



# Pre Site Visit Questionnaire

## Manna Research (*Montreal*)

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### Site Information

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#### Site location

Manna Research Inc. (Montreal)  
175 Stillview Road, 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 Investigators

### **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

**Jeannette Janzen, MD, CCFP**

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

**Education**

1988 Family Medicine Residence, C.C.F.P., St. Mary’s Hospital  
 1987 Rotating Internship, St. Mary’s Hospital  
 1986 M.D., University of Saskatchewan  
 1980 Diploma in Biblical Studies, Columbia Bible Institute

**Appointments**

2013-present Principal Investigator, Manna Research Inc.  
 2008-Present Medical Director, Pre-Travel Medicine  
 2004-present CHSLD, Chateau Sur La Lac  
 1998-2013 Associate Medical Director, Kells Medical Research Group  
 1998-present Private Family Medicine Practice, GMF Stillview  
 1988-Present Minor Emergency, Statcare Clinic  
 1994-1998 Palliative Care Unit, Chronic Geriatric Unit, Mount Sinai Hospital  
 1994-1997 Treatment of snoring problems/Tracking of Sleep Apnea disorders, West Island Snoring Clinic  
 1989-1993 Health Services, John Abbott College  
 1988 General Health Locum, Dr. R. Sawatsky  
 1988 General Health Locum, Dr. D. Furlong

**Naveen Garg, MD**

- 1 + year research experience
- > 10 clinical trials: Respiratory, Cardiovascular, Obesity, Diabetes, Lipids, Women’s studies

**Education**

Sep 2011-Present Level 1: Certificate Course in Aesthetic Medicine - American Academy of Aesthetic Medicine, California  
 Level 2: Diploma Course in Aesthetic Medicine  
 Aug 2011-May 2013 Physician’s Executive MBA, Auburn University-College of Business, Auburn  
 Jul 2008-Jun2011 Family Medicine Residency & Chief Resident - University of Connecticut/St. Francis Hospital, Hartford  
 Integrative Medicine Residency  
 Sep 2004-Mar 2008 Doctor of Medicine, Saba University School of Medicine, Netherlands  
 Sep 2001-May2004 Bachelor of Science, Physical Therapy, McGill University, Montreal  
 Aug 1999-May 2001 D.E.C., Natural Sciences, John Abbott College, Montreal

**Appointments**

Mar 2017-Present Principal Investigator/ Sub-Investigator, Manna Research Inc.  
 Mar 2012-Present President, Naveen Garg Medical Services Inc. , Montreal  
 Mar 2012-Present Family Practice, GMF Stillview, Montreal  
 Mar 2012-Present Walk-in Physician, Statcare Walk-in Clinic, Montreal  
 Mar 2012-Present Sports Medicine Physician, Concordia Physio Sport, Montreal  
 Jul 2010-Jun 2011 Chief Resident, Family Medicine Residency Program, University of Connecticut, Hartford  
 University of Connecticut, Hartford  
 St. Francis Hospital, Hartford,  
 Jul 2008-Jun 2011 PGY 1-3: Family Medicine Resident- Asylum Hill Family Medicine Center, Hartford  
 Connecticut Children’s Medical Center, Hartford  
 Jul 2008-Mar 2008 Medical Student in Various Departments and Specialities, Lincoln Medical & Mental Health Center  
 May 2003-Aug 2004 Physiotherapist for Research on Stroke & Breast Cancer Patients, Royal Victoria Hospital, Montreal

Mar 2002-Mar 2004      Physiotherapy Student, McGill University Hospitals, Montreal

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## **3**      **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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## **4**      **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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## **5**      **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

## 6 | Contract

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### **Sites usual overhead**

- 30% overhead

### **Sites turnaround**

- 1-2 week turnaround

### **Budget Negotiations**

- Business Development Director: Alysa Langburt  
Email: alysa.langburt@lmc.ca  
Phone: 514-806-3055

### **Regulatory Documentation**

- Regulatory Specialist: Dennis Kha  
Email: dennis.kha@lmc.ca  
Phone: 416-645-2928 ext 9370  
Fax: 416-645-2931  
Address: 1929 Bayview Avenue, Suite 106  
Toronto, Ontario M4G 3E8