

Documented Institutional Ethics Requirements Endocrinology, Diabetes and Metabolism Institute

Scope

Our scope includes pragmatic, community-based observational and interventional studies in **cardiometabolic health, endocrinology, diabetes, obesity, PCOS, and nutrition/lifestyle-focused digital health interventions**.

Specific focus areas include:

- Type 2 diabetes, pre-diabetes, metabolic syndrome
- Obesity and related conditions (e.g., dyslipidemia, MASLD)
- Cardiovascular diseases (coronary artery disease, stroke)
- PCOS and women's health
- Nutrition and lifestyle interventions, including plant-forward eating, dietary quality, and physical activity
- Digital health solutions including AI-driven personalized nutrition and activity coaching

Our research integrates clinical endpoints (HbA1c, glucose, BMI, waist circumference, lipids, menstrual regularity) with **behavioral adoption metrics** (dietary quality, physical activity, healthy lifestyle adherence, and app engagement).

Research Site Locations

Endocrinology, Diabetes and Metabolism Institute (EDM)

8 Shadlock St unit 1
Markham, ON L3S 3K9

Endocrinology, Diabetes and Metabolism Institute (EDM)

18 Kensington Rd unit 203
Brampton, ON L6T 4S5

Missions and Values

At the Endocrinology, Diabetes and Metabolism (EDM) Institute, our mission is to align research innovation with patient care. We believe that lifestyle-based prevention and management—including healthy eating, physical activity, and behavioral support—can reduce the burden of metabolic disease in Canada.

Our guiding values are:

- Patient-centered care: Research that serves participant well-being first.
- Scientific rigor: Evidence-based, transparent methodologies.
- Accessibility and diversity: Recruiting from diverse communities across Ontario.
- Innovation with integrity: Using AI ethically to enhance, not replace, clinical decision-making.

Research considerations are based on:

- (a) projected patient outcomes,
- (b) scientific and clinical relevance,
- (c) cost-benefit balance,
- (d) institutional capacity and resources, and
- (e) participant safety.

Privacy Considerations

EDM Institute and Durham College are committed to the highest standards of privacy and confidentiality. We comply with the **Personal Health Information Protection Act (PHIPA, Ontario)** and follow **privacy-by-design principles** in digital research.

- **Data Handling:** All personal health information (PHI) will be stored securely on encrypted servers located in Canada.
- **De-identification:** Research datasets will be de-identified before analysis.
- **Access Controls:** Staff may access PHI only within the scope of their roles.
- **Privacy Officer:** Nupur Agarwal – nupur.a@edminstitute.com

Access to Medical Records and Obtaining Consent

- Participant consent is the **default requirement** for accessing medical records or lab results.
- The consent form will authorize the research team to obtain relevant health information (e.g., lab values such as HbA1c, lipids, fasting glucose, anthropometric measurements, medication lists).
- PHI will only be accessed, used, or disclosed in accordance with PHIPA and the consent form.
- For pragmatic trials embedded in care, EDM Institute will ensure patients are fully informed of research use of their health data.

SRERS Administration

Endocrinology, Diabetes and Metabolism Institute

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):

Name: Dr. Nikhil Gupta
Email: Nikhil.gupta@edminstitute.com
Role: Institutional Representative

Name: Priyamvada Tripathi
Email: Priyamvada.Tripathi@durhamcollege.ca
Role: Institutional Representative

Name: Kanav Kahol
Email: kanavtoronto@gmail.com
Role: Institutional Representative

This access is automatically granted when the Participating Site Initial Application is created. **When Endocrinology, Diabetes and Metabolism is the Lead Applicant site, the research team should immediately create the PSIA for Endocrinology, Diabetes and Metabolism (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: Dr.
First Name: Nikhil
Surname: Gupta
Organization: Endocrinology, Diabetes and Metabolism Institute
Address: 8 Shadlock Street unit 1
City: Markham
Province/State: ON
Postcode/Zip: L3S 3K9
Telephone: 416-599-5499
Fax: 416-345-0071
Email: Nikhil.gupta@edminstitute.com