



# Pre Site Visit Questionnaire

## Manna Research (*Montreal*)

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### Site Information

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#### Site location

Manna Research (Montreal)  
175 Stillview, Suite 145  
Pointe Claire, QC  
H9R 4S3

#### Contact Information:

514 694-9940 phone  
514 694-5594 fax  
844-26-MANNA (62662) toll free  
[research@mannaresearch.com](mailto:research@mannaresearch.com) email

#### Specific clinical studies of interest

- Allergy
- Depression
- Dermatology
- Diabetes
- Digestive Disorders
- Cholesterol
- Infectious Disease
- Men's Health
- Pain & Neurology
- Obesity
- Respiratory Disease
- Rheumatology
- Urology
- Vaccines
- Women's Health

Phase II - IV Experience

#### Description of site

- Private Clinical Research Centre

#### Memberships

- Member Association of Clinical Research Professionals (ACRP)
- Member of Society of Clinical Research Associates (SOCRA)

#### Number of studies capable per site

5 enrolling studies with 4 maintenance studies

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

Site has been doing research for 17 years

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## Has the site been audited?

- Health Canada audit (March 2009) - fully compliant
- Sponsor audits for highest enrolling - positive findings only
  
- **Emergency response**
- All staff are CPR certified annually
- Lakeshore Hospital (2 minutes from the clinic)
- AED in the building

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## Study Staff

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### Principal Investigator

#### **Laurie Breger MD, CCFP, MCC**

- 17+ years research experience
- > 165 clinical trials: Respiratory, Cardiovascular, Gastrointestinal, Obesity, Diabetes, Vaccines, Psychiatry, Osteoarthritis, Lipids, Women's studies, Urology, Gout, Allergies

#### **Education**

1984	Certification, College of Family Physicians of Canada
1991	Diplomate of the National Board of Medical Examiners, USA
1978	Collège Professionnelle des Medecins du Quebec
1978	Licentiate; Medical Council of Canada

#### **Appointments**

2013-present	Principal Investigator, Manna Research (formely Kells Medical Research Group)
1998-2013	Associate Medical Director, Kells Medical Research Group
1996-present	Lecturer, McGill University
1998-present	Director, GBMC Medical Services Inc.
1979-present	General Practitioner Family Practice, Point Claire, Quebec

#### **Mirela Mitrica MD, CCFP, MCC**

- 4 + years research experience
- > 38 clinical trials: Cardiology, Lipids, Diabetes, Allergies, Women's studies

#### **Education**

2006	Certification in Family Medicine, College of Family Physicians of Canada
2006	Certification in Family Medicine, College of Family Physicians of Quebec
2003	Licentiate; Medical Council of Canada

#### **Appointments**

2013-present	Principal Investigator, Manna Research (formely Kells Medical Research Group)
2011-2013	Investigator, Kells Medical Research Group

2006-present     Family Physician, GMF Stillview and Statcare  
2011-present     Chief of Geriatric Service, CHSLD LaSalle  
2009-present     Treating Physician, CHSLD LaSalle

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### Patient Population and Recruitment

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#### Number of patients

Database of > 100,000 patients

#### Capability of screening database

Yes – access to EMR database and clinic charts

#### Catchment area

Montreal, West Island

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

- Patient database
- GP & Specialist referral network
- Advertising - radio, newspaper, central toll free number and capability of central ad campaigns for all LMC and Manna sites
- E-recruitment campaign

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### Ethics

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#### Ethics committee (local or central)

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

#### Informed consent process

- See Manna Research SOPs
- GCP/ICH Compliant

#### Confidentiality

- PIPEDA and CAI implemented
- CAI compliant

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## Facilities

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### Equipment available

- Centrifuge (calibrated yearly)
- ECG machine
- weight scale (calibrated biannually)
- 1 x -20 freezer
- 2 x fridge for study medication purposes only
- Manual blood pressure devices
- Able to do PK analysis, injections & meal tolerance tests

### Office hours

- Monday - Friday (7:30 am - 6:00 pm)
- Weekends as needed

### Monitoring space

- 3 rooms dedicated to monitoring
- Phone, analog, wireless and broadband access

### Manna Research SOPs

- ERB & HC reviewed

### Source documents

- Manna 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)

### eCRF experience

- *INFORM*
- *INET*
- *RDC*
- *ORACLE*
- *PHOSCO*
- Medidata RAVE

### 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
  - 1655 Fleetwood
  - Laval, Quebec H7N 4B2

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## Contract

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### Sites usual overhead

- 30% overhead

### Sites turnaround

- 1-2 week turnaround

### Budget Negotiations

- Director of Business Development: Alysa Langburt
  - Email: [alysa.langburt@mannaresearch.com](mailto:alysa.langburt@mannaresearch.com)
  - Phone: 514-806-3055

### Regulatory Documentation

- Regulatory Specialist: Brenda Pollock
  - Email: [Brenda.pollock@mannaresearch.com](mailto:Brenda.pollock@mannaresearch.com)
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