



# Pre Site Visit Questionnaire

## Manna Research (*Montreal*)

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### Site Information

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#### Site location

Manna Research (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 of the Society for Clinical Research Sites (SCRS)
- Member of the Canadian Association of Independent Clinical Research (CAICR)

#### 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 18 years

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PI has 20+ years experience with clinical trials

### 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**

- 18+ 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

#### **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**

- 2 + year research experience
- > 15 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
Jul 2008-Jun 2011	PGY 1-3: Family Medicine Resident- St. Francis Hospital, Hartford, 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

**Investigator Accountability**

20% research, 80% clinic

**3****Patient Population and Recruitment****Number of patients**

Database of > 100,000 patients

## Capability of screening database

Yes – able to note demographic information, medications, IICD-9 codes, medical history, lab values and medical documents

## Catchment area

Montreal, West Island

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

- Patient database
- Clinic referrals
- GP & Specialist referral network
- 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, 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
- 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 medication room, Fridges and Freezer
- Temperature monitored twice daily (min, max and average temperatures). Space for un-blinded medication preparation

## eCRF experience

- *INFORM*
- *RDC*
- *ORACLE*
- *BIRT*
- *Medidata RAVE*
- *Datalabs*
- *Medrio*

## IVRS experience

- Clinphone
- Clintrak
- Endpoint
- ICON
- Fisher Clinical Services
- Impala
- Perceptive
- Almac
- Cardinal

## Data storage

- In house:
  - Lead study coordinator's office
  - Paper charts
  - Electronic medical records (printed paper copy, certified copy)
- 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

### Legal Name

- LMC Clinical Research Inc. d.b.a. Manna Research

### Site Name

- Manna Research (Montreal)

### 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: Dennis Kha  
Email: [dennis.kha@lmc.ca](mailto:dennis.kha@lmc.ca)  
Phone: 416-645-2928 ext 9370  
Fax: 416-645-2931  
Address: 1929 Bayview Avenue, Suite 106  
Toronto, Ontario M4G 3E8