[PLEASE DELETE THIS PAGE UPON DISCUSSION OR FINALISATION OF DOCUMENT]

Instruction to use

The clauses in this Master Clinical Trial Agreement (MCTA) have been reviewed and agreed by legal representatives from Singapore Association of Pharmaceutical Industries (SAPI), Singapore Health Services (SingHealth), National Healthcare Group (NHG) and National University Health System (NUHS) with the aim to expedite agreement review process between Sponsor and Singapore's Public Healthcare Institutions.

The individual clause can be adopted to other agreements. Please consider the sub-clauses or links to other clauses.

Additional requirements that are specific to the study can be added in the Schedules section, which can be found at the end of the MCTA document. The Schedules can be reviewed separately.

If you have any questions or feedback about the MCTA, please email contact@scri.cris.sg. Our team will be on hand to address any queries.

To insert Sponsor Logo if required Upon completion 1. Remove instruction 2. Remove Table Border	To insert Institution Logo if required Upon completion 1. Remove instruction 2. Remove Table Border

Clinical Trial Research Agreement

Details of the Parties

[To include name of Institution, address as well as name of sponsor and address upon completion of document.]

This Agreement is made between the Sponsor and the Institution (each a "**Party**" and collectively the "**Parties**")

Purpose of the Agreement

According to this Agreement:

A. The Sponsor is responsible for the initiation, management, and financing of the Study.

B. The Institution, through the Principal Investigator, is responsible for the conduct of the Study at the Study Site(s) which is/are under the control of the Institution.

C. The Study will be conducted on the terms and conditions set out below.

Operative Provisions

1. INTERPRETATION

1.1 In this Agreement:

Adverse Event means any untoward medical occurrence in a Study Participant to whom an Investigational Medicinal Product has been administered, including any occurrence which is not necessarily caused by or related to the Investigational Medicinal Product. An adverse event can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of an Investigational Medicinal Product, whether or not considered related to the Investigational Medicinal Product.

Affiliates means an organisation which: (i) directly or indirectly controls either Party; or (ii) is directly or indirectly controlled by either Party; or (iii) is controlled, directly or indirectly, by the ultimate parent company of either Party. The term "**control**" as used herein means (or any variation of that term) the possession, direct or indirect, of (i) the power to direct or control the management of composition of the Board of Directors of an entity;(ii) the power to direct or control the casting of more than 50% of the votes that might be cast at a general meeting of the shareholders of a company; (iii) a beneficial interest in 50% or more of the issued share capital of an entity; or (iv) the power to direct or cause the direction of the management and policies of an entity whether through the ownership of voting securities, by contract, resolution, regulation or otherwise and any variation of that term shall be construed accordingly for the purposes of this definition and this Agreement generally

Agreement means this Agreement, including any Exhibits and Schedules.

Background Intellectual Property or **Background IP** of a Party means any Intellectual Property that was owned or controlled by such Party either (i) prior to the date of this Agreement; or (ii) developed independently of the Study without use of or reference to the other Party's Confidential Information.
Biological Samples means any physical samples obtained from Study Participants in accordance with the Protocol for the purposes of the Study.

Case Report Form means a printed, optical or electronic document or database designed to record all of the information, which is required by the Protocol to be reported to the Sponsor on each Study Participant. For the avoidance of doubt, a Case Report Form shall not include Personal Data of the Study Participant.

Confidential Information means all information (that is marked confidential or is clear by its nature confidential) in any form (including all oral and visual information and all information recorded in writing or electronically, or in any other medium or by any other method) disclosed to, or obtained by one (1) Party (the "**Receiving Party**") from the other Party (the "**Disclosing Party**") or a third party acting on the Disclosing Party's behalf, and without prejudice to the generality of the foregoing shall include the following:

(1) in respect of the Sponsor:

(a) all information and data (excluding identifiable personal data and identifiable medical records), and other confidential or proprietary information collected in the course of, resulting from, or arising directly out of the conduct of the Study, whether at the Study Site or elsewhere;

(b) the Protocol, the Investigator's Brochure, information related to the Protocol, Study Materials, the Investigational Medicinal Product and password protected Sponsor websites;

(c) know-how, trade secrets, ideas, concepts, technical and operational information, scientific or technical processes or techniques, product composition or details owned by the Sponsor or its Affiliates;

(d) know-how, methodology, trade secrets, processes, sequences, structure and organisation of the Study;

(e) information concerning the business affairs or clients of the Sponsor or its Affiliates; and

(2) in respect of the Institution, information in relation to the business, operations or strategies, Intellectual Property or other property or actual or prospective suppliers or competitors, medical records, patient and Personnel information of the Institution and its Affiliates.

Equipment means the equipment supplied to the Institution by or on behalf of the Sponsor for the purposes of the Study, as specified in **Schedule 1**.

Essential Documents means documents which individually and collectively permit evaluation of the conduct of the Study and the quality of the data produced.

ICH GCP means the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice (E6(R2)), an international ethical and scientific quality standard, compliant with ICH Guidelines, for designing, conducting, monitoring, auditing, recording, analysing, and reporting clinical trials involving human subjects that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Institution means the healthcare organisation so described on the first page of this Agreement.

Informed Consent Form means the form, reviewed and approved by the Sponsor, the Institution, IRB, and Regulatory Authorities, that each Study Participant and/or, as the case may be, her/his legal representative signs prior to enrolment in the Study indicating

consent to participate in the Study on the basis of the information on the Protocol provided in said form as well as to the collection, storage and processing of a Study Participant's personal data in relation to the Study, without the undue influence or coercion of any person directly involved in the Study, and in accordance with Applicable Laws.

Intellectual Property Rights mean all present and future industrial and intellectual property rights, including without limitation patents, copyrights, trademarks, service marks (whether registered or not), domain names, meta tags, design rights, registered designs, moral rights, rights relating to computer software, database rights and rights in databases and any similar property rights, other industrial or intellectual property rights, including those subsisting in any part of the world in inventions, unregistered designs, drawings, lay-out circuit designs, computer programs, utility models, petty patents, trade secrets, test or development results, Confidential Information, Know-how, business names, goodwill and the style or presentation of goods or services and in applications for protection of any of the above rights subsisting anywhere in the world and any application for or right to apply for registration of any of those rights, whether presently or in the future

Investigational Medicinal Product means [insert drug], a drug product or drug products whose pharmacological activity or activities will be evaluated in the Study Participants, as defined in the Protocol.

Investigator's Brochure is a compilation of the clinical and non-clinical data on the Investigational Medicinal Product(s) which are relevant to the study of the Investigational Medicinal Product in humans.

IRB means the properly constituted or appointed or designated Institutional Review Board for the Institution that is responsible for approving the Protocol.

"Know-How" means any method, technique, process, discovery, invention, innovation, specification, recipe, formula, material, molecule, gene, protein, regulatory element, design, plan, documentation, drawing, data or other technical information which is not patentable or protectable by copyright, all of which is secret, substantial and identified or at least identifiable in a tangible form and in a sufficiently comprehensive manner

Monitor means one (1) or more persons appointed by the Sponsor to monitor compliance of the Study in accordance with the local laws and regulations to conduct source data verification.

Multi-centre Study is a study conducted by several investigators according to a single protocol at more than one (1) study site.

Personal Data means personal data as defined in Section 2 of the Personal Data Protection Act 2012 ("**PDPA**") (as amended from time to time), a law that governs the collection, use, disclosure and care of Personal Data by all organisations.

Personnel means:

(1) in respect of the Sponsor, employees of the Sponsor and any of its Affiliates involved in the Study, including its agents, contractors and/or authorised representatives; and

(2) in respect of the Institution, employees of the Institution and any of its Affiliates involved in the Study, including the Principal Investigator, its agents, contractors and/or authorised representatives.

Principal Investigator means the person who will lead and co-ordinate the work of the Study at the Study Site on behalf of the Institution as named in **Schedule 1** or any other person as may be agreed from time to time in writing between the Parties as a replacement.

Protocol means the document identified in **Schedule 3** which describes the objective(s), design, methodology, statistical considerations and organisation of the Study, and subject to Clause 2.1, as amended from time to time, as agreed by the Parties, and most recently approved by the IRB.

Publication means any scientific publication or communication regarding Study Materials results in any form that is intended for disclosure to third parties, including, without limitation, manuscripts, abstracts, posters, slides or other materials used for presentations.

Regulatory Authority(ies) means any body which has jurisdiction over the conduct of the Study at the Study Site and includes both local and any overseas regulatory authorities that may audit, or require any part of the Study or Study Materials to be audited.

Serious Adverse Event means any adverse event that:
(a) results in death;
(b) is life-threatening;
(c) requires in-patient hospitalisation or prolongation of existing hospitalisation;
(d) results in persistent or significant disability or incapacity; or
(e) consists of a congenital ~~/~~anomaly or birth defect.

Software means the web-based electronic software supplied to the Institution by or on behalf of the Sponsor for the purposes of the Study, as specified in **Schedule 1**.

Sponsor means the pharmaceutical company as described on the first page of this Agreement.

Study means the clinical trial investigation sponsored by the Sponsor and conducted by the Institution at the Study Site(s) in accordance with the Protocol (as defined above) and in compliance with the terms and conditions set forth in this Agreement.

Study Completion means the point at which the database for the Study has been locked and all Essential Documents have been provided to the Sponsor and/or upon receipt by the Sponsor of the closure letter from the Principal Investigator.

Study Materials means data, results, information, Case Report Forms (or their equivalent) generated in the course of conducting the Study. For the avoidance of doubt, Study Materials do not include the Institution's ordinary patient records including the medical records of the Study Participants.

Study Participant means a person recruited to participate in the Study.

Study Site means the location(s) under the control of the Institution where the Study is actually conducted as specified in **Schedule 1**.

Sub-Investigator means any individual member of the Study team designated and supervised by the Principal Investigator at the Study Site to perform Study-related procedures and/or participate in important trial-related decisions and discussions**.**

Timelines means the dates set out in **Schedule 1** hereto as may be amended by agreement between the Parties and **Timeline** shall mean any one of such dates.

1.2 Except where the context otherwise requires:

(a) clause headings are for convenient reference only and are not intended to affect the interpretation of this Agreement;

(b) where any word or phrase has a defined meaning, any other form of that word or phrase has a corresponding meaning;

(c) any reference to a person or body includes a partnership and a body corporate or body politic;

(d) words in the singular include the plural and vice versa;

(e) all the provisions in any schedule to this Agreement are incorporated in, and form part of, this Agreement and bind the parties;

(f) a reference to a replacement of a document or standard, means any document or ruling which amends, updates, replaces or supersedes that document or standard;

(g) if a period of time is specified and dates from a given day or the day of an act or event, it is to be calculated inclusive of that day;

(h) a reference to a monetary amount means that amount in Singapore currency; and

(i) references to a Party include its Personnel.

2. THE STUDY

2.1 The Parties shall comply, and conduct the Study in accordance, with the Protocol, the terms and conditions imposed by the IRB (if any), the terms and conditions set forth in this Agreement, as well as the following:

(a) the ICH GCP;

(b) the ethical principles of the Declaration of Helsinki;

(c) any and all orders and mandates of the Regulatory Authorities;

(d) all laws, rules, regulations, guidance and guidelines applicable to the conduct of the Study as applicable in the respective jurisdictions of the Parties including, but not limited to all applicable Singapore laws, guidance, guidelines and regulations governing the conduct of clinical studies, and the Protocol. For the avoidance of doubt, the Institution shall comply only with Singapore laws, rules, regulations, guidance, and guidelines; and

(e) any Study-related instructions given by the Sponsor, any of its Affiliates or a third party authorised by the Sponsor.

(f) any and all orders and mandates of the relevant authorities and IRB and/or ethic committees.

((a) to (f) collectively referred to as "**Applicable Laws**".)

2.2 The Study shall not commence until:

(a) all the necessary approvals of the relevant Regulatory Authority(ies) and the IRB have been obtained in writing by the Sponsor and the Institution;

(b) the written approval of relevant authority(ies) or organisation that owns or is responsible for the administration of the Study Site has been obtained, if such authority or organisation is not the Institution; and

(c) the Informed Consent Form as provided by the Sponsor, has been approved by the IRB and the relevant Regulatory Authority(ies).

3. PRINCIPAL INVESTIGATOR

3.1 The Institution represents that the Principal Investigator meets the conditions as set out in this Agreement and the ICH GCP and that it has authorised the Principal Investigator as the person responsible on a day-to-day basis for the conduct of the Study in accordance with the Protocol and this Agreement. The Principal Investigator does not have authority(ies) on behalf of the Institution to amend this Agreement or the Protocol.

3.2 For the purpose of this Agreement, and as between the Sponsor and the Institution only, the Institution agrees to be responsible for the acts and omissions of the Principal Investigator in relation to the conduct of the Study, to the extent that such responsibility would attach to the Institution in accordance with its obligations under this Agreement or under the common law on the basis that the Principal Investigator is acting as an employee or as part of the Personnel of the Institution. Nothing in this clause or Agreement affects any pre-existing contractual or other arrangement which may be in place between the Institution and the Principal Investigator.

3.3 The Institution shall provide the Principal Investigator with adequate resources for the proper conduct of the Study and is further responsible for ensuring that the Principal Investigator:

(a) complies with the Applicable Laws;

(b) thoroughly familiarises himself or herself with the appropriate use of the Investigational Medicinal Product(s), as described in the Protocol, Investigator's Brochure, information relating to the Investigational Medicinal Product and any other information sources provided by the Sponsor;

(c) ensures written approval has been obtained to conduct the Study from the relevant Regulatory Authority(ies) and the Institution prior to Study initiation;

(d) conducts the Study according to the Protocol without changes and this Agreement, or as agreed to in writing by the Sponsor and the Institution and approved in accordance with Clause 3.3(g);

(e) declares to the IRB every direct and indirect financial interest which the Principal Investigator, and any person assisting the Principal Investigator in the Study, has in the Study, and completes and returns to the Sponsor a statement of certification and financial disclosure (for example, the Food and Drug Administration Form 3455 'Disclosure: Financial Interests and Arrangements of Clinical Investigators) before the commencement of the Study and consents to the disclosure of the completed form to overseas Regulatory Authorities, if required. Where information collected in the form changes during the course of the Study or within one (1) year after the last Study Participant has completed the Study as specified in the Protocol, the Principal Investigator shall inform the Sponsor of such change;

(f) ensures that the requirements in Clause 3.3(e) are complied with by the Institution's Personnel, where applicable;

(g) ensures that any amendments to the Protocol are approved by the relevant Regulatory Authority(ies), the IRB and the Sponsor prior to implementation of the amendment except where necessary to eliminate any immediate hazard to any affected Study Participant and only in accordance with the ICH GCP;

(h) ensures that prior written consent from the Sponsor and the IRB is obtained for any advertisement in respect of the Study;

(i) provides the Sponsor with evidence of his/her qualifications through a current curriculum vitae and/or other relevant documentation and a list of appropriately qualified persons to whom the Principal Investigator has delegated significant Study-related duties, if required;

(j) uses his or her best endeavours to recruit the target number of Study Participants, within the recruitment period as specified in **Schedule 1**, provided that if the overall target number of Study Participants for the Study is reached, the Sponsor may direct the Institution to cease recruitment;

(k) ensures that the target number as specified in **Schedule 1** can only be amended upon written agreement with the Sponsor;

(l) exercises independent medical judgement as to the compatibility of each prospective Study Participant with the requirements of the Protocol;

(m) advises the Sponsor of all instances in which, in the Principal Investigator's judgement, there is any question as to any prospective Study Participant's suitability for the participation in the Study, and abides by the Sponsor's decision as to whether or not to enrol that Study Participant;

(n) is available when a clinical research representative of the Sponsor visits the Study Site, as mutually agreed prior to the visit, and is contactable by telephone or electronic mail as frequently as is reasonably required for the purpose of this Agreement;

(o) completes Case Report Forms within the agreed time period. The Principal Investigator will ensure that Study Participants' identifying or personal information are de-identified or removed from all records being transferred to the Sponsor;

(p) provides regular written progress reports to the Sponsor in relation to the Study as required by the Protocol;

(q) completes and returns to the Sponsor as required any Study Materials as well as, the Investigational Medicinal Product and Equipment within a reasonable time period;

(r) is not subject to any obligations, either contractually or in any other way, which would unreasonably interfere with or prohibit the performance of work related to this Study;

(s) ensures that a valid dated and signed Informed Consent Form is obtained from each Study Participant prior to their enrolment in the Study;

(t) maintains, organises, keeps current, completes all Essential Documents and arranges for them to be stored in a secure manner, appropriate to the applicable data type and in accordance with Applicable Laws.; and

(u) maintains a record of every person assisting the Principal Investigator in the Study, containing all of the following information: (i) the person's name, (ii) qualifications, and (iii) responsibilities in the Study.

4. INSTITUTION'S OBLIGATIONS AND RESPONSIBILITIES

4.1 The Institution shall not reassign the conduct of the Study to a different Principal Investigator without prior written consent from the Sponsor, and the approval from the relevant Regulatory Authority(ies) and the IRB where applicable. The Institution shall ensure that all third parties who provide services on behalf of the Institution in connection with this Study comply with the terms and conditions of this Agreement.

4.2 If the Principal Investigator leaves the Institution or otherwise ceases to be available to conduct the Study at the Institution, the following shall apply:

(a) The Institution shall provide written notice to the Sponsor within XXX business days of becoming aware of such departure by the Principal Investigator and use reasonable endeavours to nominate as soon as practicable, a replacement reasonably acceptable to both Parties.

(b) Any successor to the Principal Investigator must be approved in writing by the Sponsor and such successor shall be required to agree to all the terms and conditions of the Protocol and this Agreement and to sign an acknowledgement on each such document as evidence of such agreement (although failure to so sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this Agreement).

(c) In the event where the Institution and the Sponsor cannot agree on a suitable replacement Principal Investigator despite reasonable endeavours by the Parties, the Sponsor may terminate this Agreement in accordance with Clause 18.

4.3 If the Principal Investigator fails to carry out those obligations specified in this Agreement, then the Institution must itself perform those obligations and rectify and

make good any breach. The Institution will ensure that its Personnel are informed of and agree to abide by all terms of this Agreement relevant to the activities they perform.

4.4 The Institution will have an adequate number of appropriately qualified Personnel for the duration of the Study and ensure that such Personnel are adequately informed about, and comply with, the Protocol, Investigational Medicinal Product(s), and their Study-related duties and functions. Subject to the policies of the Institution, the Personnel appointed by the Institution to assess Study Participants may attend an investigator meeting or a pre-study/initiation meeting, where appropriate. The Institution shall also ensure that its Personnel will, subject to its internal policies, complete such training courses relating to good clinical practice which the Sponsor may specify from time to time. The Institution shall not use the services in any capacity of anyone debarred by the US Food and Drug Administration (FDA) or any other competent authority(ies) in the course of the Study.

4.5 The Institution agrees to promptly inform the Sponsor in writing if any of the Institution's Personnel who is performing services hereunder is debarred or if any action, suit, claim, investigation or legal or administrative proceeding is pending, or, to the best of the Institution's knowledge, is threatened in relation to the debarment of the Institution or any of the Institution's Personnel performing services hereunder. The Principal Investigator represents and warrants that no action, suit, claim, investigation or legal or administrative proceeding is pending or threatened in relation to his/her debarment and in the event any of the aforesaid is threatened or commences, the Principal Investigator agrees to inform the Sponsor in writing as soon as possible.

4.6 The Institution will not engage in any conduct on the Sponsor's behalf which is in violation of, or potentially in violation of, any Applicable Laws or to the best of its knowledge, any foreign laws or regulations. The Institution and Principal Investigator acknowledge and agree that there are anti-corruption laws to which the Sponsor is subject that prohibit the payment or offering of anything of value to a government employee or official or other individual for the purpose of: (a) inducing or influencing any governmental act or decision affecting the Sponsor; (b) helping the Sponsor obtain or retain any business; (c) serving as an inducement for approval, reimbursement, prescription, or purchase of any Sponsor product (including, the Study Drug); (d) influencing the outcome of any clinical trial (including, the Study); (e) or otherwise improperly benefiting the Sponsor's business activities ("**Prohibited Payment**"). The Institution and Principal Investigator each agree to refrain from making any such Prohibited Payment in connection with this Agreement or the Study that would constitute a violation by the Institution or Principal Investigator of such anti-corruption laws.

4.7 The Institution and Investigator each acknowledge and agree that the compensation provided hereunder constitutes fair market value for the performance of the Study and that no part of the payments hereunder shall be paid to, or shared with, directly or indirectly, any government or political party official (including as applicable the Principal Investigator or Sub-Investigator) for any purpose described as prohibited in Clause 4.6 of this Agreement.

4.8 The Institution warrants that, to the best of its knowledge, it and all its Personnel:

(a) are properly registered with appropriate professional registration bodies (where applicable), have not been disqualified from practice (where applicable) or disbarred or banned from conducting clinical trials by any Regulatory Authority(ies). Furthermore, the Institution shall notify the Sponsor as soon as

practicable after it becomes aware of any such disqualification, disbarment or ban; and

(b) have not been or are not the subject of any past or pending governmental or regulatory investigation, inquiry, warning, prosecution or enforcement action (collectively, "**Agency Action**") by any Regulatory Authority(ies) related to its conduct of clinical research or the practice of medicine. The Institution shall promptly notify the Sponsor if it receives notice of any Agency Action regarding its compliance with ethical, scientific or regulatory standards for the conduct of clinical research or the practice of medicine if the Agency Action relates to events or activities that occurred prior to or during the period in which the Study was conducted.

4.9 The Institution agrees to take all reasonable security measures to ensure the safety and integrity of the Investigational Medicinal Product, Essential Documents and Study records and reports, Equipment and any Study-related materials held or located at the Study Site.

4.10 The Institution will allow regular monitoring and auditing by the Sponsor in accordance with the ICH GCP, and inspection by any Regulatory Authority(ies) (upon the Regulatory Authority's request), and as required by Regulatory Authorities or as specified in the Protocol, and permit access to the Essential Documents (including original records), Study records, reports, other Study-related materials and its Personnel as soon as is reasonably possible upon request by the Sponsor, Regulatory Authority(ies), or any third party designated by the Sponsor. Any such access is to take place at times mutually agreed, during business hours and subject to such reasonable conditions relating to occupational health and safety, security, and confidentiality as the Institution may require.

4.11 If any governmental or Regulatory Authority(ies) notifies the Institution that it will inspect the Institution's records, facilities, equipment, or procedures, or otherwise take action, in relation to the Study, the Institution shall promptly notify the Sponsor, allow the Sponsor to be present at the inspection/action (if possible) or participate in any response to the inspection/action, and provide the Sponsor with copies of any reports issued by the Regulatory Authority(ies) and the Institution's proposed and final response.

4.12 The Institution will provide the Sponsor with all reasonable assistance and cooperation to rectify any matter as the result of an audit or inspection by the Sponsor's Monitor or Regulatory Authority(ies). The associated costs will be borne by the Sponsor unless such rectification is due to the default of the Institution or the Principal Investigator.

4.13 The Institution shall make available adequate facilities, equipment and any other resources of the Institution reasonably required to safely follow the Protocol. Prior approval in writing shall have to be obtained from the Institution in the event any amendment to the Protocol requires the use of additional facilities, equipment, staff or resources of the Institution.

4.14 The Institution shall ensure accurate and timely collection, recording, and submission of data and results required to be submitted to the Sponsor pursuant to the Protocol.

4.15 The Institution will use Biological Samples collected (if any) in accordance with the Protocol, and will not use such Biological Samples in any manner or any purpose other than that described in the Protocol and in the Informed Consent Form.

4.16 The Institution shall make and retain records regarding the Study as required by the Protocol and Applicable Laws. The Principal Investigator and the Institution each agree that all research data and results generated during the course of the Study shall be the property of the Sponsor, except patient medical records. Subject to the restrictions in Clause 4.16, the Sponsor shall be allowed access to inspect and/or copy Study related records, at reasonable times, upon reasonable notice and for such use stipulated in this Agreement, subject to applicable regulations and laws and institutional policies and processes on patient confidentiality.

4.17 The Institution shall permit the Monitor and/or any of the Sponsor's authorised representatives, view-only access to the Study-related records containing the Personal Data of the Study Participants for monitoring and auditing purposes only. For the avoidance of doubt, such records shall include, without limitation, all Study-related medical records of the Study Participants, their tests results and pharmacy notes. Access to such records shall be arranged at mutually convenient times and on reasonable notice. Such records must not be transferred out of the Institution's premises, unless they have been de-identified or if such disclosure is required under Applicable Laws or requested by competent Regulatory Authorities.

4.18 The Institution will retain the records from the Study under storage conditions conducive to their stability and protection for a period of not less than fifteen (15) years or as agreed with Sponsors from Study Completion at the expense of the Sponsor, unless Applicable Laws or the Sponsor require(s) such storage to be for a longer period in which case, the records shall be stored for the applicable duration at the Sponsor's expense. The Sponsor shall have access to such records upon its request and at its cost. The Institution shall be free to destroy the records from the Study after the required retention period expires unless prior written notice, of at least three (3) months, to retain the said records beyond the required retention period is provided by the Sponsor. The Principal Investigator and the Institution shall notify the Sponsor in writing immediately in the event of loss or inadvertent destruction of any of the Study records.

5. SPONSOR OBLIGATIONS AND RESPONSIBILITIES

5.1 Prior to the commencement of the Study, the Sponsor must provide the Institution, the Principal Investigator and the relevant Regulatory Authority(ies) with all necessary current and relevant information regarding the Investigational Medicinal Product, including all relevant clinical, pharmacology and toxicology information and advice which the Sponsor is made aware of and as reasonably required to justify the nature, scope and duration of the Study.

5.2 The Sponsor will implement and maintain quality assurance and quality control systems with written standard operating procedures to ensure that the Study can be conducted and data generated, documented, recorded and reported in compliance with the Applicable Laws.

5.3 The Sponsor will notify the Institution in writing as soon as possible of any Adverse Events (including Serious Adverse Events) that occur during the course of the Study (at other study sites, including overseas sites) which may require alteration of the conduct of the Study, or which may affect the rights, interests, safety or well-being of the Study Participants.

5.4 The Sponsor will designate appropriately qualified Personnel to advise on Study-related medical questions or problems.

5.5 The Sponsor will monitor the application of the Investigational Medicinal Product in other locations (both within and outside Singapore) and advise the Institution, through the Principal Investigator, of the cessation elsewhere of any relevant study, or the withdrawal of the Investigational Medicinal Product from any other market for safety reasons or any findings the Sponsor becomes aware of that indicate that the current and/or past Study Participants are at an increased risk of a problem that was not anticipated at the time the Study was designed.

6. SERIOUS ADVERSE EVENTS REPORTING

6.1 The Institution and the Principal Investigator shall notify the Sponsor in writing of any Serious Adverse Events that have been encountered in the Study immediately and in any event no later than twenty-four (24) hours after becoming aware of it in accordance with the instructions set forth in the Protocol.

6.2 The Institution and/or the Principal Investigator shall also:

(a) promptly inform the Sponsor any new safety findings on the Investigational Medicinal Product, including any Serious Adverse Event which could suggest that the safety of any Study Participant could be adversely affected or which could impact the conduct of the Study. The Principal Investigator shall follow up on such reports and provide the additional information in a detailed, written manner to the Sponsor in accordance with the procedures set out in the Protocol; and

(b) cooperate with and supply any further information required by the Sponsor or the IRB or the Regulatory Authority(ies) with jurisdiction over the Study.

6.3 The Sponsor shall comply with its reporting obligations in accordance with the Applicable Laws

7. PAYMENTS

7.1 In consideration of the Institution conducting the Study in accordance with this agreement, the Sponsor will pay to the Institution in the manner and on the basis of the amounts and at the times set out in **Schedule 2**. No additional payments shall be made to the Institution except as otherwise provided in this Agreement or with prior written consent from the Sponsor.

7.2 The Sponsor reserves the right to refuse to pay to the Institution payments specific to Study Participants entered into the Study who do not meet the entry criteria specified in the Protocol. For the avoidance of doubt, the Sponsor shall pay the Institution for screen failures.

7.3 If a Study Participant discontinues his/her participation in the Study, only those costs incurred up until the date of discontinuation, including costs of the final visit and completion of all Case Report Forms, where appropriate, will be paid.

7.4 In the event of an early termination of this Agreement, the Sponsor shall pay:

(a) all costs reasonably incurred and falling due for payment up to the date of termination; and

(b) all non-cancellable costs and expenditure falling due for payment after the date of termination which arise from commitments reasonably and necessarily incurred by the Institution for the performance of the Study prior to the date of termination.

7.5 Payments will be made by the Sponsor within thirty (30) days upon the receipt of a valid tax invoice from the Institution.

7.6 The Parties agree that:

(a) no part of any consideration paid hereunder is for the recommending or arranging for the referral of business or the ordering of items or services; and

(b) no consideration paid hereunder is contingent upon the Institution's use or purchase of any of the Sponsor's products.

7.7 The Parties agree that the payments from the Sponsor for the services provided by the Institution and the Principal Investigator hereunder (a) represent the fair market value for such services, (b) were negotiated in an arm's length transaction, and (c) have not been determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the Parties. For work performed or expenses incurred that the Sponsor is obligated to make payment on, the Institution and the Principal Investigator will not seek additional reimbursement from another source.

8. CONFLICT OF INTEREST

The Institution and the Principal Investigator confirm that there is no conflict of interests that they are aware of between (i) the Institution and the Principal Investigator, (ii) the Institution and the Sponsor, and/or (iii) the Principal Investigator and the Sponsor, that would inhibit or affect their performance of the work specified in this Agreement. The Institution and the Principal Investigator further certify that they will promptly inform the Sponsor in the event any conflict of interests arises during the performance of this Agreement to their knowledge and certify that their performance hereunder does not violate any other agreement they may have with any other third party.

9. PUBLICITY AND DISCLOSURE

9.1 In any publicity materials relating to the Study, the Principal Investigator shall disclose that the Sponsor has retained the Principal Investigator for professional services in relation to the conduct of the Study; as well as any other relationships that the Sponsor has with the Principal Investigator which a reasonable and ethical person would expect to be disclosed.

9.2 Except as otherwise expressly set out in this Agreement, or with the other Party's written consent, neither Party will use the name, trade mark, service mark, or logo of the other the Party, in any publicity, advertising or news release or other information intended to be used for commercial or promotional purposes. The foregoing restriction shall also apply to the Institution's use of the name, trade mark, service mark, or logo of any third parties collaborating with the Sponsor on the Study and/or the Investigational Medicinal Product. However, nothing herein shall be construed as prohibiting the Parties from reporting on this collaboration or the details or results thereof to a governmental or funding agency, or of exercising by the Parties of their

publication rights under Clause 16 (subject to the limitation set out therein) and for that purpose, disclosing and/or using the name of the other Party.

9.3 Both Parties agree to make all other disclosures and/or notifications as may be required in connection with entering into, performing, or receiving compensation under this Agreement, and the Principal Investigator shall follow all Applicable Laws in this respect, including those relating to the Principal Investigator's professional relationships with decision-making authorities or bodies (if any), such as, for instance, recusal from any votes, discussions or recommendations regarding investigational or marketed products of the Sponsor, regardless of whether such are subject to the services provided under this Agreement.

9.4 The Institution and the Principal Investigator understand and agree that the Sponsor may be required to disclose certain information to governmental agencies in different jurisdictions in order to comply with local laws regulating clinical trials and hereby consent to the disclosure of the Institution's and/or the Principal Investigator's name, the Study Site contact information, the name of the Study and the identity of the sponsor for the Study. For the disclosure of any other details, the Sponsor shall obtain the written consent of the Institution.

9.5 The Institution shall obtain approval, in writing, from the Sponsor for any press statements or promotional statements regarding the Study or the Investigational Medicinal Product(s) before the statements are released, unless the statement or disclosure is:

(a) required by law;

(b) required by any policy, guideline or direction of government or any government department or agency;

(c) required by any Regulatory Authority(ies), or;

(d) in the reasonable opinion of the Institution, reasonably necessary to protect the health and safety of any individual.

10. PROVISION OF EQUIPMENT AND SOFTWARE

10.1 The Sponsor shall provide the Institution and the Principal Investigator with the Equipment and Software at the Sponsor's expense, where necessary for the conduct of the Study. Unless otherwise agreed by the Parties in writing, the Institution agrees that the Equipment and Software will be used only by its Personnel and only for the purposes of the Study.

10.2 If proper usage of the Equipment or Software requires training, the Institution agrees that:

(a) its Personnel will make themselves available for training in using the Equipment and Software, at the Sponsor's expense; and

(b) the Equipment and Software will only be used as described in written directions provided by the Sponsor.

10.3 The Institution will take reasonable care in the use and secure storage of the Equipment. Subject to the foregoing, the Sponsor will bear the risk of loss or damage of the Equipment and be responsible for the costs of any repair or replacement required

as a result of any loss of or damage to the Equipment, save to the extent that such loss or damage results directly from the negligence of the Institution's Personnel.

10.4 and the Institution is responsible for damage caused to or by the Equipment as a result of the negligence of the Institution's Personnel.

10.5 Upon Study Completion or termination of the Study or at the Sponsor's request, the Institution will, unless otherwise specified, return to the Sponsor, at the Sponsor's expense, the Equipment and Software and all related training materials and documentation.

10.6 The Sponsor will cooperate with the Institution in maintaining, at the Sponsor's reasonable expense, the Equipment in good working order, and ensuring that it is in a safe condition and compliant with the requirements of the relevant licensing and safety authorities at all times.

10.7 The Institution will not copy the Software unless specifically authorised by the Sponsor.

10.7 The Institution shall ensure that the Software and Equipment shall not be altered, modified or tampered with in any form by the Institution or its Personnel.

11. INVESTIGATIONAL MEDICINAL PRODUCT

11.1 The Institution must:

(a) ensure that the Investigational Medicinal Product made available by the Sponsor is used strictly according to the Protocol and is not used for any other purposes;

(b) provide a written explanation accounting for any missing Investigational Medicinal Product;

(c) not charge a Study Participant or third party payer for the Investigational Medicinal Product or for any services reimbursed by the Sponsor under this Agreement;

(d) keep the Investigational Medicinal Product under appropriate storage conditions (including any conditions specified in the Protocol) and in a secured area accessible only to authorised Personnel, in accordance with ICG GCP; and

(e) ensure that complete and current records are maintained for all received, dispensed and returned Investigational Medicinal Product.

11.2 The Sponsor will supply the Principal Investigator with such quantities of the Investigational Medicinal Product as will be required for the purpose of the Study. All supplied Investigational Medicinal Product will be packaged in safe and appropriately labelled containers. The Sponsor will at all times remain the sole owner of the Investigational Medicinal Product.

11.3 On termination of this Agreement, the Institution must promptly return any unused Investigational Medicinal Product to the Sponsor, or, if requested by the Sponsor, destroy it and provide evidence of such destruction.

12. CONFIDENTIALITY

12.1 The Parties agree to adhere to the principles of medical confidentiality in relation to Study Participants involved in the Study. The Sponsor shall refrain from tracing and/or identifying any Study Participant. The Sponsor agrees to inform the Institution in the event any Study Participant, for whatever reason, becomes identifiable to the Sponsor, and the Sponsor agrees to delete all such identifiable information pertaining to such Study Participant. The Sponsor shall ensure that none of the Study Participants can be identified in any reports, submissions and publications of the Sponsor. Further, the Sponsor shall adopt appropriate technical and organisational measures to prevent any unauthorised or accidental use, access or processing of any Study-related data or information relating to the Study Participants ("**Data Breach**"). Any Data Breaches shall be reported to the Principal Investigator promptly. Neither Party shall disclose the identity of Study Participants to third parties without the prior written consent of the Study Participant, except in accordance with the requirements of the relevant data protection legislation.

12.2 Subject to Clause 12.3, each Party must not, and must ensure their Personnel do not, use or disclose any Confidential Information of the other Party, other than where and only to the extent that such use or disclosure is necessary for the performance of the Study, the exercise of its rights or the performance of its obligations under this Agreement.

12.3 The Institution may use or disclose the Sponsor's Confidential Information in any of the following circumstances:

(a) for the purposes of complying with the Institution's internal complaint procedures, accident reporting procedures, quality assurance activities, disciplinary procedures or any applicable policy in relation to patient safety, Serious Adverse Events and/or reportable incidents;

(b) for the purposes of disclosing any material risks identified during the Study or subsequent to it, to the Study Participants, other principal investigators conducting the Study, medical practitioners administering treatment to Study Participants and Regulatory Authorities;

(c) for the purposes of complying with the requirements of the IRB or any Regulatory Authority(ies);

(d) to enable the Regulatory Authority(ies) to monitor the Study;

(e) where the Sponsor consents in writing to the disclosure;

(f) as part of a publication issued under the provisions of Clause 16;

(g) where release of the Confidential Information is required by law, with notice as soon as reasonably practicable to the Sponsor, and subject to the Institution providing reasonable assistance as requested by the Sponsor to obtain a protective order or other remedy to resist disclosure or ensure confidential treatment for any required disclosure;

(h) for the purposes of the Institution seeking legal advice; and

disclosure to the Institution's insurer for the purposes of insurance coverage and claims, with notice as soon as reasonably practicable to the Sponsor identifying

which of the Sponsor's Confidential Information the Institution intends to disclose to its insurer.

12.4 Where Confidential Information is disclosed in accordance with Clauses 12.3(a), 12.3(b) 12.3(h) and 12.3(i), the Confidential Information must only be used in connection with the lawful purposes of the Institution, and only disclosed to those who have a need to know it for such purposes.

12.5 The Sponsor may disclose the Institution's Confidential Information:

(a) to its insurers and lawyers only on a need to know basis for the purposes of clinical trial insurance coverage and obtaining professional advice; and

(b) if required by law, with notice given as soon as reasonably practicable to the Institution, and subject to the Sponsor providing reasonable assistance as requested by the Institution to obtain a protective order or other remedy to resist disclosure or ensure confidential treatment for any required disclosure.

12.6 The Parties are responsible for ensuring that their Personnel are aware of the obligations in respect of Confidential Information in Clause 12, and are bound in similar terms to keep such information confidential.

12.7 Information will not be Confidential Information and will not be subject to the provisions of Clause 12 where:

(a) the information has been independently received from a third party who is free to disclose it;

(b) the information is in or has entered the public domain other than as a result of a breach of this Agreement;

(c) the Receiving Party already knew the information, the prior knowledge of which it can document by prior written records; or

(d) the Receiving Party independently develops, discovers or arrives at the information without use, reference to, or reliance upon, the Confidential Information.

12.8 If requested by the Sponsor in writing, the Institution shall return all the Sponsor's Confidential Information except that required to be retained at the Study Site by the Applicable Laws and one (1) archival copy for the purpose of monitoring compliance with the terms of this Agreement.

12.9 For the avoidance of doubt, in the interest of transparency relating to its relationships with investigators and study sites or to ensure compliance with Applicable Laws, the Sponsor may publicly disclose the support it provides under this Agreement, if required by Applicable Laws. Such a disclosure by the Sponsor may identify both the Institution and the Principal Investigator, but will clearly differentiate between payments or other transfers of value to institutions and those made to individuals.

12.10 Where a Study Participant seeks medical attention from another public healthcare institution located in Singapore ("Singapore PHI") as a result of an injury suffered in the course of participation in the Study, the Institution shall be allowed to disclose Confidential Information to such Singapore PHI for the purpose of enabling the

Singapore PHI to provide appropriate medical care and treatment to the Study Participant

12.11 The obligations in this Clause 12 shall continue throughout the term of this Agreement, including any extensions thereof, and for a period of seven (7) years after the expiration or termination of this Agreement or such longer term as mandated by any applicable law, regulations, guidelines or directives. For the avoidance of doubt, confidentiality obligations with regards to trade secrets shall survive for the period that such information retains its status as a trade secret under applicable law while all patient data including all medical records, and any Personal Data (whether pertaining to the Study Participants or the Institution's Personnel) that may be disclosed by the Institution to the Sponsor shall, notwithstanding any provision to the contrary herein, be kept confidential by the Sponsor in perpetuity.

13. DATA PROTECTION AND PRIVACY

13.1 Each Party must ensure that any Personal Data of the Study Participants or the other Party's Personnel it obtains or holds as a result of the conduct of the Study is collected, stored, used, processed, transferred and disclosed by it in accordance with all Applicable Laws and the relevant Personal Data protection regulations, including the PDPA. Personal Data shall not be disclosed to the Sponsor by the Institution save where this is required directly or indirectly to satisfy the requirements of the Protocol or for the purpose of monitoring or adverse event reporting in accordance with the terms of this Agreement, provided that the Study Participant agrees to such disclosure in the Informed Consent Form.

13.2 Each Party will promptly report in writing to the other Party:

(a) any inadvertent, unauthorised and/or unlawful processing, collection, storage, disclosure, alteration, corruption, transfer, or sale or rental, destruction, or use of Personal Data of Study Participants or the other Party's Personnel; or

(b) any other act or omission that compromises the security, confidentiality, or integrity of any Personal Data collected in accordance with the terms of this Agreement,

(each of the above, an "**Incident**"), and will work with the other Party to take reasonable steps to remedy any Incident.

13.3 If in support of the Study, a Party is required to submit to the other Party its Personnel's Personal Data, the other Party shall:

(a) protect the confidentiality of the first-mentioned Party's Personnel using the same or similar standards that the other Party uses for its own employees;

(b) not use or disclose such Personal Data except as required by law or in accordance with this Agreement;

(c) impose similar confidentiality and security obligations by contract, on any contracted service providers with or to whom the other Party may use or disclose such Personal Data;

(d) take appropriate measures to protect against any unauthorised use of disclosure of such Personal Data; and

(e) promptly notify the first-mentioned Party of any breach of this clause.

14. LIABILITIES AND INDEMNITY

14.1 The Sponsor shall indemnify, defend and hold harmless the Institution, its Personnel from and against any and all demands, claims, losses, labilities, damages, causes of action, proceedings, judgments, settlements, costs and expenses (including full legal and court fees) (each a "**Claim**") which may be made or instituted against the Institution or the Institution's Personnel in connection with the Study, including but not limited to Claims that are alleged to have been caused or contributed to the proper administration of the Investigational Medicinal Product in accordance with the Protocol or the proper performance of any Study procedure required by the Protocol, or Claims that are alleged to have been caused or contributed to by any negligence, wilful misconduct, act or omission of the Sponsor and/or its Personnel, provided that:

(a) the Institution has not submitted and does not submit such Claim to a third party payor; and

(b) such Claim is not due to the natural progression of any pre-existing disease or any underlying illness.

14.2 Notwithstanding the foregoing, the Sponsor shall have no indemnification obligation or liability in respect of the following:

(a) failure of the Institution and/or the Principal Investigator to comply with (i) the terms of the Protocol or this Agreement; or (ii) reasonable instructions provided by the Sponsor concerning the Investigational Medicinal Product; or (iii) other reasonable instructions provided to the Institution and/or the Principal Investigator by the Sponsor in connection with the Study;

(b) failure of the Institution and/or the Principal Investigator to comply with the Applicable Laws;

(c) failure of the Institution and/or the Principal Investigator to render professional service or to conduct the Study in a normal, prudent manner; or

(d) negligence or wilful misconduct on the part of the Institution, the Principal Investigator, and/or the Institution's Personnel.

14.3 The Sponsor's indemnity obligation is subject to compliance by the Institution with all of its obligations with regard to Adverse Event reporting procedures as set forth in the Protocol and any appendix or attachment thereto and the provisions of Clause 14.4.

14.4 Immediate written notice of any Claim shall be provided to the Sponsor by the Institution. The Institution shall provide reasonable assistance to the Sponsor in the defence thereof and rendering all other reasonable and necessary cooperation to the Sponsor at the Sponsor's expense, in defending or settling such Claim(s) and may join in defence with counsel of its own choice at its own cost or expense. The Sponsor shall have sole control over the direction of such Claim, including any negotiations relating to the compromise and/or settlement thereof save that no settlement shall include an admission of liability on the part of the Institution or its Personnel or prejudice the rights of the Institution or its Personnel without the Institution's prior written consent, such consent not to be unreasonably withheld or delayed.

14.5 Save for breach of clauses 12 and 13 above, and death or personal injuries caused by negligence, in no circumstances shall either Party be liable to the other in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever arising or whatever the cause thereof, for any loss of profit, business, reputation, contracts, revenues or anticipated savings, or for any special, indirect or consequential damage of any nature, suffered by the other Party.

14.6 The Sponsor and the Institution will each take out and maintain an adequate and appropriate clinical trial insurance coverage for the purposes of the Study or if such insurance coverage is already in effect, will provide evidence of such insurance for the said purpose. The Sponsor will maintain insurance with respect to its activities and indemnity obligations under this Agreement and agrees to provide proof of such insurance coverage to the Institution upon its request from time to time in the form of a certificate of insurance. The Institution shall also provide the Sponsor evidence of its insurance upon request by the Sponsor. The terms of any insurance or the amount of cover shall not relieve the Sponsor or the Institution of any liabilities under this Agreement. Each Party's insurance coverage shall comply with Applicable Laws and insurance guidelines.

14.7 The Sponsor will pay for the costs of reasonable and customary medical expenses for the treatment of Study Participants in the event of Study related injuries in accordance with the applicable regulatory requirements.

15. TAXES

All applicable goods and services tax (and any increases) which relate to the subject matter of this Agreement shall be borne by the Sponsor. Save as aforesaid, it shall be the Institution's responsibility to comply with all other obligations in respect of taxes, if applicable, which relate to the subject matter of this Agreement, including without limitation those which relate to the Principal Investigator, the Institution and its Personnel.

16. PUBLICATIONS

16.1 The Institution, the Principal Investigator and other investigators (each a "**Discloser"**) involved in the Study have the right to Publish the methods, results of, and conclusions from, the Study, subject to this Clause 16 and in accordance with all applicable intellectual property and copyright laws. The Sponsor, the Institution and the Principal Investigator shall comply with Good Publication Practice Guidelines (http://www.ismpp.org) and all ethical standards concerning publications and authorship.

16.2 ~~If~~ Subject to the other requirements of Clause 16, if the Study is a Multi-centre Study, then the Institution acknowledges and agrees that no Publication of the Study results may be made until Publication (as coordinated by the Sponsor) of the results of the Multi-centre Study or one (1) year after Study Completion, whichever is the sooner.

16.3 The Institution must ensure that the Discloser provide a draft of the proposed Publication to the Sponsor at least sixty (60) days before disclosing or transmitting it to any person that is not bound by the confidentiality obligations set out in Clause 12.

16.4 The Sponsor may, within that sixty (60) period, do any one or more of the following:

(a) provide comments on the proposed Publication to the Institution, in which case the Institution must consider such comments but will not be bound to follow them;

(b) request delay of Publication for no more than one hundred and twenty (120) days to allow the Sponsor to file patent applications or take other measures to preserve or secure its Intellectual Property, in which case the Institution must abide by that request; or

(c) request that the Discloser remove specified Confidential Information (other than the results of the Study) from the Publication, in which case the Institution must remove such specified Confidential Information as is reasonably required to protect the Intellectual Property of the Sponsor.

16.5 If the Institution has not received any comments from the Sponsor on the proposed Publication within sixty (60) days of giving a copy to the Sponsor under Clause 16.3, the Discloser may proceed to make the Publication.

16.6 Authorship related to Publications shall be determined in accordance with and governed by the criteria defined by the International Committee of Medical Journal Editors (ICMJE) "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" Where the Sponsor intends to Publish the method, results or conclusions from the Study, any person named as an author on that Publication will be given a reasonable opportunity to review the Publication.

16.7 In all Publications, the Sponsor's support of the Study shall be acknowledged. A copy of the Publication will be furnished to the Institution of the staff who was acknowledged upon publication.

16.8 The Sponsor may Publish a summary of the study results and conclusions on the Sponsor's on-line Clinical Trial Register before or after Publication by another method.

16.9 The Sponsor may only use and disclose the Institution's and the Principal Investigators' names in Study publications and communications:

(a) including Study newsletters made to the Institution and any other person which is subject to substantially the same confidentiality obligations as those set out in Clause 12, in relation to the performance of the Study; or

(b) made to any third party not subject to the confidentiality obligations set out in Clause 12, with the Institution's prior written consent.

17. STUDY MATERIALS AND INTELLECTUAL PROPERTY

17.1 The Sponsor grants to the Institution and its Personnel the limited right to use the Background IP of the Sponsor and the Study Materials as required to carry out the Study in accordance with the Protocol. Neither the Institution nor any of its Personnel acquires any right or interest in any Background Intellectual Property provided by or on behalf of the Sponsor.

17.2 In order to carry out the Study, the Institution may use Intellectual Property which is part of the Institution's Background IP. Any such Background IP remains the sole property of the Institution. For the avoidance of doubt, any proprietary testing protocols, processes, programming, methodology, techniques and know-how introduced or developed by the Institution or its Personnel in conducting the Study remains the sole

and exclusive property of the Institution ("**Institution's Know-how**"). Any ideas, innovations, developments, improvements, inventions, whether or not patentable, relating to the Institution's Intellectual Property and/or the Institution's Know-how, shall be the sole and exclusive property of the Institution.

17.3 The Institution grants to the Sponsor a non-exclusive, worldwide, perpetual, irrevocable royalty free licence to use (including the right to sub-licence) the Institution's Background IP solely for the purpose of the commercialisation of the Study Materials.

17.4 Subject to Clause 17.2, all Intellectual Property in the Study Materials will vest automatically upon its creation in the Sponsor, and the Institution assigns, and (where applicable) shall ensure that its Personnel assign, to the Sponsor all Intellectual Property Rights contained in the Study Materials. The Sponsor may file any applications in respect of any such Intellectual Property in its name or the name of an Affiliate. The Institution and the Principal Investigator will provide the Sponsor with all reasonably necessary assistance in order to enable the Sponsor to apply for, obtain, maintain in force, enforce and defend any Intellectual Property Rights at the sole cost and expense of the Sponsor.

17.5 Subject to Clause 12 (Confidentiality), the Sponsor grants to the Institution a non-exclusive, perpetual, irrevocable, royalty-free licence (without the right to grant sub-licences) to use the Study Materials solely for publication purposes in accordance with Clause 16 and for patient care and internal non-commercial research, development, academic and education purposes.

18. TERM AND TERMINATION

18.1 This Agreement commences from the date specified on the first page of this Agreement or, if such date is not specified, on the date this Agreement is last signed by either the Sponsor or the Institution. In the ordinary course of events this Agreement terminates when the Sponsor makes its final payment to the Institution.

18.2 A Party may terminate this Agreement with thirty (30) days prior written notice or such shorter time period as is reasonably required in the circumstances if the other Party:

(a) is in breach of any obligation under the Agreement or the Protocol (including failure to meet a deadline without just cause and fails to remedy such breach where it is capable of remedy within thirty (30) days of a written notice from the terminating Party specifying the breach and requiring its remedy;

(b) is declared insolvent or has an administrator or receiver appointed over all or any part of its assets or ceases or threatens to cease to carry on its business; or

(c) assigns this Agreement to a person considered unsuitable to perform the Agreement as set out in Clause 24.

18.3 In addition to Clause 18.2, a Party may terminate this Agreement immediately by written notice to the other Party if it believes on reasonable grounds that:

(a) continuing the Study poses an unacceptable risk to the rights, interests, safety or well-being of Study Participants; and

(b) terminating this Agreement is the most appropriate way to respond to that risk.

18.4 Either Party may terminate this Agreement with thirty (30) days' prior written notice to the other Party. In the event of such early termination, the Sponsor will pay the reasonable costs of the Institution relating to the Study calculated in accordance with **Schedule 2**.

18.5 In the event of termination or expiry of this Agreement, the Institution must promptly initiate all appropriate action to close the Study and, subject to any applicable retention requirements imposed by Applicable Laws, return to the Sponsor (or destroy if requested by the Sponsor, and provide evidence of such destruction) any completed Case Report Forms and other materials received from the Sponsor before Study Completion, at the Sponsor's expense.

18.6 In the event of termination or expiry of this Agreement, the Sponsor must take all appropriate action to close out the Study Site in a timely manner and in accordance with Applicable Laws, ensuring the safety of the Study Participants at all times. Termination or expiry of this Agreement will be without prejudice to the accrued rights and liabilities of the Parties under this Agreement.

18.7 In the event of early termination, the Sponsor will cooperate with the Institution to ensure that Study Participants who may be affected by termination receive adequate medical care. This may include the provision of Investigational Medicinal Product in certain circumstances at the Sponsor's expense.

18.8 The following provisions survive the expiration or termination of this Agreement, Clauses 1, 2.1, 2.2, 2.3, 2.4, 3.2, 4.17, 5.5, 7, 9, 10.4, 10.5, 10.6, 10.7, 11.3, 12, 13, 14, 16, 17, 18.5, 18,6, 18.7, 18.8, 19, 20, 21 and 22, as does any other provision in this Agreement that by its nature and intent is contemplated to remain valid and enforceable after the term of the Agreement.

19. DISPUTE RESOLUTION

19.1 In the event of any dispute or difference arising out of or in connection with this Agreement including any question regarding its existence, validity or termination (a "**Dispute**"), the Parties agree to use their best endeavors to attempt to settle it informally by negotiation in good faith between 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 ("**Alternative Dispute Resolution ("ADR") Notice"**) to the other Party requesting negotiation in accordance with this clause. The negotiation will start no later than twenty (20) days after the date of the ADR Notice. If the Dispute is not resolved within thirty (30) days of the ADR Notice or such longer period as mutually agreed by the Parties, a Party may by written notice to the other refer the Dispute or difference to arbitration.

19.2 If the Parties are unable to arrive at an amicable settlement of the Dispute by negotiation in accordance with Clause 19.1 above, the Parties agree that the Dispute shall be resolved by reference to arbitration in Singapore by way of a written notice given by a Party to the other Party, which shall state the specific Dispute to be resolved and the nature of such Dispute. Any reference to arbitration in Singapore shall be a submission to arbitration administered by the Singapore International Arbitration Centre ("**SIAC**") in accordance with the Arbitration Rules of the Singapore International Arbitration Centre ("**SIAC Rules**") for the time being in force, which rules are deemed to be incorporated

by reference to this clause. The seat of the arbitration shall be Singapore. The language of the arbitration shall be the English language.

19.3 The Tribunal shall consist of one (1) arbitrator to be appointed by mutual agreement between the Parties. Either Party may propose to the other the name or names of one (1) or more persons, one (1) of whom would serve as the arbitrator. If no agreement is reached within thirty (30) days after receipt by one (1) Party of such a proposal from the other, the arbitrator shall be appointed by the President of SIAC. The arbitrator must not be a present or former employee or agent of, or consultant or counsel to, either Party or any of its Affiliates.

19.4 Any decision or award of the Tribunal appointed pursuant to Clause 19 shall be final and binding on the Parties and the execution thereof may be entered into any court having jurisdiction.

19.5 For the avoidance of doubt, it is agreed that nothing in Clause 19 shall prevent a Party from seeking urgent equitable relief before any appropriate court and the commencement of any dispute resolution proceedings shall not affect the continual performance of the Parties' obligations under this Agreement.

20. GOVERNING LAW

This Agreement shall be interpreted and governed in all respects in accordance with the laws of the Republic of Singapore for every intent and purpose.

21. NOTICES

21.1 A notice, consent, approval or other communication (each a "**notice**") under this Agreement must be:

(a) delivered to the Party's address; or

(b) sent by pre-paid mail to the Party's address.

21.2 A notice given by a Party in accordance with this clause is treated as having been given and received:

(a) if delivered to a person's address, on the day of delivery if a business day, otherwise on the next business day; or

(b) if sent by pre-paid mail, on the third business day after posting.

21.3 The addresses of the Parties for the purposes of giving any notice are set out on the front page of this Agreement.

22. WAIVER

22.1 No right under this Agreement is waived or deemed to be waived except by notice in writing signed by the Party waiving the right. A waiver by any Party in respect of any breach of a condition or provision of this Agreement will not be deemed to be a waiver in respect of any other breach.

22.2 Failure or delay by any Party to enforce any provision of this Agreement will not be deemed to be a waiver by that Party of any right in respect of any other such breach.

23. VARIATIONS

No variation or amendment of this Agreement will be effective or legally binding on any Party unless it refers to this Agreement and is evidenced in writing signed by both Parties.

24. ASSIGNMENT

Neither Party shall assign its rights under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed save that the Sponsor may by written notice to the Institution assign its rights under this Agreement to any of its Affiliates without the prior written consent of the Institution. Notwithstanding any such assignment by the Sponsor, the Sponsor shall remain liable for all of its obligations under this Agreement.

25. ENTIRE AGREEMENT

This Agreement constitutes the entire agreement between the Parties in relation to the Study including its Exhibits and Schedules and supersedes all prior representations, agreements, statements and understandings, whether verbal or in writing in relation to the Study.

26. FURTHER DOCUMENTS

Each Party will do anything (including executing any document), and will ensure that its Personnel do anything (including executing any document), that the other Party may reasonably require to give full effect to this Agreement. Where such execution of further documents is required by a Party under this Agreement, the associated costs and expenses incurred in connection with such execution shall be borne by the Party requiring such documents.

27. SEVERANCE

In the event that any term, condition or provision contained in this Agreement or the application of any such term, condition or provision shall be held by a court of competent jurisdiction to be wholly or partly illegal, invalid, unenforceable or a violation of any applicable law, statute or regulation of any jurisdiction, the same shall be deemed to be deleted from this Agreement and shall be of no force and effect; whereas the remaining terms, conditions or provisions of this Agreement shall remain in full force and effect as if such term, condition and provision had not originally been contained in this Agreement, unless the severed provisions render the continuing performance of this Agreement impossible, or materially change either Party's rights or obligations under this Agreement; in which event, the Parties hereto shall negotiate in good faith in order to agree to terms of mutually acceptable and satisfactory alternative provision(s) in place of the provision(s) so deleted.

28. RELATIONSHIP OF THE PARTIES

Nothing in this Agreement creates a relationship of employer and employee, principal and agent, joint venture or partnership between the Parties and no Party will hold itself out as an agent for the other Party.

29. FORCE MAJEURE

If any Party is delayed or prevented from the performance of any act required under this Agreement by reason of any act of God, act of nature, including any epidemic or outbreak of pandemic disease, fire, act of government or state, war, civil commotion, insurrection, embargo, prevention from or hindrance in obtaining raw material, energy or other supplies, labour disputes of whatever nature or whatever reason beyond the control of the Party (a "**Force Majeure Event**"), the affected Party shall promptly notify the other Party in writing, giving details of the Force Majeure Event, the acts affected by the Force Majeure Event and the extent to which they are affected, and performance of such acts shall be excused for the period of such event provided that if such interference lasts for any period in excess of ninety (90) days either Party may, by written notice to the other, terminate this Agreement.

30. CONFLICT

Should there be any inconsistency between the Protocol and the other terms of this Agreement, the terms of the Protocol shall have precedence with respect to science, medical practice and Study Participant care matters and the terms of this Agreement shall have precedence with respect to all other matters.

31. PARAMOUNTCY

31.1 The Sponsor acknowledges and agrees that the Institution has a paramount obligation to comply with the directives of the relevant authorities to discharge its duties with regard to public healthcare and to act at all times in the interest and welfare of its patients. The Institution shall not be required or obliged under this Agreement to act in any manner contrary to such a paramount obligation.

31.2 Without prejudice to the generality of Clause 31.1, the Sponsor acknowledges and agrees that where any of its Personnel, including any of its appointed Monitors, access the premises of the Institution or any of the Institution's Affiliates to carry out any of their duties in relation to the Study, the Sponsor shall at its cost and expense procure that such Personnel and Monitors have Immunity are vaccinated against such diseases as may be specified by the Institution from time to time in accordance with the Institution's then prevailing policies. The Sponsor shall produce evidence on demand, to the satisfaction of the Institution, of such Immunity, and shall also make such evidence available to the relevant authorities on request. The Sponsor shall ensure that such evidence is retained for (a) the duration of its Personnel's employment or engagement with the Sponsor or its contractor (as the case may be) plus at least thirty (30) days thereafter; or (b) such other period as may be specified by the Institution from time to time. For the purposes of this Clause, "**Immunity**" means such immunity criteria as may be specified by the Institution from time to time. .

32. NO THIRD PARTY BENEFICIARIES

Save in respect of any of the Indemnitees or a Party's Affiliates in respect of the rights expressly granted hereunder to such Affiliates, nothing contained in this Agreement is intended to confer upon any person (other than the Parties hereto) any right, benefit or remedy of any kind or character whatsoever or any right to enforce the terms of this Agreement under the Contracts (Rights of Third Parties) Act (Cap. 53B), and no person shall be deemed to be a third party beneficiary under or by reason of this Agreement.

33. COUNTERPARTS

This Agreement may be executed in any number of counterparts. All counterparts taken together are deemed to constitute one (1) and the same Agreement, provided that this Agreement shall be of no force and effect until the counterparts are exchanged.

34. BIOLOGICAL SAMPLES

34.1 It is expected that the Institution will, from time to time, transfer Biological Samples to the Sponsor. The Parties agree that any such transfer of Biological Samples shall be subject to the following terms and conditions.

34.2 The Biological Samples shall be transmitted to the Sponsor at the Sponsor's expense and shall be de-identified.

34.3 The Biological Samples shall be used only for the purposes of the Study and shall under no circumstances be administered to human subjects.

34.4 The Biological Samples shall not be used, analysed or modified other than necessary for the purposes of the Study and as consented to in the Study Participant's Informed Consent Form.

34.5 The Sponsor shall handle and store the Biological Samples in accordance with Applicable Laws and as specified in the Protocol (if applicable).

34.6 The Sponsor shall not attempt to identify or contact the Study Participants from whom the Biological Samples were collected, or to compromise or otherwise infringe the confidentiality of information of the Study Participants.

34.7 Upon completion of the Study, after testing as required by the Protocol, or after the end of the storage period stipulated in the Protocol and/or Informed Consent Form (if applicable), the Sponsor shall discontinue its use of the Biological Samples and shall, at its risk and expense, completely destroy all remaining Biological Samples in its possession in accordance with Applicable Laws and the instructions of the Institution (if any). A written confirmation of such disposal / destruction shall be provided to the Institution upon request.

34.8 The Institution and Principal Investigator make no warranties, express or implied, concerning the Biological Samples, and in particular the merchantability or fitness for a particular purpose of the Biological Samples. The Institution and Principal Investigator shall not be liable for any direct, consequential or other damages suffered by the Sponsor or others as a result of or in connection with the Study or the provision or use of the Biological Samples.

In witness hereof, the Parties have caused this Agreement to be executed as of respective dates written below.

Signed on behalf of the **Sponsor**

Signature : _____

Name :

Designation :

Date :

In the presence of:

Signature : _____

Name :

Designation :

Date :

Signed on behalf of the **Institution**

Signature : _____

Name :

Designation :

Date :

In the presence of:

Signature : _____

Name :

Designation :

Date :

The Principal Investigator acknowledges this Agreement and understands the obligations it imposes.

Acknowledged by the **Principal Investigator**

Signature	:	_____
Name	:	
Designation	:	
Date	:	

Schedule 1

Key Information

(To be inserted by the Sponsor)

Study Name: _____

_____

Study Site/s: _____

_____

Target number of Study Participants: Minimum:
Maximum:

Recruitment Period: Start: / / End: / /

Principal Investigator Name: _____

Address: _____

_____

State: P/code:

Equipment provided by the Sponsor: _____

_____

_____

_____

_____

Software provided by the Sponsor: _____

_____

_____

_____

Investigational Medicinal Product: _____

_____

Schedule 1

Timeline

Schedule 2

Payments

Please paste/enter text below; delete this instruction and the suggested subject matter list once the payment schedule has been included.

Schedule 3

Study Protocol Identification

Full Title: _____

_____

_____

Version Number: _____

Date: _____

List of Key Attachments: _____

_____

_____

_____

_____

_____