

Effective Date:

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SOP No: P1

PRE-STUDY VISIT**CLINICAL TRIALS CENTRE DEVELOPMENT TEAM**

James Thorburn
Johan Karlberg
Selene Tam
Yolanda Yan

APPROVED BY:_____
Investigator's Name_____
Signature/Date**REVISIONS:**

No.	Section No.	Page No.	Initials/Date

DATES OF NEXT REVISION OF THIS SOP:

Date	Signed	Date	Signed

SOP No: P1**PRE-STUDY VISIT****I. Purpose**

To describe the actions that need to be taken by the study site staff during a Pre-Study visit by the Sponsor.

II. Other Related Procedures

SOP: P2 Review of Protocol

SOP: P3 Review of Protocol Amendments

SOP: P4 Review of Investigator's Brochure

SOP: A2 Format for Investigator's Curriculum Vitae

III. Procedures

- 1) Prior to the release of any information to the Investigator, the Investigator will be required to sign a Confidentiality Statement provided by the Sponsor.
- 2) Discuss with the Monitor, or other people delegated by the Sponsor, details of the study and ensure that any written notes made at the time are retained and then subsequently filed in the Investigator's study file.
- 3) Discuss with the Monitor the recruitment rates and relevant recruitment strategies that will be utilised during the study. If there are any devices or items of equipment that are to be used by patients or subjects in the study, request the monitor to explain and/or demonstrate the item and its functions.
- 4) Ensure that details of the date of the next available Institutional Review Board (IRB) meeting or a list of alternative dates are available, as this information will be required by the Monitor.
- 5) The Investigator/Clinical Research Coordinator (CRC) will need to provide the Monitor with a signed and up-to-date copy of the Investigator's and CRC's Curriculum Vitae.
- 6) The Investigator should check with the Monitor that the study protocol is a current version.
- 7) The Investigator and CRC should briefly review the content of the Investigator's Brochure and should make notes of any points that need further clarification, explanation or expansion by the Monitor.

- 8) Discuss with the Monitor the following:
 - Insurance
 - Indemnity
 - Publication policy
 - Financial issues and other costs related to the clinical trial.
- 9) Provide the Monitor with a telephone contact number and/or fax number or email address for the Investigator or the CRC in order to allow the monitor to be able to contact the Investigator.
- 10) Accompany the Monitor on a visit of the study site in order that he/she can inspect and assess the resources available at the Investigators site.
- 11) After the Pre-study visit, the Investigator/CRC should answer the questions contained in the Pre-Study Visit Summary checklist provided in Appendix A of this SOP.

APPENDIX A**PRE-STUDY VISIT SUMMARY CHECKLIST**

Date of Visit:

Sponsor Contact Details

Duration:

ATTACH BUSINESS CARD

Protocol Name:

Protocol No:

Date of Protocol:

Is it the final version of the protocol? **Yes** **No** Draft No.

	Yes	No
1. Is the study protocol acceptable?	<input type="checkbox"/>	<input type="checkbox"/>
2. Are the benefits of the study larger than the risks?	<input type="checkbox"/>	<input type="checkbox"/>
3. Is the study scientifically sound?	<input type="checkbox"/>	<input type="checkbox"/>
4. Were the following discussed and are they acceptable:		
a) Sufficient eligible subjects for the study?	<input type="checkbox"/>	<input type="checkbox"/>
b) Insurance and Indemnity	<input type="checkbox"/>	<input type="checkbox"/>
c) Compensation	<input type="checkbox"/>	<input type="checkbox"/>
d) Publication policy	<input type="checkbox"/>	<input type="checkbox"/>
e) Schedule of payments	<input type="checkbox"/>	<input type="checkbox"/>

Signature: _____ Date: _____