protocol and consent development, Collaborative Institutional Training Initiative (CITI) training for study team members, IRBNet submission, identification of appropriate letters of support, and completeness and accuracy of the submission package.

The "Research Visits Costs Calculator (Extramural)" is a relatively new spreadsheet available to investigators at WRNMMC. This spreadsheet is required as part of a protocol submission to the DRP/IRB and it applies to extramurally funded studies. The purpose is to clearly delineate costs that are incurred by research activities, which are above and beyond what subjects would receive for standard treatment. The funds recovered in this manner will be used to reimburse those departments that incurred a cost through the execution of research. GME- as well oncology-focused research is exempt from this requirement.

I hear there are new forms coming out to use for protocol submissions. Can I still use the old forms?

There are updated forms and templates for commonly submitted protocol documents in the IRBNet forms and templates library. In the IRBNet dropbox this is named "WRNMMC Department of Research Programs (DRP) - Documents for Researchers." All packages submitted in IRBNet on and after 1 March 2014, including new protocol submissions, amendments, adverse events, and closure reports must use these new versions of the documents. Packages with old versions of the documents will be unlocked and sent back to the research team to be redone with the new document versions before they will be administratively reviewed or forwarded to the IRB. Any time you are putting together a new package in IRBNet you should check the forms and templates library to be sure you are using the current version of a form. Packages that are submitted in IRBNet before 1 March 2014 and are in the process of revisions and/or approval will continue to be processed with the document versions they are already using – they will not be required to be updated to the new forms.

Research Oversight and Compliance Office (ROCO)

The Research Oversight and Compliance Office (ROCO) includes regulatory experts responsible for ensuring that WRNMMC adheres to all Department of Defense, Federal, State, local, and institutional regulations, laws, and policies related to Humans Research Protections and the ethical conduct of research. ROCO staff support the work of the Institutional Review Boards (IRBs), facilitate the review and approval of Research Not Involving Human Subjects (RNIHS), exempt research, determine whether or not activities engage WRNMMC in research, and endorse research projects that will be reviewed by an external IRB. ROCO comprises:

- IRB Operations Office
- Determinations Officer(s)
- Post-Approval Compliance Monitoring (PACM) Program
- Training and Education Office

I heard that the WRNMMC Human Research Protections Program is undergoing a comprehensive review in support of our DoD Assurance renewal and site visitors will meet with members of the research community and audit research studies 10-14 March 2014. What should I do to prepare?

All members of the research community are encouraged to conduct an internal review of their study in preparation for the site visit. Now is the time to identify any deviations, questions or issues that may exist and take corrective action. By conducting an internal quality assurance review prior to March, you can identify, document, report, and correct errors. Now is the time to uncover and address any issues, so when the external auditing team arrives, your study will be squared-away. Following are some key points to consider:

- Regulatory files are orderly and complete. (including version control for all IRB applications, protocols and supporting documents).
- Subject files orderly and complete (including appropriate consent documents/HIPAA Authorizations signed and present).
- Adequate data security and subject confidentiality protection measures are in place.
- Investigational Products are consistently tracked from delivery through return or destruction (including documentation that only authorized individuals have access to the Investigational Products).
- Principal Investigator communicates effectively with the study team (team meetings, etc.).
- New staff members are trained on the protocol and institutional responsibilities.
- Investigators are aware of their responsibilities under local policies, DoDI 3216.02 and HIPAA.
- Research Monitors and ombudsmen (if applicable) are aware of their responsibilities under the DoDI 3216.02.
- All research staff are aware of their responsibilities under local policies, the protocol and study Standard Operation Procedures (SOPs).
- Any deviations are documented and reported to the IRB as required (if subject safety is impacted).

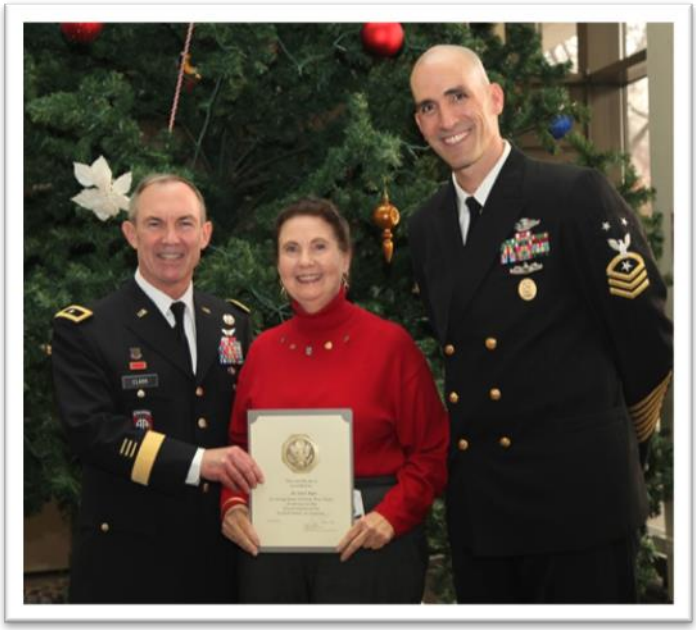
What's New?

DRP implements its SharePoint site.

Everyone in DRP recently received an invitation to our newly implemented SharePoint site. "SharePoint" is a bit of a misnomer: our Intranet site is our SharePoint site. Moving forward, DRP is looking forward to getting everyone onboard with SharePoint, and we have already begun migrating folders and files from our shared drive to our SharePoint-based Intranet site. Our goal is to have all communal and restricted documents located on our Intranet site by the end of Fiscal Year 2014.

Specialist Robert Martinez
Medical Technologist, BRL,
Soldier of the Quarter Award

Highlights



Janet Kapur
Medical Technologist, BRL, Retirement
with Brigadier General Clark and
Command Master Chief Prince