# Primary Care Model Clinical Trial Agreement (Tripartite)

**Instruction Pages**

**The information set out below provides a checklist of information that needs to be included in the Primary Care model Clinical Trial Agreement (PC-mCTA) in preparation for execution by the Parties.**

**It is the Sponsor’s responsibility to provide the required information for review by the Trial Site.**

### Footers

Complete the information set out in the footer of this document.

### Front page

Complete all of the required information.

### Recitals

Add, remove and / or update recitals as applicable to the Clinical Trial (as a preamble to the Agreement, such changes do not constitute modification to the template Agreement). Recital E should be completed where a corporate Affiliate of the Sponsor is formally empowered by the Sponsor to sign the Agreement on behalf of the Sponsor thereby binding the Sponsor as Party to the Agreement (and should be removed where this is not the case). Recital F should be retained if the Sponsor has appointed a Legal Representative within the UK or EEA, with the Legal Representative named, and otherwise deleted. Recital G should be retained if the Sponsor intends to deliver the Clinical Trial in a hub and spoke model, with this Agreement forming a head agreement for sub-agreements with Other Trial Sites and otherwise deleted (note that retention or deletion of this recital should align with retention or deletion of 4.21 in the model Agreement).

### Main Body of the Agreement

**Clause 3.3.4** – Check that this Clause references the version of the Declaration of Helsinki applicable to this Clinical Trial and update where needed.

**Clause 3.3.7** – Delete if the Clinical Trial does not involve transplantation of human cells, tissue or organs.

**Clause 3.6.1** – Delete if the Clinical Trial is not a Phase I clinical trial.

**Clause 3.6.2** – Delete if the Clinical Trial is not a dose escalation Phase I clinical trial.

**Clause 4.6.1** – Delete the non-applicable version of this subclause depending upon whether a request to defer registration has been submitted.

**Clause 4.14** – Complete the table to indicate which Party will supply each Investigational Drug and what will happen to any unused Investigation Drugs at the end of the Clinical Trial. Examples are provided of management of the Investigational Drugs at the end of the Clinical Trial; alternative ways to manage the Investigational Drugs can be used as applicable. Further information around practical expectations for the management of the return of Investigational Drugs to the Sponsor is available in the [PC-mCTA guidance notes](https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#PC-mCTA).

**Clause 4.16** – Select ‘enrols’, ‘doses’ or ‘randomises’ as appropriate to the Clinical Trial and insert target number for the Trial Site.

**Clause 4.19.9** – Insert the appropriate number of years and working days.

**Clause 4.19.9.b** – Insert e-mail address for Trial Site archiving contact.

**Clause 4.19.9.c** – Choose one option either for physical or electronic archiving to be used.

**Clauses 4.19.10** and **4.19.11** – Delete either or both clauses depending upon whether Material will be analysed locally, centrally or if no Material will be analysed.

**Clause 4.20** – Delete if no equipment or resources are provided by the Sponsor.

**Clause 4.21** – Delete if it is NOT intended that the Trial Site will subcontract with Other Trial Sites.

**Clause 5.6** – Insert amount.

**Clause 6.2.5.h.(i)** – Insert e-mail address for Personal Data Breach contact

**Clause 6.2.6** – The yellow highlighted text should be deleted: i) where the Sponsor does not intend to permit the use of Participant Identification Centres (PICs) in the Clinical Trial; ii) where the Sponsor does intend to permit the use of PICs in the Clinical Trial but, in accordance with GDPR Article 28(2), requires the Trial Site to obtain specific written authorisation from or on behalf of the Sponsor prior to engaging a PIC. The yellow highlighted text should be retained where the Sponsor does intend to permit the use of PICs in the Clinical Trial and, in accordance with GDPR Article 28(2), authorises the Trial Site to engage PICs under this general written authorisation.

**Clause 14.6** – Select the appropriate option to instruct the site whether to destroy or return Confidential Information and unused material at Investigator Site Trial Completion, except for information and material that should be retained by the Trial Site.

**Clause 18** – Complete the full names, addresses (and e-mail addresses, as applicable) for contact persons for notices to the Parties.

### Signature page

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

In England, Northern Ireland and Wales, provision of signed agreement from Trial Site to Sponsor or Sponsor’s Agent denotes that the Trial Site confirms that it has the capacity and capability to deliver the Clinical Trial and is ready to do so upon initiation by the Sponsor or the Sponsor’s Agent. Contract exchange should not occur prior to or separately from the Trial Site confirming that it is ready to be initiated to deliver the Clinical Trial. In Scotland, NHS Management Permission for the Clinical Trial to be initiated and commence will occur in addition to contract exchange, but would usually occur at the same time.

### Appendix 1

Complete Appendix 1 showing the milestones / division of responsibilities between the Parties.

### Appendix 4

The Localised OnlineiCT generated Finance Schedule should be inserted into this Financial Arrangements Appendix. Further detailed guidance for completion is included within the Financial Arrangements Appendix itself.

### Appendix 6

Check the box at Appendix 6 if it is not relevant to the specific Clinical Trial.

### Appendix 7

Complete details of any equipment and / or resources being supplied to the Trial Site for the Clinical Trial.

Where no equipment and / or resources is / are being provided, check the box at Appendix 7 to indicate the Appendix is not used.

### Appendix 8

Where applicable, attach here evidence of formal delegation of authority, from the Sponsor to the corporate Affiliate of the Sponsor, to sign this Agreement and thereby legally bind the Sponsor to its terms as a Party.

Check the box at Appendix 8 if it is not relevant to the specific Clinical Trial.

### Appendix 9

Where applicable, attach the Authority to Defer Registration of the Clinical Trial here.

Check the box at Appendix 9 if it is not relevant to the specific Clinical Trial.

**Delete these instruction notes after completing the Agreement**

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

[**INSERT** SPONSOR’S PROTOCOL REFERENCE NUMBER]

# Primary Care Model Clinical Trial Agreement (Tripartite)

**Between**

[**INSERT** NAME OF TRIAL SITE and ADDRESS OF TRIAL SITE]

**“Trial Site”**

AND

 [**INSERT** NAME OF PRINCIPAL INVESTIGATOR AND ADDRESS OF PRINCIPAL INVESTIGATOR]

**“Principal Investigator”**

AND

[**INSERT** NAME OF SPONSOR AND REGISTERED ADDRESS OF SPONSOR]

**“Sponsor”**

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

# Primary Care Model Clinical Trial Agreement (Tripartite)

### Clause

1. Definitions
2. Principal Investigator and Personnel
3. Clinical Trial Governance
4. Obligations of the Parties and the Principal Investigator
5. Liabilities and Indemnities
6. Data Protection
7. Freedom of Information
8. Confidential Information
9. Publicity
10. Publications
11. Intellectual Property
12. Finances
13. Term
14. Termination
15. Relationship of the Parties
16. Agreement and Modification
17. Force Majeure
18. Notices
19. Dispute Resolution
20. Miscellaneous

Appendix 1 Timelines and Responsibilities of the Parties

Appendix 2 ABPI Clinical Trial Compensation Guidelines 2015

Appendix 3 Form of Indemnity

Appendix 4 Financial Arrangements

Appendix 5 Conditions Applicable to the Principal Investigator

Appendix 6 Material Transfer Provisions

Appendix 7 Equipment and Resources

Appendix 8 Formal Delegation of Authority to a Corporate Affiliate of the Sponsor to Contractually Bind Sponsor

Appendix 9 Authority to Defer Registration of the Clinical Trial under Clause 4.6.1

**Whereas**

1. The Sponsor is a pharmaceutical company involved in the research, development, manufacture and sale of medicines for use in humans;
2. The Trial Site is a General Practice, or other provider of NHS commissioned primary care services, concerned with the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare;
3. The Principal Investigator is a General Medical Practitioner with a particular interest in [**area of interest**];
4. The Sponsor wishes to contract with the Trial Site to undertake a clinical trial;
5. References throughout this Agreement to Sponsor shall be construed to include reference to [**insert name of Affiliate**], as Affiliate empowered by the Sponsor to legally bind the Sponsor to this Agreement and to act on its behalf, in accordance with Appendix 8;
6. The Sponsor, being not established within the United Kingdom (UK), or a country listed under regulation 3(11A) of the Medicines for Human Use (Clinical Trials) Regulations 2004 (specifically, as amended by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019), is represented in the UK (in accordance with Regulation 3(11)(b) of those Regulations by their Legal Representative [**INSERT NAME OF LEGAL REPRESENTATIVE**].
7. The Trial Site is a Lead Trial Site in an Investigator Site comprising of more than one legal entity, with Other Trial Sites subcontracted by the Lead Trial Site via Hub and Spoke Agreement;

It is therefore, agreed that the following terms and conditions shall apply to the conduct of the Clinical Trial (as further defined below):

## Definitions

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

**ABPI Code of Practice**
means the most recent edition of the Code of Practice for the Pharmaceutical Industry, issued by the ABPI from time to time;

**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, by contract or otherwise;

**Agent**
shall include but is not limited to, any person (including the Principal Investigator, any nurse or other healthcare professional) providing services to the Trial Site under a contract for services (commonly known as an honorary contract) or otherwise any such person’s principal employer in the event that it is not the Trial Site and / or any contracted third party providing services to a Party under a contract for services or otherwise;

**Agreement**
means this Agreement comprising its clauses, schedules and any appendices attached to it and any variations made thereto in accordance with Clause 16.2;

**Auditor**
means a person being a representative of the Sponsor, or Affiliate, who is authorised to carry out a systematic review and independent examination of Clinical Trial related activities and documents to determine whether the evaluated Clinical Trial related activities were conducted, and the data were recorded, analysed and accurately reported, according to the Protocol, ICH-GCP, GMP, GVP and the applicable regulatory requirements;

**Clinical Trial**
means the investigation to be conducted at the Trial Site in accordance with the Protocol;

**Clinical Trial Authorisation**
means the authorisation of the Clinical Trial in accordance with Part 3 of the Medicines for Human Use (Clinical Trials) Regulations 2004;

**Confidential Information**means all confidential information (however recorded or preserved) disclosed by a Party and / or its Affiliate to the other 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 4 to this Agreement (‘Financial Arrangements’);

**Confidential Participant Information**

means information from which the identity of an actual or potential Participant is ascertainable either from that information alone, or from that information and other information which is in the possession of, or is likely to come into the possession of, the person Processing that information, and that information was obtained or generated by a person who, in the circumstances, owed an obligation of confidence to that individual;

**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;

**Effective Date**means the date on which the final signature is placed on this Agreement;

**EIR**

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

* **Ethically-Approved Participant Payments**

means any payments made to Participants, other than Expenses, which have been approved by the research ethics committee;

* **Expenses**

means any reasonable costs for Participants (including, as applicable, parents, carers or others who may reasonably be expected to accompany them) and the Trial Site’s Agents in relation to travel, accommodation, food, drink, and any other expenditure the Sponsor agrees to reimburse, which is incurred as a direct result of participation or involvement in this Clinical Trial;

**FOIA**
means either the Freedom of Information Act 2000 or the Freedom of Information (Scotland) Act 2002, as applicable to the place of constitution of the Trial Site;

**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;

**GMP**
means the principles and guidelines of good manufacturing practice for medicinal products for human use and for investigational medicinal products for human use laid down in Commission Directive 2003/94/EC, as modified by Schedule 2A to the Human Medicines Regulations 2012, or if Regulations have been made under the powers in regulation B17(1) of the 2012 Regulations, and have come into force, those Regulations, and, in the case of Northern Ireland, any applicable EU standard;

**GVP**
means any appropriate national UK regulations or standards on good pharmacovigilance practices and in the case of Northern Ireland any applicable EU requirement;

**Hub and Spoke Agreement(s)**

means the subcontract of this Agreement entered into between the Lead Trial Site and any Other Trial Site(s), as may be the case from time to time as agreed by the Sponsor;

**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;

**IND**
means the Investigational New Drug application process by which the United States Food and Drug Administration exempts pharmaceutical companies from the federal statute that prohibits an unapproved drug from being shipped in interstate commerce;

**Inspector**
means a person, acting on behalf of a Regulatory Authority, who conducts an official review of the documents, facilities, records and any other resources that are deemed by a Regulatory Authority to be related to a Clinical Trial and that may be located at the Trial Site;

**Intellectual Property Rights (IPR)**
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 Drugs**
means the Investigational Medicinal Product (as defined below) together with control material (for example, placebo, comparator drug, concomitant drug) as detailed in the Protocol;

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

**Investigator Site**

meansthe activities conducted under this Agreement and overseen by one Principal Investigator;

**Investigator Site Trial Completion**
means the conclusion of all Protocol required activities for all enrolled Participants at the Investigator Site;

**Investigator Trial Master 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);

**Joint Position**
means the “**Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases**,” agreed by the innovative pharmaceutical industry and published by the International Federation of Pharmaceutical Manufacturers & Associations in November 2009 (with minor revisions as of 15 January 2018);

**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 IMP, 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**

Where the Principal Investigator has oversight of Clinical Trial activities at the Trial Site and at an Other Trial Site(s), the Trial Site is the Lead Trial Site, being the ‘hub’ in a ‘hub and spoke’ trial site delivery model;

**Localised Online iCT**

means the localised, Trial Site-specific output from the online interactive Costing Tool (iCT), which is used by the Sponsor to agree the prices for the conduct of the Clinical Trial, together with any amendments thereof made in accordance with Clause 12.2 of this Agreement and Clause 4 of Appendix 4 of this Agreement, as agreed between the Parties and incorporated into this Agreement by reference;

**Material**
means any clinical biological sample, or portion thereof, derived from Participants, including information related to such Material, analysed by the Trial Site or Other Trial Site in accordance with the Protocol, or otherwise supplied under Appendix 6 (where applicable) to the Sponsor or its nominee;

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

**Multi-Centre Trial**
means a Clinical Trial that includes more than one Investigator Site;

**Other Trial Site(s)**

a legal entity (or entities) subcontracted by the Trial Site to undertake Clinical Trial related activity for which the Principal Investigator is responsible, and which therefore forms part of the same Investigator Site as the Trial Site;

**Participant**
means a person enrolled to participate in the Clinical Trial according to criteria detailed in the Protocol;

**Participant Identification Centre (PIC)**

means an NHS organisation (including an independent contractor of NHS commissioned primary care) Processing Personal Data on behalf of the Sponsor in order to identify potential Participants (but not otherwise undertaking activities such that the organisation would be a Trial Site);

**Personal Data**
means any and all information, data and material of any nature received or obtained by any Party in connection with this Agreement which is personal data as defined in the Data Protection Laws and Guidance and which relates to a Participant (or potential Participant) 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 at the Trial Site under the supervision of the Principal Investigator, including other General Practitioners at the Trial Site who have been delegated responsibilities by the Principal Investigator;

**Principal Investigator**
means the person who will take primary responsibility for the conduct of the Clinical Trial at the Investigator Site on behalf of the Trial Site and who is a Party to this Agreement;

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

**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 Clause 16.3, 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 the use of the IMP;

**Research**
means the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods, as defined by and within the scope of the UK Policy Framework;

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

**Retention Period**

means the time period in which the Clinical Trial records are retained by the Trial Site after Trial Completion, as specified in Clause 4.16.9;

**SAE**
means Serious Adverse Event and shall have the definition set out in the Medicines for Human Use (Clinical Trials) Regulation 2004;

**Sponsor Trial Master File**

means the file maintained by the Sponsor containing the documentation specified in Section 8 of the ICH GCP (Edition CPMP/ICH/135/95);

**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 important Clinical Trial related decisions within the Investigator Site;

**Timelines**
means the timelines set out in Appendix 1 for the completion of certain milestones;

**Trial Completion**
means the conclusion of all Protocol required activities for all enrolled Participants in all locations where the Sponsor (or any Affiliate of the Sponsor) is carrying out the Clinical Trial described in the Protocol on the IMP;

**Trial Monitor**
means one or more persons appointed by the Sponsor, or Affiliate, to monitor compliance of the Clinical Trial with ICH-GCP and to conduct source data verification;

**Trial Site**

The body contracted by this Agreement to conduct the Clinical Trial;

**UK Policy Framework**
means the UK Policy Framework for Health and Social Care Research (Version 3.3, November 2017).

* 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. Where the Trial Site is a Health and Social Care (HSC) organisation in Northern Ireland, references throughout this document to the NHS should be construed to include HSC as applicable.
	5. 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.
	6. 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 ineffective 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.

## Principal Investigator and Personnel

* 1. The Trial Site and the Principal Investigator represent that they are entitled to procure and will procure the services of any and all Sub-Investigators and other Personnel, to fulfil these functions and shall ensure the performance of the obligations of any and all Sub-Investigators and other Personnel set out in Appendix 5 and elsewhere in this Agreement.
	2. The Trial Site and the Principal Investigator each represent that the Principal Investigator holds the necessary registration and has the necessary expertise, time and resources to perform the Clinical Trial and the Principal Investigator acknowledges the obligations applicable to the Principal Investigator set out in this Agreement, including but not limited to those set out in Appendix 5.
	3. The Trial Site and the Principal Investigator shall notify the Sponsor if the Principal Investigator ceases to be employed by or associated with the Trial Site, is erased from the medical register (or equivalent UK professional register where the Principal Investigator is not a medical doctor) or is otherwise sanctioned by an applicable regulatory or other governmental authority, or is otherwise unavailable to continue as Principal Investigator. The Sponsor shall then be entitled to terminate this Agreement pursuant to Clause 14.3.
	4. The Trial Site and the Principal Investigator shall procure the performance of the obligations of the Personnel as set out in this Agreement.
	5. The Principal Investigator and / or Personnel shall attend any meetings regarding the Clinical Trial as reasonably requested by the Sponsor (“**Investigator Meetings**”). Such meetings to be conducted by the Sponsor to convey or exchange information with the Principal Investigator, all Sub-Investigators or other Personnel to support the effective conduct or close-out of the Clinical Trial. The Trial Site agrees that no additional compensation shall be due hereunder for Principal Investigator’s or any other Personnel’s respective participation in Investigator Meetings. The Sponsor shall reimburse or pay for reasonable pre-approved expenses for attendance at the Investigator Meetings upon receipt of documentation. It is further agreed that any such expenses will be paid at the rate of fair market value (in line with the ABPI Code of Practice) and subject to the documentation evidencing the expenses being in sufficient detail for the Sponsor’s financial reporting purposes, provided that the required detail does not impose an unreasonable administrative burden upon the Trial Site. Such expenses may be publicly reportable.
	6. The Principal Investigator represents that they will make good faith diligent efforts to ensure the completion of all case report forms in a timely manner.
	7. The Principal Investigator may appoint such other persons, as they may deem appropriate, as Sub-Investigators or other Personnel to assist in the conduct of the Clinical Trial. All Personnel will be adequately qualified, timely appointed and an updated list will be maintained. Principal Investigator shall be responsible for leading such team of Personnel. The Trial Site and Principal Investigator are responsible for the services performed by the Personnel and undertake in particular to have the services executed by competent persons. In the event that the Trial Site and / or Principal Investigator use the services of others to conduct the Clinical Trial pursuant to this Agreement, the Trial Site and Principal Investigator shall be responsible for ensuring that all are appropriate, in compliance with the terms of this Agreement. The Trial Site and the Principal Investigator shall be liable for any breach of this Agreement by the Principal Investigator and / or Personnel.

## Clinical Trial Governance

* 1. The Sponsor shall inform the Trial Site and the Principal Investigator 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 Sponsor 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 the Trial Site and the Principal Investigator shall ensure that all 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 the Trial Site and the Principal Investigator shall ensure that all 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 UK Policy Framework;
		6. the UK Research and Innovation policies and principles entitled, “[Human Biological Samples](https://www.ukri.org/about-us/policies-standards-and-data/good-research-resource-hub/human-biological-samples/)”;
		7. [**DELETE IF NOT APPLICABLE** – the ethical principles endorsed by [WHA63.22](https://apps.who.int/iris/handle/10665/341814) with regard to the Clinical Trial.]

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

* 1. When applicable, the Sponsor shall comply with the Clinical Trial Compensation Guidelines attached as Appendix 2 of this Agreement.
	2. The Trial Site and the Principal Investigator shall ensure that Sub-Investigators and any Sub-Investigators joining the Clinical Trial following the initiation of the Clinical Trial, undertake any such appropriate training as the Sponsor 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**
	The 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. The Parties agree to fulfil and ensure that their Agents fulfil regulatory requirements with respect to the reporting of adverse events.
		1. **Adverse Event Reporting in Phase I Trials**
		Notwithstanding the generality in Clause 3.6, the Parties further acknowledge and agree that with respect to Phase I trials:
1. It is the responsibility of the Sponsor to report all SUSARs (**Suspected Unexpected Serious Adverse Reactions** as defined in the Medicines for Human Use (Clinical Trials) Regulation 2004) relating to the Clinical Trial to the relevant Regulatory Authority within the timeframes set out in the Medicines for Human Use (Clinical Trial) Regulations 2004 and to report relevant follow-up information as required.
2. The Principal Investigator will provide the Sponsor with details of all SAEs irrespective of causality or whether the SAE is thought to be related to the Investigational Drugs and all other safety information as set out in the Protocol.
3. It is the responsibility of the Sponsor to submit safety reports to the relevant Regulatory Authorities as applicable and in accordance with both the Note for Guidance on Planning Pharmacovigilance Activities (ICH E2E) and the Medicines for Human Use (Clinical Trial) Regulations 2004.
4. If, during the course of the Clinical Trial, the Sponsor becomes aware of any information relating to the IMP which may impact the Clinical Trial, the Sponsor will notify the Trial Site promptly, and within seven (7) calendar days of becoming aware of the information and, if requested to do so by the Trial Site, will provide the Trial Site with a report detailing the information.
5. The Sponsor must provide any ongoing safety and toxicology data updates to the Principal Investigator immediately, to ensure the safety of the Participants in this Phase I Clinical Trial.
	* 1. **Quality Control of Data in Phase I Dose Escalation Trials**
6. The Sponsor represents and warrants that any data supplied to inform dose escalation decisions, as specified in the Protocol, shall have been subject to quality control undertaken by the Sponsor, or its Agent, and such evidence shall be provided to the Principal Investigator ahead of any dose escalation decision and implementation. Where this Clinical Trial is a Multi-Centre Trial, the Sponsor will ensure data collected from all Participants in the relevant cohort and Clinical Trial for the decision is subject to quality control from source through to presentation of the data for the decision. The Sponsor shall provide the Principal Investigator with the outcome of the dose escalation decision, data used for the decision (whilst maintaining the blind as necessary) and evidence of quality control of the data, for the Principal Investigator to carry out their duties in accordance with the Protocol and in compliance with The Medicines for Human Use (Clinical Trials) Regulations 2004.
	1. **Anti-Bribery and Corruption**
		1. Each Party warrants and represents that it has not committed any of the following acts (“**Prohibited Acts**”):
7. an offence under the Bribery Act:
8. 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
9. 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 any Party has committed or commits any of the Prohibited Acts in relation to this Agreement, the other Parties shall be entitled to terminate this Agreement in accordance with Clause 14, in addition to any other remedy available, taking into consideration the potential effects of termination on the health of Participants.

## Obligations of the Parties and the Principal Investigator

* 1. Each Party represents and warrants that it has the right and authority to enter into this Agreement and that it has the capability and capacity to fulfil its obligations under this Agreement.
	2. The Parties agree to adhere to the principles of medical confidentiality in relation to Participants involved in the Clinical Trial and potential Participants.
	3. The Sponsor shall be responsible for obtaining and maintaining Regulatory Authority approval, as well as research ethics committee favourable opinion and any other approvals needed for the conduct of the Clinical Trial.
	4. The Principal Investigator shall be responsible for:
		1. ensuring that the informed consent form, approved by the Sponsor and the relevant research ethics committee, is signed by or on behalf of each Participant before the first Clinical Trial related procedure starts for that Participant (or otherwise that the requirements of The Medicines for Human Use (Clinical Trials) Regulations 2004 (specifically as amended by the The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality Amendment) Regulations 2008, and The Medicines for Human Use (Clinical Trials) (Amendment No.2) Regulations 2006) are met in accordance with the Protocol in relation to incapacitated minors or adults in emergency situations);
		2. making any necessary disclosures of financial interests and arrangements, as defined and requested by the Sponsor, provided that such disclosures may be made prior to the commencement of work activities associated with the Clinical Trial as well as subsequent to Investigator Site Trial Completion, and that the Principal Investigator, (all) Sub-investigator(s) and Personnel shall update such disclosures as necessary to maintain their accuracy and completeness during the term of this Agreement and for any other period required by applicable law.
	5. Subject to Clause 4.6 and Clause 4.6.1, the Sponsor shall submit the Clinical Trial for listing in a free, publicly accessible clinical trial registry within forty-two (42) calendar days of initiation of the Clinical Trial by enrolment of the first Participant. The Trial Site and the Principal Investigator agree that such listing may include a summary of the Protocol, the name of the Trial Site and the Principal Investigator and the details of any Other Trial Site(s) where the Clinical Trial is being conducted.
	6. If, having considered all the circumstances, the Sponsor is of the view that the public interest benefits of registering the Clinical Trial on the timescale specified in Clause 4.5 are outweighed by the harm that registration at that time might do to the commercial value of the Investigational Medicinal Product or the commercial interests of the Sponsor, they may request the Health Research Authority (HRA) to authorise deferral of registration.
		1. [The Sponsor has not requested the HRA to authorise deferral of registration.]
		2. [The HRA has authorised Sponsor to defer registration and a copy of the authorisation is attached at Appendix 9.]
	7. The Parties shall conduct the Clinical Trial in accordance with the terms of this Agreement (including the incorporated Protocol) and:
		1. any current marketing authorisation in force within the relevant part of the UK for the IMP and the Clinical Trial Authorisation granted by the MHRA; and
		2. the terms and conditions of the favourable opinion of the research ethics committee.
	8. Until the Sponsor has obtained approval from the MHRA, the research ethics committee and any other necessary approvals, it shall not supply any Investigational Drugs to the Trial Site, nor shall it authorise the Trial Site to use its own supply of Investigational Drugs for this Clinical Trial. The Trial Site and the Principal Investigator shall ensure that neither administration of the IMP (nor any other Investigational Drug supplied by Sponsor for use in the Clinical Trial) to any Participant nor any other clinical intervention arising from the Protocol takes place in relation to any Participant until they are satisfied that all relevant approvals have been obtained.
	9. In the event of any substantial amendments (relating to any of the matters referred to in the definition of “Substantial Amendment to the Clinical Trial Authorisation,” in Regulation 11 of the Medicines for Human Use (Clinical Trial) Regulations 2004) being made to the Protocol, the amendments shall be signed by the Principal Investigator and shall be implemented by the Personnel as required by the Sponsor. The Sponsor shall initiate simultaneously the change control procedures set out in Clause 16.3 of this Agreement.
	10. The Sponsor shall make the Protocol available to the Principal Investigator and provide evidence of the approvals set out in Clause 4.7 and the Principal Investigator shall include such documents in the Investigator Trial Master File. The Sponsor shall ensure that any and all safety and / or toxicology data relating to the IMP, which the Sponsor is aware of or which comes to the attention of the Sponsor from time to time, and which may, in the reasonable opinion of the Sponsor, be materially relevant to the conduct of the Clinical Trial, will also be provided to the Principal Investigator for inclusion in the Investigator Trial Master File.
	11. Where the Investigational Drugs will be provided to the Trial Site by the Sponsor or its Agent, the Trial Site and the Principal Investigator shall not permit the Investigational Drugs supplied by or on behalf of the Sponsor for the purposes of the Clinical Trial to be used for any purpose other than the conduct of the Clinical Trial.
	12. Where the Sponsor requires the Trial Site to make use of Investigational Drugs and / or rescue medication for the Clinical Trial from the Trial Site’s own supplies, and / or to purchase such supplies specifically for the Clinical Trial from a third party, the Sponsor shall reimburse the Trial Site for the same. Reimbursement shall be at the rate current in British National Formulary (“**BNF**”) (plus VAT, where applicable) at time of purchase by the Trial Site, except where no BNF rate is available, in which case the Trial Site will invoice the Sponsor for the price at which the Trial Site purchased the Investigational Drugs and / or rescue medication.
	13. Upon termination or expiry of this Agreement all unused Investigational Drugs supplied for the purposes of the Clinical Trial shall be managed in accordance with the provisions of Clause 4.14.
	14. The Investigational Drugs shall be made available to the Trial Site, and all unused Investigational Drugs shall be managed at the termination or expiry of this Agreement, in line with the arrangements herein:

| **Investigational Drug name** | **Supply arrangements** | **Post-trial arrangements** |
| --- | --- | --- |
| [Insert name of Investigational Drug] | [Provided by the Sponsor] [Provided by the Trial Site from its own supplies] [Purchased by the Trial Site from a third party supplier] | [Return to Sponsor] [Destroy] [Donate to Trial Site] [Not applicable (Trial Site provided from its own supplies)] [In line with Protocol arrangements] [Other – please specify] |

* 1. Subject to the Trial Site’s and the Principal Investigator’s overriding obligations in relation to Participants and individual patient care, the Trial Site and the Principal Investigator shall ensure that neither they nor the Personnel shall during the term of this Agreement conduct any other Research that might hinder the Trial Site’s or Principal Investigator’s ability to enrol and study the required cohort of Participants.
	2. The Trial Site and Principal Investigator shall use their best endeavours to [enrol] / [dose] / [randomise] (**DELETE OPTIONS NOT APPLICABLE**) [a minimum of] (**DELETE IF NOT APPLICABLE**) [**INSERT NUMBER**] Participant(s), to participate in the Clinical Trial and the Parties shall conduct the Clinical Trial in accordance with the Timelines.
	3. In the event that the Clinical Trial is part of a Multi-Centre Trial, the Sponsor may amend the number of Participants to be [enrolled] / [dosed] / [randomised] pursuant to the Protocol as follows:
		1. If, in the reasonable opinion of the Sponsor, [enrolment] / [dosing] / [randomisation] of the Participants at the Trial Site is proceeding at a rate below that required to enable the Timelines to be met, and upon the Sponsor’s request to increase the [enrolment] / [dosing] / [randomisation] rate, the Trial Site is unable to comply, the Sponsor may by reasonable notice to the Trial Site and the Principal Investigator, require the Trial Site and the Principal Investigator to cease enrolment of Participants.
		2. If with respect of the Clinical Trial, the global enrolment target has been reached, upon receipt of a notice, the Trial Site and the Principal Investigator shall immediately stop the enrolment of Participants and the terms and conditions of this Agreement shall not apply to individuals who at the time of receipt of such notice have not given informed consent (where required) and have not been enrolled in the Clinical Trial. Payments shall be made according to the number of Participants enrolled up to the date of receipt of the notice.
		3. If [enrolment] / [dosing] / [randomisation] of Participants is proceeding at a rate above that which is required to meet the Timelines, the Sponsor may, with the written agreement of the Trial Site and the Principal Investigator, increase the number of Participants to be [enrolled] / [dosed] / [randomised] at the Investigator Site and the payment to be made will be adjusted in accordance with Clause 16.2.
	4. **Updating Contact Details, Including for Notices and Payments**

The Parties shall ensure that they notify the others as soon as reasonably practicable of changes to their contact details for notices, other contacts and / or changes to payment details set out in this Agreement. This shall apply from the Effective Date of this Agreement to the end of the Retention Period. Updating contact and / or payment details in this way does not constitute a variation to the Agreement.

* 1. **Access, Research Misconduct and Regulatory Authorities**
		1. The Trial Site and Principal Investigator represent that neither they nor, to the best of their knowledge arrived at after reasonable due diligence, any Other Trial Site(s) or any of the Personnel are restricted or prevented under any law from taking part in clinical research and the Trial Site and Principal Investigator will not knowingly use in any capacity the services of any person who is so restricted or prevented under any such laws with respect to the services to be performed under this Agreement. During the term of this Agreement and for one (1) year after its termination or expiry, the Trial Site and the Principal Investigator will notify the Sponsor if the Trial Site and / or the Principal Investigator, becomes aware of any restriction or prevention being applied to it, the Principal Investigator, any Other Trial Site or any of the Personnel.
		2. The Trial Site and Principal Investigator represent that they, and to the best of their knowledge arrived at after reasonable due diligence, any Other Trial Site(s), or any of the Personnel, are not the subject of any past or pending government or regulatory investigation, inquiry, warning or enforcement action (collectively “**Agency Action**”) related to its conduct of research that has not previously been disclosed to the Sponsor. The Trial Site and Principal Investigator will promptly notify the Sponsor if they becomes aware of any Agency Action regarding compliance with ethical, scientific or regulatory standards for the conduct of research, if the Agency Action relates to events or activities that occurred prior to or during the period in which the Clinical Trial is conducted.
		3. Each Party shall inform the others immediately upon becoming aware of any Serious Breach of the Protocol and / or the conditions and principles of ICH-GCP or any other rules, principle or guidance, relating to the Clinical Trial at the Investigator Site. The Sponsor shall inform the relevant Regulatory Authority of such Serious Breach in writing within seven (7) days of becoming aware of that breach. The Sponsor shall, at its discretion, inform other participating organisations that a Serious Breach has occurred but shall not be under any obligation to do so unless a regulatory obligation is applicable or as instructed by a Regulatory Authority. For the purposes of this Clause 4.19.3, a “**Serious Breach**” is a breach that is likely to affect, to a significant degree:
1. the safety or physical or mental integrity of the Participants; or
2. the scientific value of the Clinical Trial.
	* 1. The Trial Site and Principal Investigator shall permit the Trial Monitor and any Auditor or Inspector access to all relevant clinical data of the Participants for monitoring and source data verification, such access (be it on-site, or via remote means) to be arranged at mutually convenient times and on reasonable notice. The monitoring may take such form as the Sponsor reasonably thinks appropriate, including the right to inspect any facility being used for the conduct of the Clinical Trial and to examine, in-person or by remote means, any procedures or records relating to the Clinical Trial, subject to compliance with Data Protection Laws and Guidance. The Sponsor will alert the Trial Site and Principal Investigator, promptly in accordance with Clause 18.3, of significant issues (in the opinion of the Sponsor) relating to the conduct of the Clinical Trial.
		2. In the event that the Sponsor reasonably believes that there has been research misconduct in relation to the Clinical Trial, the Trial Site and Principal Investigator shall provide all reasonable assistance to any investigation undertaken by or on behalf of the Sponsor into any alleged research misconduct. The results of the investigation shall, subject to any obligations of confidentiality, be communicated to the Trial Site and Principal Investigator. In the event that the Trial Site or Principal Investigator reasonably believes that there has been research misconduct in relation to the Clinical Trial, the Sponsor shall provide all reasonable assistance to any investigation undertaken by or on behalf of the Trial Site or Principal Investigator into any alleged research misconduct. The results of the investigation shall, subject to any obligations of confidentiality, be communicated to the Sponsor.
		3. The Trial Site and Principal Investigator shall promptly inform the Sponsor of any intended or actual inspection, written enquiry and / or visit to the Investigator Site by any Regulatory Authority, in connection with the Clinical Trial, and forward to the Sponsor copies of any correspondence from any such Regulatory Authority relating to the Clinical Trial. The Trial Site and Principal Investigator will use reasonable endeavours to procure that the Sponsor may have (a) representative(s) present during any such visit or inspection and the opportunity to review and comment on the Trial Site’s (and / or any Other Trial Site(s)) response to the visit or inspection by a Regulatory Authority in connection with the Clinical Trial. The Parties further acknowledge that inspections and written enquiries by Regulatory Authorities may also occur after the conclusion of the Clinical Trial and the Parties shall cooperate with any such inspection or written enquiry.
		4. The Trial Site and Principal Investigator will permit the Sponsor to examine the conduct of the Clinical Trial and the Investigator Site upon reasonable advance notice during regular business hours to determine that the Clinical Trial is being conducted in accordance with the Protocol, ICH-GCP and the applicable regulatory requirements. The Parties agree that the Sponsor shall have the right to audit Clinical Trial records during, and subsequent to, the Clinical Trial.
		5. Upon Investigator Site Trial Completion (whether prematurely or otherwise), the Principal Investigator shall co-operate with the Sponsor in producing a report of the Clinical Trial detailing the methodology, Results and containing an analysis of the Results and drawing appropriate conclusions.
		6. The Trial Site and Principal Investigator (together with, as applicable, any Other Trial Site(s)) will archive Clinical Trial records following Investigator Site Trial Completion, in accordance with the MRC Principles and Guidelines for Good Research Practice. The Trial Site and Principal Investigator (together with, as applicable, any Other Trial Site(s)) shall retain all Clinical Trial records for a Retention Period of [**INSERT NUMBER**] years after Trial Completion. Upon the expiry of the Retention Period the Trial Site and Principal Investigator shall transfer such records to the Sponsor if requested by Sponsor, excluding any Confidential Participant Information and shall not destroy any records without the Sponsor’s prior written approval, such approval not to be unreasonably withheld or delayed. Notwithstanding the foregoing, in the event that no response is received from the Sponsor within **[INSERT NUMBER]** working days of receipt by the Sponsor of a written request by the Trial Site or Principal Investigator for approval to destroy such records, the Trial Site and Principal Investigator may proceed to destroy the records and such destruction shall not be in breach of this Agreement.
3. The Trial Site and Principal Investigator will archive the Clinical Trial records either in line with its usual archiving arrangements or will collaborate with the Sponsor to arrange appropriate archiving outside usual Trial Site practice.
4. All arrangements for access to documents at the Trial Site should be made with the Trials Site’s responsible person for archiving: [insert email address] (**recommend using a generic email address).**
5. In the event that costs of archiving are to be incurred by the Trial Site or Principal Investigator, including all preparation and retrieval costs relating to any reasonable request to access the Clinical Trial documentation, the Sponsor warrants and confirms that it or its Agent will pay all such costs as provided by the Trial Site as a one-off payment [DELETE ONE OPTION AND RETAIN THE OTHER] [for archiving physical records at close-down of the Clinical Trial at the rate applicable at the time. The minimum price for the archiving of physical records will be £750 per box (inclusive of all overheads but exclusive of VAT, where applicable), subject to the prevailing cost of the NHS provider service at Investigator Site Trial Completion] [of £750 (inclusive of all overheads but exclusive of VAT, where applicable) for the establishment of the Trial Site’s electronic Investigator Trial Master File, including the arrangements for the archiving of the same, following commencement of this Agreement]. In the event that the Clinical Trial records are archived offsite by the Sponsor and the Trial Site and Principal Investigator do not incur any costs, no amounts will be payable to the Trial Site or Principal Investigator.
6. Notwithstanding the foregoing, the Trial Site and Principal Investigator will retain responsibility for the Investigator Trial Master File and access thereto. The Investigator Trial Master File shall be archived separately to the Sponsor Trial Master File.
	* 1. [**DELETE IF NOT APPLICABLE**] Where the Trial Site and / or the Principal Investigator are responsible for analysis of Material during the course of the Clinical Trial they shall ensure that such analysis is conducted at a laboratory approved by the Sponsor or, in the case of point of care analysis, by methodology and using equipment that is acceptable to, or provided by, the Sponsor. The Trial Site and Principal Investigator shall ensure that analysis of Material is undertaken in accordance with the Protocol and any other document agreed between the Parties (including the provisions of Appendix 6).
		2. [**DELETE IF NOT APPLICABLE**] Where the Sponsor undertakes the analysis of Material and / or has contracted with a third-party laboratory (“**Central Laboratory**”) to undertake the analysis of Material, the Sponsor shall comply, and shall ensure the Central Laboratory shall comply, with the terms of Appendix 6 herein that are expressed to be the responsibility of the Sponsor.
	1. [**DELETE IF NOT APPLICABLE**] **Equipment and Resources**
	The Parties agree that the Sponsor shall arrange for the provision of the equipment and resources to the Trial Site, pursuant to the terms set out in Appendix 7.
	2. [**DELETE IF NOT APPLICABLE**] The Trial Site will enter into (a) Hub and Spoke Agreement(s) with Other Trial Site(s), whose Clinical Trial related activities are to be overseen by the Principal Investigator (such Other Trial Site(s) to have been agreed to in advance by the Sponsor) to ensure that all such Other Trial Site(s) abide by the relevant terms of this Agreement as if they were a party to it.

## Liabilities and Indemnities

* 1. In the event of any claim or proceeding in respect of personal injury made or brought against the Trial Site or Principal Investigator by a Participant, the Sponsor shall indemnify the Trial Site and the Principal Investigator, their Agents and employees in accordance with the terms of the indemnity set out in Appendix 3 hereto.
	2. Nothing in this Clause 5 shall operate so as to restrict or exclude the liability of any Party in relation to death or personal injury caused by the negligence or wilful misconduct of that Party or its Agents or employees, or to restrict or exclude any other liability of any Party that cannot be so restricted or excluded in law.
	3. In no circumstances shall a Party be liable to another Party in contract, tort or delict (if the 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.
	4. Subject to Clauses 5.2 and 5.5 the Trial Site’s and Principal Investigator’s liability to the Sponsor arising out of or in connection with any breach of this Agreement or any act or omission of the Trial Site or Principal Investigator in connection with the performance of the Clinical Trial shall in no event exceed the fees payable by the Sponsor to the Trial Site and Principal Investigator under this Agreement. In the case of equipment loaned to the Trial Site or Principal Investigator for the purposes of the Clinical Trial, the Trial Site’s and Principal Investigator’s liability for loss or damage to this equipment arising from its negligence shall exclude fair wear and tear and shall not exceed the value of the equipment. For clarity, the “**fees payable**” are the total sum of the amounts specified in Appendix 4 based on the full enrolment of Clinical Trial Participants for the full period of the Clinical Trial.
	5. In respect of any wilful and / or deliberate breach by the Trial Site or Principal Investigator, or any breach of Clauses 6, 8, 10 or 11 the Trial Site’s and Principal Investigator’s liability to the Sponsor arising out of or in connection with the breach shall not exceed two times the value of the Agreement. For clarity, the “**value of the Agreement**” is the total sum of the amounts specified in Appendix 4 based on the full enrolment of Participants for the full period of the Clinical Trial.
	6. The Sponsor will take out appropriate insurance cover or will provide an indemnity satisfactory to the Trial Site and Principal Investigator in respect of its potential liability under Clause 5.1 above and such cover shall be for a minimum of [**INSERT AMOUNT**] as detailed in the certificate of insurance provided by the Sponsor to the Trial Site and Principal Investigator. Where the Trial Site is established in England, the Clinical Negligence Scheme for General Practice will provide cover for clinical negligence in the conduct of the Clinical Trial. For Trial Sites established in Northern Ireland, Scotland or Wales, the Trial Site and Principal Investigator represent that the Principal Investigator and Personnel shall have adequate insurance or indemnity arrangements in place to cover against clinical negligence in the conduct of the Clinical Trial, until the completion of the Clinical Trial.
		1. The Sponsor shall produce to the Trial Site and Principal Investigator on request, copies of insurance certificates, together with evidence that the policies to which they refer remain in full force and effect, or other evidence concerning the indemnity. If the Trial Site is established in Northern Ireland, Scotland or Wales it or the Principal Investigator shall produce to the Sponsor on request evidence of appropriate insurance or indemnity. The terms of insurance, or of the relevant NHS clinical negligence indemnity scheme(s), or the amount of cover, shall not relieve a Party of any liabilities under this Agreement.
	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 Participants. This Clause 6 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 another Party 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 Participant Personal Data**
		1. For the purpose of the Data Protection Laws and Guidance, the Sponsor is the Controller and the Trial Site and Principal Investigator are the Sponsor’s Processors of Personal Data which the Trial Site and Principal Investigator Process for the purpose of the Clinical Trial.
		2. The Trial Site’s and Principal Investigator’s Processing of Personal Data, as Processors of the Sponsor, 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 Trial Site and / or the Principal Investigator are the Controllers of Personal Data Processed for purposes other than the Clinical Trial, for example the provision of medical care.
		4. The Trial Site and the Principal Investigator, in their roles as Processors of the Personal Data under Clause 6.2.1, agree to only Process Personal Data for and on behalf of the Sponsor in accordance with the documented instructions of the Sponsor, including with regard to transfers of Personal Data to a third country or an international organisation. If the Trial Site and / or the Principal Investigator is/are required by law to otherwise Process the Personal Data, the Trial Site and / or the Principal Investigator shall notify the Sponsor 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 Trial Site shall notify the Sponsor as soon as possible once the prohibition is lifted, if it is lifted.
		5. The Trial Site and the Principal Investigator agree to comply with the obligations applicable to Processors described by Article 28 of the GDPR, as well as those additional obligations required by the Sponsor 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 their 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 6.2.6 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, 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 Trial Site and the Principal Investigator (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 Trial Site and/or Principal Investigator as a Processor of the Sponsor, the Trial Site and / or the Principal Investigator shall:
9. promptly and without undue delay following discovery of such Personal Data Breach, send written notice of the incident via e-mail to [**insert**];
10. 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’s prior written approval; and
11. immediately take steps to investigate and mitigate the Personal Data Breach and reasonably cooperate with the Sponsor.
	* 1. In furtherance of their obligations under Article 28 GDPR, the Trial Site and Principal Investigator agree that they will not engage another Processor for the purpose of the Clinical Trial without the prior written authorisation of the Sponsor (GDPR Article 28(2)), excepting where that other Processor is a Participant Identification Centre (PIC), in which case Clause 6.2.6 (a) shall apply;
12. In accordance with GDPR Article 28(2), the Trial Site and Principal Investigator may appoint PICs, on the basis of an unmodified template data processing agreement agreed in advance with the Sponsor, by notifying the Sponsor that they intend to contract the PIC. The Sponsor will be considered to have authorised this sub-processing if it does not notify the Trial Site and the Principal Investigator to the contrary within [**INSERT NUMBER**, FOR EXAMPLE, FIVE (5)] working days.
	* 1. At the expiry or lapse of this Agreement, the Trial Site and the Principal Investigator shall, at the choice of the Sponsor, destroy or return all Personal Data to the Sponsor 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 Trial Site and / or the Principal Investigator as Controller(s) for their own purpose(s).
		2. The Trial Site and the Principal Investigator will:
			1. not process and will ensure that their Personnel do not Process Personal Data except in accordance with the Protocol and this Agreement;
			2. 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:
				1. are aware and comply with the Trial Site’s and Principal Investigator’s duties under this Clause 6 (Data Protection);
				2. 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
				3. 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.
		3. The Trial Site and the Principal Investigator agree to:
13. Provide the Sponsor with evidence of their compliance with the obligations set out in this Agreement, and / or, at the Sponsor’s discretion and on reasonable notice, to allow the Sponsor, or a third party appointed by the Sponsor, to audit the Trial Site’s and Principal Investigator’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, or its appointed third party, complying with all relevant health and safety and security policies of the Trial Site and / or the Principal Investigator.
14. Obtain prior written agreement of the Sponsor to Process Personal Data outside of the UK and the EEA.
	* 1. In addition to the Trial Site’s and the Principal Investigator’s obligations under Clause 6.2.9(b), where the Trial Site and / or the Principal Investigator, acting as the Sponsor’s Processor, Process Personal Data outside of the UK and the EEA, the Trial Site and / or the Principal Investigator warrant that they do so in compliance with the Data Protection Laws and Guidance.
	1. **Sharing of Personal Data and / or Participant Pseudonymised Data**
		1. Neither Personal Data nor Pseudonymised Data of Participants shall be transferred by the Trial Site or the Principal Investigator to the 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 a Participant in connection with the Clinical Trial or is otherwise required by applicable law.
		2. The Sponsor agrees not to transfer Personal Data or Pseudonymised Data of Participants 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 6.
		3. The Sponsor agrees to use Personal Data and / or Pseudonymised Data of Participants for the purpose of the Clinical Trial or otherwise as permitted in the approved consent form and in all circumstances for no purpose which is incompatible with the Clinical Trial purpose. The Sponsor further agrees not to disclose the Personal Data or Pseudonymised Data of Participants to any person except as required or permitted by law or applicable guidance.
		4. The Sponsor agrees to comply with the obligations placed on it 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 Sponsor agrees to ensure persons Processing Personal Data and / or processing Pseudonymised Data of actual or potential Participants under this Agreement are equipped to do so respectfully and safely. In particular:
15. to ensure any such persons (excluding employees, honorary employees, students, researchers, consultants and sub-contractors of the Trial Site, any Other Trial Site(s) and / or the Principal Investigator) understand the responsibilities for information governance, including their obligation to Process Personal Data and / or process Pseudonymised Data of Participants securely and to only disseminate or disclose for lawful and appropriate purposes;
16. to ensure any such persons (excluding employees, honorary employees, students, researchers, consultants and sub-contractors of the Trial Site, any Other Trial Site(s) and / or Principal Investigator) 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 Sponsor agrees to take reasonable steps to proactively prevent Personal Data Breaches, and / or equivalent breaches relating to Pseudonymised Data of Participants, and to respond appropriately to incidents or near misses. In particular:
17. to ensure that Personal Data and / or Pseudonymised Data of Participants 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;
18. to ensure all access to Personal Data and / or Pseudonymised Data of Participants on IT systems Processed for Clinical Trial purposes can be attributed to individuals;
19. 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 Participants to use workarounds which compromise data security;
20. to adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice;
21. to take action immediately following a Personal Data Breach or near miss.
	* 1. The Sponsor agrees to ensure Personal Data and / or Pseudonymised Data of Participants are Processed/processed using secure and up-to-date technology. In particular:
22. 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 Participants for the purposes of the Clinical Trial;
23. to put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework;
24. to ensure IT suppliers are held accountable via contracts for protecting Personal Data and / or Pseudonymised Data of Participants that they Process / process and for meeting all relevant information governance requirements.

## Freedom of Information

* 1. The Sponsor acknowledges that the Trial Site and the Principal Investigator are subject to the applicable FOIA and EIR and associated guidance and codes of practice.
	2. If the Trial Site and / or the Principal Investigator or their Agent(s) receive a request under the FOIA or EIR to disclose information relating to this Agreement (including but not limited to the Sponsor, Investigational Drugs (or their manufacturers), or the Clinical Trial), they will notify the Sponsor as soon as is reasonably practicable, and in any event, no later than five (5) working days after receiving the request. The Trial Site and / or the Principal Investigator will consult with the Sponsor in accordance with all applicable guidance.
	3. The Sponsor acknowledges that the decision on whether any exemption applies to a request for disclosure of recorded information under the FOIA or EIR is a decision solely for the Trial Site and / or the Principal Investigator, in line with which Party or Parties received the request.
	4. The Sponsor shall cooperate with the Trial Site and / or the Principal Investigator and shall use its reasonable endeavours to respond within ten (10) working days of the Trial Site’s and / or the Principal Investigator’s reasonable request for assistance.
	5. Where the Trial Site and / or the Principal Investigator determines that they will disclose information, notwithstanding any objections from the Sponsor, they will notify the Sponsor in writing, giving at least two (2) working days’ notice of their intended disclosure.

## Confidential Information

* 1. The Parties may only disclose Confidential Information to their own officers, Agents and employees (and in the case of the Sponsor, those of its Affiliates and, if applicable, other parties who may have contractual rights in the Results or to develop the IMP (for example, through a licence, collaborative agreement, Co-Promotion Agreement, Co-Development Agreement, etc. with Sponsor)) that are directly concerned with the carrying out of this Agreement. Each Party undertakes to treat as strictly confidential and not to disclose to any third party any Confidential Information of the other Parties, save where disclosure is required by a Regulatory Authority or by law (including any disclosure required to ensure compliance, by the Trial Site and / or the Principal Investigator, with the FOIA or EIR in accordance with Clause 7 of this Agreement). The Party required to make the disclosure shall inform the other Parties within a reasonable time prior to being required to make the disclosure (and, where appropriate, in accordance with Clause 7), 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 Parties, other than in accordance with this Agreement, without the prior written consent of the other Parties.
	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 (i) without limit in time in respect of Personal Data and any other information which relates to a participant or potential participant, their treatment and / or medical records (ii) for information not falling under the aforementioned, the time period for which the Trial Site retains Clinical Trial records as set out in Section 4.19.9 (subject to the permitted uses set out in this Agreement). Save as aforesaid, and unless otherwise expressly set out in this Agreement, this Clause 8 shall remain in force for a period of ten (10) years after the termination or expiry of this Agreement.

## Publicity

* 1. Subject to Clauses 4.5, 10.6 and 12.5, the Sponsor will not use the name of the Trial Site or any Other Trial Site in any publicity, advertising or news release without the prior written approval of an authorised representative of the Trial Site, such approval not to be unreasonably withheld. Nothing in this Agreement will prohibit the Sponsor from publishing the identities and contact information of the Trial Site, any Other Trial Site, and the Clinical Trial recruitment status at the Investigator Site for the purpose of registering the Clinical Trial in a publicly available clinical trials database, making information about the Clinical Trial available to potential Participants, or otherwise as may be required under Clause 4.5.
	2. The Trial Site and the Principal Investigator 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 or news release without the prior written approval of the Sponsor, such approval not to be unreasonably withheld. The provisions of this Clause 9.2 shall also apply to the Trial Site’s and the Principal Investigator’s use of the name, trademark, service mark, and / or logo of any third parties collaborating with the Sponsor on the Clinical Trial and / or the IMP (“**Sponsor Collaborators**”) provided that the Trial Site has and the Principal Investigator have been notified of the identity of the Sponsor Collaborators.
	3. Neither the Trial Site, nor the Principal Investigator, will issue any information or statement to the press or public including but not limited to advertisements for the enrolment of Participants without the prior written permission of the Sponsor, not to be unreasonably withheld, and the delivery of research ethics committee approval, where applicable.

## Publications

* 1. The Sponsor recognises that the Trial Site and Principal Investigator have a responsibility under the UK Policy Framework to ensure that results of scientific interest arising from the Clinical Trial are appropriately published and disseminated.
		1. The Sponsor agrees that employees of the Trial Site, any Other Trial Site, and the Principal Investigator shall be permitted to present at symposia, national and regional professional meetings and to publish in journals, theses or dissertations, or otherwise of their own choosing, the methods and Results of the Clinical Trial, subject to this Clause 10 and any publication policy described in the Protocol, provided any such policy is consistent with the Joint Position.
		2. If the Clinical Trial is a Multi-Centre Trial, any publication based on the results obtained at any one Investigator Site (or group of Investigator Sites) shall not be made before the first Multi-Centre publication.
		3. If a publication concerns the analyses of sub-sets of data from a Multi-Centre Trial, the publication must make reference to the relevant Multi-Centre Trial publication.
	2. Upon Investigator Site Trial Completion, and any prior publication by the Sponsor of Multi-Centre Trial data or when the Clinical Trial data are adequate (in the Sponsor’s reasonable judgment), the Trial Site, any Other Trial Site(s), and / or the Principal Investigator may prepare the data derived from the Investigator Site for publication. Such data will be submitted to the Sponsor for review and comment prior to publication.
		1. In order to ensure that the Sponsor will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to the Sponsor for review at least forty (40) working days (or the time specified in the Protocol if longer) prior to submission for publication, public dissemination, or review by a publication committee.
	3. The Trial Site and the Principal Investigator agree that all reasonable comments made by the Sponsor in relation to a proposed publication by the Trial Site, any Other Trial Site, and / or the Principal Investigator will be incorporated Trial Site and / or the Principal Investigator into the publication.
	4. The Sponsor shall ensure that the Results of the Clinical Trial are published on a free, publicly accessible clinical trial results database in accordance with the principles of the Joint Position within one (1) year after the IMP is first approved and made commercially available in any country or, if the Clinical Trial is a post-approval clinical trial, within one (1) year of Trial Completion. In respect of a clinical trial that is under review by peer reviewed journals that prohibit disclosure of Results pre-publication, the Results will be posted at the time of publication.
		1. The Trial Site and the Principal Investigator acknowledge that nothing in this Agreement prevents the Sponsor (nor any person with whom they share the methods and Results of the Clinical Trial) from presenting at symposia, national or regional professional meetings, publishing in journals, theses or dissertations or otherwise of their own choosing, the methods and Results of the Clinical Trial and in particular, but without limiting the foregoing, post a summary of the Clinical Trial Results in an on-line clinical trials register(s) before or after publication by any other method.
	5. Subject to Clause 8 regarding Confidential Information, the Trial Site and the Principal Investigator will accurately describe and will ensure that any Other Trial Site will accurately describe the financial support of the Sponsor for the Clinical Trial in all publications and presentations.
	6. In the event that the Sponsor coordinates a Multi-Centre Trial publication, the participation of the Principal Investigator or Personnel as named authors shall be determined in accordance with the Sponsor’s policy and generally accepted standards for authorship. If the Principal Investigator or other Personnel are to be named as authors of the Multi-Centre Trial publication, such person(s) shall have access to the Clinical Trial data from all sites involved in the Clinical Trial, as necessary to participate fully in the development of the Multi-Centre Trial publication.
	7. During the period for review of a proposed publication referred to in Clause 10.2.1 above, the Sponsor shall be entitled to make a reasoned request to the Trial Site and the Principal Investigator that publication be delayed for a period of up to one hundred and eighty (180) calendar days from the date of first submission to the Sponsor in order to enable the protection of proprietary information and / or Intellectual Property Rights and Know-How and the Trial Site and the Principal Investigator shall not unreasonably withhold or delay their consent to such request. The Trial Site and the Principal investigator shall not unreasonably withhold or delay their consent to a request from the Sponsor for an exceptional additional delay if, in the reasonable opinion of the Sponsor, proprietary information and / or Intellectual Property Rights and Know-How might otherwise be compromised or lost.

## Intellectual Property

* 1. All Intellectual Property Rights and Know-How owned by or licensed to the Sponsor or Affiliate(s) 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 Sponsor.
	2. All Intellectual Property Rights and Know-How owned by or licensed to the Trial Site (or any Other Trial Site(s)) and / or to the Principal Investigator 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 Trial Site (or any Other Trial Site) and / or to the Principal Investigator.
	3. All Intellectual Property Rights and Know-How arising from and relating to the Clinical Trial, the IMP (including but not limited to its formulation and use 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 Trial Site and / or the Principal Investigator (or any Other Trial Site(s)), shall vest in the Sponsor in accordance with Clauses 11.4 and 11.5 of this Agreement.
	4. In accordance with Clause 11.3, the Trial Site and the Principal Investigator hereby assign, and shall procure that their Agents assign, their rights in relation to all Intellectual Property Rights and Know-How, falling within Clause 11.3, to the Sponsor or its nominee. At the request and expense of the Sponsor, the Trial Site and the Principal investigator shall execute, and shall procure that their 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 Trial Site shall and the Principal Investigator shall promptly disclose to the Sponsor any Know-How generated pursuant to this Agreement and falling within Clause 11.3 and undertakes not to use or disclose such Know-How other than for the purposes of this Agreement.
	6. The Parties represent and warrant that they will not attempt to seek commercial advantage or infringe the IPR of the other Party or any third party, nor knowingly allow any third party to do so, by the analysis of any Material or any other process designed or intended to derive privileged information in relation to the chemical, biological or other properties of any investigational medicinal product to which Participants may have been exposed by virtue of involvement in other Research.
	7. Nothing in this Clause 11 shall be construed so as to prevent or hinder the Trial Site, the Principal Investigator (or any Other Trial Site(s)) from using their Know-How generated during the performance of the Clinical Trial in the furtherance of their 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 Sponsor.

## Finances

* 1. Arrangements relating to the financing of this Clinical Trial by the Sponsor are set out in Appendix 4. All payments will be made according to Appendix 4.
	2. In the event that any change to the Protocol results in amendment to the financial arrangements set out at Appendix 4, it is agreed that the Parties will vary Appendix 4 in accordance with Clause 16.2.
	3. Subject to Clauses 4.17 and 12.2, changes to the recruitment target set out at Clause 4.16 will be made without renegotiating the per capita payments in Appendix 4.
	4. In accordance with Clause 4.16, any payment adjustments for recruitment (over or under recruitment) will be made according to the per capita payments and other values specified in Appendix 4, including (as applicable) any inflationary uplifts in accordance with Clause 4 of Appendix 4.
	5. The Trial Site and the Principal Investigator agree that the Sponsor may make public the financial support provided to the Trial Site and the Principal Investigator by the Sponsor for the conduct of the Clinical Trial and may identify the Trial Site (and any Other Trial Site(s)) and the Principal Investigator as part of this disclosure.

## Term

* 1. This Agreement will commence on the Effective Date and shall remain in effect until Investigator Site Trial Completion or earlier termination in accordance with this Agreement.

## Termination

* 1. Either the Sponsor, the Principal Investigator or the Trial Site (the “**Terminating Party**”) may terminate this Agreement with immediate effect at any time if another Party (the “**Defaulting Party**”) is:
		1. in breach of any of the Defaulting Party’s obligations hereunder (including a failure without just cause to meet a timeline set out in this Agreement or the Protocol) and fails to remedy such breach where it is capable of remedy within twenty-eight (28) calendar days of a written notice from the Terminating Party specifying the breach and requiring its remedy;
		2. declared insolvent or has an administrator or receiver appointed over all or any part of its assets or ceases or threatens to cease to carry on its business.
	2. A Party may terminate this Agreement on notice to the other Parties with immediate effect if it is reasonably of the opinion that the Clinical Trial should cease in the interests of the health of Participants involved in the Clinical Trial.
	3. The Sponsor may terminate this Agreement on notice to the Trial Site and the Principal Investigator if the Principal Investigator is no longer able (for whatever reason) to act as Principal Investigator and no replacement mutually acceptable to the Trial Site and the Sponsor can be found. In the event that a Sub-Investigator is no longer able (for whatever reason) to act as a Sub-Investigator and no suitable replacement Sub-Investigator acceptable to the Trial Site, Principal Investigator and Sponsor can be found, the Sponsor may terminate this Agreement on notice to the Trial Site and the Principal Investigator.
	4. The Sponsor may terminate this Agreement immediately upon notice in writing to the Trial Site and the Principal Investigator for reasons not falling within Clauses 14.1.1, 14.2 or 14.3 above. In all such circumstances, the Sponsor shall confer with the Principal Investigator and use its best endeavours to minimise any inconvenience or harm to Participants caused by the premature termination of the Clinical Trial.
	5. In the event of early termination of this Agreement by the Sponsor, pursuant to Clauses 14.1, 14.2, 14.3 or 14.4 and subject to an obligation on the Trial Site and the Principal Investigator to mitigate any loss, the Sponsor shall pay all costs incurred and falling due for payment up to the date of termination, and also all non-cancellable expenditure falling due for payment after the date of termination that arises from commitments reasonably and necessarily incurred by the Trial Site and / or the Principal Investigator for the performance of the Clinical Trial prior to the date of termination, and agreed with the Sponsor.
	6. At Investigator Site Trial Completion, the Trial Site shall [destroy, and shall ensure that the Principal Investigator and any Other Trial Site(s) shall destroy,] [promptly deliver, and shall ensure that any Other Trial Site(s) and the Principal Investigator delivers, to the Sponsor] [**delete** one option] all Confidential Information and any other unused materials provided to the Trial Site, any Other Trial Site(s) and / or the Principal Investigator pursuant to this Agreement, excepting such Confidential Information and other information that forms the Investigator File, as per ICH-GCP 8.4, and other documents as agreed between Trial Site and Sponsor or that are otherwise required by applicable legislation to be retained by the Trial Site and / or any Other Trial Site(s), which will be retained in accordance with 4.19.9. Any obligation to destroy or return Confidential Information or copies thereof does not extend to automatically generated computer back-up or archival copies generated in the ordinary course of the Trial Site’s information technology systems procedures, provided that the Trial Site shall make no further use of those copies.
	7. Termination of this Agreement will be without prejudice to the accrued rights and liabilities of the Parties under this Agreement.

## Relationship of the Parties

* 1. No Party may assign its rights under this Agreement or any part thereof without the prior written consent of the other Parties, such consent not to be unreasonably withheld or delayed, except that the Sponsor may assign this Agreement at any time to a successor to all or substantially all of its business or assets to which this Agreement relates, whether by way of merger, consolidation, sale of stock, sale of assets, operation of law or otherwise, upon written notice to the Trial Site and Principal Investigator. The Sponsor shall inform the Trial Site and Principal Investigator in good time in writing about the aforementioned assignment / assignation.
	2. No Party may sub-contract the performance of all or any of its obligations under this Agreement without the prior written consent of the other Parties, such consent not to be unreasonably withheld or delayed. In the event that a 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. Any Party who so sub-contracts shall be responsible for pass-through of payments to its sub-contractors.
	3. Nothing in this Agreement shall be construed as creating a joint venture, partnership, contract of employment or relationship of principal and agent between the Parties.

## Agreement and Modification

* 1. **Order of Precedence**
	Should there be any inconsistency between the Protocol and the terms of this Agreement, or any other document incorporated herein, the terms of the Protocol shall prevail to the extent of any inconsistency except insofar as the inconsistency relates to Clauses 5, 6, 7, 8, 10, 11 and 16 of this Agreement, whereby the terms of this Agreement shall prevail.
	2. Any change in the terms of this Agreement shall be valid only if the variation is made in writing, agreed and signed by the Parties.
	3. Any amendment to the Protocol (“**Protocol Amendment**”) shall be managed by means of the change control procedure set out in this Clause.
		1. For the purposes of this Agreement, a “**Change Request**” is a request to change the obligations of the Parties arising from a Protocol Amendment.
		2. Where the Sponsor originates a Change Request, the Trial Site and / or the Principal Investigator shall provide the Sponsor, within ten (10) working days of receiving the Change Request, details of the impact that the proposed Protocol Amendment will have upon the costs of carrying out the Clinical Trial and the other terms of this Agreement.
		3. A Change Request shall become a “**Change Order**” when the requirements of the change control procedure have been satisfied and any necessary change to this Agreement is signed by the authorised representatives of the Parties.
		4. An amended financial appendix shall be signed and appended to this Agreement according to Clause 12.2 above.
	4. This Agreement contains the entire understanding between the Parties. This Agreement supersedes all other agreements, negotiations, representations and undertakings, whether written or oral, of prior date between the Parties relating to the conduct of the Clinical Trial (as overseen by the Principal Investigator) that is the subject of this Agreement, other than where a separate Investigator Site within the Trial Site has been contracted, in which case the Agreement does not supersede that agreement.

## Force Majeure

* 1. No Party shall be liable to the other Parties 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 Parties in writing when such circumstances cause a delay or failure in performance and when they cease to do so. In the event of a delay or failure in performance lasting for four (4) weeks or more, the non-affected Party or Parties shall have the right to terminate this Agreement immediately by notice in writing to the other Parties.

## Notices

* 1. Any notice required to be given by a Party shall be in writing quoting the date of the Agreement and shall be delivered by hand or sent by pre-paid first-class recorded delivery or by e-mail to the contact persons listed below, as per the contact details listed below, or such other person as one Party may inform the other Party in writing from time to time.
		1. A notice shall be treated as having been received:
1. if delivered by hand within normal business hours when so delivered, or if delivered by hand outside normal business hours, at the next start of normal business hours. For the avoidance of doubt, a notice shall be deemed to have been received when delivered to the address of the receiving Party, irrespective of whether any individual addressee has received the notice pursuant to an organisation’s internal postal arrangements; or
2. if sent by first-class recorded delivery mail on a normal business day, at 9.00am on the second business day subsequent to the day of posting or, if the notice was not posted on a business day, at 9.00am on the third business day subsequent to the day of posting. For the avoidance of doubt, a notice shall be deemed to have been received when delivered to the address of the receiving Party, irrespective of whether any individual addressee has received the notice pursuant to an organisation’s internal postal arrangements day, at 9.00am on the third business day subsequent to the day of posting; or
3. if sent by e-mail, if sent within normal business hours when so sent or, if sent outside normal business hours at the next start of the normal business hours provided the sender has either received an electronic confirmation of delivery or has telephoned the recipient and confirmed with the recipient that the e-mail has been received.
	1. Notices to the Sponsor shall be addressed to:
	[**INSERT** CONTACT NAME AND ADDRESS – INCLUDE E-MAIL ADDRESS AS APPLICABLE]
	2. Notices to the Trial Site shall be addressed to:
	[**INSERT** CONTACT NAME AND ADDRESS – INCLUDE E-MAIL ADDRESS AS APPLICABLE]
	3. Notices to the Principal Investigator shall be addressed to:
	[**INSERT** CONTACT NAME AND ADDRESS – INCLUDE E-MAIL ADDRESS AS APPLICABLE]

## 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 ten (10) working days of being requested in writing by either Party to do so.
	2. If the Trial Site is constituted in England or Wales then, in the event of failure to resolve the dispute through the steps set out in Clause 19.1, 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, a Party shall give notice in writing (“**ADR Notice**”) to the other Party or Parties requesting mediation in accordance with this Clause 19.2. 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 fifteen (15) working 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 twenty (20) working days of the ADR Notice, a Party shall be entitled to submit to the exclusive jurisdiction of the courts of England and Wales.

If the Trial Site is constituted in Scotland, then in the event of failure to resolve the dispute through the steps set out in Clause 19.1, the same may be referred to an independent third party for resolution. In the event that the Parties cannot mutually agree on the identity of an independent third party, the Parties will ask the President for the time being of the Law Society of Scotland to appoint a suitable individual to consider the matter in dispute. The person so appointed will act as an expert and not as an arbiter. 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 Parties are unable to resolve a dispute arising out of or in connection with this Agreement in accordance with Clause 19.1 and 19.2, a Party shall be entitled to submit to the exclusive jurisdiction of the Scottish courts.

If the Trial Site is constituted in Northern Ireland, then in the event of failure to resolve the dispute through the steps set out in Clause 19.1, the Parties agree to attempt to resolve the dispute by mediation. To initiate a mediation, a Party will give notice in writing to the other Party or Parties requesting mediation in accordance with this Clause 19.2. The Parties shall seek to agree the nomination of the mediator but, in the absence of agreement, the Parties shall ask the President for the time being of the Law Society of Northern Ireland to appoint a suitable mediator. The person so appointed will act as an expert and not as an arbiter. The Parties shall each bear their own costs and expenses in relation to the mediation and shall share equally the costs of the mediator. If the Parties are unable to resolve the dispute by mediation in accordance with Clause 19.1 and 19.2, a Party shall be entitled to submit to the exclusive jurisdiction of the courts of Northern Ireland.

* 1. Nothing in this Agreement shall prevent a Party from seeking an interim injunction (if the Trial Site is constituted in England or Wales or Northern Ireland) or interdict (if the Trial Site is constituted in Scotland) in respect of a breach of this Agreement. For the avoidance of doubt, nothing in this Agreement shall amount to an agreement that a Party is entitled to an interim injunction or interdict as applicable.

## Miscellaneous

* 1. **Rights of Third Parties**
	Nothing in this Agreement is intended to confer on any person any right to enforce any term of this Agreement which that person would not have had but for the Contracts (Rights of Third Parties) Act 1999, or the Contract (Third Party Rights) (Scotland) Act 2017 where the Trial Site is constituted in Scotland (each being a "**Third Party Rights Act**"). Any right or remedy of a third party that existed or is available apart from the relevant Third Party Rights Act is not affected; in particular, without limitation, any right of any Participant to claim compensation in accordance with the Clinical Trial Compensation Guidelines referred to in Appendix 2.
	2. **Waiver**
	No failure, delay, relaxation or indulgence by any Party in exercising any right conferred on such Party by this Agreement shall operate as a waiver of such right, nor shall any single or partial exercise of any such right nor any single failure to do so, preclude any other or future exercise of it, or the exercise of any other right under this Agreement.
	3. **Survival of Clauses**
	The following clauses shall survive the termination or expiry of this Agreement:

**Clause 1** Definitions

**Clause 3.2 to 3.7** Clinical Trial Governance

**Clause 4.18** Updating Contact Details, Including for Notices and Payments

**Clause 4.19** Access, Research Misconduct and Regulatory Authorities

**Clause 5** Liabilities and Indemnities

**Clause 6** Data Protection

**Clause 7** Freedom of Information

**Clause 8** Confidential Information

**Clause 9** Publicity

**Clause 10** Publications

**Clause 11** Intellectual Property

**Clause 14** Termination

**Clause 15** Relationship of the Parties

**Clause 16** Agreement and Modification

**Clause 17** Force Majeure

**Clause 18** Notices

**Clause 19** Dispute Resolution

**Clause 20** Miscellaneous

* 1. **Governing Law and Jurisdiction**
	Where the Trial Site is constituted in England then 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 Trial Site is constituted in Wales then 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 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 Trial Site is constituted in Northern Ireland, then 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.

* 1. **Counterparts and Signatures**
	This Agreement may be executed in any number of counterparts, each of which when executed shall constitute a duplicate original, but all the counterparts shall together constitute the one agreement. This Agreement may be executed through the use of an electronic signature. Transmission of the executed signature page of a counterpart of this Agreement by e-mail (in PDF, JPEG or other agreed format) to the other Parties shall take effect as delivery of an executed counterpart of this Agreement. If either method of delivery is adopted, without prejudice to the validity of the Agreement thus made, each Party shall provide the others with the original of such counterpart as soon as reasonably possible thereafter. No counterpart shall be effective until each Party has executed and delivered at least one counterpart.

|  |  |  |
| --- | --- | --- |
| Signed for and on behalf of:[**INSERT** NAME OF SPONSOR]OrSigned by [**INSERT** name of company] for and on behalf of [**INSERT** NAME OF SPONSOR], as duly authorised under Appendix 8Signature:Print name:Title: Date: | Signed for and on behalf of:[**INSERT** NAME OF TRIAL SITE]Signature:Print name:Title:Date: | Signed for and on behalf of:[**INSERT** NAME OF PRINCIPAL INVESTIGATOR]Signature:Print name:Title:Date: |

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

# Appendix 1: Timelines and Responsibilities of the Parties

The milestones and division of responsibility set out below are provided as examples only. The milestones for each Clinical Trial are to be agreed between the Sponsor and the Trial Site. Please remove this text once the document has been agreed for the Clinical Trial.

|  |  |  |  |
| --- | --- | --- | --- |
| **Milestone** | **Sponsor responsibility** | **Trial Site / Principal Investigator responsibility** | **Target date for completion at Investigator Site** |
| Investigator Site initiation visit | Yes | Yes | [ENTER DATE] |
| First Participant enrolled | No | Yes | [ENTER DATE] |
| Last Participant enrolled | No | Yes | [ENTER DATE] |
| All Case Report Form queries submitted | Yes | No | [ENTER DATE] |
| All Case Report Form queries completed | No | Yes | [ENTER DATE] |

# Appendix 2: ABPI Clinical Trial Compensation Guidelines 2015

### Preface

These guidelines contain two distinct sections:

Phase I Clinical Trials Compensation Guidelines

Phases II, III and IV Clinical Trials Compensation Guidelines

The purpose of these guidelines is to remove the distinction between the compensation arrangements benefiting healthy volunteers in Phase I trials that do not have the target disease and those patient volunteers in Phase I trials that do have the target disease, but where there is no reasonable prospect of direct benefit. These guidelines will apply to all clinical trials commenced from 1st January 2015 onwards.

### Background

The Association of the British Pharmaceutical Industry (ABPI) has long encouraged member companies to make special arrangements to compensate participants in clinical research that they have sponsored and who suffer injury as a result of such participation. The first guidelines relating to Phase I “healthy (non-patient) volunteer” studies were issued in 1970 and guidelines relating to clinical trials at Phases II-IV were first issued in 1983. The distinction between the compensation arrangements for “healthy volunteers” and for “patient volunteers” was based on the fact that “healthy volunteers” in Phase I studies would normally have no real prospect of personal benefit from participation in a Phase I study, whereas patients suffering from the target disease, participating in clinical trials at Phases II-IV, did have a prospect of benefit. It was viewed as ethically reasonable that patient volunteers should accept some of the risks inherent in testing new treatments for their disease, particularly where side-effects were foreseeable and the subject of warnings in trial information.

Since the two sets of guidelines were originally published, the ABPI has conducted periodic reviews of them and amendments have been adopted.

Recently, in relation to Phase I studies, it was noted that an increasing number of studies at Phase I with a new chemical or biological entity involve patients as well as (or instead of) healthy subjects. Many such studies explore disease-specific biomarkers; they do not investigate efficacy. Therefore, patients with the target disease participating in single dose administration and / or limited repeat dose administration studies at Phase I are not expected to gain therapeutic benefit and would not ordinarily be offered access to the medicinal product under investigation beyond the end of the study. In the circumstances, it is no longer thought ethically appropriate to distinguish between the compensation arrangements benefiting healthy volunteers that do not have the target disease and those patient volunteers that do have the target disease, but where there is no reasonable prospect of direct benefit from participation.

The ABPI and our members believe that the same compensation arrangements should apply to all patients enrolled in Phase I studies who have no prospect of direct benefit, including those with the target disease; and henceforth no distinction will be made between the status of subjects participating in Phase I research who have no prospect of direct benefit. Oncology or other studies at Phase I where material side-effects are foreseeable because of the nature of the product under research, but where patient volunteers may reasonably expect to receive therapeutic benefit, are not affected by this change of policy.

### The new guidelines

Previous guidelines in this area have been replaced in order to reflect the agreed ABPI position:

the 1988 Non-Patient Guidelines are now replaced by the compensation provisions set out in the Phase I Clinical Trials Compensation Guidelines; and

the 1991 Clinical Trial Guidelines are now replaced by the compensation provisions set out in the Phases II, III and IV Clinical Trials Compensation Guidelines.

Consequential changes to the relevant section on compensation in the ABPI’s Guidelines For Phase I Clinical Trials (2012 Edition) have also been made.

## Phase I Clinical Trial Compensation Guidelines

### Background

The Association of the British Pharmaceutical Industry requires member companies that sponsor Phase I studies that offer no prospect of direct therapeutic benefit to research subjects to ensure that the arrangements they put in place for the conduct of such studies create a legally binding obligation, through the terms of the consent form and subject information, to pay compensation to the volunteer in the event of injury due to participation in the study.

1. The following principles should be reflected in these arrangements:
	1. The volunteer should be given a clear commitment that if he/she suffers bodily injury through participation in the trial, appropriate compensation will be paid without the volunteer having to prove either that such injury arose through negligence or that the product was defective in the sense that it did not fulfil a reasonable expectation of safety. The company should not seek to remove the right of the volunteer, as an alternative, to pursue a claim on the basis of either negligence or strict liability, if the volunteer wishes to do so.
	2. Where pharmaceutical companies sponsor studies to be performed by an outside research establishment, the responsibility for paying compensation should be clarified and reflected in the contractual documentation with the volunteer. Where the sponsoring company directly provides the undertaking regarding compensation, it is recommended that the text of the undertaking reflects an unqualified obligation to pay compensation to the volunteer on proof of causation. The company can protect its rights of recourse against the research establishment in its agreement with that establishment so as to cover the position where the negligence of its contractor may have caused or contributed to the injury by the volunteer. A volunteer can reasonably expect that compensation will be paid quickly and that any dispute regarding who will finally bear the cost of the compensation paid to him will be resolved separately by the other parties to the research.
2. It is also recommended that a simple arbitration clause is included as part of the provisions concerning compensation for injury, whereby any difference or dispute in relation to the implementation of the compensation provisions may be resolved with a minimum of formality.
3. The prospect of receiving no therapeutic benefit from the trial is critical to the application of these Guidelines. Patient volunteers in oncology or other studies at Phase I who may reasonably expect to receive therapeutic benefit would not be covered by these Guidelines.

Whether such a reasonable expectation exists should be readily apparent from the study information sheet and consent form. Such studies would be governed by the principles of the revised Phase II-IV Clinical Trial Guidelines.

1. The following standard provisions reflect the type of commitment that is generally viewed as acceptable:

“The company sponsoring the study confirms that:

1. If the volunteer suffers any significant deterioration in health or well-being caused directly by participation in the study, compensation will be paid to the volunteer by the sponsoring company.
2. The amount of such compensation shall be calculated by reference to the amount of damages commonly awarded for similar injuries by an English court if liability is admitted, provided that such compensation may be reduced to the extent that the volunteer, by reason of contributory fault, is partly responsible for the injury (or where the volunteer has received equivalent payment for such injury under any policy of insurance effected by the company for the volunteer’s benefit.)
3. Any dispute or disagreement as to the application of paragraph (i) and (ii) above shall be referred to an arbitrator to be agreed between the volunteer and the company, or in the absence of agreement, to be appointed by the President of the Royal College of Physicians of London, with power in the arbitrator to consult a barrister of 10 years’ standing in respect of any issue of law including the amount of damages to be awarded as payment of compensation.
4. This agreement to pay compensation shall be construed in accordance with English law and, subject to paragraph (iii) above, the English courts shall have sole jurisdiction over any dispute which may arise out of it.”

## Phase II, III And IV Clinical Trial Compensation Guidelines

### Background

The Association of the British Pharmaceutical Industry (ABPI) favours a simple and expeditious procedure in relation to the provision of compensation for injury caused by participation in clinical trials. The Association therefore recommends that a member company sponsoring a clinical trial at Phase II, III and IV should provide without legal commitment a written assurance to the investigator – and through him to the relevant research ethics committee – that the following Guidelines will be adhered to in the event of injury caused to a patient attributable to participation in the trial in question.

1. **Basic Principles**:
	1. Notwithstanding the absence of legal commitment, the company should pay compensation to patient-volunteers suffering bodily injury (including death) in accordance with these Guidelines.
	2. Compensation should be paid when, on the balance of probabilities, the injury was attributable to the administration of a medicinal product under trial or any clinical intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the patient in the trial.
	3. Compensation should be paid to a child injured in utero through the participation of the subject’s mother in a clinical trial as if the child were a patient-volunteer with the full benefit of these Guidelines.
	4. Compensation should only be paid for the more serious injury of an enduring and disabling character (including exacerbation of an existing condition) and not for temporary pain or discomfort or less serious or curable complaints.
	5. Where there is an adverse reaction to a medicinal product under trial and injury is caused by a procedure adopted to deal with that adverse reaction, compensation should be paid for such injury as if it were caused directly by the medicinal product under trial.
	6. Neither the fact that the adverse reaction causing the injury was foreseeable or predictable, nor the fact that the patient has freely consented (whether in writing or otherwise) to participate in the trial should exclude a patient from consideration for compensation under these Guidelines, although compensation may be abated or excluded in the light of the factors described in paragraph 4.2 below.
	7. For the avoidance of doubt, compensation should be paid regardless of whether the patient is able to prove that the company has been negligent in relation to research or development of the medicinal product under trial or that the product is defective and therefore, as the producer, the company is subject to strict liability in respect of injuries caused by it.
2. **Type of Clinical Research Covered**:
	1. These Guidelines apply to injury caused to patients involved in Phase II and Phase III trials, that is to say, patients under treatment and surveillance (usually in hospital) and suffering from the ailment which the medicinal product under trial is intended to treat but for which a product licence does not exist or does not authorise supply for administration under the conditions of the trial.
	2. These Guidelines do not apply to injuries arising from Phase I studies where there is no prospect of personal benefit for the subject, whether or not they occur in hospital. Separate Guidelines for compensation exist for such studies.’
	3. These Guidelines do not apply to injury arising from clinical trials on marketed products (Phase IV) where a product licence exists authorising supply for administration under the conditions of the trial, except to the extent that the injury is caused to a patient as a direct result of procedures undertaken in accordance with the protocol (but not any product administered) to which the patient would not have been exposed had treatment been other than in the course of the trial.
	4. These Guidelines do not apply to clinical trials which have not been initiated or directly sponsored by the company providing the product for research. Where trials of products are initiated independently by doctors under the appropriate provisions of The 2004 Medicines for Human Use (Clinical trials) Regulations (SI 2004-1031), responsibility for the health and welfare of patients rests with the doctor alone (see also paragraph 5.2 below).
3. **Limitations**:
	1. No compensation should be paid for the failure of a medicinal product to have its intended effect or to provide any other benefit to the patient.
	2. No compensation should be paid for injury caused by other licensed medicinal products administered to the patient for the purpose of comparison with the product under trial.
	3. No compensation should be paid to patients receiving placebo in consideration of its failure to provide a therapeutic benefit.
	4. No compensation should be paid (or it should be abated as the case may be) to the extent that the injury has arisen:
		1. through a significant departure from the agreed protocol;
		2. through the wrongful act or default of a third party, including a doctor’s failure to deal adequately with an adverse reaction;
		3. through contributory negligence by the patient.
4. **Assessment of Compensation**:
	1. The amount of compensation paid should be appropriate to the nature, severity and persistence of the injury and should in general terms be consistent with the quantum of damages commonly awarded for similar injuries by an English Court in cases where legal liability is admitted.
	2. Compensation may be abated, or in certain circumstances excluded, in the light of the following factors (on which will depend the level of risk the patient can reasonably be expected to accept):
		1. the seriousness of the disease being treated, the degree of probability that adverse reactions will occur and any warnings given;
		2. the risks and benefits of established treatments relative to those known or suspected of the trial medicine.

This reflects the fact that flexibility is required given the particular patient’s circumstances. As an extreme example, there may be a patient suffering from a serious or life-threatening disease who is warned of a certain defined risk of adverse reaction. Participation in the trial is then based on an expectation that the benefit/risk ratio associated with participation may be better than that associated with alternative treatment. It is, therefore, reasonable that the patient accepts the high risk and should not expect compensation for the occurrence of the adverse reaction of which he or she was told.

* 1. In any case where the company concedes that a payment should be made to a patient but there exists a difference of opinion between company and patient as to the appropriate level of compensation, it is recommended that the company agrees to seek at its own cost (and make available to the patient) the opinion of a mutually acceptable independent expert, and that his opinion should be given substantial weight by the company in reaching its decision on the appropriate payment to be made.
1. **Miscellaneous**:
	1. Claims pursuant to the Guidelines should be made by the patient to the company, preferably via the investigator, setting out details of the nature and background of the claim and, subject to the patient providing on request an authority for the company to review any medical records relevant to the claim, the company should consider the claim expeditiously.
	2. The undertaking given by a company extends to injury arising (at whatever time) from all administrations, clinical interventions or procedures occurring during the course of the trial but not to treatment extended beyond the end of the trial at the instigation of the investigator. The use of unlicensed products beyond the trial period is wholly the responsibility of the treating doctor.
	3. The fact that a company has agreed to abide by these Guidelines in respect of a trial does not affect the right of a patient to pursue a legal remedy in respect of injury alleged to have been suffered as a result of participation. Nevertheless, patients will normally be asked to accept that any payment made under the Guidelines will be in full settlement of their claims.
	4. A company sponsoring a trial should encourage the investigator to make clear to participating patients that the trial is being conducted subject to the ABPI Guidelines relating to compensation for injury arising in the course of clinical trials and have available copies of the Guidelines should they be requested.
	5. If a legal remedy is pursued and the case is the subject of adjudication or settlement, the patient may not bring a further claim, based on the same facts, under these Guidelines.

**Association of the British Pharmaceutical Industry**:

7th Floor, Southside, 105 Victoria Street, London SW1E 6QT

T: +44 (0)870 890 4333

E: abpi@abpi.org.uk

# Appendix 3 – Form of Indemnity

1. The Sponsor indemnifies and holds harmless the Trial Site and the Principal Investigator and their employees and Agents against all claims and proceedings (to include any settlements or ex-gratia payments made with the consent of the Parties hereto and reasonable legal and expert costs and expenses) made or brought (whether successfully or otherwise):
	1. by or on behalf of Participants and (or their dependants) against the Trial Site and / or the Principal Investigator or any of their employees or Agents for personal injury (including death) to Participants arising out of or relating to the administration of the Investigational Medicinal Product under investigation or any clinical intervention or procedure provided for or required by the Protocol to which the Participants would not have been exposed but for their participation in the Clinical Trial;
	2. by the Trial Site, its Principal Investigator, their employees or Agents or by or on behalf of a Participant for a declaration concerning the treatment of a Participant who has suffered such personal injury.
2. The above indemnity by the Sponsor shall not apply to any such claim or proceeding:
	1. to the extent that such personal injury (including death) is caused by the negligent or wrongful acts or omissions or breach of statutory duty of the Trial Site, and / or the Principal Investigator, their employees or Agents;
	2. to the extent that such personal injury (including death) is caused by the failure of the Trial Site, and / or the Principal Investigator, their employees, or Agents to conduct the Clinical Trial in accordance with the Protocol;
	3. unless, as soon as reasonably practicable following receipt of notice of such claim or proceeding, the Trial Site and / or the Principal Investigator shall have notified the Sponsor in writing of it and shall, upon the Sponsor’s request, and at the Sponsor’s cost, have permitted the Sponsor to have full care and control of the claim or proceeding using legal representation of its own choosing;
	4. if the Trial Site, and / or the Principal Investigator, their employees, or Agents shall have made any admission in respect of such claim or proceeding, or taken any action relating to such claim or proceeding prejudicial to the defence of it without the written consent of the Sponsor, such consent not to be unreasonably withheld, provided that this condition shall not be treated as breached by any statement properly made by the Trial Site, and / or the Principal Investigator, their employees or Agents in connection with the operation of the Trial Site’s and / or the Principal Investigator’s internal complaint procedures, accident reporting procedures or disciplinary procedures, or where such a statement is required by law.
3. The Sponsor shall keep the Trial Site and / or the Principal Investigator and their legal advisors fully informed of the progress of any such claim or proceeding, will consult fully with the Trial Site and / or the Principal Investigator on the nature of any defence to be advanced and will not settle any such claim or proceeding without the written approval of the Trial Site and / or the Principal Investigator (such approval not to be unreasonably withheld).
4. Without prejudice to the provisions of paragraph 2.3 above, the Trial Site and / or the Principal Investigator will use their reasonable endeavours to inform the Sponsor promptly of any circumstances reasonably thought likely to give rise to any such claim or proceeding of which they are directly aware and shall keep the Sponsor reasonably informed of developments in relation to any such claim or proceeding even where the Trial Site and / or the Principal Investigator decides not to make a claim under this indemnity. Likewise, the Sponsor shall use its reasonable endeavours to inform the Trial Site and the Principal Investigator of any circumstances and shall keep the Trial Site and the Principal Investigator reasonably informed of developments in relation to any such claim or proceeding made or brought against the Sponsor alone.
5. The Trial Site, the Principal Investigator and the Sponsor will each give to the others such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding by or on behalf of Participants (or their dependants) or concerning such a declaration as is referred to in paragraph 1.2 above.
6. Without prejudice to the foregoing if injury is suffered by a Participant while participating in the Clinical Trial, the Sponsor agrees to operate in good faith the guidelines published in 2015 by The Association of the British Pharmaceutical Industry and entitled “Clinical Trial Compensation Guidelines” and shall request the Principal Investigator and any Sub-Investigators, to make clear to the Participants that the Clinical Trial is being conducted subject to the Association Guidelines.

# Appendix 4 – Financial Arrangements

### [Financial Arrangements Appendix Instructions

*Please delete instruction text prior to sharing the Agreement with the Trial Site.*

* **Clauses 1.2.1 and 1.2.2**: National Contract Value Review (NCVR) requires Trial Sites to accept the outcome of the national resource review and the prices generated by the interactive Costing Tool. Independent contractors of primary care NHS services are not currently subject to the full requirements of NCVR. However, individual contractors may be members of a voluntary NCVR adherence scheme. The Parties should consult prior to Sponsor provision of this Agreement to the Trial Site, to determine whether these clauses should be retained or deleted.
* **Clause 2.2:** Four options to describe the frequency of invoicing are provided to the Sponsor, or party acting on its behalf. A single option should be selected. If the final option is selected (another frequency to be agreed by the Parties) this should be based on a calendar frequency (for example twice annually), not Clinical Trial or Trial Site milestones (for example, upon recruitment of 10 Participants).
* **Clause 2.3:**Five options, to describe the arrangements for raising invoices for this Clinical Trial, are provided to the Sponsor or its Agent. The Parties can agree that more than one option may be appropriate to include in the Agreement; only the relevant option(s) should be retained. Where multiple options are chosen, the sub-option within each retained clause should also be retained and detail added. At least one option must be chosen. If only a single option is chosen, the sub-option should be removed.
* **Clause 6.3:** The Sponsor, or its Agent, should include the proposed caps for the payment of Expenses (without further authorisation) within the table prior to sharing the Agreement with the Trial Site. The template table includes examples of Expenses that may be entered here, and under which basis the cap applies. The examples can be modified, added to and / or removed as needed to reflect the Clinical Trial specific arrangements. Rows should be deleted or added to the table as needed. The Sponsor, or its Agent, may need to discuss the appropriateness of the caps with the Trial Site to accommodate the time commitment for Clinical Trial visits, the distance Participants (and, as applicable, parents, carers or others who may reasonably be expected to accompany them) need to travel to the Trial Site, and any other factors which may impact on the cap.

If there will be in Expenses paid, enter “not applicable” as the pass-through cost, and enter the cap as £0.00.

Complete the table, as agreed between both Parties, in the Appendix before the contract is executed.

* **Clause 6.4:** This clause is used to specify additional costs when the Sponsor has not designed the Clinical Trial or specific research activities within it to require out of hours working by the Trial Site’s Agents, but both Parties agree that it would be beneficial for this to happen at the Investigator Site. For example, the Trial Site might advise that they have a higher uptake locally of patients attending weekend or evening clinics instead of day time clinics, which helps with Participant retention. The table includes examples of out of hours costs which should be entered here, and the cap which applies for each type of cost. The examples can be modified as needed. Rows should be deleted or added to the table as needed. The Sponsor, or its Agent, may need to discuss the appropriateness of the caps with the Trial Site to accommodate the additional costs of out of hours working.

If the Sponsor has not designed the Clinical Trial to require out of hours working, enter “not applicable” as the out of hours cost, and enter the cost as £0.00.

Complete the table, as agreed between both Parties, in the Appendix before the Agreement is executed.

This clause does not apply to out of hours costs which are required for the delivery of the Protocol (for example, 24-hour unblinding) or which the Sponsor wants to be delivered out of hours; this is included in the National Contract Value Review and the prices in the Localised Online iCT.

* **Clause 6.5:** The Sponsor, or its Agent, should include any Ethically-Approved Participant Payments within the table prior to sharing the Agreement with the Trial Site. The table includes examples of the prices which should be entered here and allows for the Sponsor, or its Agent, to specify the basis on which the payment will be made (for example, hourly, per visit, etc.). The examples can be modified as needed. Rows should be deleted or added to the table as needed.

If there will be no Ethically-Approved Participant Payments, enter “not applicable” as the Ethically-Approved Participant Payment, and enter the price as £0.00.

Ensure the table is completed in the Appendix before the contract is executed.

* **Clause 6.6:**Three options are presented to the Sponsor or its Agent for how Expenses will be paid. More than one option may be appropriate to include in the Agreement; only the relevant option(s) should be retained. Discussion with the Trial Site to agree which option(s) are appropriate may be needed before sharing the Agreement. The options are not exclusive of each other. At least one option must be chosen. If the third option is chosen (use of a pre-payment card) the Sponsor should indicate which Party is responsible for providing the pre-payment card.
* **Clause 6.7**: Three options are presented to the Sponsor for how Ethically-Approved Participant Payments will be paid, or if no such payments are to be made. More than one option may be appropriate to include in the Agreement; only the relevant option(s) should be retained. Discussion with the Trial Site to agree which option(s) are appropriate may be needed before sharing the Agreement. Options 1 and 2 are not exclusive of each other. At least one option must be chosen.
* **Clause 6.9:**This is an optional clause for use when the Sponsor or its Agent intends to provide an Expenses float to the Trial Site to allow for Trial Site payment of Expenses. If an Expenses float is to be provided, the value of this float in GBP should be inserted into this clause. If no Expenses float is to be provided, Clause 6.9 should be deleted prior to sharing the Agreement with the Trial Site.
* **Clause 8.1.1:** The Sponsor or its Agent should indicate how many screen failures it will pay for by selecting one of the options and deleting the other. The first option should be kept if the Sponsor or its Agent will pay the Trial Site for all screen failures. The second option should be used for no or some payment of screen failures as follows:
	+ **A fixed number of screen failures**: Indicate the fixed number of screen failures which will be paid for in the first [X]. Enter ‘0’ into the second and third [X] of this clause.
	+ **A variable number of screen failures**: Indicate the initial number of screen failures which will be paid for without any conditions in the first [X]. In the second [X] indicate the number of screen failures which will be paid for based on the third [X] to indicate how many Participants need to be enrolled, dosed or randomised for payment to be made.
	+ **No screen failures**: Enter ‘0’ into every [X
* **Clause 12.1:** The Sponsor or its Agent should provide here the contact details to which invoices should be sent by the Trial Site. The Sponsor or its Agent should state here whether their preference is to receive invoices physically at this address or by email. The physical address should be provided regardless of preference.
* **Clause 12.2:** The contact details for invoice requests and invoice queries to be sent to the Trial Site should be completed by the Sponsor or its Agent following discussion with the Trial Site and prior to sharing the Agreement with the Trial Site. Whether the Trial Site chooses to receive the invoice requests or queries to its physical address or by email should be specified here.
* **Clause 12.3:**Payment details for the Trial Site should be completed by the Sponsor or its Agent following discussion with the Trial Site and prior to sharing the Agreement with the Trial Site.
* **Clause 13:**The Localised OnlineiCT generated Finance Schedule should be inserted here, after completion of iCT study resource review and prior to sharing the Agreement with the Trial Site. No modifications to the Finance Schedule should be made by either Party for studies within scope of the National Contract Value Review.
* Remove all brackets and yellow highlights prior to execution of this Agreement.

***END OF INSTRUCTIONS****]*

## Payments

* 1. This Appendix specifies all payments to be made by, or on behalf of, the Sponsor, to the Trial Site, under the Financial Arrangements and Termination Clauses within this Agreement.
	2. Clinical trials that are subject to [National Contract Value Review](https://www.england.nhs.uk/aac/what-we-do/embedding-research-in-the-nhs/national-contract-value-review/) (NCVR) must use an unmodified version of the Finance Schedule generated by the interactive Costing Tool (iCT). Changes, by either Party, to the Finance Schedule, prior to the Effective Date of this Agreement, are not permitted for clinical Trials within scope of NCVR (including independent contractors of primary care commissioned services voluntarily participating in NCVR pilot work).
		1. [**[Delete if not applicable to this Clinical Trial at this Trial Site]** In accordance with the above, the Sponsor represents and warrants that the Finance Schedule, incorporated into this Appendix by or on behalf of the Sponsor, is an unmodified version of the Finance Schedule generated by the Localised Online iCT for this Clinical Trial, following the conclusion of the study resource review.]
		2. [**[Delete if not applicable to this Clinical Trial at this Trial Site]** In accordance with the above, the Trial Site represents and warrants that prior to execution of this Agreement, no alterations have been made to the Financial Arrangements Appendix, including the Finance Schedule, provided by or on behalf of the Sponsor.
	3. Subject to Clause 9 of this Appendix, the Sponsor reserves the right to withhold payments to the Trial Site for activities conducted which were:
		1. not required by the Protocol; and / or
		2. conducted in breach of the Protocol.
	4. The Sponsor acknowledges that the Trial Site can defer funds paid under this Agreement to build research capacity in future financial years. All Parties acknowledge that there is no obligation under this Agreement on the Trial Site to either spend funds paid under the Agreement within the same financial year, or to refund the Sponsor with any sums not spent within the same financial year.

## Invoicing and Value Added Tax (VAT)

* 1. Invoices will be based on the services performed and / or data monitored. Where possible, data will be confirmed as complete and evaluable in a timely manner by (or on behalf of) the Sponsor for the invoice period, prior to the raising of the invoice. No payment will be made (unless an automatic payment has been arranged) by or on behalf of the Sponsor until a valid invoice for the amount payable has been received.
	2. The first invoice is to be raised after contract execution. Subsequent invoices will be raised on a [monthly] [quarterly] [ad hoc] [other: insert as agreed between the Parties] **(DELETE THREE AND RETAIN ONE OPTION)** basis, with the final invoice raised in accordance with Clause 2.10 of this Appendix.
	3. The Parties agree to use the following method(s) to manage invoicing:

**[****OPTION 1 (delete if not applicable)**: The Sponsor, or its Agent, will issue invoice requests, detailing visits and any additional procedures completed. The Trial Site shall invoice the Sponsor or its Agent in arrears upon receipt of an invoice request. **[Sub-Option (delete if not applicable):** This Clause is effective for invoicing relating to [**insert activities which will be invoiced using this method**]].]

* + 1. **[OPTION 2 (delete if not applicable)**: The Sponsor or its Agent will liaise with the Trial Site to agree the value and content of invoices to be raised. **[Sub-Option (delete if not applicable)**: This Clause is effective for invoicing relating to [**insert activities which will be invoiced using this method**]].]
		2. **[OPTION 3 (delete if not applicable)**: The Sponsor or its Agent will use a self-invoicing system to raise invoices on behalf of the Trial Site **[Sub-Option (delete if not applicable)**: This Clause is effective for invoicing relating to [**insert activities which will be invoiced using this method**]].]
		3. **[OPTION 4 (delete if not applicable)**: The Sponsor or its Agent will use an automated payment system to pay the Trial Site. The Trial Site shall be paid according to the evidence provided within the automated payment system of costs incurred. [**Sub-Option (delete if not applicable)**: This Clause is effective for invoicing relating to [**insert activities which will be invoiced using this method**]].]
		4. **[OPTION 5 (delete if not applicable)**: The Sponsor or its Agent will delegate responsibility to manage invoicing to the Trial Site. The Trial Site will invoice the Sponsor, or its Agent, in arrears. [**Sub-Option (delete if not applicable)**: This Clause is effective for invoicing relating to **[insert activities which will be invoiced using this method**]].**]**

Payments will be made in arrears within forty-five (45) calendar days of the date of receipt of a valid invoice (excluding disputed amounts, which will be resolved in good faith in a timely manner in accordance with Clause 2.7 of this Appendix).

* 1. Valid invoices (and, if required due to a limit being in place on the amount of information able to be included on the invoice, supporting documents sent alongside the invoice to detail any further information required by this Clause) issued by the Trial Site shall:
		1. be valid tax invoices for the purposes of VAT legislation;
		2. identify the Trial Site and IRAS ID;
		3. contain a breakdown of prices per activity covering:
1. set-up and close-down prices;
2. Per Participant prices, clearly identifying the correct Participant identification number(s), and;
3. all other prices.
	* 1. clearly state the corresponding period being invoiced for any periodic prices (for example, IMP management price);
		2. identify the purchase order number (if applicable) assigned to the Clinical Trial; and
		3. be sent to the Sponsor or its Agent at the email address provided below.
	1. The Trial Site’s failure to comply with the above invoice requirements may result in a delay in payment.
	2. Any delay in the payment of the payee invoices by or on behalf of the Sponsor will incur an interest charge on any undisputed amounts overdue of two (2) per cent per month above the National Westminster Bank plc base rate prevailing on the date the payment is due.
	3. If the Sponsor or its Agent disputes any invoice, or part of any invoice, or receives an invoice in respect of activities not provided in accordance with this Agreement, or which the Sponsor believes (acting reasonably) have not been properly provided, then the Sponsor or its Agent will make contact in a timely manner with the Trial Site’s finance team as per Clause 12.2 of this Appendix to resolve the query. If the query is not resolved, then the Sponsor or its Agent may either:
		1. withhold payment of the disputed part of the invoice in respect of the disputed amounts and / or activities, including an explanation as to why payment is withheld, in which case the Trial Site shall issue the Sponsor or its Agent with a credit note for the disputed amount and the Sponsor or its Agent will pay the undisputed amount in accordance with the Finances clause of this Agreement, or;
		2. reject the Trial Site’s invoice and request that the Trial Site submit a new invoice for the undisputed amount. On receipt of the new valid invoice, the Sponsor or its Agent shall pay the new invoice in accordance with the Finances clause of this Agreement.
	4. Any outstanding dispute remaining in relation to Clause 2.7 of this Appendix will be resolved in accordance with Clause 19 of this Agreement.
	5. The Sponsor or its Agent will notify the Trial Site of Investigator Site Trial Completion, or early termination of this Agreement, in order to trigger the generation of a final invoice. Notification will be made to: [insert email address].
	6. Upon Investigator Site Trial Completion, or early termination of this Agreement, all remaining amounts due shall be invoiced as per the terms detailed in this Financial Arrangements Appendix, subject to the following:
		1. completion of the close-out visit, where applicable;
		2. receipt of all completed and corrected case report forms and queries;
		3. receipt of the Principal Investigator’s final report, where applicable, in a form acceptable to the Sponsor as per relevant standards / requirements, and;
		4. provided all unused Investigational Medical Product and any applicable Sponsor or Vendor Resources or Equipment has been accounted for and returned, retained or destroyed in accordance with Sponsor instructions.
	7. The Sponsor or its Agent shall promptly respond to any reasonable request for invoicing data received from the Trial Site for the purposes of the final invoice, provided that the request is received within forty-five (45) calendar days of the notification of Investigator Site Trial Completion or early termination of the Agreement.
	8. **Longstop Dates**
	It is agreed that the Sponsor shall not be required to make payment for any amounts that the Trial Site fails to notify the Sponsor of within sixty (60) calendar days of the Sponsor providing the final invoicing information (if requested), in accordance with Clause 2.11 of this Appendix, or sixty (60) calendar days from Investigator Site Trial Completion, or early termination of this Agreement, if invoicing information is not requested (“**Longstop Dates**”). For the avoidance of doubt these notifications should be in accordance with table 12.1, and it is not an obligation for the Sponsor to pay invoices dated after the Longstop Date. Notwithstanding the above, this Clause does not take effect until any dispute regarding invoicing in line with Clauses 2.7 to 2.8 of this Appendix is resolved.
	9. The final invoice payment may be held by the Sponsor or its Agent until all outstanding queries have been resolved.
	10. All figures in the Finance Schedule are INCLUSIVE of all indirect costs, capacity building and Trial Site specific multipliers. All figures include all relevant taxes EXCEPT VAT which should be added to invoices where applicable.

## Pass-through Payments

* 1. It shall be the responsibility of the Trial Site to make any appropriate agreed pass-through payments, such as payments to the Principal Investigator’s principal employer (in accordance with Clause 2.1.1 of this Agreement) and / or any Participant Identification Centres, Other Trial Sites or other Agents.

## Inflation

* 1. Adjustment to the Finance Schedule to account for inflation (**“Adjustment”**) may be undertaken, at Trial Site request or as initiated by the Sponsor, a minimum of two years (twenty-four consecutive months) from the Effective Date of the Agreement and thereafter every twelve months.

The prices presented in the revised Finance Schedule, accounting for inflation, will be the prices generated by the Localised OnlineiCT on the day agreed by the Parties, and the revised prices will be applied to all Clinical Trial payments made as a result of the first and any subsequent invoices following execution of contract variation.

The revised Localised OnlineiCT Finance Schedule generated on the day agreed, will be provided by the Sponsor to the Trial Site and incorporated into this Agreement, with subsequent invoices reflecting the uplifted Finance Schedule, subject to Clause 4.1.1 of this Appendix.

For the avoidance of doubt, a contract variation in line with Clause 16.2 of this Agreement is required to update the prices in the Finance Schedule to take account of inflation.

## **Set-up, Management and Close-down Fees**

* 1. The one-off payments described in the tables under Clause 13.1 of this Appendix (Set-up, Management and Close-Down Fees) are non-refundable and will be payable upon execution of the Agreement (unless otherwise noted in the Task Breakdown).
	2. The Sponsor or its Agent will make payments to the Trial Site for prices incurred by any “for-cause" regulatory inspection triggered by actions outside of the Trial Site’s control, in line with the Finance Schedule.

## Expenses and Other Pass-through Costs

* 1. The Sponsor or its Agent agrees to pay Expenses and other pass-through costs specified in this Clause 6 (Expenses and Other Pass-through Costs) of this Appendix.
	2. Expenses include standard class public transport, licensed hackney carriages/private hire vehicles (taxis) and use of a private vehicle (the latter at 45p per mile as specified in HMRC guidance (as amended from time to time)).
	3. Expenses incurred will be paid up to the caps specified in the below table, in line with Clauses 6.1 and 6.2 of this Appendix. Expenses incurred which exceed these caps, or that are not listed in the table below, are required to receive written approval from the Sponsor or its Agent wherever possible prior to expenditure being incurred.

| **Expense** | **Cap (£)** | **Basis of cap** |
| --- | --- | --- |
| [Participant and carer travel] |  | [Per Protocol visit] |
| [Participant accommodation] |  | [For Protocol visit 1] |
| [Participant subsistence] |  | [Per Protocol visit] |
| [Trial Site’s Agent travel] |  | [Per Protocol visit to Participant’s home] |

* 1. Out of hours costs for staff time will be paid, in line with Clause 6.1 of this Appendix, where the Parties agree that out of hours working is beneficial for the delivery of the Clinical Trial at the Investigator Site but is not required by the Protocol. Costs will be paid up to the caps specified in the below table without further approval from the Sponsor or its Agent. Costs incurred which exceed these caps are required to receive written approval from the Sponsor or its Agent wherever possible prior to expenditure being incurred.

| **Out of hours cost** | **Cap (£)** | **Basis of cap** |
| --- | --- | --- |
| [Nurse time for weekend clinics] |  | [Per clinic] |
| [Nurse time for evening clinics] |  | [Total out of hours costs incurred over the Clinical Trial] |

* 1. Ethically-Approved Participant Payments will be paid as specified in the below table, in line with Clause 6.1 of this Appendix.

| **Ethically-Approved Participant Payment** | **Price (£)** | **Basis of payment** |
| --- | --- | --- |
| [Participant inconvenience payment] |  | [Entire Clinical Trial] |
| [Participant time] |  | [Per visit] |
| [Completion of questionnaires] |  | [1-month and 6-month visits] |

* 1. The Parties agree to use the following method(s) to manage the payment of Expenses:

[**OPTION 1 (delete if not applicable):** Receipts, or other appropriate documentation, where available, will be submitted to the Trial Site to support the expenditure. The Trial Site will pay Expenses directly to those who have incurred Expenses. **[Sub-Option (delete if not applicable):** This Clause is effective for the payment of Expenses relating to [**insert activities which will be paid for using this method**].]]

[**OPTION 2 (delete if not applicable):** Receipts, or other appropriate documentation, where available, will be submitted to the Sponsor or its Agent to support the expenditure. The Sponsor or its Agent will pay Expenses directly to those who have incurred Expenses. **[Sub-Option (delete if not applicable):** This Clause is effective for the payment of Expenses relating to [**insert activities which will be paid for using this method**].]]

[**OPTION 3 (delete if not applicable):** Expenses will be paid through an automated payment system (which may include provision of a pre-payment card) by the [Sponsor] [Sponsor’s Agent] [Trial Site]. **[Sub-Option (delete if not applicable):** This Clause is effective for the payment of Expenses relating to [**insert activities which will be paid for using this method**].]]

* 1. The Parties agree to use the following method(s) to manage the payment of Ethically-Approved Participant Payments:
		1. [**OPTION 1 (delete if not applicable):** The Trial Site will make Ethically-Approved Participant Payments directly to Participants.]
		2. [**OPTION 2 (delete if not applicable):** The Sponsor or its Agent will make Ethically-Approved Participant Payments directly to Participants.]
		3. [**OPTION 3 (delete if not applicable):** There are no Ethically-Approved Participant Payments to be made for this Clinical Trial.]
	2. If the Trial Site receives payment from the Sponsor or its Agent for pass-through-related costs and Expenses, the Trial Site shall ensure that the Principal Investigator and Personnel will maintain records, supported by receipts of the expenditures where possible, and make available de-identified copies, if possible, at monitoring visits, if requested. The Sponsor or its Agent will reimburse the Trial Site for all such payments upon confirmation of spend and itemised inclusion in the invoice.
	3. [**DELETE IF NOT APPLICABLE** - An Expenses float of £[XX.XX] will be provided and replenished as necessary by the Sponsor or its Agent upon receipt of invoice from the Trial Site. Any balance remaining in the float at the end of the Clinical Trial will be refunded to the Sponsor or its Agent.]

## Participant Visit Fees

* 1. Payments will be made according to the visit and investigation payments set out in Clause 13.2 of this Appendix (Participant Visit Fees) and include all indirect prices, capacity building and applicable Trial Site specific multipliers.
	2. Please note that tables may have been added below, as a result of the study resource review, for unscheduled activities that may occur for selected Participants only. This table will indicatively state the additional visit prices applicable for those selected Participants.

## Payment for screen failure and discontinuation

* 1. For the purpose of this Appendix, a “Screen Failure” is defined as a Participant who is eligible with respect to Protocol defined eligibility criteria to enter the screening process, gave informed consent but is found to be ineligible for treatment allocation.

The Trial Site will receive payment per Screen Failure [**DELETE** ONE OPTION AND RETAIN THE OTHER] [for all Screen Failures, provided that it was not evident from information available to the Trial Site at the time of screening that the potential Participant could not be eligible] [for an initial [X] Screen Failures. Payment for any Screen Failures at the Trial Site after this cap is reached requires approval from the Sponsor or its Agent, and if given will be based on payment for [X] Screen Failures per [X] Participants [enrolled] [dosed] [randomised] **(delete options not selected in Clause 4.13 of the main Agreement)**] at the Trial Site.

All costs associated with each Screen Failure are payable by the Sponsor or its Agent on a pro rata basis as per the individual task price set out in the list of screening activities present for the screening visit in the Localised OnlineiCT.

* 1. A Participant who discontinues from the Clinical Trial, prior to completion of all the Protocol defined visits and assessments, because of adverse events, disease progression, coexistent disease, as a result of a decision made by the Principal Investigator, withdrawal of participation by Participant, and / or non-compliance or non-attendance, will be considered evaluable and payment will be made on a pro-rata basis.
	2. The value of payments under Clause 8.2 of this Appendix will be based on completion of visits, procedures and investigations as defined in the Participant table in this Appendix to cover all relevant costs and pass-through expenses in respect of such Participants, provided that the data relating to such Participants are adequately recorded in the Case Report Forms up to the time of discontinuation.
	3. Participants who are entered into the Clinical Trial but who do not satisfy the Protocol eligibility criteria at the time of entry must be either discontinued from the Clinical Trial or dealt with as outlined in the Protocol. Appropriate payment, if applicable, will be agreed on a case by case basis between the Sponsor or its Agent and Trial Site at the time of occurrence in respect of such Participants.

## Unscheduled Visits

* 1. Unscheduled visits and unscheduled events which are foreseeable (usually are included in the protocol) are reflected in the Finance Schedule (“Planned Unscheduled Visits"). Sponsor agreement is therefore already in place for these to occur. Planned Unscheduled Visits will be paid at the price for the relevant procedures and investigations set out in the version of the Localised OnlineiCT current at the time of the Planned Unscheduled Visit, including relevant Trial Site specific multipliers.
	2. Where an unscheduled visit or unscheduled event which was not expressly set out in the Protocol, and therefore not captured in the Finance Schedule, is required for the Clinical Trial (“Unplanned Unscheduled Visit”), it shall be carried out in line with the activities included in the Protocol. The Trial Site shall request and receive written Sponsor approval for the Unplanned Unscheduled Visit, wherever possible, prior to the visit occurring. Unplanned Unscheduled Visits will be paid at the price for the relevant procedures and investigations set out in the version of the Localised Online iCT current at the time of the Unplanned Unscheduled Visit, including relevant Trial Site specific multipliers. The individual procedures and investigations within the Unplanned Unscheduled Visit are included in Additional Itemised Costs in Clause 13, Finance Schedule.

## Central Laboratory Costs

* 1. Any central laboratory costs, including shipment costs, will be paid for by the Sponsor and have been excluded from this Agreement.

## All Other Fees

* 1. All other remaining fees not previously listed are included in Clause 13.3 (All Other Fees) of this Appendix. Payments will be made on an ‘as required’ basis and include all interactive Costing Tool defined Trial Site specific multipliers.

## Payment Details

* 1. Invoices should be sent to the following invoice address:

|  |  |
| --- | --- |
| Job title: | *[insert relevant details]* |
| Address:(If this address is in the UK, VAT should be added to the invoice at the appropriate rate) | *[insert relevant details]* |
| Reference on Invoice: | *[insert relevant details]* |
| Telephone No:  | *[insert relevant details]* |
| Email: | *[insert relevant details]* |
| Contact for escalation: (**OPTIONAL** – remove if not applicable) | *[insert generic email address]* |

The preferred method for sharing the invoice is [post] [email]. **(delete one option)**

* 1. Invoicing requests and invoicing queries to the Trial Site should be sent to:

|  |  |
| --- | --- |
| Job title: | *[insert relevant details]* |
| Address: | *[insert relevant details]* |
| Reference on Invoice: | *[insert relevant details]* |
| Telephone No:  | *[insert relevant details]* |
| Email: | *[insert relevant details]* |

The preferred method for sharing the invoicing requests and invoicing queries is [post] [email]. **(delete one option)**

* 1. Payments by the Sponsor or its Agent will be made by BACS to:

|  |  |
| --- | --- |
| Bank: | *[insert relevant details]* |
| Bank Address: | *[insert relevant details]* |
| Account Name: | *[insert relevant details]* |
| Account No: | *[insert relevant details]* |
| Sort Code: | *[insert relevant details]* |
| Swift Code: | *[insert relevant details]* |
| IBAN No: | *[insert relevant details]* |
| VAT Code: | *[insert relevant details if applicable or mark as Not Applicable]* |
| Payee Reference:(Recommend that IRAS ID is used) | *[insert relevant details]* |
| Email for remittance:(Delete row if this is the same email address provided in Clause 12.2) | *[insert relevant details]* |

## Finance Schedule

[The Sponsor or its Agent should insert here the Finance Schedule generated from the site-level Localised Online iCT relevant to this Trial Site, following completion of iCT study resource review and prior to sharing this Agreement with the Trial Site for contract execution. Modifications to the Finance Schedule generated by the Localised Online iCT are not permitted for studies within the scope of National Contract Value Review. **DELETE THIS GUIDANCE FOLLOWING INSERTION OF FINANCE SCHEDULE**]

* 1. **Set-up, Management and Close-Down Fees**

[Insert content in the “Set-up, Management and Close-Down Fees” section of the Localised Online iCT export here.]

* 1. **Participant Visit Fees**

[Insert content in the “Clinical Trial Participant Visit Fees” section of the Localised Online iCT export here.]

* 1. **All Other Fees**

[Insert content in the “All Other Fees” section of the Localised Online iCT export here.]

# Appendix 5 – Conditions Applicable to the Principal Investigator

1. The Principal Investigator is free to participate in the Clinical Trial and there are no rights that may be exercised by, or obligations owed to, any third party that may prevent or restrict the performance by the Principal Investigator of the obligations set out in the Agreement.
2. Where the Trial Site is not the Principal Investigator’s substantive employer, the Principal Investigator must notify their substantive employer of the proposed participation in the Clinical Trial and where relevant, the supervision of Personnel, and further, the Principal Investigator must have obtained consent from the substantive employer for participation in the Clinical Trial.
3. The Principal Investigator is not the subject of any regulatory litigation or misconduct litigation or investigation. No data produced by the Principal Investigator in any other clinical trial has been rejected because of concerns as to its accuracy or because it was generated by fraudulent means.
4. The Principal Investigator has considered and is satisfied that facilities appropriate to the Clinical Trial are available at the Trial Site, and any Other Trial Site(s), and that in the performance of obligations under this Agreement, is satisfied that they will be supported by medical and other staff of sufficient number and experience to enable the Trial Site, and any Other Trial Site(s), to perform the Clinical Trial efficiently and in accordance with the obligations under this Agreement.
5. Where the Trial Site is not the Principal Investigator’s substantive employer, and the Principal Investigator is not a partner at the Trial Site, the Principal Investigator holds a contract for services (commonly known as an honorary contract) with the Trial Site.
6. During the Clinical Trial, the Principal Investigator will not serve as principal investigator or sub-investigator in any clinical trial for another sponsor if such activity may adversely affect the ability of the Principal Investigator to perform their obligations under this Agreement.
7. The Principal Investigator and Personnel carry medical liability insurance, or are otherwise covered by an equivalent NHS scheme, and the details and evidence of the coverage will be provided to the Sponsor upon request.

# Appendix 6 – Material Transfer Provisions

 [ ]  If this box is checked, this Appendix 6 (Material Transfer Provisions) is not used.

Where the Protocol requires the Trial Site to supply Material to the Sponsor this Appendix 6 shall apply.

1. In accordance with the Protocol, the Trial Site shall send Material to the Sponsor or, in accordance with Section 7 of this Appendix, to a third party nominated by the Sponsor.
2. The Trial Site and the Principal Investigator warrant that all Material has been collected with appropriate informed consent and has been collected and handled in accordance with applicable law (including, without limitation, the Human Tissue Act 2004) and as required by the Protocol.
3. Subject to Section 2 of this Appendix, the Material is supplied without any warranty, expressed or implied, including as to its properties, merchantable quality, fitness for any particular purpose, or freedom from infection.
4. The Sponsor shall ensure, or procure through an agreement with the Sponsor’s nominee as stated in Section 1 of this Appendix, that:
	1. the Material is used in accordance with the consent of the Participant 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, where such approval is required, and provided it is in accordance with the Participant’s consent.
5. The Parties shall comply with all relevant laws, regulations and codes of practice governing the Clinical Trial and the use of Material.
6. The Trial Site and the Sponsor shall each be responsible for keeping a record of the Material that has been transferred according to this Appendix 6.
7. To the extent permitted by law and set forth in accordance with Section 5 of this Appendix, the Trial Site, the Principal Investigator and their 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 of this Appendix, 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 Trial Site, the Principal Investigator, or their 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 of this Appendix, 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 6.
9. Unless otherwise agreed, any surplus Material that is not returned to the Trial Site or retained for future research shall be destroyed in accordance with the Human Tissue Act 2004.

# Appendix 7 – Equipment and Resources

 [ ]  If this box is checked, this Appendix 7 (Equipment and Resources) is not used.

1. **Sponsor-Provided Equipment**

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

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

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

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 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 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- Participants 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-Participants 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 (DELETE ENTIRE ALTERNATIVE IF NOT APPLICABLE)**

After completion of the Clinical Trial at the Investigator Site, or at an earlier time specified by Sponsor, the Sponsor will contact the 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 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 Trial Site.

**Alternative #2 – Return of Sponsor Resources to Sponsor and transfer of Sponsor Equipment to the Trial Site with value included in funding. (DELETE ENTIRE ALTERNATIVE IF NOT APPLICABLE)**

After completion of the Clinical Trial at the Investigator Site, or at an earlier time specified by Sponsor, the Sponsor will contact the 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 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 Trial Site.

The total compensation for Clinical Trial conduct allocated to the 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 Trial Site at the termination of this Agreement, provided that the Trial Site (through the Principal Investigator) has enrolled the targeted number of Participants (or some other number of Participants 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 Trial Site. (DELETE ENTIRE ALTERNATIVE IF NOT APPLICABLE)**

After completion of the Clinical Trial at the Investigator Site, or at an earlier time specified by Sponsor, the Sponsor will contact the 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 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 Trial Site.

After completion of the Clinical Trial at the Investigator Site, Sponsor will make Sponsor Equipment available for purchase by the 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** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
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|  |  |  |  |
|  |  |  |  |

**Permitted Uses of Vendor Property**

**[OPTION 1 (delete if not applicable)**: The Trial Site will use Vendor Property only for purposes of this Clinical Trial.**]**

**[OPTION 2 (delete if not applicable)**:**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 Investigator 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 Trial Site, the property of Sponsor, the Vendor or the licensor, as the case may be.
	2. **Liability**: Equipment and Resources Only.

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 Participant 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 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 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 Trial Site’s wilful misconduct, negligent acts or omissions. Under no circumstances shall the 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 Trial Site shall not insure the [**Sponsor Equipment**], [**Sponsor Material**] or [**Vendor Property**].

# Appendix 8 – Formal Delegation of Authority to a Corporate Affiliate to Contractually Bind Sponsor

[ ]  If this box is checked, this Appendix 8 (Formal Delegation of Authority to a Corporate Affiliate to Contractually Bind Sponsor) is not used.

# Appendix 9 – Authority to Defer Registration of the Clinical Trial

[ ]  If this box is checked, this Appendix 9 (Authority to Defer Registration of the Clinical Trial) is not used.

**FINAL PAGE**