



# Pre Site Visit Questionnaire

## LMC Manna Research (Bayview)

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### Site Information

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#### Site location

LMC Manna Research (Bayview)  
107-1929 Bayview Avenue  
Toronto, Ontario  
M4G 3E8

#### Contact Information:

416 645-2929 phone  
416 645-2930 fax  
833-323-JOIN (5646) Toll Free  
[torontoresearch@lmc.ca](mailto:torontoresearch@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 I - IV Experience

#### Description of site

- Private Clinic
- Ministry of Health Funded Diabetes Education Center
- Private Clinical Research Center

#### 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 16 years

#### Has the site been audited?

- No FDA audit
- Health Canada audit (February 2008) - fully compliant

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- Sponsor audits for highest enrolling - positive findings only

## Emergency response

- Sunnybrook Women's College Hospital 500 meter
- All staff are CPR certified annually and some staff ACLS certified

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## Study Staff

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### Principal Investigator

#### **Ronnie Aronson MD, FRCPC, FACE**

- 19+ years research experience
- > 210 clinical trials: Endocrinology & Metabolism

### Sub Investigators

#### **Alexander Abitbol MD, FRCPC, FACE**

- 3+ years research experience
- > 31 clinical trials: Endocrinology & Metabolism

#### **Samantha Sandler MD, FRCPC**

- 12+ years research experience
- > 65 clinical trials: Endocrinology & Metabolism

#### **Adam Telner MD, FRCPC, FACP**

- 8+ years research experience
- > 50 clinical trials: Endocrinology & Metabolism

#### **Andrew Boright MD, FRCPC, FACP**

- 7+ years research experience
- > 45 clinical trials: Endocrinology & Metabolism

#### **Loren David Grossman BSc, MD, FRCPC, FACP**

- 20+ years research experience
- > 65 clinical trials: Endocrinology & Metabolism

#### **Oren Steen MD**

- 4+ years research experience
- > 35 clinical trials: Endocrinology & Metabolism

#### **Alexander Abitbol MD**

- 3+ years research experience
- > 31 clinical trials: Endocrinology & Metabolism

#### **Priya Narula (Physician Assistant), BSc, CCPA**

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

## Investigator Accountability

40% research, 60% clinic

## Investigator's Education and/or Academic Appointments

### Speciality Areas: Endocrinology & Metabolism

#### Education

2016	GCP Training, Transclerate
2015	Advanced Cardiac Life Support Certification, ACLS Certification Institute
1998	Fellowship, American College of Endocrinology
1995	Certification, Endocrinology & Metabolism; Royal College of Physicians American Board of Internal Medicine
1995	Fellowship, Internal Medicine; Royal College of Physicians
1995	Certification, Internal Medicine; Royal College of Physicians American Board of Internal Medicine
1991	General License; College of Physicians & Surgeons, Ontario
1990	Doctor of Medicine; University of Toronto
1990	Licentiate; Medical Council of Canada

#### Appointments

2014-present	Medical Director, LMC Diabetes & Endocrinology
1997-2014	Executive Director, LMC Diabetes & Endocrinology
2006-present	Tariff Chair, Ontario Medical Association Section of Endocrinology
1995-2000	Oakville Trafalgar Memorial Hospital

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## 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

All of Toronto – 6 million lives

### 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

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## Ethics

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### Ethics committee (local or central)

- Central Ethics
- 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

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## Facilities

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### Equipment available

- Refrigerated and room temperature centrifuges (calibrated yearly)
- 2 x Microcentrifuges Minispin Plus
- 3 x YSI Glucose and Lactate Analyzer
- 3 x ECG machine (Brentwood software) - calibrated daily
- 330 kg weight scale (calibrated yearly)
- 1 x -20 freezer (calibrated yearly)
- 2 x -70 freezer (calibrated yearly)
- 4 x medical fridge for study medication purposes only (calibrated yearly)
- ABPM machine
- Manual and automatic blood pressure device
- Digital ear thermometer
- Epi-pen and benedryl
- Emergency crash cart
- Defibrillator
- Able to do PK analysis, injections, glucose clamping, meal tolerance (MTT) & VO<sub>2</sub> max tests

### Office hours

- Monday - Friday (7:30 am - 6:00 pm) – late phase
- Weekends as needed – late phase
- CPU – 24 hours per day / 7 days per week

### Monitoring space

- 3 rooms dedicated to monitoring
- Phone, analog, wireless and broadband access
- Access to a fax and photocopy machine

## LMC|Manna Research 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 Fridges and Freezers
- 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

## 6 | Contract

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### Sites usual overhead

- 30% overhead

### Legal Name

- LMC Clinical Research Inc.

### Site Name

- LMC Clinical Research Inc. (Bayview)

### Sites turnaround

- 1-2 week turnaround

### Budget Negotiations

- Budgets and Contracts: 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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