



# Pre Site Visit Questionnaire

## LMC Manna Research (*Montreal Glen*)

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### Site Information

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#### Site location

LMC Manna Research (Montreal Glen)  
5325 Crowley Avenue, Suite 301  
Montreal, Quebec  
H4A 2C6

#### Contact Information:

438 802-4536 phone  
438 738-4144 fax  
800-701-ENDO (3636) Toll Free  
yaleresearch@LMC.ca

#### 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

6-8 enrolling studies with 10 maintenance studies

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

Site has been doing research for >1 years

#### Has the site been audited?

- No FDA audit
- No Health Canada audit

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- No Sponsor audit

## Emergency response

- Montreal General Hospital 1.5 km
- Royal Victoria Hospital 5.4km
- All staff are CPR certified annually

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## Study Staff

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### Principal Investigator

*Jean-François Yale MD, CSPO*

- 31+ years research experience
- > 103 clinical trials: Endocrinology & Metabolism

### Sub Investigators

*Wen Hu MD, FRCPC*

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

*Mark Sherman MDCM, FRCPC*

- 11+ years research experience
- >53 clinical trials: Endocrinology & Metabolism

### Investigator Accountability

25% research, 75% clinic

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

#### Speciality Areas: Endocrinology & Metabolism

##### Education

2017	Transclerate GCP Training
1983-1985	Post-Doctoral Fellow, McGill Nutrition, McGill University
1983	Certification in Endocrinology, Centre de services partagés du Québec
1980	License Registration, Corporation Professionnelle des Médecins du Québec
1980	License of the Medical Council of Canada
1975-1979	Doctor of Medicine, Université de Sherbrooke

##### Appointments

2017-present	Principal Investigator, LMC Clinical Research Inc.
2017-present	Associate Endocrinologist, LMC Diabetes & Endocrinologist
2001-present	Geographical Full-Time Professor, Department of Medicine, McGill University
2000-present	Senior Physician with Admitting Privileges special privileges <i>in vitro</i> radioisotopes, Department of Medicine, McGill University Health Centre
1991-2008	Director, Metabolic Day Centre, Royal Victoria Hospital
1991-2005	Consultant, >35 Associations, Companies & Governments

1991-2001	Assistant Physician with Admitting Privileges, special privileges <i>in vitro</i> radioisotopes, Department of Medicine, Royal Victoria Hospital
1990-present	Associate Member in the School of Dietetics and Human Nutrition, Faculty of Agriculture and Environmental Sciences, McGill University
1985-1991	Geographical Full-Time Assistant Professor, Department of Medicine and Nutrition and Food Science, McGill University
1985	Assistant Physician with Admitting Privileges, Department of Medicine, Royal Victoria 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

Montreal area

### 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 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 freezer
- 1 x medical fridge for study medication purposes only
- ABPM machine
- 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

- 2 rooms 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

### 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  
1655 Fleetwood  
Laval, Quebec H7N 4B2  
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. (Montreal Glen)

### Sites turnaround

- 1-2 week turnaround

### Budget Negotiations

- Budget & Contract: 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 & Clinic Specialist: Natalie Gibbs  
Email: [natalie.gibbs@lmc.ca](mailto:natalie.gibbs@lmc.ca)  
Phone: 416-645-2928 ext 9316  
Fax: 416-645-2931  
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