



# Pre Site Visit Questionnaire

## Manna Research (*Mirabel*)

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### Site Information

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#### Site location

Manna Research (Mirabel)  
101-13714 du Cure-Labelle  
Mirabel, QC  
J7J 2K8

#### Contact Information:

450-420-0270 phone

450-420-0259 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

8-10 enrolling studies with 20-25 maintenance studies

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

Site has been doing research for 13 years

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PI has 27 years experience with clinical trials

### Has the site been audited?

- Health Canada audit (Sep 2010) - fully compliant
- FDA audit (Jun 2011) – fully compliant
- Sponsor audits for highest enrolling - positive findings only

### Emergency response

- All staff are CPR certified annually
- Crash Cart
- AED in clinic next door
- Hospital De Saint-Jérôme Cissss Saint-Jérôme(9km's from the clinic)

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## Study Staff

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### Principal Investigator

#### **Guy Tellier, MD**

- 27+ years research experience
- > 100+ clinical trials: Respiratory, Cardiovascular, Gastrointestinal, Obesity, Diabetes, Vaccines, Psychiatry, Osteoarthritis, Lipids, Women's studies, Urology, Gout, Allergies, etc.

#### **Education**

1982-1983	Medical Council of Canada Licence (M.C.C.L.), Medical Intern Hôpital Saint-Luc, and Hôpital Sainte-Justine, Montréal, Québec, Canada
1977-1982	University of Montréal, Medical Doctorate, Faculty of Medicine, Montréal, Québec, Canada (Permit # 83181)
1975-1977	Édouard-Montpetit College, Longueuil, Québec, Canada, College diploma in Health Sciences

#### **Appointments**

2013-ong.	Family Doctor, Clinique médicale Mirabel, Mirabel, Québec, Canada
2006-ong.	Emergency Physician in private clinic, Clinique médicale Mirabel, Mirabel, Québec, Canada
1983-2006	Physician in the Emergency Department at the Hôtel-Dieu Hospital in Saint-Jérôme, the Clinique médicale Saint-Antoine, the Clinique médicale Saint-Jérôme and the Polyclinique Saint-Jérôme, Saint-Jérôme, Québec, Canada
1987-1996	Emergency Physician in private clinic, Clinique médicale Saint-Sauveur, Québec, Canada
1987-1997	Emergency Physician in private clinic, Clinique médicale de Rosemère, Québec, Canada
1987-1995	Emergency Physician private clinic, Clinique familiale des Basses-Laurentides (Lafontaine), Québec, Canada
1988-1992	Member of Crash Team, this team was responsible for answering medical calls in case of a disaster at Mirabel International Airport in Mirabel. There were many simulated disasters during my time there. Mirabel, Québec, Canada
1987-1996	Emergency Physician in private clinic at the Clinique médicale of Blainville, Québec, Canada
1987-1992	Emergency Physician in private clinic at the Centre médical des Laurentides (Saint-Lin)
1985-1986	Emergency physician for distant regions, Lasarre Québec, Canada
1983-1986	General Partitionner at Clinique médicale de Saint-Jérôme, Saint-Jérôme, Québec, Canada

## Sub-Investigator

### ***Gilbert Gagne, MD***

- 13+ years research experience
- > 90+ clinical trials: Respiratory, Cardiovascular, Gastrointestinal, Obesity, Diabetes, Vaccines, Psychiatry, Osteoarthritis, Lipids, Women's studies, Urology, Gout, Allergies, etc.

### ***Education***

2018	ARP/ACSM Certified Ringside Physicians
1989-1992	Medical Intern Family Medicine, CHUL, Hôpital Saint-François-d'Assise, Québec, Québec, Canada
1989	Medical Council of Canada Licence (M.C.C.L.)
1984-1989	University Montréal, Québec, Québec, Canada – Medical Doctorate, Faculty of Medicine
1982-1984	Health Sciences, College diploma, Stanislas French College

### ***Appointments***

2016-ong.	Associate member, Family medicine unit, Saint-Jérôme, Québec, Canada
2014-ong.	Examinator, The College of Family Physicians of Canada
2014-ong.	Professional Boxing Physician
2005-ong.	Sub-Investigator, Omnispec clinical research inc., Mirabel, Québec, Canada
2004-ong.	Elderly cares Physician in private clinic, Manoir Chomedey, Laval, Québec, Canada
1999-ong.	Sports Medicine Physician, Clinique sportive Synergie, Laval, Québec, Canada
1999-ong.	Family Medicine Physician Clinique médicale Mirabel, Mirabel, Québec, Canada
	Family Medicine Physician, CLSC Arthur-Buies, Saint-Jérôme, Québec, Canada
1994-1998	Family Medicine Physician, Centre hospitalier Laurentien, Sainte-Agathe, Québec, Canada
1993-1994	Emergency Physician, Hôpital Jean-Talon, Montréal, Québec, Canada
	Emergency Physician, Hôpital Saint-Luc, Montréal, Québec, Canada
1992-1993	Family Medicine Physician, Hotel-Dieu de Saint-Quentin, Saint-Quentin, New-Brunswick, Canada

## Investigator Accountability

40% research, 60% clinic

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## Patient Population and Recruitment

### Number of patients

Database of > 50,000 patients

### Capability of screening database

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

### Catchment area

Mirabel and surrounding area

### 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 implemented

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## Facilities

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### Equipment available

- Centrifuge (calibrated yearly)
- ECG machine
- weight scale (calibrated biannually)
- 1 x -20 freezer
- 1 x -70 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 (8:00 am - 4:00 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 I 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*
- *INET*
- *RDC*
- *ORACLE*
- *PHOSCO*
- Medidata RAVE

## 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)

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## 6 | Contract

### Sites usual overhead

- 30% overhead

### Legal Name

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

### Site Name

- Manna Research (Mirabel)

## **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  
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