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Toronto, Ontario
M5G 1M1 Canada
www.ctontario.ca

Documented Institutional Ethics Requirements
Hamilton Health Sciences Corporation

Privacy Policy

Clinical Connect may not be used as a source for patient research participant data. For example, if the coordinator for the research study is also a clinical nurse/respiratory therapist treating the patient clinically and has access to clinical connect to see patient data, they cannot access Clinical Connect for research related data.

Explore Research

On February 24, 2025, Explore Research was launched at Hamilton Health Sciences (HHS). Explore Research is an implied consent/opt-out recruitment model that includes permission to be contacted by members of the HHS research team and consent for HHS research team members to pre-screen electronic health records to confirm eligibility. **No REB waivers of consent are required for Explore Research**. Starting February 24, 2025, all new patients registered in Epic will automatically be included in Explore Research, and existing patients will be opted in at their next encounter with our hospital. Patients can opt-out at any time and this process is handled according to HHS policies. At this time, Explore Research relies on Reporting Workbench; researchers can use this tool to search for patients who have not opted out and meet the study-specific inclusion/exclusion criteria (these fields are called the 'reporting workbench criteria'). Alternately, clinical personnel within the circle of care can identify potential participants to the research team. Once these potential patients are identified, HHS researchers/research staff can pre-screen records as required to conduct a more thorough eligibility assessment. If the patient continues to meet the initial eligibility for study screening, the HHS researchers/research staff can contact the potential participant in-person, via phone or by email.

HHS has created template contact scripts for the initial contact with patients. Patients approached through Explore Research should be advised that "I am (if telephone contact: calling from) or (if in person contact: from) or (if email: emailing from) Hamilton Health Sciences. As a patient at our hospital, we want to provide you with opportunities for participation in research."

Researchers are expected to submit all contact scripts to the REB; reporting workbench criteria do not need to be submitted to the REB. HHS recognizes that the REB review will be according to the policies/procedures of the REB of Record. Similarly, while Explore Research is an institutional platform conducted outside of the REB's purview, HHS recognizes that the REB of Record will ultimately determine whether this recruitment approach is suitable for each specific study. REBs with questions about Explore Research can contact:

Informed Consent Language

Requesting External Medical Records (not applicable to studies reviewed by OCREB):
If applicable, the following paragraph should be added to the confidentiality section of the informed consent form:

"If you are admitted to another hospital for any reason or die from natural or other causes while participating in this study, your medical records will be requested in order to collect information relevant to your study participation. By signing this consent form, you are allowing such access."

For Studies Built in Epic:
Interventional clinical trials and certain observational studies may be built in Epic if the study meets institutional requirements. For studies that meet the requirements to be built in Epic, the following text must be added to the informed consent form, in an appropriate section that references privacy and confidentiality:

"Your participation in this study will be recorded in your electronic health record (EHR), also called a medical record, at Hamilton Health Sciences. If you participate, some of the information about you that is collected for this study,

including the results of tests described in this consent form, will be stored in your EHR and accessible to others working at this hospital (like your current and future health care provider(s)). This hospital may share patient information stored in its EHR with other hospitals and healthcare providers in Ontario. In addition, any person or company to whom you give access to your medical record may have access to this information. The study team can tell you what information about you will be stored electronically, and what may be shared outside of this hospital."

Research Sites Under Hamilton Health Science Corporation's Auspices:

- Hamilton General Hospital
- McMaster University Medical Centre
- McMaster Children's Hospital
- Juravinski Hospital
- St. Peter's Hospital
- West Lincoln Memorial Hospital
- Juravinski Cancer Centre
- Main Street West Urgent Care Centre
- Ron Joyce Children's Health Centre
- Regional Rehabilitation Centre
- David Braley Research Institute

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SRERS Administration
Hamilton Health Sciences Corporation

Cross-Appointed Researchers

For researchers sharing cross-appointments at more than one institution (e.g., Hamilton Health Sciences Corporation, St. Joseph's Healthcare Hamilton and/or McMaster University), you must use the credentials for the institution where the research is being conducted.

For example, if the researcher is cross-appointed between Hamilton Health Sciences Corporation (HHS) and McMaster University, and the research will be conducted (e.g., participants recruited and/or intervention administered) at HHS, the researcher's organization and the institutional representatives must be those associated with HHS.

Institutional Research Administration Requirements

All REB approved projects conducted at HHS must receive Institutional Authorization (IA) prior to initiating the study. The request for IA is submitted through PI-PORT. If the Principal Investigator (PI) does not have a PI-PORT account, they can find the registration link on the HHS HUB and the McMaster University SharePoint. Once they receive their HHS Scientist Appointment, the PI will receive an email containing their PI-PORT ID and a unique link to their PI-PORT. This email can be shared with their research team to facilitate completion of the IA instrument for new studies.

IA is granted on a per-protocol basis once all requisite approvals have been obtained.

Initiating a Study at HHS

There are 2 things required before research teams begin study activities at HHS:

- CTO REB of Record Approval for the HHS Site
- Institutional Authorization has been granted

*Account opening is separate from these requirements and should proceed in accordance with institutional processes.

Stream Collaborators

The following collaborators must be given a role on the initial study-wide application, called the Clinical Trial Initial Application (CTIA), or Observational Study Initial Application (OSIA) and the Participating Site Initial Application (PSIA):

Name: Sasha Eskandarian
Email: eskandars@hhsc.ca
Role: Institutional Representative

Name: Dana Kilgour
Email: kilgourd@hhsc.ca
Role: Institution Admin

Name: Vanessa Manning
Email: manningv@hhsc.ca
Role: Institution Admin

Name: Kristina Szabo
Email: szabok@hhsc.ca
Role: Institution Admin

Name: Lauren Gogo
Email: gogo@hhsc.ca
Role: Institution Admin

Name: Michaela Marcincinova
Email: marcincino@HHSC.CA
Role: Institution Admin

Name: Laura Puri
Email: puri@hhsc.ca
Role: Institution Admin

Name: Bianca Bier
Email: bbier@hhsc.ca
Role: Institution Admin

Name: Ishan Dey
Email: deyis@hhsc.ca
Role: Institution Admin

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Name: Beverly Pond
Email: pondb@hhsc.ca
Role: Institution Admin

Name: Mercedes Camargo
Email: camargom@HHSC.CA
Role: Institution Admin

This access is automatically granted when the Participating Site Initial Application is created. **When HHS is the Lead Applicant site the research team should immediately create the PSIA for the participating HHS site(s) (right after creating the new study).** This will ensure that access is automatically granted as required above, otherwise the research team will need to manually add these roles to the CTIA/OSIA prior to submission.

Institution Representative in application forms

The Primary Institution Representative must be indicated as follows in the applications within Stream:

Title:	Ms.
First Name:	Sasha
Surname:	Eskandarian
Organization:	Hamilton Health Sciences Corporation
Address:	C5-119, 237 Barton St. E
City:	Hamilton
Province/State:	ON
Postcode/Zip:	L8L 2X2
Telephone:	416-721-4890
Fax:	N/A
Email:	eskandars@hhsc.ca

The Secondary Institution Representative field should be left blank.