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Our Hospital Partners:



<http://www.hoteldieu.com/research-h-institute>



<http://www.providencecare.ca/LearningResearch/ResearchInstitute/Pages/default.aspx>

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Contact Us

kgfri@kgh.kari.net
(613) 549-6666, ext. 3344
<http://www.kgh.on.ca/research>



Connell 4 Update



The William J. Henderson Centre for Patient-Oriented Research, once complete, will be a game-changer for research in the Kingston region and will also help to enhance research space for the new integrated research institute. When complete, the approximately 10,000 square-foot new facility, located at KGH, will be state-of-the-art and will offer clinicians, basic scientists, and nursing/allied health researchers the ability to bring innovative diagnostic and therapeutic approaches to the point of care.

In June 2016, the Ministry of Health and Long-Term Care (MOHLTC) granted approval to commence construction, which began on July 18, 2016. While we initially anticipated that the new Centre would be completed and occupied by April 2017, we have adjusted the pace of the construction in order to minimize the impact on patient care at the hospital and are now anticipating a June 2017 completion date. To date demolition has occurred and the walls are going up. Stay tuned for regular updates, pictures, and a tour.

In another area of the hospital in our Gastrointestinal Diseases Research Unit we commenced construction of Dr. Elaine Petrof's new RE-POOPULATE lab, which will be fully operational by the end of December 2016.

Research Support Staff Profile

This is the first in a new series of profiles that will be posted periodically in our Research Newsletter. What's the profile going to be about?

At all three academic hospitals, there are research support staff working endless hours to meet the various deadlines involved in getting a research project up and running. The staff in these research offices are the experts at navigating their institution's approval processes, managing several projects simultaneously, mentoring new hires, and compassionately holding a research participant's hand in their journey to help us find new and better ways of preventing, diagnosing and treating disease. Who are these unsung heroes?

Let me introduce our first dedicated research staff member from Hotel Dieu Hospital:

Coordinator Profile: Darlene Brady (GI Research)

Darlene Brady is a Research Coordinator for the GI Research Group at HDH. An essential support person for eight clinician-scientists, she's winding up a long career in research in preparation for her retirement next year.

How did you get into this role and how long have you been a Research Coordinator?

My career in research started after I graduated from the 3 year Animal Care Technology program at St. Lawrence College. I worked fulltime as a research assistant in Cancer research for a few years and eventually part time when I became a mom. A family move out of Kingston led me to working as a lab technician and phlebotomist for MDS Cobourg (now known as Life Labs). I returned to Kingston in the early 90s continuing with MDS Kingston for 10 years and also working as a casual phlebotomist for HDH. A Research Coordinator position became available (previously held by Tracie Hanna) and I applied. My lab tech experience landed me the Research Coordinator position and I have been in this position since 2003.

What's the most satisfying part of your job?

Seeing clinical trial patients respond dramatically to a study medication while participating in a clinical trial. They are always so thankful and happy to "get their life back".

What's the most challenging part of your job?

As a Research Coordinator supporting investigator-initiated and industry-led trials, working on multiple studies at one time and keeping on top of each of those studies!

Dream job?

Retirement at this point in my life!

Best advice to research support staff?

For my current position at HDH, don't expect a 9 to 5 job with typical breaks and lunch hours, at specific times, like other positions in the hospital. Be prepared to give more than 100%.

Darlene has weathered many changes in the research environment, from increased regulatory and site-created document requirements to industry-imposed repeated GCP training. She has become very savvy over the years to be efficient and still comply! For

example, I learned about the Site Master binder from Darlene. That one-stop shop for CVs, GCP, biohazard and transportation safety training certificates, lab licenses, etc., has been a real work-saver for me.

A research coordinator today has to jump through many hoops to have everything in place for the PI to start and complete their research project: creating and negotiating fair budgets, obtaining all the necessary approvals, managing research equipment and the required calibration and documentation, creating site specific Standard Operating Procedures (SOPs), logs, source documents, recruiting, scheduling, collecting data, processing and shipping human samples, data entry, annual ethics renewals, safety reporting, preparing for quality assurance visits, preparing the documents for study closures and archiving....to name a few tasks.

I'm sure I've missed a few items but you get the gist of it. Darlene is currently training someone to replace her as she plans to retire in a few months and enjoy her new grandchild. We wish you all the best, Darlene because we know from experience you have earned your retirement!

Lisa McAvoy

Research Administration Facilitator
Kingston General Hospital Research Institute

Registering Clinical Trials on the NIH registry -The Final Rule

If you have research projects registered or are responsible for updating clinicaltrial.gov records there are new clinical trial reporting requirements. The links below outline the new changes that will be enforced:

- The New England Journal of Medicine (Trial Reporting in ClinicalTrials.gov-the Final Rule): <http://www.nejm.org/doi/full/10.1056/NEJMSr1611785#t=article>
- 42CFR Part 11 Clinical Trials Registration and Results Information Submission: <https://www.gpo.gov/fdsys/pkg/FR-2016-09-21/pdf/2016-22129.pdf>

N2 Updates



N2 10th Annual meeting SAVE THE DATE: February 2-3, 2017

St. Andrew's Club and Conference Centre (<http://www.standrewsclub.ca>) in downtown Toronto. Cost is \$50.00 plus HST for Members. Anyone employed or affiliated with KGH, HDH, PC are considered members as each institution has a membership with N2.

To register: <https://events.oicr.on.ca/n2-2017>

Presentations will include:

- ICH E6 (R2) GCP Revision Update
- TCPS (2014) Proposed Revisions Update
- Health Canada: Transparency and what that means
- ICST Update

Version 7 of N2 SOPs: Coming soon: May 15, 2017

Canadianized Version of Clinical Research Coordinator CITI Training Module: Coming soon: 2017

Clinical Research Associates Advisory Committee Meetings

We will be re-instating the face-to-face meetings in the New Year.

Save the dates:

- February 2017 (KGH)
- April 2017 (HDH)
- June 2017 (PC-Mental Health Site)
- September 2017 (KGH)
- November 2017 (HDH)

Please go to this doodle poll so we can figure out exact dates:

<http://doodle.com/poll/648iwh5nivbiiv96>

Reminders:

Kingston SOCRA Chapter

- If you are interested in presenting at a Kingston SOCRA Chapter meeting, contact:

Karen Murphy
Phone: 613-533-6430
Email: kmurphy@ctg.queensu.ca

Research News and Media

- Want to showcase your research? Are you publishing research findings that are a "first," a major breakthrough, or are unusual or interesting? Contact:

Mary Anne Beaudette
KGHRI Communications Consultant
Phone: 613-549-6666, ext. 3722
Email: beaudetm@kgh.kari.net

- For all media-related inquiries, contact:

John Pereira
KGH Strategic Communications Advisor (Media Relations)
Phone: 613-549-6666 , ext. 6875
Email: pereiraj@kgh.kari.net