[**INSERT** FULL NAME OF THE STUDY]

[**INSERT** PROTOCOL REFERENCE NUMBER]

# Model Agreement for Hub and Spoke Arrangements Between Lead Trial Sites and Other Trial Sites for Non-Commercial Research Studies

Between

[INSERT NAME and ADDRESS OF NHS ORGANISATION / GENERAL PRACTICE / INDEPENDENT CONTRACTOR OF NHS PRIMARY CARE SERVICES which is the named Lead Trial Site for the Study]

**“Lead Trial Site”**

AND

[INSERT NAME and ADDRESS OF [NHS ORGANISATION / GENERAL PRACTICE / INDEPENDENT CONTRACTOR OF NHS PRIMARY CARE SERVICES which is the Other Trial Site to the named Lead Trial Site for the Study]

**“Other Trial Site”**

Each of which shall be a **“Party”** and collectively the **“Parties”**

**Whereas**

*[N.B The recitals should appropriately match those in the Head Agreement]*

1. The Sponsor / Co-Sponsor / Joint Sponsor, [**INSERT NAME**], is an NHS organisation / University / OTHER;
2. The Study is coordinated on behalf of the Sponsor by [**INSERT NAME OF ORGANISATION**] which is a [Clinical Trials Unit / Experimental Cancer Medicine Centre / Biomedical Research Unit/Centre / Primary Care Clinical Trials Unit / OTHER];
3. The Lead Trial Site is contracted to act as the Processor of the Sponsor (as Controller) for Personal Data Processed for the purpose of the Study;
4. The Lead Trial Site has a particular interest and expertise in [**INSERT DETAILS**];
5. The Sponsor has contracted with the Lead Trial Site to undertake the study using the unmodified template model Non-Commercial Agreement July 2022 (“mNCA”);
6. The Other Trial Site is an NHS Organisation, General Practice or other independent contractor of NHS primary care services involved in the provision of healthcare, concerned with the treatment and prevention of disease and / or clinical research for the improvement of healthcare;
7. [**FOR OPTIONAL USE ONLY WITH WELSH TRIAL SITES AND OTHER TRIAL SITES**] The Central Management Function is a central delivery group on behalf of the Lead Trial Site consisting of experts in trial and facilities management overseeing the delivery service across the region / nation;
8. **[FOR OPTIONAL USE ONLY WITH WELSH TRIAL SITES AND OTHER TRIAL SITES]** The Other Trial Site has been selected by the Central Management Function and wishes to contract with the Lead Trial Site to provide services identified in this Agreement for the purpose of the Study.
9. Where either Party is a Health and Social Care (HSC) organisation in Northern Ireland, references throughout this document to the NHS should be construed to include HSC as applicable.

In respect of the clinical research Study entitled **[Insert FULL TITLE]** the above Parties hereby agree as follows:

## Definitions

* 1. In this Agreement, the following words and phrases have the following meanings:

**Agent**shall include but is not limited to, any person undertaking a function in connection with this Agreement (including the principal investigator, any nurse or other health professional), any such person’s principal employer in the event it is not the Lead Trial Site and where such person is providing services to a Party under a contract for services or otherwise (including clinical academics) and / or any contracted third party providing services to a Party under a contract for services or otherwise;

**Agreement**
means this Agreement comprising its clauses, schedules and any appendices attached to it and any variations made thereto in accordance with Clause 14.1;

**[FOR OPTIONAL USE ONLY WITH WELSH TRIAL SITES AND OTHER TRIAL SITES] Central Management Function**

means the central delivery group appointed on behalf of the Lead Trial Site overseeing the delivery service with contractual arrangements in place with the Lead Trial Site;

**Clinical Data**
means any data which relate to a specific Participant which may include, without limitation, medical records, medical imaging data, scans, questionnaires, readouts of individual biomedical or genetic analysis;

**Confidential Information**means all information disclosed, (whether in writing, orally or by another means and whether directly or indirectly) by or on behalf of a Party ("**Disclosing Party**") to the other Party ("**Receiving Party**") directly relating to the Study including, but not limited to information, the release of which is likely to prejudice the commercial business interests of the Disclosing Party, or which is a trade secret, including Know-How and shall also include any data disclosed which is Personal Data and / or special category Personal Data, all as defined in the Data Protection Legislation, and / or information that is otherwise confidential patient information;

**Controller**
shall have the meaning set out in the Data Protection Laws and Guidance;

**Data Protection Legilsation**
means the GDPR, the Data Protection Act 2018, the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019, as well as any legally enforceable NHS requirements, Codes of Practice or Guidance issued by the Information Commissioner’s Office, in each case in force from time to time in England, Northern Ireland, Scotland and / or Wales;

**Data Subject**as defined in the Data Protection Legislation;

**EEA**
means the European Economic Area comprising the countries of the European Union as well as Iceland, Liechtenstein and Norway;

**EIR**

means either the Environmental Information Regulations 2004 or the Environmental Information (Scotland) Regulations 2004, as applicable to the place of constitution of each Party;

**FOIA**

means either the Freedom of Information Act 2000 or the Freedom of Information (Scotland) Act 2002, as applicable to the place of constitution of each Party;

**Funder**

means the organisation(s) detailed in Appendix 1 that is / are providing support to the Study;

**GDPR**means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of Personal Data and on the free movement of such data, as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019;

**Intellectual Property Rights**means patents, trademarks, trade names, service marks, domain names, copyrights, moral rights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them;

**Intervention**

means, in the case of a Study of (a) medical device(s), the medical device(s) to be investigated as specified in the Protocol. In the case of other clinical trials, the intervention that is to be investigated as specified in the Protocol;

**Know-How**
means all technical and other information which is not in the public domain, including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, manufacturing data and information contained in submissions to regulatory authorities;

**Material**means any clinical biological sample or portion thereof, derived from Participants, including any information related to such Material, supplied by the Other Trial Site to the Lead Trial Site and / or Sponsor;

**MHRA**

means the Medicines and Healthcare Products regulatory Agency;

**mNCA**

means the unmodified model non-commercial agreement between the Lead Trial Site and the Sponsor that governs the conduct of the Study at the Lead Trial Site, and of which this Agreement is a sub-contract;

**Monitor**means one or more persons appointed by the Lead Trial Site, [[**FOR OPTIONAL USE ONLY WITH WELSH TRIAL SITES AND OTHER TRIAL SITES**] the Central Management Function on behalf of the Lead Trial Site], or the Sponsor to monitor compliance of the Study with ICH GCP and to conduct source data verification;

**NHS contract**

means an agreement in which the Other Trial Site and the Lead Trial Site are both NHS organisations as referenced within either Section 9(1) of the National Health Service Act 2006 Section 9(1), or Article 8(2) of the Health and Personal Social Service (Northern Ireland) Order 1991, or Section 17A of the National Health (Scotland) Act 1978, or Section 7(1) of the NHS (Wales) Act 2006 as applicable;

**Participant**
means any person who consents (where consent is necessary) and is enrolled to take part in the Study and who takes part in the Study under the care of the Other Trial Site;

**Personal Data**
means any and all information, data and material of any nature received or obtained by any Party in connection with this Agreement which is personal data as defined in the Data Protection Legislation and which relates to an actual or potential Participant or their treatment or medical history;

**Personnel**
means the persons who will undertake the conduct of the Study at the Other Trial Site under the oversight of the Principal Investigator;

**Process**

shall have the meaning set out in the Data Protection Legislation (and “Processing” and “Processed” shall be construed accordingly);

**Principal Investigator**
means the authorised health professional responsible for the conduct of the Study at both the Lead Trial Site and Other Trial Site, and if the Study is conducted by a team of authorised health professionals at the Lead Trial Site and / or Other Trial Site, the Principal Investigator is the leader responsible for that team;

**Processor**
shall have the meaning set out in the Data Protection Laws and Guidance;

**Protocol**
means the full description of the Study with the reference number set out on the front page of this Agreement, together with any amendments thereof made in accordance with the mNCA, and incorporated into this Agreement by reference;

**Pseudonymised Data**means individual-level data relating to a Participant or potential Participant (as opposed to aggregated data) who is made no longer identified or identifiable from that data by virtue of the replacement of personal identifiers with a code, or equivalent, and which is safeguarded as non-identifiable in accordance with this Agreement;

**Results**
means the research findings produced in the Study as published by the Sponsor and the Chief Investigator;

**Sponsor**means the individual, company, institution, organisation or group of organisations that has taken on the responsibility for initiation, managing and financing (or arranging the financing) the Study;

**Study**

means the clinical research study that is the subject of this Agreement;

**Study Data**

all discoveries, data, information, theories, methods, computer programmes, format of presentations and applications of the same and all manifestations or expressions of the same in physical, chemical, biological, molecular, electronic or written form arising from the performance of the Study;

**Sub Investigator**means any individual member of Personnel, designated and supervised by the Principal Investigator at the Other Trial Site to perform Study related procedures and / or to make Study related decisions;

**Sub-Processor**
means the Other Trial Site contracted by the Lead Trial Site to Process Personal Data on behalf of the Sponsor (as per GDPR Article 28(2)).

## General

* 1. Any reference to a statutory provision, code or guidance shall be deemed to include reference to any subsequent modification or re-enactment of it.

## Obligations of the Parties

* 1. To the extent applicable to each, the Parties shall comply with, and the Lead Trial Site shall ensure that the Principal Investigator and all personnel who are providing any manner of service related to the Study comply with, all relevant laws and codes of practice, which may include but not be limited to:
		1. The Human Rights Act 1998;
		2. The Data Protection Legislation;
		3. The Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006, to be determined in accordance with the place of constitution of the Trial Site;
		4. Where the Study is not a Clinical Trial of an Investigational Medicinal Product, the Mental Capacity Act 2005 (or a combined Clinical Trial of a Medicinal Product and Clinical Investigation of a Medical Device), the Adults with Incapacity (Scotland) Act 2000 or The Mental Capacity (Northern Ireland) Act 2016, to be determined in accordance with the place of constitution of the Trial Site;
		5. The Medicines Act 1968;
		6. The Human Medicines Regulations 2012;
		7. The Medicines for Human Use (Clinical Trial) Regulations 2004;
		8. The Bribery Act 2010;
		9. Relevant law having effect by virtue of ss2-4 of the European Union (Withdrawal) Act 2018;
		10. (In Northern Ireland) laws of the European Union having effect as a result of the Protocol on Ireland / Northern Ireland;
		11. the UK Research and Innovation policies and principles entitled, “Human Biological Samples”;
		12. the UK Policy Framework for Health and Social Care Research.
	2. The Parties shall conduct the Study in accordance with:
		1. the Protocol;
		2. the terms of all relevant regulatory permissions and approvals. These may include, but are not limited to:
			1. the terms and conditions of the favourable opinion given by the relevant NHS Research Ethics Committee;
			2. the Clinical Trials Authorisation (CTA) granted by the Medicines and Healthcare products Regulatory Agency (the "MHRA");
			3. the letter of no objection from the MHRA for the clinical investigation of a non-CE marked medical device or a CE marked medical device being used for a new purpose.
	3. The Parties shall carry out their respective responsibilities in accordance with this Agreement.
	4. The Other Trial Site confirms that the Sponsor and / or Lead Trial Site shall, on the giving of reasonable prior written notice to the Other Trial Site, have the right to audit the Other Trial Site’s compliance with this Agreement. The Lead Trial Site confirms that the Sponsor may appoint an auditor to carry out such an audit. Such right to audit shall include access during normal working hours to the Other Trial Site and to all relevant documents and other information relating to the Study.
	5. Each Party shall:
		1. promptly notify the other Party should any responsible body, such as, but not limited to, the MHRA, conduct or give notice of intent to conduct any inspection of either Party in relation to the Study;
		2. allow the Sponsor, and where the Other Trial Site is being inspected allow the Lead Trial Site, to support the preparations for such inspection, and;
		3. following the inspection, provide the Sponsor with the results of the inspection relevant to the Study. The Sponsor will be responsible for sharing such results with the Funder if required.
	6. In accordance with Participant consent, the Other Trial Site shall permit the Sponsor’s appointed representatives, the Lead Trial Site and any appropriately appointed Monitor access to all relevant Clinical Data for monitoring, source data verification and adverse event reporting or investigation as appropriate, and permit the Lead Trial Site access to the records of Participants to the extent considered necessary by the Lead Trial Site and the Principal Investigator for the oversight of the Study and safety of Participants. Such access will be arranged at mutually convenient times and on reasonable notice. Such monitoring may take such form as the Sponsor and the Lead Trial Site reasonably thinks appropriate including the right to inspect any facility being used for the conduct of the Study, reasonable access to relevant members of staff at the Other Trial Site and the right to examine any procedures or records relating to the Study, subject at all times to Clause 6 of this Agreement. The Lead Trial Site will alert the Other Trial Site promptly to significant issues (in the opinion of the Lead Trial Site and / or Sponsor) relating to the conduct of the Study.
	7. [**Delete if not applicable:** The Other Trial Site shall use reasonable endeavours to recruit Participants to participate in the Study as set out in Appendix 1.]

## Principal Investigator, Sub Investigator and Personnel

* 1. The Other Trial Site represents that:
		1. It has the necessary expertise, time and resources to perform the Study, as required by the Protocol, and as instructed by the Principal Investigator, as outlined in Appendix 2; and
		2. it is entitled to procure and will procure the services of the Sub Investigator and Personnel to fulfil the functions required in this Agreement; and
		3. the Sub Investigator and Personnel hold the necessary registration and have the necessary expertise to perform the Study.
	2. The Other Trial Site shall ensure that the Sub Investigator and Personnel are made aware of and acknowledge the obligations applicable to them as set out in this Agreement, including but not limited to those set out in Appendices 2 and 3.
	3. The Lead Trial Site represents that:
		1. it is entitled to procure and will procure the services of the Principal Investigator; and
		2. the Principal Investigator holds the necessary registration and has the necessary expertise, time and resources to perform the Study.
	4. The Lead Trial Site shall ensure that the Principal Investigator is made aware of and acknowledges the obligations applicable to them as set out in this Agreement, including but not limited to those set out in Appendix 3.
	5. The Other Trial Site shall ensure that the Sub Investigator, and / or other Personnel as appropriate, attend any meetings regarding the Study as reasonably requested by the Lead Trial Site (“**Study Meetings**”). The Other Trial Site agrees that no additional compensation shall be due hereunder for the Sub-Investigator’s or any other Personnel’s participation in any Study Meetings. The Lead Trial Site shall reimburse or pay for reasonable pre-approved expenses for attendance at the Study Meetings upon receipt of documentation. It is further agreed that any such expenses will be paid at the rate of fair market value. Such expenses may be publicly reportable.
	6. The Other Trial Site represents that it will support the Sub Investigator and Personnel to make good faith diligent efforts to ensure the completion of all case report forms in a timely manner under the instruction and oversight of the Principal Investigator.

## Liability and Indemnity

* 1. Both Parties acknowledge that the Lead Trial Site has entered into a mNCA with the Sponsor that includes liability and indemnity provisions whereby the Sponsor shall indemnify the Lead Trial Site and its Agents, against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands (“Claims”) to the extent they arise or result from the negligent acts or omissions of, or the wilful misconduct of the Sponsor, and / or contracted third party, in its performance of the mNCA or in connection with the Study.
	2. Both Parties acknowledge that the Other Trial Site is a contracted Agent of the Lead Trial Site.
	3. Subject to Clause 5.1 the Other Trial Site acknowledges that its total liability to the Sponsor and / or Lead Trial Site together shall not exceed the level of liability of the Lead Trial Site to the Sponsor in the mNCA. The Other Trial Site also acknowledges that the liability of the Sponsor and / or Lead Trial Site to the Other Trial Site shall not exceed the Sponsor’s level of liability to the Lead Trial Site in the mNCA.
	4. Where a Party is a non-NHS / HSC organisation, or an NHS / HSC organisation that is not covered by an NHS indemnity scheme, then that Party shall maintain all proper insurance or equivalent indemnity arrangements to cover liabilities arising from its participation in the Study, in respect of any claims brought by or on behalf of a Participant. Where a Party is covered by an NHS indemnity scheme, it shall maintain its cover therein or otherwise ensure it has appropriate cover against claims arising as a result of clinical negligence by that Party and / or its Agents brought by or on behalf of a Participant. Each Party shall provide to the other such evidence of their insurance or equivalent indemnity cover maintained pursuant to this Clause 5.4 as the other Party shall from time to time reasonably request; such evidence might comprise confirmation that an NHS / HSC organisation is a member of, or otherwise covered by, one of the NHS indemnity schemes.
	5. Nothing in this Clause 5 shall operate so as to restrict or exclude the liability of any Party, or of the Sponsor, in relation to death or personal injury caused by the negligence or wilful misconduct of that Party or its Agents or employees, or of the Sponsor, or to restrict or exclude any other liability of any Party, or of the Sponsor, that cannot be so restricted or excluded in law.
	6. In no circumstances shall either Party be liable to the other Party, or to the Sponsor in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever arising or whatever the cause thereof, for any loss of profit, business, reputation, contracts, revenues or anticipated savings or for any special, indirect or consequential damage of any nature, which arises directly or indirectly from any default on the part of any other Party.
	7. Nothing in this Agreement will operate to limit or exclude any liability for fraud.

## Data Protection

**Confidentiality**

* 1. The Parties agree to comply with all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality) in relation to Participants and potential Participants.
	2. The Other Trial Site agrees to treat the Confidential Information in this Agreement (including the Protocol) and the Results, excluding any Clinical Data of the Study, as Confidential Information and the Lead Trial Site agrees to treat Personal Data and confidential patient information as Confidential Information.

**Data Processing Terms**

* 1. For the purpose of the Data Protection Legislation, the Sponsor is the Controller, the Lead Trial Site is the Sponsor's Processor and the Other Trial Site is the Sub-Processor of the Lead Trial Site in relation to all Processing of Personal Data that is Processed for the purpose of this Study and for any future research use under the Controllership of the Sponsor, that would not have taken place but for this Agreement regardless where that Processing takes place.
	2. The Parties acknowledge that whereas the Sponsor is the Controller in accordance with Clause 6.3, the Other Trial Site is the Controller of the Personal Data collected for the purpose of providing clinical care to the Participants. This Personal Data may be the same Personal Data that is processed for research purposes under the separate Controllership of the Sponsor in accordance with this Agreement.
	3. Where the Other Trial Site is the Lead Trial Site's Sub-Processor and thus where the Processing is undertaken by the Other Trial Site for the purposes of the Study, Clauses 6.6 to 6.9 below will apply. For the avoidance of doubt, such Clauses do not apply where the Other Trial Site is Processing the Participant Personal Data as a Controller.
	4. The Other Trial Site agrees only to Process Personal Data for and on behalf of the Lead Trial Site in accordance with the instructions of the Sponsor, as provided by the Sponsor and / or Lead Trial Site, and for the purpose of the Study and to ensure the Sponsor’s and Lead Trial Site’s compliance with the Data Protection Legislation.
	5. The Other Trial Site agrees to comply with the obligations applicable to Processors described by Article 28 of the GDPR including, but not limited to, the following:
		1. to implement and maintain appropriate technical and organisational security measures sufficient to comply at least with the obligations imposed on the Controller by Article 28(1);
		2. to not engage another Processor without the prior written authorisation of the Sponsor (Article 28(2));
		3. to process the Personal Data only on documented instructions of the Sponsor, as provided by the Sponsor and / or Lead Trial Site, unless required to do otherwise by legislation, in which case the Other Trial Site shall notify the Lead Trial Site before Processing, or as soon as possible after Processing if legislation requires that the Processing occurs immediately, unless legislation prohibits such notification on important grounds of public interest (Article 28(3)(a));
		4. to ensure that Personnel authorised to Process Personal Data are under confidentiality obligations (Article 28(3)(b));
		5. to take all measures required by Article 32 GDPR in relation to the security of processing (Article 28(3)(c));
		6. to respect the conditions described in Article 28(2) and (4) for engaging another Processor (Article 28(3)(d));
		7. to, taking into account the nature of the Processing, assist the Lead Trial Site and / or the Sponsor, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising Data Subjects’ rights (Article 28(3)(e));
		8. to assist the Controller, to ensure compliance with the obligations pursuant to Article 32 to 36 GDPR taking into account the nature of the Processing and the information available to the Other Trial Site (Article 28(3)(f));
		9. to, at the choice of the Sponsor, destroy or return all Personal Data to the Sponsor at the expiry or early termination of the Agreement, unless storage is legally required (Article 28(3)(g)) or where that Personal Data is held by the Other Trial Site as Controller for the purpose of clinical care or other legal purposes; and
		10. to maintain a record of Processing activities as required by Article 30(2) GDPR.
	6. The Other Trial Site shall ensure that:
		1. its Agents do not Process Personal Data except in accordance with this Agreement (and in particular the Protocol);
		2. it takes all reasonable steps to ensure the reliability and integrity of any of its Agents who have access to the Personal Data and ensure they:
1. are aware and comply with the Other Trial Site’s duties under this clause;
2. are subject to mandatory training in their information governance responsibilities and have appropriate contracts including sanction, including for breach of confidence or misuse of data; and
3. are informed of the confidential nature of the Personal Data and understand the responsibilities for information governance including their obligation to Process Personal Data securely and to only disseminate or disclose for lawful and appropriate purposes.
	1. The Other Trial Site agrees to:
		1. allow the Lead Trial Site and / or Sponsor(s) or another auditor appointed by the Lead Trial Site and / or Sponsor(s) to audit the Other Trial Site’s compliance with the obligations described by this Agreement, Data Protection Legislation in general and Article 28 GDPR in particular, on reasonable notice subject to the Lead Trial Site / Sponsor complying with all relevant health and safety and security policies of the Other Trial Site and / or to provide the Lead Trial Site or Sponsor with evidence of its compliance with the obligations set out in this Agreement; and
		2. obtain prior written agreement of the Sponsor to Process Personal Data outside of the UK and the EEA.
	2. Where the Other Trial Site stores or otherwise Processes Personal Data outside of the UK and the European Economic Area as the Sponsor’s Processor, it warrants that it does so in compliance with the Data Protection Legislation.

**Sharing of Personal Data and / or Pseudonymised Data**:

* 1. Neither Personal Data nor Pseudonymised Data will be disclosed to the Lead Trial Site or Sponsor by the Other Trial Site, save where this is required directly or indirectly to satisfy the requirements of the Protocol, or in relation to a claim or proceeding brought by a Participant or potential Participant in connection with the Study.
	2. 6.136.12 The Lead Trial Site agrees to use and warrants that the Sponsor has agreed to use Personal Data and Pseudonymised Data solely in connection with the operation of the Agreement, or otherwise for purposes not incompatible with this original purpose (Article 5, 1 (b) GDPR), and not otherwise. In particular:
		1. not to disclose Personal Data or Pseudonymised Data to any person except in accordance with applicable legal requirements and codes of practice.
	3. The Lead Trial Site represents that the Sponsor has agreed to comply with the obligations placed on a Controller by the Data Protection Legislation. This is not limited to, but includes, being responsible for and able to demonstrate compliance with the principles relating to Processing of Personal Data (Article 5 GDPR).
	4. The Lead Trial Site has procured that the Sponsor will ensure that persons processing Personal Data and / or Pseudonymised Data under the mNCA are equipped to do so respectfully and safely. The Lead Trial Site represents and warrants that its own personnel are equipped to do so respectfully and safely. The Lead Trial Site represents that the Sponsor has committed to the following for persons other than the Lead Trial Site’s personnel, and the Lead Trial Site commits to the following for its own personnel:
		1. to ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Other Trial Site) Processing Personal Data understand the responsibilities for information governance, including their obligation to Process Personal Data and Pseudonymised Data securely and to only disseminate or disclose for lawful and appropriate purposes;
		2. to ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Other Trial Site) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable data breaches.
	5. The Lead Trial Site will proactively prevent data security breaches and will respond appropriately to incidents or near misses and represents that it has procured the same from the Sponsor. In particular both Lead Trial Site and Sponsor will, within their respective remits:
		1. ensure that Personal Data and Pseudonymised Data are only accessible to persons who need it for the purposes of the Study and remove access as soon as reasonably possible once it is no longer needed;
		2. ensure all access to Personal Data and Pseudonymised Data on IT systems Processed for Study purposes can be attributed to individuals;
		3. review processes to identify and improve processes which have caused breaches or near misses, or which force persons Processing Personal Data to use workarounds which compromise data security;
		4. adopt measures to identify and resist cyber-attacks against services and respond to relevant external security advice;
		5. take action immediately following a data breach or near miss.
	6. The Lead Trial Site will ensure that data are Processed using secure and up to date technology and represents that it has procured the same from the Sponsor. In particular, both Lead Trial Site and Sponsor will, within their respective remits:
		1. ensure no unsupported operating systems, software or internet browsers are used to support the Processing of Personal Data or Pseudonymised Data for the purposes of the Study;
		2. put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework such as Cyber Essentials;
		3. ensure IT suppliers are held accountable via contracts for protecting Personal Data and / or Pseudonymised Data they Process and for meeting all relevant information governance requirements.

## Freedom of Information

* 1. Parties to this Agreement which are subject to the EIR and the FOIA and which receive a request under EIR or FOIA to disclose any information that belongs to another Party [and] / [or] Sponsor shall notify and consult that Party [and] / [or] Sponsor in accordance with clause 16, as soon as reasonably practicable, and in any event, not later than seven (7) working days after receiving the request.
	2. The Parties acknowledge and agree that the decision on whether any exemption applies to a request for disclosure of recorded information under EIR or FOIA is a decision solely for the Party responding to the request.
	3. Where the Party responding to an EIR or FOIA request determines that it will disclose information it will notify the other Party in writing, giving at least four (4) working days’ notice of its intended disclosure.

## Confidential Information

* 1. Subject to Clause 10 below, the Other Trial Site agrees to treat the Results, excluding any Clinical Data of the Study, as Confidential Information of the Lead Trial Site and the Sponsor. The Lead Trial Site confirms that the Sponsor agrees to treat Personal Data and confidential patient information as Confidential Information.
	2. The Party receiving Confidential Information agrees:
		1. to take all reasonable steps to protect the confidentiality of the Confidential Information and to prevent it from being disclosed otherwise than in accordance with this Agreement;
		2. to ensure that any of its employees, students, researchers, consultants or sub-contractors who participate in the operation of the Study are made aware of, and abide by, the requirement of this Clause 8.2;
		3. to use Confidential Information solely in connection with the operation of the Agreement and not otherwise, except in the case where the Confidential Information is Personal Data and / or confidential patient information, where it may be used solely on the basis of maintaining the common law duty of confidentiality and in accordance with the requirements of the Data Protection Legislation, including but not limited to an appropriate legal basis / special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose;
		4. not to disclose Confidential Information in whole or in part to any person without the Disclosing Party’s prior written consent or, where the Confidential Information is Personal Data and / or confidential patient information, without maintaining the common law duty of confidentiality and in accordance with the requirements of the Data Protection Legislation, including but not limited to an appropriate legal basis / special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose;
		5. That in the event of a Party to this Agreement visiting the establishment of another Party to this Agreement, the visiting Party undertakes that any further Confidential Information that may come to the visiting Party’s knowledge as a result of any such visit, shall be treated as Confidential Information in accordance with this Clause 8. The Trial Site represents and warrants that where the Sponsor visits the establishment of a Party to this Agreement, the Sponsor has undertaken that any further Confidential Information that may come to its knowledge as a result of any such visit shall be treated as Confidential Information in accordance with this Clause 8.
	3. The provisions of Clauses 8.1 and 8.2 shall not apply to the whole or any part of the Confidential Information that is:
		1. lawfully obtained by the Receiving Party free of any duty of confidentiality;
		2. already in the possession of the Receiving Party and which the Receiving Party can show from written records was already in its possession (other than as a result of a breach of Clause 8.1 or 8.2);
		3. in the public domain (other than as a result of a breach of Clause 8.1 or 8.2);
		4. independently discovered by employees of the Receiving Party without access to or use of Confidential Information;
		5. necessarily disclosed by the Receiving Party pursuant to a statutory obligation;
		6. disclosed with prior written consent of the Disclosing Party;
		7. necessarily disclosed by the Receiving Party by virtue of its status as a public authority in terms of the EIR or the FOIA;
		8. published in accordance with the provisions of Clause 10.
	4. The restrictions contained in Clause 8.3 shall remain in force without limit in time in respect of Personal Data and / or Pseudonymised Data and any other confidential patient information which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly set out in this Agreement, these clauses shall remain in force for a period of ten (10) years after the termination or expiry of this Agreement.

## Intellectual Property

* 1. All Background Intellectual Property Rights (including licences) and Background Know-How and their improvements used in connection with the Study shall remain the property of the Party introducing the same and the exercise of such rights for purposes of the Study shall not knowingly infringe any third party’s rights.
	2. All Intellectual Property Rights and Know-How in the Protocol and other documents and information disclosed by or on behalf of the Sponsor, and in the Study Data, excluding clinical procedures developed or used by the Other Trial Site or Lead Trial Site independently of the Study, shall belong to the Sponsor. The Other Trial Site hereby assigns all such Intellectual Property Rights, and undertakes to disclose all such Know-How, to the Lead Trial Site for onward disclosure to the Sponsor.
	3. Subject to clauses 9.1 and 9.2, all Intellectual Property Rights deriving or arising from the Material or any derivations of the Material provided to the Sponsor by the Other Trial Site shall belong to the Sponsor.
	4. At any time within the duration of the Study, the Other Trial Site shall at the request and expense of the Sponsor execute all such documents and do all acts necessary to fully vest the Intellectual Property Rights in the Sponsor. To give effect to this clause 9.4, the Other Trial Site shall ensure that its Agents involved in the Study assign such Intellectual Property Rights falling within clauses 9.2 and 9.3 and disclose such Know-How to the Other Trial Site.
	5. Subject to this clause 9.5 and clause 9.6, nothing in this clause 9 shall be construed so as to prevent or hinder the Other Trial Site from using its own Know-How or Study Data that is Clinical Data gained during the performance of the Study, at its own risk, in the furtherance of its normal activities of providing clinical care to the extent that such use does not result in the disclosure or misuse of Confidential Information or the infringement of an Intellectual Property Right of the Sponsor, or their funder, or the holder of the Intellectual Property Rights of the Study Drug and / or Intervention. This Clause 9.5 does not permit the disclosure of any of the Study Data, all of which remain confidential until publication of the Results in accordance with clause 10. Any Study Data not so published remains the Confidential Information of the Sponsor, or their funder, or the holder of the Study Drug and / or Intervention Intellection Property Rights.

## Publications and Publicity

* 1. Neither Party shall use the name, logo or registered image of the other Party or the Agents of such other Party or the Sponsor or its Agents in any publicity, advertising or press release, related to this Agreement, without the prior written approval of an authorised representative of Party and / or the Sponsor.
	2. The content and timing of any publicity, advertising or press release shall be agreed by both Parties and the Sponsor **[[FOR OPTIONAL USE ONLY WITH WELSH TRIAL SITES AND OTHER TRIAL SITES]** and the Central Management Function], such agreement not to be unreasonably withheld.
	3. In accordance with all relevant laws, regulations and codes of practice, the Lead Trial Site represents and warrants that the Sponsor has agreed it has an obligation to and shall publish the Results of the full Study. The Lead Trial Site has agreed with the Sponsor that it shall not publish any Study Data, including through presentation or submission of an abstract, without the prior permission in writing from the Sponsor (which shall not be unreasonably withheld or delayed). The Other Trial Site warrants that it will seek written permission from the Sponsor through the Lead Trial Site **[[FOR OPTIONAL USE ONLY WITH WELSH TRIAL SITES AND OTHER TRIAL SITES]** and the Central Management Function] (which shall not be unreasonably withheld or delayed) to publish any Study Data, including through presentation or submission of an abstract.

## Financial and Supplies Arrangements

* 1. The Parties agree to financing of the Study service provision as set out in Appendix 1.
	2. Where payments are agreed:
		1. the Parties agree that prior to receiving payment the Other Trial Site shall submit an invoice in accordance with Appendix 1 setting out the costs incurred and payment claimed;
		2. payment by the Lead Trial Site shall be without prejudice to any claims or rights which the Sponsor may have against the Other Trial Site and shall not constitute any admission by the Lead Trial Site as to the performance by the Other Trial Site of its obligations under this Agreement.
	3. The Parties agree to the procurement and provision of any medicine, equipment, materials, consumables software or other items necessary for the Study as set out in Appendix 1. Any such items provided by the Lead Trial Site or on behalf of the Sponsor to the Other Trial Site shall be used only for the Study and in accordance with the Protocol, or otherwise as agreed in Appendix 1.
	4. The Lead Trial Site confirms that the Sponsor shall use any Study Data, Material or other information provided by or derived from a Participant and provided by or on behalf of the Other Trial Site to the Sponsor in accordance with the consent provided by the Participants and the Protocol, and in respect of Materials also in accordance with Appendix 4.
	5. The Lead Trial Site shall have no liability for any failure to make payments if required funding is not provided to the Lead Trial Site by the Sponsor.

## Term

* 1. This Agreement will commence on the date the final signatory signed the Agreement and shall remain in effect until completion of the Study (which means the conclusion of all Protocol required activities for all enrolled Participants) and close-out of the Lead Trial Site or earlier termination in accordance with Clause 13 of this Agreement.

## Termination

* 1. This Agreement may be terminated immediately by notice in writing by either Party if the other Party is:
		1. in material or continuing breach of any of its obligations under this Agreement and fails to remedy the breach (if capable of remedy) for a period of thirty (30) calendar days after written notice by the non-breaching Party; or
		2. declared insolvent or has an administrator or receiver appointed over all or any part of its assets or ceases or threatens to cease to carry on its business.
	2. The Lead Trial Site may terminate this Agreement by notice in writing:
		1. if the regulatory permissions and approvals previously granted to perform the Study are withdrawn;
		2. if funding is withdrawn or terminated for any reason or if it has been agreed that there are insufficient funds available to continue the Study;
		3. if the Sponsor is advised to do so by the study management committee / group, trial oversight committee, study oversight group or other similar arrangements as defined in the Protocol;
		4. in the event of cessation of Study Drug / Intervention, equipment or similar necessary for the Study, or information or resources critical to the Study;
		5. if the Principal Investigator becomes unavailable to continue their supervision of the Study for any reason and a replacement acceptable to both Parties and the Sponsor is not found.
	3. The Other Trial Site may terminate this Agreement by notice in writing:
		1. if the Sub-Investigator becomes unavailable to continue their supervision of the Study at the Other Trial Site for any reason and a replacement acceptable to both Parties acting reasonably is not found.
	4. In the event of termination or expiry of this Agreement, or if the Other Trial Site chooses to cease Participant recruitment (where it is recruiting Participants, if applicable, at its Other Trial Site in accordance with clause 13.6, the following provisions shall apply:
		1. The Parties shall work together to facilitate an orderly cessation of the Study at the Other Trial Site (or, if applicable, cessation of recruitment of Participants at its Other Trial Site where the Other Trial Site has chosen to cease recruiting in accordance with Clause 13.6), taking into account the rights, safety, well-being and continuity of treatment (if appropriate) of the Participants and applicable law.
		2. The Lead Trial Site shall, subject to the prior compliance of the Other Trial Site with its obligations on termination, upon receipt of a valid invoice submitted in accordance with Appendix 1, pay the Other Trial Site any outstanding monies due to the Other Trial Site as at the date of termination.
		3. The Other Trial Site shall ensure that there is prompt refund to the Lead Trial Site of the amount, if any, by which the cumulative cost paid by the Lead Trial Site to the Other Trial Site under this Agreement exceeds the actual commitments incurred by the Other Trial Site up to the date of termination, or cessation of Participant recruitment, and any other costs in accordance with Appendix 1 and, if applicable, in the event of cessation of recruitment of Participants at its Other Trial Site where the Other Trial Site has chosen to cease recruiting in accordance with Clause 13.6, an amendment in writing signed by the Sponsor and the Lead Trial Site shall be made to any payments due under Appendix 1 to reflect the reduction in recruitment numbers.
		4. The Other Trial Site shall provide to the Lead Trial Site all study data and other relevant information and / or data relating to work undertaken by the Other Trial Site prior to and including the date of termination and co-operate with all reasonable requests from the Lead Trial Site including any continued monitoring of Participants in accordance with Protocol.
		5. The Other Trial Site shall ensure that all reasonable instructions by the Sponsor and the Lead Trial Site as regards the return or disposal of all unused supplies, or medical devices or other equipment or items previously provided to the Other Trial Site for the purposes of the Study are complied with.
		6. The Other Trial Site shall ensure that the instructions of the Lead Trial Site regarding the transfer and / or storage of all information, material or data relating to the Study collected by the Other Trial Site in the course of carrying out the Study are complied with.
		7. Unless otherwise agreed in writing with the Lead Trial Site, the costs and expenses of returning, dispatching, transferring or storing items shall be in accordance with Appendix 1.
	5. Termination under this Clause 13 will be without prejudice to any other rights or remedies of either Party under this Agreement or at law, and will not affect any accrued rights or liabilities of either Party at the date of termination.
	6. Where the Other Trial Site has agreed to recruit Participants, the Other Trial Site will notify the Lead Trial Site in accordance with Clause 16 if, for any reason, it elects to cease Participant recruitment.

## Agreement and Modification

* 1. Any variations to this Agreement shall be valid only if made in writing and signed by authorised signatories of the Parties.
	2. This Agreement including its Appendices contains the entire understanding between the Parties and supersedes all other agreements, negotiations, representations and undertakings, whether written or oral of prior date between the Parties relating to the Study that is the subject of this Agreement.

## Force Majeure

* 1. No Party shall be liable for any delay in performance or failure to perform its obligations under this Agreement if such delay or failure is due to an occurrence beyond its reasonable control. The Party affected by such occurrence shall promptly notify the other Party If the circumstances causing the delay or failure to perform continue for longer than thirty (30) calendar days, the other Party shall be entitled to terminate this Agreement by notice in writing with immediate effect.

## Notices

* 1. Any notice under this Agreement shall be in writing, signed by the relevant Party to the Agreement and delivered personally, by courier, by recorded delivery post, or by email, providing evidence of receipt.
	2. Notices shall be delivered to the name and address specified below:

[insert Other Trial Site and Lead Trial Site contact details for Notices, including email address.]

* 1. Notices:
		1. by post will be effective upon the earlier of actual receipt or seven (7) calendar days after mailing;
		2. by hand will be effective upon delivery; and
		3. by email will be effective when sent in legible form, but only if, following transmission, the sender does not receive a non-delivery message.

## Assignment and Subcontracting

* 1. The Other Trial Site shall not novate or assign all or any part of their rights or obligations under this Agreement without the prior written consent of the Lead Trial Site.
	2. The Other Trial Site must not sub-contract the performance of all or any of its obligations under this Agreement without the prior written consent of the Lead Trial Site, such consent not to be unreasonably withheld or delayed.
	3. In the event that either Party sub-contracts its responsibilities under this Agreement, it shall be responsible for the acts and omissions of its sub-contractors as though they were its own.

## Dispute Resolution

* 1. In the event of a dispute arising under this Agreement, authorised representatives of the Parties will discuss and meet as appropriate to try to resolve the dispute within seven (7) calendar days of being requested in writing by either Party to do so. If the dispute remains unresolved, it will then be referred to a senior manager from each of the Parties who will use all reasonable endeavours to resolve the dispute within a further fourteen (14) calendar days.
	2. If the Parties are unable to resolve a dispute using the procedure outlined in Clause 18.1, the Parties will attempt to resolve the dispute by the appropriate method of (in line with Clause 21 (Governing Law)):
		1. in England or Wales Parties will refer the dispute to mediation in accordance with the Centre for Effective Dispute Resolution Model Mediation Procedure; or
		2. in Scotland Parties will refer the dispute to an independent third party. If the Parties are unable to agree on the identity of the third party, the Parties will ask the President of the Law Society of Scotland to appoint a suitable individual to consider the matter. The person so appointed will act as an expert and not as an arbiter; or
		3. in Northern Ireland Parties will refer the dispute to a mediator agreed by the Parties. Where the Parties are unable to agree on the identity of a mediator, the Parties will ask the President of the Law Society of Northern Ireland to appoint a suitable mediator.
	3. Each Party shall each bear its own costs in relation to the settlement of any disputes and the Parties shall share equally the costs of any independent third party involved to assist in the resolution of the dispute unless the independent third party directs that costs be apportioned differently.
	4. Any decision reached in accordance with this Clause 18 shall be final and binding upon the Parties.
	5. Notwithstanding the provisions of Clauses 18.2 to 18.4, where the Agreement is an NHS Contract, any dispute between the Parties shall be referred for determination by:
		1. The Secretary of State for Health if both Parties are NHS Organisations in England;
		2. The Department of Health if both Parties are NHS Organisations in Northern Ireland;
		3. The Scottish Ministers if both Parties are NHS Organisations in Scotland;
		4. The Welsh Ministers if both parties are NHS Organisations in Wales; or
		5. Where one Party is an NHS Organisation in one jurisdiction and one Party is an NHS Organisation in another jurisdiction, by the appropriate representative bodies in both jurisdictions specified in Clauses 18.5.1, 18.5.2, 18.5.3 or 18.5.4 acting jointly.
	6. Where the Agreement is not an NHS Contract and the Parties are unable to resolve a dispute in accordance with Clause 18.8, the Parties will attempt to resolve the dispute in accordance with the relevant subclause 18.6.1, 18.6.2 or 18.6.3, determined in accordance with Clause 18:
		1. in England or Wales Parties will refer the dispute to mediation in accordance with the Centre for Effective Dispute Resolution Model Mediation Procedure; or
		2. in Scotland Parties will refer the dispute to an independent third party to act as a mediator between the Parties. If the Parties are unable to agree on the identity of the third party, the Parties will ask the President of the Law Society of Scotland to appoint a suitable individual to consider the matter. The person so appointed will act as an expert mediator and not as an arbiter; or
		3. in Northern Ireland Parties will refer the dispute to a mediator agreed by the Parties. Where the Parties are unable to agree on the identity of a mediator, the Parties will ask the President of the Law Society of Northern Ireland to appoint a suitable mediator.

## General

* 1. Should there be any inconsistency between the Protocol and the other terms of this Agreement, or any document incorporated therein, the terms of the Protocol shall prevail to the extent of such inconsistency except insofar as the inconsistency relates to Clauses 5, 6, 7, 8, 9 and / or 10 of this Agreement where these terms of the Agreement shall prevail.
	2. No failure or delay by any Party to exercise any right under this Agreement will operate as a waiver of it, nor will any partial exercise preclude any future exercise of the same.
	3. If any clause or part of this Agreement is found by any court, tribunal, administrative body or authority of competent jurisdiction to be illegal, invalid or unenforceable then that provision shall, to the extent required, be severed from this Agreement and shall be effective without, as far as possible, modifying any other clause or part of this Agreement and shall not affect any other provisions of this Agreement which shall remain in full force and effect.
	4. Except as provided in this clause 19.4 this Agreement does not create any right enforceable by any person who is not a Party to it under the Contracts (Rights of Third Parties) Act 1999 or the Contract (Third Party Rights) (Scotland) Act 2017. For the avoidance of doubt, the obligations of the Other Trial Site to the Sponsor set out in clauses 3, 6, 7, 8, 9 and 10 confer upon the Sponsor the right to enforce those obligations
	5. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together shall constitute one and the same instrument.

## Survival of Clauses

* 1. The following clauses shall survive the termination or expiry of this Agreement:

**Clause 1** Definitions

**Clause 5**  Liabilities and Indemnities

**Clause 6** Data Protection

**Clause 7** Freedom of Information

**Clause 8** Confidential Information

**Clause 9** Intellectual Property

**Clause 10** Publications and Publicity

**Clauses 13.4 and 13.5** Termination

**Clause 20** Survival of Clauses

**Clause 21** Governing Law

**Appendix 4** Material Transfer Provisions

## Governing Law

* 1. By the signing of this Agreement the Parties agree that the conduct of the Study is governed by and subject to the national laws and regulations of the Lead Trial Site.

Signed by the duly authorised representatives of the Parties.

|  |  |
| --- | --- |
| Signed for and on behalf of:[INSERT NAME OF LEAD TRIAL SITE]Signature:Print name:Title: Date: | Signed for and on behalf of:[INSERT NAME OF OTHER TRIAL SITE]Signature:Print name:Title:Date: |

*N.B. It is a requirement in Scotland, and best practice throughout the UK, that the signature pages of the Agreement are part of the body of the Agreement. Please therefore ensure that the last clause of the Agreement appears on the same page as the signature block.*

# Appendix 1 – Financial Arrangements and Supplies

[This section has been left blank to be agreed and completed between the Parties. It should be consistent with Clause 11 and reflect the tasks within the Work Plan in Appendix 2. This section should list the payment amounts, frequency of payment and invoicing arrangements. Where there are supplies or equipment provided to the Other Trial Site, full details should also be included in this section including the management of the investigational medicinal product(s) where applicable.]

# Appendix 2 – Other Trial Site Duties as required by the Protocol and instructed by the Lead Trial Site “Work Plan”

[This section has been left blank to be agreed and completed between the Parties. Please note that where duties include the transfer of any clinical biological sample, or portion thereof derived from Participants’ “Material”, Appendix 4 should be adhered to. Where the Other Trial Site is agreeing any task within this Work Plan, they are confirming that they are adhering to appropriate legislation and clinical governance, they have the suitable facilities, staffing, expertise and licensing to complete the Work Plan, and have and receive the appropriate training e.g. GCP, Study specific, Immunology etc. For ease, please divide Appendix 2 into 4 sections headed: Set-up / close down, Location management, Screening, dosing and follow-up, and Unscheduled events. Include a bulleted list of all the agreed tasks required in the Work Plan.]

**The following is an example which may be used**:

**Set-up / close down**

The Other Trial Site will:

* release relevant Other Trial Site Personnel as applicable to attend weekly planning and set up meetings with the Principal Investigator and the Lead Trial Site team ahead of the planned study date according to a standard agenda;
* provide to the Principal Investigator and the Lead Trial Site team a weekly record, and report planning progress working with the Lead Trial Site team to plan and implement Study set up and close down as per the Protocol;
* share information and documentation with the Lead Trial Site that is required to support confirmation of capacity and capability by the Lead Trial Site;
* ensure Other Trial Site Personnel complete all required Study related and professional training;
* assure the Principal Investigator of the overall Study conduct of processes and Other Trial Site Personnel at the Other Trial Site;
* ensure Other Trial Site Personnel demonstrate clear understanding of the Protocol, and read and understand Investigator’s Brochure (IB) including potential risks and side effects of the investigational medicinal product / device, according to the role and responsibilities of each Other Trial Site Personnel within the Study team, and as confirmed by the delegation log signed by the Principal Investigator;
* in accordance with the Protocol, and required as part of the delegated roles and responsibilities within the Study delegation log, ensure all required documents reviewed by the research ethics committee that have subsequently been reviewed by the Principal Investigator are read, understood and implemented / actioned.
	+ At a minimum these documents will include:
	+ Protocol, Protocol amendments and administrative changes
	+ Participant information sheet(s), informed consent form(s) and all revisions
	+ Communications and advertisements, written information to be provided to the Participants
	+ Investigator brochure & all IND safety reports
	+ Serious adverse events
	+ Deviations / violations / exemptions
	+ Annual reports
* file all Study documentation and related correspondence within the Lead Trial Site File held by the Lead Trial Site;
* ensure records are available for routine monitoring and inspection by Sponsor or regulatory authorities;
* inform the Principal Investigator immediately of any pending regulatory inspection;
* ensure that the Other Trial Site Personnel are available for monitoring visits;
* attend all Study related meeting required by Principal Investigator and Sponsor.

**Location management**

The Other Trial Site will:

* identify and agree a location or locations for Study delivery with the Lead Trial Site and the Principal Investigator;
* provide assurance that the location or locations is/are compliant with health and safety and security and infection prevention and control policies and standards;
* ensure the Other Trial Site is specifically and sufficiently mitigated in relation to cyber and anti vax protester security risks;
* provide adequate equipment and facilities, prepared and fit for purpose for the delivery of the proposed Study to comply with the Protocol specification;
* ensure the Other Trial Site has appropriate information technology software, hardware and technical support;
* ensure the Other Trial Site has contact telephone numbers for relevant Study-related information;
* provide name and contact information for an operational / research delivery single point of contact and at least one member of Personnel at the Other Trial Site;
* ensure the Other Trial Site has adequate car parking, access and participant flow capacity to support the delivery of the Protocol.

**Screening, dosing and follow up**

The Other Trial Site will:

* work with the Lead Trial Site to identify eligible Participants for the Study;
* monitor and report screening attendance and screen failures as directed by the Principal Investigator and Sponsor;
* identify Personnel to manage and assure the Principal Investigator of documented accountability of all investigational medicinal product and supplies according to Protocol and related SOPs;
* provide a clinic schedule that is accessible to the target Participant population;
* verify identification of all Participants attending for any Study visit;
* obtain informed consent and deliver all Study visit related activities according to the Protocol;
* maintain adequate and accurate records including clinic attendance and all Protocol procedures;
* ensure data in eCRFs can be verified / signed-off in line with documented information in the source documents;
* provide safety reports to the Principal Investigator for assessment of causality within the timelines stated within the Protocol;
* report all serious adverse events to the Principal Investigator;
* assess and notify the Principal and Sponsor of GCP breaches;
* report Study performance data and monitor research delivery to time and target;
* Escalate issues around recruit to time and target to facilitate resolution.

**Unscheduled events**

The Other Trial Site will:

* provide out of hours medical telephone cover as defined by the Protocol and as delegated by the Principal Investigator. Manage unscheduled events as stated in the Protocol;
* identify a location within the Other Trial Site suitable for the delivery of unscheduled visits in accordance with the Participants’ needs and Protocol requirements;
* provide a mechanism for home visits as required and defined by the Protocol and / or identified by the Lead Trial Site or Sponsor;
* maintain adequate and accurate records including unscheduled clinic attendance and all unscheduled Protocol procedures;
* ensure data in eCRFs can be verified / signed-off in line with documented information in the source documents where applicable and as per the Protocol;
* provide safety reports to the Principal Investigator for assessment of causality within the timelines stated within the Protocol;
* report all serious adverse events to the Principal Investigator.

# Appendix 3 – Principal Investigator Oversight of Duties Listed in the Work Plan

[This section includes only optional, suggested text and guidance to be agreed and completed between the Parties. In addition to the obligations of Clauses 3 and 4 of the min Agreement, this section, provides details of task specific Principal Investigator oversight.]

# The following is an example which may be used:

**PI responsibilities as identified in the most up to date approved version of the Protocol and summarised as followed:**

Chair OMG for study and meet weekly with Sub Investigators and delivery team with a standard agenda

Read and understand Investigator’s Brochure (IB) including potential risks and side effects of the investigational medicinal product (IMP) / device

Demonstrate clear understanding of Study Protocol

Completion of all required Study related and professional training

Be accountable for the overall Study conduct of processes and Study staff at the Other Trial Site

Review and sign off delegation logs and sign off training

Oversee the accountability of all IMPs and supplies

Provide oversight of all safety reports and assessment of causality

Report all serious adverse events to the Sponsor

Notify the Sponsor of potential Protocol or GCP breaches

Report Study performance data and monitor research delivery to time and target.

Escalate issues around recruit to time and target to facilitate resolution

Maintain adequate and accurate records

Ensure data in eCRFs can be verified / signed-off in line with documented information in the source documents where applicable and as per the Protocol

Ensure records are available for routine monitoring and inspection by the Sponsor or regulatory authorities

Inform the Other Trial Site immediately of any pending regulatory inspection

Oversee and ensure that both you and your staff be available for monitoring visits

Attend all Study related meetings required by the Sponsor

Disclose any changes in their financial relationship to the Sponsor

# Appendix 4 – Material Transfer Provision

Where the Protocol requires the Other Trial Site to supply Material to the Sponsor, or the Lead Trial Site, this Appendix 4 shall apply. **For the purpose of this Appendix 4** **only**, the Lead Trial Site has procured through the mNCA that the Sponsor is liable and responsible of the activities in which the Sponsor is referenced in this Appendix.

1. In accordance with the Protocol, the Other Trial Site shall send Material to the Sponsor or the Lead Trial Site, or, in accordance with Section 7 below, to a third party nominated by the Sponsor.
2. Both Parties warrant that all Material has been collected with appropriate informed consent and has been collected and handled in accordance with applicable law (including, without limitation, the Human Tissue Act 2004) and as required by the Protocol.
3. Subject to Section 2 above, the Material is supplied without any warranty, expressed or implied, including as to its properties, merchantable quality, fitness for any particular purpose, or freedom from infection.
4. The Sponsor shall ensure, or procure through an agreement with the Sponsor’s nominee as stated in Section 1 above, that:
	1. the Material is handled and stored in accordance with applicable law;
	2. the Material shall not be redistributed or released to any person other than in accordance with the Protocol or for the purpose of undertaking other research approved by an appropriate ethics committee and in accordance with the Participant’s consent.
5. Both Parties and the Sponsor shall comply with all relevant laws, regulations and codes of practice governing the Study and the use of human biological material.
6. Both Parties and the Sponsor shall each be responsible for keeping a record of the Material that has been transferred according to this Appendix 4.
7. To the extent permitted by law, the Other Trial Site and its Personnel shall not be liable for any consequences of the supply to or the use by the Sponsor of the Material, or of the supply to or the use by any third party to whom the Sponsor subsequently provides the Material, or the Sponsor’s nominee as stated in Section 1 above, save to the extent that any liability that arises is a result of the negligence of the Other Trial Site.
8. The Sponsor undertakes that, in the event that Material is provided to a third party in accordance with Section 1 above, it shall require that such third party shall undertake to handle any Material related to the Study in accordance with all applicable statutory requirements and codes of practice and under terms no less onerous than those set out in this Appendix 4.
9. Unless otherwise agreed, any surplus Material that is not returned to the Other Trial Site or retained for future research shall be destroyed in accordance with the Human Tissue Act 2004.

**FINAL PAGE**