# Clinical Research Organisation Model Clinical Trial Agreement (CRO-mCTa) for investigational Advanced Therapy Medicinal Products

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

**It is the responsibility of the Sponsor or CRO to provide the required information for review by the Participating Organisation.**

### Footers

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

### Front page

Complete all of the required information.

### Contents page

If Appendices 6, 7 and/or 9 are not used, delete reference(s) in the Contents Page.

### 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 Participating Organisation is in Northern Ireland and otherwise deleted.

### Main Body of the Agreement

**Definition of Quality Agreement** – In a Clinical Trial involving an advanced therapy medicinal product, the Quality Agreement would ordinarily be entered into between the Sponsor or an Affiliate of the Sponsor and the Participating Organisation (and not any third party manufacturer). The Sponsor should also consider whether a Quality Agreement is needed in light of the specific IMP or simply a material transfer agreement or instructions to the Participating Organisation on collection of Starting Material.

**Definition of Material** – Use square-bracketed wording in a Clinical Trial of an allogeneic advanced therapy medicinal product and samples are taken for laboratory testing from a donor of Starting Material.

**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**.7.1 – Delete if the Clinical Trial is not a Phase I clinical trial in patients (please note that the mCTAs should not be used in Phase I clinical trials with healthy volunteers).

**Clause 4** –The Sponsor should consider whether long-term follow-up of Clinical Trial Subjects should be covered by this agreement or a separate agreement.

**Clause 4.3** – Select the appropriate option depending on whether the Site has its own licence from the Human Tissue Authority or MHRA or it is relying on a licence held by the Sponsor or a third party.

**Clause 4.7** – Delete square-bracketed wording for Clinical Trials where the Sponsor determines that a Quality Agreement is not necessary.

**Clause 4.13** – Select ‘enrols’, ‘doses’ or ‘randomises’ as appropriate to the Clinical Trial and inset target number for the Participating Organisation.

**Clause 4.15.9** – Insert the appropriate number of years.

**Clauses 4.15.10** and **4.15.11** – Delete either or both clauses depending upon whether Material will be analysed locally, centrally or if no Material will be analysed. Where no Material will be analysed, delete the definition ‘Material’.

**Clauses 4.15.12** –References to the Quality Agreement should be removed if the Sponsor determines that one is not necessary. Appendix 1, 6 and 8 may be used by the Sponsor if the Sponsor determines that a Quality Agreement is not necessary.

**Clause 4.16** – Delete if no equipment or resources are provided by the Sponsor or CRO.

**Clause 5.6** – Insert amount.

**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 Participating Organisation 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 Participating Organisation to engage PICs under this general written authorisation.

**Clause 15.1** – where a satellite site unconnected with the Participating Organisation is involved in undertaking activities such as collection of Starting Material, the Sponsor should consider whether express consent to sub-contracting to that site should be provided in this clause. Alternatively, the Sponsor may elect to contract directly with that satellite site with this fact called out in Appendix 1.

**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.

### Appendix 1

Complete Appendix 1 showing the milestones/division of responsibilities between the Parties and target Site completion date and consider in a Clinical Trial involving an advanced therapy medicinal product whether study initiation milestones should also take into account the need to screen potential Clinical Trial Subjects together with any other milestones related to Starting Material procurement if appropriate.

### Appendix 4

The detailed financial arrangements with respect to the Clinical Trial should be appended as Appendix 4. Sponsors, CROs and Participating Organisations should note the Guidance provided with respect to the matters for inclusion in Appendix 4.

### Appendix 6

Appendix 6 should be omitted if not relevant to the specific Clinical Trial.

### Appendix 7

Complete details of any equipment and/or resources being supplied to the Participating Organisation for the Clinical Trial. Clearly indicate whether liability will be determined in accordance with the main body of the Agreement, or pursuant to a Master Indemnity Agreement (MIA). Where no equipment and/or resources is/are being provided, Appendix 7 should be omitted.

### Appendix 8

Clearly set out which Sponsor responsibilities for Site management will be performed by the CRO. If the Sponsor has formally empowered the CRO to sign this Agreement and thereby legally bind the Sponsor to its terms as a Party, this must be explicitly evidenced.

### Appendix 9

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.

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

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

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

# Clinical Trial Agreement

**Between**

[**INSERT** NAME OF PARTICIPATING ORGANISATION and ADDRESS OF PARTICIPATING ORGANISATION]

**“Participating Organisation”**

AND

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

**“Sponsor”**

AND

[**INSERT** NAME OF CRO and REGISTERED ADDRESS OF CRO]

**“CRO”**

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

# Clinical Trial Agreement

### 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. Financial Arrangements
13. Term
14. Termination
15. Relationship of the Parties
16. Agreement and Modification
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18. Notices
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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 – **DELETE IF NOT USED**

Appendix 7 Equipment and Resources – **DELETE IF NOT USED**

Appendix 8 Sponsor’s Clinical Trial Related Duties and Functions Under ICH-GCP to be Performed by CRO

Appendix 9 Formal Delegation of Authority to a Corporate Affiliate of the Sponsor to Contractually Bind Sponsor – **DELETE IF NOT USED**

**Whereas**

1. The Sponsor is a pharmaceutical company involved in the research, development, manufacture and sale of medicines for use in humans;
2. The Sponsor has entered into an agreement with the CRO, which is a Contract Research Organisation;
3. The Participating Organisation is concerned with the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare;
4. The Sponsor and the CRO wish to contract with the Participating Organisation to undertake a clinical trial;
5. References throughout this Agreement to Sponsor shall be construed to include reference to XXXX, as Affiliate empowered by the Sponsor to legally bind the Sponsor to this Agreement and to act on its behalf, in accordance with Appendix 9;
6. Where the Participating Organisation is an HSC organisation in Northern Ireland, references throughout this document to the NHS should be construed to include NHS/HSC as applicable;
7. 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**].

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 or CRO, save where there are contractual arrangements in place to exclude such affiliate. For the purposes of this definition, a business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity;

**Agent**
shall include but is not limited to, any person (including the Principal Investigator, any nurse or other healthcare professional) providing services to the Participating Organisation 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 Participating Organisation and/or any contracted third party providing services to a Party under a contract for services or otherwise;

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

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

**Confidential Information**means all confidential information (however recorded or preserved) disclosed by a Party and/or its Affiliate to another 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’);

**CRO**
means the contract research organisation that is a signatory to this Agreement;

**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; and, pending a favourable decision from the competent authorities of the EU on the adequacy of the UK data protection regime will include the requirements set out or referenced in Part Three, Title VII, Article 71(1) of the Withdrawal Agreement signed by the UK and the EU in December 2019;

**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;

**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 Participating Organisation;

**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;

**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 Site;

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

**Investigational Drugs**
means the Investigational Medicinal Product (as defined below) together with control material (e.g. 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;

**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;

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

**MIA**
means the Master Indemnity Agreement that may be applicable in the part of the United Kingdom where the Participating Organisation is constituted;

**Material** [**Delete if 4.15.10, 4.15.11 and Appendix 6 are not required**]
means any clinical biological sample, or portion thereof, derived from Clinical Trial Subjects, including information related to such Material, analysed by the Participating Organisation in accordance with the Protocol, or otherwise supplied under Appendix 6 to the Sponsor or its nominee;

**Multi-Centre Trial**
means a Clinical Trial where at least one other institution is participating in the Clinical Trial;

**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 Clinical Trial Subject (or potential Clinical Trial Subject) and/or their treatment or medical history;

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

**Personnel**
means the persons who will undertake the conduct of the Clinical Trial at the Site(s) on behalf of the Participating Organisation under the supervision of the Principal Investigator;

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

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

**Principal Investigator**
means the person who will take primary responsibility for the conduct of the Clinical Trial at the Site on behalf of the Participating Organisation;

**Protocol**
means the full description of the Clinical Trial with the reference number set out on the front page of this Agreement along with written instructions for the collection of Starting Material and administration of the IMP, 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;

* **Quality Agreement**
means an agreement to be entered into between the Participating Organisation or an Affiliate or sub-contractor of the Participating Organisation on the one hand and the Sponsor or an Affiliate of the Sponsor on the other hand allocating responsibility for compliance with GMP and other regulatory requirements as regards the collection, storage, testing, processing and transportation of Starting Material in order to facilitate manufacture of the IMP in accordance with GMP, such agreement to be expressly approved by the employee of the Participating Organisation responsible for the oversight of the Participating Organisation’s cell laboratory, bone marrow transplant unit, apheresis unit or equivalent function and, where applicable, by the registered medical practitioner responsible for collection of Starting Material by invasive means;

**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 Research Governance Framework;

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

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

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

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

**Site**means the physical location(s) where the Clinical Trial will be conducted, under the primary responsibility of the Principal Investigator, within the Participating Organisation;

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

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

* **Starting Material**
means any cells, tissues or other material collected from a Clinical Trial Subject or other donor for use in the manufacture of the IMP;

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

* **Third Party Agreement**
shall have the meaning set out in the Human Tissue (Quality and Safety for Human Application) Regulations 2007;

**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 Clinical Trial Subjects 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, CRO or Affiliate, to monitor compliance of the Clinical Trial with ICH-GCP and to conduct source data verification.

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

## Principal Investigator and Personnel

* 1. The Participating Organisation represents that it is entitled to procure, and the Participating Organisation will procure the services of the Principal Investigator, any and all Sub-Investigators and other Personnel, to fulfil these functions and shall ensure the performance of the obligations of the Principal Investigator, any and all Sub-Investigators and other Personnel set out in Appendix 5 and elsewhere in this Agreement.
		1. Where the Participating Organisation is not the Principal Investigator’s substantive employer it will notify the Principal Investigator’s substantive employer in a timely way of his/her proposed involvement in the Clinical Trial. Any financial or other arrangements relating to the Principal Investigator's involvement in the Clinical Trial will be agreed directly between the Participating Organisation and the Principal Investigator’s substantive employer.
	2. The Participating Organisation represents that the Principal Investigator holds the necessary registration and has the necessary expertise, time and resources to perform the Clinical Trial and will ensure that the Principal Investigator is made aware of and 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 Participating Organisation shall notify the Sponsor and CRO if the Principal Investigator ceases to be employed by or associated with the Participating Organisation, 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 Participating Organisation shall use all reasonable endeavours to find a replacement acceptable to all Parties, subject to the Participating Organisation’s overriding obligations in relation to Clinical Trial Subjects and individual patient care. If no mutually acceptable replacement can be found the Sponsor or CRO may terminate this Agreement pursuant to Clause 14.3.
	4. The Participating Organisation shall procure, and shall ensure that the Principal Investigator procures, 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 or CRO (“**Investigator Meetings**”). Such meetings to be conducted by the Sponsor or CRO 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 Participating Organisation 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 or CRO 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 financial reporting purposes of the Party making payment, provided that the required detail does not impose an unreasonable administrative burden upon the Participating Organisation. Such expenses may be publicly reportable.
	6. The Participating Organisation represents that it will support the Principal Investigator to make good faith diligent efforts to ensure the completion of all case report forms in a timely manner.
	7. The Participating Organisation through the Principal Investigator may appoint such other persons as the Principal Investigator 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. The Principal Investigator shall be responsible for leading such team of Personnel. The Participating Organisation 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 Participating Organisation and/or Principal Investigator use the services of others to conduct the Clinical Trial pursuant to this Agreement, the Participating Organisation and Principal Investigator shall be responsible for ensuring that all are appropriate, in compliance with the terms of this Agreement. The Participating Organisation shall be liable for any breach of this Agreement by the Principal Investigator and/or Personnel.

## Clinical Trial Governance

* 1. The [Sponsor][CRO] (**delete as appropriate**) shall inform the Participating Organisation 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][CRO] (**delete as appropriate**) 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 Participating Organisation shall ensure that the Principal Investigator and 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 Participating Organisation;
		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;
		10. The Blood Safety and Quality Regulations 2005;
		11. The Human Tissue (Quality and Safety for Human Application) Regulations 2007.
	3. The Parties shall comply with, and the Participating Organisation shall ensure that the Principal Investigator and 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 including the European Commission Guidelines on Good Clinical Practice specific to Advanced Therapy Medicinal Products;
		2. GMP including the European Commission Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products;
		3. GVP;
		4. the World Medical Association Declaration of Helsinki entitled, “Ethical Principles for Medical Research Involving Human Subjects (1996)”;
		5. the Research Governance Framework;
		6. the Medical Research Council Guidelines entitled, “Human Tissue and Biological Samples for Use in Research,”;
		7. [**DELETE IF NOT APPLICABLE** – the ethical principles set out in WHA63.22 (<http://www.who.int/transplantation/en/>) with regard to the Clinical Trial.]

In addition, where the Clinical Trial is conducted as part of an IND, the Participating Organisation will comply with any other relevant requirements notified by the Sponsor or CRO to the Participating Organisation.

* 1. When applicable, the Sponsor shall comply with the Clinical Trial Compensation Guidelines attached as Appendix 2 of this Agreement.
	2. The Participating Organisation shall ensure that the Principal Investigator, 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 or CRO 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. **Location of the Clinical Trial**
	The Parties acknowledge that the Participating Organisation might have responsibility for several hospitals that may have the potential to be involved in the Clinical Trial. It is agreed however, that only those Sites that have been approved by the relevant Regulatory Authority (and any applicable research ethics committee), shall participate in the Clinical Trial. Additional Sites may only be included in the Clinical Trial if all Parties are in agreement and the relevant regulatory approval(s), including research ethics approval, has been obtained, if applicable.
	4. **Adverse Event Reporting**
	All 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. All 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 3.7, the Parties further acknowledge and agree that with respect to Phase I trials:
1. It is the responsibility of the [Sponsor][CRO] (**delete as appropriate**) 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][CRO] (**delete as appropriate**) 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][CRO] (**delete as appropriate**) 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), The Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the Medicines for Human Use (Clinical Trial) Regulations 2004.
4. If, during the course of the Clinical Trial, the Sponsor or CRO becomes aware of any information relating to the IMP which may impact the Clinical Trial, the [Sponsor][CRO] (**delete as appropriate**) will notify the Participating Organisation promptly, and within seven (7) calendar days of becoming aware of the information, and if requested to do so by the Participating Organisation, will provide the Participating Organisation with a report detailing the information.
5. The [Sponsor][CRO] (**delete as appropriate**) must provide any ongoing safety and toxicology data updates to the Principal Investigator immediately, to ensure the safety of the Clinical Trial Subjects in this Phase I Clinical Trial.
	1. **Anti-Bribery and Corruption**
		1. Each Party warrants and represents that:
6. It has not committed any offence under the Bribery Act 2010 or any of the following acts (“**Prohibited Acts**”):
7. 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 any 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 any other Party or for showing or not showing favour or disfavour to any person in relation to this Agreement or any other agreement with any other Party; or
8. 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 any other Party.
	* 1. If any Party has committed or commits any of the Prohibited Acts or has committed or commits any offence under the Bribery Act 2010 in relation to this Agreement, then any other Party 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 Clinical Trial Subjects.

## 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 Clinical Trial Subjects involved in the Clinical Trial.
	3. The [Sponsor] [and/or] [CRO] (**delete as appropriate**, in line with Appendix 8) 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. The Participating Organisation shall be responsible for obtaining and maintaining any licences necessary for its collection, testing, storage and shipment of any Starting Material [and each of the Sponsor and the CRO shall comply with all terms of such licences that are applicable to its activities hereunder as may be set out in a supplemental agreement including any Third Party Agreement].] **or** [The Sponsor [and/or] [CRO] (**delete as appropriate**, in line with Appendix 8) shall furthermore be responsible for obtaining and maintaining any licences necessary for the Participating Organisation’s collection, testing, storage and shipment of any Starting Material and the Participating Organisation shall comply with all terms of such licences that are applicable to its activities hereunder as may be set out in a supplemental agreement including any Third Party Agreement.
	4. The CRO shall perform such of the Sponsor’s Clinical Trial related duties and functions in respect of the Clinical Trial under ICH-GCP as contained in Appendix 8.
	5. The Principal Investigator shall be responsible for:
		1. ensuring that the informed consent form, approved by the Sponsor [or CRO] and the relevant research ethics committee, is signed by or on behalf of each Clinical Trial Subject before the first Clinical Trial related procedure starts for that Clinical Trial Subject (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 and/or CRO, provided that such disclosures may be made prior to the commencement of work activities associated with the Clinical Trial as well as subsequent to 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.
	6. The Sponsor or CRO shall submit the Clinical Trial for listing in a free, publicly accessible clinical trial registry within twenty-one (21) days of initiation of the Clinical Trial by enrolment of the first Clinical Trial Subject. The Participating Organisation agrees that such listing may include a summary of the Protocol, the name of the Participating Organisation and the details of the Site(s) where the Clinical Trial is being conducted. Subject to Clause 6 of this Agreement, in the event that the Sponsor or CRO intends to publish the name of the Principal Investigator on a publicly accessible clinical trial registry, the Sponsor or CRO shall be responsible for obtaining the written permission of the Principal Investigator for the use of the Principal Investigator’s name (and any other personal information) in such a publication.
	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, as the case may be, 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 or CRO has obtained approval from the MHRA, the research ethics committee and any other necessary approvals, it shall not supply, nor shall the Sponsor authorise the CRO to supply, the Investigational Drugs to the Participating Organisation. The Participating Organisation shall ensure that neither the collection of Starting Material nor the administration of the IMP (nor any other Investigational Drug supplied by Sponsor and/or CRO for use in the Clinical Trial) to any Clinical Trial Subject nor any other clinical intervention mandated by the Protocol takes place in relation to any Clinical Trial Subject until it is satisfied that all relevant approvals have been obtained and the Quality Agreement and any Third Party Agreement has been executed by the Participating Organisation and the Sponsor or one of its Affiliates.
	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 or CRO. The Sponsor or CRO shall initiate simultaneously the change control procedures set out in Clause 16.3 of this Agreement.
	10. The [Sponsor][CRO] (**delete as appropriate**) 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 Site File. The [Sponsor][CRO] (**delete as appropriate**) shall ensure that any and all safety and/or toxicology data relating to the IMP, of which the Sponsor or CRO are aware or which comes to the attention of the Sponsor or CRO from time to time, and which may, in the reasonable opinion of the Sponsor or CRO, be materially relevant to the conduct of the Clinical Trial, will also be provided to the Principal Investigator for inclusion in the Site File.
	11. The Participating Organisation shall not, and will ensure that 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. Upon termination or expiry of this Agreement all unused Investigational Drugs supplied for the purposes of the Clinical Trial shall, at the Sponsor [or CRO’s] option, either be returned to the Sponsor or CRO, or disposed of in accordance with the Protocol or the reasonable written instructions of the Sponsor or CRO.
	12. Subject to the Participating Organisation’s and the Principal Investigator’s overriding obligations in relation to Clinical Trial Subjects and individual patient care, the Participating Organisation shall ensure that neither it nor the Principal Investigator, nor the Personnel shall during the term of this Agreement conduct any other Research that might hinder the Participating Organisation’s or Principal Investigator’s ability to enrol and study the required cohort of Clinical Trial Subjects.
	13. The Participating Organisation shall use its best endeavours to ensure that the Principal Investigator enrols/doses/randomises a minimum of [**INSERT NUMBER**] Clinical Trial Subject(s), to participate in the Clinical Trial and the Parties shall conduct the Clinical Trial in accordance with the Timelines.
	14. In the event that the Clinical Trial is part of a Multi-Centre Trial, the Sponsor [or CRO] may amend the number of Clinical Trial Subjects to be enrolled pursuant to the Protocol as follows:
		1. If, in the reasonable opinion of the Sponsor [or CRO], enrolment of the Clinical Trial Subjects at the Participating Organisation is proceeding at a rate below that required to enable the Timelines to be met, and upon request by the Sponsor or CRO to increase the enrolment rate, the Participating Organisation is unable to comply, the Sponsor or CRO may by notice to the Participating Organisation, require the Participating Organisation to cease enrolment of Clinical Trial Subjects.
		2. If with respect of the Clinical Trial, the global enrolment target has been reached, upon receipt of a notice, the Participating Organisation shall ensure that the Principal Investigator shall immediately stop the enrolment of Clinical Trial Subjects and the terms and conditions of this Agreement shall not apply to individuals who at the time of receipt of such notice have not signed informed consent and have not been enrolled in the Clinical Trial. Payments shall be made according to the number of Clinical Trial Subjects enrolled up to the date of receipt of the notice.
		3. If enrolment of Clinical Trial Subjects is proceeding at a rate above that which is required to meet the Timelines, the Sponsor [or CRO] may, with the written agreement of the Participating Organisation, increase the number of Clinical Trial Subjects to be enrolled at the Site and the payment to be made will be adjusted in accordance with Clause 16.2.
	15. **Access, Research Misconduct and Regulatory Authorities**
		1. The Participating Organisation represents that neither it nor, to the best of its knowledge arrived at after reasonable due diligence, any of the Personnel, including the Principal Investigator, are restricted or prevented under any law from taking part in clinical research and the Participating Organisation 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 Participating Organisation and the Principal Investigator will notify the Sponsor and CRO if the Participating Organisation and/or the Principal Investigator, becomes aware of any restriction or prevention being applied to it, the Principal Investigator or any of the Personnel.
		2. The Participating Organisation represents that it and, to the best of its knowledge arrived at after reasonable due diligence, the Principal Investigator 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 or CRO. The Participating Organisation will promptly notify the Sponsor and CRO if it 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. Any Party shall inform both of the other Parties 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 Site. The Sponsor or CRO shall inform the relevant Regulatory Authority of such serious breach in writing within seven (7) days of becoming aware of that breach. The Sponsor or CRO shall, at its discretion, inform other sites 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 4.15.3, 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 Clinical Trial Subjects; or
2. the scientific value of the Clinical Trial.
	* 1. The Participating Organisation shall permit the Trial Monitor and any Auditor or Inspector access to all relevant clinical data of the Clinical Trial Subjects for monitoring and source data verification, such access to be arranged at mutually convenient times and on reasonable notice. The monitoring may take such form as the Sponsor or CRO reasonably thinks appropriate, including the right to inspect any facility being used for the conduct of the Clinical Trial and to examine any procedures or records relating to the Clinical Trial, subject to compliance with Data Protection Laws and Guidance. The Sponsor or CRO will alert the Participating Organisation, promptly in accordance with Clause 18.4, of significant issues (in the opinion of the Sponsor or CRO) relating to the conduct of the Clinical Trial.
		2. In the event that the Sponsor or CRO reasonably believes that there has been research misconduct in relation to the Clinical Trial, the Participating Organisation shall, and shall ensure that the Principal Investigator shall, provide all reasonable assistance to any investigation undertaken by or on behalf of the Sponsor or CRO into any alleged research misconduct. The results of the investigation shall, subject to any obligations of confidentiality, be communicated to the Participating Organisation. In the event that the Participating Organisation reasonably believes that there has been research misconduct in relation to the Clinical Trial, the Sponsor and CRO shall each provide all reasonable assistance to any investigation undertaken by or on behalf of the Participating Organisation into any alleged research misconduct. The results of the investigation shall, subject to any obligations of confidentiality, be communicated to the Sponsor and CRO.
		3. The Participating Organisation shall promptly inform the Sponsor and CRO of any intended or actual inspection, written enquiry and/or visit to the Site by any Regulatory Authority, in connection with the Clinical Trial, and forward to the Sponsor and CRO copies of any correspondence from any such Regulatory Authority relating to the Clinical Trial. The Participating Organisation will use reasonable endeavours to procure that the Sponsor and/or CRO may have (a) representative(s) present during any such visit or inspection and the opportunity to review and comment on the Participating Organisation’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 all Parties shall cooperate with any such inspection or written enquiry.
		4. The Participating Organisation will permit the Sponsor and CRO to examine the conduct of the Clinical Trial and the 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 and CRO shall have the right to audit Clinical Trial records during, and subsequent to, the Clinical Trial.
		5. Upon Site Trial Completion (whether prematurely or otherwise), the Principal Investigator shall co-operate with the Sponsor and CRO 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 Participating Organisation shall retain all Clinical Trial records for a period of [**INSERT NUMBER**] years after Trial Completion. Upon the expiry of the record retention period specified above the Participating Organisation shall transfer such records to the Sponsor or CRO if requested by Sponsor or CRO and shall not destroy any records without [Sponsor][CRO] (**delete as appropriate**) prior written approval, such approval not to be unreasonably withheld or delayed.
3. The Sponsor or CRO will reimburse the Participating Organisation in full for the costs of archiving the Clinical Trial records or, in agreement with the Participating Organisation, will arrange for the archiving of the Clinical Trial records on behalf of the Participating Organisation. In the event that costs of archiving are to be incurred by the Participating Organisation, it is agreed that all such costs will be reasonable and subject to prior written agreement with the Sponsor or CRO. Reimbursement will be paid to the Participating Organisation in accordance with Appendix 4. In the event that the Clinical Trial records are archived offsite by the Sponsor or CRO and the Participating Organisation does not incur any costs, no amounts will be payable to the Participating Organisation.
	* 1. [**DELETE IF NOT APPLICABLE**]Where the Participating Organisation is responsible for analysis of Material during the course of the Clinical Trial it shall ensure that such analysis is conducted at a laboratory approved by the [Sponsor][CRO] (**delete as appropriate**) or, in the case of point of care analysis, by methodology and using equipment that is acceptable to, or provided by, the [Sponsor][CRO] (**delete as appropriate**). The Participating Organisation shall ensure that analysis of Material is undertaken in accordance with the Protocol and any other document agreed between the [Sponsor][CRO] (**delete as appropriate**) and the Participating Organisation (including the provisions of Appendix 6).
		2. [**DELETE IF NOT APPLICABLE**]Where the [Sponsor][CRO] (**delete as appropriate**) undertakes the analysis of Material and/or has contracted with a third-party laboratory (“**Central Laboratory**”) to undertake the analysis of Material, the [Sponsor][CRO] (**delete as appropriate**) 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][CRO] (**delete as appropriate**).
		3. Where the Participating Organisation is responsible for collecting Starting Material during the course of the Clinical Trial, the Participating Organisation shall ensure this is undertaken in accordance with the Protocol and any other document agreed between the Sponsor and the Participating Organisation (including the provisions of Appendix 6 and the Quality Agreement). The Sponsor [and/or] [CRO] (**delete as appropriate**, in line with Appendix 8) shall comply, and shall ensure any third party processing the Starting Material shall comply, with the terms of Appendix 6 herein that are expressed to be the responsibility of the Sponsor with respect to the Starting Material.
	1. [**DELETE IF NOT APPLICABLE**]**Equipment and Resources**
	The Parties agree that the Sponsor and/or CRO shall arrange for the provision of the equipment and resources to the Participating Organisation, pursuant to the terms set out in Appendix 7.

## Liabilities and Indemnities

* 1. In the event of any claim or proceeding in respect of personal injury made or brought against the Participating Organisation by a Clinical Trial Subject, the Sponsor shall indemnify the Participating Organisation, its 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 any Party be liable to another Party in contract, tort or delict (if the Participating Organisation 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. The CRO expressly disclaims any liability in connection with Investigational Drugs caused by or allegedly caused by the use or misuse of the Investigational Drugs other than liability for death, personal injury or loss of or damage to property which liability is the result of negligence on the part of the CRO.
	4. Subject to Clauses 5.2 and 5.5 the Participating Organisation’s liability to the Sponsor and CRO arising out of or in connection with any breach of this Agreement or any act or omission of the Participating Organisation in connection with the performance of the Clinical Trial shall in no event exceed the amount of fees payable by the Sponsor or CRO to the Participating Organisation under this Agreement. In the case of equipment loaned to the Participating Organisation for the purposes of the Clinical Trial, the Participating Organisation’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.
	5. In respect of any wilful and/or deliberate breach by the Participating Organisation, or any breach of Clauses 6, 8, 10 or 11 the Participating Organisation’s liability to the Sponsor and CRO arising out of or in connection with the breach shall not exceed two times the value of the Agreement.
	6. The Sponsor will take out appropriate insurance cover or will provide an indemnity satisfactory to the Participating Organisation 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 or CRO to the Participating Organisation. The Participating Organisation will maintain its membership of the relevant NHS clinical negligence indemnity scheme(s) for the duration of the Clinical Trial.
		1. The Sponsor shall produce to the Participating Organisation 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. The Participating Organisation shall produce to the Sponsor or CRO on request evidence of its continued membership of the relevant NHS clinical negligence indemnity scheme(s). The terms of insurance, or of the relevant NHS clinical negligence indemnity scheme(s), or the amount of cover, shall not relieve any 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 Clinical Trial Subjects. 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 a 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 Clinical Trial Subject Personal Data**
		1. For the purpose of the Data Protection Laws and Guidance, the Sponsor is the Controller and the Participating Organisation and CRO are Processors of Personal Data Processed for the purpose of the Clinical Trial.
		2. The Participating Organisation’s Processing of Personal Data, as a Processor 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 Participating Organisation is the Controller of Personal Data Processed for purposes other than the Clinical Trial, e.g. the provision of medical care.
		4. The Participating Organisation, in its role as Processor of the Personal Data under Clause 6.2.1, agrees 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 Participating Organisation is required by law to otherwise Process the Personal Data, the Participating Organisation shall notify the [Sponsor] [and the] [or the] [CRO] (**delete as appropriate**) before undertaking the Processing, 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 Participating Organisation shall notify the [Sponsor] [and the] [or the] [CRO] (**delete as appropriate**) as soon as possible once the prohibition is lifted, if it is lifted.
		5. The Participating Organisation agrees 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 its systems, in keeping with its obligations as an NHS organisation, thereby providing guarantee to the Sponsor pursuant to GDPR Article 28(1);
2. ensuring that Personnel authorised to Process Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality (Article 28(3)(b));
3. taking all measures required by GDPR Article 32 in relation to the security of Processing (GDPR Article 28(3)(c));
4. subject to Clause 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 Participating Organisation (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 Participating Organisation as a Processor of the Sponsor, the Participating Organisation shall: (i) promptly and without undue delay following discovery of such Personal Data Breach, send written notice of the incident via e-mail to [**insert**]; (ii) not make any statements or notifications about the Personal Data Breach, as it relates to the Processing for the purpose of the Clinical Trial, to any individual affected by the incident, the public or any third party without [Sponsor’s] [CRO’s] (**delete as appropriate**) prior written approval; and (iii) immediately take steps to investigate and mitigate the Personal Data Breach and reasonably cooperate with the Sponsor and/or CRO.
	* 1. In furtherance of its obligations under Article 28 GDPR, the Participating Organisation agrees that it will not engage another Processor for the purpose of the Clinical Trial without prior written authorisation from or on behalf 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;
9. In accordance with GDPR Article 28(2) the Participating Organisation may appoint PICs, on the basis of an unmodified template data processing agreement agreed in advance with or on behalf of the Sponsor, by notifying the [Sponsor] [CRO] (**delete as appropriate**) that they intend to contract the PIC. The Sponsor will be considered to have authorised this sub-processing if [Sponsor] [CRO] (delete as appropriate) does not notify the Participating Organisation to the contrary within [**INSERT NUMBER**, FOR EXAMPLE, FIVE (5)] business days.
	* 1. At the expiry or lapse of this Agreement, the Participating Organisation 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 Participating Organisation as Controller for its own purpose(s).
		2. The Participating Organisation will:
10. ensure that its Personnel and the Principal Investigator, do not Process Personal Data except in accordance with the Protocol and this Agreement;
11. take all reasonable steps to ensure the reliability and integrity of the Principal Investigator and any of its Personnel who have access to the Personal Data and will ensure that the Principal Investigator and the Personnel:
12. are aware and comply with the Participating Organisation’s duties under this Clause 6 (Data Protection);
13. 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
14. are informed of the confidential nature of the Personal Data and understand their responsibilities for information governance, including their obligation to Process Personal Data securely and to only disseminate or disclose it for lawful and appropriate purposes.
	* 1. The Participating Organisation agrees to:
15. Provide the Sponsor and/or CRO with evidence of its compliance with the obligations set out in this Agreement, and/or, at the Sponsor and/or CROs discretion and on reasonable notice, to allow the Sponsor and/or CRO, or a third party appointed by the Sponsor and/or CRO, to audit the Participating Organisation’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 and/or CRO, or the appointed third party, complying with all relevant health and safety and security policies of the Participating Organisation.
16. Obtain prior written agreement of the [Sponsor] [CRO] [**delete as appropriate**]to Process Personal Data outside of the UK and the EEA.
	* 1. In addition to the Participating Organisation’s obligations under Clause 6.2.9(b), where the Participating Organisation, acting as the Sponsor’s Processor, Processes Personal Data outside of the UK and the EEA, the Participating Organisation warrants that it does so in compliance with the Data Protection Laws and Guidance.
	1. **Sharing of Personal Data and/or Clinical Trial Subject Pseudonymised Data**
		1. Neither Personal Data nor Pseudonymised Data of Clinical Trial Subjects shall be transferred by the Participating Organisation to the Sponsor and/or CRO 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 Clinical Trial Subject in connection with the Clinical Trial or is otherwise required by applicable law.
		2. The Sponsor and CRO agree not to pass Personal Data or Pseudonymised Data of Clinical Trial Subjects provided under this Agreement to a third party, unless that third party is bound by contractual obligations at least as stringent as in this Clause 6.
		3. The Sponsor and CRO agree to use Personal Data and/or Pseudonymised Data of Clinical Trial Subjects for the purpose of the Clinical Trial and in all circumstances for no purpose which is incompatible with the Clinical Trial purpose. The Sponsor and CRO further agree not to disclose the Personal Data or Pseudonymised Data of Clinical Trial Subjects 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 and CRO agree to ensure persons Processing Personal Data and/or Pseudonymised Data of Clinical Trial Subjects under this Agreement are equipped to do so respectfully and safely. In particular:
17. to ensure any such persons (excluding employees, honorary employees, students, researchers, consultants and sub-contractors of the Participating Organisation) understand the responsibilities for information governance, including their obligation to Process Personal Data and/or Pseudonymised Data of Clinical Trial Subjects securely and to only disseminate or disclose for lawful and appropriate purposes;
18. to ensure any such persons (excluding employees, honorary employees, students, researchers, consultants and sub-contractors of the Participating Organisation) 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 and CRO agree to take reasonable steps to proactively prevent Personal Data Breaches, and/or equivalent breaches relating to Pseudonymised Data of Clinical Trial Subjects, and to respond appropriately to incidents or near misses. In particular:
19. to ensure that Personal Data and/or Pseudonymised Data of Clinical Trial Subjects are only accessible to persons who need it for the purposes of the Clinical Trial and to remove access as soon as reasonably possible once it is no longer needed;
20. to ensure all access to Personal Data and/or Pseudonymised Data of Clinical Trial Subjects on IT systems Processed for Clinical Trial purposes can be attributed to individuals;
21. to review processes to identify and improve processes which have caused Personal Data Breaches or near misses, or which force persons Processing Personal Data and/or Pseudonymised Data of Clinical Trial Subjects to use workarounds which compromise data security;
22. to adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice;
23. to take action immediately following a Personal Data Breach or near miss.
	* 1. The Sponsor and CRO agree to ensure Personal Data and/or Pseudonymised Data of Clinical Trial Subjects are Processed using secure and up-to-date technology. In particular:
24. to ensure no unsupported operating systems, software or internet browsers are used to support the Processing of Personal Data and/or Pseudonymised Data of Clinical Trial Subjects for the purposes of the Clinical Trial;
25. to put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework;
26. to ensure IT suppliers are held accountable via contracts for protecting Personal Data and/or Pseudonymised Data of Clinical Trial Subjects that they Process and for meeting all relevant information governance requirements.

## Freedom of Information

* 1. The Sponsor and CRO acknowledge that the Participating Organisation is subject to the FOIA and associated guidance and codes of practice.
	2. If the Participating Organisation or its Agent(s) receive a request under the FOIA to disclose information relating to or connected with this Agreement (including but not limited to the Sponsor, CRO, Investigational Drugs (or their manufacturers), or the Clinical Trial), it will notify the Sponsor or CRO, as applicable, as soon as is reasonably practicable, and in any event, no later than five (5) working days after receiving the request. The Participating Organisation will consult with the Sponsor and/or CRO in accordance with all applicable guidance.
	3. The Sponsor and CRO acknowledge that subject to Clause 7.3.1, the decision on whether any exemption applies to a request for disclosure of recorded information under the FOIA is a decision solely for the Participating Organisation.
		1. The Sponsor and CRO shall cooperate with the Participating Organisation and shall use their reasonable endeavours to respond within ten (10) working days of the Participating Organisation’s reasonable request for assistance.
	4. Where the Participating Organisation determines that it will disclose information, notwithstanding any objections from the Sponsor or CRO, it will notify the Sponsor and/or CRO as applicable in writing, giving at least two (2) working days’ notice of its intended disclosure.

## Confidential Information

* 1. Each Party may only disclose Confidential Information to its officers, Agents and employees (and in the case of the Sponsor or CRO, 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 license, 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, save where disclosure is required by a Regulatory Authority or by law (including any disclosure required to ensure compliance, by the Participating Organisation, with the FOIA in accordance with Clause 7 of this Agreement). The Party required to make the disclosure shall inform the disclosing Party, 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, other than in accordance with this Agreement, without the prior written consent of the disclosing Party.
	2. The obligations of confidentiality set out in this Agreement, shall not apply to information that is:
		1. published or becomes generally available to the public other than as a result of a breach of this Agreement by the receiving Party;
		2. in the possession of the receiving Party prior to its receipt from the disclosing Party, as evidenced by contemporaneous written evidence, and is not subject to a duty of confidentiality;
		3. independently developed by the receiving Party, as evidenced by contemporaneous written evidence and is not subject to a duty of confidentiality;
		4. obtained by the receiving Party from a third party that is not subject to a duty of confidentiality.
	3. In the event of a Party visiting the establishment of another Party, the visiting Party undertakes that any further Confidential Information that may come to the visiting Party’s knowledge as a result of any such visit, shall be treated as Confidential Information in accordance with this Clause 8.
	4. This Clause 8 shall remain in force without limit in time in respect of Personal Data and any other information which relates to a patient, his or her treatment and/or medical records. Save as aforesaid, and unless otherwise expressly set out in this Agreement, this Clause 8 shall remain in force for a period of ten (10) years after the termination or expiry of this Agreement.

## Publicity

* 1. Subject to Clauses 4.5, 10.5 and 12.3, neither the Sponsor nor the CRO will use the name of the Participating Organisation or any Site in any publicity, advertising or news release without the prior written approval of an authorised representative of the Participating Organisation, such approval not to be unreasonably withheld. Nothing in this Agreement will prohibit the Sponsor or CRO from publishing the identities and contact information of the Participating Organisation and the Clinical Trial recruitment status at the 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 Clinical Trial subjects, or otherwise as may be required under Clause 4.6.
	2. The Participating Organisation will not, and will ensure that the Principal Investigator and the Personnel do not, use the name of the Sponsor or CRO, or the name(s) of any of their 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 and/or CRO as appropriate, such approval not to be unreasonably withheld. The provisions of this Clause 9.2 shall also apply to the Participating Organisation’s use of the name, trademark, service mark, and/or logo of any third parties collaborating with the Sponsor or CRO on the Clinical Trial and/or the IMP (“**Sponsor or CRO Collaborators**”) provided that the Participating Organisation has been notified of the identity of the Sponsor or CRO Collaborators.
	3. Neither the Participating Organisation, 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 Clinical Trial Subjects without the prior written permission of the Sponsor or CRO as appropriate, not to be unreasonably withheld, and the delivery of research ethics committee approval, where applicable.

## Publications

* 1. The Sponsor recognises that the Participating Organisation and Principal Investigator have a responsibility under the Research Governance 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 Participating Organisation 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 Site (or group of 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 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 Participating Organisation and/or the Principal Investigator may prepare the data derived from the Site(s) 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 sixty (60) 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 Participating Organisation agrees and shall ensure that the Principal Investigator agrees that all reasonable comments made by the Sponsor in relation to a proposed publication by the Participating Organisation and/or the Principal Investigator will be incorporated by the Participating Organisation 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 Participating Organisation acknowledges that nothing in this Agreement prevents the Sponsor and/or CRO (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 Participating Organisation will accurately describe and will ensure that the Principal Investigator 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 or CRO coordinates a Multi-Centre publication, the participation of the Principal Investigator or Personnel as named authors shall be determined in accordance with the Sponsor or CRO’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 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 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 Participating Organisation that publication be delayed for a period of up to six (6) months 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 Participating Organisation shall not unreasonably withhold or delay its consent to such request. The Participating Organisation shall not unreasonably withhold or delay its 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 CRO 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 CRO.
	3. All Intellectual Property Rights and Know-How owned by or licensed to the Participating Organisation 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 Participating Organisation.
	4. 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 Participating Organisation, shall vest in the Sponsor in accordance with Clauses 11.5 and 11.6 of this Agreement.
	5. In accordance with Clause 11.4, the Participating Organisation hereby assigns, and shall procure that its Agents assign, its rights in relation to all Intellectual Property Rights and Know-How, falling within Clause 11.4, to the Sponsor or its nominee. At the request and expense of the Sponsor, the Participating Organisation shall execute, and shall procure that its Agents shall execute, all such documents and do all such other acts as the Sponsor may reasonably require in order to vest fully and effectively all such Intellectual Property Rights and Know-How in the Sponsor or its nominee.
	6. The Participating Organisation shall and will ensure that the Principal Investigator promptly disclose to the Sponsor and CRO any Know-How generated pursuant to this Agreement and falling within Clause 11.4 and undertakes not to use or disclose such Know-How other than for the purposes of this Agreement.
	7. Nothing in this Clause 11 shall be construed so as to prevent or hinder the Participating Organisation from using its Know-How generated during the performance of the Clinical Trial in the furtherance of its normal activities, to the extent that such use does not result in the disclosure or misuse of Confidential Information or the infringement of any Intellectual Property Right or Know-How of the Sponsor.

## Financial Arrangements

* 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 amend Appendix 4 in accordance with Clause 16.2.
	3. The Participating Organisation agrees that the Sponsor may make public the financial support provided to the Participating Organisation by the Sponsor for the conduct of the Clinical Trial and may identify the Participating Organisation as part of this disclosure.
	4. The Sponsor or CRO will notify the Participating Organisation of Site Trial Completion in order to trigger the generation of a final invoice in accordance with Appendix 4.
	5. The Party making payment shall promptly respond to any reasonable request for invoicing data received from the Participating Organisation for the purposes of the final invoice for the specific Site(s), provided that the request is received within forty-five (45) days of the notification of Site Trial Completion.
	6. **Longstop Dates**
	It is agreed that the Party making payment shall not be required to make payment for any amounts that the Participating Organisation fails to notify the Party making payment of within sixty (60) days of that Party providing the final invoicing information (if requested), in accordance with Clause 12.5, or sixty (60) days from Site Trial Completion if invoicing information is not requested (“**Longstop Dates**”). For the avoidance of doubt, it is not an obligation for either the Sponsor or CRO to pay invoices dated after the Longstop Date.
	7. The Party making payment will make payment to the Participating Organisation of invoices within forty-five (45) days of the date of receipt of invoices (excluding disputed amounts, which will be resolved in good faith in a timely manner in accordance with Clause 19).
	8. Any delay in the payment of the payee invoices by a Party 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.

## Term

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

## Termination

* 1. The Sponsor, CRO or the Participating Organisation (the “**Terminating Party**”) may terminate this Agreement with immediate effect at any time if another Party or the Principal Investigator (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. Any 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 Clinical Trial Subjects involved in the Clinical Trial.
	3. The Sponsor or CRO may terminate this Agreement on notice to the Participating Organisation if the Principal Investigator is no longer able (for whatever reason) to act as Principal Investigator and no replacement mutually acceptable to the Parties 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 Participating Organisation and Sponsor can be found, the Sponsor or CRO may terminate this Agreement on notice to the other Parties.
	4. The Sponsor may terminate this Agreement immediately upon notice in writing to the Participating Organisation 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 Clinical Trial Subjects caused by the premature termination of the Clinical Trial.
	5. In the event of early termination of this Agreement by the Sponsor or CRO, pursuant to Clauses 14.1, 14.2, 14.3 or by the Sponsor pursuant to Clause 14.4 and subject to an obligation on the Participating Organisation and the Principal Investigator to mitigate any loss, the Party making payment 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 Participating Organisation for the performance of the Clinical Trial prior to the date of termination, and agreed with the Party making payment.
	6. In the event of early termination, if payment (whether for salaries or otherwise) has been made by the Sponsor or CRO to the Participating Organisation in advance for work not completed, such monies shall be applied to termination related costs, agreed as per Clause 14.5, and the Participating Organisation shall issue a credit note and repay the remainder of the monies within forty-five (45) days of receipt of written notice from the Sponsor or CRO.
	7. At Site Trial Completion, the Participating Organisation shall promptly deliver, and shall ensure that the Principal Investigator delivers, to the Sponsor or CRO all Confidential Information and any other unused materials provided to the Participating Organisation 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 Participating Organisation and Sponsor or CRO or that are otherwise required by applicable legislation to be retained by the Participating Organisation, which will be retained by the Participating Organisation in accordance with 4.15.9.
	8. 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. CRO may assign or otherwise transfer this Agreement in whole including all prior rights and responsibilities but not in part or otherwise to the Sponsor or another party subject to the consent of the Sponsor. The CRO shall promptly inform the Participating Organisation of any such transfer and provide the Participating Organisation with a copy of the assignment or other transfer agreement duly executed by the CRO and the Sponsor or other party and a copy of the Sponsor’s written consent thereto.
	2. Except as provided in Clause 15.1, 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 and/or CRO 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 Participating Organisation. Sponsor, or CRO, shall inform the Participating Organisation in good time in writing about the aforementioned assignment/assignation. 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 any 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. The Sponsor shall use all reasonable endeavours to procure the punctual, true and faithful performance and observance by the CRO of its obligations under Appendix 8. In the event of any material breach of the obligations of the CRO under Appendix 8, and on receipt of notice from the Participating Organisation to do so, the Sponsor shall from the date of such notice assume all rights and obligations of the CRO under Appendix 8 and at its own expense perform or, subject to the agreement of the Participating Organisation (such agreement not to be unreasonably withheld or delayed), take whatever steps may be necessary to procure the performance of the obligations of the CRO under Appendix 8 by another party.
	4. In the event that the CRO passes a resolution or the court makes an order that the CRO be wound up otherwise than for the purpose of bona fide reconstruction or amalgamation, or a receiver, manager or administrator on behalf of a creditor is appointed in respect of the CRO’s business or any part thereof, or the CRO is unable to pay its debts within the meaning of Section 123 of the Insolvency Act 1986 then, on receipt of notice from the Participating Organisation to do so, the Sponsor shall from the date of such notice assume all the rights and obligations of the CRO under Appendix 8 and at its own expense perform or, subject to the agreement of the Participating Organisation (such agreement not to be unreasonably withheld or delayed), take whatever steps may be necessary to procure the performance of the obligations of the CRO under Appendix 8 by another party.
	5. Nothing in this Agreement shall be construed as creating a joint venture, partnership, contract of employment or relationship of principal and agent between any of 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 change 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 or CRO originates a change request, the Participating Organisation shall provide the Sponsor or CRO, within fourteen (14) 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 all 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 and supersedes all other agreements (other than the agreement contracting the CRO to work on behalf of the Sponsor with regards to this Clinical Trial), negotiations, representations and undertakings, whether written or oral, of prior date between the Parties relating to the Clinical Trial that is the subject of this Agreement.

## Force Majeure

* 1. No Party shall be liable to any other Party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, terrorist activity, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstances shall promptly notify the other Parties in writing when such circumstances cause a delay or failure in performance (“**a Delay**”) and when they cease to do so. In the event of a Delay lasting for four (4) weeks or more, the non-affected 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 any 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 Parties 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 other 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 other 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 & ADDRESS – INCLUDE E-MAIL ADDRESS AS APPLICABLE]
	2. Notices to the CRO shall be addressed to:
	[**INSERT** CONTACT NAME & ADDRESS – INCLUDE E-MAIL ADDRESS AS APPLICABLE]
	3. Notices to the Participating Organisation shall be addressed to:
	[**INSERT** CONTACT NAME & 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 seven (7) days of being requested in writing by any Party to do so. If the dispute remains unresolved, it will then be referred to a senior manager from each of the Parties who will use all reasonable endeavours to resolve the dispute within a further fourteen (14) days.
	2. If the Participating Organisation 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 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 twenty (20) days after the date of the ADR Notice. The Parties shall each bear their own costs and expenses in relation to settlement of any disputes in terms of this Clause 19 and shall share equally the costs of the independent third party. If the dispute is not resolved within thirty (30) days of the ADR Notice, a Party shall be entitled to submit to the exclusive jurisdiction of the Courts of England and Wales.

If the Participating Organisation 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 Participating Organisation 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 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 any Party from seeking an interim injunction (if the Participating Organisation is constituted in England or Wales or Northern Ireland) or interdict (if the Participating Organisation is constituted in Scotland) in respect of a breach of this Agreement. For the avoidance of doubt, nothing in this Clause shall amount to an agreement that any of the Parties 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 Participating Organisation 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 Clinical Trial Subject 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 3.8** Clinical Trial Governance

**Clause 4.15** 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 Participating Organisation 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 Participating Organisation 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 Participating Organisation 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 Participating Organisation 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 (a) fax or (b) email (in PDF, JPEG or other agreed format) to another Party 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]Signature:Title: Date: | Signed for and on behalf of:[**INSERT** NAME OF CRO]Signature:Title: Date: | Signed for and on behalf of:[**INSERT** NAME OF PARTICIPATING ORGANISATION]Signature:Title:Date: |

# 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, CRO and the Participating Organisation in accordance with the specific Clinical Trial arrangements that are applicable at each Site. Please remove this text once the document has been agreed for the Clinical Trial.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Milestone** | **Sponsor responsibility** | **CRO responsibility** | **Participating Organisation responsibility** | **Target date for completion at Site** |
| Site Initiation visit | Yes | Yes | Yes | [ENTER DATE] |
| First Clinical Trial Subject [screened/enrolled] | No | Yes | Yes | [ENTER DATE] |
| Last Clinical Trial Subject enrolled | No | Yes | Yes | [ENTER DATE] |
| All Case Report Form queries submitted | Yes | No | No | [ENTER DATE] |
| All Case Report Form queries completed | No | Yes | 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 Participating Organisation and its 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 Clinical Trial Subjects and (or their dependants) against the Participating Organisation or any of its employees or Agents for personal injury (including death) to Clinical Trial Subjects 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 Clinical Trial Subjects would not have been exposed but for their participation in the Clinical Trial;
	2. by the Participating Organisation, its employees or Agents or by or on behalf of a Clinical Trial Subject for a declaration concerning the treatment of a Clinical Trial Subject 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 Participating Organisation, its employees or Agents;
	2. to the extent that such personal injury (including death) is caused by the failure of the Participating Organisation, its 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 Participating Organisation 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 Participating Organisation, its 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 Participating Organisation, its employees or Agents in connection with the operation of the Participating Organisation’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 Participating Organisation and its legal advisors fully informed of the progress of any such claim or proceeding, will consult fully with the Participating Organisation on the nature of any defence to be advanced and will not settle any such claim or proceeding without the written approval of the Participating Organisation (such approval not to be unreasonably withheld).
4. Without prejudice to the provisions of paragraph 2.3 above, the Participating Organisation will use its reasonable endeavours to inform the Sponsor promptly of any circumstances reasonably thought likely to give rise to any such claim or proceeding of which it is directly aware and shall keep the Sponsor reasonably informed of developments in relation to any such claim or proceeding even where the Participating Organisation decides not to make a claim under this indemnity. Likewise, the Sponsor shall use its reasonable endeavours to inform the Participating Organisation of any circumstances and shall keep the Participating Organisation reasonably informed of developments in relation to any such claim or proceeding made or brought against the Sponsor alone.
5. The Participating Organisation and the Sponsor will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding by or on behalf of Clinical Trial Subjects (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 Clinical Trial Subject 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 Clinical Trial Subjects that the Clinical Trial is being conducted subject to the Association Guidelines.

# Appendix 4 – Financial Arrangements

**The Industry Costings Template should be used by the Sponsor or CRO to formulate the budget with respect to the Clinical Trial. When the template has been populated the agreed financial arrangements should form this Appendix.**

**Note**: This Appendix should only be used to specify financial matters and should not be used to include additional or different terms to those set out in the Agreement.

**Please remove this text once the document has been agreed for the Clinical Trial.**

# 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 Participating Organisation is not the Principal Investigator’s substantive employer, the Principal Investigator must notify his/her 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 Participating Organisation and that in the performance of obligations under this Agreement, is satisfied that he/she will be supported by medical and other staff of sufficient number and experience to enable the Participating Organisation to perform the Clinical Trial efficiently and in accordance with the obligations under this Agreement.
5. Where the Participating Organisation is not the Principal Investigator’s substantive employer, the Principal Investigator holds a contract for services (commonly known as an honorary contract) with the Participating Organisation.
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 his/her obligations under this Agreement.
7. The Participating Organisation carries medical liability insurance covering the Principal Investigator, or is 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

**[DELETE IF NOT APPLICABLE]**

Where the Protocol requires the Participating Organisation to supply Material and/or Starting Material to the Sponsor or CRO this Appendix 6 shall apply.

1. In accordance with the Protocol, the Participating Organisation shall send Material and/or Starting Material to the Sponsor, CRO or, in accordance with Section 7 below, to a third party nominated by the Sponsor or CRO.
2. The Participating Organisation warrants that all Material and/or Starting Material has been collected with appropriate informed consent and has been collected and handled in accordance with applicable law (including, without limitation, the Human Tissue Act 2004) and as required by the Protocol.
3. Subject to Section 2 above, the Material and/or Starting 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 or CRO shall ensure, or procure through an agreement with the nominee of the Sponsor or CRO as stated in Section 1 above, that:
	1. the Material and/or Starting Material is used in accordance with the consent of the Clinical Trial Subject and the approval of all Regulatory Authorities for the Clinical Trial and the Protocol;
	2. the Material and/or Starting Material is handled and stored in accordance with applicable law;
	3. the Material and/or Starting 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 Clinical Trial Subject’s consent.
5. The Parties shall comply with all relevant laws, regulations and codes of practice governing the Clinical Trial and the use of human biological material.
6. The Participating Organisation and the Sponsor or CRO shall each be responsible for keeping a record of the Material and/or Starting Material that has been transferred according to this Appendix 6.
7. To the extent permitted by law, the Participating Organisation and its Personnel shall not be liable for any consequences of the supply to or the use by the or CRO of the Material and/or Starting Material, or of the supply to or the use by any third party to whom the Sponsor or CRO subsequently provides the Material and/or Starting Material, or the nominee of the Sponsor or CRO as stated in Section 1 above, save to the extent that any liability that arises is a result of the negligence, wrongful acts or omissions or breach of statutory duty of the Participating Organisation or its Personnel, or their failure to comply with the terms of this Agreement.
8. The Sponsor and/or CRO undertakes that, in the event that Material and/or Starting Material is provided to a third party in accordance with Section 1 above, it shall require that such third party shall undertake to handle any Material and/or Starting 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 and/or Starting Material that is not returned to the Participating Organisation or retained for future research shall be destroyed in accordance with the Human Tissue Act 2004.

# Appendix 7 – Equipment and Resources

**[DELETE WHOLE APPENDIX IF NOT APPLICABLE]**

1. Sponsor/CRO Provided Equipment

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

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

| **No.** | **Equipment** | **Estimated Original Value** | **Depreciation** |
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Where applicable, the Sponsor/CRO Equipment will be provided with current records of calibration and electrical safety testing.

1. Sponsor/CRO Provided Resources

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

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

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

1. Disposition of Sponsor/CRO Equipment and Sponsor/CRO Resources

**Alternative #1 – Return to Sponsor/CRO**

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

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

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

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

If any Sponsor/CRO Equipment is so transferred, it will be transferred ‘as is’ and neither the Sponsor nor the CRO make any representation or provide any warranty of any kind concerning it.

**Alternative #3 – Return of Sponsor/CRO Resources to Sponsor or CRO and purchase of Sponsor/CRO Equipment by Participating Organisation.**

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

After completion of the Clinical Trial at the Site, Sponsor or CRO will make Sponsor/CRO Equipment available for purchase by the Participating Organisation 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 or CRO will ensure that any transfer of ownership is documented in writing.

If any Sponsor/CRO Equipment is so transferred, it will be transferred ‘as is’ and neither the Sponsor nor the CRO makes any representation or provides 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 or CRO** 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**

The Participating Organisation will use Vendor Property only for purposes of this Clinical Trial.

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

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

**Alternative #1 – indemnity provided by this Appendix 7**

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

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

Sponsor or CRO shall be responsible for organising and ensuring payment for all costs associated with the routine maintenance of the [**Sponsor/CRO Equipment**], [**Sponsor/CRO Resources**] [and] [**Vendor Property**] and will replace the same at no cost to the Participating Organisation 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 Participating Organisation shall be liable for any damage, loss or destruction of the [**Sponsor/CRO Equipment**], [**Sponsor/CRO Resources**] or [**Vendor Property**] and for any losses attributable to the [**Sponsor/CRO Equipment**], [**Sponsor/CRO Material**] [or] [**Vendor Property**] caused by the Participating Organisation’s wilful misconduct, negligent acts or omissions. Under no circumstances shall the Participating Organisation 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 Participating Organisation shall not insure the [**Sponsor/CRO Equipment**], [**Sponsor/CRO Material**] or [**Vendor Property**].

**Alternative #2 – Equipment is supplied under an MIA**

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

# Appendix 8 – Sponsor’s Clinical Trial Related Duties and Functions Under ICH-GCP to be Performed by CRO

# Appendix 9 – Formal Delegation of Authority to a Corporate Affiliate to Contractually Bind Sponsor

**FINAL PAGE**