Today is the start of a dialogue about why research may currently be perceived to be increasingly in the “too-hard-to-do box” and something that not as many people are inclined to embrace. The first installment of this dialogue is – “Changing the Culture of WRNMMC Research.”

We have every reason to be proud of the actual research that has been and continues to be carried out at WRNMMC. We have world-class scientists and ground-breaking results. Most importantly though, I like to believe that every single researcher realizes the immense privilege it is for us to be able to do research here at WRNMMC. I have also been around long enough now to witness what I believe has become a slow erosion of the “culture” of research, not just here at WRNMMC, but within research organization worldwide. At one time, research was an integral part of clinical care and senior investigators took junior officers under their wing ensuring scientific rigor and statistical thoroughness. Protocols were never released for IRB consideration with spelling errors, bad grammar, or attachment omissions because this reflected poorly on all.

Where once all young clinicians were hungry to work with senior investigators and glean the knowledge of accumulated experience, today there is more reliance upon others to assure scientific quality and administrative accuracy. We have brought this upon ourselves in the research community (writ large) by the mission creep of scientific reviews that second-guess scientific judgment within the clinical departments, over-exuberant administrative reviews that have turned our review staff into English teachers, and IRBs that question all of the above.

Mission creep has disenfranchised research mentors and brought us to cursory reviews by these very mentors since “administrative/scientific/IRB committee(s) will do the review anyway.”

The Department of Research Programs will be embarking on an experiment – a concerted effort to reverse this culture shift by enabling return of the responsibility for mentoring and scientific review back to the lowest levels. Please join us in this new grand experiment to revitalize research.

Peter J. Weina, PhD, MD, FACP, FIDSA
COL, MC, USA
Chief, Department of Research Programs
In an effort to improve awareness of our team’s capabilities and the unique resources we offer, this month I’m going to comment on one of the many useful pieces of equipment in the BRL, our Inductively Coupled Plasma Mass Spectrometer [ICP-MS] Medical Application. Our staff can assist you with research projects that utilize this piece of equipment!

This research equipment is currently configured to simultaneously quantitate most metals on the periodic chart, identify elemental isotopes and isotopic ratios, as well as trace elements even if the ion is less than one parts per trillion in the sample. The ICP-MS system is ideally suited to perform trace metal analysis, isotope ratios, elemental speciation, chromium cell viability, and nanoparticle characterization.

Three recently published journal articles have demonstrated interesting results using the ICP-MS.

In the first article, an in vivo study was conducted concerning gold nanoparticles and appeared in the journal Translational Oncology [Dec 2013; 6(6): 722–731]. The study question concerned whether or not nanoscale agents may provide an innovative strategy for improving the therapeutic index in treating sarcoma. One of the authors stated the following: “In this work, we investigated the imaging and radiosensitizing effects of GNPs (Gold nanoparticles) in cellular and animal models of human sarcoma.” The ICP-MS instrument was used to quantify the total gold uptake in muscle, brain, and tumors. Findings confirmed that P-GNP (PEGylated Gold Nanoparticles) accumulate in sarcomas and that GNP may be used to measure the effect of sarcoma treatment.

The second article concerned trace metal analysis and appeared in the American Journal of Analytical Chemistry [2012, 3, 646-650]. In this study, the ICP-MS was chosen because it was capable of accurately analyzing reduced sample volumes. The authors described the measurement of trace elements Mg, Cu, Fe, Zn and ultra-trace elements Cd, Co, Mn, Pb in 150 μL of human serum and plasma samples. (These were irreplaceable archival samples.) The investigators used the data to test their hypothesis relating to environmental exposure to pollutants, antibodies, and other proteins. The ICP-MS system was used to analyze 1,888 blinded human plasma samples. The conclusion of this study was that “…the minimal sample volume required by the analysis is important because it preserves sample and allows researchers to couple trace element measurement with other analytical techniques to measure antibodies, proteins, DNA adducts and genotypes.”

In the third article, the topic concerned ultra-trace metals and appeared in another methods journal, the Journal of Atoms and Molecules [(6); 2012 / 425–436]. The goal of the study was to quantitate metallic impurities, and the ICP-MS was used for the determination of metallic impurities present in Vitamin K1 parenteral injections. This investigation compared heavy metal contents in market available dosage forms in different brands of phytonadione emulsions and concentrations and compared them with United States Pharmacopeia (USP) 232 guidelines. The finding was that “…the concentration of heavy metals differed between brands,” and “the ICP-MS was found to be efficient to meet the needs of the new USP guidelines and extend the metal analysis capabilities of the modern laboratory to meet even more challenging analyses.”

2. “Measurement of the Trace Elements Cu, Zn, Fe, and Mg and the Ultratrace Elements Cd, Co, Mn, and Pb in 150 μL of Human Serum and Plasma Samples by Inductively Coupled Plasma-Mass Spectrometry”
3. “Method Validation for Determination of Heavy Metals in Phytonadione Emulsion (LM) Dosage Forms by ICP-MS.”
4. Phytonadione Injectable Emulsion, widely used therapeutic agent in the treatment haemorrhagic disease of the newborn). This study measured Arsenic (As), lead (Pb), Cadmium (Cd), Mercury (Hg), Chromium (Cr), Copper (Cu) and Nickel (Ni) present in phytonadione emulsion.
Center for Nursing Science & Clinical Inquiry (CNSCI)

COL Jeffrey S. Ashley, AN, PhD
Chief & Senior Nurse Scientist

CNSCI welcomes its newest member, CDR Jason McGuire.

Welcome aboard!

CDR Jason M. McGuire, PhD, CRNA
Nurse Scientist

Dr. McGuire comes to us from the Uniformed Services University of the Health Sciences where he taught in the Graduate School of Nursing, Nurse Anesthesia Program. Dr. McGuire received his bachelor of science in nursing degree from Regis University in 1996, his master of science in nurse anesthesia degree from Georgetown University and completed the Navy Nurse Corps Anesthesia Program in 2004, and his PhD from the University of San Diego in 2011.

Since 2011 Dr. McGuire has served as a journal reviewer for the Journal of PeriAnesthesia Nursing and as an IRB member at Walter Reed National Military Medical Center. He is an expert nurse anesthesia clinician and an experienced researcher and author in the field of emergence delirium. He is a passionate educator of nursing, anesthesia, research, and evidence-based practice.

Research Administration

Jeremy Nelson
Administrator
Directorate of Education, Training, & Research

I’m happy to announce that the Research Infrastructure Cell is now complete with the onboarding of Kenneth Harvey. Ken is our new Research Financial Analyst and will be handling all reimbursable invoicing. Welcome aboard Ken!

Reminder from the DRP June 2014 newsletter: DRP offers researchers the support of our expert Research Infrastructure Cell: An in-house group of Subject Matter Experts who are poised to help with research, development, testing, and evaluation (RDT&E) projects that fall outside the scope of GME; that is, extramurally funded studies.

Kenneth Harvey
Research Financial Analyst
Research Infrastructure Cell

Kenneth graduated his bachelors in finance from Salisbury University then in August 2013 received his bachelors in Accounting from University of Maryland University College. His experience includes Full Cycle Accounting, Budget and Financial Analysis in Private and Government Sectors. His most recent experience includes serving as a Budget Analyst in support from SPAWAR (Navy) and a Senior Auditor/Consultant for the Air Force SAF/FMPA with concentration in Medical Equipment and Real Property Construction in Progress (CIP) with the Army.
Research Protocol Development

LCDR Ruben D. Acosta, MC
Chief, Research Protocol Development

On a bimonthly basis, a statistical contribution is provided by one of our staff biostatisticians. This month’s section was provided by Francois Tuamokumo, PhD.

Sensitivity and Specificity

This article is about sensitivity and specificity. It is motivated by the fact that, quite often, researchers provide these parameters without discussing the error rates that are an integral part of evaluating the efficacy of a new instrument as a screening tool for diagnostic purposes.

How are sensitivity and specificity defined?

The sensitivity of an instrument is defined as the true positive results that the test determines when applied to individuals who are known to have the condition (e.g., disease) as indicated by some gold standard. Similarly, specificity is defined as the true negative results that the test determines when applied to individuals who are known not to have the condition (e.g., disease). While these parameters give us a qualitative feel about what the instrument can potentially do, the instrument’s overall performance can be evaluated by incorporating error rates.

In order to incorporate error rates, we need to know or at least have an empirical estimate from the underlying population of interest, the proportion of individuals who have the disease, and those who do not have the disease. This information, in the language of Bayes’ concept, is called the prior probabilities. In conjunction with sensitivity and specificity, this information will enable us to estimate the proportions of individuals in the population, according to the instrument, with the disease and without the disease.

How well did the instrument perform?

This question can be answered by estimating four concerns that this 2x2 sensitivity-and-specificity-contingency table inherently possesses. The following four concerns, according to Bayes’ concept, are called the posterior probabilities, of which we shall be interested in two (i.e., items 2 and 4):

1. Of the individuals who tested positive, what proportion of them actually have the disease?
2. Of the individuals who tested positive, what proportion of them actually do not have the disease? (This proportion is called the false positive rate.)
3. Of the individual that tested negative, what proportion of them actually do not have the disease?
4. Of the individuals that tested negative, what proportion of them actually have the disease? (This proportion is called the false negative rate.)

It is on the basis of an analysis of these error rates and some other considerations that will determine, to a great extent, whether a particular instrument should be used as a screening tool. Hence, the take on this article is that in wanting to evaluate a tool for its efficacy, the decision should not be based solely on sensitivity, specificity, and predictive values, since these are just a mere component of the big picture.
Research Oversight and Compliance Office (ROCO)

Mary Kelleher
Chief, ROCO

This month the Research Oversight and Compliance Office (ROCO) would like to highlight some tips for Principal Investigators to help ensure adequate supervision and oversight of their research studies. Supervision and oversight should be provided even for individuals who are highly qualified and experienced and it should be documented in a research oversight plan.

A plan might include the following elements, to the extent they apply to a particular study:

- Routine meetings with associate investigators and study staff to review progress of the study and update them on any changes to the study or other procedures;
- Routine meetings with the sponsor’s monitors (if applicable) or WRNMMC Post-Approval Compliance Monitoring Program;
- A procedure for correcting problems identified by associate investigators or study staff, outside monitors or auditors, or other parties involved in the conduct of a study;
- A procedure for documenting the performance of delegated tasks in a satisfactory manner and, where appropriate, verifying findings (e.g., observation of the performance of selected assessments or independent verification by repeating selected assessments);
- A procedure for ensuring that the consent process is being conducted in accordance with federal regulations 32 CFR 219 and 21 CFR 50 and WRNMMC requirements and that study subjects understand the nature of their participation, risks, etc.;
- A procedure for ensuring that information in source documents is accurately captured on the Data Collection Forms, Case Report Forms, or elsewhere as appropriate to the study;
- A procedure for dealing with data queries and discrepancies identified by the study monitor or other individuals responsible for oversight of the study; and/or
- Procedures for ensuring associate investigators and study staff comply with the IRB-approved protocol and reporting requirements of the IRB and sponsor.

ROCO Staffing Updates – Who to Contact

As of July 7, 2014, Debarati Dasgupta has moved into a new position as the Research Compliance Officer (RCO) at WRNMMC. We are very pleased that she will remain here at WRNMMC and look forward to the development and expansion of our Post-Approval Compliance Monitoring Program under her leadership. Please reference the chart below for POCs who can address your questions for the IRB Operations Office, the Determinations Official, the Center for Nursing Science and Clinical Inquiry, and education and training requirements. All staff can be found in the Global Address List (GAL).

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<thead>
<tr>
<th>IRBNet access/status of my IRBNet submission</th>
<th>Angela</th>
<th>Quispe</th>
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<tr>
<td>Status of my submission scheduled for a convened IRB meeting</td>
<td>Marcus</td>
<td>Morgan</td>
</tr>
<tr>
<td>Status of my submission to the IRB that underwent Expedited IRB Review</td>
<td>Dee</td>
<td>Groover</td>
</tr>
<tr>
<td>Determining if protocol is human subjects research and if it is Exempt from further review</td>
<td>Mary</td>
<td>Kelleher</td>
</tr>
<tr>
<td>Determining if studies are QI/PI, EBP-PS, LSS, or Research</td>
<td>Wendy</td>
<td>Gilbert</td>
</tr>
<tr>
<td>Studies that are relying on external IRB</td>
<td>Beth</td>
<td>Narvaez</td>
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<tr>
<td>Research training and certification (MERF/CITI)</td>
<td>MAJ Scott</td>
<td>Baumgartner</td>
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Post-Approval Compliance Monitoring (PACM) Program

Debarati Dasgupta, MS, CHRC, CIP
Research Compliance Officer

The purpose of the Post-Approval Compliance Monitoring (PACM) Program is to ensure the protection of human subjects in research, to provide education to all research community members, and to identify the strengths and weaknesses of research practice at WRNMMC.

It is with great excitement that I re-introduce members of the Post-Approval Compliance Monitoring (PACM) Program. The team consists of highly qualified Clinical Trial Auditors.

(From left to right)

Robert Roogow, MS, CIM
301-319-7736
Robert.J.Roogow.ctr@health.mil
Robert brings 16 years’ experience in clinical research, including seven years conducting research and eight years serving as the Regulatory Compliance Officer and Chief Operating Officer of an independent IRB in Florida. He is a subject matter expert in the area of human subjects protection and GCP compliance, and is a certified IRB Manager.

Debarati Dasgupta, MS, CHRC, CIP
301-400-0692
debarati.dasgupta.civ@health.mil
Debarati has 15 years’ experience specializing in human subjects protection, healthcare research and GCP compliance. She brings valuable knowledge of clinical research implementation and conduct through her experience as a clinical research associate on multiple NIH- and industry-sponsored studies. Her expertise in human subjects protection stems from her time serving as the IRB Administrator for a community-based healthcare organization in Maryland for over seven years and as a manager and surveyor for the Department of Veteran Affairs Human Research Protection Accreditation Program through the National Committee for Quality Assurance. Debarati is certified in Healthcare Research Compliance and is a certified IRB Professional.

Diane Beaner
301-295-8226; Diane.M.Beaner.ctr@health.mil
Diane brings 13 years’ experience in the area of human subjects protection, healthcare research and GCP compliance. Her experience working in clinical research includes six aggregate years as a senior protocol reviewer and as a clinical trials auditor at WRAMC and WRNMMC. Diane brings a strong knowledge base of human research regulatory compliance.

Alison Griffin, CCRA
301-295-8323; Alison.Griffin.ctr@health.mil
Alison, a certified Clinical Research Associate, has 10 years’ experience monitoring multicenter clinical trials conducted by the NIH and the Department of Veteran Affairs. She has also worked as a Clinical Research Coordinator for clinical trials in psychiatry. Alison brings valuable expertise in GCP compliance and FDA regulations pertaining to human subjects research.

We provide many services to the research community, including directed educational sessions on various aspects of the conduct of quality human subjects research, assistance with self-assessments, and not-for-cause evaluations of research files and investigator SOPs. In the next few months, we will launch a customer survey to help us gauge the educational needs of our research community. We would greatly appreciate your feedback. We invite you to send your post-approval compliance questions and ideas on how we can better serve YOU to: WRNM-PACM_Info@health.mil. We’re here to help!
Bi-annual Research Summits

Convene, Connect, Collaborate

The Department of Research Programs (DRP) hosts bi-annual Research Summits – typically in the Spring and Fall. This year, our Spring Summit was re-scheduled to Summer – and was held from 1200-1700 on 22 JUL in the GME Conference Room 4008/09, 4th Floor, Building 5 (HEROES). More than 60 people attended.

DRP’s bi-annual Research Summits offer forums for diverse speakers from the National Capital Region (NCR) to present overviews of ongoing research initiatives, studies, registries, funding, challenges, solutions, and opportunities for collaboration. Diverse speakers present very short overviews (10-12 minutes) and their comments are followed by a couple of minutes (3-5) of lively audience question and answer.

At the July Summit, BG Clark welcomed attendees with inspiring words about the strategic importance of research and collaboration. ETR Director COL Nelson offered energetic support for showcasing ongoing research, mentioning that this kind of program allows us to de-silo our extraordinary initiatives and promotes areas for collaboration. Often, he reminded us, we learn indirectly – or not at all – about work being conducted in the NCR that might have informed our own projects. COL Weina, DRP Chief, followed with insightful remarks regarding putting speakers and audience members together for a focused set of presentations - to bring current initiatives into the room.

Among the 14 talks at the recent Summer Summit were Bill Mahr’s impressive overview of the MURTHA Cancer Center’s Research Focus and Goals. Dr. Joshua Bernstein, of the Audiology and Speech Pathology Research Center, spoke about Cochlear Implants for Single-Sided Deafness; and CDR Janine Danko presented the state-of-the-art resources of BRL: DRP’s Biomedical Research Laboratory. Cardiologist LTC Todd Villines presented a compelling talk about his team’s Coronary CT Angiography Research Program; and Dr. Charmagne Beckett opened the Summit with a lively discussion of the Navy Bloodborne Infection Management Center’s (NBIMC) Apheresis of Blood Components from Health Volunteers for In Vitro Research.

COL Michael Nelson, Director of Education, Training, and Research at WRNMMC, closed the summit, thanking speakers, attendees, and DRP for their combined commitment to research, to collaboration, and to learning.

Audience members went away with an enlivened and broadened view of some of the work being studied, researched, conducted, sourced, funded, and supported in the NCR – and with great connections for potential collaboration.

The Fall Summit will be held 28 OCT in the same location. Please contact Mr. Daniel Rosen for more information and to register as a speaker:

daniel.g.rosen.civ@health.mil or 301-295-8258.
Clinical Investigation Strategic Priority Working Group

On July 17, 2014, COL Michael Nelson and WRNMMC DRP hosted this event bringing together researchers from WRNMMC, Uniformed Services University, FBCH, and the National Institutes of Health. To our knowledge this is the first time that a military treatment facility is establishing a clinical research strategic plan that will help focus future research efforts and be used to expand academic partnerships with USU, NIH, medical centers and industry.
Behind the Scenes

Every month we will now be featuring this new section where we will focus on one person “behind the scenes.” The questions will remain the same every month, but the person highlighted will change. This first month we feature Ms. Robin Howard, Supervisory Biostatistician. This interview was conducted at Robin’s desk.

What role do you play in human subjects research?

I assist the researchers in several ways. First, I help design the study and write the sample size and data analysis sections of the protocol. After the protocol is approved, I help with a randomization schedule, analyze the data and may contribute to the presentation and manuscript. I also assist the IRB by reviewing research for scientific validity. So, I serve as an “assistant coach” for the research team, yet I must also act as a “referee” for the research process. I also compile metrics for the department. A current focus is time to approval.

What specifically do you do to get protocols approved or help researchers do their research?

I try to design the research so that it is approved quickly and to ensure that the research is well-received by the journals.

What can researchers do to make your role more effective and efficient?

Meet in person. It’s faster. It’s easier. I understand the medicine and researchers understand the statistics more clearly in face-to-face meetings. There’s nothing like using visuospatial skills; drawing a picture really helps!

What tips would you offer researchers to get their protocols approved faster or to improve their research?

First, meet with a statistician (Dr. Francois Tuamokumo, Ms. Minoo Rouhanian or myself) and a protocol development specialist (i.e., Verna Parchment or Deborah Kessler, Senior Protocol Development Specialists, or Vicki Miskovsky, Erica Reed, Gwen Wright, or Denise Neath, Protocol Development Specialists) as early as possible in the protocol planning process. On Monday and Thursday mornings, we can come over to the hospital to meet with investigators. And Marcus Morgan can set up an appointment for you to sit down with us. Marcus can be reached at (301) 295-8239. Then, while your research is being reviewed, stop by our offices to check on the progress of your submission, perhaps before or after you visit the gym here in Building 17.
Every month we will also now be featuring this second new section where we will conduct an interview focusing interesting IRB-approved research. The questions flow from the topic and interview conducted. Dr. Gerard Riedy of NICOE has kindly agreed to be interviewed this month. The interview was conducted on Wednesday, July 16, 2014, at the NICOE complex, Building 51.

Gerard Riedy, MD, PhD
Director, National Capital Neuroimaging Consortium
National Intrepid Center of Excellence

“Advanced Imaging Acquisition and Data Analysis for a military Traumatic Brain Injury (TBI) Neuroimaging Database”

“Brain Indices of Risk for PTSD after Mild TBI”

“Thank you for meeting with us, DRP has its own newsletter. Right now our focus is on research, finding out what is going on here, perhaps help you network. The newsletter is a place to showcase your research.”

Dr. Riedy started, “We have three scanners lined up in the hallway, about ten million dollars’ worth of equipment—the goal of our project which started at the old Walter Reed Army Medical Center, before they built this building then it migrated over here, is to find an object measure of mild Traumatic Brain Injury. Right now, mTBI is based on your Glasgow Coma Scale at time of injury, any post-traumatic amnesia, and loss of consciousness. A lot of those things can be somewhat subjective in a war zone and lost so people come in with a history of traumatic brain injury that meets with a clinical criteria and we’re trying to find an objective imaging criteria. We’re trying to get a neuro-imaging signature of TBI. For this we use MRIs, PETCTs, and something called a magnetoencephalography. The MEG is new. The other two are standard in radiology imaging. Typically these instruments look at brain structure. You get a picture of your brain and if you’ve got an abnormality based on location and the appearance of it you can predict what it is or you can give it a differential. Radiologists often give differentials.”

“So you’re now able to see what you couldn’t in the past?”

Dr. Riedy responded, “We can and it’s been getting better. But that’s sort of the standard way to do things. So what we’ve done is taken it a step further and looked not just at structure of the brain, we look at the function of the brain. We give them tasks to do using a magnet, something call functional MRI. We give them a memory task, which is one of the common complaints. We give them a go, no-go task and f look at the executive function. We also do a resting-state task to see how the brain acts at rest. Therefore we can also probe not only the brain structure in looking for lesions but also the brain function. And these are the things they complain about. They don’t come in and say ‘My brain hurts and it’s right here,’ They come in and say ‘Listen, I got a bad memory, I can’t remember things, I used to be able to do my job without a problem and now I’m just worn out at the end of the day.’ As far as the research itself, we’ve employed people from around the country with the money we’ve got to conduct Congressionally direct medical research. Keeping them here and employed is a challenge. There is a lot of expertise in order to do this type of imaging. You couldn’t take this and import it down to Fort Belvoir and say ‘Go!’ It takes a team of people to not only tell the machine to collect this type of data – imaging – but then to process it properly and look for those breaks in fibers and look for the changes in the brain function compared to normal. And that’s a challenge in a military that tends to pay for equipment and some physicians but not really researchers. Once we figure this out, to export this technology to other MTFs and the VA is going to be a challenge. Our biggest realistic challenge that could be fixed quite easily is normal controlled volunteers, which we have a hard time getting. On this campus we can only scan people who are DEERS-eligible. I could volunteer, you could volunteer, and most of my staff could volunteer, and we could triple our normal scans with people in this building alone, but we can’t scan them because we’re not in the military, so we’ve got to get out and talk to people ‘Hey, you want to volunteer?’ When you’ve done 850 with TBI at Walter Reed and the NICoE, and you’ve only done 21 controls, it’s difficult to try to compare those data sets.”
Monthly Meeting

*Highlights*

- LCDR Acosta started the meeting by introducing the new DRP logo.
- CDR Danko was recognized by Uniformed Services University for service in interviewing prospective medical students.
- Angela Quispe was recognized for ten years’ of Federal Civilian service

*Updates Noted during Meeting*

Congratulations to Debarati Dasgupta on her new position as the Research Compliance Officer. Her formal start date was 7 July 2014. She did an excellent in her old position as Director of Institutional Review Board (IRB) Operations. Mary Kelleher will be doubling up as Acting Director of IRB Operations Office for the time being.

*Feedback on July Newsletter*

Comments included the following:

- A very nice newsletter!
- The volume of pictures can be distracting, at times.
- Another fine body of work.
- Could you include a section on advice to get my protocol approved faster?

We welcome your feedback to improve our newsletter by providing the most state-of-the-art information regarding military medical research at WRNMMC.

Please send feedback on the newsletter to WRNM-DRPNewsletterFeedback@health.mil


(CWRMMC authors: Weintrob AC, Ganesan A)


(WRMMC author: Jurgens J)


(WRMMC author: Gill A)


(LWRMMC authors: Minter A, Tan E, Kwok M)


(WRMMC author: Young PE)


(Additional WRMMC author: French LM)


(MWRMMC author: Dretsch M)


(WRMMC author: Oh J)


(Additional WRMMC authors: Little D, Nee R, Oliver JD 3rd, Bohen EM, Yuan CM)


(Additional WRMMC author: Warkentient TE)


(WRMMC author: Yu CE)


(WRMMC author: Cho R)


(Additional WRMMC author: Vigersky RA)