

Standard Operating Procedure:

Teletrials Overarching Processes

**SOP Number: TT-SOP-01A**

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| Approved by: | VCCC Teletrials Steering Committee |

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**Amendment History**

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Developed by the Victorian Comprehensive Cancer Centre (VCCC) in conjunction with the Parkville Cancer Clinical Trials Unit (PCCTU), based on the Clinical Oncology Society of Australia (COSA) Australasian Tele-trials Model.

**A picture containing screenshot

Description generated with very high confidenceviccompcancerctr.org**

**Introduction and Background**

A Teletrial is the conduct of clinical trials from a Primary Site utilising Telehealth communication to engage Satellite Sites, (forming a clinical trial cluster) in designated regions to enhance patient reach, recruitment and management. Teletrials provide an opportunity to increase access to clinical trials for patients living in regional, rural and remote locations. The Clinical Oncology Society of Australia published the Australasian Tele-trial Model and subsequent Standard Operating Procedures (SOPs). The Victorian Comprehensive Cancer Centre have adapted the model and SOPs to the Victorian Context.

1. Objective

To describe the variations to normal clinical trial procedure when undertaking a Teletrial.

1. Scope

This SOP applies to the principal investigator, sub-investigators and to all members of the study team.

1. Ownership and Responsibility

The principal investigator is responsible to ensure all study team members have the necessary expertise and experience to successfully perform the task(s) delegated to them.

1. Glossary of Terms

Please refer to SITE-SOP-Glossary-of-Terms (see Related Documents) for full supporting glossary of terms.

1. Procedure

5.1 Site Selection Process

Sites will be selected on a per trial basis based on their capability and competency. The Principal Investigator and sponsor are responsible for selecting appropriate Satellite Sites.

* 1. Contracts

For an Investigator Initiated Teletrial the Clinical Trial Activities Agreement for implementation in the case of an Investigator Initiated Study by Teletrial (appendix 1) should be utilised. The agreement considers the lack of head agreement and will be signed by the Primary site (PS) and each Satellite site (SS).

For Sponsored Trials in Victoria the head agreement between the sponsor and primary site will remain the Medicines Australia standard CTRA. The Clinical Trial Research Agreement Subcontract for Studies Conducted Under a Teletrials Model (appendix 2) should be utilised between the Primary and each Satellite site.

* 1. Indemnity

Public hospitals and clinicians are covered for professional and medical Indemnity within their VMIA insurance, subject to the terms conditions and exclusions of the policy wording. Private hospitals and non-employed clinicians will need to provide evidence of professional and medical indemnity from their providers.

* 1. Documentation of Investigational Site Staff Qualifications

The Principal Investigator must ensure all investigational site staff, at both PS and SS, or Independent Third Party, and External Service Providers are qualified by education, training and experience, including GCP training, to assume responsibilities to perform the delegated study-related duties and functions. The Principal Investigator is responsible for ensuring all investigational site staff have a current CV in the research office/SMF for sighting by sponsor and / or regulatory authority. SS study staff are permitted to use a Transcelerate approved abbreviated CV template. The CV should detail clinical experience and relevant training. CV’s are required to be updated every two years unless a change in position has occurred, at which time a new CV must be provided if the staff member continues involvement with the trial. The SS staff will retain the wet ink original CVs and will provide the PS with a copy.

* 1. Supervision Plan

The Supervision Plan outlines processes for a Principal Investigator in the supervision of any individual or party to whom he/she delegates study-related duties and functions conducted at a study site, which includes, but is not limited to, details on joint consultations using telehealth, collation and monitoring of documents, frequency of joint trial meetings across a cluster (with minutes of these meetings) and clarification of activities performed by the PI and the SI, other study staff and independent third party ie external service providers. The Supervision Plan template (appendix 3) must be completed by the Principal Investigator/delegate and agreed with the team and sponsor prior to commencement of the study.

The Supervision Plan for each Satellite Site will be stored in the Satellite Site Site File (SSSF) and a certified copy of each stored in the Study Master File. The Supervision Plan must be updated with any new processes or delegated responsibilities and agreed to by the team and sponsor prior to any changes taking place.

* 1. Delegation Log

It is the responsibility of the principal investigator/delegate to ensure the delegation log is completed prior to clinical trial initiation and maintained throughout the study. The delegation log must be completed in line with SOP-04 Delegation of Duties.

Delegated activities to be performed by the Satellite Site are trial specific and should be agreed and documented at the time of site selection. Back up of staff, as required at satellite site(s) must also be recorded in the Delegation logs. The Delegation Log will be stored at the Satellite Site until the trial closed out and then sent to the Primary Site for archiving.

* 1. Randomisation

The Primary site PI remains responsible for the randomisation of the patient on to the trial. Notification of randomisation and result of randomisation to the satellite site is the responsibility of the primary site PI. The requirement for when randomisation occurs will be protocol specific and will differ for each trial and will be documented in the supervision plan.

* 1. Administration of trial treatments

Drug ordering, storage, administration and destruction will be outlined in the supervision plan

* 1. Source Documents and Record Keeping

All essential documents must be managed in line with SOP-11 Essential Documentation Management.

The SS sub-investigator/delegate must:

* maintain adequate Source Documents and trial records including all key observations on each of the site’s trial participants;
* store all trial-related documents in a Satellite Site Study File (SSSF)
* ensure, for both paper and electronic documents, all changes, corrections and amendments are tracked, and version dates and numbers, are updated to reflect the changed data and to maintain the integrity of the data. An explanation of the changes is noted in a record of change.
* ensure that for telehealth consultations, the call is documented in the participant’s medical record at each site by agreeing in the supervision plan where the original and Certified Copies are stored. The written record will include a brief summary of the consultation; follow up instructions and that the visit was conducted via telehealth.
* for paper records, ensure that a Certified Copy of any key essential documentation generated at the satellite site is sent to the primary site for filing in the Site Master File (SMF).
* where Electronic Medical Records (EMR) are in use, ensure that access to the patient’s trial related information is limited to authorised users only. Where access cannot be limited measures must be put in place to ensure the patient’s privacy and confidentiality are respected eg print the trial related information, sign as a Certified Copy and place in a paper record for access by Sponsor, regulatory inspectors and auditors etc.
  1. Completion of Case Report Forms (CRF)

Data is entered into the eCRF at the satellite site for each visit conducted at the satellite site. Source data for all visits will be collated at the satellite site in the patient file. The Principal Investigator/delegate at the PS will be responsible for uploading the source data into the CRF or eCRF.

* 1. Therapeutic Goods Administration Notification:

The Principal Investigator is responsible for listing all sites, both primary and satellite, on the Clinical Trials Notification (CTN). Each site that administers the investigational product must be listed on the CTN.

* 1. Communications between the satellite and primary sites

The SS will hold regular study teleconference meetings with the PI to provide trial updates, monitor protocol conduct and staff resourcing. The primary site PI whilst on the videoconference will make all trial related decisions, unless otherwise stated.

If a trial patient is admitted to a non-primary site hospital, the on-call physician will triage and manage the patient. The primary site PI must be notified of the admission and will provide appropriate advice and arrange transfer if clinically required.

* 1. Communication with Human Research Ethics Committee

The Principal Investigator/delegate is responsible for ethics submissions and all communication with Human Research Ethics Committee. The Principal Investigator/delegate must include in the relevant section of the ethics application that the trial may be undertaken using Telehealth with Satellite Sites, if applicable, and that the informed consent process and/or some or all study assessments will be undertaken using Telehealth, face to face consultation or a combination of both.

* 1. Communication with Research Governance Office

The responsible party for communicating with the local Research Governance Office (RGO) will be trial specific and outlined in the Supervision Plan. Each Satellite Site will need to obtain governance approval from their local RGO prior to commencement of the study at that site.

* 1. Informed Consent

Where appropriate the consent process will be delegated by the PI to the Sub-investigator at the SS and the procedure will be as follows:

* + Pre-Screening for eligibility will be undertaken at the SS.
  + The consent interview will be conducted by the Sub I, but whenever possible the PI will be present via videoconference and their involvement documented in the medical record
  + The main Primary site study coordinator and the satellite site nurse may be present if possible.
  + Once the patient agrees to participate, the patient and the Sub I will sign the Informed Consent document
  + The satellite site will send a certified copy of the PICF to the PS via Email and file the original as a source document

When the consent process cannot be delegated to the SS, the procedure will be as follows:

* + Pre-Screening for eligibility will be undertaken by the PI via videoconference
  + The patient and SS study coordinator will be present in same room and the consent interview will be conducted by the PI via video conference
  + Once the patient agrees to participate, the patient will sign the PICF at the SS and the PI will sign the PICF at the PS.
  + Certified copies of both PICFs will be provided to the other site and stored in the SMF and SSSF.
  + The SS Study Coordinator will document the process in the medical record.
  1. Safety reporting occurring at satellite site

The process for reporting of safety events, including protocol deviations / violations, to CPI will be documented in each trial Supervision Plan.

1. Dissemination and Implementation

Approved SOPs will be made available to both PS and SS. SOPs will be made available in hard copy format or electronically upon request. Any updates to the existing approved SOPs will be disseminated internally and will be effective immediately.

1. Monitoring Compliance and Effectiveness

Compliance with this SOP will be monitored as part of the sponsors monitoring and audit process. Any queries concerning the effectiveness of this SOP identified during the monitoring process or through use will be addressed and may result in the requirement to update the SOP.

1. Review and Updating

This SOP will be reviewed every three years, or when changes to legislation or working practices that impact upon the content of this document. This SOP may be merged with another SOP if appropriate or removed entirely if it becomes redundant.

1. Reference(s)

COSA Australasian Teletrial Model

Australian ICH GCP (Including Teletrials) SOPs

1. Related Documents

SITE-SOP-Glossary-of-Terms

SITE-SOP-02: Informed Consent Process

SITE-SOP-03: Clinical Trial Training

SITE-SOP-04: Delegation of Duties

SITE-SOP-11: Essential Documentation Management

SITE Training Log

SITE Delegation of Duties Log

**Appendix 1 – Investigator Initiated Teletrial Agreement**

**DRAFT 1, 10 August 2018**

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| --- | --- |
|  | **Clinical Trial Activities Agreement** |
|  | Investigator initiated study by tele-trial |
|  |  |
|  | **[Insert name of Primary Site]**  **[Insert name of Satellite Site]** |

Parties

**[Insert name of Primary Site]** (ABN [insert]) of [*insert address*] Victoria (**Primary Site**)

**[Insert name of Satellite Site]** (ABN [insert]) of [*insert address*] (**Satellite Site**)

Background

A Primary Site is a Victorian public hospital which undertakes cancer research, education and treatment activities. The Satellite Site is a rural or regional health services provider.

B Primary Site has initiated the Study which will be conducted as an investigator-initiated study at various sites.

C To enable patients who are in rural or regional sites to participate in the Study, Primary Site will engage the Satellite Site to perform the Study Activities at the Site utilising a tele-trials model.

D The Primary Site and the Satellite Site wish to enter this agreement to detail their arrangements regarding the conduct of the Study Activities by the Satellite Site at the Site.

# Engagement and term of agreement

# Engagement

* 1. The Primary Site engages the Satellite Site to perform the Study Activities on the terms and conditions set out in this agreement and the Satellite Site accepts that engagement.

# Term

* 1. This agreement commences on the Commencement Date and will remain in force until the End Date, unless terminated earlier or extended in accordance with this agreement.

# Study Activities

## Performance of Study Activities

* 1. The Satellite Site must perform the Study Activities in accordance with this agreement. At all times during the Term, the Satellite Site must:
     1. perform the Study Activities promptly, carefully and to the highest practicable standards;
     2. perform the Study Activities exercising all due care, skill and judgement, in an efficient and professional manner and in accordance with accepted professional and industry practices;
     3. hold all authorisations, permits and licences required under any law to perform the Study Activities; and
     4. comply with the requirements of all laws of any kind applying to the performance of the Study Activities.

## Study Activities to be conducted by Satellite Site at the Site

* 1. Without limiting clause 2.1, the Satellite Site will perform the Study Activities at the Site in accordance with:
     1. the Supervision Plan;
     2. the Protocol;
     3. any condition of the Reviewing HREC;
     4. any requirements of Regulatory Authorities;
     5. the requirements of the Australian Therapeutic Goods Administration in Access to Unapproved Therapeutic Goods – Clinical Trials in Australia (October 2004) or replacement and any other TGA publication or guideline that relates or may relate to clinical trials, or other such regulations or guidance governing the conduct of clinical research in the jurisdiction of the Study;
     6. the GCP Guideline; and
     7. the *National Statement on Ethical Conduct in Human Research* (2007) published by the Australian National Health and Medical Research Council.

# Obligations regarding performance of Study Activities

## Primary Site obligations

* 1. The Primary Site will perform the activities which are specified as attaching to the Primary Site in the Supervision Plan.

## Study Activities performance

* 1. In relation to its performance of the Study Activities at the Site, the Satellite Site will:
     1. ensure written approval has been obtained to conduct the Study from the Reviewing HREC prior to performance of any Study Activities and that the Study Activities are subject to the continuing oversight of the Reviewing HREC throughout their conduct;
     2. ensure that informed consent to participate in the Study is obtained from each Study Participant prior to any Study Activities being performed in relation to such Study Participant and documented using an information and consent document which has been reviewed and approved by the Reviewing HREC;
     3. complete and provide a copy to the Primary Site:
        1. any Case Report Forms created or completed by it in accordance with the requirements of the Protocol; and
        2. any other Study related materials reasonably requested by the Primary Site.

## Personnel

* 1. The Satellite Site must make available sufficient Personnel with the necessary skills, expertise, qualifications and training to carry out the Study Activities. The Satellite Site must ensure that any of its Personnel who perform the Study Activities:
     1. exercise due care, skill and judgement and perform the Study Activities in an efficient and professional manner;
     2. are competent, hold appropriate professional qualifications and hold and maintain all such practice registrations and certifications (including, where appropriate, in relation to GCP) as may be required by law;
     3. are adequately informed and instructed about the Study and in relation to the Study Activities they are required to perform; and
     4. attend an investigator meeting or a pre-Study or initiation meeting and any other meeting reasonably required by the Primary Site.

## No debarment

* 1. The Satellite Site represents and warrants that neither it, nor any of its Personnel performing Study Activities:
     1. has been debarred, disqualified or banned from conducting clinical trials or any study similar to the Study, in any jurisdiction; or
     2. is under investigation by any Regulatory Authority for debarment or any similar regulatory action in any jurisdiction.
  2. The Satellite Site will notify the Primary Site immediately if any such investigation, disqualification, debarment, or ban occurs during the Term.

## Facilities and resources

* 1. The Satellite Site will make available adequate facilities, equipment and other resources reasonably required to perform the Study Activities, including appropriate facilities, support and systems to facilitate and enable the performance of the Study Activities by way of a tele-trials or tele-health process.
  2. The Satellite Site represents and warrants that its technology and other systems which will be used to perform the Study Activities are secure, comply with all laws (including Relevant Privacy Laws) and conform to the current relevant Australian Standard (where such exists) or where an Australian Standard does not exist, to generally accepted industry standards.

**Notifications**

* 1. The Satellite Site will:
     1. immediately notify the Satellite Site of any issue relating to the safety of Study Participants, even if the issue arises after the termination or ending of this agreement;
     2. immediately notify the Primary Site of any Adverse Events and Serious Adverse Events that occur during the Study Activities in accordance with the Protocol and relevant ethical and regulatory guidelines; and
     3. promptly notify the Primary Site of any request for information made, or any other action taken, by a Regulatory Authority in relation to the conduct of the Study Activities at the Site.

## Records

* 1. The Satellite Site will create and maintain full records and documentation in relation to the Study Activities in accordance with industry standards and as required under the Protocol.
  2. The Satellite Site must retain and preserve a copy of all Created Materials, including copies of signed consent forms, Case Report Forms, Protocol, information relating to the Investigational Product, correspondence and investigator files for at least fifteen years from the End Date and in accordance with relevant laws, whichever is longer.

**Reports**

* 1. The Satellite Site will provide regular written reports to the Primary Site in relation to the Study Activities as required by the Protocol and otherwise as reasonably requested from time to time by the Primary Site.

## Satellite Site to provide information and assistance

* 1. The Satellite Site must promptly provide all information, and such other assistance, which is reasonably requested by the Primary Site from time to time to enable the Primary Site to comply with its obligations regarding the Study, including assisting the Primary Site in relation to any request, enquiry or investigation made by a Regulatory Authority regarding the conduct of the Study to the extent related to the Study Activities.

**Monitoring and audit**

* 1. The Satellite Site will allow regular monitoring visits by the Primary Site (or its delegate) and any Regulatory Authority.
  2. The Satellite Site will permit the Primary Site to audit all records related to the Institution’s performance of the Study Activities and this agreement during the Term and for a period of 3 years after the End Date.

## Improper payments

* 1. The Satellite Site warrants, represents and undertakes to the Primary Site that it has not offered, promised or paid, either directly or indirectly, any Benefit to a government official (including, but not limited to, a healthcare professional employed by a government-owned healthcare facility) to induce such government official to act in any way in connection with his or her official duties with respect to services performed under this agreement or to otherwise obtain an improper advantage for the Primary Site (**Improper Payment**), and has not received an Improper Payment, and will not offer, promise, pay, authorise or receive any Improper Payment in the future. For the purposes of this clause, Benefit includes but is not limited to money, financial or other advantage, travel expenses, entertainment, business or investment opportunities, charitable donations or any other thing of value.

# Investigational Product

## Supply of Investigational Product

* 1. The Primary Site will supply, or facilitate the supply, to the Satellite Site sufficient quantities of Investigational Product for the conduct of the Study Activities.

## Use of Investigational Product

* 1. The Satellite Site will use all Investigational Product made available to it for the purpose of the Study Activities in accordance with the Protocol and the directions of the Primary Site.
  2. The Satellite Site will promptly return or destroy, as requested by the Primary Site, any unused Investigational Product.
  3. The Satellite Site must:
     1. ensure that all Investigational Product made available to it for the purpose of the Study Activities is used strictly according to the Protocol or the directions of the Primary Site and is not used for any other purposes;
     2. provide a written explanation accounting for any missing Investigational Product;
     3. not charge or a Study Participant or third-party payer for Investigational Product; and
     4. keep all Investigational Product under appropriate storage conditions (including any conditions specified in the Protocol) in a secure area accessible only to authorised Personnel and ensure that complete and current records are maintained for all received, dispensed and returned Investigational Product.

## No representations or liability regarding Investigational Product

* 1. The Primary Site makes no representations and gives no warranties about whether sufficient quantities of Investigational Product will be supplied to the Satellite Site or in relation to the timing of that supply. The Primary Site will not be liable if it does not make such supply on time or at all.
  2. The Satellite Site acknowledges that the Primary Site is not the manufacturer, supplier or importer of the Investigational Product. Accordingly,
     1. The Primary Site makes no representations and gives no warranties in relation to the Investigational Product, including (but not limited to):
        1. the quality, fitness for purpose or merchantability of the Investigational Product; and
        2. that the Investigational Product is free from defects or fit for its intended purpose; and
     2. to the fullest extent permitted by law, the Primary Site excludes all liability in relation to the Investigational Product and the Institution’s use of the Investigational Product.

# Study funding

## Study Funds

* 1. In consideration of the Satellite Site performing its obligations under this agreement, the Primary Site will pay to the Satellite Site the Study Funds in the manner and on the basis of the amounts and at the times set out in Schedule 4.

# Invoices

* 1. The Satellite Site will submit to the Primary Site an invoice monthly, or as otherwise agreed by the parties.
  2. The Satellite Site will send invoices to the Primary Site to the address specified in item 1 of Schedule 4 or such other address as notified by the Primary Site to the Satellite Site.

**Payment terms**

* 1. The Primary Site will pay all invoices submitted by the Satellite Site within thirty business days of the invoice date, provided it is reasonably satisfied the relevant activities have been performed in accordance with this agreement. The Primary Site will pay all invoices submitted by the Satellite Site in Australian dollars in the manner specified in item 2 of Schedule 4.

**Payments not wages or salary**

* 1. The payments made by the Primary Site to the Satellite Site are not wages or salary. The Satellite Site is responsible for paying any tax, charge or levy that applies to the payments it receives under this agreement.

# GST

* 1. All amounts expressed in this agreement are GST exclusive. The Satellite Site warrants that it is registered under the GST Law. To the extent that the consideration to be paid or provided under this agreement is expressed to be GST exclusive, a party must also pay the GST payable on a taxable supply made to it. The party making the taxable supply must provide a tax invoice to the other party at or before the time that the other party is required to pay the GST. Terms used in this clause have the meanings given to them in the GST Law.

# Confidentiality and privacy

## Confidential information

* 1. Subject to clause 6.2, the parties must not, and must ensure their Personnel do not, use or disclose any Confidential Information, other than where and only to the extent such use or disclosure is necessary for the performance of a party’s respective obligations under this agreement or the conduct of the Study Activities.
  2. A party may use or disclose Confidential Information in any of the following circumstances:
     1. For complying with its internal complaint procedures, accident reporting procedures, quality assurance activities, disciplinary procedures or any applicable policy in relation to patient safety, Adverse Events or Serious Adverse Events and/or reportable incidents.
     2. For disclosing any material risks identified during the Study or Study Activities or subsequent to it or them, to Study Participants, Study researchers, medical practitioners administering treatment to Study Participants, relevant human research ethics committees and regulatory authorities and government agencies.
     3. For complying with the requirements of any Regulatory Authority or government agency.
     4. For monitoring of the Study or the Study Activities by the Reviewing HREC.
     5. Where the party which owns the Confidential Information consents in writing to the disclosure.
     6. Where the Confidential Information has been independently received from a third party who is free to disclose it.
     7. Where the Confidential Information has been developed by or for the receiving party independently of the Confidential Information disclosed under this agreement.
     8. Where the Confidential Information has entered the public domain other than as a result of a breach of this agreement.
     9. Where release of the Confidential Information is required by law, with notice as soon as reasonably practical to the other party.
     10. For the purpose of legal advice.
     11. For the purpose of a disclosure to its insurer.
  3. The Primary Site may disclose the terms of this agreement and any Confidential Information of the Satellite Site to any other party involved in the funding or conduct of the Study, to the extent such disclosure is required in relation to the conduct of the Study and for the Primary Site to perform any obligation regarding the conduct of the Study.

**Disclosures to Personnel**

* 1. Each party may disclose the Confidential Information of the other to their Personnel requiring access to the Confidential Information for performing any respective obligations under this agreement.

**Period of confidentiality**

* 1. The obligations set out in clauses 6.1 to 6.4 (inclusive) will remain in effect during the Term and for a period of five years following termination or expiration of this agreement.

**Return of Confidential Information**

* 1. A receiving party will at the written request of the disclosing party, upon termination of this agreement return all the disclosing party's Confidential Information to the disclosing party or destroy all such Confidential Information in its or their possession, subject to any applicable retention requirements imposed by law or its insurer.

## Privacy

* 1. The parties must ensure that any Personal Information collected, received or arising in connection with this agreement, including but not limited to Personal Information of a party’s Personnel and of Study Participants, is collected, stored, used and disclosed in accordance with Relevant Privacy Laws.
  2. The Satellite Site agrees that the Primary Site may use and disclose the Personal Information of the Institution’s Personnel for any purpose related to the Study and this agreement and the Satellite Site will obtain the consent of its Personnel in relation to such use and disclosure.
  3. The Satellite Site must promptly notify the Primary Site of any loss of, or unauthorised use or disclosure of, Personal Information relating to a Study Participant or the Primary Site Personnel (**Data Breach**) of which it becomes aware. The Satellite Site must provide all reasonable assistance to the Primary Site so that the Primary Site can satisfy its obligations regarding any Data Breach.

# Intellectual Property and Publications

## Ownership of Background Intellectual Property

* 1. Each party acknowledges and agrees that all rights in any Background Intellectual Property which is provided by a party to the other in connection with this agreement remain the property of that party. Subject to clause 7.2, nothing in this agreement confers on a party any right, title or interest in or in respect of any Background Intellectual Property of the other party.

## Institution’s Background Intellectual Property

* 1. The Satellite Site grants to the Primary Site a world-wide, non-exclusive, irrevocable, perpetual, royalty free and licence fee free licence to use (including the right to sub-licence) the Institution’s Background Intellectual Property for any purpose connected with the conduct of the Study, for further research related to the Study, for Publication purposes and for the commercialisation of the Created Materials.

## Ownership of Created Materials

* 1. All Intellectual Property in the Created Materials will vest automatically upon its creation in the Primary Site and the Satellite Site presently assigns to the Primary Site all existing and future Intellectual Property rights (including all future copyright) contained in the Created Materials. The Satellite Site agrees to execute or procure the execution by its Personnel of any documents reasonably necessary to give effect to this assignment.
  2. The Satellite Site must promptly disclose to the Primary Site all Intellectual Property rights the Satellite Site creates or develops in the course of this agreement.
  3. The Satellite Site must not, and must ensure its Personnel do not, use or disclose the Created Materials for any purpose, other than in accordance with this agreement.
  4. Without limiting clause 7.3, the Satellite Site must procure that all of its Personnel who create any Intellectual Property in connection with this agreement or the Study activities sign an agreement whereby they irrevocably consent to all acts or omissions by the Primary Site that may otherwise constitute an infringement of their ‘moral rights’ (as that term is defined in the *Copyright Act 1968* (Cth)).

## Publications

* 1. The Satellite Site will ensure notification and consultation with participating parties, including the VCCC, prior to distributing any publicity, including articles, news release or other public announcement, or representations, written or verbal, whether to the public press or otherwise, relating to this agreement, the Study Activities or the Study.

## Publicity and announcements

* 1. The Satellite Site will not make or cause to be made any publicity, publish any articles, news release or other public announcement, or make any representations, written or verbal, whether to the public press or otherwise, relating to this agreement, the Study Activities or the Study, without the Primary Site’s prior written consent.

## Use of Names

* 1. Except as required by applicable laws, a party will not use another party’s or their Affiliates' names, logos, trademarks or products in any public statement, advertising, public relations or promotional material, without the prior approval of the other party.

# Liability and indemnity

# Liability

* 1. Subject to clause 8.2, to the extent permitted by law, the total liability of the Primary Site, its Related Entities, and their respective directors, officers and Personnel in respect of any and all defaults of any obligations under this agreement or otherwise at law is limited to the amount of the Study Funds in aggregate.
  2. The Primary Site, its Related Entities, and their respective directors, officers and Personnel will not be liable (including without limitation, in tort or contract) for any indirect, consequential or special loss, damage, cost or expense of any kind including but not limited to loss of savings and profit suffered or incurred by the Satellite Site in connection with this agreement.

## Release and indemnity

* 1. The Satellite Site releases and indemnifies, and will continue to release and indemnify, the Primary Site, its Related Entities and their respective directors, officers and Personnel from and against all actions, claims, demands, costs and expenses (including the costs of defending or settling any action, claim or demand) made, sustained, brought or prosecuted in any manner directly based upon, occasioned by or attributable to any injury to any person (including death) or loss of or damage to property (including any infringement of Intellectual Property rights) which may arise in relation to:
     1. any intentional, unlawful or negligent act or omission of the Satellite Site or its Personnel under this agreement or in connection with the conduct of the Study Activities by the Satellite Site or its Personnel; and
     2. any breach of the terms and conditions of this agreement by the Institution,

except to the extent the action, claim, demand, cost or expense is caused by an unlawful or negligent act or omission of the Primary Site, its Related Entities and their respective directors, officers and Personnel.

# Insurance

## Parties to maintain insurance

* 1. The Satellite Site must maintain such insurances as are reasonably available and necessary to provide indemnity to it in relation to any liability which it may incur in conducting the Study Activities or performing its obligations under this agreement.
  2. The Satellite Site satisfies the requirements of clause 9.1 if it is a Victorian Public Entity.
  3. If the Satellite Site is not a Victorian Public Entity it must maintain insurance cover which:
     1. is issued on an occurrence made basis, or if issued on a claims made basis it must meet the further requirements of clause 9.4;
     2. is continuously maintained throughout the period of the conduct of the Study, subject to clause 9.4;
     3. contains a minimum limit of indemnity of $20 million for any one claim, $20 million for any one event and $20 million in the aggregate for any one year (or such other amount as may be reasonably specified by the Primary Site from time to time);
     4. contains a deductible or self-insured retention amount no greater than $25,000 for any one claim or event;
     5. provides cover for professional indemnity and medical indemnity liability;
     6. provides indemnity in relation to liabilities arising from the conduct of human clinical trials, including the Study Activities;
     7. provides indemnity in respect of injury, loss or damage arising from the use of equipment involving the emission of ionising radiation; and
     8. does not exclude risks relating to Human Immune-deficiency Virus or Acquired Immune Deficiency Syndrome.
  4. If an Satellite Site is not a Victorian Public Entity and chooses an insurance policy written on a claims made basis, then it must maintain the policy or policies for at least 7 years after the End Date, or alternatively, obtain run-off cover which has the same effect if the business has ceased.
  5. The Satellite Site will provide written evidence which is reasonably acceptable to the Primary Site of its insurance arrangements within 5 business days of a request made by the Primary Site.

# Termination

## Termination by either party

* 1. Either party may terminate this agreement with fifteen business days’ prior written notice or such shorter time period as is reasonably required in the circumstances if the other party:
     1. breaches any provision of this agreement and fails to remedy the breach (where it is capable of remedy) within 15 business days of a written notice from the first party specifying the breach and requiring its remedy. For the avoidance of doubt, the Primary Site’s failure to pay a disputed invoice does not constitute a breach of this agreement; or
     2. suffers an Insolvency Event.

## Termination by the Primary Site

* 1. The Primary Site may:
     1. terminate this agreement at any time after the Commencement Date by giving at least 60 calendar days’ notice to the Institution; and
     2. immediately terminate this agreement by giving written notice to the Satellite Site if any agreement entered between the Primary Site and any third party regarding the Study (including funding of the Study) is terminated for any reason.

## Termination for safety reasons

* 1. The Primary Site may terminate this agreement immediately by written notice to the Satellite Site if it has formed the opinion, based on reasonable grounds and evidence, that continuing the Study Activities poses an unacceptable risk to the rights, interests, safety or well-being of Study Participants.

# Obligations upon ending or termination of this agreement

* 1. Upon termination of this agreement, the Satellite Site must cease performing the Study Activities, subject to clause 10.5.1.
  2. In the event of early termination of this agreement, the following will apply:
     1. The Satellite Site will conduct an orderly closure of the Study Activities and will ensure that the health and safety of Study Participants is not compromised by the early ending of the Study Activities and that Study Participants who may be affected by termination receive adequate medical care.
     2. The Satellite Site must not perform any Study Activities for which payment would otherwise be required to be made by the Primary Site without the prior written approval of the Primary Site.
     3. Unless this agreement is terminated pursuant to clause 10.1, the Primary Site will pay the Satellite Site for Study Activities performed up until the date of termination calculated in accordance with Schedule 3.
     4. Subject to any applicable retention requirements imposed by law, the Satellite Site will submit to the Primary Site all records, material and reports created (or required to be created) under this agreement, including any Case Report Forms it has created or completed.
     5. Subject to Relevant Privacy Laws, the Satellite Site will provide to the Primary Site reasonable access to any Study Activities files and Site master files as the Primary Site may require for a period of 3 years after the ending or termination of this agreement. Such access will be subject to any reasonable requirements of the Satellite Site regarding privacy, confidentiality, security and occupational health and safety.

**Clauses surviving expiration or termination of agreement**

* 1. The following clauses will survive the expiration or termination (for whatever reason) of this agreement:
     1. clauses 3.9 to 3.14;
     2. clause 4.6;
     3. clause 5 (Study funding);
     4. clause 6 (Confidentiality and privacy);
     5. clause 7 (Intellectual Property and Publications);
     6. clause 8 (Liability and Indemnity);
     7. clause 9 (Insurance);
     8. clauses 10.4, 10.5 and 10.6 (Obligations at end of agreement);
     9. clause 12 (Dispute resolution);
     10. clause 13 (Notices);
     11. clause 14.11 (Governing law); and
     12. any clause which states it will survive, or its obligations endure beyond, the expiration or termination of this agreement.

# Parties’ representatives

# Primary Site Representative

* 1. The Primary Site appoints the Primary Site Representative as its duly authorised representative under this agreement. Any notice, information or communication given or made to the Primary Site Representative will be deemed to have been given or made to the Primary Site.
  2. The Primary Site must give written notice to the Satellite Site immediately if its representative is removed or replaced, together with the details of its new representative.

# Satellite Site Representative

* 1. The Satellite Site appoints the Satellite Site Representative as its duly authorised representative under this agreement. Any notice, information, instruction or other communication given or made to the Satellite Site Representative will be deemed to have been given or made to the Institution.
  2. The Satellite Site must give written notice to the Primary Site immediately if its representative is removed or replaced, together with the details of its new representative.

**Responsibilities of Representatives**

* 1. Each party’s representative will be responsible for the day to day administration of this agreement on behalf of the party appointing them. The representatives must be available and able to be contacted during normal business hours.

# Dispute resolution

## Procedures to be followed

* 1. If a dispute arises in connection with this agreement, the parties will adhere to the following procedures.
  2. In the first instance two representatives of each party shall meet and endeavour to resolve the dispute in an expeditious and informal manner. If resolution is not achieved within fifteen business days, then the chief executive officer (or equivalent) of each of the parties or delegate shall meet to resolve the dispute.
  3. If resolution is not achieved within ten business days of the chief executive officer (or equivalent) of each of the parties meeting, then either party may give the other a dispute notice requiring that the dispute be resolved in accordance with this clause 12.
  4. If a dispute notice is issued, an attempt shall be made to resolve the dispute with the help of a mediator to be appointed jointly by the parties. If the parties do not agree on a mediator within fifteen business days after the notice is given, the mediator is to be appointed by the then current President of the Law Society of the State or Territory in which the Primary Site is located. Each of the parties must co-operate fully with the mediator and will pay an equal share of the fees and expenses the mediator is entitled to. If the dispute is not resolved within twenty business days of the mediator being appointed, the mediation shall cease and any party may then commence legal proceedings.

## Parties to cooperate

* 1. The parties shall cooperate to ensure that these procedures are carried out expeditiously.

## Interlocutory relief

* 1. Clause 12 does not restrict or limit the right of either party to obtain interlocutory relief, or to immediately terminate this agreement where this agreement provides such a right.

# Notices

## Giving notice

* 1. Any notice (which includes, without limitation, a demand, request, consent, approval and any other communication made, required or authorised under this agreement) given under this agreement must be:
     1. in writing;
     2. directed to the recipient’s address specified in Schedule 1, as varied by any notice; and
     3. hand delivered or sent by prepaid post, facsimile or email to that address.

## Receipt of notice

* 1. A notice given in accordance with clause 13.1 is taken to be received by the recipient:
     1. if hand delivered, on delivery;
     2. if sent by prepaid post, four business days after the date of posting; or
     3. if sent by facsimile, when the sender’s facsimile system generates a message confirming successful transmission of the total number of pages of the notice unless, within eight business hours after that transmission, the recipient informs the sender that it has not received the entire notice; or
     4. if sent by email, on the day of transmission provided that the sender can give evidence of transmission and the intended recipient does not give evidence of non-receipt.

In all cases, a notice received after 5:00 pm in the place of receipt or on a day that is not a business day is taken to be received by the recipient at 9:00 am on the next business day.

## Signing of notice

* 1. A notice given under this agreement is sufficiently signed if:
     1. in the case of a corporation, it is signed by a director, secretary or other officer of the corporation; or
     2. in the case of an individual, it is signed by that individual.

## Other modes of service permitted

* 1. The provisions of this clause are in addition to any other mode of service permitted by law.

# General

## Subcontracting

* 1. The Primary Site may subcontract any of its obligations under this agreement.
  2. The Satellite Site must not subcontract any of its obligations under this agreement without the prior written consent of the Primary Site, which consent may be withheld in the Primary Site’s absolute discretion.

# Assignment and novation

* 1. The Satellite Site party must not transfer, assign or novate this agreement or any part of this agreement without the prior written consent of the Primary Site, which consent may be withheld in the Primary Site’s absolute discretion.

## Force majeure

* 1. 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, performance of such act shall be excused for the period of such event provided that if such interference lasts for any period in excess of thirty business days each party may, by written notice to the others, terminate this agreement.

## Priority

* 1. In the event of an inconsistency, this agreement is to be interpreted in accordance with the following order of priority:
     1. first, by reference to the terms and conditions set out in the body of this agreement;
     2. second, by reference to the terms of the Schedules; and
     3. finally, by reference to any other documents or information incorporated by reference into this agreement.

## Preferred construction

* 1. The parties agree that a construction of this agreement that results in all provisions being enforceable is to be preferred to any other construction.

## Severance

* 1. If, despite the application of clause 14.6, any clause or part of a clause is illegal, unenforceable or invalid, that clause or part is to be treated as removed from this document, but the rest of this document is not affected.

# Enforcement of indemnity

* 1. A party can enforce its rights of indemnity under this agreement without first incurring any expense or making any payment.

# Entire agreement

* 1. This agreement constitutes the entire agreement between the parties in relation to their respective obligations concerning the Study and replaces any prior arrangements, agreements, representations or undertakings.

## Variation

* 1. Any variation to this agreement must be in writing and signed by the parties.

# Governing law

* 1. This agreement is governed by the law of the State of Victoria, Australia and each party submits to the exclusive jurisdiction of the courts of that State. The parties will not object to the exercise of jurisdiction by those courts on any basis.

# Separate documents

* 1. This agreement is properly executed if each party executes either this document or an identical document. In the latter case, this document takes effect when the separately executed documents are exchanged between the parties.

# Waiver

* 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.
  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.

# Costs

* 1. Except as otherwise set out in this agreement, each party must pay its own costs in relation to preparing, negotiating and executing this agreement and any document related to this agreement.

## Further acts

* 1. The parties must promptly do and perform all acts and things and execute all documents as may from time to time be required, and at all times will act in good faith, for the purposes of or to give effect to this document.

## Party preparing document not to be disadvantaged

* 1. No rule of contract interpretation must be applied in the interpretation of this agreement to the disadvantage of one party on the basis that it prepared or put forward this agreement or any document comprising part of this agreement.

## No agency or partnership

* 1. The relationship between the parties is that of principal and independent contractor. No party is an agent, representative or partner of any other party by virtue of this document. The Satellite Site must not represent itself as an agent, representative or partner of the Primary Site in any circumstances.

## No authority to act

* 1. No party has any power or authority to act for or to assume any obligation or responsibility on behalf of another party, to bind another party to any agreement, negotiate or enter into any binding relationship for or on behalf of another party or pledge the credit of another party except as specifically provided in this document or by express agreement between the parties.

## Time for action

* 1. If the day on or by which something is required to be done or may be done is not a business day, that thing must be done on or by the next business day.

## Name and logos

* 1. A party must not use the other party’s name, logo or brand in any way without the prior written permission of the other party.

# Definitions and Interpretation

## Definitions

* 1. In this agreement, unless the contrary intention appears:

**Adverse Event** means any untoward medical occurrence in a patient or clinical investigation subject administered the Investigational Product and which does not necessarily have a causal relationship with this treatment. An Adverse Event includes any unfavourable and unintended sign, symptom, or disease temporally associated with the use of the Investigational Product, whether or not related to the Investigational Product.

**Background Intellectual Property** means any information, techniques, inventions, discoveries, methods, systems, know-how, software and materials (regardless of the form or medium in which they are disclosed or stored) that are provided by one party to the other party for use in the conduct of the Study or the Study Activities which is:

(a) in existence as at the Commencement Date; or

(b) created, developed or generated by a party after the Commencement Date other than in the course of or incidental to performing any of its obligations under this agreement.

**Case Report Form** means a printed or electronic document or database designed to record all of the information required by the Protocol to be reported to the Primary Site on each Study Participant.

**Commencement Date** means the commencement date specified in Schedule 1.

**Confidential Information** means:

(a) in respect of the Primary Site:

(i) the Protocol and information relating to the Investigational Product;

(iii) information, know-how, trade secrets, ideas, concepts, technical and operational information, scientific or technical processes or techniques, product composition or details owned by the Primary Site;

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

(v) information concerning their business affairs or clients;

(vi) all information collected in the course of, resulting from, or arising directly out of the conduct of the Study, whether at the Site or elsewhere;

(b) in respect of the Institution:

(i) information in relation to the Institution’s business, operations or strategies, intellectual or other property or actual or prospective suppliers or competitors; and

(ii) information, know-how, trade secrets, ideas, concepts, technical and operational information, scientific or technical processes or techniques, product composition or details owned by the Institution.

but Confidential Information does not include Personal Information.

**Created Materials** means all the materials, data, results, outputs and information, including Case Report Forms, created by the Satellite Site in performing the Study Activities or in connection with this agreement.

**End Date** means the end date specified in Schedule 1.

**GCP Guideline** means the Committee for Proprietary Medicinal Products (CPMP)/International Conference on Harmonisation (ICH) Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) as adopted with annotation by the TGA.

**GST** means tax that is payable under the GST Law and imposed as goods and services tax.

**GST Law** means any law relating to GST including *A New Tax System (Goods and Services Tax) Act 1999* (Cth).

**Insolvency Event** means anything that reasonably indicates that there is a significant risk that that person is or will become unable to pay its debts as they fall due, including without limitation:

(a) a meeting of the person’s creditors being called or held;

(b) a step being taken to make the person bankrupt;

(c) the appointment of a controller or administrator as defined in section 9 of the *Corporations Act 2001* (Cth);

(d) the person entering into any type of arrangement with, or assignment for the benefit of all or any of its creditors;

(e) the person being made subject to a deed of company arrangement; or a step being taken to have a receiver, receiver and manager, liquidator or provisional liquidator appointed to the person or any of its assets; and

(f) the person is declared insolvent.

**Satellite Site Representative** means the Satellite Site representative specified in Schedule 1, or other person from time to time appointed by the Satellite Site and notified to the Primary Site to be the Satellite Site Representative for the purposes of this agreement.

**Intellectual Property** means all industrial and intellectual property rights, including without limitation:

(a) patents, copyright, future copyright, trade business, company or domain names, rights in relation to circuit layouts, plant breeders’ rights, registered designs, registered and unregistered trade marks, know how, trade secrets and the right to have confidential information kept confidential, any and all other rights to intellectual property which may subsist anywhere in the world; and

(b) any application or right to apply for registration of any of those rights.

**Investigational Product** means the medicine(s) being trialled or tested in the Study which is specified in Schedule 1 and includes, where the context requires, any placebo.

**Personal Information** means information or an opinion (including information or an opinion forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

**Personnel** means employees, agents, contractors and/or authorised representatives.

**Protocol** means the document described and set out in Schedule 5.

**Publish** means to publish by way of a paper, article, manuscript, report, poster, internet posting, presentation slides, abstract, outline, video, instruction material or other disclosure of Created Materials, in printed, electronic, oral or other form. **Publication** has a corresponding meaning.

**Regulatory Authority** means any government body which has jurisdiction over the conduct of the Study and includes the Australian Therapeutic Goods Administration.

**Related Entity** means an associate of the person for the purposes of sections11 to 16 (inclusive) of the *Corporations Act 2001* (Cth).

**Relevant Privacy Laws** means the *Health Records Act 2001* (Vic), the *Privacy and Data Protection Act 2014* (Vic) and any other legislation, code or guideline which applies in the jurisdiction in which the Primary Site is located and which relates to the protection of Personal Information.

**Reviewing HREC** means the human research ethics committee reviewing the Study on behalf of the Institution.

**Primary Site Representative** means the Primary Site representative specified in Schedule 1, or other person from time to time appointed by the Primary Site and notified to the Satellite Site to be the the Primary Site Representative for the purposes of this agreement.

**Serious Adverse Event** means any untoward medical occurrence that at any dose:

(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/incapacity; or

(e) is a congenital anomaly/birth defect.

**Site** means the means the location(s) under the control of the Satellite Site where the Satellite Site actually conducts the Study Activities.

**Study** means the research study which is described in Schedule 1.

**Study Activities** means the services and activities the Satellite Site must perform under this agreement, including those specified in Schedule 2.

**Study Funds** means the rates, charges and costs set out in Schedule 4.

**Study Participant** means a person recruited by the Satellite Site to participate in the Study or a person on or in respect of whom any Study Activities are performed.

**Supervision Plan** means the plan set out in Schedule 3.

**Term** means the period during which this agreement remains in force.

**Victorian Public Entity** means a body, entity or agency incorporated pursuant to the *Health Services Act 1988* (Vic) and which is an insured under a program or scheme of insurance that is arranged by the Victoria Managed Insurance Authority.

## Interpretation

* 1. In this agreement, except where the context otherwise requires:
     1. a reference to a person or body includes a government agency, partnership, trust, joint venture, association, corporation or a body corporate;
     2. clause headings are for convenience only and are not intended to affect the interpretation of this agreement;
     3. where any word or phrase has a defined meaning, any other form of that word or phrase has a corresponding meaning;
     4. words in the singular include the plural and vice versa;
     5. all the provisions in any schedule to this agreement are incorporated in, and form part of, this agreement;
     6. 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;
     7. a reference to a monetary amount means that amount in Australian currency;
     8. a reference to any law or legislation includes any statutory amendment or re-enactment, and any subordinate legislation or regulations issued there under;
     9. a reference to any agreement or document is to that agreement or document as amended, novated, supplemented or replaced from time to time;
     10. a reference to a recital clause or schedule, is a reference to a recital, clause or schedule in this document;
     11. a reference to a business day means a day on which all banks are open for business generally in Melbourne, Victoria; and
     12. a covenant or agreement on the part of two or more persons binds them jointly and severally.

## Execution

**Executed** as an agreement

Date:

|  |  |
| --- | --- |
| Signedfor and on behalf of **Primary Site** by its authorised officer in the presence of:  ...................................................  Signature of witness  ………………........…………………........  Name of witness | ...................................................  Signature of authorised officer  ………………........…………………........  Name of authorised officer |

|  |  |
| --- | --- |
| Signed for and on behalf of [insert name of Institution] by its authorised officer in the presence of: ........................................................  Signature of witness  ……………………………………………………  Name of witness | ………………........………………….......…  Name of authorised officer  ...............................................  Signature of authorised officer |

## Schedule 1

|  |
| --- |
| **Commencement Date** (clause 1.2)  [*Insert*] |
| **End Date** (clause 1.2)  [*Insert*] |
| **Study**  [*Insert*] |
| **Investigational Product** (clause 4)  [*Insert*] |
| **Primary Site Representative** (clause 11.1)  [*Insert* |
| **Satellite Site Representative** (clause 11.3)  [*Insert* |
| **Notices** (clause 13)  **Primary Site**  [*Insert*]  **Satellite Site**  [*Insert*] |

## Schedule 2 – Study Activities

[insert details]

## Schedule 3 – Supervision Plan

[*insert*]

## Schedule 4 – Study Funds

[*Insert details of Study funds*.]

**1 Address for invoices**

The Satellite Site will send invoices to the following address of Primary Site:

*[Insert address]*

*Attention: [Name]*

**2 Manner in which the Primary Site is to pay**

The Primary Site will make all payments required under this agreement in the following manner:

By cheque addressed to:

[*Insert details*]

;or

By electronic transfer into the following account(s):

[*Insert account details*]

## Schedule 5 - Protocol

**Title:** [*insert*]

**Date:** [*insert*]

**Appendix 2 – Teletrials Sub-Agreement**

**CLINICAL TRIAL RESEARCH AGREEMENT SUBCONTRACT**

**FOR STUDIES CONDUCTED UNDER A TELE-TRIALS MODEL**

This **DEED** of Agreement is made on the day of 20

**BETWEEN:** The Institution so described in **Schedule 1** (the **‘Institution’**)

**AND:** each **Subcontractor** so described in **Schedule 1** (each a **‘Subcontractor’**)

**RECITALS**

1. The Institution is bound by the *Health Services Act 1988* (Vic).
2. The Institution has been engaged by the Sponsor to perform the Study under the Head Agreement.
3. The Institution seeks for each Subcontractor to perform activities on its behalf for the Study.
4. The Parties agree to perform their respective activities relating to the Study as set out in this Subcontract.

**OPERATIVE PROVISIONS**

1. **RECITALS**

The Parties acknowledge the truth and accuracy of the Recitals in every particular.

1. **DEFINITIONS AND INTERPRETATION**
   1. Definitions

The definitions in the Head Agreement apply to this Subcontract in context except for the following definitions:

**Activities** means the subcontracted activities described in **Item 6** of **Schedule 1** both common to all Subcontractors and specific to each relevant Subcontractor as specified.

**Certificate of Insurance** means the certificate of insurance required pursuant to **clause 16** in the manner so described in **Schedule 4**;

**Commencement Date** means the date so described in **Item 1** of **Schedule 1**.

**Completion Date** means the date so described in **Item 2** of **Schedule 1**.

**Head Agreement** means the clinical trial research agreement between the Institution and the Sponsor attached as **Schedule 3**.

**HREC Approval** means the approval to conduct the Study given by the Reviewing HREC, as amended from time to time by the Reviewing HREC.

**Party** means each of the Institution and each Subcontractor.

**Schedule** means a document referenced in this Subcontract and described as a schedule to this Subcontract.

**Sponsor** means the sponsor who is a party to the Head Agreement.

**Subcontract** means this document and all annexures, attachments and schedules incorporated by reference.

**Subcontractor** means each organisation so described in **Item 5** of **Schedule 1** on condition it executes this Subcontract.

**Subcontractor’s Confidential Information** means, in respect of a Subcontractor, information in relation to the Subcontractor’s business, operations or strategies, intellectual or other property or actual or prospective suppliers or competitors, but does not include Personal Information.

**Subcontractor’s Investigator** is the person employed or engaged by the Subcontractor responsible for the conduct of the Activities, as described in Schedule 1.

* 1. Interpretation

1. In this Subcontract, the index and clause headings have been inserted for ease of reference only and are not intended to affect the meaning or interpretation of this Subcontract.
2. The following rules apply in interpreting this Subcontract, unless the context otherwise requires:
   1. words importing a gender include the other gender;
   2. words in the singular include the plural and vice versa;
   3. all dollar amounts refer to Australian currency;
   4. a reference to any legislation includes any subordinate legislation made under it and any legislation amending, consolidating or replacing it;
   5. a reference to an entity or person includes an individual, corporation, partnership or other legal entity;
   6. a party includes its executors, administrators, liquidators, successors and permitted assigns;
   7. “consent” means prior written consent;
   8. “in writing” means either by letter, email or facsimile;
   9. a reference to a clause, attachment or annexure is a reference to a clause, attachment or annexure to this Subcontract;
   10. if a day on which an act is to be done is a Saturday, Sunday or public holiday in the place where the act is to be done, the act may be done on the next Business Day in that place, unless the Parties agree otherwise;
   11. if any expression is defined, other grammatical forms of that expression will have corresponding meanings, unless the context otherwise requires;
   12. a reference to a clause is a reference to all of its sub-clauses;
   13. a document or agreement or a provision of a document or agreement, is a reference to that document, agreement or provision as amended, supplemented, replaced or novated.
3. **TERM**
   1. This Subcontract commences on the Commencement Date and will continue until the Completion Date unless terminated earlier in accordance with this Subcontract.
   2. The Parties may extend the Completion Date by mutual written agreement.
   3. If the Commencement Date is earlier than the date of commencement of the Head Agreement, then the Commencement Date will be deemed to be the date of commencement of the Head Agreement.
4. **NATURE OF THIS SUBCONTRACT**

This document constitutes a subcontract permitted under the Head Agreement and the Institution remains responsible to the Sponsor under the Head Agreement for its subcontracted obligations and is liable to the Sponsor under the Head Agreement for all acts and omissions of each Subcontractor as if they were the Institution’s acts and omissions in accordance the Head Agreement.

1. **SUBCONTRACTED ACTIVITIES**

Each Subcontractor will perform the Activities in accordance with:

1. the Protocol;
2. the terms of the Head Agreement applicable to the Institution which apply to those Activities;
3. the principles of good scientific and clinical research practices;
4. all applicable local, State and Federal laws, legislation, regulations, rules and by-laws; and
5. the TGA approval for the Study, the HREC Approval and all relevant Reviewing HREC directions issued from time to time.
6. **INVESTIGATIONAL PRODUCT**

Where a Subcontractor’s pharmacy will handle and dispense medicine(s) constituting an Investigational Product, it will:

1. use the medicine(s) solely for the Study and not for any other purpose; and
2. dispose of, or destroy, the medicine(s) in accordance with the instructions of the Institution and the instructions of the Sponsor communicated by the Institution, in accordance with applicable laws, regulations and the Institution’s policies and procedures.
3. **MEETINGS**

Each Subcontractor’s Investigator for the Study will meet with each other Party’s investigator for the Study in relation to the Study as convened by, and agreed with, the Institution from time to time, including to discuss findings, the conduct of the Activities and any amendment or variation to the Protocol that may be required from time to time.

1. **MONITORING VISITS AND REGULATORY AUTHORITIES**
   1. Subject to clause 12, each Subcontractor will allow regular monitoring visits in accordance with the same terms as those applicable to the Institution under the Head Agreement.
   2. If a Subcontractor is contacted by any Regulatory Authority in connection with the conduct of the Study it will immediately notify the Institution, unless prevented from doing so by law.
   3. Each Subcontractor will provide the Institution with all reasonable assistance and cooperation to rectify any matter raised by a Regulatory Authority or as the result of an audit of the Institution or Study Site. This includes execution of any documents reasonably requested by the Institution in connection with the requirements of a Regulatory Authority or the Sponsor as a result of such an audit. The cost will be borne by the Sponsor unless such rectification is due to the default of the Subcontractor or its Personnel.
   4. Each Subcontractor:
2. warrants that it is not and has not been debarred or disqualified from participating in clinical research by any United States Regulatory Authority or by any other Regulatory Authority, and that it will not employee, engage or communicate with any person or organisation in connection with the Study that is or has been so debarred or disqualified; and
3. will promptly notify both the Institution and Sponsor in the event that it becomes aware that it has used or involved, or is currently using or involving, in connection with the Study a person of the type described in this clause.
4. **RECORDS AND INTELLECTAL PROPERTY**
   1. Each Subcontractor must:
5. retain and preserve a copy of all Study Materials in accordance with the same terms as those applicable to the Institution under the Head Agreement;
6. ensure that no Study Materials are destroyed before the expiration of the time period specified in the Head Agreement without the written approval of the Institution; and
7. liaise with the Institution prior to destroying any Study Materials and retain the Study Materials for such longer period as reasonably required by the Institution.
   1. The Institution grants to each Subcontractor and its Personnel the same rights to use the Background IP and Study Materials granted to the Institution under the Head Agreement on the same conditions (except for the right to sub-license or transfer) for the purposes of the Study.
   2. Each Subcontractor grants to the Institution and the Sponsor a licence to that Subcontractor’s Background IP on the same terms as the licence granted by the Institution to the Sponsor to the Institution’s Background IP specified in the Head Agreement.
   3. All Intellectual Property in the Study Materials created by each Subcontractor will vest automatically upon its creation in the Sponsor on the same terms as those applicable to the Institution under the Head Agreement.
8. **PAYMENTS AND INVOICING**

The terms and conditions under this Subcontract for the payment and invoicing between the Parties of any fees in relation to the Study are specified in Schedule 2.

1. **PERSONNEL**
   1. Each Subcontractor warrants that each person engaged by it to perform any part of the Activities:
2. is competent;
3. has the necessary and appropriate qualifications, licenses, admissions, memberships and skills to ensure they are both qualified and able to perform the relevant activities; and,
4. in the case of any part of the Activities required to be performed by a health professional of a type subject to the *Health Practitioner Regulation National Law (Victoria) Act 2009* (Vic), at all times the relevant health professional meets their registration and accreditation requirements under that Act.
   1. Each Subcontractor must not engage any allied health, nursing or medical Personnel to perform any part of the Activities unless those Personnel are appropriately credentialed, including with the Institution where required.
   2. Each Subcontractor will give written notice to the Institution promptly upon becoming aware that it no longer complies with the warranties and assurances provided in this clause.
5. **CONFIDENTIALITY**
   1. Each Subcontractor must not use ‘*health information*’ as defined in section 3 of the *Health Records Act 2001* (Vic) other than in accordance with that Act.
   2. Subject to clause 12.3, each Subcontractor must not, and must ensure its Personnel do not, use or disclose any Confidential Information of the Institution or the Sponsor, other than where, and only to the extent that, such use or disclosure is necessary for the performance of the Activities, the exercise of its rights or the performance of its obligations under this Subcontract.
   3. Each Subcontractor may use or disclose the Institution’s or Sponsor’s Confidential Information in any of the circumstances applicable to the Institution set out in the Head Agreement on the same terms as those applicable to the Institution under the Head Agreement:
   4. Where Confidential Information is disclosed in accordance with clause 12.3, the Confidential Information must only be used in connection with the legitimate purposes of the Subcontractor, and only disclosed to those who have a need to know it for such purposes and are obligated to keep the information confidential.
   5. The Institution or Sponsor may disclose each Subcontractor’s Confidential Information:
6. on a need to know and confidential basis to its Affiliates and for the purpose of obtaining legal advice; or
7. if required by law, with notice as soon as reasonably practical to the Subcontractor, and subject to the Sponsor upon request providing reasonable assistance to enable the Subcontractor to obtain a protective order or other remedy to resist disclosure or ensure confidential treatment for any required disclosure.
   1. Each Party is responsible for ensuring that its Personnel are aware of the obligations in respect of Confidential Information, and are bound in similar terms to keep such information confidential.
   2. Information will not be Confidential Information where it satisfies the requirements of the Head Agreement for the same.
8. **PRIVACY**
   1. Each Subcontractor must ensure that any Personal Information of Study Participants or Personnel it obtains or holds as a result of the conduct of the Study is collected, stored, used and disclosed by it in accordance with the Relevant Privacy Laws.
   2. Each Subcontractor will promptly report to the Institution any unauthorised access to, use or disclosure of Personal Information of Study Participants (**‘Incident’**) of which it becomes aware, and will work with the Institution to take reasonable steps to remedy the Incident.
   3. Each Subcontractor agrees that the Sponsor may collect, use and disclose routine work-related Personal Information regarding the Subcontractor’s Personnel in connection with the Study, such as names, titles and business contact information (**‘Subcontractor Personnel Information’**) and may provide that information to the Sponsor’s business partners and vendors working with Sponsor on matters related to the Study solely for the following purposes:
9. compliance with laws and regulations regarding possible financial conflicts of interest;
10. assessment of Personnel qualifications to conduct the Study;
11. Study quality control and management; or
12. to relevant ‘human research ethics committees’ (as that term is defined in the *NHMRC Statement on Ethical Conduct in Human Research* (2007) or its current replacement) Regulatory Authorities in connection with their performance of review or oversight responsibilities for the Study.
    1. Where required, each Subcontractor will notify, and obtain the consent of, its relevant Personnel for the use and disclosure of their Personal Information included in Subcontractor Personnel Information for the purposes described in this section.
    2. Sponsor must comply with the Relevant Privacy Laws applicable to it regarding its collection, storage, use and disclosure of Subcontractor Personnel Information.
13. **PROMOTIONAL MATERIAL AND PUBLICATION**
    1. Subject to clause 14.2, each Party will not use the name or names of other Parties, the Sponsor, or their Personnel in any advertising or sales promotional material or in any Publication without prior written permission.
    2. Sponsor may disclose that each Subcontractor is involved in the Study, the type of services performed by each Subcontractor, and the existence and terms of this Subcontract only where required for compliance with applicable laws and regulations.
14. **SECURITY**
    1. Each Subcontractor warrants that:
15. it has documented information security policies, standards and/or procedures in place to protect the confidentiality, privacy and integrity of information in its possession and control, including ‘health information’ as that term is defined under Relevant Privacy Laws; and
16. it has reasonable measures in place for identifying threats and vulnerabilities to its information system(s), including in respect of Personnel training and mobile device storage.
17. **INSURANCE**
    1. Each Subcontractor warrants that it has, or will:
18. effect and maintain professional indemnity and public liability insurance in accordance with Item 1 of Schedule 4; and
19. on request by the Institution, provide a Certificate of Insurance in accordance with Item 2 of Schedule 4.
    1. This clause 16 continues in operation for so long as any obligations remain in connection with this Subcontract.
20. **INDEMNITY**
    1. Each Subcontractor indemnifies the Institution against any liabilities not expressly indemnified by the Sponsor that are causedor contributed to, by the Subcontractor, including loss or damage suffered by the Institution as a result of:
21. breaches of security;
22. corruption of data;
23. infringement of intellectual property rights; and
24. professional negligence.
25. **ANTI-BRIBERY / ANTI-CORRUPTION**

Each Subcontractor warrants, represents and undertakes that it has not offered, promised or paid, either directly or indirectly, any Benefit to a government official (including, but not limited to, a healthcare professional employed by a government-owned healthcare facility) to induce such government official to act in any way in connection with his or her official duties with respect to services performed under this Subcontract or to otherwise obtain an improper advantage for the Subcontractor, the Institution or Sponsor (**‘Improper Payment’**), and has not received an Improper Payment, and will not offer, promise, pay, authorise or receive any Improper Payment in the future. For the purposes of this clause 16, Benefit includes but is not limited to money, financial or other advantage, travel expenses, entertainment, business or investment opportunities, charitable donations or any other thing of value.

1. **TERMINATION**
   1. A Party may terminate this Subcontract for breach of this Subcontract provided that it gives thirty (30) days prior notice of the breach to the other Party and that the breach is not rectified within that period.
   2. Termination of this Subcontract will be without prejudice to the rights accruing to the Parties prior to the date of termination.
   3. If a Party is wholly or partially precluded from complying with its obligations under this Subcontract by failure to obtain and maintain an HREC Approval, the Party may by written notice to the other Parties terminate the Subcontract, with immediate effect, without further liability for its failure to obtain and maintain such approvals.
   4. The Institution may terminate this Subcontract in the event, and on the same grounds that, the Head Agreement is terminated.
   5. If a Party terminates this Subcontract:
2. the Subcontract is terminated as between the terminating Party and the other Parties; and
3. remains in operation as between the other Parties other than the terminating Party.
   1. The following provisions survive termination of this Agreement, clauses 2, 4, 6, 8.1, 8.2, 9, 12, 13, 14.1, 20.
4. **GENERAL**
   1. Each Subcontractor shall not subcontract further their obligations under this Subcontract without the express written permission of the Institution.
   2. Each Party must do all things necessary or desirable to give effect to the provisions of this Subcontract including by signing all documents and performing all acts.
   3. This Subcontract:
5. contains the entire agreement of the Parties; and
6. supersedes all prior representations, conduct and agreements,

with respect to its subject matter.

* 1. Each Party is responsible for its own costs of entering into and performing this Subcontract.
  2. Any failure by a Party at any time to enforce a clause of the Subcontract, or any forbearance, delay or indulgence granted by a Party to another will not constitute a waiver of the Party’s rights.
  3. No provision of the Subcontract will be deemed to be waived unless that waiver is in writing and signed by the waiving Party.
  4. A waiver by a Party of a breach of any part of the Subcontract will not be a waiver of any subsequent breach of the same part nor a waiver of a breach of any other part.
  5. To the extent that any portion of this Subcontract is void or otherwise unenforceable then that portion will be severed and this Subcontract will be construed as if the severable portion had never existed.
  6. This Subcontract may be executed in two or more identical copy counterparts, each of which together will be deemed an original, but all of which together will constitute one and the same instrument.
  7. In the event that any signature executing this Subcontract or any part of this Subcontract is delivered by facsimile transmission or by scanned e-mail delivery of a ".pdf" format data file or equivalent, such signature will create a valid and binding obligation of the Party executing (or on whose behalf such signature is executed) with the same force and effect as if such signature page were an original. For execution under this clause to be valid the entire Subcontract upon execution by each individual party must be delivered to the remaining Parties.
  8. The laws of the State of Victoria, Australia, apply to this Subcontract and each Party irrevocably submits to the exclusive jurisdiction of the Courts of Victoria, Australia, and Courts competent to hear appeals from those Courts.

**EXECUTION**

Executed as a deed of agreement on the dates below:

|  |  |  |
| --- | --- | --- |
| **Signed, sealed and delivered for and on behalf of the [INSERT INSTITUTION] ABN [INSERT ABN]**  by its duly authorised officer:    (name and title/position of person signing)  this day of 2018  in the presence of:    (insert name and title/position of witness) |  | (signature of authorised officer)    (signature of witness) |
|  |  |  |
| **Signed, sealed and delivered for and on behalf of [INSERT SUBCONTRACTOR] ABN [INSERT ABN]** by its duly authorised officer:    (print name and title/position of person signing)  this day of 2018  in the presence of    (print name and title/position of witness) |  | (signature of person signing)    (signature of witness) |

[*Replicate the above execution block as required for the number of Subcontractors*]

**SCHEDULE 1 - PARTICULARS**

| **Item No.** | **Item** | **Detail** | |
| --- | --- | --- | --- |
|  | **Commencement Date** | **[INSERT DATE]**  If no date is inserted, this is the date the last Party to sign this Agreement signed this Agreement. | |
|  | **Completion Date** | **[INSERT DATE HREC APPROVAL LAPSES]** | |
|  | **Study Title** | **[INSERT STUDY TITLE]** | |
|  | **Institution** | **[INSERT ENTITY NAME]** ABN **[INSERT ABN]** located at **[INSERT PRINCIPAL ADDRESS OF BUSINESS]** | |
|  | **Subcontractor/s** | **No.** | **Subcontractor Details** |
|  | **[INSERT ENTITY NAME]** ABN **[INSERT ABN]** located at **[INSERT PRINCIPAL ADDRESS OF BUSINESS] Subcontractor’s Investigator: [INSERT NAME AND CONTACT DETAILS OF SUBCONTRACTOR’S INVESTIGATOR]** |
|  | [*Replicate the above as required for the number of Subcontractors*] |
|  | **Activities** | **Activities common to all Subcontractors** | |
| The following Activities specified in the Head Agreement and Protocol:   * [*Specify Activities (including assessments) that all satellite sites will need to perform, for example:*   + *Pharmacy set-up*   + *Pharmacy annual administration*   + *Pharmacy storage*   + *Pharmacy close-out*] | |
| **Activities relevant to specific Subcontractors** | |
|  | [*Specify exceptions to the above list applicable to specific Subcontractors corresponding with the* ] |

**SCHEDULE 2 – PAYMENTS AND INVOICING**

**[INSERT PAYMENTS AND INVOICING TERMS AND CONDITIONS]**

**SCHEDULE 3 – HEAD AGREEMENT**

**[ATTACH HEAD AGREEMENT]**

**SCHEDULE 4 – INSURANCE ARRANGEMENTS**

| **Item** | **Description** | **Details** |
| --- | --- | --- |
|  | **Insurance Requirements** | **Public liability**  Insured amount: $10 million per claim and in the annual aggregate.  **Professional indemnity**  Insured amount: $5 million per claim and in the annual aggregate. |
|  | **Certificate of Insurance** | The Certificate of Insurance must have the following details:   * Insurance provider * Insured Entity * Additional Insured * Protocol/ CTN number * Limits of Liability in AUD/ Per occurrence amount and Annual Aggregate * Excess/ deductible/ Self-insured risk |

**Appendix 3 – Supervision Plan**

**Supervision plan for xxx satellite site for the Clinical Trial protocol (xxx) via the Tele-Trial model**

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**Background**

This document details the supervision plan for the xxx, to enable recruitment and assessment of participants on study using a Tele-Trial model. The Principal Investigator (PI) for a clinical trial using the tele-trial model will oversee and conduct the trial according to exactly the same responsibilities outlined by ICH-GCP and regulatory requirements, as any clinical trial, whether the activity is completed at the primary site or satellite sites and ensure the safety of the human participants in the trial. Duties may be delegated by the PI, but the PI remains accountable for all activity completed for the clinical trial and must ensure any personnel working on the trial are adequately trained and supported in all aspects of the trial.

**Complementary documents and processes**

This supervision plan is complementary to:

* the feasibility assessment;
* the site selection process;
* site(s) initiation
* training protocol
* the delegation log and
* the Queensland Health adopted (QH) Standard Operating Procedures (SOP) for tele-trial model which include:
  + Documentation of Investigational Site Staff Qualifications, Training Records and Adequacy of Resources
  + The Study Site Master File and Essential Documents
  + Communication with Human Research Ethics Committee (HREC), Research Governance Office (RGO), Sponsor and Insurer.
  + Protocol and Investigational Brochure (IB) Development
  + Management of Investigational Product
  + Participant Informed Consent Process and Documentation
  + Case Report Forms, Source Documents, Record Keeping and Archiving
  + Site Initiation and Close Out
  + Safety Data Monitoring and Reporting Requirements for Clinical Trials
  + Investigator Responsibilities
  + Handling and Shipping of Biological Substances in Clinical Trials
  + Standard Operating Procedure (SOP) Creation, Implementation and Revision

**Cluster**

The trial cluster refers to the group of sites involved in the conduct of the study, including the primary site who assumes overall responsibility for the conduct of the study and one or more satellite sites, which conduct the study under the direction of the primary site using the tele-trials model.

This supervision plan applies to the all sites participating in the xxx Clinical Trial

The primary and satellite sites for the cluster are:

1. Primary site: xxx
2. Satellite site: xxx

**Document History**

|  |  |  |
| --- | --- | --- |
| **Date** | **Activity** | **Responsible parties** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**Responsibilities Matrix**

|  |  |  |  |
| --- | --- | --- | --- |
| **Clinical Trial Activity** | **Insert initials of PS staff (as per Appendix A)** | **Insert initials of SS staff (as per Appendix A)** | **Comments – insert plan and study logistics** |
| **Communication** | | | | |
| Coordination of regular study teleconference meetings |  |  |  |
| Liaison between satellite site and sponsor re site visits |  |  |  |
| **Education** | | | | |
| Ensuring all staff at both primary and satellite sites are trained in appropriate aspects of the trial. |  |  |  |
| **Research governance at satellite site – initial application** | | | | |
| Creation of local satellite site(s) SSA application |  |  |  |
| **Staff coverage at satellite site** | | | | |
| Arranging for back up staff as required at satellite site(s) |  |  |  |
| **Recruitment and consenting of participants at satellite site** | | | | |
| Recruitment and consenting |  |  |  |
| **Randomisation of Satellite Site Patients** | | | | |
| Randomisation of a patient onto the trial |  |  |  |
| **Clinical care decisions** | | | | |
| Allocation of responsibility for trial related management decisions and management of hospitalized participants & documenting in delegation logs |  |  |  |
| **Safety reporting** | | | | |
| Reporting of safety events, including protocol deviations / violations, to sponsor |  |  |  |
| Reporting of safety events, including protocol deviations / violations, to HREC |  |  |  |
| **Funds management** |  |  |  |
| Payment to satellite sites |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| CPI = Coordinating Principal Investigator | RC = Research Coordinator | LSI = Lead Sub-Investigator | SI = Sub-investigator | Ph – Pharmacist |

| **Clinical Trial Activity** | **Responsible party – insert initials of staff**  **(as per Appendix A)** | | | | | | | **Comments – insert plan and study logistics** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Primary Site (PS) responsibility** | | **Satellite site with direct supervision from PS** | **Satellite site with support from PS** | **Satellite site** | **NA** |  | |
| **Research governance at satellite site – initial application** | | | | | | | | | |
| Completion of local SSA application |  | |  |  |  |  |  | |
| Creation of site specific documentation |  | |  |  |  |  |  | |
| Obtaining local site HoD sign offs |  | |  |  |  |  |  | |
| Submission to local site RGO |  | |  |  |  |  |  | |
| Responding to local site RGO queries |  | |  |  |  |  |  | |
| **Start up at satellite site** | | | | | | | |  | |
| Satellite site start up - general |  | |  |  |  |  |  | |
| Satellite site start up – Pharmacy |  | |  |  |  |  |  | |
| Satellite site start up – Pathology |  | |  |  |  |  |  | |
| Satellite site start up – Medical imaging |  | |  |  |  |  |  | |
| Provision of other trial related equipment |  | |  |  |  |  |  | |
| **Investigational product (IP) for satellite site** | | | | | | | | | |
| Ordering of IP |  | |  |  |  |  |  | |
| Receipt of IP |  | |  |  |  |  |  | |
| Dispensing of IP |  | |  |  |  |  |  | |
| Reconciliation of IP | |  |  |  |  |  |  | |
| **Screening of potentially eligible participants at satellite site** | | | | | | | | | |
| Screening (Inclusion / exclusion criteria) |  | |  |  |  |  |  | |
| **Data/eCRF Entry for patients recruited at satellite site** | | | | | | | | | |
| Recruitment process documented in participant’s medical file |  | |  |  |  |  |  | |
| Storage of source documents |  | |  |  |  |  |  | |
| Data entry (not eCRF) |  | |  |  |  |  |  | |
| eCRF Entry |  | |  |  |  |  |  | |
| Storage of Site documents at satellite site as per GCP |  | |  |  |  |  |  | |
| **Participant study involvement at satellite site** | | | | | | | | | |
| Scheduling of next visit |  | |  |  |  |  |  | |
| Notification of participant of next visit |  | |  |  |  |  |  | |
| Scheduling of study tests / procedures |  | |  |  |  |  |  | |
| Booking of study tests / procedures with relevant department(s) |  | |  |  |  |  |  | |
| Study visit(s) requirements e.g. physical exam; tests etc. |  | |  |  |  |  |  | |
| **Clinical care decisions** | | | | | | | | | |
| Trial related treatment decisions and management of hospitalized patients at satellites (e.g. progression, need for additional investigations). |  | |  |  |  |  |  | |
| **Safety reporting occurring at satellite site** | | | | | | | | | |
| Reporting of safety events, including protocol deviations / violations, to CPI |  | |  |  |  |  |  | |
| Reporting of safety events, including protocol deviations / violations, to site RGO |  | |  |  |  |  |  | |
| **Research governance at satellite site – amendments** | | | | | | | | | |
| Amendment of site specific documentation |  | |  |  |  |  |  | |
| Obtaining local site HoD sign offs if required |  | |  |  |  |  |  | |
| Submission to local site RGO |  | |  |  |  |  |  | |
| Responding to local site RGO queries |  | |  |  |  |  |  | |
| **Study close out – satellite site** | | | | | | | | | |
| Satellite site close out |  | |  |  |  |  |  | |
| Satellite site archiving |  | |  |  |  |  |  | |
| Satellite site close out – Pharmacy |  | |  |  |  |  |  | |
| Satellite site close out – Pathology |  | |  |  |  |  |  | |
| Satellite site close out – Medical imaging |  | |  |  |  |  |  | |

**Appendix A – Study staff**

(To be used in conjunction with delegation log)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Title** | **First name** | **Surname** | **Role in study** | **Initials** | **Comments** |
| Primary Site Study Staff | | | | | |
|  |  |  | Coordinating Principal Investigator (CPI) |  |  |
|  |  |  | Research Coordinator (RC) |  |  |
|  |  |  | Pharmacist (Ph) |  |  |
| Satellite Site Study Staff | | | | | |
|  |  |  | Lead Sub-investigator (LSI) |  |  |
|  |  |  | Sub-investigator (SI) |  |  |
|  |  |  | Research Coordinator (RC) |  |  |
|  |  |  | Research Coordinator (RC) |  |  |
|  |  |  | Pharmacist (Ph) |  |  |
|  |  |  | Sub investigator (SI) |  |  |
|  |  |  | Sub investigator (SI) |  |  |
|  |  |  | Sub investigator (SI) |  |  |
|  |  |  | Sub investigator (SI) |  |  |

**Signatures to the agreement of the supervision plan**

Primary site PI signature:

Satellite site lead SI signature: