

Documented Institutional Ethics Requirements Toronto Heart Centre

Scope

Various cardiac conditions are highly prevalent and on the rise in Canada, contributing substantially to healthcare costs and patient quality of life. For example, over 60,000 Canadians will experience a heart attack, or Myocardial Infarction (MI), per year. Other cardiac conditions, such as Atrial Fibrillation (AF), in which the heart beats rapidly and irregularly, are also highly prevalent. Alarming, AF is the most common cardiac disturbance contributing significantly to cardiovascular morbidity and mortality. By the year 2050, an estimated 250% increase in the prevalence of AF is expected. Given their high prevalence and risks of future cardiac hospitalization and death, treatment approaches that target modifiable risk factors are strongly warranted. Indeed, there is a global need to prevent future cardiac events by providing patients with user-friendly and accessible resources, including education and information that is based on current clinical practice guidelines. New approaches to provide follow-up care are critical, as less than one third of patients post-MI receive the appropriate cardiac rehabilitation. Moreover, local in-person cardiac clinics are often inaccessible in rural Canadian regions, thus limiting access to cardiac care across the nation. Virtual app-based programs developed and monitored by cardiac specialists have the potential to overcome physical barriers and provide more equitable access to resources, which can, in turn, reduce healthcare costs and emergency department visits. It is imperative that resources provided to patients incorporate the most up to date recommendations and are based on clinical practice guidelines in cardiac medicine.

Missions and Values

The primary objective of the trial (entitled the VIRTUES trial) is to determine the usability and feasibility of guideline-driven recommendations provided to cardiac patients within each module of a virtual app-based program, as well as assess the impact of recommendations on patients' general health.

Privacy Considerations

The VIRTUES platform has been designed by web-developers through the Cardiovascular Network of Canada (CANet) who have ensured its compliance with all applicable provincial and federal privacy laws and regulations.

Informed Consent Form Requirements

Once a participant is deemed eligible to participate in the trial, the research coordinator at each given site will review the letter of information detailing the study proceedings and obtain informed consent from the participant. Only after the participant has had all of his/her questions answered and understands the study proceedings thoroughly will written informed consent be obtained. A dedicated letter of information and consent form has already been approved at the provincial level on CTO; this will be submitted through CTO for approval at the site level and will be used after research ethics board approval through CTO is successfully obtained.

Access to Medical Records and Obtaining Consent

Once enrolled in the VIRTUES trial, participants will be able to enter in their medical history data on the platform. Any missing or incomplete information can be supplemented by the research coordinator at the site. This is done through access to the participant's secure electronic medical records and is clearly indicated in the consent form. If a participant does not wish to partake in any aspect of VIRTUES, s/he is fully entitled to this decision, as participation is voluntary.

SRERS Administration Toronto Heart Centre

Reminder: Institutional Research Administration Requirements

The CTO Streamlined System provides a streamlined approach to research ethics review. Each participating site must ensure that all necessary institutional authorizations and contracts/agreements are in place prior to beginning the research.

CTO Stream

Collaborators:

The following collaborators must be given a role on all Provincial Initial Application (PIA) forms and Centre Initial Application (CIA) forms.

Email: alvin.pagunuran.md@gmail.com
Role: Institutional Representative

This access is automatically granted when the Centre Initial Application is created. **When Toronto Heart Centre is the Provincial Applicant site the research team should immediately create the CIA for Toronto Heart Centre (right after creating the PIA).** This will ensure that access is automatically granted as required above, otherwise the research team will need to manually add these roles to the PIA prior to submission.

Institution Representative in application forms

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

Title: Dr.
First Name: Chi-Ming
Surname: Chow
Organization: Toronto Heart Centre
Address: 2300 Yonge Street, Suite 906
City: Toronto
Province/State: Ontario
Postcode/Zip: M4P 1E4
Telephone: 647-776-2500
Fax: 647-260-0279
Email: cardio@mac.com

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

Title: Dr.
First Name: Alvin
Surname: Pagunuran
Organization: Toronto Heart Centre
Address: 2300 Yonge St #906
City: Toronto
Province/State: Ontario
Postcode/Zip: M4P 1E4
Telephone: 647-776-2500
Fax:
Email: alvin.pagunuran.md@gmail.com