**Hong Kong Baptist University**  
**Standard Operating Procedures for Human Clinical Research (Chinese Medicine)**

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<th>Full Form</th>
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<td>AVA</td>
<td>Academy of Visual Arts</td>
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<tr>
<td>CREP</td>
<td>Clinical Research Ethics Panel</td>
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<td>CTA</td>
<td>Clinical Trial Agreement</td>
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<tr>
<td>Declaration of Helsinki</td>
<td>Declaration of Helsinki of the World Medical Association</td>
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<tr>
<td>GCP</td>
<td>Good Clinical Practice for Proprietary Chinese Medicines</td>
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<tr>
<td>GS</td>
<td>Graduate School</td>
</tr>
<tr>
<td>HA</td>
<td>Hospital Authority</td>
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<tr>
<td>REC</td>
<td>Research Ethics Committee</td>
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<td>HKBU</td>
<td>Hong Kong Baptist University</td>
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<td>RC</td>
<td>Research Committee</td>
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<td>SAE</td>
<td>Serious Adverse Event</td>
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<td>SOP</td>
<td>Standard Operating Procedure</td>
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1. Introduction

Hong Kong Baptist University (HKBU) is committed to encouraging, fostering and supporting research productivity and research excellence. Promotion of an ethical research culture is central to the University’s policy and practice.

The University requires all research to obtain ethical and/or safety approval from the Research Ethics Committee (REC) via its three specialist panels. This assures protection of the rights and welfare of persons and animals participating in the research, and also to ensure that all potential hazards as known by the investigator have been disclosed and that acceptable safety measures will be implemented.

Clinical Research is premised on trust. At times, it places research subjects at risk for the good of the community. The community and the research subjects therefore have legitimate expectations that a system of protection should be in place. In this connection, besides the Human (non-clinical) Research Ethics Panel and Animal Research Ethics Panel, the Clinical Research Ethics Panel (CREP) has also been formed to review clinical research applications and keep under review the guidelines on ethical research.

2. Research Ethics Committee

The REC, reporting to the Research Committee (RC), is responsible for policy review and development relating to research ethics, as well as review of complaints and appeals. With the Graduate School (GS) providing administrative and secretarial support, the three panels under REC are tasked to review, on grounds of ethics and/or safety, research proposals which involve the use of human or animal subjects.

Terms of Reference

a) To provide advice and recommend to the Senate via the Research Committee on policies and procedures in relation to research ethics.

b) To give coherence to the work of the three panels and effect cross-linkages between them and with the Faculties’ research ethics committee or similar entities.

c) To monitor the implementation of policies relating to research ethics.

d) To review appeals or complaints concerning teaching and research ethics.

e) To make recommendation to the Research Committee on matters related to the findings of the Investigation Panel on research ethics issues.

f) To appoint working groups where appropriate for discharging duties of the Committee.
g) To consider reports from the three Panels on different aspects of research ethics.

h) To receive reports from Faculties/Schools/AVA on ethical clearance of student projects at all levels.

i) To submit an annual report to the Research Committee at the end of the academic year.

3. The Clinical Research Ethics Panel

The CREP is established under the REC to review, approve and monitor human clinical trial intervention. The CREP is responsible for performing ethics and scientific review and overseeing clinical research (including use of medical products and clinical procedures for Chinese Medicine) under HKBU.

The CREP is established and operated primarily in compliance with:

a) the Declaration of Helsinki of the World Medical Association (Declaration of Helsinki);

b) the Good Clinical Practice for Proprietary Chinese Medicines (GCP);

c) this standard operating procedure (SOP); and

d) the guideline(s) or working manual(s) [ref: R16 REC] of the REC, where applicable.

Examples of Medical Products

Medical products may include:

a) drugs (e.g. chemical drugs and biological drugs);

b) medical devices (e.g. implants, diagnostic kits and imaging machines which are specific to Chinese medicine);

c) Chinese/herbal medicines (e.g. proprietary/traditional Chinese medicines);

d) health/nutritional supplements;

Examples of Clinical Procedures

Clinical procedures may include:

a) clinical examinations/assessments (e.g. venipuncture);

b) nursing procedures;

c) physiotherapies;

d) occupational therapies;

e) psychotherapies;

f) behavioral therapies;

g) alternative therapies (e.g. acupuncture); and

h) diagnostic imaging methods (e.g. X-ray examination).

Examples of Activities Not Defined as Clinical Studies
For the avoidance of doubt, clinical studies do not include:

a) the use of medical products/procedures solely for the purpose of clinical care (e.g. emergency use of an unregistered Chinese herbal medicine with a patient in a life-threatening condition);
b) evaluation of individual patients’ medical records solely for the purpose of clinical care;
c) investigation of clinical data for quality assurance purpose (e.g. clinical audits); and
d) investigation on general statistical information relating to hospital services or disease patterns (e.g. number of hospital admissions per year, year-on-year change in the number of patients attending a specialist out-patient clinic);

provided that such activities are not intended to form a part of a research project or to derive a research publication.

Membership
The membership of the CREP is nominated by the Chair of REC in accordance to the following composition recommended by GCP and the Hospital Authority (HA):

a) at least 5 reviewers
b) at least 1 reviewer who has scientific or healthcare background
c) at least 1 reviewer who has neither scientific nor healthcare background
d) at least 1 legal expert
e) at least 1 reviewer who is independent from the University
f) including both male and female reviewers

4. Standards of Operating Procedures

4.1 Types of Review: The CREP conducts two types of review i.e. Panel Review and Expedited Review which follows the established application procedures (Appendix 1: Application Workflow for Clinical Trial)

4.1.1 Panel Review
All clinical research involving more than minimal risk to participants are reviewed by all members of the CREP.

4.1.2 Expedited Review
Under the following circumstances, clinical research could be considered under expedited review. The research:

a) does not involve additional clinical intervention (drug or invasive procedure) or carry no more than minimal risk to the Research Subjects, and
b) does not include vulnerable subjects, and
c) does not raise privacy concerns; or
d) is a collaborative research that the human ethics approval had been obtained from ethics committee of other institutions (such approval must be submitted with the application to CREP); or
e) is a resubmission of research or ethics application for amendment(s) and that prior ethics approval had been obtained.

The proposal is sent to a minimum of two members of the CREP. Normally, application for minor amendments / renewal should also be considered under expedited review.

4.2 Application

The Principal Investigator (PI) has overall responsibility in technical, administrative, fiscal and risk management of a given clinical trial. PIs should refer to the “Important Notes to Principal Investigator for Human Clinical Trial Intervention [appendix 2]” before preparing the application. The following documents must be submitted to the CREP and with endorsement by the respective Head of Department/Unit:

- A duly completed Application Form [appendix 3] for clinical research;
- The research protocol;
- Consent form and information to be provided to Research Subjects (such as recruitment notice, invitation letter and safety information) in suitable language(s);
- Curriculum vitae and relevant experience of all investigator(s);
- Conflict of interest declaration by the investigator(s) [appendix 4] (for sponsored research);
- Letter of Indemnity [appendix 5] for the standard indemnity agreement and procedure (for sponsored research);
- Draft Clinical Trial Agreement [appendix 6] (CTA) (for sponsored research);
- Other relevant documents

Application must be submitted to the CREP at least 2 months before commencement of the research project.

4.3 Endorsement

The application must be endorsed by the respective Department/Unit Head before filing the application to CREP. The Department/Unit Head must confirm the following:

- Services priority of the department will not be affected;
- Research team is competent;
- The investigator has sufficient resources to conduct the Clinical Research safely;
- Therapeutic intervention(s), if any, can be performed by appropriate personnel proficient in managing conditions that may arise; and
- The Study Site has sufficient facilities to support the Clinical Research; and
- If the Clinical Research is sponsored, the CTA has been approved (or under process) by the Research Committee and an approved Letter of Indemnity is in place (or under process).

4.4 Reviewing Process

Upon receipt of applications involving human clinical trial intervention, the CREP Secretary registers application and checks if forms are duly completed and all supporting documents are enclosed within 1 week. Chair of CREP would consider whether Panel Review / Expedited Review is required and arrange with the Graduate School for the logistics within 2 weeks.

4.4.1 Panel Review

Normally initial application for clinical research should go through panel review. The Chair of CREP would invite all members of the panel for a meeting within 3-5 weeks, to discuss and decide approval outcomes based on the approval considerations stipulated below.

The quorum for a Standard Panel review meeting is five and the composition of the reviewers participating in a review meeting shall fulfill the minimum requirements as stipulated in Section 3 above. If necessary, expert advisor(s) might be invited to participate in a review meeting or provide expert advice on an application/submission, provided that each expert advisor shall sign a statement of confidentiality. The expert advisor(s) shall not be eligible to vote for the application/submission. Principal investigator (or his/her designee) might also be invited to participate and/or present the application/submission in a meeting.

Application documents would be distributed to all CREP members seven calendar days prior to the meeting. Members who are not able to attend to the meeting should provide comments to the Chair in advance.

4.4.2 Expedited Review

Refers to 4.1.2, normally re-submission and application for amendment(s) should go through expedited review. The Chair of CREP would invite 2 members of the panel to review the application and the Chair would decide the approval outcomes.

Confidentiality Undertaking and Conflict of Interest Declaration

All reviewers and members are required to sign the Confidentiality Undertaking and Conflict of Interest Declaration [appendix 7] on the Assessment Report.
4.5 Approval Considerations

In performing a review, the CREP members will evaluate the study’s ethical aspects in accordance with the ethical principles of research and the following ethical considerations:

<table>
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<tr>
<th>Key Dimensions</th>
<th>Common Considerations</th>
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| Research Products/Procedures | - The research has a reasonable prospect of improving healthcare or furthering knowledge;  
                               - Involvement of clinical interventions (e.g. medical products or clinical procedures)  
                               - Potential risks and related scientific rationale  
                               - Potential benefits and related scientific rationale  
                               - The research has a favourable risk-benefit ratio |
| Study Design          | - Significance of research questions  
                               - Correlation of study design and research questions  
                               - Use of randomization or other research specific subject assignment methods  
                               - Involvement of placebo, impeding access to available treatment, or withdrawal of ongoing treatment driven by study protocol  
                               - Statistical considerations |
| Study Execution       | - Expertise and experience of all investigators and study personnel  
                               - Study site facilities  
                               - Mechanism of ongoing safety monitoring and reporting  
                               - Medical emergency arrangements |
| Participant’s Right   | - Participant type and vulnerability  
                               - Involvement of healthy volunteers or participants without the targeted diseases/conditions  
                               - Participant recruitment strategies  
                               - Informed consent documents and process referring to “Informed Consent Statement Checklist & Sample [appendix 8]” of the Human Ethics application form  
                               - Alternative treatments if Research Subject refuses to participate in, or withdraws from, the study;  
                               - Possible scenarios where the Research Subject’s participation may be terminated;  
                               - Anticipated expenses to be borne by, or payment to be made to, Research Subjects;  
                               - Means of contact for query and urgent medical attention to adverse outcomes;  
                               - Protection of participants’ personal data |
| Potential Research Bias| - Conflicts of interest, potential conflicts of interest and declaration of interest  
                               - Public disclosure of study information (e.g. by registration with public clinical trial registries)  
                               - Publication plan |
| Potential Liability   | - Insurance |
Key Dimensions | Common Considerations
---|---
Management | • Indemnity (for sponsored clinical studies)

### 4.6 Outcome

The CREP will normally notify the HKBU applicant about the approval outcome within 6 – 8 weeks from receipt of the duly completed application with all required documents. An approval notification providing the approval outcome and comments will be issued to the PI. Research activity cannot begin until the protocol has been approved by the CREP.

#### 4.6.1 Approval

The research proposal is approved with indication of the research approval period granted. Research activity can be started.

#### 4.6.2 Approval-in-principle

The research proposal is approved with condition(s) or subject to the required clarifications/amendments. PI shall provide the CREP with the clarifications or amendments as required.

#### 4.6.3 Released

The research proposal is not approved as submitted either because there is insufficient information to make a decision or the proposal is not ethically sound. However, the research proposal can be re-submitted after revision to address concerns raised by the CREP and this should be reviewed by the Chair of CREP.

#### 4.6.4 Rejected

The research proposal is ethically unacceptable and may not be re-submitted to the CREP.

### 4.7 Appeal of the decision

The PI may appeal to REC on the decision within 30 days of the announcement of approval outcome. The Chair of REC can assign an appeal panel of no less than three members from REC to review the decision of CREP (not to perform another ethics review). Its decision is EITHER to “uphold the decision of CREP” OR “revert back to the CREP for another ethics review”.

### 5. Reports and Monitoring

#### 5.1 Annual Report

The CREP has the right to monitor ongoing clinical studies. The PI should submit annual report [appendix 9] for notification of the research study progress.
5.2 Final Report

A final report [appendix 10] should be submitted for notification of completion, abandonment or premature termination of the research study within 3 months from the date of formal closure of the study.

5.3 Amendment

No amendment to the protocol can be made without approval by the CREP. PI must submit amendment request [appendix 11] to the CREP for any changes to an approved study. The CREP would review the changes and consider if approval could be granted to the project.

5.4 Serious Adverse Event (SAE) Report

A serious adverse event is an adverse event occurred during a clinical study:

- a) Death;
- b) Life-threatening;
- c) Inpatient hospitalization or prolongation of existing hospitalization;
- d) Persistent or significant disability or incapacity; or
- e) Congenital anomaly or birth defect.

All SAEs should be reported [appendix 12] to the CREP within 24 hours of its identification. PI shall assess the causal relationship to the research study and/or participation. Depending on the research project relatedness of the SAE, PI should decide on the necessity to modify the study protocol, the consent, and to update subjects of the previously unknown/unexpected risks. PI shall provide information about the SAE to the CREP; and follow the SAE until resolution or conclusion of the event, and report the follow up actions to the CREP by fifteen working days after initial SAE reporting.

5.5 Possible notification mechanism between ethics committees

The CREP has the discretion to notify other ethics committees on the SAE, subject to the agreement(s) between ethics committees outside HKBU (if applicable).

6. Student Project

Student should not initiate clinic research under normal circumstances. Student’s supervisor should take the role as PI of a clinical research and accepts responsibility for all project-related liabilities.

If students are involved in the clinical research as project team members, the students concerned
must be under suitable and sufficient supervision by the PI. The PI should also make sure that the research subjects will not be exposed to additional health (including psychological) hazards or the project does not involve vulnerable subjects.

7. Handling of Complaints

In response to the allegations of the research misconducts, procedures on handling of complaints stipulated in the “Policy on Responsible Conduct of Research” (section 4) will be followed. If there is a genuine concern on the safety of Research Subjects, the CREP reserves the right to suspend the Clinical Research while the complaint is under investigation.

8. Review and Update of Standard Operating Procedures

<table>
<thead>
<tr>
<th>Approval of SOP</th>
<th>This SOP is approved by the Research Committee. The originally signed copy shall be kept by the Graduate School.</th>
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<tr>
<td>Review of SOP</td>
<td>This SOP will be reviewed by reviewer(s) delegated by the Chair of REC at least every three years. Additional reviews may be performed as deemed required by the Chairman of REC or CREP.</td>
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</table>
| Updating of SOP | REC will duly consider the recommendations by the reviewer(s) in order to finalize an updated SOP. Whether or not any change is made to the SOP,  
|                 | a) the version and review history at the front part of the SOP shall be updated;  
|                 | b) the updated SOP shall be approved by the Chair of REC by signing on the cover page; and  
|                 | c) the originally signed copy shall be kept by the Graduate School. |

The REC may, as it deems required, develop and maintain guidelines and/or working manuals to supplement this SOP. The Chair of REC shall have the authority to approve guidelines and working manuals. In the event of any conflict or inconsistency between a guideline/working manual and this SOP, this SOP shall prevail.

9. Records Management

Central Register: A central register for the clinical studies reviewed by the CREP will be maintained. The register contains basic information about reviewed clinical studies (whether approved, disapproved, ongoing or closed). Graduate School is responsible for maintaining an updated central record and making the data available to the REC and RC and the Governing Body(ies) as required.
**Records Retention:** The CREP shall retain all essential documents and records relating to ethics and scientific review and oversight of each clinical study, including:

a) documents and records relating to initial review of the study (e.g. application, study documents submitted by the principal investigators, review meeting minutes, list of reviewers and their conflicts of interest declaration, relevant correspondences between the CREP and principal investigator, and the written decision(s)/opinion(s) of CREP);

b) documents and records relating to continuous oversight of the study (e.g. records for review of amendments/changes, new information or deviations/compliance incidents, progress/annual/SEA reports); and

c) documents and records of study audits by the CREP (e.g. audit reports and records of follow-up actions), if applicable.

**Records Retention Period for Approved Studies:** All essential records with respect to each approved clinical study shall be retained for a minimum period of three (3) years from the earlier of:

a) the date of the final report to the CREP; or

b) the date of termination of the study by the CREP.

**Records Retention Period for Disapproved Studies:** All essential records with respect to each disapproved clinical study shall be retained until the earlier of:

a) the expiry of the 30-day period after the written notification of the decision(s)/opinion(s) of CREP (to allow the principal investigator to make resubmission); and

b) the conclusion of a resubmission.
10. Appendices

Appendix 1: Application Procedural Flowchart for Clinical Trial
Appendix 2: Important Notes to Principal Investigator for Human Clinical Trial Intervention
Appendix 3: Application Form for Clinical Research
Appendix 4: Investigator’s Conflict of Interest Declaration Form
Appendix 5: Indemnity for Clinical Research
Appendix 6: Clinical Trial Agreement (DRAFT)
Appendix 7: Assessment Report on Research Proposal (SAMPLE)
Appendix 8: Informed Consent Statement Checklist & Sample
Appendix 9: Clinical Research Annual Progress Report Form
Appendix 10: Clinical Research Final Report Form
Appendix 11: Clinical Research Protocol Amendment Application Form
Appendix 12: Serious Adverse Event (SAE) Report Form
Is it a research involving human clinical trial intervention?  
- **Yes**  
  Follow Standard Operating Procedures for Human Clinical Research:  
  Submit the application to the CREP (with endorsement by the respective Head of Department/Unit) \[SOP 4.2\]  
  - Within 1 week  
  - CREP Secretary registers application and checks if forms are duly completed and all supporting documents are enclosed.  
  - The Chair of CREP would consider whether Panel Review / Expedited Review is required and arrange with the CREP Secretary.  
  - The CREP Secretary will send the set of application to the CREP members according to the type of review.  
  - All reviewers and members are required to sign the Confidentiality Undertaking and Conflict of Interest Declaration.  
  - Within 2 weeks  
  - Panel Review \[SOP 4.4.1\]  
  - Expedited Review \[SOP 4.4.2\]  
  - Within 3-5 weeks  
  - Approval Outcome  
  An approval notification providing the approval outcome and comments will be issued to the PI within 6 – 8 weeks from receipt of the duly completed application with all required documents.  
  - Approval \[SOP 4.6.1\]  
  - Approval-in-principle \[SOP 4.6.2\]  
  - Released \[SOP 4.6.3\]  
  - Rejected \[SOP 4.6.4\]  

- **No**  
  Follow normal procedures set by panels under REC

**Appeal of Approval Outcome**  
- The PI may appeal to REC on the decision within 30 days of the announcement of approval outcome.  
- The Chair of REC can assign a panel of no less than three members from REC to review the decision of CREP (not to perform another ethics review). Its decision is EITHER to “uphold the decision of CREP” OR “revert back to the CREP for another ethics review”.

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**Application Procedural Flowchart for Clinical Trial**
Important Notes to Principal Investigator for Human Clinical Trial Intervention

The Principal Investigator (PI) has overall responsibility in technical, administrative, fiscal and risk management of a given clinical trial, s/he must:

1. Obtain approvals from REC via CREP and relevant regulatory body (where applicable) before commencing a research.
2. Ensure insurance covered all study participants.
3. Ensure competency of research team members in research conduct and care of participants.
4. Ascertain competency and safe operation of collaborating sites.
5. Oversee research conducts to ensure research is carried out in a manner which is safe, efficient and ethical.
6. Ensure that written informed consent is obtained from each study participant prior to enrollment.
7. Control access to test articles and keep record of their use.
8. Ensure adequate and accurate records of all required observations and data during the study for each study participant.
9. Protect the privacy of subjects and confidentiality of data.
10. Monitor subjects’ safety and well-being throughout study. Coordinate and report all Suspected, Unexpected, Serious Adverse Reactions. This should be done in a timely fashion. Depending on the seriousness and study relatedness of the adverse events, investigators should decide on the necessity to modify the study protocol, the consent form, and to update subjects of the previously unknown/unexpected risk.
11. Permit appropriate monitoring bodies/authorities (including REC/CREP) to inspect and monitor records of the trial.

What to submit?

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<th>No.</th>
<th>Description</th>
<th>Requirement</th>
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<tr>
<td>1.</td>
<td>Application Form [appendix 3]</td>
<td>Mandatory</td>
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<tr>
<td>2.</td>
<td>The research protocol</td>
<td>Mandatory</td>
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<tr>
<td>3.</td>
<td>Informed Consent Statement to be provided to Research Subjects (such as recruitment notice, invitation letter and safety information) in suitable language(s) (refer to “Informed Consent Statement Checklist &amp; Sample [appendix 8]” of the Human Ethics application form)</td>
<td>Mandatory</td>
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<tr>
<td>4.</td>
<td>Curriculum vitae and relevant experience of the all investigator(s)</td>
<td>Mandatory</td>
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<td>5.</td>
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<td>8.</td>
<td>Other relevant documents</td>
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**HONG KONG BAPTIST UNIVERSITY**

**Research Ethics Committee (REC)**

**REC/Ethics/Human (Clinical Research)**

**Important Notes:**

(a) All clinical research activities are required to seek prior approval from the REC via Clinical Research Ethics Panel (CREP) before commencement of the research project. This assures protection of the rights and welfare of persons participating in the research.

(b) This application is applicable for research INVOLVING subjects in the category of pregnant women; fetuses; prisoners; human in vitro fertilization; persons with mental or physical disabilities; persons with serious illness; persons who are economically or educationally disadvantaged and minors.

(c) Only endorsed applications by Department Head will be submitted to the CREP for approval.

(d) All documents must be typed and legible; please use layman terminologies to explain your research project.

(e) CREP reserves the right to return incomplete/outdated application to the PI and this will result in delay in approving the application.

The Principal Investigator (PI) has overall responsibility in technical, administrative, fiscal and risk management of a given clinical trial, s/he must:

1. Obtain approvals from REC via CREP and relevant regulatory body (where applicable) before commencing a research.
2. Ensure insurance covered all study participants.
3. Ensure competency of research team members in research conduct and care of participants.
4. Ascertain competency and safe operation of collaborating sites.
5. Oversee research conducts to ensure research is carried out in a manner which is safe, efficient and ethical.
6. Ensure that written informed consent is obtained from each study participant prior to enrollment.
7. Control access to test articles and keep record of their use.
8. Ensure adequate and accurate records of all required observations and data during the study for each study participant.
9. Protect the privacy of subjects and confidentiality of data.
10. Monitor subjects’ safety and well-being throughout study. Coordinate and report all Suspected, Unexpected, Serious Adverse Reactions. This should be done in a timely fashion. Depending on the seriousness and study relatedness of the adverse events, investigators should decide on the necessity to modify the study protocol, the consent form, and to update subjects of the previously unknown/unexpected risk.

11. Permit appropriate monitoring bodies/authorities (including REC and CREP) to inspect and monitor records of the trial.

**Documents Enclosed:**

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<tbody>
<tr>
<td>1. A duly completed Application Form</td>
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<td>2. The research protocol</td>
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**Section A. Project Information**

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<tr>
<td>Duration (months)</td>
<td>Start Date</td>
</tr>
<tr>
<td>Principal Investigator (PI)</td>
<td>Position</td>
</tr>
<tr>
<td>Telephone</td>
<td>Email</td>
</tr>
</tbody>
</table>

Other investigator(s) involved in the research (*)

Co-I (Internal/External*): Dept/Org*

Co-I (Internal/External*): Dept/Org*

(please add new entries for all investigators)

**For Office Use**

| Date received | REC reference no. |
| Protocol version | Consent form version |
| Date of meeting | Result |

**Section B. Checklist**

Check the box(es) for the appropriate category(ies) AND sub-category(ies) that apply to your research project.

1. ☐ This project is a clinical study which involves giving intervention and/or inducing potential risks to participants.
2. ☐ Clinical studies of drugs and medical devices only when condition (a) OR (b) is met.
□ (a) Research on drugs for which an investigational new drug application is not required.
□ (b) Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

3. □ Collection of blood samples by finger stick; heel stick; ear stick, or venipuncture as follows:
□ (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week; OR
□ (b) from other adults and minors\(^1\) considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

4. □ Prospective collection of biological specimens for research purposes by noninvasive means.
5. □ Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
6. □ Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
7. □ Collection of data from voice, video, digital, or image recordings made for research purposes.
8. □ Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
9. □ Use of minors under age 18, or economically or educationally disadvantaged persons.
10. □ Use of deception.
11. □ Use of prisoners, pregnant women, fetuses, the seriously ill, or persons with mental disabilities, or incompetent individuals.
12. □ Collection of information or recording of behavior which, if known outside of the research, could reasonably place the subject at risk of civil or criminal liability or damage the subject’s financial standing, employability, insurability, reputation, or be stigmatizing.
13. □ Collection of information regarding sensitive aspects of the subject's behavior such as: drug and alcohol use, illegal conduct, or sexual behavior.
14. □ This project includes procedures that present more than minimal risk to the subject.
15. □ This project includes procedures not listed above.

---

**Section C. Research Protocol and Documentation**

<table>
<thead>
<tr>
<th>Summary of the research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please provide a summary stating the general nature and purpose of the proposed research, and where the study will take place.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Criteria used to recruit/select subjects.</th>
<th>□ Age</th>
<th>□ Sex</th>
<th>□ Socio-economic status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marital Status</td>
<td>Others, please specify: __________________________</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of subjects to be recruited/selected</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>List specific eligibility requirements for subjects (or describe the screening procedures)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Type(s) of subjects</th>
<th>□ Male (M)</th>
<th>□ Female (F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No:</td>
<td>No:</td>
<td></td>
</tr>
<tr>
<td>Minor (Under age 18)</td>
<td>Age range:</td>
<td></td>
</tr>
<tr>
<td>Fetuses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant women</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prisoners</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Persons with mental disabilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Persons with physical disabilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Persons with serious illness</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

\(^1\) Minors are defined as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.”
- Persons who are economically disadvantaged
- Persons who are educationally disadvantaged
- Other vulnerable subjects, please specify: ________________________

**Your relationship with the subjects.**
- Teacher/Student
- Superintendent / Principal/Teacher
- No relationship
- Others, please specify: __________________________

**Rewards to the subjects.**
You may choose more than one option.
- Monetary Dollar Value:$ _______
- Gift Dollar Value:$ _____
- Class credit Credit earned: _______

Describe the payment arrangements
Any rewards if the subjects withdraw prior to the completion of the study?
- Yes  □  No  □  N/A
If Yes, the dollar value is: $ _______  Others: ___________________________

**Consent from the subjects.**
Necessary information will be provided to the subjects so that they can understand their roles and the risks involved in participating in the study?
- Yes, each subject will be provided with the Informed Consent Statement.
- Yes, each subject will be provided with the Study Information Sheet.
- Others, please specify: _____________________________

The subjects will attend a briefing session (e.g. a meeting, or equivalent) so that the PI could explain the project details and the subjects could ask questions about the study?
- Yes  □  No
If Yes, please describe the arrangement:
_____________________________________________________________________
_____________________________________________________________________
If no, please explain why a briefing session would not be arranged:
_____________________________________________________________________
_____________________________________________________________________

**Conduct of the Research Study**

- **By interview**
  Will the subjects be taped?
  - Yes. I will keep/destroy the tapes within ________(duration) upon completion of my research study. 3
  - No
Where will the interview take place?
If the interview takes place during class time, what will non-participants do?
- Dismiss from class
- Reading time
- Others: ______________________
Time needed to complete the interview: _______ minutes / hours (please circle)

- **By questionnaire**
  How will the questionnaires be distributed AND collected?
  - By mail
  - By Email (Subject should be told that their confidentiality cannot be guaranteed while their data are on the internet)
  - Face-to-face
  - Others
Time needed to complete the questionnaire _______ minutes / hours (please circle)
Confidentiality statements are included in the questionnaires
- Yes  □  No  □  N/A

- **Others**
  Describe what the subjects will do (action).
  Will the subjects be taped?
  - Yes. I will keep/destroy the tapes within ________(duration) upon completion of my research study. 3
  - No
Will you use an electric device that is attached directly to the subjects?
- Yes  □  No  □  N/A

---

2 Signed parental/guardian informed consent must be obtained when minor subjects and vulnerable adult subjects are involved in the research. For other subjects, it is generally required that information about the research will be given to the subjects either in written or oral form by following the “Study Information Sheet”. The Study Information Sheet should contain information listed on Appendix A (Items 1-9) and a sample is also included in Appendix A1 to assist the investigators.

3 The Research Committee approved that for longitudinal studies, record may be kept up to seven years. Please provide justifications for any period longer than that.
Explain how the subjects will be protected from shock: _________________________
_____________________________________________________________________

Where will the action take place?

Time needed to complete the above action _____ minutes / hours (please circle)

If the action takes place during class time, what will non-participants do?
☐ Dismiss from class ☐ Reading time ☐ Others:

<table>
<thead>
<tr>
<th>Potential risks of the research study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any potential risks related to the conduct of the research study?</td>
</tr>
<tr>
<td>Types of risks. You may choose more than one option</td>
</tr>
<tr>
<td>Do you have any contingency plan for protecting against or minimizing the potential risks?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Record Keeping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Format of recording and keeping the data. You may choose may more than one choice.</td>
</tr>
<tr>
<td>Identifiers are used for identifying the subjects?</td>
</tr>
</tbody>
</table>
| Describe How will you destroy/dispose of the records? | ☐ Name ☐ Job Title ☐ Others: ________________________________
| The identifiers will be kept for _________ (duration). |
| ☐ Number code. The subject will be identified by the code? ☐ Yes ☐ No |
| The code list will be stored in ________________________________ |
| When will the code list be destroyed? ________________________________ |

<table>
<thead>
<tr>
<th>Insurance (Applicable to clinical research that involves giving intervention/ including potential risks to participants)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of the Insurance Company</td>
</tr>
<tr>
<td>Estimated insured amount</td>
</tr>
<tr>
<td>Insurance coverage for the participants</td>
</tr>
<tr>
<td>Funding source of the premium You may choose more than one option.</td>
</tr>
<tr>
<td>☐ Others: ________________________________</td>
</tr>
<tr>
<td>Cost Centre to be charged: ____________________</td>
</tr>
<tr>
<td>Budget Controller: ____________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Research Output</th>
</tr>
</thead>
<tbody>
<tr>
<td>How will the report be written?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional methods to preserve confidentiality for any of the procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any additional information to which you would like to draw the reviewer(s)’ attention</td>
</tr>
</tbody>
</table>
Section D. Approval

I. Declaration by the Principal Investigator / Co-investigator(s)

My project team and I agree the Important Notes above and pledge to conform the above and to the following:

As one engaged in investigation utilizing human subjects, I acknowledge the rights and welfare of the human subject involved. I acknowledge my responsibility as investigator to secure the informed consent of the subject by explaining the procedures, in so far as possible, and by describing the risks as weighed against the potential benefits of the investigation.

I assure the REC and CREP that all procedures performed under the project will be conducted in accordance with prevailing standards of research ethics in the academic community. Any deviation of the project (e.g., change in principal investigator, research methodology, subject recruitment procedures, etc.) will be submitted to the CREP in the form of an amendment for its approval prior to implementation.

I understand that it is the sole responsibility of the researcher to ensure that the research is in full compliance with the Personal Data (Privacy) Ordinance.

I also undertake to thoroughly inform the Co-I(s) as stated in Section A of the necessary aforementioned details.

Signature: _____________________________ (PI)                      Date: _________________________

II. Endorsement by Department Head/Chair of the Departmental Research Committee

I hereby endorse this application and confirm the following:

1. Department is aware of the protection of the rights and welfare of the persons participating in the research;
2. Services priority of the department will not be affected;
3. Research team is competent;
4. The investigator has sufficient resources to conduct the Clinical Research safely;
5. Therapeutic intervention(s), if any, can be performed by appropriate personnel proficient in managing conditions that may arise; and
6. The Study Site has sufficient facilities to support the Clinical Research; and
7. If the Clinical Research is sponsored, the CTA has been approved (or under process) by the Research Committee and an approved Letter of Indemnity is in place (or under process).

Signature: _____________________________ Date: _________________________

Name: _____________________________ Capacity: ___________________________ Department: ___________________________
Investigator’s Conflict of Interest Declaration Form
(to be completed by each investigator of the project)

Public trust in a clinical research depends partly on how well conflict of interest is handled during its operation. An investigator who has potential conflicting interest with a commercial sponsor must inform the Clinical Research Ethics Panel (CREP) of such relationships to allow a fair review to be conducted.

All investigators involving in a pre-licensing trial of drug/medical device or study of unlicensed use must each submit a conflict of interest declaration record to the CREP.

<table>
<thead>
<tr>
<th>REC Ref:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Title:</td>
<td></td>
</tr>
</tbody>
</table>

I declare the following conditions concerning me and my immediate family members*, which could cause conflict of interest:

* a person who is related to the person by blood, marriage, adoption or affinity (CAP 527). The types of blood relationships covered include mother, father, brother, sister, son, daughter, grandmother, grandfather, grandchild, aunt, uncle, cousin, nephew and niece. Relationship of marriage is that of husband and wife who are lawfully married. Relationships of affinity are those created by marriage, and include, for instance, mother-in-law and father-in-law.

I will also report potential conflict of interest to the CREP that may arise in the course of the approved study.

_________________________  ______________________  ________________
Name                      Signature                       Date
Appendix 5

Indemnity for Clinical Research
(for sponsored research)

THIS INDEMNITY is provided on ____________________________

By the Sponsor:
Name of Company: ____________________________ (the “Sponsor”)
Address: ____________________________
Fax No.: ____________________________

To the following Indemnitees:
(1) The Hong Kong Baptist University and the following Department/Unit under the management and control of the Hong Kong Baptist University:

(name)
Fax No.: ____________________________

(2) Name of the Principal Investigator:

(name)
Fax No.: ____________________________

Together with their respective trustees, officers, agents, employees and students (collectively the “Indemnitees” and individually the “Indemnitee”).

WHEREAS
(A) The Sponsor wishes to carry out the following clinical trial through the Institution and the Principal Investigator:
Title: ____________________________ (the “Study”)
Study Protocol No.: ____________________________ (the “Study Protocol”) on human subjects (the “Study Subjects”).

(B) The Institution and the Principal Investigator agree to carry out the Study on the terms and conditions under a separate agreement (the “Agreement”) provided that this Indemnity is given by the Sponsor.

NOW, THEREFORE, in consideration of the agreement of the Institution and the Principal Investigator to conduct the Study, the Sponsor agrees to provide indemnity to the Indemnitees as follows:

1. (a) Subject always to Clauses 2(b), 3(a) and 4, the Sponsor shall indemnify and hold harmless the Indemnitees and each of them from any and all losses, damages, costs (including legal costs), expenses, liabilities, claims, demands, actions, prosecutions, judgments which any of the Indemnitees may suffer or incur (the “Claim”) arising out of or in connection with the Study or the Agreement, or any breach of the Sponsor’s obligations under the Agreement or any default, act, omission, negligence or statement of the Sponsor, its officers, agents, employees or sub-contractors in connection with or in relation to the subject matter of the Study.

(b) This Indemnity extends to reimbursement of all reasonable legal costs that the Hong Kong Baptist University may incur as a result of participating in, or in connection with, or arising out of the Study, as follows:
(i) reporting any death during the Study to the Coroner under the Coroners Ordinance, dealing with the Police investigation, and preparing for and attending any Death Inquest and/or hearing arising out of or in connection with such reporting;
(ii) dealing with the media, the Medical Council, government or statutory authority or any inquiry commissioned by government or statutory authority.
This Indemnity also extends to reimbursement to the Hong Kong Baptist University of the actual costs that it may incur in providing treatment to any Study Subject or any of the Indemnitees which treatment would not have been necessary but for their participation in the Study.

2. (a) For the purposes of Clause 1(a), the Sponsor will at the Sponsor’s sole expense provide the Indemnitees with a lawyer acceptable to the Indemnitees to deal with the Claim. Provided Always that such lawyer must be retained on the basis that he will act in accordance with the Indemnitees’ reasonable instructions. If the lawyer provided by the Sponsor does not act in accordance with the relevant Indemnitee’s reasonable instructions or if a conflict of interest arises between the Sponsor and the relevant Indemnitee, such Indemnitee shall have the conduct of the Claim and shall have the right to instruct its own lawyer at the Sponsor’s expense subject to the Sponsor’s written approval which approval shall not be unreasonably withheld.

(b) The Indemnitee shall not in any event admit liability, compromise, settle or take any action prejudicial to the defence of any Claim without the prior written approval of the Sponsor which approval shall not be unreasonably withheld.

(c) In the event that the Sponsor confirms in writing that Clause 4 below is not applicable and it will provide a full indemnity to the Indemnitees, then the Sponsor shall have full conduct of the Claim Provided Always that the Sponsor shall not admit liability on behalf of the relevant Indemnitee in any event.

3. (a) The Indemnitees shall notify the Sponsor within 60 days after becoming aware of any Claim or event under Clause 1 provided that the Institution may notify on behalf of the Principal Investigator and the other Indemnitees.

(b) Without prejudice to any rights under this Indemnity, the parties agree to provide reasonable assistance to each other in dealing with any Claim or event under Clause 1.

4. The indemnity under Clause 1 does not apply to the extent that it is proven to have been caused by the negligence, malpractice or violation of the Study Protocol by any of the Indemnitees. In such event, the Sponsor shall only be liable for such proportion which is not caused by such negligence, malpractice or violation of the Study Protocol.

5. (a) This Indemnity shall be governed by and construed in accordance with the laws of Hong Kong. The application of the Contracts (Rights of Third Parties) Ordinance is expressly excluded and no person who is not a party to this Indemnity shall be entitled to enforce any right or term of this Indemnity pursuant to the Contracts (Rights of Third Parties) Ordinance.

(b) Any notice to be served on the other party for the purpose of this Indemnity shall be deemed served if faxed to the number specified in this Indemnity with the correct answerback.

(c) The singular shall include plural and vice versa.

(d) The Sponsor undertakes to send a copy of this duly signed Indemnity to the Graduate School, Hong Kong Baptist University (Fax No. 3411 5133).

IN WITNESS whereof the parties or their authorized representatives have set their hands the day and year first above written.

Signed for and on behalf of the Sponsor: 

Signed for and on behalf of the Institution and its Principal Investigator:

Name of Sponsor: 

Chairman, Research Committee

Appendix 6
THIS COVER AGREEMENT is made the [●] day of [●], [●]

BETWEEN:

(1) [●], a company incorporated under the laws of [●], with its registered office situated at [●] ("Sponsor"); and

(2) The Hong Kong Baptist University, a statutory body incorporated under the Hong Kong Baptist University Ordinance, Chapter 1126 of the laws of Hong Kong ("HKBU").

WHEREAS:

(A) The Sponsor wishes to carry out clinical trials at Department/Unit of HKBU.

(B) The HKBU agrees to the clinical trial terms and conditions ([●] template) attached hereto as Exhibit 1 ("Terms and Conditions") for and on behalf of the Department/Unit. [to be discussed]

NOW IT IS HEREBY AGREED AS FOLLOWS:

1. The parties agree that effective from the date of this Cover Agreement, the Terms and Conditions shall apply to all clinical trials to be sponsored by the Sponsor or the Sponsor’s Affiliate (as defined below) and carried out at the Department/Unit, subject to the agreement amongst the Sponsor (or the Sponsor’s Affiliate if applicable), the relevant Department/Unit and the principal investigator as to the particulars of each sponsored clinical trial by their completion and execution of the Schedules to the Terms and Conditions ("Schedules"). The Terms and Conditions together with the completed and executed Schedules shall constitute the agreement (the “Agreement”) for that sponsored clinical trial. For the avoidance of doubt, any Affiliate entering into an Agreement for a particular clinical trial shall be deemed to be the Sponsor for the purposes of such Agreement.

For the purpose of this Agreement, "Affiliate" shall mean any person or entity controlling, controlled by, or under common control with the Sponsor, and for this purpose, "control", "controlling" and "controlled by" shall mean the direct or indirect ownership of more than 50% of the shares or interests entitled to vote for the directors thereof or the equivalent, for so long as such entitlement subsists, or equivalent power over management thereof.

2. This Cover Agreement shall be governed by and construed in accordance with the laws of Hong Kong. The application of the Contracts (Rights of Third Parties) Ordinance is expressly excluded and no person who is not a party to this Cover Agreement shall be entitled to enforce any right or term of this Cover Agreement pursuant to the Contracts (Rights of Third Parties) Ordinance.

IN WITNESS whereof the parties or their authorised representatives have set their hands the day and year first above written.
SIGNED by [●]  )
For and on behalf of the  )
Hong Kong Baptist University  )

SIGNED by [●]  )
For and on behalf of the Sponsor  )
EXHIBIT 1: CLINICAL TRIAL TERMS AND CONDITIONS

([●] template)
CLINICAL TRIAL TERMS AND CONDITIONS ([ template])
(“TERMS AND CONDITIONS”)

I. RECITALS & PARTIES

(A) The company referred to in Schedule 1 (”Sponsor”) wishes to appoint the principal investigator (“Principal Investigator”) to conduct a sponsored clinical trial (“Study”) in a clinical trial setting at the clinical department (“Study Site”) of the Department/Unit (“Institution”) managed and controlled by the Hong Kong Baptist University in accordance with the study protocol (“Study Protocol”), the details of which are set out in Schedule 1, subject to these Terms and Conditions and the following schedules to the Terms and Conditions (“Schedules”) (the Terms and Conditions and the Schedules are collectively referred to as the “Agreement”):

Schedule 1 - Study Arrangements
Schedule 2 - Budget for the Study
Schedule 3 - Payment Schedule
Schedule 4 - Conditions Applicable to the Principal Investigator
Schedule 5 - Indemnity Agreement

(B) The Principal Investigator agrees to carry out the Study on the terms and conditions of this Agreement, the date of this Agreement (and its effective date, if any) are set out in Schedule 1.

II. OPERATIVE PROVISIONS

1. Interpretation

1.1. In this Agreement, unless the context otherwise requires the following expressions shall have the following meanings:

“Budget” means the estimated sum of money to be provided by the Sponsor to the Institution to enable the Principal Investigator to conduct the Study which consists of the components set out in Schedule 2;

“Case Report Forms” means the printed or electronic case report forms to be completed by the Principal Investigator and/or members of the Study Team in respect of the Study, the form of which and data covered are to be agreed between the parties;

“Ethics Committee” means the relevant institutional review board or ethics committee responsible for the ethical review of the Study;

“Evaluable Subject” means a Subject who meets all inclusion criteria (and is not excluded by the exclusion criteria) to enrol in the Study as specified in the Study Protocol;
“Hong Kong” means the Hong Kong Special Administrative Region of the People’s Republic of China;

“Hong Kong Baptist University” means the statutory body established by the Hong Kong Baptist University Ordinance (Chapter 1126), that manages and controls the Department/Unit in which the Study Site is located;

“Patient Records” means the medical records belonging to the Institution which record treatment of a patient of the Hong Kong Baptist University (including the Evaluable Subject and is not anonymised) and are kept in accordance with Hong Kong Baptist University’s policies and practices from time to time;

“ICH GCP Guidelines” means the International Conference on Harmonisation (ICH) of Technical Requirements for the Registration of Pharmaceuticals for Human Use Guidelines on Good Clinical Practice;

“Indemnity Agreement” means the separate indemnity agreement to be entered into in relation to the Study in the form of Schedule 5;

“Informed Consent Form” means the informed consent form provided by the Sponsor or otherwise agreed between the parties;

“Intellectual Property Rights” means patents, trademarks, copyrights, design rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them, other intellectual property rights arising from or in connection with the Study, whether or not any of them are registered and including applications for registration, renewal or extension of any of them;

“Know How” means all technical and other information which is not in the public domain;

“Payment Schedule” means Schedule 3 under and in accordance with which the Sponsor shall pay the Institution for the Study;

“Product” means the product under investigation, the name of which is set out in Schedule 1 and, if applicable, the placebo required for the Study;

“Recruitment End Date” means the date on which Evaluable Subject recruitment shall end as set out in Schedule 1 unless agreed otherwise in accordance with Clause 7.3;

“Study Monitor” means the person appointed by the Sponsor to monitor the progress and results of the Study;

“Study Records” means all anonymous or anonymised Case Report Forms, and other materials created for the Study by the Principal Investigator and/or members of the Study Team but excluding (a) any data from which it is possible to identify the Evaluable Subject and (b) any Patient Records;
Records;

“Study Team” means the Principal Investigator and all persons involved in conducting the Study at the Study Site;

“Subject” means a subject who agrees to participate in the Study by having given informed consent using the Informed Consent Form, whether or not he is eventually enrolled into the Study.

1.2. Except where the context otherwise requires, words denoting the singular include the plural and vice versa, words denoting any gender include all genders, and words denoting persons include firms and corporations and vice versa.

1.3. References herein to Clauses and Schedules are to the clauses and schedules of this Agreement. In the event of any conflict or inconsistency between any provision of the Clauses and any provision of the Schedules, the former shall prevail, but only to the extent of the conflict or inconsistency. In the event of any conflict between this Agreement, the Study Protocol and the Indemnity Agreement, the terms of the Indemnity Agreement shall prevail. In the event of any conflict between this Agreement and the Study Protocol, the terms of this Agreement shall prevail. In the event of any conflict or inconsistency between the Schedules, the later in time shall prevail, but only to the extent of the conflict or inconsistency.

1.4. References herein to any enactment, order, regulation or other similar instrument shall be construed as a reference to the enactment, order, regulation or instrument as amended by any subsequent enactment, order, regulation or instrument or as contained in any subsequent re-enactment thereof.

1.5. The words “other”, “including” or any similar expression do not limit the generality of any preceding words and are not to be construed as being limited to the same class as the preceding words where a wider construction is possible.

1.6. The clause and subject headings are for convenience only and shall not affect the interpretation of this Agreement.

2. Commencement and Duration

2.1. This Agreement shall commence on the date that the Conditions Precedent in Clause 3 are satisfied or such other date (if later) agreed by the parties in writing and shall continue in force, subject to the terms hereof, until the completion of the Study at the Study Site, subject always to early termination in accordance with Clause 17.

3. Conditions Precedent

The following are conditions precedent:

(a) The Principal Investigator has:
(i) obtained the appropriate management approval from the Institution to conduct the Study at the Study Site in accordance with this Agreement; and

(ii) agreed to continue to meet the conditions set out in Schedule 4 by his signature.

(b) The Sponsor has entered into the Indemnity Agreement in the form set out in Schedule 5.

4. Approval of Ethics Committee and Clinical Trial Governance

4.1. The Principal Investigator shall at the expense of the Sponsor as set out in the Budget be responsible for seeking approval of the Study, Study Protocol, Informed Consent Form and Study advertisements, if any, from the Ethics Committee prior to commencing the Study.

4.2. In the event that the Ethics Committee requires any changes to the Study Protocol, Informed Consent Form or Study advertisements (if any), such changes shall not be implemented without the prior written consent of the Sponsor.

4.3. For the avoidance of doubt, neither the Institution nor the Principal Investigator shall be held liable or responsible for any failure by the Ethics Committee to grant approval for the Study, or changes to the Study Protocol, Informed Consent Form or Study advertisements.

4.4. Any amendment to the Study Protocol must be agreed by the parties in writing and approved by the Ethics Committee. In the event that the Institution or the Principal Investigator does not agree to such amendment or written approval is not granted by the Ethics Committee, the Institution and Sponsor shall have the right to terminate this Agreement in accordance with the provisions of Clause 17.1(a).

5. The Study

5.1. The Study is anticipated to last for the period set out in Schedule 1.

5.2. The Principal Investigator undertakes to follow the procedures of the Study Protocol, provided that all such procedures are in accordance with the international standards set out in the Study Protocol and comply with the laws and ethical practices of Hong Kong.

5.3. The Principal Investigator undertakes that the Study will be conducted with due skill, care and diligence and in accordance with the relevant provisions of the ICH GCP Guidelines and all legal and ethical requirements in Hong Kong from time to time.
5.4. The Principal Investigator shall not commence the Study until written approval from the Ethics Committee has been granted in accordance with Clause 4.1. In the event that approval is delayed the parties shall agree reasonable extensions of any time limits in this Agreement.

5.5. The Study shall be carried out under the proper supervision of the Principal Investigator and can be terminated at any time by the Institution or the Sponsor in accordance with Clause 17.1 or Clause 17.2.

5.6. The Sponsor undertakes that it will expediently report to the Principal Investigator and the Ethics Committee any “serious adverse events” (as defined in the Study Protocol) which are experienced at any other study site in the event that this Study is conducted as a part of a multi-centre study.

5.7. The Institution shall notify the Sponsor if the Principal Investigator is no longer able to act as the Principal Investigator (owing to ceasing to be employed by or associated with the Institution or otherwise), and shall use its reasonable endeavours to find a replacement mutually acceptable to both the Sponsor and the Institution. The replacement mutually acceptable to both the Sponsor and the Institution shall be the “Principal Investigator” for the purposes of this Agreement. If no mutually acceptable replacement can be found, the Sponsor shall have the right to terminate this Agreement pursuant to Clause 17.3.

6. Supply of Product

6.1. The Sponsor shall in a timely fashion supply sufficient quantities of the Product to the Principal Investigator as shall be required for the purpose of the Study.

6.2. The Institution and the Principal Investigator agree to use the Product only for the purposes of carrying out the Study.

6.3. The Product shall remain at all times the sole property of the Sponsor and at no time shall any rights or ownership be vested in the Institution or the Principal Investigator. All remaining/unused Product shall at the expense of the Sponsor be returned to the Sponsor or disposed of as the Sponsor may direct after completion or early termination of the Study.

6.4. Supply of the Product to the Evaluable Subjects after completion of the Study may be arranged by the Sponsor.

7. Recruitment of Evaluable Subjects

7.1. The Principal Investigator shall inform each Subject of the nature of the Study and obtain the Subject’s or the Subject’s legally acceptable representative’s prior informed consent to undergo the Study in accordance with the Informed Consent Form.

7.2. The Principal Investigator shall use all reasonable endeavours to recruit such number
of Evaluable Subjects to participate in the Study prior to the Recruitment End Date and in accordance with the timelines set forth in the Study Protocol.

7.3. The parties may agree in writing to extend the Recruitment End Date if so desired subject to agreement being reached on the timing of payment of sums due on the Recruitment End Date.

7.4. If the Principal Investigator is able, and the Sponsor agrees to recruit, more Evaluable Subjects in Hong Kong than the number stipulated in this Agreement, the Sponsor shall confirm its agreement to such increase in number in writing to the Institution. Each additional Evaluable Subject shall be paid as an Evaluable Subject in accordance with the Budget.

8. Budget and Payment

In consideration of the Institution agreeing to enter into this Agreement and allowing the Principal Investigator to carry out the Study, the Sponsor agrees to pay the Institution in accordance with the Budget and the Payment Schedule.

9. Confidentiality

9.1 (a) The Sponsor shall keep confidential the Evaluable Subjects’ personal data (including clinical data obtained from their Patient Records or through their involvement in the Study) and shall disclose such to persons within the Sponsor’s organisation strictly on a need-to-know basis (and without in any way identifying the Evaluable Subjects unless absolutely necessary) subject to such persons undertaking to keep such personal data confidential.

(b) Where so provided in the Informed Consent Form and informed consent has been obtained in accordance with Clause 7.1, the Institution or the Principal Investigator may:

(i) in compliance with requests or pursuant to the Institution’s reporting obligation, disclose the Evaluable Subjects’ personal data to the Ethics Committee or the agents of government or regulatory authority in relation to the Study; and

(ii) disclose the Evaluable Subjects’ personal data to the Sponsor, the Study Monitor or the Sponsor’s auditor for the purposes of the Study for the duration of the Study and for three (3) years after completion of the Study.

(c) Where the Evaluable Subjects’ data are to be presented whether in the form of published results or otherwise, they must be presented in a form from which the Evaluable Subjects cannot be identified and which no longer constitutes personal data within the meaning of the Personal Data (Privacy) Ordinance or other applicable law or regulation in Hong Kong.
9.2 (a) The parties shall treat as confidential the business affairs that one party has disclosed to the other pursuant to or in connection with this Agreement.

(b) The obligations of confidentiality set out in this Clause 9.2 shall not apply to confidential information which is:

(i) published or generally available to the public through no fault of the receiving party;

(ii) in the possession of the receiving party prior to the date of this Agreement and is not subject to a duty of confidentiality;

(iii) independently developed by the receiving party and is not subject to a duty of confidentiality; or

(iv) obtained by the receiving party from a third party not subject to a duty of confidentiality.

(c) The obligation under Clause 9.2 shall survive termination of this Agreement.

9.3 The Institution and the Principal Investigator shall treat as confidential any and all information that they obtain relating to or through the Study (whether or not generated by the Principal Investigator and members of the Study Team), including without limitation, the Product, data of the Evaluable Subjects arising from the Study, or results of the Study ("Confidential Information") and shall only disclose such to persons within the Institution strictly on a need-to-know basis. Subject to Clause 11, the Institution and Principal Investigator shall use all reasonable endeavours to keep the Confidential Information confidential for the duration of the Study and for ten (10) years after completion of the Study provided always that this obligation shall not apply to the whole or any part of the Confidential Information to the extent that such information:

(a) is trivial or obvious;

(b) was already in the public domain at the time of its disclosure by the Sponsor to the Institution, Principal Investigator and/or Study Team member;

(c) entered the public domain subsequent to the time of its disclosure by the Sponsor to the Institution through no fault of the Institution, Principal Investigator and/or Study Team member;

(d) is independently developed by the Institution, Principal Investigator and/or Study Team member;

(e) is obtained by the Institution, Principal Investigator and/or Study Team member from a third party not subject to a duty of confidentiality;
(f) is information requested for the purposes of providing medical treatment to any Subject provided that prior written consent is obtained from the Sponsor which consent cannot be unreasonably delayed or withheld;

(g) is required by any law, regulation, competent authority or governmental or internationally recognized document or guideline such as (but not limited to) the ICH GCP Guidelines, or any judicial or quasi-judicial order or guideline to be disclosed provided written notice has been given to the Sponsor prior to such disclosure; or

(h) is of a nature that the Institution and/or Principal Investigator in its/his absolute discretion believes should be disclosed to government, health authorities, the Ethics Committee or regulators, whether related to adverse effects of the Product and/or the procedures in the Study Protocol or otherwise, provided written notice has been given to the Sponsor prior to such disclosure.

For the avoidance of doubt, Clause 9.3 does not apply to information documented in the Patient Records.

9.4 Each party acknowledges that any breach of this Clause 9 will cause irreparable injury to the other party not in breach and which could not be adequately compensated in monetary damages. The party not in breach may be entitled to equitable remedies, including but not limited to injunctive relief, specific performance and restraining orders in respect of any such breach. Equitable relief shall be in addition to all other remedies available to the parties, including but not limited to damages.

10. Ownership of the Results of the Study

10.1. All Intellectual Property Rights and Know How arising out of the Study, except for the Patient Records and the rights to extract information from the Patient Records which shall at all times be owned by the Institution (“Excluded IPR”), shall be vested in or be exclusively licensed to the Sponsor.

10.2. The Institution and the Principal Investigator hereby assign their rights in all Intellectual Property Rights, and to the extent possible in all Know How, arising out of the Study other than Excluded IPR to the Sponsor and, at the expense of the Sponsor, the Institution and the Principal Investigator shall execute all such documents and do all such other acts and things as the Sponsor may reasonably require in order to vest fully and effectively all such Intellectual Property Rights and Know How arising out of the Study in the Sponsor or its nominee.

10.3. It is expressly agreed that neither Sponsor nor Institution transfer by operation of this Agreement to the other party hereto any patent right, copyright, or other proprietary right that either party owns or controls, except as specifically set forth herein.

10.4. Institution agrees that any inventions, discoveries, or improvements arising out of work performed hereunder in the Study that are (i) dependent on Sponsor’s patent claims, or are (ii) expressly anticipated by the Protocol (hereinafter “Sponsor’s Inventions”) shall be assigned to Sponsor and shall be promptly disclosed by Institution
10.5. All other inventions developed under this Agreement ("Other Inventions") that are developed solely by Institution shall be owned by Institution. All Other Inventions developed by one or more employees of both Sponsor and Institution under this Agreement shall be owned jointly by Sponsor and Institution. Institution shall grant Sponsor an option to negotiate to obtain an exclusive, royalty bearing, worldwide license, including the right to sublicense, to make, have made, use, and sell products incorporating such sole Other Inventions or Institution’s rights to jointly owned Other Inventions. Sponsor’s option may be exercised at any time during a period of ninety (90) days (the "Option Period") after the written submission to Sponsor of each such Invention by notice in writing from Sponsor to Institution. Upon Sponsor’s exercise of its option with regard to any particular Invention, Institution and Sponsor will negotiate in good faith in an attempt to reach a license agreement satisfactory to both parties (the "Negotiation Period"). Unless extended by the written mutual consent of the parties, the Option Period and the Negotiation Period shall not exceed ten (10) months in the aggregate. Upon the expiration of the unexercised option or the Negotiation Period, Institution shall have no further obligation to Sponsor under this Agreement with regard to specific Other Inventions under consideration.

10.6. It is recognized and understood that research, inventions, and technologies owned by HKBU and existing at the date when this Agreement becomes effective are the separate property of HKBU, and are not affected by this Agreement, and the Sponsor shall have no claims or rights in such separate inventions and technologies. The Sponsor further agrees that any research, inventions, discoveries, or improvements solely developed by HKBU arising out of the Study after this Agreement period shall be owned by HKBU.

11. Registration and Publication

11.1. The Sponsor shall, as appropriate, register the Study with the United States clinical trial registry at ClinicalTrials.gov, any other public clinical trial registry recognized by the World Health Organization or the International Committee of Medical Journal Editors, or the Sponsor’s own clinical trial registry.

11.2. The Sponsor acknowledges that the Institution is dedicated to a free scholarly exchange and to public dissemination of the results of their scholarly activities. Notwithstanding Clauses 9 and 10, the Principal Investigator and the Institution (including its trustees, officers, physicians, other employees and students) shall, subject only to the provisions of this Clause 11, have the right to publish, disseminate, or otherwise disclose information and materials relating to or arising out of the Study.

11.3. The Sponsor recognises that the Institution and the Principal Investigator may wish that results of scientific interest arising from the Study are appropriately published and disseminated. The Sponsor agrees that employees of the Institution shall be permitted to present at symposia, national or regional professional meetings, and to publish in journals, theses or dissertations, publicly accessible worldwide register(s), or otherwise of their own choosing, methods and results of the Study subject to Clause
11.4 and the publication policy described in the Study Protocol. If the Study is a multi-centre clinical trial, any publication based on the results obtained at the Study Site shall not be made before the first publication for the entire multi-centre study. If a publication concerns the analyses of sub-sets of data from a multi-centred study the publication shall make reference to the relevant multi-centre publication(s).

11.4. Upon completion of the Study, and any prior publication of multi-centre data, or when the Study data are adequate (in Sponsor’s reasonable judgment), the Institution or the Principal Investigator may prepare the data deriving from the Study for publication. The Institution or the Principal Investigator (as the case may be) shall send to the Sponsor for review and comment a copy of any publication or presentation (e.g. manuscript, abstract or poster) (collectively the “Proposed Publication”) which it/he proposes to submit to a journal or scientific meeting or for a press release at least sixty (60) days prior to such submission.

11.5. The Sponsor undertakes to comment on the Proposed Publication within sixty (60) days from the date of its submission. Subject to Clause 11.6, the Institution or the Principal Investigator will not be allowed to submit the Proposed Publication to any other person until the expiration of such sixty (60) day period. The Institution and the Principal Investigator agree that all reasonable comments made by the Sponsor in relation to a Proposed Publication will be incorporated into the publication, if the Institution or the Principal Investigator considers it not reasonable to incorporate a comment made by the Sponsor, the Institution or the Principal Investigator shall give the Sponsor written notice explaining the reason thereof not less than three (3) days before the date that the Proposed Publication is to be published.

11.6. The Sponsor has the discretion to delete or modify any Confidential Information from the Proposed Publication, provided such discretion is exercised reasonably.

11.7. The Principal Investigator or the Institution shall have the right to publish the data collected from the Study, on their own or in collaboration with other participating investigators and/or the Sponsor.

11.8. In the event that the Study is conducted on a multi-centre, multi-national basis, the order of authorship of the first international publication of the entire study shall be ranked in descending order with the investigator who recruits the highest number of Evaluable Subjects being the first author to be listed on the first international publication and the investigator who recruits the least number of Evaluable Subjects being the last author on the list.

11.9. During the period for review of a Proposed Publication, the Sponsor shall be entitled to make a reasoned request to the Institution or the Principal Investigator (as the case may be) that publication be delayed for a period of up to six (6) months from the date of first submission to the Sponsor in order to enable the Sponsor to take steps to protect its proprietary information and the Institution or Principal Investigator (as the case may be) shall not unreasonably withhold its/his consent to such a request.

11.10. The Institution and the Principal Investigator acknowledge and agree that the Sponsor
may present at symposia, national or regional professional meetings and publish or make public in journals, theses or dissertations, publicly accessible worldwide register(s), or otherwise of their own choosing, a summary of the Study Protocol, methods and results of the Study. In particular but without limiting the foregoing, the Institution and the Principal Investigator agree that the Sponsor may, in accordance with its standard operating process on publication and disclosure of sponsored clinical trial results with respect to pharmaceutical products, make the Study results public by posting a summary of the same on the Sponsor’s online clinical trial register before or after publication or by another method of the Sponsor’s choice. In the event the Sponsor coordinates a multi-centre publication, the participation of the Principal Investigator as a named author shall be determined in accordance with the Sponsor’s policy and generally accepted standards for authorship. In addition, the Institution and the Principal Investigator agree that the Sponsor may in respect of the Study at any time make public the name of the Principal Investigator, the details of the Institution with which the Principal Investigator is affiliated in one or more publicly accessible worldwide registers.

11.11. Otherwise than in accordance with Clause 11.10, the Sponsor will not use the name of the Institution, nor of any member of the Institution’s staff, in any publicity, advertising or news release in connection with the Study without the prior written approval of an authorised representative of the Institution, such approval not to be unreasonably withheld. The Institution will not use the name of Sponsor nor of any of its employees, in any publicity in connection with the Study without the prior written approval of Sponsor.

12. Completion, Monitoring and Auditing of Study Records

12.1. For the duration of the Study and for a period of three (3) years after completion of the Study:

(a) The Principal Investigator shall upon completion of all Case Report Forms for all Evaluable Subjects and reasonable notice from the Sponsor, make himself available to the Study Monitor at all reasonable times for an audit of the Study Records against the Patient Records in order to verify the accuracy of the clinical data and compliance with all applicable regulations;

(b) In the event that the Sponsor identifies and notifies the Principal Investigator of any deficiency in the Study Records, the Principal Investigator will take all reasonable steps to rectify such deficiencies; and

(c) The Institution agrees to allow the Sponsor’s auditors to inspect the Study Records, the Patient Records, the associated data and the study facilities, whenever reasonably requested upon provision of thirty (30) days’ prior written notice once in any 12-month period.

12.2. The Sponsor will report on the Study activity to the Institution and the Principal Investigator, the frequency of which is set out in the Study Protocol or as may
reasonably be required. The Sponsor will also alert the Institution and the Principal Investigator promptly to significant issues relating to the Study, such as those pertaining to reasonably knowable risks of the Study or the Product, safety data and recommendations to ensure patient safety.

12.3. If any governmental or regulatory authority notifies the Institution that it will inspect the Institution’s records, facilities, equipment or procedures, or otherwise take action related to the Study, the PI as appropriate shall promptly notify the Sponsor, allow the Sponsor to be present at the inspection/action, participate in any response to the inspection/action, and provide the Sponsor with copies of any reports issued by the authority and the Institution’s proposed response, unless prohibited by the governmental/regulatory authority or by law.

12.4. Without prejudice to the terms and conditions in the Indemnity Agreement set out in Schedule 5, the Sponsor shall fully indemnify the Indemnitees (as defined in the Indemnity Agreement) in the event that provision of any information under this Clause 12 is in breach of any laws, regulations or codes of conduct.

12.5 (a) The PI shall upon the request and at the cost of the Sponsor archive the Study Records as a custodian for a period of fifteen (15) years upon completion or early termination of the Study (“Archiving Period”). In the event the PI is unable to retain the Study Records for the Archiving Period for whatever reasons, the Sponsor shall on the Institution’s request (i) archive, on behalf of the Institution and the Principal Investigator and at the Sponsor’s expense, such Study Records in the Sponsor’s own storage facility or an independent third-party storage facility, provided that all Study Records shall be placed and sealed in carton boxes at the Study Site before being transported to any of such storage facilities and shall not be retrieved, transferred to another place, or accessed to for whatever purpose without the prior written consent of the Institution; or (ii) pay the Institution reasonable costs for making special arrangement for archiving of the Study Records. The Institution shall not be liable for misplacement, loss or damage of the Study Records in whatever media they may be stored, including without limitation deterioration in their quality or their retrieval (from computer or similar database).

(b) Subject to the Institution’s prevailing policies and practices on Patient Records, the Institution may inform the Sponsor of the arrangement that the Sponsor may make at the Sponsor’s cost to archive the Patient Records for the Archiving Period. In providing such information, the Institution shall not be liable for misplacement, loss or damage of the Patient Records in whatever media they may be stored, including without limitation deterioration in their quality or their retrieval (from computer or similar database).

13. Limitation of Liability and Indemnity

13.1. In the event of any claim or proceeding in respect of personal injury made or brought against the Institution or the Principal Investigator by an Evaluable Subject, the
Sponsor shall indemnify the Institution, the Principal Investigator, its servants, agents and employees in accordance with the terms of the indemnity set out in Schedule 5.

13.2. The Institution’s and Principal Investigator’s entire aggregate liability to the Sponsor for any loss or damage arising from any act or omission relating to this Agreement regardless of the form of action, whether in contract or tort (including in each case negligence), strict liability or otherwise, shall be limited to the total Budget pursuant to this Agreement.

13.3. Nothing in this Agreement shall exclude or limit the liability of any party for death or personal injury resulting from its negligence or the negligence of its employees while acting in the course of their employment.

14. Use of Parties’ Names

14.1. Subject to Clause 11.10, the Sponsor agrees not to use the name of the Institution, the Principal Investigator or of any trustee, officer, agent, employee or student of the Institution or any variation or combination of such names, for any purpose whatsoever, without receiving the prior written approval of the Institution, such approval not to be unreasonably withheld or delayed where such information is needed to be disclosed in necessary communication with or submissions to competent health, regulatory or other governmental authorities in connection with the Study.

14.2. Subject to Clause 11.3, the Institution agrees not to use the name of the Sponsor or of any trustee, officer, agent or employee of the Sponsor or any variation or combination of such names, for any purpose whatsoever, without receiving the prior written approval of the Sponsor, such approval not to be unreasonably withheld or delayed where such information is needed to be disclosed in necessary communication with or submissions to competent health, regulatory or other governmental authorities in connection with the Study.

15. Protection of Personal Data

The parties confirm that they are aware of the provisions of the Personal Data (Privacy) Ordinance (Chapter 486 of the laws of Hong Kong) and all parties warrant that they will duly observe all obligations under this Ordinance.

16. Confidentiality of Agreement

The parties agree to keep the existence and terms of this Agreement confidential and not to reveal the existence or terms of this Agreement to any other person (except to officers, agents, employees or sub-contractors in connection with or in relation to the performance of this Agreement) without the consent of the other party, except where any disclosure is required by law or competent health authorities.
17. Termination

17.1. Either the Institution or the Sponsor may terminate this Agreement:

(a) at any time upon giving to the other party thirty (30) days’ prior written notice; or

(b) at any time by notice in writing to the other party (as from the date of service of such notice) if the other party commits a material breach of any provision hereof which is not remediable or, if remediable, is not remedied within thirty (30) days after the non-breaching party has given written notice to the breaching party requiring such breach to be remedied.

17.2. The Institution or the Sponsor may terminate this Agreement on notice to the other party with immediate effect if in the reasonable opinion of either party or the Ethics Committee the Study should cease in the interests of the health, safety or well-being of the Evaluable Subjects involved in the Study.

17.3. The Sponsor may terminate this Agreement on notice to the Institution if the Principal Investigator named in Schedule 1 is no longer able (for whatever reason) to act as Principal Investigator and no replacement mutually acceptable to the Institution and Sponsor can be found within fourteen (14) days of such named person ceasing to act as the Principal Investigator.

17.4. Upon termination of this Agreement, the Sponsor shall:

(a) pay the Institution all sums due under the Budget on a pro-rata basis up to the date of termination; and

(b) reimburse the Institution any of its prepaid, committed or accrued expenses incurred up to the date of termination in accordance with the terms of this Agreement;

and after compliance with this Clause 17.4, any unused funds previously paid by the Sponsor to the Institution shall be refunded forthwith to the Sponsor.

17.5. In the event of early termination of this Agreement, the Principal Investigator shall inform the Ethics Committee with an explanation of the reason(s) for early termination of the Study.

17.6. Upon termination of this Agreement for any reason, the Principal Investigator shall promptly terminate the conduct of the Study to the extent medically permissible for any Evaluable Subjects and subject to Clause 6.4 shall, within seven (7) working days, make all unused quantities of the Product and any other unused materials and all Confidential Information provided by the Sponsor pursuant to this Agreement ready for collection by the Sponsor.
18. Consequences of Termination

18.1. Subject to Clause 18.2 upon termination of this Agreement, none of the parties shall have any further obligation or right with respect to the others.

18.2. All provisions of this Agreement which in order to give effect to their meaning need to survive termination shall remain in full force and effect including (but without limitation) the provisions of this Clause and Clauses 1 (Interpretation), 10 (Ownership of the Results of the Study), 13 (Limitation of Liability and Indemnity), 14 (Use of Parties’ Names), 15 (Protection of Personal Data), 16 (Confidentiality of Agreement), 27 (No Poaching) and Schedule 5 (Indemnity Agreement). For the avoidance of doubt, the separate Indemnity Agreement shall continue in full force and effect notwithstanding termination of this Agreement.

19. Insurance

19.1. The Sponsor shall from the date hereof maintain such insurance coverage as is necessary to cover in full its potential liabilities in connection with or arising out of the Study and this Agreement. The Sponsor shall upon the Institution’s request supply details of such insurance coverage to the Institution including copies of relevant policy documentation and/or the insurance certificate.

19.2. The insurance taken out by the Sponsor does not relieve the Institution, the Principal Investigator and the Study Team from any obligation to maintain its/their own liability insurance policy.

19.3. Sponsor agrees to reimburse the Institution, other accredited medical care providers, or Study participants (as appropriate) for any medical care required by Study participants that occurs as a direct result of participation in the Study and that is not covered by the participants' medical insurance. Sponsor’s obligations under this section will not apply to the extent that the medical care is the result of:

(a) injuries or illnesses primarily due to a participant’s underlying medical condition,

(b) known risks of routine patient care portions of the protocol, or

(c) Institution’s negligence or willful misconduct.

20. Force Majeure

20.1. For the purposes of this Agreement, the expression “Force Majeure” shall mean any cause affecting the performance by a party of its obligations under this Agreement which arises from acts, events, omissions, happenings or non-happenings beyond its
reasonable control including war, hostilities, revolution, civil commotion, strike, epidemic, accident, wind, fire, flood, or any disaster or an industrial dispute or because of any Act of God. Any act, event, omission, happening or non-happening will only be considered Force Majeure if it is not attributable to the wilful act, neglect or failure to take reasonable precautions of the affected party, its servants, agents or employees.

20.2. No party shall in any circumstances be liable to the other party for any loss of any kind whatsoever including any damages or abatement of payments made hereunder whether directly or indirectly caused to or incurred by the other party by reason of any failure or delay in the performance of its obligations hereunder which is due to Force Majeure provided always that each party shall use all reasonable endeavours to continue to perform, or resume performance of, such obligations hereunder after the Force Majeure event.

21. Amendments

No amendment to the provisions of this Agreement shall be effective unless agreed upon by a written instrument executed by the authorised representatives of each party.

22. Notices and Communications

22.1. Any notice or other document to be given under this Agreement shall be in writing and shall be deemed to have been duly given if left at or sent by hand or by registered post, or by facsimile or such other electronic media which may from time to time be agreed by the parties to a party at the address or facsimile number set out in Schedule 1 for such party or such other address or facsimile number as one party may from time to time designate by written notice to the other.

22.2. Any such notice or other document shall be deemed to have been received by the addressee three (3) working days following the date of dispatch if the notice or other document is sent by registered post, or simultaneously with the delivery or transmission if sent by hand or if given by facsimile or other electronic means.

23. Waiver

No failure or delay on the part of any of the parties to exercise any right or remedy under this Agreement shall be construed or operate as a waiver thereof nor shall any single or partial exercise of any right or remedy preclude the further exercise of such right or remedy as the case may be. The rights and remedies provided in this Agreement are cumulative and are not exclusive of any rights or remedies provided by law.

24. Severability

If any provision of this Agreement is held to be invalid, illegal or unenforceable for any
reason, such provision shall be severed and the remainder of the provisions hereof shall continue in full force and effect as if this Agreement had been executed with the invalid provision eliminated. In the event of a holding of invalidity so fundamental as to prevent the accomplishment of the purpose of this Agreement, the parties shall immediately commence good faith negotiations to remedy such invalidity.

25. No Agency

Neither the Institution nor the Sponsor shall have authority to commit the other party in any way whatsoever and both parties shall make this clear as circumstances warrant.

26. Independent Contractor

Nothing contained in this Agreement shall be construed as establishing or creating any relationship other than that of independent contractor between the Institution and the Sponsor.

27. No Poaching

Neither Sponsor nor Institution (unless they otherwise agree) shall for a period beginning on the date hereof until twelve (12) months after termination of this Agreement directly or indirectly solicit or procure (otherwise than by general advertising) the employment of any employee, agents or sub-contractors of the other party.

28. Entire Agreement

This Agreement, the Study Protocol and the Indemnity Agreement constitute the entire agreement between the parties with respect to this matter and supersede any and all prior agreements, understandings, or arrangements, whether oral or written, in respect of the Study.

29. Assignment

Neither Sponsor nor Institution may assign its rights or obligations under this Agreement to any third party without the prior written consent of the other party, such consent not to be unreasonably withheld. Save that Sponsor shall have the right to assign its rights to any other company in the Sponsor’s group of companies subject to a thirty (30) days prior written notice to the Institution and compliance with all relevant requirements of the Ethics Committee and competent regulatory authorities and the entering into by the parties of all necessary agreements for such assignment.

30. Disputes
30.1 In the event of a dispute, the parties agree to attempt to settle it by negotiation in good faith amongst the parties by submitting each such dispute to appropriate senior management representatives of each party in an effort to effect a mutually acceptable resolution thereof. To initiate such a negotiation, a party must give notice in writing (“Dispute Resolution Notice”) to the other party requesting negotiation in accordance with this Clause 30.1. The negotiation will start no later than twenty (20) days after the date of the Dispute Resolution Notice. If the dispute is not resolved within thirty (30) days of the Dispute Resolution Notice, a party may by written notice to the other refer the dispute to arbitration in accordance with Clause 30.2 below.

30.2 If the parties are unable to settle a dispute arising out of or in connection with this Agreement by negotiation, the dispute will be finally settled by arbitration in accordance with the UNCITRAL Arbitration Rules as at present in force (the “UNCITRAL Rules”). The appointing authority shall be the Hong Kong International Arbitration Centre (“HKIAC”). The place of arbitration shall be in Hong Kong at HKIAC. There shall be only one arbitrator.

30.3 Any such arbitration shall be administered by HKIAC in accordance with HKIAC Procedures for Arbitration in force from time to time.

30.4 The aforesaid dispute resolution procedure does not preclude any party from seeking remedies in Hong Kong courts.

30.5 The performance of any obligations under this Agreement shall not cease or be delayed by the aforesaid dispute resolution procedure.

31. Warranty

31.1 The Institution and Sponsor each warrants that the person executing this Agreement is authorised to do so on its behalf and that the execution, delivery and performance of this Agreement does not in any way conflict with any other agreement, including but not limited to, any policy or guidelines binding on those persons.

31.2 The Sponsor warrants that the Product and the use of the Product in the Study does not and will not infringe the intellectual property or other rights of any third party and agrees to indemnify and hold harmless the Institution and the Principal Investigator against all costs, claims, damages and expenses arising from any third party claim that the Institution’s or the Principal Investigator’s participation in the Study and use of the Product infringes the intellectual property or other rights of that third party.

32. Governing Law and Jurisdiction

This Agreement shall be governed by and construed in accordance with the laws of Hong Kong. The application of the Contracts (Rights of Third Parties) Ordinance is expressly excluded and no person who is not a party to this Agreement shall be entitled
to enforce any right or term of this Agreement pursuant to the Contracts (Rights of Third Parties) Ordinance.
THE SCHEDULES – SUBJECT TO THE TERMS AND CONDITIONS OF
[.] TEMPLATE

These Schedules are entered into by the parties hereunder in respect of the Study referred to in Part 4(a) of Schedule 1, subject to the Terms and Conditions ([ . ] Template). The Terms and Conditions form an integral part of these Schedules and are incorporated herein by reference. The Terms and Conditions and these Schedules are together referred to as the “Agreement” for the Study.

Schedule 1 – Study Arrangements

1.  (a) The date of this Agreement is: [ • ]
(b) The effective date of this Agreement is: [ • ]

2.  The Sponsor is [ • ], a company incorporated under the laws of [ • ], with its registered office situated at [ • ]

3.  (a) The Institution is: [ • ]
(b) The Principal Investigator is: [ • ]
(c) The Study Site is: Department of [ • ]
    Tel: [ • ]
    Fax: [ • ]

4.  (a) The Study and the title of the Study Protocol is: [ • ]
(b) The reference number of the Study Protocol is: [ • ]
(c) The Study is anticipated to last: [ • ] months
(d) The Product to be investigated under the Study is: [ • ]
(e) Target number of Evaluable Subjects to be recruited is: [ • ]
(f) Recruitment End Date of Evaluable Subjects is: [ • ]

5.  (a) Completion of Case Report Form during the Study: within [ • ] days
(b) Response to data queries during the Study: within [ • ] days
(c) Response to data queries during the final clean up: within [ • ] days
(d) Completion of Case Report Forms on completion or early termination of the Study is: within [●] days

(e) Archiving Period is: [●] years

6. Notices and Communications:

(a) To the Institution:
   [insert name of Department/Unit]
   [insert address]
   Tel: [●]
   Fax: [●]

(b) To the Principal Investigator:
   [●]

(c) To the Sponsor:
   [●]

7. The Sponsor warrants that the Study Protocol complies with the ICH GCP Guidelines, the laws and ethical requirements of Hong Kong and the following version of the Declaration of Helsinki: [●]
THE SCHEDULES – SUBJECT TO THE TERMS AND CONDITIONS OF

[.] TEMPLATE

Schedule 2 – Budget for the Study

[EXAMPLE:]

1. Fixed cost to cover the basic costs to be incurred for the Study:
   
   [ • ] and the Institution’s administrative costs of HK$15,000.00

2. Study costs for the Study:
   
   (a) Treatment cost per Evaluable Subject (up to the maximum number of Evaluable Subjects under this Agreement or additional Evaluable Subjects agreed by the Sponsor), provided that the Evaluable Subject completes the treatment and/or concludes with a “withdrawal/conclusion visit” in accordance with the Study Protocol, is: [ • ]
   
   (b) Follow-up cost per “Follow Up Visit” completed by the Evaluable Subject in accordance with the Study Protocol is: [ • ]
   
   (c) Screening failure cost per Subject screened according to the Study Protocol but who cannot be enrolled as an Evaluable Subject is: [ • ]
   
   (d) Additional assessment costs for each actual additional assessment performed for each Evaluable Subject in accordance with the Study Protocol is: [ • ]
   
   (e) [Nature of Assessment] [Cost]
   
   (f) Others (if any): [ • ]

3. The detailed breakdown of the Budget (if any) is attached to this Schedule 2.
Payments due to the Institution under the Budget shall be made by the Sponsor according to the following schedule:

[EXAMPLE:]

1. The fixed cost of [ HK$ ] shall be paid in full upon full execution of this Agreement.

2. The treatment cost, follow-up cost, screening failure cost and additional assessment costs shall be paid in March, June, September and December every year during the course of the Study. The amount of each payment due to the Institution shall be calculated in respect of the number of screened Subjects and Evaluable Subjects and the number of visits and additional assessments completed by each Evaluable Subject in accordance with the Budget in Schedule 2.

3. Payments are to be made payable to “Hong Kong Baptist University”.
Schedule 4 – Conditions Applicable to the Principal Investigator

I, being the Principal Investigator of the Study at the Study Site, have read and understood the Agreement.

I hereby agree to comply with the Agreement and following conditions during the period of the Agreement:

(i) I am free to participate in the Study and there are no rights which may be exercised by or obligations owed to any third party which might prevent or restrict my performance of the obligations detailed in the Agreement.

(ii) I am not involved in any regulatory or misconduct litigation or investigation by any relevant regulatory authority such as the Food and Drug Administration of the United States of America, the Medicines Control Agency of the United Kingdom or the European Medicines Evaluation Agency of the European Union. No data produced by me in any previous clinical study have been rejected because of concerns as to their accuracy or because they were generated by fraud.

(iii) I have considered, and am satisfied that, facilities appropriate to the Study are available to me at the Study Site and that I am supported, and will continue to be supported, by medical and other staff of sufficient number and experience to enable performance of the Study efficiently and in accordance with the obligations under the Agreement.

(iv) I am covered by appropriate medical liability insurance and details and evidence of the coverage will be provided to the Sponsor upon request.

(v) Neither myself, nor my spouse nor any dependent children, have entered into and will not enter into any financial arrangements with the Sponsor to hold financial interests in the Sponsor and/or the Product that are required to be disclosed pursuant to the United States Code of Federal Regulations Title 21 Part 54 (“21 CFR 54”), namely: (i) any financial arrangement whereby the value of the compensation paid in respect of the performance of the Study could be influenced by the outcome of the Study (as more fully defined in 21 CFR 54.2(a)); (ii) any proprietary interest in the Product (as more fully defined in 21 CFR 54.2(c)); (iii) any significant equity interest exceeding US$50,000 in the Sponsor (as more fully defined in 21 CFR 54.2(b)); and (iv) any significant payments from the Sponsor (except for the Budget for the Study) such as grants to fund ongoing research, compensation in the form of equipment, retainers for ongoing consultation or honoraria (as more fully defined in 21 CFR 54.2(f)). In the case of subparagraphs (iii) and (iv), I understand that such prohibitions will be valid during the duration of my carrying out the Study and for one (1) year following completion of the Study.

Signed by [Dr ]

Date: ___________________________
THE SCHEDULES – SUBJECT TO THE TERMS AND CONDITIONS OF
[.] TEMPLATE

Schedule 5 – Indemnity Agreement

Indemnity for Clinical Research
(for sponsored research)

THIS INDEMNITY is provided on ____________________________

By the Sponsor:

Name of Company: ____________________________

Address: ____________________________ (the “Sponsor”)

Fax No.: ____________________________

To the following Indemnitees:

(1) The Hong Kong Baptist University and the following Department/Unit under the
management and control of the Hong Kong Baptist University:

____________________

(the “Institution”).

Fax No.: ______

(2) Name of the Principal Investigator:

____________________

(the “Principal Investigator”).

Fax No.: ______

Together with their respective trustees, officers, agents, employees and students (collectively
the “Indemnitees” and individually the “Indemnitee”).

WHEREAS

(A) The Sponsor wishes to carry out the following clinical trial through the Institution and
the Principal Investigator:

Title: ____________________________ (the “Study”)

Study Protocol No.: ____________________________ (the “Study Protocol”) on
human subjects (the “Study Subjects”).

(B) The Institution and the Principal Investigator agree to carry out the Study on the terms
and conditions under a separate agreement (the “Agreement”) provided that this
Indemnity is given by the Sponsor.

NOW, THEREFORE, in consideration of the agreement of the Institution and the Principal
Investigator to conduct the Study, the Sponsor agrees to provide indemnity to the Indemnitees
as follows:

1. (a) Subject always to Clauses 2(b), 3(a) and 4, the Sponsor shall indemnify and hold
harmless the Indemnitees and each of them from any and all losses, damages,
costs (including legal costs), expenses, liabilities, claims, demands, actions,
prosecutions, judgments which any of the Indemnitees may suffer or incur (the
“Claim”) arising out of or in connection with the Study or the Agreement, or any breach of the Sponsor’s obligations under the Agreement or any default, act, omission, negligence or statement of the Sponsor, its officers, agents, employees or sub-contractors in connection with or in relation to the subject matter of the Study.

(b) This Indemnity extends to reimbursement of all reasonable legal costs that the Hong Kong Baptist University may incur as a result of participating in, or in connection with, or arising out of the Study, as follows:

(i) reporting any death during the Study to the Coroner under the Coroners Ordinance, dealing with the Police investigation, and preparing for and attending any Death Inquest and/or hearing arising out of or in connection with such reporting;

(ii) dealing with the media, the Medical Council, government or statutory authority or any inquiry commissioned by government or statutory authority.

(c) This Indemnity also extends to reimbursement to the Hong Kong Baptist University of the actual costs that it may incur in providing treatment to any Study Subject or any of the Indemnitees which treatment would not have been necessary but for their participation in the Study.

2. (a) For the purposes of Clause 1(a), the Sponsor will at the Sponsor’s sole expense provide the Indemnitees with a lawyer acceptable to the Indemnitees to deal with the Claim Provided Always that such lawyer must be retained on the basis that he will act in accordance with the Indemnitees’ reasonable instructions. If the lawyer provided by the Sponsor does not act in accordance with the relevant Indemnitee’s reasonable instructions or if a conflict of interest arises between the Sponsor and the relevant Indemnitee, such Indemnitee shall have the conduct of the Claim and shall have the right to instruct its own lawyer at the Sponsor’s expense subject to the Sponsor’s written approval which approval shall not be unreasonably withheld.

(b) The Indemnitee shall not in any event admit liability, compromise, settle or take any action prejudicial to the defence of any Claim without the prior written approval of the Sponsor which approval shall not be unreasonably withheld.

(c) In the event that the Sponsor confirms in writing that Clause 4 below is not applicable and it will provide a full indemnity to the Indemnitees, then the Sponsor shall have full conduct of the Claim Provided Always that the Sponsor shall not admit liability on behalf of the relevant Indemnitee in any event.

3. (a) The Indemnitees shall notify the Sponsor within 60 days after becoming aware of any Claim or event under Clause 1 provided that the Institution may notify on behalf of the Principal Investigator and the other Indemnitees.

(b) Without prejudice to any rights under this Indemnity, the parties agree to provide reasonable assistance to each other in dealing with any Claim or event under Clause 1.

4. The indemnity under Clause 1 does not apply to the extent that it is proven to have been caused by the negligence, malpractice or violation of the Study Protocol by any of the Indemnitees. In such event, the Sponsor shall only be liable for such proportion which is not caused by such negligence, malpractice or violation of the Study Protocol.

5. (a) This Indemnity shall be governed by and construed in accordance with the laws of Hong Kong. The application of the Contracts (Rights of Third Parties) Ordinance is expressly excluded and no person who is not a party to this
Indemnity shall be entitled to enforce any right or term of this Indemnity pursuant to the Contracts (Rights of Third Parties) Ordinance.

(b) Any notice to be served on the other party for the purpose of this Indemnity shall be deemed served if faxed to the number specified in this Indemnity with the correct answerback.

(c) The singular shall include plural and vice versa.

(d) The Sponsor undertakes to send a copy of this duly signed Indemnity to the Graduate School, Hong Kong Baptist University (Fax No. 3411 5133).

IN WITNESS whereof the parties or their authorized representatives have set their hands the day and year first above written.

Signed for and on behalf of the Sponsor: Signed for and on behalf of the Institution and its Principal Investigator:

Name of Sponsor: Chairman, Research Committee
IN WITNESS whereof the parties or their authorised representatives have set their hands the day and year as referred to in Part 1(a) of Schedule 1.

SIGNED by [●]
Chairman, Research Committee

[ name ]

SIGNED by [●]
for and on behalf of the Sponsor

[ name ]
[ title ]

SIGNED by [●]
Principal Investigator

Dr [ name ]
Part I.  Project Title:  
<Project title> (REC Ref.)

Principal Investigator(s):  
<Name> (Dept)

Part II.  Recommendation by Reviewer

This protocol for the use of human subjects has been reviewed and I have the following recommendations:

☐ Recommended for Approval  ☐ Not Recommended  ☐ Withdrawn

☐ Further Clarification

Comments/Conditions:

Part III.  Declaration

Public trust in REC and CREP and its decision depends partly on how well conflict of interest is handled during its operation. Irrespective of whether a reviewer has been biased, conflict of interest exists when s/he has financial or close personal relationships with the investigator or sponsor that could inappropriately influence her or his actions, particularly if the sponsor is an agency with a proprietary or financial interest in the research outcome.

As a CREP reviewer, you are required to disclose relationships that could be viewed as presenting a potential conflict of interest in reviewing research applications. Close personal relationship or financial relationship such as employment, consultancy, stock ownership, scholarship, donation and honorarium are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of a reviewer, the REC, and of science itself. As it is not possible to provide an exhaustive list of conditions that could give rise to a conflict of interest situation, members are reminded that conflict can occur for other reasons.

I declare that there is no potential conflict of interest and undertake not to disclose to another party any information that may be released to me in the course of research ethics reviews, whether orally or in whatever format, such as written, graphic, digitalized, computerized etc., and any compilations, analyses, conclusions or materials whatsoever drawn or derived therefrom.

Signature : ____________________________
Name of Assessor / Position : ____________________________
Faculty/Department/Unit : ____________________________
Institution/Organization : ____________________________
Informed Consent Statement Checklist & Sample

- An investigator has the ultimate responsibility in an informed consent process, and shall ensure that:
  a) The informed consent form(s) and any other written information (including any subsequent amendment of such documents) to be provided to each human subject are submitted to and approved by the CREP and the local regulatory authority (if needed) before they are used;
  b) The informed consent discussion with each human subject is conducted either personally by the investigator or through a qualified person designated by the investigator;
  c) Each human subject is provided with sufficient opportunity to ask any question he/she may have in relation to the study and sufficient time to consider his/her participation in the study;
  d) Each informed consent form is signed and dated personally by the human subject and the person who conducted the informed consent discussion (i.e. either the investigator or his/her designee); and
  e) Each fully signed informed consent form shall be properly kept.

- An Informed Consent Statement has two purposes:
  (1) to enable potential research subjects to make an informed choice as to their participation in a study, and
  (2) to document their decision to participate.

In order to make an informed choice, potential subjects must understand the study, how they are involved in the study, what sort of risks it poses to them, and what to do if something untoward happens. The words and language used to describe these factors must be understandable to potential subjects.

- Samples of a Consent Statement and an Information Sheet are provided in Appendix 8-1. Following the sample format will help to ensure that the necessary criteria for approval are included. Checking off an item as it is written into the statement/sheet will assist you in assuring that each element has been addressed in the document.

- Investigators are advised to conduct briefing session to explain the project details and consent to the subjects; the subjects could also ask questions about the study.

**Items to be included in the Consent Statement**

**Informed Consent Statement** required elements: Items 1-9. Each must be included in the informed consent statement submitted.

1. Use the heading "Hong Kong Baptist University, Informed Consent Statement".
2. List the title of the project.
3. Invite the subjects to participate and state that the study involves research and describe the following:
   a. purpose
   b. procedures (identify any that are experimental)
   c. expected duration of the subject's participation
   d. reasonably foreseeable risks or discomforts
   e. safeguards to be used to minimize risks
   f. any benefits to the subject or to others; or the extent of contribution to the body of literature/knowledge
4. Describe the extent, if any, to which confidentiality of records identifying the subject will be maintained.
   If subjects are identified in reports, *signed consent* is required. If research is conducted over the internet, you must tell subjects that you cannot guarantee confidentiality while their data is on the internet.
5. State the terms of subject compensation for study participation, if any. If the subjects will be paid (or receive other compensation) for participation, state how and when they will receive payment and/or compensation (i.e., compensation = toys, books, gifts, etc.). List the value of gifts or services. Explain if there will be any partial payment if the subject withdraws prior to completion of the study.
6. Include an invitation for the subject to ask any questions at any time about the study and its procedures, or their rights as subjects. Also, *if applicable*, include a statement that if the subject experiences adverse effects, the investigator should be contacted immediately.
7. Include the investigator's name, address, and telephone number that the subject may use to ask questions and report any study related problems
8. Tell the subject that participation is voluntary. Further, state that refusal to participate will involve no penalty or
loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any
time without penalty, or loss of benefits to which the subject is otherwise entitled. Tell subjects what will happen
to their data if they withdraw from the study.

9. Include a statement that says subject has read and understands the consent form, acknowledges receiving a copy
of the form, and agrees to participate in the study. Provide a line for signature(s) and the date. Provide two
copies of the Consent Form, one to be retained by the subject and one to be signed by the subject and, if applicable,
the subject's parent(s)/guardian/legal representative and returned to you.

If subjects are minors use the following guidelines for obtaining consent:

- 6 years old and younger - only parent(s)/guardian/legal representative need sign;
- 7-8 years old - signature of minor is optional, requires signature of parent(s)/guardian/legal representative;
- 9 through 17 years old - requires signature of both minor and parent(s)/guardian/legal representative.

When appropriate, one or more of the following additional elements of information (items 10-18) shall also be provided
to each subject, in either the Informed Consent Statement:

10. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination
of participation by the subject. (Explain what will happen to data if a subject withdraws. If data are gathered that
contain subject identifiers, the disposition of the data must be stated.)

11. The approximate number of subjects involved in the study should be indicated when the subject population is
small in number. If subjects might be identifiable in reports because individual responses will be described, a
statement to this effect should be included in the consent statement or information sheet.

12. If you plan to audio tape, videotape or film the subjects, you have to request permission to do so in writing and
indicate how you will be using this material (Research purposes only? Research and instruction? Who will have
access to or view the tapes? Will subjects be allowed to preview the tapes? What will happen to the tapes at the
end of the study? What will happen to the tapes if the subject withdraws?). All possible uses of the
tapes/films/photos (current & future) must be described. If tapes are kept by the PI beyond the end of the study
and/or archived, then the following statement must be included: “The tapes/films/photos will not be used for any
additional purposes without your additional permission.” and signed/document consent is required.

13. **IF DECEPTION IS USED**, include a statement to the effect that the research cannot be fully described at this
time, but at the conclusion of participation, an explanation will be provided. (**Provide a copy of the debriefing
script with your packet for Panel review.**)

14. ***Emergency Medical Treatment.*** If the study involves risk procedures (exercise, medical, stress, alcohol, and so
on), the following paragraph is to be included:

"In the unlikely event of physical injury resulting from your participation in this research, emergency
medical treatment will be provided at no cost to you. Be certain that you immediately notify the researcher
if you are injured. If you require additional medical treatment you will be responsible for the cost. No other
compensation will be provided if you are injured in this research."

15. A statement that the particular treatment or procedure may involve currently unforeseeable risks to the subject
(or to the embryo or fetus, if the subject is or may become pregnant).

16. Anticipated circumstances under which the subject's participation may be terminated by the investigator without
regard to the subject's consent.

17. Any additional costs to the subject that may result from participation in the research. (If subjects will be charged
for participation in the research project, then all costs must be itemized on the consent form. If alternative, non-
investigational procedures are available, then these procedures should be discussed and the average costs
included in the consent form.)

18. A statement that significant new findings developed during the course of the research, and which may be related
to the subject's willingness to continue participation, will be provided to the subject.
Hong Kong Baptist University

Informed Consent Statement

[List title of study here] (item 2)

You are invited to participate in a research study. (item 3) The purpose of this study is

________________________________________________________________________________
________________________________________________ __________________________________

________________________. (item 3-a)

Information

Describe all procedures, preferably in chronological order, which will be employed in the study. (item 3-b)
State the amount of time required of the subject per session and for the total duration of the study
(items 3-c)
The number of subjects that will be participating in the research. (item 11)
Information concerning taping or filming. (if any, item 12)
A disclaimer for the use of deception. (if any, item 13)

Benefits

List the benefits you anticipate will be achieved from this research, either to the subjects, others, or the body of knowledge. (item 3-f)

Reasonably foreseeable risks or discomforts

List the foreseeable risks or discomforts, if any, of each of the procedures to be used in the study, and any measures which will be used to minimize the risks. (items 3-d & e)
A statement that the particular treatment or procedure may involve currently unforeseeable risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant). (item 15)

Emergency medical treatment

In the unlikely event of physical injury resulting from your participation in this research, emergency medical treatment will be provided at no cost to you. Be certain that you immediately notify the researcher if you are injured. If you require additional medical treatment you will be responsible for the cost. No other compensation will be provided if you are injured in this research. (item 14, if applicable add here)

Confidentiality

Describe the extent, if any, to which confidentiality of records identifying the subject will be maintained. OR, explain when and how confidentiality will be broken.
If subjects are identified in reports, signed consent is required.
If research is conducted over the internet, you must tell subjects that you cannot guarantee confidentiality while their data is on the internet. (item 4)
Compensation and insurance

For participating in this study you will receive ______________. If you withdraw from the study prior to its completion, you will receive ________________. (item 5, if applicable)

Contact

If you have questions at any time about the study or the procedures, you may contact the researcher, [name]__, at __[address]__, and __[phone number]__. If you feel you have not been treated according to the descriptions in this form, or your rights as a participant in research have been violated during the course of this project, you may contact the Research Ethics Committee by email at hkbu_rec@hkbu.edu.hk or by mail to Graduate School, Hong Kong Baptist University, Kowloon Tong, Hong Kong. (items 6 & 7)

Participation

Your participation in this study is voluntary; you may decline to participate without penalty. If you decide to participate, you may withdraw from the study at any time without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed your data will be returned to you or destroyed. (items 8 & 10)

Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. (item 16)

Any additional costs to the subject that may result from participation in the research. (If subjects will be charged for participation in the research project, then all costs must be itemized on the consent form. If alternative, non-investigational procedures are available, then these procedures should be discussed and the average costs included in the consent form.) (if any, item 17)

A statement that significant new findings developed during the course of the research, and which may be related to the subject's willingness to continue participation, will be provided to the subject. (item 18)

Consent (item 9)

I have read and understand the above information. I have received a copy of this form. I agree to participate in this study.

Signature of the Subject ______________________________ Date ____________________________

Signature of the Parent(s)/Guardian(s) ________________ Date ____________________________

Signature of the Investigator __________________________ Date ____________________________
NOTES TO INVESTIGATORS:

1. Researchers are urged by REC and CREP to use the wording in the checklist and sample, as it applies to their study, and to follow the format of the sample, unless researcher supported reasons are provided for the alternatives. Use of unnecessary alternative wording or different format may slow down the review process. The form should be written in second person ("You are invited..."). Use of first person ("I") can be interpreted as suggestive and coercive.

   ^This phrase should only be included when the study also requires the use of the Emergency Medical Treatment Statement.

2. Study Information Sheets for mail surveys may take the format of a letter, as long as all the required information is included.

3. If the Informed Consent Statement or Study Information Sheet is to be in a foreign language, submit the foreign language version and an English translation.

4. Be sure to follow the directions in item 9 on the checklist for preparing the signature lines. Separate forms should be prepared when young minors are used; one for the minors and one for the parents. If the minors are age 15 and above a single form may be acceptable with signature lines for both the minor and parent.

5. If your form is more than one page, there should be a line at the bottom of each page for the subject's initials, except for the last page where the signature is obtained.

6. Be sure to include any of the items 10-18 on the Informed Consent Statement Checklist that are appropriate to your study. While items 15-18 are not specifically covered in the sample, if they apply to your study they must be included.
## 同意聲明書清單及樣本

- 研究員在說明「同意聲明書」過程中承擔最終責任，並應確保：
  a) 所有給予以為研究單位 (下稱「參與者」)所提供的同意聲明書和其他書面文件 (包括任何後續修訂) 都需提交至臨床研究倫理小組 (下稱 CREP) 和當地監管機構 (如需要)，有關文件獲批准後才能使用；
  b) 研究員親自向參與者討論及說明「同意聲明書」，或由研究員委任一個合適人員進行說明；
  c) 參與者有足夠機會就研究項目內容進行提問，同時給予參與者足夠時間來考慮是否參與這項研究；
  d) 每份「同意聲明書」需由參與者親自簽字並註明日期，同時，進行討論的人員 (即研究員或其委任人員) 需一同簽字並註明日期；
  e) 每份簽署完整的「同意聲明書」需妥善保管。

- 「同意聲明書」的目的：
  1. 確保參與者能夠在充分知情的情況下選擇參與研究。
  2. 以文件形式記錄參與者參與研究的決定。
  研究員必須讓研究對象決定參與研究前了解這項研究內容，他們需如何參與這項研究，這項研究將給他們帶來什麼程度的風險，以及如果發生非預期的效果的應變措施。研究員需用研究對象可理解的文件和用語來說明研究細節。

- 「同意聲明書」樣本及有關資訊可在附錄 8 查看。研究員在撰寫有關聲明時，請参照樣本所列出的各項，確保必要的條文包括在其「同意聲明書」及相應的文件中。

- 研究員應安排介紹會議跟參與者闡述並解釋研究項目細節及相關研究資訊，參與者藉此就研究進行提問。

## 同意聲明書事項

每份提交的同意聲明書中必須包括以下第 1 至第 9 點。

1. 請使用標題「香港浸會大學，同意聲明書」。
2. 請列出研究項目的名稱。
3. 邀請參與者的參與及說明研究項目的以下各方面：
   a. 目的；
   b. 流程（指明那部份是實驗性質）；
   c. 參與者的預期參與時間；
   d. 合理範圍內可預見的風險或不適；
   e. 用於降低風險的保障措施；
   f. 任何對參與者或他人的益處，或對文獻資訊、知識的貢獻程度
4. 請描述並列出將保留參與者那些保密檔案 (如適用)。
   如果在報告中提及參與者，則需參與者簽署同意聲明書。如果研究是通過互聯網進行的，研究員必須告訴參與者研究員不能保證他們的資料在互聯網上的保密性。
5. 請闡述任何對參與者的補償條款（如有）；如果參與者因參與研究收到報酬 (或得到補償) ，請闡述參與者將會收到的報酬和/或補償 (報酬如：玩具、書籍、禮物等) 。請列出禮物或服務的價值。若參與者中途退出，請說明參與者會否獲得部份報酬或補償。
6. 邀請參與者在任何時間及階段就研究、其流程及參與者的權益向研究員提問。同時，請清楚註明 (如適用) 若參與者遇到不良反應，可立即聯絡研究員。
7. 請註明研究員姓名、地址以及聯絡電話，以用於參與者提出和反映任何關於研究的問題。
8. 請註明參與者是屬自願性參與的，並進一步闡釋參與者有權拒絕參與研究，當中亦不涉及罰款或其利益損失；同時，參與者有權隨時停止參與，而不受懲罰或其利益損失。若參與者停止參與，請通知參與者其相關資料的安排。

9. 請註明參與者已閱讀並理解「同意聲明書」的內容，確認收到一份同意聲明書的副本，並同意參加是次研究。請提供簽名和簽署日期的位置。請準備一式兩份同意聲明書，一份將由參與者保留，另一份將需參與者簽署。參與者和/或其家長/監護人/法定代表人簽署後，並退回給研究員。

如果參與者未成年，請依照下列準則並獲得以下相應人士的同意：
6 歲及以下：家長（監護人）/監護人/法定代表人簽名；
7 至 8 歲：參與者的簽名是選擇性的，家長/監護人/法定代表人需要簽名；
9 至 17 歲：參與者及家長/監護人/法定代表人均需要簽名。
如有需要，可於同意聲明書插入一項或多項的注意事項（見下第 10 至 18 項注意事項）並知會參與者：

10. 若參與者自行決定退出研究，請列明退出研究後果和終止參與研究的流程（若參與者退出，請說明其相關資料的處理方法；如果資料包含參與者的個人資料，必須說明相關資料的處理方法。）

11. 請闡述研究中涉及參與者的大概數量，若參與者數量較少，需列明具體數字。如果參與者可能會在報告中被識別其身份或報告其研究反應，請在同意聲明書中包括相關同意聲明。

12. 如果研究對參與者進行錄音、錄像、拍攝，研究員需要得到參與者的同意並書面說明研究員將如何使用相關資料、用途及目的（例如：是否可僅用於研究目的？研究與指導？誰將有權翻查錄音、錄像？參與者可允許預覽錄音、錄像嗎？在研究結束時，相關資料如何處理？如果參與者退出了，錄音、錄像如何處理？），所有的錄音/錄像/照片在現階段及將來有可能的用途都需要清楚闡述。如果研究員需要在研究結束之後保存錄音或錄像檔案，研究員必須包括以下的聲明：「在沒有獲得你的許可時，錄音/錄像/照片將不會被用作其他用途。」及簽署/記錄其參與者的同意。

13. 研究員如能事先向參與者完全講解研究內容以避免影響研究結果，研究員亦請提供一份聲明說明在這段期間研究將不能全部描述，但是在參與研究結束時將會提供解釋。（請提供一份彙報簡報供委員會審核。）

14. **急診醫療。** 如果這項研究涉及到風險流程（運動、醫療、壓力、酒精等），請包括以下說明：「如因參與這項研究而造成人身傷害時，緊急醫療治療將會被提供，你無需承擔任何成本。如在研究過程中受傷，請立即通知研究員。如果你需要額外的醫療處理，所需成本將自行負責。如果你在這項研究中受傷，將不會有任何其他補償。」^

15. 聲明須註明參與者所接受的特殊治療或過程可能涉及不可預見的風險（如果參與者現在或日後可能懷孕，或對胚胎或胎兒有不可預見的風險）。

16. 預期的情況下，研究員可以終止參與者參與研究，而不用獲得參與者的同意。

17. 參與研究可能產生額外費用（如果參與者因參加研究項目而繳費，所有費用必須逐項列明在同意聲明書中。若有其他程序涉及費用，相關的程序應事先討論確認，並把費用在同意聲明書中列明。）

18. 研究的過程中若有顯著新發現，而新發現可能影響參與者考慮是否繼續參與，研究員需讓參與者選擇是否願意繼續參與。
樣本副本
注意：描述/注意事項編號只供參考，請不要包括在同意聲明書中。

香港浸會大學
同意聲明書
[研究項目名稱](注意事項 2)

你接受邀請參與這項研究 (注意事項 3) 這項研究目的是

____________________________________________________________________________________________
______________________________________________________________________________

(注意事項 3a)

資訊
描述研究全部流程，最好是按時間順序排列。(注意事項 3-b).
闡述參與者所需參與每一次會議的時間和研究總時間。(注意事項 3-c).
參加這次研究項目的參與者人數。(注意事項 11).
關於錄影或拍攝資訊及安排。(注意事項 12).
免責聲明。(注意事項 13).

益處
列出從本研究中你預期將會得到的益處，對參與者或他人的益處，或對知識的貢獻程度。(注意事項 3-f).

合理可預見風險或不適
列明在每項研究流程中可預見的風險或不適(如有)，及任何措施來減低風險。(注意事項 3-d & e).
聲明須註明參與者所接受的特殊治療或過程可能涉及不可預見的風險(如果參與者現在是或日後可能懷孕，或對胚胎或胎兒有不可預見的風險)(注意事項 15).

緊急醫療
如果這項研究涉及到風險流程（運動、醫療、壓力、酒精等），請包括以下說明：
「如因參與這項研究而造成人身傷害時，緊急醫療治療將會被提供，你無需承擔任何成本。如在研究過程受傷，請緊記立即通知研究員。如果你需要額外的醫療處理，所需成本將自行負責。如果你在這項研究中受傷，將不會有任何其他補償。」(注意事項 14，或按需要加以補充，請提供)

保密性條例
請描述並列出將保留參與者那些保密檔案(如適用)。或說明於那些時間或情況下保密協定可能失效
如果參與者會在報告中被識別其身份或報告其研究反應，必須要簽署同意聲明書。(注意事項 4)

補償及保險
因參與此次研究項目，參與者將得到 ____________。如果參與者在完成之前退出研究，參與者會收到 ____________。 (注意事項 5，如適用)

聯絡方式
如參與者對研究或過程有任何問題，可聯絡研究員：[姓名]，地址是 [地址]，聯絡電話是 [聯絡電話]。如果參與者認為沒有得到「同意聲明書」中的所描述的待遇，或作爲研究的參與者，其權利受到侵害，你可以通過發送郵件至: hkbu_rec@hkbu.edu.hk 或郵寄到：香港九龍塘香港浸會大學研究院聯絡研究倫理委員會 (REC)。 (注意事項 6 & 7)
參與
參與者是自願參與這項研究，參與者可以拒絕參加而不會產生任何處罰。如果決定參加，參與者有權在任何時候退出研究，而不會產生任何罰款，或利益損失；如果參與者在研究資料收集完全部後退出，參與者的資料將被退還給參與者或銷毀。（注意事項 8 & 10）

預期的情況下，研究員可以終止參與者參加研究，而不用獲得參與者的同意。（注意事項 16）

參與研究可能產生額外費用（如果參與者因參加研究項目的而繳費，所有費用必須逐項列明在同意聲明書中。若有其他程序涉及費用，相關的程序應事先討論確認，並把費用在同意聲明書中列明。）（如有，注意事項 17）

研究的過程中若有顯著新發現，而新發現可能影響參與者考慮是否繼續參與，研究員需讓參與者選擇是否願意繼續參與。（注意事項 18）

同意聲明（注意事項 9）

我已經閱讀並理解上述聲明。我已收到此表格的副本。我同意參加這項研究。

參與者簽名___________________________________________ 簽名日期____________________

家長/監護人簽名_______________________________________ 簽名日期____________________

研究員簽名___________________________________________ 簽名日期____________________

補充說明：

1. 除非研究員有充分理據，REC 及 CREP 建議研究員應其研究範疇按照清單及欄本中的文字、措辞及欄本的格式撰寫同意聲明書。使用不必要的替代理文字或不同的格式可能會減慢審查過程。聲明書應該用第二個稱謂（“你被邀請……”）。使用第一人稱謂（“我”）可以被誤解為暗示性和強迫性的用意。

   ^這句話只包括在研究需要使用緊急醫療聲明。

2. 若以郵件方式進行訪問，研究聲明書可用信函格式，並涵蓋所有資訊。

3. 如果使用非英語版本的同意聲明書或有關資訊，須同時提交非英語版本和英文翻譯版本。

4. 在準備同意聲明書簽名部份時，須按照注意事項 9 的說明。若參與者年齡為 14 歲或以下，需準備兩套同意聲明書；小童及家長（監護人）/監護人/法定代表人各持一套。若參與者年齡為 15 歲或以上，一份同意聲明書是可以被接受的，但需同時有未成年參與者的簽名處和監護人簽名處。

5. 如果你的表格是一頁以上，應在每頁的底部加上一條線讓參與者作簡簽，最後一頁需簽名。

6. 研究員可因應其研究範疇在同意聲明書中包括注意事項第 10 至 18 項。注意事項 15-18 中並沒有包含在欄本中，如此事項適用於你的研究，請必須包括在內。
Clinical Research Annual Progress Report Form
(please enclose any relevant supporting documents with this report form)

Part I. Project Details
REC Ref:
Project Title:
Principal investigator:
Project start date: Anticipated end date:

Part II. Progress report
Reporting period:
Maximum number of participants/samples/records planned (local):
No. completed study:
No. recruited:
No. withdrew:
Withdrawal reasons:

Part III. Changes
Study protocol change?    Yes    No
Investigator change?     Yes    No
Have they been reported? Yes    No
Nature of change:

Part IV. Summary of Serious Adverse Events
Does the SAE affect the study?    Yes    No
If yes, how it affects the study:

Part V. Summary of Complaints from Subjects

Part VI. Interim Analysis of Data
According to schedule?    Yes    No    Not Applicable

Part VII. Updated Information
Updated information that may affect a subject’s willingness to continue (e.g. recall of investigation product)
New evidence that addresses the research hypothesis    Yes    No
Describe new information and actions taken:

Part VIII. Current progress of Study
Continue according to the plan
Extend study period, due to:
Premature termination, due to:

Report by:
Name                      Signature                      Date
### Appendix 10

Clinical Research Final Report Form  
*(please enclose any relevant supporting documents with this report form)*

#### Part I. Project Details

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>REC Ref.</td>
<td></td>
</tr>
<tr>
<td>Project Title</td>
<td></td>
</tr>
<tr>
<td>Principal investigator</td>
<td></td>
</tr>
<tr>
<td>Project start date</td>
<td></td>
</tr>
<tr>
<td>Anticipated end date</td>
<td></td>
</tr>
</tbody>
</table>

#### Part II. Final report

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting period</td>
<td></td>
</tr>
<tr>
<td>Planned sample size</td>
<td></td>
</tr>
<tr>
<td>No. completed study</td>
<td></td>
</tr>
<tr>
<td>No. recruited</td>
<td></td>
</tr>
<tr>
<td>No. withdrew</td>
<td></td>
</tr>
<tr>
<td>Withdrawal reasons</td>
<td></td>
</tr>
</tbody>
</table>

#### Part III. Summary of Serious Adverse Events

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the SAE affect the study?</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td>If yes, how it affects the study</td>
<td></td>
</tr>
</tbody>
</table>

#### Part IV. Summary of Complaints from Subjects

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
</table>

#### Part V. Study Duration

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>According to schedule</td>
<td></td>
</tr>
<tr>
<td>Extended</td>
<td></td>
</tr>
<tr>
<td>Premature termination</td>
<td></td>
</tr>
</tbody>
</table>

#### Part VI. Summary of Study Outcomes

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
</table>

Report by:

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td></td>
</tr>
<tr>
<td>Signature</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td></td>
</tr>
</tbody>
</table>
Clinical Research Protocol Amendment Application Form
(please enclose any relevant supporting documents with this form)

Part I. Project Details

<table>
<thead>
<tr>
<th>REC Ref:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Title:</td>
<td></td>
</tr>
<tr>
<td>Principal investigator:</td>
<td></td>
</tr>
<tr>
<td>Project start date:</td>
<td>Anticipated end date:</td>
</tr>
<tr>
<td>Sponsor</td>
<td>Amendment no.</td>
</tr>
</tbody>
</table>

Part II. Proposed Amendments (Append new document with changes)

<table>
<thead>
<tr>
<th>Original details of the proposal</th>
<th>Amendment</th>
<th>Reason for change</th>
<th>Will change increase risk to participants?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Submitted by:

________________________  __________________________  ____________
Name                     Signature                Date
# Serious Adverse Event (SAE) Report Form

*(please enclose any relevant supporting documents with this report form)*

## Part I. Project Details

<table>
<thead>
<tr>
<th>REC Ref:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Title:</td>
<td></td>
</tr>
<tr>
<td>Principal investigator:</td>
<td></td>
</tr>
<tr>
<td>Project start date:</td>
<td>Anticipated end date:</td>
</tr>
<tr>
<td>Maximum number of subjects/samples/records planned (local)</td>
<td></td>
</tr>
</tbody>
</table>

## Part II. Study Site(s) Involved

- Overseas site(s)
- Local site(s)

(Submit report(s) from sponsor)

Location of study site: __________

## Part III. Subject Outcome at Time of Report

<table>
<thead>
<tr>
<th>Status</th>
<th>Outcome</th>
<th>Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete recovery</td>
<td>Recovery with sequelae</td>
<td>Events not yet resolved</td>
</tr>
<tr>
<td>Unknown</td>
<td>Death</td>
<td></td>
</tr>
</tbody>
</table>

## Part IV. Serious Adverse Events

<table>
<thead>
<tr>
<th>Subject reference:</th>
<th>Code</th>
<th>Initials</th>
<th>Age</th>
<th>Sex</th>
</tr>
</thead>
</table>

Relevant medical history & current treatments:

Nature of SAE: *(Describe temporal relationship with intervention & other concomitant therapies)*

<table>
<thead>
<tr>
<th>SAE start date</th>
<th>SAE stop date</th>
<th>Frequency</th>
<th>Type of SAE</th>
<th>Seriousness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Initial</td>
<td>One episode</td>
<td>Intermittent</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Death</td>
<td>Life threatening</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Significant disability/incapacity</td>
<td>Required hospitalization</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Persistent disability/incapacity</td>
<td>Prolonged hospitalization</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Congenital anomaly/birth defect</td>
<td>None of the above</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Other medically important condition</td>
<td></td>
</tr>
</tbody>
</table>

## Part V. Suspected relationship to Study

<table>
<thead>
<tr>
<th>Definite</th>
<th>Probable</th>
<th>Possible</th>
<th>Not related</th>
<th>Not assessable</th>
</tr>
</thead>
</table>

## Part VI. Remedial actions

<table>
<thead>
<tr>
<th>Remedial</th>
<th>On the</th>
<th>For all subjects/study design:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjusted dosage</td>
<td>None</td>
<td>Interrupted temporarily</td>
</tr>
<tr>
<td>Discontinued/terminated study</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Report by: __________

Name: __________
Signature: __________
Date: __________