



Pre Site Visit Questionnaire

LMC Diabetes & Endocrinology (*Bayview*)

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Site Information

Site location

LMC Diabetes & Endocrinology (Bayview)
107-1929 Bayview Avenue
Toronto, Ontario
M4G 3E8

Contact Information:

416 645-2929 phone
416 645-2930 fax
800-701-ENDO (3636) Toll Free
torontoresearch@lmc.ca email

Specific clinical studies of interest

- Type 1 & Type 2 Diabetes Mellitus
- Diabetes Complications - Neuropathy, Nephropathy, and Retinopathy
- Lipid Disorders
- Obesity
- Osteoporosis
- Hypertension
- Cardiac & Diabetes Prevention
- Women's Health

Phase I - IV Experience

Description of site

- Private Clinic
- Ministry of Health Funded Diabetes Education Center
- Private Clinical Research Centre

Memberships

- Member of the Society for Clinical Research Sites (SCRS)

Number of studies capable per site

6-8 enrolling studies with 10 maintenance studies

How long has the site been involved in clinical research?

Site has been doing research for 15 years

Has the site been audited?

- No FDA audit
- Health Canada audit (February 2008) - fully compliant
- Sponsor audits for highest enrolling - positive findings only

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Emergency response

- Sunnybrook Women's College Hospital 500 meter
- All staff are CPR certified annually

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Study Staff

Principal Investigator

Ronnie Aronson MD, FRCPC, FACE

- 18+ years research experience
- > 200 clinical trials: Endocrinology & Metabolism

Sub Investigators

Samantha Sandler MD, FRCPC

- 11+ years research experience
- > 55 clinical trials: Endocrinology & Metabolism

Adam Telner MD, FRCPC, FACP

- 6+ years research experience
- > 40 clinical trials: Endocrinology & Metabolism

Andrew Boright MD, FRCPC, FACP

- 6+ years research experience
- > 35 clinical trials: Endocrinology & Metabolism

Loren David Grossman BSc, MD, FRCPC, FACP

- 19+ years research experience
- > 55 clinical trials: Endocrinology & Metabolism

Oren Steen MD

- 3+ years research experience
- >25 clinical trials: Endocrinology & Metabolism

Priya Narula (Physician Assistant), BSc, CCPA

- 4+ years research experience
- > 30 clinical trials: Endocrinology & Metabolism

Investigator Accountability

40% research, 60% clinic

Investigator's Education and/or Academic Appointments Speciality Areas: Endocrinology & Metabolism

Education

2016	GCP Training, Transcelerate
1998	Fellowship, American College of Endocrinology
1995	Certification, Endocrinology & Metabolism; Royal College of Physicians American Board of Internal Medicine
1995	Fellowship, Internal Medicine; Royal College of Physicians
1995	Certification, Internal Medicine; Royal College of Physicians American Board of Internal Medicine
1991	General License; College of Physicians & Surgeons, Ontario
1990	Doctor of Medicine; University of Toronto
1990	Licentiate; Medical Council of Canada

Appointments

2014-present	Medical Director, LMC Diabetes & Endocrinology
2006-present	Tariff Chair, Ontario Medical Association Section of Endocrinology
1997-2014	Executive Director, LMC Diabetes & Endocrinology
1995-2000	Oakville Trafalgar Memorial Hospital

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Patient Population and Recruitment

Number of patients

> 200,000 for the database plus an additional 24,000 per year (60% diabetes)

Capability of screening database

Yes - able to note medical history, medications, most recent lab values and consented interest in research

Catchment area

All of Toronto

How are subjects recruited to meet the agreed upon targets?

- Patient database
- GP & Specialist referral network
- Diabetes triage - rapid assessment for newly diagnosed drug naive and metformin only patients failing orals requiring addition of OHA's or insulin initiation
- Advertising - radio, newspaper, central toll free number and capability of central ad campaigns for all LMC sites
- Public forums & expos
- Community involvement - Pharmacy days, and local presentations
- E-recruitment campaign

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Ethics

Ethics committee (local or central)

- Central Ethics
- Worked with IRB Services, Schulman, Quorum, WIRB, Veritas, Canadian Shield, Optimum, etc.

Informed consent process

- See LMC Diabetes & Endocrinology SOPs
- GCP/ICH Compliant

Confidentiality

- PIPEDA implemented

5 Facilities

Equipment available

- Refrigerated and room temperature centrifuges (calibrated yearly)
- 2 x Microcentrifuges Minispin Plus
- 2 x YSI Glucose and Lactate Analyzer
- ECG machine (Brentwood software) - calibrated daily
- 330 kg weight scale (calibrated yearly)
- 1 x -20 freezer (calibrated yearly)
- 1 x -70 freezer (calibrated yearly)
- 2 x medical fridge for study medication purposes only (calibrated yearly)
- ABPM machine
- Manual and automatic blood pressure device
- Emergency crash cart
- Defibrillator
- Able to do PK analysis, injections, glucose clamping & meal tolerance tests

Office hours

- Monday - Friday (7:30 am - 6:00 pm)
- Weekends as needed

Monitoring space

- 3 rooms dedicated to monitoring
- Phone, analog, wireless and broadband access
- Access to a fax and photocopy machine

LMC Diabetes & Endocrinology SOP

ERB & HC reviewed

Source documents

- LMC specific templates for source creation and study specific logs

Drug accountability and storage

- Secured and Locked Drug Cabinets, Medical Fridges and Freezers
- Temperature monitored daily (min, max and average temperatures)
- Sensaphone (remote monitoring, early detection system)
- Pharmacy for study-specific storage and dispensing requirements

eCRF experience

- *INFORM*
- *INET*
- *RDC*
- *ORACLE*
- *PHOSCO*
- Medidata RAVE

IVRS experience

- Clinphone
- S Clinica
- ICON
- Fisher Clinical Services
- Impala
- Almac
- Perceptive
- IXRS
- IWRS

Data storage

- In house:
 - Lead study coordinator's office
 - Paper charts / Electronic medical records
- Long term storage:
 - Iron Mountain x 25 years
Address: Records Management Division
70 Talman Court
Concord, Ontario L4K 4L5
1-877-840-2111

6 | Contract

Sites usual overhead

- 30% overhead

Sites turnaround

- 1-2 week turnaround

Budget Negotiations

- Research, President: Karri Venn RD, CDE, CCRC
Email: karri.venn@lmc.ca
Phone: 647-274-4133 direct line

- Budgets and Contracts: Nichelle Farrell
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Regulatory Documentation

- Regulatory Specialist: Natalie Gibbs
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