



Pre Site Visit Questionnaire

LMC Diabetes & Endocrinology (*Thornhill*)

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Site Information

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 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 14 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

Principal Investigator

Ronald Goldenberg MD, FRCPC, FACE

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

Sub Investigators

Robert Schlosser MD, FRCPC

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

David Sionit MD

- 1 year research experience
- > 9 clinical trials: Endocrinology & Metabolism

Rachel Shekhman (Physician Assistant), BHSc, CCPA

- 2 year research experience
- > 10 clinical trials: Endocrinology & Metabolism

Investigator Accountability

25% research, 75% clinic

Investigator's Education and/or Academic Appointments

Speciality Areas: Endocrinology & Metabolism

Education

1997	Fellowship, American College of Endocrinology
1989	Certification, Endocrinology & Metabolism; Royal College of Physicians & Surgeons, American Board of Internal Medicine
1988	Fellowship, Royal College of Physicians & Surgeons of Canada
1987	Certification, Internal Medicine; Royal College of Physicians & Surgeons, American Board of Internal Medicine
1989	Residency, University of Toronto
1984	Doctor of Medicine, University of Toronto, with honors

Appointments

2014-present	Associate Endocrinologist, LMC Diabetes & Endocrinologist
1999-2014	Endocrinologist & Medical Co-Director, LMC Diabetes & Endocrinology
1989-current	North York General Hospital, Staff Endocrinologist
2001-03	Diabetes Center, Medical Director, North York General Hospital
1991-03	Diabetes Education Center, Medical Director, North York General Hospital, Branson
1999-02	Ontario Medical Association, Chair, Section on Endocrinology and Metabolism
1998-99	Ontario Medical Association, Co-Chair, Section on Endocrinology and Metabolism
1996-02	Ontario Association of Endocrinologists, Chair

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Patient Population and Recruitment

Number of patients

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

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

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Facilities

Equipment available

- Refrigerated centrifuge (calibrated yearly)
- ECG machine (Brentwood software) - calibrated daily
- 330 kg weight scale (calibrated every 6 months)
- 1 x -75 freezer
- 1 x medical fridge for study medication purposes only
- ABPM machine (do we still have this?)
- 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

- 1 room dedicated to monitoring
- Phone, analog, wireless and broadband access

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

IVRS experience

- Clinphone
- S Clinica
- ICON

- Fisher Clinical Services
- Impala
- Almac

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

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

Regulatory Documentation

- Regulatory & Clinic Specialist: Natalie Gibbs
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