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Quarterly Research News

Official Newsletter of the Office of Research

In This Issue

Clinical Trial Spotlight: MA.40

The Office of Research and the Oncology Department are excited to roll out a new clinical trial in July 2021.

MA.40 is a double-blinded placebo controlled randomized phase III trial. The trial will compare progression free survival (PFS) using RECIST 1.1 in patients with ER+/HER2- advanced (metastatic or loco-regionally recurrent not amenable to curative therapy) breast cancer treated with ipatasertib and fulvestrant versus placebo and fulvestrant after progression on first line CDK 4/6 inhibitor plus AI treatment.

Approximately 4-6 eligible patients will be enrolled yearly over a 2 year recruitment period. Potential patients will be recruited from Chemotherapy Clinic 2. Patients are enrolled in the trial for 5 years.

MA.40 is sponsored by CCTG (supported by Hoffmann-La Roche Ltd.) and is led by Dr. Vikaash Kumar and supported by Clinical Research Coordinator, Edeliza Mendoza.

Resident(s)	Project Title
Dr. Nathasha Dias Dr. Raymond Fok	Exploring Feedback in Family Medicine Virtual Clinics During the COVID-19 Pandemic: A Cross-Sectional Study
Dr. Lloyd Mai	Introduction of Virtual Balint Groups to Improve Resident Group Cohesion During the COVID-19 Pandemic
Dr. David Field Dr. Susy Lam	"It's All in the Communication": Evaluating Patient Transfer Communication Tools Between Long-term Care/Retirement Homes and the Markham-Stouffville Hospital Emergency Department: An Eastern York Region North Durham Ontario Health Team Initiative
Dr. Annie Qu Dr. Mike Sung	Using an Educational Training Program to Improve Resident Knowledge and Confidence in Performing Large Joint (Knee and Shoulder) Injections
Dr. Jack Caradonna	One-Pager Project - Topics: ACLS, Meningitis, Ischemic Heart Disease
Dr. Adam Zoccoli	One-Pager Project – Topics: Dehydration, Epistaxis, Poisoning

MFMTU 2020-21 Resident Academic Projects

By Dr. Donatus Mutasingwa & Joanne Permaul

One of the highlights of the academic year in the Markham Family Medicine Teaching Unit (MFMTU) is Resident Academic Project Day! Throughout their final year of residency, our second-year residents are tasked with completing an academic project, as required by the Department of Family and Community Medicine (DFCM) at the University of Toronto. This year's event took place virtually on June 2nd, 2021. Congratulations to Nathasha and Raymond whose project was judged as this year's winning presentation and was selected to present at the DFCM, University of Toronto Academic Project Day! A special thank you is extended to this year's judges, Dr. Gail Morris and Ms. Jadie Stone.

Meet Dr. Susan Kirsch

Dr. Susan Kirsch is a community-based pediatric endocrinologist. She works at the Pediatric Diabetes Clinic at Markham Stouffville Hospital and at the Richmond Hill Children's Clinic. Dr. Kirsch worked part-time for ten years as a clinical research physician for growth hormone studies for Eli Lily. She has recently completed two industry-sponsored trials (RM-493 15 and 22) investigating setmelanotide for the treatment of obesity. Currently, Dr. Kirsch is the PI for ADDAM, a study investigating accurate diagnosis of diabetes. She has numerous publications, such as: Canadian GeNeSIS study, Imaging in SHOX Deficiency, acid-labile subunit deficiency, disruption of the homeodomain transcription factor orthopedia homeobox (Otp) OTP, Heterozygous Variants in kisspeptin deficiency, CD-Diet study, and CGM- TIME Trial. She has participated in the training of medical students, pediatric residents, and pediatric endocrine fellows.

Dr. Kirsch has been instrumental in bringing industry-sponsored trials to paediatric patients at MSH.

New Impact Assessment Process

The Office of Research has established a new processed called, Impact Assessment (IA). The IA process is conducted for all human research studies that will impact the various departments at Markham Stouffville Hospital (MSH). Impacted departments include, but are not limited to: Pharmacy, Diagnostic Imaging (DI), Pathology, Laboratory, Nursing, and Cardiac Diagnostics.

It is the responsibility of the Principal Investigator (PI) to ensure the IA form is accurate and contains all information necessary for the research study.

PROCEDURE:

The IA form is available on the Research Acorn page. The following steps will be taken to obtaining IA:

- The PI or Delegate will obtain the most up-to-date version of the IA form and complete all required sections.
- The PI or Delegate will consult with the Research Manager to ensure the IA form is completed accurately and contains all relevant information.
- The Research Manager will schedule a Study Impact Meeting with all impacted departments stakeholders. The calendar invitation will include a copy of the IA form and all relevant documents for review (protocol, lab/pharmacy manual, IB, etc.). Departments will have at minimum 2 weeks to review the study material.
- The PI or Delegate will prepare a Study Impact Meeting PowerPoint using a template provided.
- During the Study Impact Meeting the PI and/or Delegate will provide a brief overview of the study, then the impact on each department, one-by-one.
- If any concerns arise from the Study Impact Meeting the PI, Delegate and Research Manager will follow up with the impacted department stakeholders separately. If there are substantial concerns from multiple departments, the Research Manager will make the decision to hold another Study Impact Meeting with all impacted department stakeholders at a future date.
- The IA process will continue once all impacted departments have given written documentation (email or a signed IA form approval page) providing clearance for the study.
- The PI, Delegate, and Research Manager will then start the contractual/budget review and REB process.
- The PI or Delegate can also start the process of SIV or SEV/SQV.

More information can be found on the Research Department Acorn page . If you have any questions, please contact Michelle Dimas at mdimas@msh.on.ca

ACTIVE STUDY HIGHLIGHTS

- KIT (*PI: Dr. Rayzel Shulman*)
- Bridging the Gap (*PI: Alanna Landry*)
- ReACT Algorithm (*PI: Dr. Vikaash Kumar*)
- LUS (*PI: Dr. William Cherniak*)
- COVID-19 Cohort Study (*PI: Dr. Jeya Nadarajah*)
- COVID NeoOutcomes (PI: Dr. Taslim Dawood)

UPDATES FROM THE REB

The MSH REB has released several new REB application forms. There will be a grace period for old forms that are submitted, however **effective September 1, 2021** outdated forms received will be turned away.

The following revised forms are effective immediately:

- Renewal Application form
- Study Closure Form
- Amendment Form

New forms that will be released soon:

- Local and external SAE Reporting Form
- Personnel Change Form

Please keep an eye on the REB Acorn page for new and updated forms. Changes will also be made to the external REB website which is currently under construction as we update the pages with new information.

RESEARCH COMMUNITY SPOTLIGHT

Clinical trials at MSH relies on the continued support and collaboration with various departments across the hospital. Laboratory Medicine has been instrumental in the successful activation and completion of many trials.

We would like to highlight a couple of amazing lab staff that have been incredible colleagues to work with: **Laura Kononow** has assisted with various clinical trials by providing logistical, education and training support. **Nita Mehta** has been invaluable in providing research operational support, including the rollout and activation of trials, ongoing laboratory sample collection, processing and shipment. **Mohamed Bhugun** has helped provide budgetary and cost analysis guidance to help evaluate the feasibility of trials requiring lab support.

Laboratory Medicine has assisted with numerous trials, including but not limited to: Rhythm RM493-015 and 022, Serology COVID-19, HCW Seroprevalence and Anti SARS-CoV-2, ADDAM Study Part I and II, EB05, MA40, Hip Attack I and II, CATCO, and CONCOR-1.

We would also like to thank the blood bank staff and lab tech's for all their hard work and contribution.

The Office of Research would like to extend our sincere gratitude for all your help, collaboration and guidance. We look forward to many more successful studies in the future.

MSH REB Frequently Asked Questions

How to apply to the Research Ethics Board (REB)?
Please submit your REB application to ResearchAdmin@msh.on.ca. Hard copy and handwritten submissions are not accepted.

Who can be a Principal Investigator (PI)?
The PI must be an employee or credentialed professional staff at MSH. This does not include volunteers, residents and students.

How long is my REB approval good for?
Studies are to be renewed annually.

How do I apply for annual/continued review?
Please submit the annual renewal form 30 days prior to the expiration of the study. Once reviewed and approved by the REB, an official annual renewal letter will be issued with a new expiration date.

How do I make a change to my research study?
To change the currently approved research study and approved documents, please submit an Amendment Application Form to the REB along with revised or new documents.

What research training do I need?
All personnel involved in the study will need TCPS2. You may also need GCP and Health Canada Division 5