[**INSERT** FULL NAME OF THE CLINICAL TRIAL]

[**INSERT** PROTOCOL REFERENCE NUMBER]

# Model Agreement for Hub and Spoke Arrangements Between Lead Trial Sites and Other Trial Sites for Commercially Sponsored Clinical Trials

Between

[INSERT NAME and ADDRESS OF NHS ORGANISATION which is the named Lead Trial Site for the Clinical Trial]

**“Lead Trial Site”**

AND

[INSERT NAME and ADDRESS OF [NHS ORGANISATION/UNIVERSITY which is the Other Trial Site to the named Lead Trial Site for the Clinical Trial]

**“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, [**INSERT NAME**], is a pharmaceutical company or commercial organisation involved in the research, development, and manufacture of medicines for use in humans;
2. 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 Clinical Trial;
3. The Lead Trial Site has a particular interest and expertise in [INSERT DETAILS];
4. The Sponsor has contracted with the Lead Trial Site to undertake the Clinical Trial using the template Head Agreement;
5. The terms of this Agreement will be subject to the Head Agreement agreed by the Lead Trial Site and the Sponsor;
6. The Other Trial Site is an NHS Organisation or University involved in the provision of healthcare, concerned with the treatment and prevention of disease and/or clinical research for the improvement of healthcare;
7. If the Other Trial Site and the Lead Trial Site are both NHS Organisations, then this agreement is an NHS agreement;
8. [**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;
9. The Other Trial Site wishes to contract with the Lead Trial Site to provide services identified in this Agreement for the purpose of the Clinical Trial;
10. References throughout this Agreement to Sponsor shall be construed to include reference to [**XXXX]**, as Affiliate empowered by the Sponsor to legally bind the Sponsor to the Head Agreement between Sponsor and the Lead Trial Site.

It is therefore, agreed that the following terms and conditions shall apply to the conduct of the duties undertaken by the Other Trial Site for the purpose of the Clinical Trial (as further defined below):

## Definitions

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

**Affiliate**
means any business entity that controls, is controlled by or is under the common control with the Sponsor, save where there are contractual arrangements in place to exclude such affiliate. For the purposes of this definition, a business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity;

**Agent**shall include but is not limited to, any person providing services to either Party under a contract for services (commonly known as an honorary contract or Letter of Access) or otherwise any such person’s principal employer in the event that it is not either of the Parties 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 amendments made thereto in accordance with Clause 13.1;

**[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 Trial**
means the clinical trial to be conducted with the Principal Investigator oversight at the Lead Trial Site and Other Trial Site in accordance with the Protocol;

**Clinical Trial Subject**
means a person enrolled to participate in the Clinical Trial according to criteria detailed in the Protocol. For the purposes of this Agreement this may also include persons identified by the Other Trial Site as potential Clinical Trial Subjects, prior to their enrolment and irrespective of whether they are enrolled if they have been identified by the Other Trial Site;

**Confidential Information**means all confidential information (however recorded or preserved) disclosed by a Party, and/or its Affiliate, **[[FOR OPTIONAL USE ONLY WITH WELSH TRIAL SITES AND OTHER TRIAL SITES]** Central Management Function]], and or the Sponsor of the Clinical Trial, to a Party, in connection with the Clinical Trial, which is information that would be regarded as confidential by a reasonable business person, including (but not limited to):

* business, affairs, plans, intentions or market opportunities
* operations, processes, product information, designs, trade secrets or Know-How
* any information developed by the Parties in connection with the Clinical Trial in the course of carrying out this Agreement
* the Protocol, the Investigator Brochure(s) relating to the Clinical Trial and Appendix 1 to this Agreement (‘Financial Arrangements and Supplies’);

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

**Data Protection Laws and Guidance**
means the GDPR, the Data Protection Act 2018, the Privacy and Electronic Communications (EC Directive) Regulations 2003, 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**shall have the meaning set out in the Data Protection Laws and Guidance;

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

**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;

**Head Agreement**means the agreement between the Lead Trial Site and the Sponsor that governs the conduct of the Clinical Trial at the Lead Trial Site, being based upon an unmodified model Clinical Trial Agreement (mCTA), Clinical Research Organisation model Clinical Trial Agreement (CRO-mCTA), or Primary Care mCTA;

**ICH GCP**
means the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95); together with such other Good Clinical Practice requirements as may apply within the UK from time to time, including the requirements of any regulations made under regulation 57 of the Medicines for Human Use (Clinical Trials) Regulations 2004/1031 (as amended by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019) and any relevant guidance issued under those Regulations and, in the case of Northern Ireland, any applicable EU requirement;

**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;

**Investigational Medicinal Product “IMP”**means the product that is being studied as detailed in the Protocol;

**Know-How**
means all technical and other information that is not in the public domain (other than as a breach of confidence) including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, the Investigational Medicinal Product, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information contained in submissions to Regulatory Authorities, whether or not protected by Intellectual Property Rights or any applications for such rights;

**Lead Trial Site**

means the Party to this Agreement, contracted by the Sponsor to conduct the Clinical Trial and hereby subcontracting to the Other Trial Site duties related to that conduct, as per Appendix 2, to be overseen by the PI, as per Appendix 3;

**MHRA**means the Medicines and Healthcare products Regulatory Agency;

**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 Clinical Trial with ICH GCP and to conduct source data verification;

**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 Laws and Guidance and which relates to an actual or potential Clinical Trial Subject, and/or their treatment or medical history;

**Personal Data Breach**means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, Personal Data transmitted, stored or otherwise Processed;

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

**Process**

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

**Principal Investigator**
means the authorised health professional responsible for the conduct of the Clinical Trial at both the Lead Trial Site and Other Trial Site, and if the Clinical Trial 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 Clinical Trial with the reference number set out on the front page of this Agreement, together with any amendments thereof made in accordance with the Head Agreement, and incorporated into this Agreement by reference;

**Pseudonymised Data**means individual-level data relating to a natural person (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;

**Regulatory Authority**means any regulatory authority responsible for the review and approval of the Clinical Trial and (where applicable) the use of the IMP;

**Results**
means the research findings produced in the Clinical Trial;

**Investigator Site File**means the file maintained by the Principal Investigator containing the documentation specified in Section 8 of the ICH GCP (Edition CPMP/ICH/135/95);

**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 Clinical Trial;

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

**SUSAR**means Suspected Unexpected Serious Adverse Reaction and shall have the definition set out in the Medicines for Human Use (Clinical Trials) Regulation 2004;

**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 provided, however, that the provisions of the Declaration of Helsinki relating to post-trial supply of IMP (as further defined herein) shall be those that are explicitly indicated in this Agreement and all subsequent modifications to or re-enactments of the Declaration of Helsinki, whether set out in a modification or amendment or otherwise, shall not apply to this Agreement.
	2. The headings to clauses are inserted for convenience only and shall not affect the interpretation or construction of this Agreement.
	3. Where appropriate, words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders.
	4. A reference to this Agreement or to any other agreement or document referred to in this Agreement is a reference to this Agreement or such other agreement or document as amended, varied or novated (in each case other than in breach of the provisions of this Agreement) from time to time.

## Principal Investigator and Personnel

* 1. The Other Trial Site represents that it is entitled to procure and will procure the services of the Sub-Investigator(s) to fulfil the functions required in this Agreement, as required by the Protocol, and as instructed by the Principal Investigator, as outlined in Appendix 2.
	2. The Lead Trial Site represents that it is entitled to procure and will procure the services of the Principal Investigator [[**FOR OPTIONAL USE ONLY WITH WELSH TRIAL SITES AND OTHER TRIAL SITES**] and the Central Management Function]], and represents that the Principal Investigator holds the necessary registration and has the necessary expertise, time and resources to perform the Clinical Trial. The Lead Trial Site shall ensure that the Principal Investigator is made aware of and acknowledges the obligations applicable to the Principal Investigator, as set out in this Agreement, including but not limited to those set out in Appendix 3.
	3. The Other Trial Site represents that the Sub-Investigator and Personnel have the necessary time and resources to perform the Clinical Trial. The Other Trial Site shall ensure that the Sub-Investigator and Personnel are made aware and acknowledge the obligations application to them as set out in this Agreement, including but not limited to those set out in Appendix 2.
	4. The Other Trial Site will ensure that the Sub-Investigator and/or other Personnel as appropriate, attend any meetings regarding the Clinical Trial as reasonably requested by the Lead Trial Site (“Clinical Trial 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 Clinical Trial Meetings. [The Lead Trial Site shall reimburse or pay for reasonable pre-approved expenses for attendance at the Clinical Trial Meetings upon receipt of sufficient evidence. It is further agreed that any such expenses will be paid at the rate of fair market value. Such expenses may be publicly reportable. **DELETE IF NOT APPLICABLE**]
	5. The Other Trial Site represents that, where applicable, it will support the Sub Investigator and Personnel to make good faith diligent efforts to ensure the completion of all case report forms (CRFs) in a timely manner under the instruction and oversight of the Principal Investigator.

## Clinical Trial Governance

* 1. The Lead Trial Site shall inform the Other Trial Site of the name and telephone number of the Trial Monitor and the name of the person who will be available as a point of contact. The Lead Trial Site shall also provide the Principal Investigator with an emergency telephone number to enable serious adverse event reporting at any time.
	2. To the extent applicable to each, the Parties shall comply with, and shall ensure that their respective Personnel who are providing any manner of service related to the Clinical Trial comply with, all relevant laws including but not limited to:
		1. The Human Rights Act 1998;
		2. The Data Protection Laws and Guidance;
		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. The Medicines Act 1968;
		5. The Human Medicines Regulations 2012;
		6. The Medicines for Human Use (Clinical Trial) Regulations 2004;
		7. The Bribery Act 2010;
		8. Relevant law having effect by virtue of ss2-4 of the European Union (Withdrawal) Act 2018;
		9. (In Northern Ireland) laws of the European Union having effect as a result of the Protocol on Ireland/Northern Ireland.
	3. The Parties shall comply with, and shall ensure that their respective Personnel who are providing any manner of service related to the Clinical Trial comply with, all relevant guidance relating to medicines and clinical trials from time to time in force, including but not limited to:
		1. the ICH-GCP;
		2. GMP;
		3. GVP;
		4. the World Medical Association Declaration of Helsinki entitled, “Ethical Principles for Medical Research Involving Human Subjects (1996)”;
		5. the Research Governance Framework;
		6. the Medical Research Council Guidelines entitled, “Human Tissue and Biological Samples for Use in Research,”;
		7. [**DELETE IF NOT APPLICABLE** – the ethical principles set out in WHA63.22 (<http://www.who.int/transplantation/en/>) with regard to the Clinical Trial.]

In addition, where the Clinical Trial is conducted as part of an IND, the Other Trial Site will comply with any other relevant requirements notified by the Lead Trial Site to the Other Trial Site.

* 1. The Lead Trial Site represents that the Sponsor has committed to comply with the ABPI Clinical Trial Compensation Guidelines.
	2. The Parties shall ensure that any members of their respective Personnel joining the Clinical Trial following the initiation of the Clinical Trial, undertake any such appropriate training as the Lead Trial Site or Principal Investigator may consider necessary for the conduct of the Clinical Trial, including but not limited to the training and provision of information given during Investigator Meetings.
	3. **Adverse Event Reporting**
	Both Parties acknowledge the obligation to comply with the Protocol and/or applicable regulations governing the collection and reporting of adverse events of which they may become aware during the course of the Clinical Trial. Both Parties agree to fulfil and ensure that their Agents fulfil regulatory requirements with respect to the reporting of adverse events.
	4. **Anti-Bribery and Corruption**
		1. Each Party warrants and represents that:
1. It has not committed any offence under the Bribery Act 2010 or any of the following acts (“Prohibited Acts”):
2. other than in accordance with applicable laws, valid agreements and the provisions of this Agreement, offered, given or agreed to give any officer or employee of the other Party any gift or consideration of any kind, as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this Agreement or any other agreement with the other Party or for showing or not showing favour or disfavour to any person in relation to this Agreement or any other agreement with the other Party; or
3. in connection with this Agreement, paid or agreed to pay any commission other than a payment in accordance with this Agreement that has not otherwise been disclosed in writing to the other Party.
	* 1. If either Party has committed or commits any of the Prohibited Acts or has committed or commits any offence under the Bribery Act 2010 in relation to this Agreement, the other Party shall be entitled to terminate this Agreement in accordance with Clause 12, in addition to any other remedy available, taking into consideration the potential effects of termination on the health of Clinical Trial Subjects.

## Obligations of the Parties

* 1. The Other Trial Site shall permit the Lead Trial Site access to the records of Clinical Trial Subjects to the extent considered necessary by the Lead Trial Site and the Principal Investigator for the safety of Clinical Trial Subjects. The Other Trial Site shall also permit access for the Monitor, such access to be arranged at mutually convenient times and on reasonable notice.
	2. The Lead Trial Site confirms that the Principal Investigator shall be responsible for reporting adverse events as outlined in the Protocol.
	3. The Lead Trial Site confirms that if the Principal Investigator is not present at the Other Trial Site at the time the adverse event has occurred or has been recorded, the Principal Investigator will assess the causality and categorisation of the adverse event remotely.
	4. The Other Trial Site confirms that in the event of Clause 5.3, the Sub-Investigator will support the Principal Investigator in his assessment of the causality and categorisation of the adverse event.
	5. Where it is not possible to determine remotely the causation and categorisation of the adverse event, the Principal Investigator will visit the Other Trial Site to complete a full assessment within the timeframe and obligations stipulated in the Protocol.
	6. The Lead Trial Site confirms that if the Principal Investigator has assessed and determined that the adverse event is categorised as a SUSAR, the Principal Investigator will call an urgent Clinical Trial meeting (“**Exceptional Investigator Team Meeting**”). The Exceptional Investigator Team Meeting will consist of the Principal Investigator (chair), the Sub-Investigator and (where appropriate) other Personnel to discuss the causation and categorisation. The Principal Investigator will complete all the appropriate reporting documents within the timeframe and obligations stipulated in the Protocol.
	7. The Lead Trial Site confirms that through the Head Agreement between itself and the Sponsor, the Sponsor has confirmed that during the course of the Clinical Trial, if the Sponsor becomes aware of any information relating to the IMP which may impact the Clinical Trial, the Sponsor will notify the Lead Trial Site promptly, and within seven (7) calendar days of becoming aware of the information, and if requested to do so, the Sponsor will provide a report detailing the information which will be disseminated by the Lead Trial Site to the Sub Investigator and Personnel as a matter of urgency.
	8. Subject to Clause 12, the Other Trial Site shall inform the Lead Trial Site within 24 hours of becoming aware of any situation which it considers would render it unable to complete its obligations under this Agreement.
	9. [**DELETE IF NOT APPLICABLE**]**Equipment and Resources**
	The Parties agree that the Lead Trial Site/Sponsor shall arrange for the provision of the equipment and resources to the Other Trial Site, pursuant to the terms set out in Appendix 5.

## Liability

* 1. Both Parties acknowledge that the Lead Trial Site has entered into a Head Agreement between itself and the Sponsor setting out the indemnity provided by the Sponsor.
	2. Both Parties acknowledge that the Other Trial Site is a contracted Agent of the Lead Trial Site.
	3. Subject to Clause 6.1 the Other Trial Site acknowledges that its liability to the Sponsor and/or Lead Trial Site shall not exceed the level of liability of the Lead Trial Site to the Sponsor in the Head Agreement. 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 Head Agreement.
	4. In the event of any claim or proceeding in respect of personal injury made or brought against the Lead Trial Site or Other Trial Site by a Clinical Trial Subject, the Lead Trial Site represents that the Sponsor shall indemnify the Lead Trial Site and Other Trial Site, their Agents and employees in accordance with the terms of the indemnity set out in the ABPI Clinical Trials Compensation Guidelines 2015 and the ABPI Form of Indemnity.
	5. Nothing in this Clause 6 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 in contract, tort or delict (if the Other Trial Site is constituted in Scotland) (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

* 1. The Parties agree:
		1. to comply with all Data Protection Laws and Guidance in Processing the Personal Data of actual and potential Clinical Trial Subjects. This Clause 7 is in addition to and does not replace, relieve or remove a Party’s obligations or rights under the Data Protection Laws and Guidance.
		2. When one Party is Processing Personal Data, as Controller, for which the other Party, or the Sponsor, is at that time a separate and independent Controller, to promptly and without undue delay, notify and inform that other Party in the event of any Personal Data Breach that relates to that Personal Data.
	2. **Processing of the Personal Data of potential and actual Clinical Trial Subjects**:
		1. For the purpose of the Data Protection Laws and Guidance, the Sponsor is the Controller, the Lead Trial Site is the Processor and the Other Trial Site is the Sub-Processor of the Lead Trial Site in relation to Personal Data Processed for the purpose of the Clinical Trial.
		2. The Other Trial Site’s Processing of Personal Data as a Sub-Processor of the Lead Trial Site shall be governed by this Agreement, including the Protocol, which sets out the subject matter, duration, nature and purpose of the Processing, the type of Personal Data and the categories of Data Subjects, and obligations and rights of the Sponsor as Controller.
		3. The Other Trial Site is the Controller of Personal Data Processed for its own purposes other than the Clinical Trial, e.g. the provision of medical care.
		4. The Other Trial Site, in its role as Sub-Processor of the Personal Data under Clause 7.2.1, agrees to only Process Personal Data for and on behalf of the Lead Trial Site in accordance with the documented instructions of the Sponsor and/or Lead Trial Site, including with regard to transfers of Personal Data to a third country or an international organisation. If the Other Trial Site is required by law to otherwise Process the Personal Data, the Other Trial Site shall notify the Lead Trial Site before undertaking the Processing, or as soon as possible thereafter unless such notification is prohibited on important grounds of public interest in accordance with GDPR Article 28(3)(a). In the case of such prohibition, the Other Trial Site shall notify the Lead Trial Site as soon as possible once the prohibition is lifted, if it is lifted.

* + 1. The Other Trial Site agrees to comply with the obligations applicable to Processors described by Article 28 of the GDPR, as well as those additional obligations required by Lead Trial Site pursuant to this Agreement, including but not limited to the following:
1. implementing and maintaining appropriate technical and organisational security measures for Personal Data Processed in its systems, in keeping with its obligations as an NHS organisation, thereby providing guarantee to the Sponsor pursuant to GDPR Article 28(1);
2. ensuring that Personnel authorised to Process Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality (Article 28(3)(b);
3. taking all measures required by GDPR Article 32 in relation to the security of Processing (GDPR Article 28(3)(c);
4. subject to Clause 72.6, complying with the conditions described in GDPR Article 28(2) and (4) for engaging another Processor (GDPR Article 28(3)(d);
5. taking into account the nature of the Processing, assist the Sponsor and/or the Lead Trial Site, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising Data Subjects’ rights (GDPR Article 28(3)(e);
6. assisting the Controller, to ensure compliance with the obligations pursuant to GDPR Articles 32 to 36, taking into account the nature of the Processing and the information available to the Other Trial Site (GDPR Article 28(3)(f);
7. maintaining a record to demonstrate compliance with this Clause and Data Protection Laws and Guidance, including the records required pursuant to GDPR Article 30(2);
8. in the event of any Personal Data Breach by the Other Trial Site as a Sub-Processor of the Lead Trial Site, the Other Trial Site shall:
(i) promptly and without undue delay following discovery of such Personal Data Breach, send written notice of the incident via email to [insert]; (ii) not make any statements or notifications about the Personal Data Breach, as it relates to the Processing for the purpose of the Clinical Trial, to any individual affected by the incident, the public or any third party without Sponsor or Lead Trial Site’s prior written approval; and (iii) immediately take steps to investigate and mitigate the Personal Data Breach and reasonably cooperate with the Sponsor and the Lead Trial Site.
	* 1. In furtherance of its obligations under Article 28 GDPR, the Other Trial Site agrees that it will not engage another Processor for the purpose of the Clinical Trial without the prior written authorisation of the Sponsor and Lead Trial Site (GDPR Article 28(2)).
		2. At the expiry or lapse of this Agreement, the Other Trial Site shall, at the choice of the Lead Trial Site, destroy or return all Personal Data to the Sponsor or Lead Trial Site unless there is a legal requirement for retention and storage (GDPR Article 28(3)(g) and/or where that Personal Data is held by the Other Trial Site as Controller for its own purpose(s).
		3. The Other Trial Site will:
9. ensure that its Personnel do not Process Personal Data except in accordance with the Protocol and this Agreement;
10. take all reasonable steps to ensure the reliability and integrity of any of its Personnel who have access to the Personal Data and will ensure that the Personnel:
11. are aware and comply with the Other Trial Site’s duties under this Clause 7 (Data Protection);
12. are subject to mandatory training in their information governance responsibilities and have appropriate contracts, including sanctions, including for breach of confidence or misuse of Personal Data; and
13. are informed of the confidential nature of the Personal Data and understand their responsibilities for information governance, including their obligation to Process Personal Data securely and to only disseminate or disclose it for lawful and appropriate purposes.
	* 1. The Other Trial Site agrees to:
14. provide the Lead Trial Site with evidence of its compliance with the obligations set out in this Agreement at the Lead Trial Site discretion and on reasonable notice, to allow the Sponsor, Lead Trial Site or a third party appointed by the Sponsor or Lead Trial Site, to audit the Other Trial Site’s compliance with the obligations described in this Agreement, Data Protection Laws and Guidance (including but not limited to Article 28 GDPR), subject to the Sponsor, Lead Trial Site or appointed third party, complying with all relevant health and safety and security policies of the Other Trial Site;
15. obtain prior written agreement of the Sponsor or Lead Trial Site to Process Personal Data outside of the UK and the EEA.
	* 1. In addition to the Other Trial Site’s obligations under Clause 7.2.9, where the Other Trial Site, acting as the Lead Trial Site’s Sub-Processor, Processes Personal Data outside of the UK and the EEA, the Other Trial Site warrants that it does so in compliance with the Data Protection Laws and Guidance.
	1. **Sharing of Personal Data and/or Clinical Trial Subject or Potential Subject Pseudonymised Data**:
		1. Neither Personal Data nor Pseudonymised Data of Clinical Trial Subjects shall be transferred by the Other Trial Site to the Lead Trial Site or Sponsor unless this is required directly or indirectly to satisfy the purposes of this Agreement, or for the purposes of monitoring and reporting of adverse events or in relation to a claim or proceeding brought by an actual or potential Clinical Trial Subject in connection with the Clinical Trial or is otherwise required by applicable law.
		2. The Lead Trial Site agrees not to pass Personal Data or Pseudonymised Data of Clinical Trial Subjects provided under this Agreement to a third party unless that third party is bound by contractual obligations at least as stringent as in this Clause 7.
		3. The Lead Trial Site agrees to use Personal Data and/or Pseudonymised Data of Clinical Trial Subjects / potential Subjects for the purpose of the Clinical Trial and in all circumstances for no purpose which is incompatible with the Clinical Trial purpose. The Lead Trial Site further agrees not to disclose the Personal Data or Pseudonymised Data of Clinical Trial / Investigation Subjects / potential Subjects to any person except as required or permitted by law or applicable guidance.
		4. The Lead Trial Site confirms that the Sponsor has agreed to comply with the obligations placed on the Sponsor as a Controller pursuant to Data Protection Laws and Guidance, including but not limited to demonstrating compliance with the principles relating to Processing of Personal Data (Article 5 GDPR).
		5. The Lead Trial Site confirms that the Sponsor has agreed to ensure that persons Processing Personal Data and/or processing Pseudonymised Data of actual or potential Clinical Trial / Investigation Subjects under this Agreement are equipped to do so respectfully and safely. In particular:
16. to ensure any such persons (excluding employees, honorary employees, students, researchers, consultants and sub-contractors of the Other Trial Site or Lead Trial Site) understand the responsibilities for information governance, including their obligation to Process Personal Data and/or Pseudonymised Data of Clinical Trial Subjects securely and to only disseminate or disclose for lawful and appropriate purposes;
17. to ensure any such persons (excluding employees, honorary employees, students, researchers, consultants and sub-contractors of the Participating Organisation or Lead Trial Site) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable Personal Data Breaches.
	* 1. The Lead Trial Site agrees to take reasonable steps to proactively prevent Personal Data Breaches, and/or equivalent breaches relating to Pseudonymised Data of Clinical Trial Subjects, and to respond appropriately to incidents or near misses. In particular:
18. to ensure that Personal Data and/or Pseudonymised Data of Clinical Trial Subjects are only accessible to persons who need it for the purposes of the Clinical Trial and to remove access as soon as reasonably possible once it is no longer needed;
19. to ensure all access to Personal Data and/or Pseudonymised Data of Clinical Trial Subjects on IT systems Processed for Clinical Trial purposes can be attributed to individuals;
20. to review processes to identify and improve processes which have caused Personal Data Breaches or near misses, or which force persons Processing Personal Data and/or processing Pseudonymised Data of Clinical Trial Subjects to use workarounds which compromise data security;
21. to adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice;
22. to take action immediately following a Personal Data Breach or near miss.
	* 1. The Lead Trial Site agrees to ensure Personal Data and/or Pseudonymised Data of Clinical Trial Subjects are Processed/processed using secure and up to date technology. In particular:
23. to ensure no unsupported operating systems, software or internet browsers are used to support the Processing of Personal Data and/or processing of Pseudonymised Data of Clinical Trial Subjects for the purposes of the Clinical Trial;
24. to put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework;
25. to ensure IT suppliers are held accountable via contracts for protecting Personal Data and/or Pseudonymised Data of Clinical Trial Subjects they Process/process and for meeting all relevant information governance requirements.
	1. **Intellectual Property**
		1. All Intellectual Property Rights and Know-How owned by or licensed to either Party or the Sponsor, or Affiliate(s) of either Party or the Sponsor, prior to and after the date of this Agreement, other than any Intellectual Property Rights and Know-How arising from the Clinical Trial, are and shall remain, the property of the relevant Party or the Sponsor.
		2. All Intellectual Property Rights and Know-How arising from and relating to the Clinical Trial / Investigation, the IMP (including but not limited to the formulation of the IMP, where applicable, and used alone or in combination with other drugs), and/or the Protocol, but excluding any clinical procedure and improvements thereto that are clinical procedures of the Lead Trial Site or Other Trial Site, shall vest in the Sponsor in accordance with Clauses 7.4.3 and 7.4.4 of this Agreement.
		3. The Other Trial Site shall, and will ensure that its Agents shall, promptly disclose to the Lead Trial Site any Intellectual Property Rights or Know-How generated by the Other Trial Site or its Agents pursuant to this Agreement and undertakes not to use or disclose such Intellectual Property Rights or Know-How other than for the purposes of this Agreement.
		4. In accordance with Clause 7.4.2, the Other Trial Site hereby assigns, and shall procure that its Agents assign, its rights in relation to all Intellectual Property Rights and Know-How, falling within Clause 7.4.2, to the Sponsor or its nominee. At the request and expense of the Sponsor, the Other Trial Site shall execute, and shall procure that its Agents shall execute, all such documents and do all such other acts as the Sponsor may reasonably require in order to vest fully and effectively all such Intellectual Property Rights and Know-How in the Sponsor or its nominee.
		5. The Other Trial Site shall promptly disclose to the Lead Trial Site to disseminate to the Sponsor any Know-How generated pursuant to this Agreement and falling within Clause 7.4.4 and undertakes not to use or disclose such Know-How other than for the purposes of this Agreement.
		6. Nothing in this Clause 7.4 shall be construed so as to prevent or hinder the Other Trial Site from using Know-How gained during the performance of the Clinical Trial in the furtherance of its normal activities, to the extent that such use does not result in the disclosure or misuse of Confidential Information or the infringement of any Intellectual Property Right or Know-How of the Lead Trial Site or the Sponsor.

## Confidential Information

* 1. The Parties shall ensure that only those of their respective officers, Agents and employees (and in the case of the Lead Trial Site, those of the Sponsor and (if applicable) other parties who may have contractual rights in the Results or to develop the IMP (for example, through a license, collaborative agreement, Co-Promotion Agreement, Co-Development Agreement, etc. with Sponsor)) directly concerned with the carrying out of this Agreement, have access to the Confidential Information of the other Party. Each Party undertakes to treat as strictly confidential and not to disclose to any third party any Confidential Information of the other Party, save where disclosure is required by a Regulatory Authority or by law (including any disclosure required to ensure compliance by the Other Trial Site with the Freedom of Information Act 2000 or for Scotland, the Freedom of Information (Scotland) Act 2002). The Party required to make the disclosure shall inform the other Party, within a reasonable time prior to being required to make the disclosure of the requirement to disclose and the information required to be disclosed. Each Party undertakes not to make use of any Confidential Information of the other Party other than in accordance with this Agreement, without the prior written consent of the other Party.
	2. The obligations of confidentiality set out in this Agreement, shall not apply to information that is:
		1. published or becomes generally available to the public other than as a result of a breach of this Agreement by the receiving Party;
		2. in the possession of the receiving Party prior to its receipt from the disclosing Party, as evidenced by contemporaneous written evidence, and is not subject to a duty of confidentiality;
		3. independently developed by the receiving Party, as evidenced by contemporaneous written evidence and is not subject to a duty of confidentiality;
		4. obtained by the receiving Party from a third party that is not subject to a duty of confidentiality.
	3. In the event of a Party visiting the establishment of the other Party, 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.
	4. This Clause 8 shall remain in force without limit in time in respect of Personal Data and any other 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, this Clause 8 shall remain in force for a period of 10 years after the termination or expiry of this Agreement.

## Publications and Publicity

* 1. The Lead Trial Site represents that in the Head Agreement with the Sponsor, the Sponsor recognises that the Lead Trial Site and Principal Investigator have a responsibility under the UK Policy Framework for Health and Social Care to ensure that results of scientific interest arising from the Clinical Trial are appropriately published and disseminated.
	2. Subject to Clause 9.1, the Other Trial Site warrants that all intention and consideration for its Personnel to present at symposia, national or regional professional meetings, and/or to publish in journals of their own choice, the methods and/or Results of the Clinical Trial will not be permitted without the written consent of the Lead Trial Site [[FOR OPTIONAL USE ONLY IN WALES]and the Central Management Function]]. All requests will not unreasonably be withheld. This is to protect the Confidential Information clauses already agreed by the Lead Trial Site with the Sponsor.
	3. The Other Trial Site will not, and will ensure that the Personnel do not, use the name of the Sponsor, the Sponsor’s employees, nor the name of the Clinical Trial, nor the IMP in any publicity, advertising, statement to the press or news release without the prior written consent of the Lead Trial Site [[FOR OPTIONAL USE ONLY IN WALES]and the Central Management Function]].

## Financial and Supplies Arrangements

* 1. The Parties agree to financing of the Clinical Trial 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 Clinical Trial as set out in Appendix 1. Any such items provided by the Lead Trial Site or on behalf of the Lead Trial Site to the Other Trial Site shall be used only for the Clinical Trial and in accordance with the Protocol, or otherwise as agreed in Appendix 1.
	4. [DELETE IF NOT APPLICABLE] The Lead Trial Site shall use any Study Data, Material or other information provided by or derived from a Clinical Trial Subject, and provided by or on behalf of the Other Trial Site, in accordance with the consent provided by the Clinical Trial Subject 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 CRO or 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 Clinical Trial (which means the conclusion of all Protocol required activities for all enrolled Clinical Trial Subjects) and close-out of the Lead Trial Site or earlier termination in accordance with Clause 12 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. 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 Clinical Trial 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 Clinical Trial;
		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 supply of IMP, medical device, equipment or similar necessary for the Clinical Trial, or information or resources critical to the Clinical Trial;
		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 Clinical Trial 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 Clinical Trial Subject recruitment (where applicable) in accordance with Clause 12.6, the following provisions shall apply:
		1. The Parties shall work together to facilitate an orderly cessation of the Clinical Trial at the Other Trial Site (or cessation of recruitment of Clinical Trial Subjects where the Other Trial Site has chosen to cease recruiting in accordance with Clause 12.6), taking into account the rights, safety, well-being and continuity of treatment (if appropriate) of the Clinical Trial Subjects 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, in the event of cessation of recruitment of Clinical Trial Subjects where the Other Trial Site has chosen to cease recruiting in accordance with Clause 12.6, an amendment in writing signed by the Sponsor and the Lead Trial Site shall me 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 or Sponsor 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 or Sponsor including any continued monitoring of Clinical Trial Subjects in accordance with Protocol.
		5. The Other Trial Site shall ensure that all reasonable instructions by the Sponsor 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 Clinical Trial 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 Clinical Trial collected by the Other Trial Site in the course of carrying out the Clinical Trial 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 12 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. The Other Trial Site will notify the Lead Trial Site in accordance with Clause 12 if, for any reason, it elects to cease Clinical Trial Subjects recruitment.

## Agreement and Modification

* 1. Any amendments 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 Clinical Trial that is the subject of this Agreement.

## Force Majeure

* 1. Neither Party shall be liable to the other Party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, terrorist activity, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstances shall promptly notify the other Party in writing when such circumstances cause a delay or failure in performance (“a Delay”) and when they cease to do so. In the event of a Delay lasting for four (4) weeks or more, the non-affected Party shall have the right to terminate this Agreement immediately by notice in writing to the other Party.

## 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.]

* 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) 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) days.
	2. Where the Agreement is an NHS Contract as defined in Section 9(1) National Health Service Act 2006 or Section 17 National Health (Scotland) Act 1978 or Section 7 (1) of the NHS (Wales) Act 2006 or a HSS contract (now HSC contract) as defined in Article 8 of the Health and Personal Social Service (Northern Ireland) Order 1991 as applicable (“**NHS Contract**”), any dispute between the Parties not resolved in accordance with Clause 17.1 shall be referred for determination by:
		1. The Secretary of State for Health if both Parties are NHS Organisations in England;
		2. The Secretary of State and the Department of Health, Social Services and Public Safety acting jointly 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 17.2.1, 17.2.2, 17.2.3 or 17.2.4 acting jointly.
	3. Where the Agreement is not an NHS Contract and the Parties are unable to resolve a dispute in accordance with Clause 17.1, the Parties will attempt to resolve the dispute in accordance with the relevant subclause 17.3.1, 17.3.2 or 17.3.3, determined in accordance with Clause 19:
		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.
	4. 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.
	5. Any decision reached in accordance with this Clause 17 shall be final and binding upon the Parties.

## 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 6, 7, 8, 9, 16 and/or 18 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 expressly stated nothing in this Agreement shall confer or purport to confer on any third party any benefit or any right to enforce any term of this Agreement.
	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.
	6. **Survival of Clauses**
	The following clauses shall survive the termination or expiry of this Agreement:

**Clause 1** Definitions

**Clause 4**  Clinical Trial Governance

**Clause 4.14** Access, Research Misconduct and Regulatory Authorities

**Clause 6** Liabilities

**Clause 7** Data Protection

**Clause 8** Confidential Information

**Clause 9** Publications and Publicity

**Clause 12** Termination

**Clause 13** Agreement and Modification

**Clause 14** Force Majeure

**Clause 15** Notices

**Clause 17** Dispute Resolution

**Clause 18** General

## Governing Law

* 1. Where the Lead Trial Site is constituted in England, this Agreement shall be governed and construed in accordance with the laws of England and Wales and the Courts of England and Wales shall have exclusive jurisdiction to hear any dispute relating to this Agreement.

Where the Lead Trial Site is constituted in Wales, this Agreement shall be governed and construed in accordance with the laws of England and Wales as applied in Wales and the Courts of England and Wales shall have exclusive jurisdiction to hear any dispute relating to this Agreement.

Where the Lead Trial Site is constituted in Scotland, this Agreement shall be governed and construed in accordance with the laws of Scotland and the Courts of Scotland shall have exclusive jurisdiction to hear any dispute relating to this Agreement.

Where the Lead Trial Site is constituted in Northern Ireland, this Agreement shall be governed and construed in accordance with the laws of Northern Ireland and the Courts of Northern Ireland shall have exclusive jurisdiction to hear any dispute relating to this Agreement.

Signed by the duly authorised representatives of the Parties.

|  |  |
| --- | --- |
| Signed for and on behalf of:[INSERT LEAD TRIAL SITE DETAILS]Signature:Title: Date: | Signed for and on behalf of:[INSERT OTHER TRIAL SITE DETAILS]Signature:Title:Date |

# 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 10 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 IMP 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 Clinical Trial Subjects “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, Clinical Trial specific, Immunology etc. For ease, please divide Appendix 2 into 3 sections headed: Screening, Dosing and Follow Up and in a numbered list, list all the agreed tasks required in the Work Plan.]

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

**Set up/close down**

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 Clinical Trial 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 Clinical Trial related and professional training;
* assure the Principal Investigator of the overall Clinical Trial 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 IMP/device, according to the role and responsibilities of each Other Trial Site Personnel within the Clinical Trial 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 Clinical Trial delegation log, ensure all required EC/IRB reviewed documents 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
	+ Informed consent(s) and all revisions
	+ Communications and advertisements, written information to be provided to the Clinical Trial Subjects
	+ Investigator Brochure & all IND safety reports
	+ Serious Adverse Events
	+ Deviations/Violations/Exemptions
	+ Annual reports
* file all Clinical Trial documentation and related correspondence within the Lead Trial Investigator Site File held by the Lead Trial Site;
* ensure records are available for routine monitoring and inspection by Sponsor, CRO or regulatory authorities;
* inform the Principal Investigator and CRO immediately of any pending regulatory inspection;
* ensure that the Other Trial Site Personnel are available for monitoring visits;
* attend all Clinical Trial related meeting required by Principal Investigator and Sponsor.

**Location management**

Other Trial Site will:

* identify and agree a location or locations for Clinical Trial 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 Clinical Trial 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 Clinical Trial- 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 and dosing and follow up**

Other Trial Site will:

* work with the Lead Trial Site to identify eligible Clinical Trial Subjects for the Clinical Trial;
* 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 IMP and supplies according to Protocol and related SOPs;
* provide a clinic schedule that is accessible to the target Clinical Trial population;
* verify identification of all Clinical Trial Subjects attending for any Clinical Trial visit;
* obtain informed consent and deliver all Clinical Trial- 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 Clinical Trial performance data and monitor research delivery to time and target;
* Escalate issues around RTT to facilitate resolution.

**Unscheduled events**

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 Clinical Trial Subjects needs and Protocol requirements;
* provide a mechanism for home visits as 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;
* 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 has been left blank to be optionally agreed and completed between the Parties. In addition to the obligations of Clauses 3 and 5, this section, if required, provides details of task specific Principal Investigator oversight. This is an optional appendix and can remain blank as oversight requirements of the Principal Investigator are addressed in the Protocol which is referenced in this Agreement.]

# 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 standard agenda

Ensure the EC/IRB reviews and approves all required documents but at minimum:

 Protocol, protocol amendments and administrative changes

 Informed consent(s) and all revisions

Communications and advertisements, written information to be provided to the patient

 Investigator Brochure & all IND safety reports

 Serious Adverse Events

 Deviations/Violations/Exemptions

 Annual reports

Read and understand Investigator’s Brochure (IB) including potential risks and side effects of the 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 Investigational Product and supplies

Provide oversight of all safety reports and assessment of causality

Report all Serious Adverse Events to the Sponsor and IRB

Assess and Notify sponsor of GCP breaches

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

Escalate issues around RTT 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

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

Inform CRO immediately of any pending regulatory inspection

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

Attend all study related meeting required by sponsor

Disclose any changes in his/her financial relationship to the sponsor company

# 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**, reference to Sponsor should mean that the Lead Trial Site can confirm that the Sponsor has agreed through the terms of the Head Agreement between the Lead Trial Site and the Sponsor.

[DELETE IF NOT APPLICABLE]

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 warrants 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 item 1 above, that:
	1. the Material is used in accordance with the consent of the Clinical Trial Subject and the approval of all Regulatory Authorities for the Clinical Trial and the Protocol:
	2. the Material is handled and stored in accordance with applicable law;
	3. 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 Clinical Trial Subject’s consent.
5. Both Parties and the Sponsor shall comply with all relevant laws, regulations and codes of practice governing the Clinical Trial 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, wrongful acts or omissions or breach of statutory duty of the Participating Organisation or its Personnel, or their failure to comply with the terms of this Agreement.
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 Clinical Trial 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 Participating Organisation or retained for future research shall be destroyed in accordance with the Human Tissue Act 2004.

# Appendix 5 – Equipment and Resources

**[DELETE WHOLE APPENDIX IF NOT APPLICABLE. WHERE APPLICABLE, THE INFORMATION PROVIDED SHOULD DRAW AS RELEVENT FROM THAT SET OUT IN THE HEAD AGREEMENT]**

1. Sponsor-Provided Equipment

[ ]  Please check this box if no Equipment will be provided by the Sponsor

* 1. Sponsor will provide the CE-Marked equipment identified below (“**Sponsor Equipment**”) for use by the Other Trial Site in the conduct or reporting of the Clinical Trial:

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Equipment** | **Estimated Original Value** | **Depreciation** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Where applicable, the Sponsor Equipment will be provided with current records of calibration and electrical safety testing.

1. Sponsor-Provided Resources

[ ]  Please check this box if no Resources will be provided by the Sponsor

* 1. Sponsor will provide the Sponsor owned or licensed proprietary resources identified below (“**Sponsor Resources**”) for use by the Other Trial Site in the conduct or reporting of the Clinical Trial.
	2. Sponsor Resources Supplied: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
1. Permitted Uses of Sponsor Equipment and Sponsor Resources
	1. The Other Trial Site may use Sponsor Equipment and Sponsor Resources only for the purpose of this Clinical Trial.

[**Alternatively, specify permitted uses**. If use for non-Clinical Trial Subjects is permitted for Equipment, specify that (1) a charge will be assessed (deducted from Clinical Trial funding) based on estimated or actual usage or (2) the Trial Site agrees that use of the Equipment for non-Clinical Trial Subjects will not be charged to the patient or third-party payer. Non-Clinical Trial use of Sponsor Resources is generally not permitted.]

1. Disposition of Sponsor Equipment and Sponsor Resources

**Alternative #1 – Return to Sponsor**

After completion of the Clinical Trial at the Other Trial Site, or at an earlier time specified by Sponsor, the Sponsor or Lead Trial Site will contact the Other Trial Site to make arrangements for return of any [**Sponsor Equipment**] [and] [**Sponsor Resources**], at Sponsor’s expense, to the Sponsor or a location designated by Sponsor. The Other Trial Site’s responsibilities under this Agreement for the [**Sponsor Equipment**] [and] [**Sponsor Resources**] will cease or transfer to the Sponsor at the time of removal from the Other Trial Site.

**Alternative #2 – Return of Sponsor Resources to Sponsor and transfer of Sponsor Equipment to the Other Trial Site with value included in funding.**

After completion of the Clinical Trial at the Other Trial Site, or at an earlier time specified by Sponsor, the Sponsor or Lead Trial Site will contact the Other Trial Site to make arrangements for return of any [**Sponsor Equipment**] [and] [**Sponsor Resources**], at Sponsor’s expense, to the Sponsor or a location designated by Sponsor. The Other Trial Site’s responsibilities under this Agreement for the [**Sponsor Equipment**] [and] [**Sponsor Resources**] will cease or transfer to the Sponsor at the time of removal from the Other Trial Site.

The total compensation for Clinical Trial conduct allocated to the Other Trial Site has been calculated to include the estimated depreciated value of Sponsor Equipment at the termination of this Agreement. The Sponsor will transfer title or arrange for transfer of title in Sponsor Equipment to the Other Trial Site at the termination of this Agreement, provided that the Other Trial Site (through the Principal Investigator) has (where applicable) enrolled the targeted number of Clinical Trial Subjects (or some other number of Clinical Trial Subjects agreeable to the Sponsor), has complied with the terms of the Agreement and has satisfactorily completed all Protocol requirements. The Sponsor will ensure that this transfer is documented in writing and the Parties hereby acknowledge and agree that the estimated depreciated value of Sponsor Equipment at termination of this Agreement is part of the total compensation payable for Clinical Trial conduct.

If any Sponsor Equipment is so transferred, it will be transferred ‘as is’ and Sponsor does not make any representation or provide any warranty of any kind concerning it.

**Alternative #3 – Return of Sponsor Resources to Sponsor and purchase of Sponsor Equipment by Other Trial Site.**

After completion of the Clinical Trial at the Other Trial Site, or at an earlier time specified by Sponsor, the Sponsor will contact the Other Trial Site to make arrangements for return of any [**Sponsor Equipment**] [and] [**Sponsor Resources**], at Sponsor’s expense, to the Sponsor or a location designated by Sponsor. The Other Trial Site’s responsibilities under this Agreement for the [**Sponsor Equipment**] [and] [**Sponsor Resources**] will cease or transfer to the Sponsor at the time of removal from the Other Trial Site.

After completion of the Clinical Trial at the Other Trial Site, Sponsor will make Sponsor Equipment available for purchase by the Other Trial Site at its then depreciated value. If Clinical Trial conduct is completed significantly earlier or later than originally estimated, the depreciated value identified in the table above will be adjusted accordingly. The Sponsor will ensure that any transfer of ownership is documented in writing.

If any Sponsor Equipment is so transferred, it will be transferred ‘as is’ and Sponsor does not make any representation or provide any warranty of any kind concerning it.

1. Vendor-Provided Equipment or Resources

[ ]  Please check this box if no Equipment or Resources will be provided by a Vendor

* 1. **The Sponsor** will arrange for a vendor to provide the following equipment or proprietary materials (“Vendor Property”) for use in this Clinical Trial:

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Equipment** | **Estimated Original Value** | **Depreciation** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Permitted Uses of Vendor Property**

The Other Trial Site will use Vendor Property only for purposes of this Clinical Trial.

**[Alternatively, specify permitted uses.]**

1. Disposition of Vendor Property
	1. The Vendor will determine the disposition of Vendor Property after completion of the Clinical Trial at the Other Trial Site.
2. Ownership, Responsibilities, and Liability
	1. **Ownership**: Sponsor Equipment and Sponsor Resources and Vendor Property are and remain for the duration of the Clinical Trial at the Other Trial Site, the property of Sponsor, the Vendor or the licensor, as the case may be.
	2. **Liability**: Equipment and Resources Only.

**Alternative #1 – indemnity provided by this Appendix 7 [N.B. THIS OPTION MUST BE SELECTED FOR OTHER TRIAL SITES IN ENGLAND OR NORTHERN IRELAND]**

The Sponsor has no liability for damages of any sort, including personal injury or property damage resulting from the use of [**Sponsor Equipment**], [**Sponsor Resources**] [or] [**Vendor Property**] except to the extent that:

1. such damages were caused by the wilful misconduct, negligent acts or omissions of Sponsor or the Vendor; or
2. a personal injury to a Clinical Trial Subject is one covered by the indemnity detailed in Appendix 3 of this Agreement.

Sponsor shall be responsible for organising and ensuring payment for all costs associated with the routine maintenance of the [**Sponsor Equipment**], [**Sponsor Resources**] [and] [**Vendor Property**] and will replace the same at no cost to the Other Trial Site in the event replacement of the foregoing is deemed required as a result of equipment failure or routine maintenance.

Subject to Clause 5.4 of the Agreement, the Other Trial Site shall be liable for any damage, loss or destruction of the [**Sponsor Equipment**], [**Sponsor Resources**] or [**Vendor Property**] and for any losses attributable to the [**Sponsor Equipment**], [**Sponsor Material**] [or] [**Vendor Property**] caused by the Other Trial Site’s wilful misconduct, negligent acts or omissions. Under no circumstances shall the Other Trial Site be liable for any damage caused as a result of using the equipment per instructions or due to normal wear and tear. To avoid doubt, the Other Trial Site shall not insure the [**Sponsor Equipment**], [**Sponsor Material**] or [**Vendor Property**].

**Alternative #2 – Equipment is supplied under an MIA [N.B. THIS OPTION IS ONLY AVAILABLE FOR OTHER TRIAL SITES IN SCOTLAND OR WALES WHERE THE SPONSOR HAS AN MIA]**

The [**Sponsor**] [**Vendor**] is providing the [**Sponsor Equipment**] [**Vendor Property**] to the Other Trial Site pursuant to the terms of an MIA. The MIA that shall apply to the provided [**Sponsor Equipment**] [**Vendor Property**] is the MIA applicable to the place where the Other Trial Site is constituted.

**FINAL PAGE**