



# Pre Site Visit Questionnaire

## LMC Diabetes & Endocrinology (*Barrie*)

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### Site Information

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#### Site location

LMC Diabetes & Endocrinology (Barrie)  
370 Bayview Drive, Suite 110  
Barrie, Ontario  
L4N 7L3

#### Contact Information:

705-737-0830 phone  
705-737-0679 fax  
800-701-ENDO (3636) Toll Free  
<mailto:barrieresearch@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 enrolling studies with 6 maintenance studies

#### How long has the site been involved in clinical research?

Site has been doing research for 8 years

#### Has the site been audited?

- No FDA audit
- No Health Canada audit
- Sponsor audits for highest enrolling - positive findings only

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## Emergency response

- Royal Victoria Hospital (<12 km from site)
- All staff are CPR certified annually

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## Study Staff

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### Principal Investigator

*Hani Alasaad MBBS, DABIM, FRCPC, FACP, FACE*

- 3+ years research experience
- > 20 clinical trials: Endocrinology & Metabolism

### Sub Investigators

*Suzan Abdel-Salam MD*

- 7+ years research experience
- > 27 clinical trials: Endocrinology & Metabolism

*Gul-E-Rana BScPA, CCPA*

- <1 year research experience
- > 10 clinical trials: Endocrinology & Metabolism

### Investigator Accountability

20% research, 80% clinic

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

#### Speciality Areas: Endocrinology & Metabolism

##### Education

2016	GCP Training	Transclerate GCP Training
1989-1990	Rotating Internship	King Khalid University Hospital and affiliated hospitals, Riyadh, Saudi Arabia
1990-1994	Residency in Internal Medicine	Security Forces Hospital and Riyadh Medical Complex, Riyadh Saudi Arabia
1994-1997	Residency in Internal Medicine	Dalhousie University affiliated hospitals, Halifax, Nova Scotia, Canada
1997-1999	Fellowship in Endocrinology Diabetes & Metabolism	Dalhousie University affiliated hospitals, Halifax, Nova Scotia, Canada

##### Appointments

2012-present	Associate, Endocrinologist	LMC Diabetes & Endocrinology
2000-2012	Consultant Internist / Endocrinologist	Division of Endocrinology, Department of Medicine, Security Forces Hospital, Riyadh, Saudi Arabia
1999-2000	Senior Registrar	Security Forces Hospital, Riyadh, Saudi Arabia

1997-1999	Fellow in Endocrinology, Diabetes and Metabolism	Victoria General Hospital, Halifax Infirmary, Queen Elizabeth II Health Sciences Center, Camphill Medical Center and Abby J. Lane Center at Dalhousie University, Halifax, Canada
1996-1997	Senior Resident in Internal Medicine	Victoria General Hospital, Halifax Infirmary and Camphill Medical Center, Dalhousie University, Halifax, Canada
1994-1996	Junior Resident in Internal Medicine	Victoria General Hospital, Dalhousie University, Halifax, Canada
1990-1994	Resident in Internal Medicine	Security Forces Hospital and Riyadh Medical Complex, Riyadh, Saudi Arabia
1989-1990	Rotation Intern	King Khalid University Hospital, Riyadh, Saudi Arabia

### 3 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

Barrie, Innisfil, Midland, Collingwood, Orillia, Bradford, Newmarket, Alliston, Wasaga, Stayner, Meaford & Thornbury

#### 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

### 4 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

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## **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 -20 freezers
- 1 x fridge for study medication purposes only
- 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
- 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 cell
- Budgets and Contracts: 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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