

Documented Institutional Ethics Requirements CReATe Fertility Centre

Scope

The CReATe Fertility Centre is a comprehensive reproductive care and research facility.

Missions and Values

Our mission is to provide state-of-the-art and compassionate care in a safe environment for our patients and staff, undertake innovative research, and provide excellent teaching and mentorship.

Our values:

- Integrity
- Innovation
- Evidence-based decision making
- Patient-centred care
- Excellence
- Safety

Privacy Considerations

The protection of research participant privacy and data security are paramount to study design and implementation in our clinic and research program. All studies involving PHI and access to medical records are approved by an internal review and approval process, including a study personnel training and data management plan, reflecting best practices in privacy and data security, including data de-identification and file encryption. Only authorized study personnel trained in PHIPA, data management (collection, handling/sharing, storage and disposal) and research ethics (TCPS2, GCP) have access to PHI and study data, and for limited times during the data collection phases of the study. All data files are encrypted and stored on restricted company servers or encrypted database, and study binders are kept in locked cabinets in restricted office space.

Access to Medical Records and Obtaining Consent

Research participants provide written informed consent to having authorized research personnel access medical records and collect necessary PHI only, as specified in REB-approved study protocols.

SRERS Administration CReATe Fertility 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 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):

Email: andree@createivf.com
Role: Institutional Representative

This access is automatically granted when the Participating Site Initial Application is created. **When CReATe Fertility Centre is the Lead Applicant site the research team should immediately create the PSIA for CReATe Fertility Centre (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 CTO Stream:

Title:	Mr.
First Name:	Andrée
Surname:	Gauthier-Fisher
Organization:	CReATe Fertility Centre, Research Program
Address:	790 Bay Street, Suite 420
City:	Toronto
Province/State:	Ontario
Postcode/Zip:	M5G 1N8
Telephone:	416-323-7727 x2266
Fax:	N/A
Email:	andree@createivf.com

The Secondary Institution Representative field should be left blank.