

Supporting Investigator-Initiated Research

Investigator-initiated clinical trials represent an important component of the research conducted at Capital Health. When investigator-initiated trials involve a drug or natural health product, compliance with certain regulations and guidelines is mandatory. In these situations the investigator assumes not only the responsibilities of the investigator but also those of the sponsor.

It is essential for the investigator to be aware of these requirements; otherwise, in the event of a regulatory inspection (e.g., Health Canada) or an internal quality audit, the investigator could be cited for non-compliance, leading to suspension or termination of their research.

Inadequate education and support can lead to gaps in the protection of research participants and regulatory compliance. When an audit or inspection brings shortcomings to light, it is usually impossible to implement the infrastructure required to satisfy regulatory requirements at such a late stage. This is a frustrating experience which may dissuade a researcher from pursuing future research. It is imperative that investigators make themselves aware of the requirements they must meet early on in the planning process.

The good news is that there are supports available to researchers through Capital Health Research Services. The staff have the expertise to support investigators and their teams with education, training and/or consultations. We can offer you the assistance you need quickly and effectively.

Options include consultations, ongoing guidance and your choice of the following seminars:

- Regulatory requirements for research
- ICH-GCP investigator responsibilities
- Division 5 regulations
- Sponsor-investigator responsibilities for ICH-GCP compliant research
- Investigator-initiated research agreements
- Financial management

Support is available at your convenience. To fit a consultation or training seminar into your busy schedule, choose your preferred location, date and time of day. To take advantage of any of the above options, please contact: janet.gallant@cdha.nshealth.ca



Janet Gallant, Program Manager
Research Education

February–March 2013

What's new...

Raymond P. LeBlanc Award in Research and Innovation



Dr. Ray LeBlanc, recently retired VP, Capital Health Research and Innovation, is shown with Dr. Tom Marrie, Dean, Dalhousie University Faculty of Medicine, at Dr. LeBlanc's retirement celebration.

On February 21 a number of Ray LeBlanc's colleagues gathered at the Life Sciences Research Institute to wish him well on his retirement from Capital Health. To honour his contribution to the local research community, a new award has been created.

The Raymond P. LeBlanc Award in Research and Innovation will be given to a Capital Health employee, including nurses, allied health professionals, managers and administrative staff. The goal of this award is to encourage participation in evidence based practice and knowledge translation at Capital Health. It will be awarded to an employee or team motivated to contribute to the creation of an organizational environment that promotes and values critical thinking, data-based decision making, access to new knowledge and practices, and the use of new methods to improve practice and patient care.

The \$5000 award will be available annually, sourced from the Research Endowment Fund in the QEII Foundation and sponsored by Learning and Professional Practice in partnership with Research Services and the QEII Foundation. Details about the application process will follow later.

Point of Care Research Project

The Point-of-Care Research Training Pilot Program which began in 2009 concluded this past December at the School of Health Sciences Research Day. Two of the participants presented the results of their research projects as part of the program completion. The Point-of-Care training program was the product of a collaboration between Capital Health and the Dalhousie University Faculty of Health

Professions, through the School of Health Sciences. The program reflected Capital Health's strategy to integrate research and patient care and was supported by a grant from the Nova Scotia Health Research Foundation (NSHRF).

Since the program's inception, 16 front-line practitioners have engaged in training
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Education...

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for the development of research skills; six research proposals were developed; and three research studies were completed. The presenters were:



Trish Bilski

Research title:
Nurses and Personal Care Workers Perceptions, Experiences and Beliefs about What Constitutes a Successful Fall Prevention Program in Long-Term Care



David Landry

Research title:
Identifying Sources of Decisional Conflict in Patients Choosing a Chronic Kidney Disease Treatment Option

Several judges evaluated the oral presentations. Trish Bilski scored highest and was awarded a \$1500 education grant. David Landry placed second and received a \$600 education grant.

Trish and David have been accepted to present their results at national conferences and plan to publish. David is involved in a second research project as well. Congratulations to these point-of-care researchers!

Educational Opportunities

Date	Series	Topic	Time	Location
April 3, 2013	Qualitative Health Research Seminar Series	Thinking about theory in qualitative health research Olga Kitts Qualitative Methodologist, RMU	12 noon -- 1 p.m.	Room 114, Centre for Clinical Research
April 11, 2013	Qualitative Health Research Seminar Series	Selecting your data generating methods Olga Kitts Qualitative Methodologist, RMU	12 noon -- 1 p.m.	Room 114, Centre for Clinical Research
April 18	Qualitative Health Research Seminar Series	Analysing your qualitative data Olga Kitts Qualitative Methodologist, RMU	12 noon -- 1 p.m.	Room 114, Centre for Clinical Research
April 30- May 1	Research Education Program Please register with: janet.gallant@cdha.nshealth.ca	Diving into Clinical Trials? Sink or Swim! Janet Gallant Program Manager Research Education	8 a.m. -- 4 p.m.	Room 114, Centre for Clinical Research
May 7, 2013	Research Education Across Atlantic Canada (REACH) Please register with michelle.rodén@cdha.nshealth.ca	Budgeting for clinical trials – Cory Schlievert, Coordinator, Contract Facilitation and Support – Jennifer Thurlow, Coordinator, Grant Facilitation and Support	12 noon sharp -- 1 p.m.	Royal Bank Theatre, Halifax Infirmary

For your information...

Consulting capacity grows at the Research Methods Unit (RMU)

Over the last year, the Research Methods Unit (RMU) added the four new consultants below, who have been working on a wide range of projects for the research community at Capital Health, the IWK Health Centre and Dalhousie University. For further information, visit the Research Methods Unit at www.cdha.nshealth.ca/rmu

Kara Thompson is a Biostatistician in the RMU and holds a faculty Lecturer position in the Department of Medicine, Dalhousie University. Kara graduated from the University of Guelph with a BSc in Toxicology and an MSc in Applied Biostatistics. She worked as a biostatistician in the Department of Medicine Research Office for ten years. Her interests include systematic reviews and meta-analysis, Cox proportional hazards modeling, competing risk analyses and their applications to practical research initiatives. She is experienced in the following statistical packages for data analysis: SAS, R Studio, SPSS, Comprehensive Meta-Analysis, RevMan, and NCSS/PASS. Current research activities include leading a NSHRF funded Cochrane review in epilepsy after traumatic brain injury.



Kara Thompson

Chris Theriault, PEng, is the Senior Research Database Specialist at the RMU. Chris has an Engineering degree from Dalhousie University. Chris' experience in health research databases was built through more than five years of supporting a variety of research projects in the Department of Medicine. Chris' engineering background has exposed him to large-scale industrial applications of data management. He consults on data management needs including database creation, data preparation and cleaning, and data analysis. Chris also writes syntax or code for algorithms of varying complexity, producing summary scores and other calculated results. Areas of activity include Hematology, Rheumatology, Respiriology, Endocrinology, Physical Medicine and Rehabilitation and Psychiatry.



Chris Theriault

Olga Kits is the Qualitative Methodologist for the RMU. Olga received an MA from Queen's University, Kingston, Ontario, and a BA(H) from Hood College, US. She has been involved in qualitative health research for over 20 years and has participated in a large variety of single and multi-site research studies in university, regulatory, and government settings. Olga worked in research and policy at the College of Physicians and Surgeons of Ontario and the Ontario Ministry of Health & Long Term Care and performed contract research for the Canadian Cancer Society and The Law Commission of Canada. Olga has worked on a variety of qualitative health research studies at Dalhousie.



Olga Kits

Joe Fraser is a Research Database Specialist at the RMU and builds and programs databases, and prepares data for statistical analysis. Current RMU projects include providing database support to clinical drug, osteoporosis, and psychology studies. Joe holds Bachelor's degrees in English and Education, and is a graduate of the Centre of Geographic Sciences in Lawrencetown, NS. Joe has experience as a GIS specialist and programmer and has designed custom web-mapping tools to share infrastructure data between departments of the Halifax Port Authority, and has overseen the creation of mapping data produced for the Nova Scotia Geomatics Centre. Joe's main interests include database and GIS technology and computer programming.



Joe Fraser

Funding Opportunities...

<i>Funding Opportunities</i>			
Deadline	Program Name	Agency	Website
April 12, 2013	Grants for preclinical, translational and clinical research areas that investigate all aspects of Angelman syndrome	Angelman Syndrome Foundation	http://www.angelman.org/research/2013-call-for-research-proposals/
Expression of interest: April 30, 2013 Letter of intent: Sep. 02, 2013	Mental Health Network (TRAM Network in Youth and Adolescent Mental Health)	CIHR and The Graham Boeckh Foundation (GBF)	https://www.researchnet-recherche-net.ca/rnr16/vwOpprtntyDtls.do?prog=1779&view=currentOpps&org=CIHR&type=EXACT&resultCount=25&sort=program&all=1&masterList=true
Letter of intent: May 1, 2013 Invitation to apply: June 14, 2013 Application: Nov. 15, 2013	Discovery Frontiers Call for Proposals: Advancing Big Data Science in Genomics Research Overview	Natural Sciences and Engineering Research Council of Canada (NSERC), Genome Canada, CIHR and CFI	http://www.nserc-crsng.gc.ca/Professors-Professeurs/Grants-Subs/FrontiersCall-AppelFrontiers_eng.asp
May 24, 2013	2013 Prostate Cancer Foundation Award	Prostate Cancer Foundation	http://www.pcf.org
Application: May 29, 2013	Operating Grant : E-Rare-2 Joint Transnational Call on Rare Diseases	CIHR and Joint Transnational Call (JTC)	https://www.researchnet-recherche-net.ca/rnr16/vwOpprtntyDtls.do?prog=1762&view=currentOpps&org=CIHR&type=EXACT&resultCount=25&sort=program&all=1&masterList=true
June 6, 2013	ICRH Emerging Network Grants	CIHR Institute of Circulatory and Respiratory Health in partnership with the CIHR Institute of Aging, the Heart and Stroke Foundation of Canada and Hypertension Canada	https://www.researchnet-recherche-net.ca/rnr16/vwOpprtntyDtls.do?prog=1636&view=currentOpps&org=CIHR&type=EXACT&resultCount=25&sort=program&all=1&masterList=true
Registration: Aug. 20, 2013 Application: Oct. 1, 2013	Catalyst Grant: Secondary Analysis of Neuroimaging Databases	CIHR and International Collaborative Research Strategy for Alzheimer's Disease.	https://www.researchnet-recherche-net.ca/rnr16/vwOpprtntyDtls.do?prog=1631&view=currentOpps&org=CIHR&type=EXACT&resultCount=25&sort=program&all=1&masterList=true
Sept. 15, 2013	Capital Health Research Fund Competition	Capital Health	http://www.cdha.nshealth.ca/discovery-innovation/research-fund-competiton
Oct. 15, 2013	Health Challenges in Chronic Inflammation Initiative	CIHR Institute of Musculoskeletal Health and Arthritis and the Institute of Infection and Immunity and several partners	https://www.researchnet-recherche-net.ca/rnr16/vwOpprtntyDtls.do?prog=1662&view=currentOpps&org=CIHR&type=EXACT&resultCount=25&sort=program&all=1&masterList=true

Research resources...

ICH-GCP Training for Investigators

Health Canada Inspectors request that investigators and research staff working on clinical trials involving drugs receive training on the applicable regulations (Division 5) and the International Conference on Harmonization: Good Clinical Practices (ICH-GCP). In the course of inspections they have requested documentation of training. To meet this need, Janet Gallant, Program Manager, Research Education, is offering the following training sessions upon request:

ICH-GCP Overview and Investigator Responsibilities (1 hour)

Division 5 Regulations and ICH-GCP Highlights (1 hour)

If you would like to have either or both of these training sessions provided to you and/or your research team at your chosen time and location, please contact:

Janet Gallant (902) 473-2118 janet.gallant@cdha.nshealth.ca

Planning and Development

The Planning and Development Office is working to grow the quality and quantity of the research enterprise. Development and Planning contacts are:

Julia Taylor (902) 473-2273 julia.taylor@cdha.nshealth.ca

Shane Grant (902) 473-3829 shane.grant@cdha.nshealth.ca

Research Methods Unit (RMU)

Do you need help refining the methods for your research project, developing an analysis plan, building a database, managing your data, analyzing your data, or advice on qualitative research methods or data collection? Would you like a quote for methods support for an upcoming funding application? The RMU can help. Our priority is to support your research.



It's easy—visit our web site to download an RMU Consultation Request form. Complete and send the form to us. We'll be in touch shortly thereafter to book an initial consult during which we will work with you to identify the best solution(s) for your needs. For more information about how the RMU can help your research, how the RMU consulting process works, or to request a quote for an upcoming research grant application, please visit: www.cdha.nshealth.ca/rmu or contact the RMU: rmu@dal.ca

Clinical Research Unit

Researchers now have access to a 5,400 square-foot, state-of-the-art Clinical Research Unit (CRU), located at the IWK Health Centre, for inpatient and outpatient research needs. Visit the CCfV web site at www.centerforvaccinology.ca for more information and a photo tour of the unit. All inquiries are welcomed. If you would like to tour the CRU and find out more about its services, please contact: Cathy Brown (902) 470-7015 catherine.brown@iwk.nshealth.ca



Research in Progress

This newsletter is produced by Research Services. You can view it at: <http://www.cdha.nshealth.ca/discovery-innovation/research-progress-newsletter>

Please direct inquiries, comments about or items for the newsletter to: Emily Walker (902) 473-5156 emily.walker@cdha.nshealth.ca