



# Pre Site Visit Questionnaire

## LMC Diabetes & Endocrinology (*Brampton*)

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### Site Information

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#### Site location

LMC Diabetes & Endocrinology (Brampton)  
2130 North Park Drive, Suite 238  
Brampton, ON  
L6S 0C9

#### Contact Information:

905 595 0560 phone  
905 595 0562 fax  
800-701-ENDO (3636) Toll Free  
[bramptonresearch@lmc.ca](mailto:bramptonresearch@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 4 maintenance studies

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

Site has been doing research for 6 years

#### Has the site been audited?

- No FDA audit
- No Health Canada audit
- Sponsor audit for highest enrollment – positive findings only

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## Emergency response

- William Osler Hospital - 2 km from site
- All staff are CPR certified annually

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## Study Staff

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### Principal Investigator

**Harpreet Bajaj MBBS, MPH, DAIBM**

- 7+ years research experience
- > 44 clinical trials: Endocrinology & Metabolism

### Sub Investigators

**Prakash Chandra MBBS, MS, DABIM**

- 5+ years research experience
- > 29 clinical trials: Endocrinology & Metabolism

**Nupur Bahl MD**

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

**Keerat Singh BScPA**

- <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
1995-99	Bachelor of Medicine and Bachelor of Surgery	Maulana Azad Medical College, University of Delhi, India
2002-04	Master of Public Health (MPH), Epidemiology	University of Albany SUNY, NY

##### Appointments

2000-01	Clinical Internship
2001-02	Junior Residency (Externship) in Emergency Medicine
2004-07	Internship and Residency in Internal Medicine
2007	GCP Training (CITI Collaborative Institutional Training Initiative)
2007-09	Clinical Fellowship in Endocrinology, Diabetes and Metabolism
2009-current	Associate Endocrinologist, LMC Diabetes & Endocrinology

## 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

Brampton, Streetsville, Caledon, Malton, Georgetown, Mississauga

### 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

## 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 -70 freezer
- 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 Fridges and Freezers
- 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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## 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](mailto:karri.venn@lmc.ca),  
Phone: 647-274-4133 direct line
  
- 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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