Canadian SHIELD
Ethics Review Board
OHRP Registration IORG0003491
FDA Registration IRB00004157
Registered with CAREB, NCEHR

501 Deerhurst Drive,
Suite 102,
Burlington, ON L7L 5T1

Phone: (905) 681 8661
Fax: (905) 681 8668
www.cserb.com

SITE INFORMATION FORM (PHASE I)

As part of the requirements for Ethics Approval, CSERB must be assured that the Investigator, who is legally responsible for the conduct of the research, has sufficient resources (ICH E.6 4.) to manage all responsibilities assigned as part of the study, including the protection of the trial participants. In addition, the Investigator must be able to personally oversee the proposed research (21 CRF 56.102 (b)).

Information on this document:

New Information: ☐ **Updated Information:** ☐ **Previously Submitted:** ☐

The following information is correct and complete as of: ____/_____/_____
DD MMM YYYY

PROTOCOL INFORMATION

Sponsor/CRO name: _____

Study medication/device name: _____

Project name/code number: _____

Study/protocol number: _____

Study/protocol version number and date: (dd/MMM/yy): _____

Study/protocol title: _____

_____

_____

STAFF INFORMATION

Investigator name: _____ Tel: _____
Fax: _____

Investigator name: _____ Tel: _____
Fax: _____

Investigator name: _____ Tel: _____
Fax: _____

Secretary name: _____ Tel: _____
Fax: _____

Research nurse name: _____ Tel: _____
Fax: _____

Pharmacist name: _____ Tel: _____
Fax: _____

Clinical laboratory head name: _____ Tel: _____
Fax: _____

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SITE INFORMATION

Study site address: (where study subjects are treated):_____

Name of clinical laboratory: _____

Location (address) of clinical laboratory: _____

Location (address) of pharmacy: _____

Location (address) of pharmacy: _____

Location of medical records department: _____

Location of storage area for CRFs: _____

Study facilities and equipment:

- Access to public transport; [] Yes [] No [] NA [] Comment
  Specify: _____
- Proximity to a general hospital with emergency room; [] Yes [] No [] NA [] Comment
  Specify: _____
- Capability for specialised studies (eg radio-labelled studies);[] Yes [] No [] NA [] Comment
  Specify: _____
- Environmental control maintenance (eg temperature and light);[] Yes [] No [] NA [] Comment
  Specify: _____
- Backup storage area for specimens in case of power loss; [] Yes [] No [] NA [] Comment
  Specify: _____
- Disaster recovery scheme; [] Yes [] No [] NA [] Comment
  Specify: _____
- Alert system for disaster; [] Yes [] No [] NA [] Comment
  Specify: _____
- Inventory control procedures; [] Yes [] No [] NA [] Comment
  Specify: _____
- SOPs; [] Yes [] No [] NA [] Comment
  Specify: _____
- Documentation of computer validation; [] Yes [] No [] NA [] Comment

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Specify: _____

· **Safety and emergency equipment and procedures:**

Emergency medication supplies; [] Yes [] No [] NA [] Comment

Specify: _____

Oxygen; [] Yes [] No [] NA [] Comment

Specify: _____

Suction; [] Yes [] No [] NA [] Comment

Specify: _____

Defribillator with ECG monitor; [] Yes [] No [] NA [] Comment

Specify: _____

Continuous ECG monitors with arrhythmia detection; [] Yes [] No [] NA [] Comment

Specify: _____

Endotracheal tubes; [] Yes [] No [] NA [] Comment

Specify: _____

Stretchers; [] Yes [] No [] NA [] Comment

Specify: _____

Wheelchairs; [] Yes [] No [] NA [] Comment

Specify: _____

Pumps for IV administration; [] Yes [] No [] NA [] Comment

Specify: _____

· Alarm system to locate the sites of emergencies; [] Yes [] No [] NA [] Comment

Specify: _____

· Centrifuge; [] Yes [] No [] NA [] Comment

Specify: _____

· Refrigerators; [] Yes [] No [] NA [] Comment

Specify: _____

· Freezers; [] Yes [] No [] NA [] Comment

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Specify: _____

· Adequate space (eg offices, wards, archives); [] Yes [] No [] NA [] Comment

Specify: _____

· Ability to perform analyses at night or during weekends; [] Yes [] No [] NA [] Comment

Specify: _____

· Facilities for handling and storage (long-term) of biological samples; [] Yes [] No [] NA [] Comment

Specify: _____

· Rooms for pharmacodynamic measurements; [] Yes [] No [] NA [] Comment

Specify: _____

· Central clock in study rooms; [] Yes [] No [] NA [] Comment

Specify: _____

· Cleaning facilities; [] Yes [] No [] NA [] Comment

Specify: _____

· Computerised data management system to control sample movement; [] Yes [] No [] NA [] Comment

Specify:_____

· Facilities to prepare labels for tubes; [] Yes [] No [] NA [] Comment

Specify: _____

· Facilities for leisure activities; [] Yes [] No [] NA [] Comment

Specify: _____

· Screening rooms; [] Yes [] No [] NA [] Comment

Specify: _____

· Showers and toilets; [] Yes [] No [] NA [] Comment

Specify: _____

· Laboratory rooms; [] Yes [] No [] NA [] Comment

Specify: _____

· Kitchen for supply of standardised meals; [] Yes [] No [] NA [] Comment

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Specify: _____

· Adequate number of beds (typically 12); [] Yes [] No [] NA [] Comment

Specify: _____

· Data entry procedures (eg direct, electronic); [] Yes [] No [] NA [] Comment

Specify: _____

· Capability for electronic data transfer; [] Yes [] No [] NA [] Comment

Specify: _____

Study site personnel:

· Staff with experience in clinical pharmacology and pharmacokinetics; [] Yes [] No [] NA [] Comment

· Staff with experience in venipuncture; [] Yes [] No [] NA [] Comment

· Staff with experience in diets and standardised meals; [] Yes [] No [] NA [] Comment

· Staff with technical experience to handle biological samples; [] Yes [] No [] NA [] Comment

· Staff with experience in drug-of-abuse testing; [] Yes [] No [] NA [] Comment

· Staff with experience in resuscitation; [] Yes [] No [] NA [] Comment

· Staff with experience in use of emergency equipment; [] Yes [] No [] NA [] Comment

· Qualified pharmacist for dispensing the study medication/device; [] Yes [] No [] NA [] Comment

Study subject population:

· Adequate source of healthy volunteers; [] Yes [] No [] NA [] Comment

Specify: _____

· Sufficiently large volunteer panel; [] Yes [] No [] NA [] Comment

Specify: _____

· Access to special populations: [] Yes [] No [] NA [] Comment

  · Elderly; [] Yes [] No [] NA [] Comment

  · Postmenopausal women; [] Yes [] No [] NA [] Comment

  · Renally-impaired individuals; [] Yes [] No [] NA [] Comment

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- Hepatically-impaired individuals; [] Yes [] No [] NA [] Comment
- Specify any other populations: _____

- Procedures to inform primary care physicians of study participation;[] Yes [] No [] NA [] Comment

CONTACT INFORMATION AND PARTICIPANT REIMBURSEMENT

Contact information to be listed in Informed Consent Form (for questions about the study):

Name: _____

Phone number: _____

Contact information for use in case of a research-related injury:

Name: _____

Phone number: _____

REIMBURSEMENT

Subjects will be reimbursed as follows: _____

CONFIRMATION OF INFORMATION

_____

Printed or Typed Name of Person Completing This Form

I certify that the information contained above is accurate. I acknowledge Canadian SHIELD Ethics Review Board has the authority to oversee this study and suspend the study if necessary to protect the rights and welfare of the study participants. I agree to provide Canadian SHIELD Ethics Review Board with the information they require to conduct initial and continuing review of this study on a timely basis and that if the information is not provided, Canadian SHIELD may suspend the study.

_____ _____

Signature **Date**

(____) _____

Phone number

Information to be filled in by Canadian SHIELD Ethics Review Board:

Protocol Tracking No.:_____ Protocol No.:_____

Sponsor:_____ Date of Protocol:_____

Date Presented to Board:_____

Date Received: _____