661 University Avenue, Suite 460
MaRS Centre, West Tower
Toronto, Ontario
M5G 1M1 Canada
www.ctontario.ca

Documented Institutional Ethics Requirements
Cardio Health Clinical Trials

Missions and Values

Provide high quality clinical trial management services for the pharmaceutical and biotechnology industries, to accelerate the development of new, safe, and effective therapies that help transform and positively impact our community by always delivering the best care to our partners and clients.

Strong Ethics Dependability, Integrity Safety Good, Clinical Practice, Commitment Compliance.

Privacy Considerations

Accuro or Clinical Connect EMR 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 the EMR to see patient data, they cannot access it for research related data.

1. Identifiers such as name, initials or full date of birth (e.g. year/month/day) may not permitted for release for research purposes. These must be replaced with ID numbers, pseudo initials and partial date of birth (Month/Year) on any data released from the institution.
2. Please note that access to shared electronic health systems such as Connecting Ontario, OLIS, eHealth is not permitted for research purposes. Shared electronic health systems may not be used as a source for research participant data.

Informed Consent Form Requirements

1. For studies that include pregnancy testing: the following paragraph should be included: The results of the pregnancy test will be told to you (the participant) by one of the study team members in private. Every effort will be made to keep positive pregnancy test results private. These results will not be shared with your parents/guardian unless you request it.
2. In the list of organizations who may have direct access to original (identifiable) medical/clinical study records, include the following bullet:
   • This institution and affiliated sites, to oversee the conduct of research at this location

NOTE: this bullet must replace alternate wording (e.g., “insert research site name, to oversee the ethical conduct of research at this site”) present in the provincially-approved consent form.

Cross-Appointed Researchers

For researchers sharing cross-appointments at more than one institution (e.g., Cardio Health London, Toronto, Hamilton or Scarborough locations), you must use the credentials for the institution where the research is being conducted. For example, if the researcher is cross-appointed between Cardio Health Clinical Trials London (CHCTL) and Toronto, Scarborough, and/or the Hamilton location, and the research will be conducted (e.g., participants recruited and/or intervention administered) at CHCTL, the researcher’s organization and the institutional representatives must be those associated with CHCTL.

For interventional clinical trials being conducted at any of Cardo Health Clinical Trials site, the following text must be added into the Informed Consent: Your participation in this study will be recorded in your electronic health record (EHR), also called a medical record, at any of our sites. 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 the sites (like your current and future health care provider(s)). These

661 University Avenue, Suite 460
MaRS Centre, West Tower
Toronto, Ontario
M5G 1M1 Canada
www.ctontario.ca

sites 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.

Access to Medical Records and Obtaining Consent

For the duration of the clinical study and up to 25 years after the study has closed, there will be the need to have access to medical records solely for the purpose of the trial by clinical trial staff at the sites.
Once the record has been kept the info will be reviewed upon request from sponsor of the study or Ethics Committee to resolve and or get more information on any serious adverse event.

While in the study only study personnel will have access to certain health information, for the purpose of verifying study related data only.

661 University Avenue, Suite 460
MaRS Centre, West Tower
Toronto, Ontario
M5G 1M1 Canada
www.ctontario.ca

SRERS Administration
Cardio Health Clinical Trials

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.

Contracts/Agreements

Institutional approval of any study is conditional upon a fully executed study contract agreement with Cardio Health Clinical Trials Network, Principal investigator, and the study sponsor. All research staff must enter a research confidentiality agreement and document all conflicts of interest. No study can begin in any capacity until all study agreements have been fully executed.

Cross-Appointed Researchers

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: naheed@cardiohealth.ca
Role: Institutional Representative

This access is automatically granted when the Centre Initial Application is created. **When Cardio Health Clinical Trials (CHCT) is the Provincial Applicant site, the research team should immediately create the CIA for CHCT (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: Naheed
Surname: Rizvi
Organization: Cardio Health Clinical Trials
Address: 1807-202 Wonderland Road, North
City: London
Province/State: Ontario
Postcode/Zip: N6G 5C2
Telephone: 226-783-4649
Fax: N/A
Email: naheed@cardiohealth.ca

The Secondary Institution Representative field should be left blank.