



# Pre Site Visit Questionnaire

## LMC Manna Research (Etobicoke)

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### Site Information

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#### Site location

LMC Manna Research (Etobicoke)  
1723 Kipling Avenue, Suite 2B  
Etobicoke, Ontario  
M9R 4E1

#### Contact Information:

416 645-1035 phone  
416 645-1036 fax  
800-701-ENDO (3636) Toll Free  
[etobicokeresearch@lmc.ca](mailto:etobicokeresearch@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)
- Member of the Canadian Association of Independent Clinical Research (CAICR)

#### Number of studies capable per site

8-12 enrolling studies with 10-14 maintenance studies

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

Site has been doing research for 9 years

#### Has the site been audited?

- No FDA audit
- Health Canada audit (August 2014) – Fully compliant

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- Sponsor audit for highest enrolling - positive findings only

## Emergency response

- Humber River Regional Hospital 5 km
- All staff are CPR certified annually

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## Study Staff

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### Principal Investigator

*Hasnain Khandwala MB, BS, FRCPC*

- 12+ years research experience
- > 78 clinical trials: Endocrinology & Metabolism

### Sub Investigators

*Nadeem Aslam, MBBS, FACE, FACP*

- 19+ years research experience
- > 37 clinical trials: Endocrinology & Metabolism

*Jonathan Vecchiarelli, MD, FRCP*

- 3+ 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

2017	GCP Training	Transcelerate GCP Training
1987-93	MBBS	Dow Medical College, Karachi
1995-98	Residency in Internal Medicine	Wayne St. University, Detroit, MI
1998	Certification in Internal Medicine	American Board of Internal Medicine
1998-00	Fellowship in Endocrinology	Baylor College of Medicine, Houston, TX
2000	Certification in Endocrinology Diabetes & Metabolism	American Board of Internal Medicine
2003	Certification in Internal Medicine	Royal of Physician & Surgeons of Canada
2003	Certification in Endocrinology & Metabolism	Royal of Physician & Surgeons of Canada

### **Appointments**

2006-Present	Principal Investigator, LMC Clinical Research Inc.
2006-Present	Associate Endocrinologist, LMC Diabetes & Endocrinology
2000-06	Associate Professor of Medicine, Division of Endocrinology, University of Saskatchewan, Saskatoon, SK
2000-06	Attending Physician, Royal University Hospital, Saskatoon, SK

## **3**

### **Patient Population and Recruitment**

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#### **Number of patients**

> 200,000 for the database plus an additional 30,000 per year (60% diabetes) – all of LMC Diabetes & Endocrinology locations

#### **Capability of screening database**

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

#### **Catchment area**

Etobicoke, Malton, Brampton & Mississauga

#### **How are subjects recruited to meet the agreed upon targets?**

- Patient database – able to query for study candidates
- GP & Specialist referral network
- Diabetes triage - rapid assessment for newly diagnosed T1D & T2D 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|Manna sites
- Community engagement - public forums, pharmacy days, educational events & expos
- E-recruitment & social media campaigns – patient advocates & testimonials

## **4**

### **Ethics**

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#### **Ethics committee (local or central)**

- Central Ethics only
- Worked with IRB Services, Schulman (Advarra), Quorum, WIRB, Veritas, Canadian Shield, Optimum, etc.

#### **Informed consent process**

- See LMC|Manna Research SOPs
- GCP/ICH Compliant

#### **Confidentiality**

- PIPEDA

## 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 -20 freezers
- 2 x fridge for study medication purposes only
- Manual and automatic blood pressure devices
- Digital ear thermometer
- Epi-pen and benedryl
- Able to do PK analysis, injections & meal tolerance tests (MTT)

### 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

### Source documents

- LMC|Manna Research 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)
- Pharmacy for study-specific storage and dispensing requirements
- Back-up generator available

### 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 – locked cabinets
  - Paper charts / electronic medical records – clinic chart & certified copy for paper research chart
- 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

### Legal Name

- LMC Clinical Research Inc.

### Site Name

- LMC Clinical Research Inc. (Etobicoke)

### Sites turnaround

- 1-2 week turnaround

### Budget Negotiations

- Budgets and Contracts Specialist: Nichelle Farrell  
Email: [nichelle.farrell@LMC.ca](mailto:nichelle.farrell@LMC.ca)  
Phone: 416-645-2928 ext 9205  
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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