Model Clinical Trial Agreement

The information set out below provides a checklist of information that needs to be included in the mCTA in preparation for execution by the parties.

It is the Sponsor's responsibility to provide the required information for review by the Participating Organisation.

1. **Footers**
   Complete the information set out in the Footer of this Document.

2. **Front Page**
   Complete all of the required information.

3. **Contents Page**
   If either Appendix 6 or Appendix 7 are not used, delete reference in the Contents Page.

4. **Definitions** - Complete the following definitions as appropriate:

   Clause 3.3.4 - Check that this Clause references the Declaration of Helsinki applicable to this Clinical Trial.

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

   Clauses 4.13.8 and 4.13.9 – Delete either or both clauses depending upon whether Material will be analysed locally, centrally or if no Material will be analysed,

   Clause 4.13.11 - Insert the appropriate number of years.

   Clause 4.14 - Delete if no equipment or resources are provided by the Sponsor.

   Clause 5.6 - Insert amount.

   Clause 18 - Complete the full names and addresses for contact persons.

5. **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.

6. **Appendix 1**
   Complete Appendix 1 showing the milestones/division of responsibilities between the Parties and target site completion date.

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

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

9. **Appendix 7**
   Complete details of any equipment being supplied for the Clinical Trial. Clearly indicate whether liability will be determined in accordance with the main body of the Agreement, or pursuant to an MIA. Where no equipment is being provided, Appendix 7 should be omitted.

Delete this instruction page 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"

&

[IF APPLICABLE, INSERT "*THE LEGAL REPRESENTATIVE IN THE EEA OF [INSERT RELEVANT CORPORATE ENTITY NAME"*] DELETE IF NOT APPLICABLE]

[INSERT NAME OF SPONSOR AND REGISTERED ADDRESS OF SPONSOR]

the "Sponsor"

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

Clinical Trial Agreement

Whereas

A. The Sponsor is a pharmaceutical company involved in the research, development, manufacture and sale of medicines for use in humans;

B. The Participating Organisation is concerned with the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare;

C. The Sponsor wishes to contract with the Participating Organisation to undertake a clinical trial.

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

1. DEFINITIONS

1.1. 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 which controls, is controlled by or is under the common control with the Sponsor. 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) any such person's principal employer in the event that it is not the Participating Organisation and where such person is providing services to the Participating Organisation under a contract for services (commonly known as an honorary contract) or otherwise 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);
Auditor	means a person being a representative of the Sponsor 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 (as defined below) to the other Party including but not limited to: • Any information that would be regarded as confidential by a reasonable business person relating to the business, affairs, plans, intentions or market opportunities of the disclosing party; and • The operations, processes, product information, , designs, trade secrets or Know-How of the disclosing party; • Any information developed by the Parties in the course of carrying out this Agreement;
Data Protection Laws & Guidance	means the EU Data Protection Directive 95/46/EC, the Data Protection Act 1998 and all successor legislation, including but not limited to the General Data Protection Regulation (EU) 2016/679 as well as any applicable 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;
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;
GMP	means any relevant European Union and appropriate national regulations on good manufacturing practices;
GVP	means any relevant current European Union and appropriate national regulations on good pharmacovigilance practices;
ICH GCP	means the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) together with such other good clinical practice requirements as are specified in Directive 2001/20/EC of the European Parliament and the Council of 4 April 2001 relating to medicinal products for human use and in guidance published by the European Commission pursuant to such Directive;

IND	means the Investigational New Drug application process by which the United Stated 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 Medicinal Product or IMP	means the Clinical Trial drug or control material as defined 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;
Know-How	means all technical and other information which is not in the public domain (other than as a breach of confidence) including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, the 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;
MIA	means the Master Indemnity Agreement that may be applicable in the part of the United Kingdom where the Participating Organisation is constituted;
Material	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;
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;
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 and incorporated into this Agreement by reference;
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 as published by the Sponsor;
Site	means the physical location(s) where the Clinical Trial will be conducted 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;
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;
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 to monitor compliance of the Clinical Trial with ICH GCP and to conduct source data verification;

1.2. 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 or re-enactments of the said provisions, whether set out in a modification or amendment to the Declaration of Helsinki or otherwise, shall not apply to this Agreement.

1.3. The headings to clauses are inserted for convenience only and shall not affect the interpretation or construction of this Agreement.

1.4. Where appropriate, words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders.

1.5. A reference to this Agreement or to any other agreement or document referred to in this agreement is a reference to this Agreement or such other agreement or document as amended, varied or novated (in each case other than in breach of the provisions of this Agreement) from time to time.

2. PRINCIPAL INVESTIGATOR AND PERSONNEL

2.1. The Participating Organisation represents that it is entitled to procure and the Participating Organisation will procure the services of the Principal Investigator to act as Principal Investigator and shall ensure the performance of the obligations of the Principal Investigator set out in Appendix 5 and elsewhere in this Agreement.

2.1.1. 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.

2.2. 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.

2.3. The Participating Organisation shall notify the Sponsor if the Principal Investigator ceases to be employed by or associated with the Participating Organisation or is otherwise unavailable to continue as Principal Investigator. The Participating Organisation shall use all reasonable endeavours to find a replacement acceptable to both the Sponsor and the Participating Organisation, 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 may terminate this Agreement pursuant to Clause 14.3.

2.4. 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.

2.5. The Principal Investigator and/or Personnel shall attend any meetings regarding the Clinical Trial as reasonably requested by the Sponsor ("***Investigator Meetings***"). Such meetings to be conducted by the Sponsor to convey or exchange information with the

Principal Investigator, all Sub-Investigators or other Personnel to support the effective conduct or close-out of the Clinical Trial. The 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 shall reimburse or pay for reasonable pre-approved expenses upon receipt of documentation. It is further agreed that any such expenses will be paid at the rate of fair market value (in line with the ABPI Code of Practice) and subject to the documentation evidencing the expenses being in sufficient detail for the Sponsor's financial reporting purposes provided that the required detail does not impose an unreasonable administrative burden upon the Participating Organisation.

3. CLINICAL TRIAL GOVERNANCE

3.1. The Sponsor 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 shall also provide the Principal Investigator with an emergency telephone number to enable serious adverse event reporting at any time.

3.2. The Parties shall comply with all relevant laws, including but not limited to:

3.2.1. Laws of the European Union if directly applicable or of direct effect;
3.2.2. The Human Rights Act 1998;
3.2.3. The Data Protection Act 1998;
3.2.4. 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;
3.2.5. The Medicines Act 1968;
3.2.6. The Human Medicines Regulations 2012;
3.2.7. The Medicines for Human Use (Clinical Trial) Regulations 2004.

3.3. The Parties shall comply with all relevant guidance relating to medicines and clinical trials from time to time in force including but not limited to:

3.3.1. the ICH GCP;
3.3.2. GMP;
3.3.3. GVP;
3.3.4. the World Medical Association Declaration of Helsinki entitled, "Ethical Principles for Medical Research Involving Human Subjects (1996)";
3.3.5. the Research Governance Framework;
3.3.6. the Medical Research Council Guidelines entitled, "Human Tissue and Biological Samples for Use in Research,";
3.3.7. [**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 to the Participating Organisation.

3.4. When applicable, the Sponsor shall comply with the Clinical Trial Compensation Guidelines attached as Appendix 2 of this Agreement.

3.5. The Participating Organisation shall ensure that the Principal Investigator, Sub-Investigators and any Sub-Investigators joining the Clinical Trial following the initiation of the Trial, undertake any such appropriate training as the Sponsor may consider

necessary for the conduct of the Clinical Trial, including but not limited to the training and provision of information given during Investigator Meetings.

3.6. **Location of the Clinical Trial**. The Parties acknowledge that the Participating Organisation might have responsibility for several hospitals which may have the potential to be involved in the Clinical Trial. It is agreed however, that only those Sites which 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 both Parties are in agreement and the relevant regulatory approval/s, including research ethics approval, has been obtained, if applicable.

3.7. **Adverse Event Reporting**. Both Parties acknowledge the obligation to comply with applicable regulations governing the collection and reporting of adverse events of which they may become aware during the course of the Clinical Trial. Both Parties agree to fulfill and ensure that their Agents fulfil regulatory requirements with respect to the reporting of adverse events.

3.7.1. **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:

a. It is the responsibility of the Sponsor to report all SUSARs 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;

b. The Principal Investigator will provide the Sponsor with details of all SAEs irrespective of causality or whether the SAE is thought to be related to the IMP;

c. It is the responsibility of the Sponsor to submit an annual safety report to the relevant Regulatory Authorities at the end of the Reporting Year, as set out in the Medicines for Human Use (Clinical Trial) Regulations 2004. The Sponsor will provide the Participating Organisation with a copy of the annual safety report, within one calendar month of submission to the Regulatory Authorities.

d. If, during the course of the Clinical Trial, the Sponsor becomes aware of any information relating to the IMP which may impact the Clinical Trial, the Sponsor will notify the Participating Organisation promptly, or at least within seven calendar days of becoming aware of the information, and if requested to do by the Participating Organisation, will provide the Participating Organisation with a report detailing the information.

3.8. **Anti-Bribery & Corruption**

3.8.1. Each Party warrants and represents that:

a. It has not committed any offence under the Bribery Act 2010 or any of the following acts ("***Prohibited Acts***"):

(i) other than in accordance with the provisions of this Agreement, offered, given or agreed to give any officer or employee of the other Party any gift or consideration of any kind, as an inducement or reward for doing or not doing or for having done or not having done

any act in relation to the obtaining or performance of this or any other agreement with the other Party or for showing or not showing favour or disfavour to any person in relation to this or any other agreement with the other Party; or

(ii) in connection with this Agreement, paid or agreed to pay any commission other than a payment in accordance with this Agreement which has not otherwise been disclosed in writing to the other Party.

3.8.2. If either Party has committed or commits any of the Prohibited Acts or has or commits any offence under the Bribery Act 2010 in relation to this Agreement, the other Party shall be entitled to terminate this Agreement in accordance with Clause 14, in addition to any other remedy available, taking into consideration the potential effects of termination on the health of Clinical Trial Subjects.

4. OBLIGATIONS OF THE PARTIES AND THE PRINCIPAL INVESTIGATOR

4.1. 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.

4.2. The Sponsor shall be responsible for obtaining and maintaining Regulatory Authority approval as well as research ethics committee favourable opinion and any other approvals needed for the conduct of the Clinical Trial.

4.3. The Principal Investigator shall be responsible for:

4.3.1. ensuring that the informed consent form, approved by the Sponsor and the relevant research ethics committee, is signed by or on behalf of each Clinical Trial Subject before the first Clinical Trial related procedure starts for that Clinical Trial Subject;

4.3.2. making any necessary disclosures of financial interests and arrangements, as defined and requested by the Sponsor, provided that such disclosures may be made prior to the commencement of work activities associated with the Clinical Trial as well as subsequent to Site Trial Completion.

4.4. The Sponsor 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 will include a summary of the Protocol, the name of the Participating Organisation and the details of the Site where the Clinical Trial is being conducted. Subject to Clause 6 of this Agreement, in the event that the Sponsor intends to publish the name of the Principal Investigator on a publicly accessible clinical trial registry, the Sponsor shall be responsible for obtaining the written consent of the Principal Investigator for the use of the Principal Investigator's name (and any other personal information) in such a publication.

4.5. The Parties shall conduct the Clinical Trial in accordance with the terms of this Agreement and:

4.5.1. The Protocol;

4.5.2. any current marketing authorisation for the IMP or, as the case may be, the Clinical Trial Authorisation granted by the MHRA;

4.5.3. the terms and conditions of the favourable opinion of the research ethics committee.

4.6. Until the Sponsor has obtained approval from the MHRA, the research ethics committee and any other necessary approvals, it shall not supply the IMP to the Participating Organisation. The Participating Organisation shall ensure that neither administration of the IMP 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.

4.7. In the event of any substantial amendments (relating to any of the matters referred to in the definition of "*Substantial Amendment to the Clinical Trial Authorisation*," in Regulation 11 of the Medicines for Human Use (Clinical Trial) Regulations 2004) being made to the Protocol, the amendments shall be signed by the Principal Investigator and shall be implemented by the Personnel as required by the Sponsor. The Sponsor shall initiate simultaneously the change control procedures set out in Clause 16.3 of this Agreement.

4.8. The Sponsor shall make the Protocol available to the Principal Investigator and provide evidence of the grant of the approvals set out in Clause 4.5 and the Principal Investigator shall include such documents in the Site File. The Sponsor shall ensure that any and all safety and/or toxicology data relating to the IMP, which the Sponsor is aware of or which comes to the attention of the Sponsor from time to time, and which may, in the reasonable opinion of the Sponsor, be materially relevant to the conduct of the Clinical Trial, will also be provided to the Principal Investigator for inclusion in the Site File.

4.9. The Participating Organisation shall not and will ensure that the Principal Investigator shall not permit the IMP to be used for any purpose other than the conduct of the Clinical Trial. Upon termination or expiration of this Agreement all unused IMP shall, at the Sponsor's option, either be returned to the Sponsor, or disposed of in accordance with the Protocol or the Sponsor's reasonable written instructions.

4.10. 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 trial which might hinder the Participating Organisation's or Principal Investigator's ability to enroll and study the required cohort of Clinical Trial Subjects.

4.11. The Participating Organisation shall use its best endeavours to ensure that the Principal Investigator enrols **[INSERT NUMBER]** Clinical Trial Subjects, to participate in the Clinical Trial and the Parties shall conduct the Clinical Trial in accordance with the Timelines.

4.12. In the event that the Clinical Trial is part of a Multi-Centre Trial, the Sponsor may amend the number of Clinical Trial Subjects to be enrolled pursuant to the Protocol as follows:

4.12.1. If in the reasonable opinion of the Sponsor, enrollment 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 the Sponsor's request to increase the enrollment rate, the Participating Organisation is unable to comply, the Sponsor may by notice to the Participating Organisation, require the Participating Organisation to cease enrolment of Clinical Trial Subjects.

4.12.2. 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.

4.12.3. If enrolment of Clinical Trial Subjects is proceeding at a rate above that which is required to meet the Timelines, the Sponsor 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.

4.13. **Access, Research Misconduct and Regulatory Authorities**

4.13.1. The Participating Organisation represents that neither it nor, to the best of its knowledge, 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 expiration, the Participating Organisation and the Principal Investigator will notify the Sponsor 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.

4.13.2. The Participating Organisation represents that it and, to the best of its knowledge, 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. The Participating Organisation will promptly notify the Sponsor 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.

4.13.3. Each Party shall inform the other 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 shall inform the relevant Regulatory Authority of such serious breach in writing within seven (7) days of becoming aware of that breach. The Sponsor shall, at its discretion, inform other 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 4.13, a "serious breach" is a breach that is likely to affect, to a significant degree:

a. the safety or physical or mental integrity of the Clinical Trial Subjects; or

b. the scientific value of the Clinical Trial.

4.13.4. 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 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 & Guidance. The Sponsor will alert the Participating Organisation, promptly in accordance with Clause 18.3, of significant issues (in the opinion of the Sponsor) relating to the conduct of the Clinical Trial.

4.13.5. In the event that the Sponsor 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 into any alleged research misconduct undertaken by or on behalf of the Sponsor. 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 shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Participating Organisation. The results of the investigation shall, subject to any obligations of confidentiality, be communicated to the Sponsor.

4.13.6. The Participating Organisation shall promptly inform the Sponsor 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 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 may have a representative 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 both Parties shall cooperate with any such inspection or written enquiry.

4.13.7. The Participating Organisation will permit the Sponsor 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 shall have the right to audit Clinical Trial records during and subsequent to the Clinical Trial.

4.13.8. [**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 or, in the case of point of care analysis, by methodology and using equipment, that is acceptable to, or provided by, the Sponsor. The Participating Organisation shall ensure that analysis of Material is undertaken in accordance with the Protocol and any other document agreed between the Sponsor and the Participating Organisation.

4.13.9. **[DELETE IF NOT APPLICABLE]** Where the Sponsor undertakes the analysis of Material and/or has contracted with a third party laboratory ("***Central Laboratory***") to undertake the analysis of Material, the Sponsor shall comply,

and shall ensure the Central Laboratory shall comply, with the terms of Appendix 6 herein that are expressed to be the responsibility of the Sponsor.

4.13.10. Upon Site Trial Completion (whether prematurely or otherwise), the Principal Investigator shall co-operate with the Sponsor in producing a report of the Clinical Trial detailing the methodology, Results and containing an analysis of the Results and drawing appropriate conclusions.

4.13.11. 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 not destroy any records without Sponsor's prior written approval, such approval not to be unreasonably withheld of delayed.

a. The Sponsor 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. 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 and the Participating Organisation does not incur any costs, no amounts will be payable to the Participating Organisation.

4.14. **[DELETE IF NOT APPLICABLE] Equipment & Resources**. The Parties agree that the Sponsor shall arrange for the provision of the equipment and resources to the Participating Organisation, pursuant to the terms set out in Appendix 7.

5. LIABILITIES & INDEMNITIES

5.1. 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, Agents and employees in accordance with the terms of the indemnity set out in Appendix 3 hereto.

5.2. 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 negligence of that Party or its Agents or employees or to restrict or exclude any other liability of either Party which cannot be so restricted or excluded in law.

5.3. In no circumstances shall either Party be liable to the other 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.

5.4. Subject to Clauses 5.2 and 5.5 the Participating Organisation's liability to the Sponsor 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 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.

5.5. In respect of any willful 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 arising out of or in connection with the breach shall not exceed two times the value of the Agreement.

5.6. 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**]. In respect of any one occurrence or series of occurrences arising from one event.

5.6.1. 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 terms of insurance or the amount of cover shall not relieve the Sponsor of any liabilities under this Agreement.

5.7. Nothing in this Agreement will operate to limit or exclude any liability for fraud.

6. DATA PROTECTION

6.1. The Parties agree to:

6.1.1. adhere to the principles of medical confidentiality in relation to Clinical Trial Subjects involved in the Clinical Trial; and

6.1.2. comply with all Data Protection Laws & Guidance in processing the personal data and sensitive personal data (as defined in Data Protection Laws & Guidance) of Clinical Trial Subjects.

6.2. Subject to arrangements set out in the consent form signed by each Clinical Trial Subject, personal data and sensitive personal data (both as defined in the Data Protection Laws and Guidance) shall not be disclosed to the Sponsor save where this is permitted by Data Protection Laws & Guidance and necessary to satisfy the requirements of the Protocol or in relation to a claim or proceeding brought by a Clinical Trial Subject in connection with the Clinical Trial.

6.3. The Sponsor shall not disclose personal data or sensitive personal data (as defined in Data Protection Laws & Guidance) to third parties without the prior written consent of the Clinical Trial Subject or as otherwise permitted by Data Protection Laws & Guidance and in accordance with the NHS Confidentiality Code of Practice (November 2003), the Confidentiality Code of Practice for Health and Social Care in Wales (August 2005) or the NHS Scotland Code of Practice on Protecting Patient Confidentiality (August 2003) as applicable.

6.4. The Parties agree that the Sponsor shall be responsible for collecting consent from the Principal Investigator, all Sub-Investigators and all Personnel (as applicable) to the processing of their personal data by the Sponsor. For the avoidance of doubt, all processing of the personal data of the Principal Investigator, all Sub-Investigators and all Personnel shall at all times be in accordance with the Data Protection Laws & Guidance. The Participating Organisation agrees to provide reasonable assistance to the Sponsor in this regard. In the event that the Principal Investigator, any Sub-

Investigator or any member of Personnel refuses to provide such consent, the Parties agree that he/she will not engage in Clinical Trial duties.

7. FREEDOM OF INFORMATION

7.1. The Sponsor acknowledges that the Participating Organisation is subject to the FOIA and associated guidance and codes of practice.

7.2. If the Participating Organisation or its Agent(s) receive a request under the FOIA to disclose information that belongs to the Sponsor or its Affiliates, it will notify the Sponsor as soon as is reasonably practicable, and in any event, not later than five (5) working days after receiving the request. The Participating Organisation will consult with the Sponsor in accordance with all applicable guidance.

7.3. The Sponsor acknowledges 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.

7.3.1. The Sponsor shall cooperate with the Participating Organisation and shall use its reasonable endeavours to respond within ten (10) working days of the Participating Organisation's reasonable request for assistance.

7.4. Where the Participating Organisation determines that it will disclose information, notwithstanding any objections from the Sponsor, it will notify the Sponsor in writing, giving at least two (2) working days' notice of its intended disclosure.

8. CONFIDENTIAL INFORMATION.

8.1. The Participating Organisation and the Sponsor shall ensure that only those of its officers, Agents and employees (and in the case of the Sponsor, those of its Affiliates) directly concerned with the carrying out of this Agreement, have access to the Confidential Information of the other Party. Each Party undertakes to treat as strictly confidential and not to disclose to any third party any Confidential Information of the other Party, save where disclosure is required by a Regulatory Authority or by law (including any disclosure required to ensure compliance by the Participating Organisation, with the FOIA in accordance with Clause 7 of this Agreement). The Party required to make the disclosure shall inform the other within a reasonable time prior to being required to make the disclosure (and, where appropriate in accordance with Clause 7) of the requirement to disclose and the information required to be disclosed. Each Party undertakes not to make use of any Confidential Information of the other Party other than in accordance with this Agreement, without the prior written consent of the other Party.

8.2. The obligations of confidentiality set out in this Agreement, shall not apply to information which is:

8.2.1. published or becomes generally available to the public other than as a result of a breach of this Agreement by the receiving Party;

8.2.2. 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;

8.2.3. independently developed by the receiving Party, as evidenced by contemporaneous written evidence and is not subject to a duty of confidentiality;

8.2.4. obtained by the receiving Party from a third party which is not subject to a duty of confidentiality.

8.3. In the event of a Party visiting the establishment of the other Party, the visiting Party undertakes that any further Confidential Information which 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.

8.4. This Clause shall remain in force for a period of ten (10) years after the termination or expiration of this Agreement.

9. PUBLICITY.

9.1. Subject to Clauses 4.4, 10.5 and 12.3, the Sponsor will not 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.

9.2. The Participating Organisation will not and will ensure that the Principal Investigator and the Personnel do not use the name of the Sponsor, the Sponsor's employees, nor the name of the Clinical Trial, nor the IMP in any publicity, advertising or news release without the prior written approval of the Sponsor, such approval not to be unreasonably withheld. The provisions of this Clause 9.2 shall also apply to the Participating Organisaton's use of the name, trademark, servicemark, and/or logo of any third parties collaborating with the Sponsor on the Clinical Trial and/or the IMP ("***Sponsor Collaborators***") provided that the Participating Organisation has been notified of the identity of the Sponsor Collaborators.

9.3. 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, not to be unreasonably withheld, and the delivery of research ethics committee approval, where applicable.

10. PUBLICATIONS

10.1. 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.

10.1.1. 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.

10.1.2. 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.

10.1.3. 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.

10.2. 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.

10.2.1. 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.

10.3. 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.

10.4. 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 for 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.

10.4.1. The Participating Organisation acknowledges that the Sponsor may present at symposia, national or regional professional meetings, publish 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.

10.5. The Participating Organisation/Principal Investigator will disclose the financial support of the Sponsor for the Clinical Trial in all publications and presentations.

10.6. In the event that the Sponsor coordinates a Multi-Centre publication, the participation of the Principal Investigator or Personnel, as named authors shall be determined in accordance with the Sponsor's policy and generally accepted standards for authorship. If the Principal Investigator or other Personnel are to be named as authors of the Multi-Centre publication, such person 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.

10.7. 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 Sponsor to take steps to protect its proprietary information and/or Intellectual Property Rights and Know-How and the Participating Organisation shall not unreasonably withhold 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, the Sponsor's proprietary information and/or Intellectual Property Rights and Know-How might otherwise be compromised or lost.

11. INTELLECTUAL PROPERTY

11.1. All Intellectual Property Rights and Know-How owned by or licensed to the Sponsor prior to and after the date of this Agreement other than any Intellectual Property Rights and Know-How arising from the Clinical Trial are and shall remain the property of the Sponsor.

11.2. 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.

11.3. All Intellectual Property Rights and Know-How arising from and relating to the Clinical Trial, the IMP (including but not limited to its formulation and use alone or in combination with other drugs), and 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 11.4 and 11.5 of this Agreement.

11.4. In accordance with Clause 11.3, the Participating Organisation hereby assigns, and shall procure that the Principal Investigator assigns, its rights in relation to all Intellectual Property Rights and Know-How, falling within Clause 11.3, to the Sponsor or its nominee. At the request and expense of the Sponsor, the Participating Organisation shall execute, and shall procure that the Principal Investigator executes, all such documents and does 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.

11.5. The Participating Organisation shall and will ensure that the Principal Investigator shall promptly disclose to the Sponsor any Know-How generated pursuant to this Agreement and falling within Clause 11.3 and undertakes not to use or disclose such Know-How other than for the purposes of this Agreement.

11.6. Nothing in this Clause 11 shall be construed so as to prevent or hinder the Participating Organisation from using Know-How gained during the performance of the Clinical Trial in the furtherance of its normal activities, to the extent that such use does not result in the disclosure or misuse of Confidential Information or the infringement of any Intellectual Property Right or Know How of the Sponsor. The Sponsor shall have the right to use the Know-How gained during the performance of the Clinical Trial in the furtherance of its development of the IMP.

12. FINANCIAL ARRANGEMENTS

12.1. 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 on presentation of a VAT invoice to the Sponsor by the Participating Organisation.

12.2. 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.

12.3. 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.

12.4. The Sponsor will notify the Participating Organisation of Site Trial Completion in order to trigger the generation of a final invoice for that specific Site.

12.5. The Sponsor 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.

12.6. **Longstop Date** – It is agreed that the Sponsor shall not be required to make payment for any amounts which the Participating Organisation fails to notify the Sponsor of within sixty days (60) of the Sponsor 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 the Sponsor to pay invoices dated after the Longstop Date.

12.7. The Sponsor will make payment to the Participating Organisation of invoices within forty-five (45) days of the date of receipt of invoices.

12.8. Any delay in the payment of the payee invoices by the Sponsor will incur an interest charge on any undisputed amounts overdue of two (2) per cent per month above the National Westminster Bank plc base rate prevailing on the date the payment is due.

13. TERM

13.1. 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.

14. TERMINATION

14.1. Either the Sponsor or the Participating Organisation (the "***Terminating Party***") may terminate this Agreement with immediate effect at any time if the other Party or the Principal Investigator (the "***Defaulting Party***") is:

14.1.1. 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;

14.1.2. where, the Participating Organisation is constituted in England and is 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 or, in the case of the Participating Organisation, if it is a Foundation Trust authorised pursuant to the National Health Service Act (2006) and following such authorisation any step or proceedings is taken against the Participating Organisation by the Independent Regulator under Sections 52-55 of that Act; or if not and the Secretary of State makes an order under the National Health Service Act (2006) in respect of the Participating Organisation transferring its liabilities to one of the bodies referred to

in Section 70 of that Act or, where the Participating Organisation is constituted in Wales and is declared insolvent or has an administrator or receiver appointed over all or any part of its assets or, ceases tor threatens to cease to carry on its business or in the case of the Participating Organisation, the Welsh Ministers make an order under Sections 26 to 28 or 29 of the National Health Service (Wales) Act 2006 or where the Participating Organisation is constituted in Scotland and is declared insolvent of 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 or, in the case of the Participating Organisation, if the Scottish Ministers make an order under the National Health Service (Residual Liabilities) Act 1996 in respect of the Board transferring its property rights and liabilities to one of the bodies referred to in Section 2(2) of that Act or, where the Participating Organisation is constituted in Northern Ireland, is 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 or, in the case of the Participating Organisation if it is a Health and Social Care Trust as defined in the Health and Social Care (Reform) Act (Northern Ireland) 2009, the Department makes an Order under Part iv of Schedule 3 of the Health and Personal Social Services (Northern Ireland) Order 1991, in respect of the Participating Organisation; or if not and the Department makes an Order under the Health and Social Care (Reform) Act (Northern Ireland) 2009 in respect of the Participating Organisation transferring its property rights and liabilities to one of the bodies referred to in Section 1 (5) of that Act.

14.2. A Party may terminate this Agreement on notice to the other Party 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.

14.3. The Sponsor 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 Participating Organisation and the Sponsor can be found. In the event that a Sub-Investigator is no longer able (for whatever reason) to act as a Sub-Investigator and no suitable replacement Sub-Investigator acceptable to the Participating Organisation and Sponsor can be found, the Sponsor may terminate this Agreement on notice to the Participating Organisation.

14.4. 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.

14.5. In the event of early termination of this Agreement by the Sponsor, pursuant to Clauses 14.1, 14.2, 14.3 or 14.4 and subject to an obligation on the Participating Organisation and the Principal Investigator to mitigate any loss, the Sponsor shall pay all costs incurred and falling due for payment up to the date of termination, and also all non-cancellable expenditure falling due for payment after the date of termination which 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 Sponsor.

14.6. In the event of early termination, if payment (whether for salaries or otherwise) has been made by the Sponsor to the Participating Organisation in advance for work not completed, such monies shall be applied to termination related costs 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.

14.7. At Site Trial Completion, the Participating Organisation shall promptly deliver, and shall ensure that the Principal Investigator delivers, to the Sponsor all Confidential Information and any other unused materials provided to the Participating Organisation and/or the Principal Investigator pursuant to this Agreement.

14.8. Termination of this Agreement will be without prejudice to the accrued rights and liabilities of the Parties under this Agreement.

15. RELATIONSHIP OF THE PARTIES

15.1. Neither Party may assign its rights under this Agreement or any part thereof without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed. Neither Party may sub-contract the performance of all or any of its obligations under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed. Any Party who so sub-contracts shall be responsible for pass-through of payments to its subcontractors and for the acts and omissions of its sub-contractors as though they were its own.

15.2. Nothing in this Agreement shall be construed as creating a joint venture, partnership, contract of employment or relationship of principal and agent between the Parties.

16. AGREEMENT & MODIFICATION

16.1. **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 and 11 of this Agreement.

16.2. 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.

16.3. Any amendment to the Protocol ("***Protocol Amendment***") shall be managed by means of the change control procedure set out in this Clause.

16.3.1. For the purposes of this Agreement, a "change request" is a request to change the obligations of the Parties arising from a Protocol Amendment;

16.3.2. Where the Sponsor originates a change request, the Participating Organisation shall provide the Sponsor, within thirty-five (35) days of receiving the change request, details of the impact which the proposed Protocol Amendment will have upon the costs of carrying out the Clinical Trial and the other terms of this Agreement.

16.3.3. A change request shall become a "change order" when the requirements of the change control procedure have been satisfied and any necessary change to this Agreement is signed by the authorised representatives of the Parties.

16.3.4. An amended financial appendix shall be signed and appended to this Agreement according to Clause 12.2 above.

16.4. This Agreement contains the entire understanding between the Parties and supersedes all other agreements, negotiations, representations and undertakings,

whether written or oral, of prior date between the Parties relating to the Clinical Trial, which is the subject of this Agreement.

17. FORCE MAJEURE

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

18. NOTICES

18.1. Any notice required to be given by either 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 email to the contact persons listed below or such other person as one Party may inform the other Party in writing from time to time.

18.1.1. A notice shall be treated as having been received:

a. 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

b. if sent by first class recorded delivery mail on a normal business day, at 9am on the second business day subsequent to the day of posting or, if the notice was not posted on a business day, at 9am 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 9am on the third business day subsequent to the day of posting; or

c. if sent by email, 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 email has been received.

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18.2. Notices to the Sponsor shall be addressed to:

[INSERT CONTACT NAME & ADDRESS – INCLUDE EMAIL ADDRESS]

18.3. Notices to the Participating Organisation shall be addressed to:

[INSERT CONTACT NAME & ADDRESS – INCLUDE EMAIL ADDRESS]

19. DISPUTE RESOLUTION

19.1. In the event of a dispute arising under this Agreement, authorised representatives of the Parties will discuss and meet as appropriate to try to resolve the dispute within seven (7) days of being requested in writing by either Party to do so. If the dispute remains unresolved, it will then be referred to a senior manager from each of the Parties who will use all reasonable endeavours to resolve the dispute within a further fourteen (14) days.

19.2. 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, either Party shall give notice in writing ("***ADR Notice***") to the other Party 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, either 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, either 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, either Party will give notice in writing to the other Party 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, either Party shall be entitled to submit to the exclusive jurisdiction of the courts of Northern Ireland.

19.3. Nothing in this Agreement shall prevent either Party from seeking an interim injunction (if the Participating Organisation is constituted in England or Wales or Northern

Ireland) or interdict (if the Participating Organisaiton 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 either of the Parties is entitled to an interim injunction or interdict as applicable.

20. MISCELLANEOUS

20.1. **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 ("***Third Party Rights Act***") or any broadly equivalent Scottish legislation where the Participating Organisation is constituted in Scotland. Any right or remedy of a third party that existed or is available apart from the Third Party Right 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.

20.2. **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.

20.3. **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 4.12	Access, Research Misconduct and Regulatory Authorities
Clause 5	Liabilities & 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 & Modification
Clause 17	Force Majeure
Clause 18	Notices
Clause 19	Dispute Resolution
Clause 20	Miscellaneous

20.4. **Governing Law & 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.

20.5. **Counterparts & 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 the other 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 PARTICIPATING ORGANISATION]** Signature: Title: Date

APPENDICES

Appendix 1 –Timelines & Responsibilities of the Parties

The milestones and division of responsibility set out below are provided as examples only. The milestones for each Clinical Trial are to be agreed between the Sponsor and the 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	Participating Organisation responsibility	Target Date for Completion at Site.
Site initiation visit	X	X	
First Clinical Trial Subject enrolled		X	
Last Clinical Trial Subject enrolled		X	
All Case Report Form queries submitted	X		
All Case Report Form queries completed		X	

Appendix 2 – ABPI Clinical Trial Compensation Guidelines 2015

Clinical Trial Compensation Guidelines

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 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:

    1.1. 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.

    1.2. 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.

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

   "The company sponsoring the study confirms that:

i. 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.

ii. 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.)

iii. 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.

iv. 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 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

1.1. Notwithstanding the absence of legal commitment, the company should pay compensation to patient-volunteers suffering bodily injury (including death) in accordance with these Guidelines.

1.2. 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.

1.3. 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.

1.4. 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.

1.5. 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.

1.6. 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.

1.7. 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

2.1. 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.

2.2. 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.'

2.3. 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.

2.4. These Guidelines do nor 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

3.1. 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.

3.2. 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.

3.3. No compensation should be paid to patients receiving placebo in consideration of its failure to provide a therapeutic benefit.

3.4. No compensation should be paid (or it should be abated as the case may be) to the extent that the injury has arisen:

3.4.1. through a significant departure from the agreed protocol;

3.4.2. through the wrongful act or default of a third party, including a doctor's failure to deal adequately with an adverse reaction;

3.4.3. through contributory negligence by the patient.

4. Assessment of Compensation

4.1. 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.

4.2. 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):

4.2.1. the seriousness of the disease being treated, the degree of probability that adverse reactions will occur and any warnings given;

4.2.2. 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.

4.3. 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.

5. Miscellaneous

5.1. 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.

5.2. 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.

5.3. 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.

5.4. 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.

5.5. 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

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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):

    1.1. 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;

    1.2. 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:

    2.1. 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;

    2.2. 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;

    2.3. 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;

    2.4. 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 dependents) 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 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 which 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 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 to the Sponsor this Appendix 6 shall apply.

1. In accordance with the Protocol, the Participating Organisation shall send Material to the Sponsor or, in accordance with Section 7 below, to a third party nominated by the Sponsor.

2. The Participating Organisation warrants that all Material has been collected with appropriate informed consent and has been collected and handled in accordance with applicable law (including, without limitation, the Human Tissue Act 2004) and as required by the Protocol.

3. Subject to Section 2 above, the Material is supplied without any warranty, expressed or implied, including as to its properties, merchantable quality, fitness for any particular purpose, or freedom from infection.

4. The Sponsor shall ensure, or procure through an agreement with the Sponsor's nominee as stated in item 1 above that:

   4.1. the Material is used in accordance with, the consent of the Clinical Trial Subject, and the approval of all Regulatory Authorities for the Clinical Trial and the Protocol;

   4.2. the Material is handled and stored in accordance with applicable law;

   4.3. the Material shall not be redistributed or released to any person other than in accordance with the Protocol or for the purpose of undertaking other research approved by an appropriate ethics committee and in accordance with the Clinical Trial Subject's consent; and

   4.4. no alteration shall be made to the title, coding or acronym of the Material.

5. The Parties shall comply with all relevant laws, regulations and codes of practice governing the Clinical Trial use of human biological material.

6. The Participating Organisation and the Sponsor shall each be responsible for keeping a record of the Material that has been transferred according to this Appendix 6.

7. To the extent permitted by law the Participating Organisation and its Personnel shall not be liable for any consequences of the supply to or the use by the Sponsor of the Material or of the supply to or the use by any third party to whom the Sponsor subsequently provides the Material or the Sponsor's nominee as stated in Section 1 above, save to the extent that any liability which arises is a result of the negligence, wrongful acts or omissions or breach of statutory duty of the Participating Organisation or its Personnel or their failure to comply with the terms of this Agreement. .

8. The Sponsor undertakes that, in the event that Material is provided to a third party in accordance with Section 1 above, it shall require that such third party shall undertake to handle any Material related to the Clinical Trial in accordance with all applicable statutory requirements and codes of practice and under terms no less onerous than those set out in this Appendix 6.

9. Unless otherwise agreed, any surplus Material that is not returned to the Participating Organisation or retained for future research shall be destroyed in accordance with the Human Tissue Act 2004.

Appendix 7 – Equipment & Resources

[DELETE IF NOT APPLICABLE]

1. Sponsor Provided Equipment

1.1. Sponsor will provide the CE Marked equipment identified below ("*Sponsor Equipment*") for use by the Participating Organisation in the conduct or reporting of the Clinical Trial:

#	Equipment	Estimated Original Value	Depreciation
1			
2			
3			
4			
5			
6			

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

2. Sponsor Provided Resources

2.1. Sponsor will provide the Sponsor owned or licensed proprietary resources identified below ("*Sponsor Resources*") for use by the Participating Organisation in the conduct or reporting of the Clinical Trial.

2.2. Sponsor Resources Supplied: _____

3. Permitted Uses of Sponsor Equipment and Sponsor Resources

3.1. The Participating Organisation may use Sponsor Equipment and Sponsor Resources only for the purpose of this Clinical Trial.

[Alternatively, specify permitted uses. If use for non-Clinical Trial Subjects is permitted for Equipment, specify that (1) a charge will be assessed (deducted from Clinical Trial funding) based on estimated or actual usage or (2) The 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.]

4. Disposition of Sponsor Equipment and Sponsor Resources

4.1. Alternative #1 – Return to Sponsor

After completion of the Trial at the Site, or at an earlier time specified by Sponsor the Sponsor will contact the Participating Organisation to make arrangements for return of any [Sponsor Equipment] [and] [Sponsor Resources], at Sponsor's expense, to the Sponsor or a location designated by Sponsor. The Participating Organisation's

responsibilities under this Agreement for the [Sponsor Equipment] [and] [Sponsor Resources] will cease or transfer to the Sponsor at the time of removal from the 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 the Sponsor will contact the Participating Organisation to make arrangements for return of any [Sponsor Equipment] [and] [Sponsor Resources], at Sponsor's expense, to the Sponsor or a location designated by Sponsor. The Participating Organisation's responsibilities under this Agreement for the [Sponsor Equipment] [and] [Sponsor Resources] will cease or transfer to the Sponsor at the time of removal from the 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 Equipment at the termination of this Agreement. The Sponsor will transfer title or arrange for transfer of title in Sponsor 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 lesser number of Clinical Trial Subjects agreeable to the Sponsor), has complied with the terms of the Agreement and has satisfactorily completed all Protocol requirements. The Sponsor will ensure that this transfer is documented in writing and the parties hereby acknowledge and agree that the estimated depreciated value of Sponsor Equipment at termination of this Agreement is part of the total compensation payable for Clinical Trial conduct.

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

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

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

After completion of the Trial at the Site, Sponsor will make Sponsor 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 will ensure that any transfer of ownership is documented in writing.

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

5. Vendor-Provided Equipment or Resources

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

#	Equipment	Estimated Original Value	Depreciation
1			
2			
3			
4			
5			
6			

5.2. **Permitted Uses of Vendor Property** The Participating Organisation will use Vendor Property only for purposes of this Clinical Trial.

[Alternatively, specify permitted uses.]

6. Disposition of Vendor Property

6.1. The Vendor will determine the disposition of Vendor Property after completion of the Trial at the Site.

7. Ownership, Responsibilities, and Liability

7.1. **Ownership**. Sponsor Equipment and Sponsor Resources and Vendor Property are and remain for the duration of the Clinical Trial at the Participating Organisation, the property of Sponsor, the Vendor or the licensor, as the case may be.

7.2. **Liability – Equipment & Resources Only.**

Alternative #1 – indemnity provided by this Appendix 7

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

a. such damages were caused by the willful misconduct, negligent acts or omissions of Sponsor or the Vendor; or

b. a personal injury to a Clinical Trial Subject is one covered by the indemnity detailed in Appendix 3 of this Agreement.

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

Subject to clauses 5.4 of the Agreement, the Participating Organisation shall be liable for any damage, loss or destruction of the [Sponsor Equipment], [Sponsor Resources] or [Vendor Property] and for any losses attributable to the [Sponsor Equipment], [Sponsor Material] [or] [Vendor Property] caused by the 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 Equipment], [Sponsor Material] or [Vendor Property].

Alternative #2 – Equipment is supplied under an MIA

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

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