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

[**INSERT** PROTOCOL REFERENCE NUMBER]

# Vaccination Trials Model Service Level Agreement for NHS Organisations and University Service Providers

Between

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

**“Investigator Site”**

AND

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

**the “Service Provider”**

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

**Whereas**

1. The Sponsor is a pharmaceutical company or organisation involved in the research, development, and manufacture of medicines for use in humans;
2. The Investigator 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 Investigator Site has a particular interest and expertise in Public Health and Immunology studies;
4. The Sponsor has contracted with the Investigator Site to undertake the Clinical Trial using the template model Clinical Trial Agreement (“mCTA”) where the Sponsor is a commercial organisation; or the model Non-Commercial Agreement (“mNCA”) where the Sponsor is a non-commercial organisation;
5. The terms of this Agreement will be subject to the mCTA/mNCA agreed by the Investigator Site and the Sponsor;
6. The Service Provider is an NHS Organisation or University involved in the provision of healthcare, concerned with the treatment and prevention of disease and clinical research for the improvement of healthcare;
7. If the Service Provider and the Investigator Site are both NHS Organisations, then this agreement is an NHS agreement;
8. The Central Management Function is a central delivery group consisting of experts in immunology, trial and facilities management overseeing the delivery service across the region/nation;
9. The Service Provider has been selected by the Central Management Function and wishes to contract with the Investigator 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 site agreement between Sponsor and the Investigator Site.

It is therefore, agreed that the following terms and conditions shall apply to the conduct of the duties undertaken by the Service Provider 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);

**Agreement**
means this agreement comprising its clauses, schedules and any appendices attached to it;

**Clinical Trial**
means the clinical trial to be conducted with the Principal Investigator oversight at the Service Provider Location(s) 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 Service Provider as potential Clinical Trial Subjects, prior to their enrolment and irrespective of whether they are enrolled if they have been identified by the Service Provider;

**Confidential Information**means all confidential information (however recorded or preserved) disclosed by a Party (as defined below), or by 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 relating to the business, affairs, plans, intentions or market opportunities of the disclosing Party, including (but not limited to):

* the operations, processes, product information, designs, trade secrets or Know-How of the disclosing party
* any information developed by the Parties in the course of carrying out this Agreement
* in the case of Confidential Information of the Sponsor, the Protocol, the Investigator Brochure(s) relating to the Clinical Trial and Appendix 1 to this Agreement (‘Financial Arrangements’);

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

**Data Protection Laws and Guidance**means the General Data Protection Regulation (EU) 2016/679 (“GDPR”) and 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;

**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 are specified in Directive 2001/20/EC of the European Parliament and the Council of 4 April 2001 relating to medicinal Product for human use and in guidance published by the European Commission pursuant to such Directive;

**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 which 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;

**mCTA/mNCA**means the agreement between the Investigator Site and the Sponsor that governs the conduct of the Clinical Trial at the Investigator Site;

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

**Monitor**means one or more persons appointed by the Investigator Site, the Central Management Function 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 or 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 or otherwise Processed;

**Personnel**
means the persons who will undertake the conduct of the Clinical Trial at the Service Provider Location(s) on behalf of the Service Provider 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 medical clinician (who is an experienced researcher and investigator of clinical trials), who will lead and co-ordinate the work of the Clinical Trial at the Service Provider Location(s) on behalf of the Investigator Site;

**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 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;

**Service Provider Location(s)**means the premises of the Service Provider where the Clinical Trial will be conducted;

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

**Sponsor**an Individual, company, institution, organisation or group of organisations that takes on responsibility for initiation, managing and financing (or arranging the financing) of the research;

**Sub Investigator**means any individual member of Personnel (who is a medical clinician, experienced researcher and investigator of clinical trials), designated and supervised by the Principal Investigator at the Service Provider Location(s) to perform Clinical Trial related procedures and/or to make Clinical Trial related decisions;

**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 Service Provider contracted by the Investigator 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.
	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 Service Provider represents that it is entitled to procure and will procure the Sub-Investigator and other Personnel to fulfil the functions required in this Agreement and has the necessary expertise, time and resources to perform the Clinical Trial, as required by the Protocol, and instructed by the Principal Investigator outlined in Appendix 2.
	2. The Investigator Site represents that it is entitled to procure and will procure the Principal Investigator, and represents that the Principal Investigator holds the necessary registration and has the necessary expertise, time and resources to perform the Clinical Trial. The Investigator Site shall ensure that the Principal Investigator is made aware of and acknowledges the obligations applicable to him as set out in this Agreement, including but not limited to those set out in Appendix 3.
	3. The Service Provider represents that it is entitled to procure and will procure the Personnel, and represents that the Personnel hold the necessary registration and have the necessary expertise, time and resources to perform the Clinical Trial. The Service Provider shall ensure that the 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 Service Provider must ensure the Sub-Investigator and/or other Personnel as appropriate, attend any meetings regarding the Clinical Trial as reasonably requested by the Investigator Site (“Clinical Trial Meetings”). The Service Provider 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 Investigator 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 Service Provider 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.

## Clinical Trial Governance

* 1. The Parties must comply with all laws applicable to the performance of the Clinical Trial including, but not limited to, the Human Rights Act 1998, the Data Protection Laws and Guidance, the Medicines Act 1968, the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended), the Bribery Act 2010, the Freedom of Information Act 2000, and with all relevant guidance relating to medicines and clinical trials from time to time in force including, but not limited to, the ICH GCP, the World Medical Association Declaration of Helsinki entitled 'Ethical Principles for Medical Research Involving Human Subjects' (1996 version) and the UK Policy Framework for Health and Social Care Research v3.3, November 2017, as amended from time to time.

## Obligations of the Parties

* 1. The Service Provider shall permit the Investigator Site access to the records of Clinical Trial Subjects to the extent considered necessary by the Investigator Site and the Principal Investigator for the safety of Clinical Trial Subjects. The Service Provider shall also permit access for the Monitor, such access to be arranged at mutually convenient times and on reasonable notice.
	2. The Investigator Site confirms that the Principal Investigator shall be responsible for reporting adverse events as outlined in the Protocol.
	3. The Investigator Site confirms that if the Principal Investigator is not present at the Service Provider Location(s) 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 Service Provider 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 Service Provider Location to complete a full assessment within the timeframe and obligations stipulated in the Protocol.
	6. The Investigator Site confirms that if the Principal Investigator has assessed remotely 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 Investigator Site confirms that through the site 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 Investigator Site promptly or 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 to the Sub Investigator and Personnel as a matter of urgency.
	8. Subject to Clause 12, the Service Provider shall inform the Investigator Site within 24 hours of becoming aware of any situation which it considers would render it unable to complete its obligations under this Agreement.

## Liability

* 1. Both Parties acknowledge that the Investigator Site has entered into a mCTA/ mNCA between itself and the Sponsor setting out the indemnity provided by the Sponsor.
	2. Subject to Clause 6.1 the Service Provider acknowledges that its liability to the Sponsor and/or Investigator Site shall not exceed the level of liability of the Investigator Site to the Sponsor in the mNCA/mCTA. The Service Provider also acknowledges that the liability of the Sponsor and/or Investigator Site to the Service Provider shall not exceed the Sponsor’s level of liability to the Investigator site in the mNCA/mCTA.
	3. Where the Sponsor is a commercial organisation, in the event of any claim or proceeding in respect of personal injury made or brought against the Investigator Site or Service Provider by a Clinical Trial Subject, the Investigator Site represents that the Sponsor shall indemnify the Investigator Site and Service Provider, 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.
	4. 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.
	5. In no circumstances shall either Party be liable to the other Party in contract, tort or delict (if the Service Provider 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.
	6. 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 potential and actual 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 the Parties are acting as independent Controllers, to promptly and without undue delay, notify and inform the other Party in the event of any Personal Data Breach that relates to Personal Data Processed for the purpose of the Clinical Trial.
	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 Investigator Site is the Processor and the Service Provider is the Sub-Processor of the Investigator Site in relation to Personal Data Processed for the purpose of the Clinical Trial.
		2. The Service Provider’s Processing of Personal Data as a Sub-Processor of the Investigator 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 Service Provider is the Controller of Personal Data Processed for purposes other than the Clinical Trial, e.g. the provision of medical care.
		4. The Service Provider, 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 Investigator Site in accordance with the documented instructions of the Sponsor and/or Investigator Site, including with regard to transfers of Personal Data to a third country or an international organisation. If the Service Provider is required by law to otherwise Process the Personal Data, the Service Provider shall notify the Investigator 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).
		5. The Service Provider agrees to comply with the obligations applicable to Processors described by Article 28 of the GDPR, as well as those additional obligations required by Investigator 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 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 Investigator 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 Investigator 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 Service Provider as a Sub-Processor of the Investigator Site, the Service Provider 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 Investigator 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 Investigator Site.
	* 1. In furtherance of its obligations under Article 28 GDPR, the Service Provider agrees that it will not engage another Processor for the purpose of the Clinical Trial without the prior written authorisation of the Sponsor and Investigator Site (GDPR Article 28(2)).
		2. At the expiry or lapse of this Agreement, the Service Provider shall, at the choice of the Investigator Site, destroy or return all Personal Data to the Sponsor or Investigator 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 Service Provider as Controller for its own purpose(s).
		3. The Service Provider 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 Service Provider’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 Service Provider agrees to:
14. provide the Investigator Site with evidence of its compliance with the obligations set out in this Agreement at the Investigator Site discretion and on reasonable notice, to allow the Sponsor, Investigator Site or a third party appointed by the Sponsor or Investigator Site, to audit the Service Provider’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, Investigator Site or appointed third party, complying with all relevant health and safety and security policies of the Service Provider;
15. obtain prior written agreement of the Sponsor or Investigator Site to Process Personal Data outside of the EEA.
	* 1. Where the Service Provider, acting as the Site Investigator’s Sub-Processor, Processes Personal Data outside of the EEA, the Service Provider 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 or Clinical Trial Subjects shall be transferred by the Service Provider to the Investigator Site or Sponsor unless this is required directly or indirectly to satisfy the requirements 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 Investigator 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 Investigator 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 Investigator 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 Investigator 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 Investigator Site confirms that the Sponsor has agreed to ensure that persons Processing Personal Data and/or Pseudonymised Data of Clinical Trial / Investigation Subjects / potential Subjects under this Agreement are equipped to do so respectfully and safely. In particular:
16. to each ensure that their Agents understand the responsibilities for information governance, including their obligation to Process Personal Data or Pseudonymised Data of Clinical Trial Subjects / potential Subjects securely and to only disseminate or disclose for lawful and appropriate purposes;
17. to each ensure that their Agents 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 Investigator Site agrees 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 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 Investigator Site agrees to ensure Personal Data and/or Pseudonymised Data of Clinical Trial Subjects are 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 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 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 Service Provider, shall vest in the Sponsor in accordance with Clauses 7.4.3 and 7.4.4 of this Agreement.
		3. The Service Provider shall, and will ensure that its Agents shall, promptly disclose to the Investigator Site any Intellectual Property Rights or Know-How generated by the Service Provider 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 Service Provider 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 Service Provider 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 Service Provider shall promptly disclose to the Investigator 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 Service Provider 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 Investigator 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 Investigator 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 Service Provider 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 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 Investigator Site represents that in the mCTA/mNCA with the Sponsor, the Sponsor recognises that the Investigator Site and Principal Investigator have a responsibility under the UK Policy Framework for Health and Social Care v3.3, November 2017 to ensure that results of scientific interest arising from the Clinical Trial are appropriately published and disseminated.
	2. Subject to Clause 9.1, the Service Provider warrants that all intention and consideration for its Personnel to present at symposia, national or regional professional meetings, publish in journals of their own choice, the methods and Results of the Clinical Trial will not be permitted without the written consent of the Investigator Site and the Central Management Function. This is to protect the Confidential Information clauses already agreed by the Investigator Site with the Sponsor.
	3. The Service Provider 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 Investigator Site 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 Service Provider shall submit an invoice in accordance with Appendix 1 setting out the costs incurred and payment claimed;
		2. payment by the Investigator Site shall be without prejudice to any claims or rights which the Sponsor may have against the Service Provider and shall not constitute any admission by the Investigator Site as to the performance by the Service provider 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 Investigator Site or on behalf of the Investigator Site to the Service Provider shall be used only for the Clinical Trial and in accordance with the Protocol, or otherwise as agreed in Appendix 1.
	4. The Investigator 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 Service Provider to the Sponsor 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. [DELETE IF NOT APPLICABLE]

## 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 Investigator 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 Investigator 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 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 his/her supervision of the Study for any reason and a replacement acceptable to both Parties and the Sponsor is not found.
	3. The Service Provider may terminate this Agreement by notice in writing:
		1. if the Sub-Investigator becomes unavailable to continue his supervision of the Clinical Trial at the Service Provider Location(s) 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 Service Provider chooses to cease Clinical Trial Subjects recruitment at its Service Provider Location(s) 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 Service Provider Location(s) (or cessation of recruitment of Clinical Trial Subjects at its Service Provider Location(s) where the Service Provider 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 Investigator Site shall, subject to the prior compliance of the Service Provider with its obligations on termination, upon receipt of a valid invoice submitted in accordance with Appendix 1, pay the Service Provider any outstanding monies due to the Service Provider as at the date of termination.
		3. The Service Provider shall ensure that there is prompt refund to the Investigator Site of the amount, if any, by which the cumulative cost paid by the Investigator Site to the Service Provider under this Agreement exceeds the actual commitments incurred by the Service Provider 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 at its Service Provider Location(s) where the Service Provider has chosen to cease recruiting in accordance with Clause 12.6, an amendment in writing signed by the Sponsor and the Investigator Site shall me made to any payments due under Appendix 1 to reflect the reduction in recruitment numbers.
		4. The Service Provider shall provide to the Investigator Site all Study Data and other relevant information and/or data relating to work undertaken by the Service Provider prior to and including the date of termination and co-operate with all reasonable requests from the Investigator Site including any continued monitoring of Clinical Trial Subjects in accordance with Protocol.
		5. The Service Provider 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 Service Provider for the purposes of the Clinical Trial are complied with.
		6. The Service Provider shall ensure that the instructions of the Investigator Site regarding the transfer and/or storage of all information, material or data relating to the Clinical Trial collected by the Service Provider in the course of carrying out the Clinical Trial are complied with.
		7. Unless otherwise agreed in writing with the Investigator 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 Service Provider will notify the Investigator Site in accordance with Clause 12 if, for any reason, it elects to cease Clinical Trial Subjects recruitment at its Service Provider Location(s).

## 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.

## 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 facsimile, or by email, providing evidence of receipt.
	2. Notices shall be delivered to the name and address specified below:

[insert Service Provider and Investigator 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 Service Provider shall not novate or assign all or any part of their rights or obligations under this Agreement without the prior written consent of the Investigator Site.
	2. The Service Provider must not sub-contract the performance of all or any of its obligations under this Agreement without the prior written consent of the Investigator 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. In the event of failure to resolve the dispute through the steps set out in Clause 17.1, the Parties agree to attempt to settle it by mediation in accordance with the Centre for Effective Dispute Resolution Model Mediation Procedure. To initiate a mediation, either Party shall give notice in writing (“ADR Notice”) to the other Party requesting mediation in accordance with this clause 17.2. The Parties shall seek to agree the nomination of the mediator, but in the absence of agreement the mediator shall be nominated by the President for the time being of the British Medical Association. The person so appointed will act as an expert and not as an arbitrator. The mediation will start no later than twenty (20) days after the date of the ADR Notice. The Parties shall each bear their own costs and expenses in relation to settlement of any disputes in terms of this Clause 19 and shall share equally the costs of the independent third party. If the dispute is not resolved within thirty (30) days of the ADR Notice, either Party shall be entitled to submit to the exclusive jurisdiction of the courts of England and Wales.

## 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 3, 4, 5, 6, 7 and/or 8 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.

## Governing Law

* 1. Where the Investigator 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 Investigator 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 Investigator 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 Investigator 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 INVESTIGATOR SITE DETAILS]Signature:Title: Date: | Signed for and on behalf of:[INSERT SERVICE PROVIDER 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 Service Provider, full details should also be included in this section including the management of the IMP where applicable.]

# Appendix 2 – Service Provider Duties as required by the Protocol and instructed by the Investigator 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 Service Provider 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.]

# 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.]

# Appendix 4 – Material Transfer Provision

Where the Protocol requires the Service Provider to supply Material to the Sponsor of the Investigator Site this Appendix 4 shall apply. **For the purpose of this Appendix 4** **only**, reference to Sponsor should mean that the Investigator Site can confirm that the Sponsor has agreed through the terms of a site agreement between the Investigator Site and the Sponsor.

[DELETE IF NOT APPLICABLE]

1. In accordance with the Protocol, the Service Provider shall send Material to the Sponsor or the Investigator 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 Service Provider 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.

**FINAL PAGE**