



Pre Site Visit Questionnaire

LMC Diabetes & Endocrinology (*Brampton*)

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Site Information

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 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 4 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

Principal Investigator

Harpreet Bajaj MD, MPH, D. ABIM

- 6+ years research experience
- > 40 clinical trials: Endocrinology & Metabolism

Sub Investigators

Prakash Chandra MD, MS, D.ABIM

- 4+ years research experience
- > 23 clinical trials: Endocrinology & Metabolism

Investigator Accountability

20% research, 80% clinic

Investigator's Education and/or Academic Appointments

Speciality Areas: Endocrinology & Metabolism

Education

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

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

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

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

Equipment available

- Refrigerated centrifuge (calibrated yearly)
- ECG machine (Brentwood software) - calibrated daily
- 330 kg weight scale (calibrated every 6 months)
- 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

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*

IVRS experience

- *Clinphone*
- *S Clinica*
- *ICON*
- *Fisher Clinical Services*
- *Impala*

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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