



# Pre Site Visit Questionnaire

## LMC Diabetes & Endocrinology (*Bayview*)

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### Site Information

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#### 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](mailto: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 13 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**

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### **Principal Investigator**

**Ronnie Aronson MD, FRCPC, FACE**

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

### **Sub Investigators**

**Samantha Sandler MD, FRCPC**

- 9 + years research experience
- > 50 clinical trials: Endocrinology & Metabolism

**Adam Telner MD, FRCPC, FACP**

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

**Andrew Boright MD, FRCPC, FACP**

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

**Loren David Grossman BSc, MD, FRCPC, FACP**

- 17 + years research experience
- > 50 clinical trials: Endocrinology & Metabolism

**Oren Steen MD**

- 1 year research experience
- 18 clinical trials: Endocrinology & Metabolism

**Priya Narula (Physician Assistant), BSc, CCPA**

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

### **Investigator Accountability**

40% research, 60% clinic

### **Investigator's Education and/or Academic Appointments**

**Speciality Areas: Endocrinology & Metabolism**

### **Education**

1998	Fellowship, American College of Endocrinology
1998	Certification, International Society Clinical Densitometry
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
1997-2014	Executive Director, LMC Diabetes & Endocrinology
2006-current	Tariff Chair, Ontario Medical Association Section of Endocrinology
1995-2000	Oakville Trafalgar Memorial Hospital

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### **Patient Population and Recruitment**

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#### **Number of patients**

> 110,000 for the database plus an additional 20,000 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**

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#### **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

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## **Facilities**

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### **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
- 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

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## 6 Contract

### Sites usual overhead

- 30% overhead

### Sites turnaround

- 1-2 week turnaround

### Budget Negotiations

- Director of Research: Karri Venn RD, CDE, CCRC, PMP  
Email: [karri.venn@lmc.ca](mailto:karri.venn@lmc.ca),  
Phone: 647 274-4133 cell

### Regulatory Documentation

- Regulatory & Clinic Specialist: Natalie Gibbs  
Email: [natalie.gibbs@lmc.ca](mailto:natalie.gibbs@lmc.ca)  
Phone: 416-645-2928 ext 316  
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