



# Pre Site Visit Questionnaire

## LMC Diabetes & Endocrinology (*Thornhill*)

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### Site Information

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#### Site location

LMC Diabetes & Endocrinology (Thornhill)  
531 Atkinson Avenue, Suite 17  
Thornhill, Ontario  
L4J 8L7

#### Contact Information:

905 763-8660 phone  
905 763-0708 fax  
800-701-ENDO (3636) Toll Free  
[thornhillresearch@lmc.ca](mailto:thornhillresearch@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 2 - 4 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 16 years

#### Has the site been audited?

- FDA audit (Oct 2014) – No Form 483
- FDA audit (June 2011) – No Form 483
- Health Canada audit (February 2009) - fully compliant

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- Sponsor audit for highest enrolling - positive findings only

## Emergency response

- North York General Hospital Branson Site 3 km
- York Central Hospital 2 km
- All staff are CPR certified annually

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## Study Staff

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### Principal Investigator

**Robert Schlosser MD, FRCPC**

- 18+ years research experience
- >163 clinical trials: Endocrinology & Metabolism

### Sub Investigators

**Ronald Goldenberg MD, FRCPC, FACE**

- 18+ years research experience
- >160 clinical trials: Endocrinology & Metabolism

**David Sionit MD**

- 2+ year research experience
- >16 clinical trials: Endocrinology & Metabolism

**Amanda Warwick (Physician Assistant), PA-C, MSHS**

- 3+ years research experience
- >14 clinical trials: Endocrinology & Metabolism

### Investigator Accountability

25% research, 75% clinic

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

#### Speciality Areas: Endocrinology & Metabolism

##### Education

2016	Transclerate GCP Training
1992	Certification, Endocrinology & Metabolism Royal College of Physicians & Surgeons, American Board of Internal Medicine
1991	Fellowship, Royal College of Physicians & Surgeons of Canada
1991	Certification, Internal Medicine, Royal College of Physicians & Surgeons of Canada, American Board of Internal Medicine
1991	Residency, Internal Medicine, University of Toronto, Toronto, Ontario
1987	Doctor of Medicine, with Honours, University of Toronto, Toronto, Ontario

##### Appointments

2017-Present Principal Investigator, LMC Diabetes & Endocrinology

1998-Present	Sub-Investigator, LMC Diabetes & Endocrinology
1998- Present	Endocrinologist & Medical Co-Director, LMC Diabetes & Endocrinology
1993- Present	Staff Endocrinologist, Mackenzie Richmond Hill Hospital, Richmond Hill ON
1993- 2007	Diabetes Education Centre, Medical Director, Mackenzie Richmond Hill Hospital, Richmond Hill ON

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## Patient Population and Recruitment

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### Number of patients

>200,000 for the database plus an additional 24,000 per year and growing

### Capability of screening database

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

### Catchment area

Thornhill, Vaughan, Markham, Woodbridge & North York

### 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, internet, central toll free number and capability of central ad campaigns for all LMC sites
- Public forums & expos
- Community involvement - Pharmacy days, and local presentations

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## Ethics

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### Ethics committee (local or central)

- Central Ethics only
- 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

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### Equipment available

- Refrigerated centrifuge (calibrated yearly)
- ECG machine (Brentwood software) - calibrated daily
- 330 kg weight scale (calibrated yearly)
- 1 x -75 freezer
- 1 x medical fridge for study medication purposes only
- ABPM machine
- Manual and automatic blood pressure devices
- Epi-pen and benedryl
- Able to do PK analysis, injections & meal tolerance tests

### Office hours

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

### Monitoring space

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

### LMC Diabetes & Endocrinology SOP

- ERB & HC reviewed and approved

### Source documents

- LMC specific templates for source creation and study specific logs

### Drug accountability and storage

- Secured and Locked Drug Cabinets, Medical Fridge and Freezer
- Temperature monitored daily (min, max and average temperatures)
- Sensaphone (remote monitoring, early detection system)

### 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

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## Contract

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### 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](mailto:karri.venn@lmc.ca),  
Phone: 647 274-4133 direct line
- Research, President: Nichelle Farrell  
Email: [nichelle.farrell@LMC.ca](mailto:nichelle.farrell@LMC.ca)  
Phone: 416-645-2928 ext9205  
Fax: 416-645-2931

### Regulatory Documentation

- Regulatory Specialist: Natalie Gibbs  
Email: [natalie.gibbs@lmc.ca](mailto:natalie.gibbs@lmc.ca)  
Phone: 416-645-2928 ext 9316  
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