



# Pre Site Visit Questionnaire

## LMC Diabetes & Endocrinology (Calgary)

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### Site Information

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#### Site location

LMC Diabetes & Endocrinology (Calgary)  
5940 MacLeod Trail SW (Suite 102)  
Calgary, Alberta  
T2H 2G4

#### Contact Information:

403 288-3224 phone  
403 288-6409 fax  
800 701-ENDO (3636) Toll Free  
[calgaryresearch@lmc.ca](mailto:calgaryresearch@lmc.ca) Email

#### Specific clinical studies of interest

- Type 1 & Type 2 Diabetes Mellitus
- Diabetes Complications - Neuropathy, Nephropathy, and Retinopathy
- Lipid Disorders
- Obesity
- Osteoporosis
- Hypertension
- Cardiac & Diabetes Prevention
- Women's Health

*Phase 2 - 4 Experience*

#### Description of site

- Private Clinic
- Private Clinical Research Center

#### Memberships

- Member of the Society for Clinical Research Sites (SCRS)

#### Number of studies capable per site

4-5 enrolling studies with 5-6 maintenance studies

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

Site has been doing research for 16 years

#### Has the site been audited?

- No FDA audit
- Health Canada audit in December 2009 - Compliant with minimal observations
- Sponsor audits - Had positive findings

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## Emergency response

- Rockyview General Hospital - 5 km from site
- All staff are CPR certified annually

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## Study Staff

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### Principal Investigator

*Stuart Ross MB, CH.B, FRACP, FRCP*

- 17 + years research experience
- >150 clinical trials: Endocrinology & Metabolism

### Sub Investigators

*Ronnie Aronson MD, RRCPC, FACE*

- 16 + years research experience
- > 200 clinical trials: Endocrinology & Metabolism

*Akshay Jain MD*

- 3 years research experience
- < 9 clinical trials: Endocrinology & Metabolism

### Investigator Accountability

20% research, 80% clinic

### Investigator's Education and/or Academic Appointments

#### Speciality Areas: Endocrinology & Metabolism

##### Education

1965	M.B. Ch.B - Medicine	Otago University, Dunedin, New Zealand
1971	MRACP	Member Royal Australasian College of Physicians
1974	FRACP	Fellow Royal Australasian College of Physicians
1980	FRCP(C)	Canada

##### Appointments

1966-67	Rotating Internship and Residency, Auckland Hospital Board
1968-70	Senior Resident in Endocrinology, Auckland Hospital Board
1970-72	Bank of New Zealand Research Fellow in Carbohydrate Metabolism, Auckland, New Zealand, Dr. H. K. Ibbertson (Professor of Endocrinology)
1972-75	Canadian Medical Research Fellow, McGill University, Montreal (Dr. J. Dupre)
1975-81	Assistant Professor of Medicine - University of Calgary
1975-91	Director, Diabetes Education and Treatment Centre Foothills Provincial Hospital
1981-92	Associated Professor of Medicine
1992-current	Clinical Professor of Medicine
1994-current	Director, Calgary Metabolic and Education Research Centre
2009-current	Associate, Endocrinologist, LMC Diabetes & Endocrinology

## 3 Patient Population and Recruitment

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### Number of patients

>110,000 for the database plus an additional 20,000 per year and growing

### Capability of screening database

Yes - able to note medical history, medications and interest in research

### Catchment area

Calgary

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

- Patient database
- GP & Specialist referral network
- Diabetes triage - rapid assessment for newly diagnosed drug naive and metformin only patients failing orals requiring addition of OHA's or insulin initiation
- Advertising - radio, newspaper, central toll free number and capability of central ad campaigns for all LMC sites
- Public forums & expos
- Community involvement - Pharmacy days, and local presentations

## 4 Ethics

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### Ethics committee (local or central)

Local ethics only – Health Research Ethics Board of Alberta – Clinical Trials Committee (HREBA-CTC)

### Informed consent process

- See LMC Diabetes & Endocrinology SOPs
- GCP/ICH Compliant

### Confidentiality

- PIPEDA implemented
- Alberta Health Act

## 5 Facilities

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### Equipment available

- Refrigerated and ambient centrifuge (calibrated yearly)
- ECG machine (calibrated yearly)
- 330 kg weight scale (calibrated every 6 months)
- 1 x -20 freezers
- 1 x medical fridge for study medication purposes only
- Manual and automatic blood pressure devices

- Able to do PK analysis, injections & meal tolerance tests
- Thermometers (fridge, freezer & drug rooms) - calibrated yearly
- Data loggers - temperature measured every 10 minutes - calibrated yearly

### **Office hours**

- Monday - Friday (7:30 am - 4:00 pm)
- Weekends as needed

### **Monitoring space**

- 1 room dedicated to monitoring - can accommodate 2 monitors
- Phone, analog, wireless and broadband access

### **LMC Diabetes & Endocrinology SOP**

- ERB & HC reviewed and approved

### **Source documents**

- LMC specific templates for source creation and study specific logs

### **Drug accountability and storage**

- Secured and Locked Drug Cabinets, Medical Fridge and Freezer
- Temperature monitored daily (min, max and average temperatures)
- Sensaphone (remote monitoring, early detection system)

### **eCRF experience**

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

### **IVRS experience**

- Clinphone
- S Clinica
- ICON
- Fisher Clinical Services
- Impala
- Almac

### **Data storage**

- In house: Lead study coordinator's office, paper charts, electronic medical records
- Long term storage: Iron Mountain x 25 years  
Address: Unit 20 5350 86 Ave.SE  
Calgary, AB T2C 4L7  
Records Management Division

## 6 Contract

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### Sites usual overhead

- 30% overhead

### Sites turnaround

- 1-2 week turnaround

### Budget Negotiations

- Director of Research:

Karri Venn RD, CDE, CCRC, PMP  
Email: [karri.venn@lmc.ca](mailto:karri.venn@lmc.ca),  
Phone: 647 274-4133 cell

### Regulatory Documentation

- Regulatory & Clinic Specialist:

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