



Pre Site Visit Questionnaire

Manna Research Inc. (*Burlington North*)

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Site Information

Site location

Manna Research Inc. (Burlington North)
2951 Walkers Line, Second floor
Burlington, ON
L7M 4Y1

Contact Information:

416 294 0724 phone
289-812-0225 fax
lydia.frost@lmc.ca email

Specific clinical studies of interest

- Allergy
- Depression
- Dermatology
- Diabetes
- Digestive Disorders
- Cholesterol
- Cardiovascular
- 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 Center

Number of studies capable per site

3-5 enrolling studies with 8-10 maintenance studies

How long has the site been involved in clinical research?

Site has been doing research for 8 years
PI has 8 years experience with clinical trials

Has the site been audited?

- Health Canada audit (2013) - fully compliant

Emergency response

- All staff are CPR certified annually
- Oakville Trafalgar Memorial Hospital (8.4 km)
- Crash cart, oxygen, and defibrillator on site

2**Study Staff****Principal Investigator****Timothy Salter, MD**

- 8+ years research experience
- > 50+ clinical trials: Primary Care

Education

1977 – 1979	Chief Resident, Family Practice Program	University of Toronto
1973 – 1977	MD	University of Toronto
1969 – 1973	Bachelor of Science	McMaster University

Professional Activities

2016 -Present	Principal Investigator/ Sub-Investigator	Manna Research Inc.
2011 -Present	Principal Investigator/ Sub-Investigator	Aviva Clinical Trials
2003 – Present	Family Practice Physician	Halton Family Health
1979 – Present	Active Admitting Member	Joseph Brant Memorial Hospital

Sub Investigator**Huma Numair, MD**

- 5 + years research experience
- > 15 clinical trials: Primary Care

Investigator Accountability

20% research, 80% clinic

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

Database of > 20,000 patients

Capability of screening database

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

Catchment area

Burlington, Hamilton, Oakville, St Catherines, Guelph, Milton

How are subjects recruited to meet the agreed upon targets?

- Patient database
- Clinic referrals
- GP & Specialist referral network
- Online applications through our Improving Health website
- Advertising - TV, radio, newspaper, central toll free number and capability of central ad campaigns for all LMC and Manna sites
- E-recruitment campaigns

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Ethics

Ethics committee (local or central)

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

Informed consent process

- See SOPs
- GCP/ICH Compliant

Confidentiality

- PIPEDA implemented

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Facilities

Equipment available

- Centrifuge –ambient and temperature adjustable (calibrated yearly)
- ECG machine - self calibrating
- 220 kg digital weight scale (calibrated yearly)
- 1 x -20 freezer (calibrated yearly)
- 1 x fridge for study medication purposes only (calibrated yearly)
- Manual and automatic blood pressure devices (calibrated yearly)
- Emergency crash cart
- Defibrillator
- Able to do PK analysis, meal tolerance tests, injections, and infusions

Office hours

- Monday to Friday (8:00 am - 4:00 pm)
- Saturdays as needed

Monitoring space

- Closed door office dedicated to monitoring
- Phone, analog, wireless and broadband access
- Access to a fax and photocopy machine

SOPs

- ERB & HC reviewed

Source documents

- Specific templates for source creation and study specific logs

Drug accountability and storage

- Secured and Locked medication room, Fridges and Freezer (-20)
- 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:
 - 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
70 Talman Court
Concord, Ontario L4K 4L5
1-877-840-2111

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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
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