CLINICAL TRIAL AGREEMENT FOR PHARMACEUTICAL AND BIOPHARMACEUTICAL INDUSTRY SPONSORED RESEARCH IN NHS HOSPITALS IN ENGLAND

**[Full Title – Clinical Trial]**

**[Sponsor’s Protocol Reference Number]**

This agreement is effective from the last date of the final signature

**is between**

**[…. insert name….]NHS [FOUNDATION] TRUST, of [.…insert address….]**

**(Hereinafter known as the “Trust”)**

**AND**

**[….insert name*….*], of [….insert address….]**

**(Hereinafter known as the “Sponsor / Affiliate”)**

**NOW**

**WHEREAS** the Sponsor of the Trial for the above Protocol is [… insert Sponsor name and address…] (hereinafter known as the “Sponsor”). The Sponsor of the Trial has an intra-company agreement concerning clinical trial matters whereby it authorises its UK affiliate company [… insert Affiliate name…] to undertake certain activities regarding execution of clinical trials.

**WHEREAS** (… insert Affiliate name…) is an affiliate of The Sponsor (… insert Sponsor…), (insert Affiliate name) is referred to in this Agreement as the Affiliate. Where the term Affiliate is used it may refer to regulatory obligations that will be fulfilled by (… insert Sponsor name…)

**WHEREAS** the Sponsor / Affiliate is a pharmaceutical company involved in the research, development, manufacture and sale of medicines for use in humans

**WHEREAS** the Sponsor / Affiliate is developing new treatments and therapies in the field of [….insert field….]

**WHEREAS** theTrust is concerned with the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare

**WHEREAS** the Trust has a particular interest and expertise in [….insert area of expertise….]

**WHEREAS** the Trust has particular sites for undertaking the Trial at [… insert name(s) of hospitals to be involved in the trial] “the Trial Site(s)”

**WHEREAS** theSponsor / Affiliate wishes to contract with the Trustto undertake a clinical trial entitled:

 “ …… insert title and EUDRACT number or Unique Identifier number…… ”

It is agreed that theTrust and Sponsor / Affiliateshall participate in the aforementioned clinical trial in accordance with this Agreement.

# DEFINITIONS

## The following words and phrases have the following meanings:

“Affiliate” means any business entity that is the legal representative of the sponsor for this Trial, being established in the EU and which controls, is controlled by, or is under the common control with the Sponsor including any nominated / Affiliate. For the purposes of this definition, a business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity.

“Agent(s)” shall include, but shall not be limited to, any person (including the Investigator, any nurse or other health professional), any such person’s principal employer in the event it is not the Trust and where such person is providing services to the Trust 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.

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

“Chief Investigator” means the person who takes responsibility for the Clinical Trial in the UK.

“Clinical Trial” means the investigation to be conducted at the Trial Sitein accordance with the Protocol numbered […insert identification number…].

“Clinical Trial Authorisation” means a clinical trial authorised in accordance with Part 3 of the Medicines for Human Use (Clinical Trials) Regulations 2004.

“Clinical Trial Subject” means a person recruited to participate in the Clinical Trial.

“Confidential Information”means any and all information, data and material of any nature belonging to the Trust or to the Sponsor and/or its Affiliates which either Party may receive or obtain in connection with this Agreement which is Personal Data or Sensitive Personal Data (as both terms are defined in the Data Protection Act 1998, ("the 1998 Act")) which relates to any patient of the Trust or his or her treatment or medical history, or other information, the release of which is likely to prejudice the commercial interests of the Trust or the Sponsor respectively, or which is a trade secret, including know how

“DSUR” means the Development Safety Update Report.

“Exploratory Clinical Trial” means a Clinical Trial designed to generate, rather than test, hypotheses, as set out in the ICH Harmonised Tripartite Guideline E9: Statistical Principles for Clinical Trials 1998.

“Good Manufacturing Practice” or “GMP” means any relevant current European Union and appropriate national regulations on good manufacturing practices.

“GPP” means any relevant current European Union and appropriate national regulations on good pharmacovigilance practices.

“HRA Approval” means the approval required before research may commence in the NHS in England. It comprises a review by a Research Ethics Committee as well as an assessment of regulatory compliance and related matters undertaken by dedicated HRA staff.

“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 States Food and Drug Administration exempts pharmaceutical companies from the Federal statute that prohibits an unapproved drug from being shipped in interstate commerce.

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

“Intellectual Property Rights” means patents, trade marks, 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 the 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.

“Investigator” means the person who will take primary responsibility for the conduct of the Clinical Trial at the Trial Site on behalf of the Trust or any other person as may be agreed from time to time between the Parties as a replacement.

“IRAS” means the Integrated Research Application System that is the single system for applying for permissions and approvals for health and social care / community care research in the UK

“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 (IFPMA) in November 2009.

“Know How” means all technical and other information which is not in the public domain (other than as a result of a breach of confidence), including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, 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.

“Licensing Authority” means the licensing authority within the meaning of section 6 of the Medicines Act 1968 (c.67).

“Material” means any clinical biological sample, or portion thereof, derived from Participants including information related to such material supplied by The Trust to the Sponsor or its nominee under appendix 6

“Party” means the Sponsor / Affiliate, or the Trust and “Parties” shall mean both of them.

“Protocol” means the full description of the Clinical Trial governed by this Agreement which is hereby incorporated into this Agreement and all amendments thereto as the Parties may from time to time agree in accordance with clauses 4.7, 10.2 and 14.2 and which have also been signed by the Investigator. Such amendments will be signed by the Parties and form a part of this Agreement.

“Regulatory Authority” includes, but is not limited to, the Medicines and Healthcare products Regulatory Agency, the U.S. Food and Drug Administration, the European Medicines Agency and the General Medical Council.

“Results” means the research findings produced in the Clinical Trial as published by the Sponsor

“R&D Office” means the Trust department responsible for the administration of this Clinical Trial on behalf of the Trust.

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

“Sub-investigator” means any individual member of a clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial related decisions (e.g. associates, residents, research fellows).

“Trial Monitor” means one or more persons appointed by the Sponsor / Affiliate to monitor compliance of the Clinical Trial with ICH GCP and to conduct source data verification.

“Trial Site(s)” means any premises approved by the Trust in which the Clinical Trial will be conducted.

“Trial Site Personnel” means the persons who will undertake the conduct of the Clinical Trial at the Trial Site on behalf of the NHS Trust under the supervision of the Investigator.

## Any reference to a statutory provision, code or guidance shall be deemed to include reference to any subsequent modification or re-enactment of it.

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

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

# INVESTIGATOR AND TRIAL SITE PERSONNEL

## The Trustrepresents that it is entitled to procure and the Trustwill procure the services of […insert name of Investigator…] to act as Investigator and shall ensure the performance of the obligations of the Investigator set out in Appendix 5 and elsewhere in this Agreement. Where the Trust is not the Investigator’s principal employer, it will notify the principal employer in a timely way of his proposed involvement in the Clinical Trial. Any financial or other arrangements relating to the Investigator’s involvement in the Clinical Trial will be agreed directly between the Trust and the principal employer.

## The Trustrepresents that the Investigator holds the necessary registration and has the necessary expertise, time and resources to perform the Clinical Trial and will ensure that the Investigator is made aware of and acknowledges the obligations applicable to the Investigator set out in Appendix 5 and elsewhere in this Agreement.

## The Trustshall notify the Sponsor / Affiliate if the Investigator ceases to be employed by or associated with the Trust or is otherwise unavailable to continue as Investigator, and shall use all reasonable endeavours to find a replacement acceptable to both the Sponsor / Affiliate and the Trust, subject to the Trust’s overriding obligations in relation to Clinical Trial Subjects and individual patient care. If no mutually acceptable replacement can be found the Sponsor / Affiliate may terminate this Agreement pursuant to clause 12.3 below.

## The Trust shall procure and shall ensure that the Investigator procures the performance of the obligations of the Trial Site Personnel as set out in this Agreement

## 2.5 Trial Site Personnel and/or Investigator shall attend any meetings regarding this Clinical Trial as reasonably requested by Sponsor / Affiliate ("**Investigator Meetings**"). Such meetings may be conducted by Sponsor / Affiliate to convey or exchange information with all investigators, or other Trial Site Personnel to support the effective conduct or close-out of this Clinical Trial. The Trust agrees that no additional compensation shall be due hereunder for Trial Site Personnel or any other Investigators respective participation in Investigator Meetings. Sponsor / Affiliate may reimburse or pay the Trust for reasonable pre-approved expenses incurred by Trial Site Personnel or Investigator for participating in Investigator Meetings upon receipt of documentation in form and detail sufficient for the Sponsor / Affiliate to recognise such expenses for Sponsor’s / Affiliate’s tax reporting purposes, provided that the Trust complies with Sponsor / Affiliate instructions and their applicable standards and policies related to travel and hospitality and other policies governing interactions with healthcare professionals.

# CLINICAL TRIAL GOVERNANCE

## The Sponsor / Affiliate shall inform the Trust and the 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 / Affiliate shall also provide the Investigator with an emergency telephone number to enable adverse event reporting at any time.

## The Parties shall comply with all relevant laws of the EU if directly applicable or of direct effect and all relevant laws and statutes of England and Wales including but not limited to, the Human Rights Act 1998, the Data Protection Act 1998, the Human Tissue Act 2004, the Medicines Act 1968, the Human Medicines Regulations 2012, the Medicines for Human Use (Clinical Trial) Regulations 2004, and with all relevant guidance relating to medicines and clinical trials from time to time in force including, but not limited to, ICH GCP, GMP, GPP,the World Medical Association Declaration of Helsinki entitled 'Ethical Principles for Medical Research Involving Human Subjects' (1996), the relevant NHS Research Governance Framework and the Medical Research Council Guidelines entitled “Human Tissue and Biological Samples for use in Research”. In addition, where the Clinical Trial is conducted as part of an IND, the Trust will comply with any other relevant requirements notified by the Sponsor / Affiliate to the Trust.

## The Sponsor / Affiliate shall comply with all guidelines from time to time in force and published by The Association of the British Pharmaceutical Industry in relation to clinical trials and in particular those entitled “Clinical Trial Compensation Guidelines 2015”) a copy of which is set out in Appendix 2.

## The Trust shall ensure that the Investigator, Sub-investigators and any new Sub-investigators subsequently joining the Trial, undertake any such appropriate training as the Sponsor / Affiliate consider necessary for the conduct of the Trial.

## Neither Party shall commit (and warrants that in entering into the Agreement it has not committed) any of the following acts:

### provide or offer to provide to, or request from, any person in the employment of or in the service of the other Party any gift or consideration not contemplated by the financial arrangements set out at clause 10 below in relation to the negotiation or performance of this Agreement or the Clinical Trial

### make payment or agree to make payment of any commission to any person in the employment of or in the service of the other Party in relation to this Agreement or the Clinical Trial.

## If either Party, any of its employees, Agents or sub-contractors, or any person acting on their behalf, commits any of the acts referred to in clause 3.5 above or if either Party or any of their employees, Agents or sub-contractors commits any offence under the Bribery Act 2010, in relation to this Agreement or the Clinical Trial, then the other Party shall be entitled, acting reasonably, in addition to any other remedy available, to terminate this Agreement with immediate effect, taking into consideration the potential effects of termination on the health of the Clinical Trial Subjects.

## In addition, the Trust represents, warrants and covenants, as of the effective date to and through the expiration or termination of this Agreement:

### that the Trust, and, to the best of its knowledge, the Trust’s owners, directors, officers, employees, or any agent, representative, subcontractor or other third Party acting for or on the Trust’s behalf (collectively "Representatives"), shall not, directly or indirectly, offer, pay, promise to pay, or authorise such offer, promise or payment, of anything of value, to any individual or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any applicable laws, rules and regulations concerning or relating to public or commercial bribery or corruption ("Anti-Corruption Law(s)"),

### that the Trust’s books, accounts, records and invoices related to this Agreement or related to any work conducted for or on behalf of Sponsor / Affiliate are and will be complete and accurate and

### that Sponsor / Affiliate may terminate this Agreement (a) if the Trust or its Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) if Sponsor / Affiliate has a good faith belief that the Trust or its Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws.

## Should there be any inconsistency between the Protocol and the other terms of this Agreement, or any other document incorporated therein, including the Sponsor / Affiliate’s Standard Operating Procedures, the terms of the Protocol shall prevail to the extent of such inconsistency except insofar as the inconsistency relates to clauses 5, 6, 8 and/or 9 of this Agreement.

# OBLIGATIONS OF THE PARTIES AND THE INVESTIGATOR

## The Chief Investigator, with the support of the Sponsor / Affiliate, shall be responsible for obtaining and maintaining all HRA Approvals, research ethics committee favourable opinions and approvals for amendments, for the conduct of the Clinical Trial and the Sponsor / Affiliate shall keep the Trust fully apprised of the progress of HRA Approval submissions and shall upon request provide the Trust with all correspondence relating to such submissions.

## The Sponsor / Affiliate 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 Trial Subject. The Trust agrees that such listing shall include a summary of the Protocol, the name of the Investigator at the Trial Site and the details of the institutions conducting the Clinical Trial.  Prior to commencement of the Clinical Trial, the Trust shall procure the written consent of the Investigator in respect of disclosure of his or her name in the publicly accessible registry on a worldwide basis.

## The Sponsor / Affiliate shall ensure that the results of the Clinical Trial will be 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 Investigational Medicinal Product is first approved and made commercially available in any country, or for a post-approval Clinical Trial, within one (1) year of Clinical 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.

## The Parties shall conduct the Clinical Trial in accordance with:

### the Protocol, which is hereby incorporated by reference;

### any current marketing authorisation for the Investigational Medicinal Product or, as the case may be, the Clinical Trial Authorisation granted by the relevant Licensing Authority; and

### the terms and conditions of the HRA Approval

## Until the Sponsor / Affiliate has obtained all required documentation from the Regulatory Authority and HRA Approval, it shall not supply the Investigational Medicinal Product to the Trust. The Trust shall ensure that neither administration of the Investigational Medicinal Product to any Clinical Trial Subject nor any other clinical intervention mandated by the Protocol takes place in relation to any such Clinical Trial Subject until it is satisfied that all relevant regulatory approvals and HRA Approval have been obtained.

## 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 Investigator and shall be implemented by the Trial Site Personnel as required by the Sponsor / Affiliate. The Sponsor / Affiliate shall initiate simultaneously the change control procedures set out in clause 14 below.

## The Sponsor / Affiliate shall make available to the Investigator copies of the documentation referred to in sub-paragraph 4.4.1 and evidence of grant of the authorisations listed in 4.4 above and the Investigator shall include such documents, together with the HRA Approval, in the Site File.

## Neither the Trust nor the Investigator shall permit the Investigational Medicinal Product to be used for any purpose other than the conduct of the Clinical Trial and upon termination or expiration of this Agreement all unused Investigational Medicinal Product shall, at the Sponsor / Affiliate’s option, either be returned to the Sponsor / Affiliate or disposed of in accordance with the Protocol or the Sponsor / Affiliate’s written instructions.

## The Trust shall use its best endeavours to ensure that the Investigator recruits […insert number…] Clinical Trial Subjects to participate in the Clinical Trial and the Parties shall conduct the Clinical Trial in accordance with the timelines.

## In the event that the Clinical Trial is part of a multi-centre clinical trial (which for the purposes of this Agreement shall mean that at least one other institution is taking part) the Sponsor / Affiliate may amend the number of Clinical Trial Subjects to be recruited pursuant to clause 4.9 above as follows:

### the Sponsor / Affiliate may require further recruitment of Clinical Trial Subjects at the Trial Site to cease if in the reasonable opinion of the Sponsor / Affiliate, recruitment of Clinical Trial Subjects at the Trial Site is proceeding at a rate below that required to enable the relevant Timeline to be met, and upon Sponsor / Affiliate’s request to increase the inclusion rate, the Principal Investigator is unable to comply or

### if the global recruitment target for all clinical centres of the Sponsor / Affiliate and its affiliates have been reached Upon receipt of a notice subject to clause 4.13, the Investigator shall immediately stop the recruitment and inclusion 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 included in the Clinical Trial. Payments shall only be made according to the number of Clinical Trial Subjects screened and recruited and included up to the date of the notice. The Sponsor / Affiliate will not take any responsibility or have a duty to make any payment or provide IMP for the Clinical Trial Subjects recruited after the date of the notice.

### If recruitment of Clinical Trial Subjects is proceeding at the rate above that required to meet the relevant timelines, , the Investigator may increase the number and amend the rate of Clinical Trial Subjects to be recruited and enrolled at the Trial Site.

## The following provisions relate to access, research misconduct and Regulatory Authorities:

### The Trust represents that to the best of its knowledge that neither it nor any Trial Site Personnel, including the Investigator, are restricted or prevented under any healthcare or medicines law from taking part in clinical research activities and the Trust 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 services to be performed under this Agreement. During the term of this Agreement and for one (1) year after its termination, the Trust and the Investigator will notify the Sponsor / Affiliate if they become aware of any restriction or prevention being applied to the Investigator or any of the Trial Site Personnel

### The Trust represents that it and, to the best of its knowledge, the Investigator are not the subject of any past or pending governmental or regulatory investigation, inquiry, warning or enforcement action (collectively, “Agency Action”) related to its conduct of research that has not been disclosed to Sponsor / Affiliate.  The Trust will promptly notify Sponsor / Affiliate 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 was conducted.

### Each Party shall inform the other immediately upon becoming aware of any serious breach of the conditions and principles of ICH GCP in connection with the Clinical Trial or the Protocol. The Sponsor / Affiliate shall inform the relevant Regulatory Authorities of such serious breach in writing within seven (7) days of becoming aware of that breach. For the purposes of this clause 4.7, a “serious breach” is a breach which is likely to affect, to a significant degree, (i) the safety or physical or mental integrity of the Clinical Trial Subjects of the Clinical Trial; or (ii) the scientific value of the Clinical Trial.

### The Trust shall permit the Trial Monitor and any Auditor or Inspector access to all relevant clinical data of Clinical Trial Subjects for monitoring and source data verification, such access to be arranged at mutually convenient times and on reasonable notice. Such monitoring may take such form as the Sponsor / Affiliate 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, in accordance with the provisions of clause 6.2 of this Agreement. The Sponsor / Affiliate will alert the R&D Office of the Trust promptly to significant issues (in the opinion of the Sponsor / Affiliate) relating to the conduct of the Clinical Trial. 4.11.5 In the event that the Sponsor / Affiliate reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Trust and the Investigator shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Sponsor / Affiliate, the results of which the Party on whose behalf the investigation was undertaken shall, subject to any obligations of confidentiality, communicate to the Trust. In the event that the Trust reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Sponsor / Affiliate shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Trust, the results of which shall, subject to any obligations of confidentiality, be communicated to the Sponsor / Affiliate.

### The Trust shall promptly inform the Sponsor / Affiliate of any intended or actual inspection, written enquiry and/or visit to the Trial Site by any Regulatory Authority in connection with the Clinical Trial and forward to the Sponsor / Affiliate copies of any correspondence from any such Regulatory Authority relating to the Clinical Trial. The Trust will use all reasonable endeavours to procure that the Sponsor / Affiliate may have a representative present during any such visit, and the opportunity to review and comment on any Trust response to Regulatory Authority inspections in respect of the Clinical Trial. Such requests not to be unreasonably withheld or denied.

### The Trust will permit the Sponsor / Affiliate to examine the conduct of the Clinical Trial and the Trial 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 Trust acknowledges that the Clinical Trial is subject to inspection by Regulatory Agencies worldwide and that such inspections may occur after completion of the Clinical Trial and may include auditing of Clinical Trial records. The Sponsor / Affiliate may also audit Clinical Trial records during or after the Clinical Trial as part of its monitoring of Clinical Trial conduct. The Sponsor / Affiliate’s examination of the Clinical Trial and Trial Site includes auditing of Clinical Trial records both during and after the Clinical Trial as part of its monitoring of Clinical Trial conduct.

## The Trust shall ensure that any Material required to be tested by the Trust during the course of the Clinical Trial is tested in accordance with the Protocol (and other documents accompanying the IRAS submission to the HRA) and at a laboratory approved by the Sponsor / Affiliate. Where the Sponsor / Affiliate has contracted with a third-party laboratory (“Central Laboratory”) to undertake the processing and analysis of clinical biological samples the Sponsor / Affiliate shall comply, and shall ensure that the Central Laboratory shall comply, with the terms of Appendix 6 herein.

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## Upon completion of the Clinical Trial (whether prematurely or otherwise) the Investigator shall co-operate with the Sponsor / Affiliate in producing a report of the Clinical Trial detailing the methodology, results and containing an analysis of the results and drawing appropriate conclusions.

## Subject to the Trust’s and the Investigator’s overriding obligations in relation to Clinical Trial Subjects and individual patient care, neither the Trust nor the Investigator nor Trial Site Personnel shall during the term of this Agreement conduct any other trial which might hinder the Trust’s or Investigator’s ability to recruit and study the required cohort of Clinical Trial Subjects.

## All Clinical Trial records must be retained for [… insert applicable number of years – see guidance….] years after completion or termination of the Study. No records will be destroyed without Sponsor / Affiliate’s prior written approval.

## The Investigator shall be responsible for ensuring that the informed consent form approved by the Sponsor / Affiliate and Ethics Committee is signed by or on behalf of each Clinical Trial Subject before the first Trial related procedure starts for the Clinical Trial Subject.

# LIABILITIES AND INDEMNITY

## In the event of any claim or proceeding in respect of personal injury made or brought against the Trust by a Clinical Trial Subject, the Sponsor / Affiliate shall indemnify the Trust, its servants, Agents and employees in accordance with the terms of the indemnity set out at Appendix 3 hereto.

## Nothing in this clause 4.17 shall operate so as to restrict or exclude the liability of any Party in relation to death or personal injury caused by the negligence of that Party or its servants, Agents or employees or to restrict or exclude any other liability of either Party which cannot be so restricted or excluded in law.

## In no circumstances shall either Party be liable to the other Party in contract, tort (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 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.

## Subject to clauses 5.2 and 5.5, the Trust's liability to the Sponsor / Affiliate arising out of or in connection with any breach of this Agreement or any act or omission of the Trust in connection with the performance of the Clinical Trial shall in no event exceed the amount of fees payable by the Sponsor / Affiliate to the Trust under this Agreement. In the case of equipment loaned to the Trust for the purposes of the Clinical Trial, the Trust’s liability arising from its negligence shall exclude fair wear and tear and shall not exceed the value of the equipment.

## In respect of any wilful and/or deliberate breach by the Trust, or any breach of clauses 6, 8 and/or 9, the Trust’s liability to the Sponsor / Affiliate arising out of or in connection with the breach shall not exceed [twice / three times] the value of the Agreement.

## The Sponsor / Affiliate will take out appropriate insurance cover or will provide an indemnity satisfactory to the Trust 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 and in the annual aggregate. The Sponsor / Affiliate shall produce to the Trust, 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 any insurance or the amount of cover shall not relieve the Sponsor / Affiliate of any liabilities under this Agreement.

# DATA PROTECTION, FREEDOM OF INFORMATION AND CONFIDENTIALITY

## Data Protection

### The Parties agree to adhere to the principles of medical confidentiality in relation to Clinical Trial Subjects involved in the Clinical Trial. Personal data (as defined in the Data Protection Act 1998) shall not be disclosed to the Sponsor / Affiliate by the Trust save where this is required to satisfy the requirements of the Protocol or for the purpose of monitoring or adverse event reporting, or in relation to a claim or proceeding brought by the Clinical Trial Subject in connection with the Clinical Trial. The Sponsor / Affiliate shall not disclose the identity of Clinical Trial Subjects to third parties without prior written consent of the Clinical Trial Subject, exceptin accordance with the provisions of the Data Protection Act 1998 Act and the principles set out in the NHS Confidentiality Code of Practice (November 2003), unless in relation to a claim or proceeding brought by the Clinical Trial Subject in connection with the Clinical Trial.

### Each Party shall comply with the Data Protection Act 1998 and any other applicable data protection legislation. In particular where either Party is acting as the data processor of the other Party ("data controller"), the Party processing data on behalf of the data controller agrees to comply with the obligations placed on the data controller by the seventh data protection principle ("the Seventh Principle") set out in the 1998 Act, namely:

#### to maintain technical and organisational security measures sufficient to comply at least with the obligations imposed on the data controller by the Seventh Principle;

#### only to process Personal Data for and on behalf of the data controller, in accordance with the instructions of the data controller and for the purpose of the Clinical Trial and to ensure the data controller’s compliance with the 1998 Act;

#### to allow the data controller to audit the processing Party's compliance with the requirements of this clause on reasonable notice and/or to provide the data controller with evidence of its compliance with the obligations set out in this clause 6.

#### the processing Party shall obtain prior agreement of the data controller to store or process Personal Data at sites outside the European Economic Area (comprising the countries of the European Community, Norway, Iceland and Liechtenstein).

#### both Parties agree to use all reasonable efforts to assist each other to comply with the 1998 Act. For the avoidance of doubt, this includes providing the other with reasonable assistance in complying with subject access requests served under Section 7 of the 1998 Act and consulting with the other prior to the disclosure of any Personal Data created in connection with the conduct or performance of the Clinical Trial in relation to such requests.

### Sponsor / Affiliate may collect information from Investigator and Trial Site Personnel, including names, titles and business contact information (“Trial Site Personnel Data”) and may provide that information to Sponsor / Affiliate’s Affiliates, its business partners and vendors working with Sponsor / Affiliate on matters related to the Clinical Trial, to fulfill Sponsor / Affiliate’s business purposes including:

#### Compliance with laws and regulations regarding possible financial conflicts of interest

#### Assessment of personnel qualifications to conduct the Clinical Trial;

#### Quality control and Clinical Trial management; and

#### Disclosures to Research Ethics Committees or national or international Regulatory Authorities in connection with their performance of review or oversight responsibilities for the Clinical Trial

#### posting on websites or printed materials and being held on databases for determining potential involvement in future research activities.

6.1.4 Trial Site Personnel Data may also be aggregated with data from other Sponsor / Affiliate sources and evaluated for business decisions including those involving future research.  Sponsor / Affiliate may store or process such Trial Site Personnel Data in the U.S. or other countries at Sponsor / Affiliate or Sponsor / Affiliate-associated facilities, as long as a business need or legal obligation exists and appropriate safe harbor certification is produced by the Sponsor / Affiliate.  These countries might be out of the European Economic Area and may not have protections for personal information equivalent to the UK. Nevertheless, personal information will be handled in accordance with principles and requirements based on the European Directive on the protection of personal data (95/46/EC) and UK Data Protection Act.

6.1.5 The Investigator and Trust personnel may have access to Site Personnel Data about themselves that the Sponsor / Affiliate has collected and may have corrections made to Trial Site Personnel Data about themselves that is inaccurate. The Trust agrees to obtain the permission of their personnel for the transfer and use of Trial Site Personnel Data for the purposes described in this clause. .

6.1.6 The Investigator and the Trust may contact the Sponsor / Affiliate with enquiries regarding Sponsor / Affiliate’s collection or use of Trial Site Personnel Data. The Sponsor / Affiliate agrees to comply with all applicable laws and regulations regarding Sponsor / Affiliate’s use of Trial Site Personnel Data.

**6.2. Freedom of Information**

### 6.2.1. The Sponsor / Affiliate acknowledges that the Trust is subject to the Freedom of Information Act 2000 ("FOIA") and the Codes of Practice issued under the FOIA as may be amended, updated or replaced from time to time.

### If the Trust or its Agent receives a request under the FOIA to disclose any information that belongs to the Sponsor / Affiliate or its Affiliates, it will notify the Sponsor / Affiliate in accordance with Clause 16 as soon as is reasonably practicable, in any event, not later than five (5) working days after receiving the request and will consult with the Sponsor / Affiliate in accordance with all applicable guidance.

### The Sponsor / Affiliate acknowledges and agrees that:

#### (a) subject to clause 6.2.3(b), the decision on whether any exemption applies to a request for disclosure of recorded information under the FOIA is a decision solely for the Trust;

#### (b) where the Trust is managing a request as referred to in clause 6.2.2, the Sponsor / Affiliate shall co-operate with the Trust and shall use its reasonable endeavours to respond within ten (10) working days of the Trust’s request for assistance in determining whether or not an exemption to the FOIA applies.

### Where the Trust determines that it will disclose the Confidential Information, notwithstanding any objections from the Sponsor / Affiliate, it will notify the Sponsor / Affiliate in writing, giving at least two (2) working days notice of its intended disclosure.

## **Confidential Information**

### 6.3.1. The Trust and the Sponsor / Affiliate shall ensure that only those of its officers, Agents and employees (and in the case of the Sponsor / Affiliate 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 Trust with the FOIA, in accordance with clauses 6.2 above). 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 6.2), 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.

### The obligations of confidentiality set out in this clause 6.3 shall not apply to Confidential Information which is (i) published or becomes generally available to the public other than as a result of a breach of the undertakings hereunder by the receiving Party, (ii) 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, (iii) independently developed by the receiving Party as evidenced by contemporaneous written evidence and is not subject to a duty of confidentiality, (iv) obtained by the receiving Party from a third Party not subject to a duty of confidentiality.

### 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 6.3.

### This clause shall remain in force without limit in time in respect of Confidential Information which comprises Personal Data or which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly set out in this Agreement, this clause shall remain in force for a period of ten (10) years after the termination or expiry of this Agreement.

# PUBLICITY

# The Sponsor / Affiliate will not use the name of the Trust, nor of any member of the Trust's staff, in any publicity, advertising or news release without the prior written approval of an authorised representative of the Trust, such approval not to be unreasonably withheld. The Trust will not, and will ensure that the Investigator and Trial Site Personnel do not, use the name of the Sponsor / Affiliate or of any of its employees, nor the name of the Clinical Trial, nor the name of the Investigational Medicinal Product, in any publicity, advertising or news release without the prior written approval of the Sponsor / Affiliate, such approval not to be unreasonably withheld. The Trust and the Investigator agree to the use of their names in Clinical Trial publications and communications, including clinical trial websites.

## 7.2 Neither The Trust nor the 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, where appropriate, its review and the delivery of a favourable opinion by the research ethics committee and the prior written permission of the Sponsor / Affiliate

1. PUBLICATION

## The Sponsor / Affiliate recognises that the Trust and Investigator have a responsibility under the Research Governance Framework for Health and Social Care to ensure that results of scientific interest arising from the Clinical Trial are appropriately published and disseminated. The Sponsor / Affiliate agrees that employees of the Trust and the Investigator shall be permitted to present at symposia, national or regional professional meetings, and to publish in journals, theses or dissertations, or otherwise of their own choosing, methods and results of the Clinical Trial, subject to this clause 8 and any publication policy described in the Protocol, provided any such policy is consistent with the Joint Position. If the Clinical Trial is multi-centred (as defined in clause 4.11 above), any publication based on the results obtained at the Trial Site (or a group of sites) shall not be made before the first multi-centre publication. If a publication concerns the analyses of sub-sets of data from a multi-centred Clinical Trial the publication shall make reference to the relevant multi-centre publication(s).

## Upon completion of the Clinical Trial, and any prior publication by Sponsor / Affiliate of multi-centre data, or when the Clinical Trial data are adequate (in Sponsor / Affiliate's reasonable judgement), the Trust and/or the Investigatormay prepare the data derived from the Trial Site for the Clinical Trial for publication. Such data will be submitted to the Sponsor / Affiliate for review and comment prior to publication. In order to ensure that the Sponsor / Affiliate will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to the Sponsor / Affiliate for review at least sixty (60) days (or the time limit specified in the Protocol if longer) prior to submission for publication, public dissemination, or review by a publication committee.

## The Trust agrees, and shall ensure that the Investigator agrees, that all reasonable comments made by the Sponsor / Affiliate in relation to a proposed publication by the Trust and/or the Investigator will be incorporated by the Trust and/or the Investigator into the publication.

## The Trust acknowledges that the Sponsor / Affiliate may present Results at symposia, national or regional professional meetings, and publish in journals, theses or dissertations, or otherwise of their own choosing, methods and results of the Clinical Trial and in particular, but without limiting the foregoing, post a summary of Clinical Trial results in on-line clinical trials register(s) before or after publication by any other method. The Trust / Investigator will disclose all sponsorship and financial support of Sponsor / Affiliate for the Study in any publication.  In the event the Sponsor / Affiliate coordinates a multi-centre publication, the participation of the Investigator or other representatives of the Trust as a named author shall be determined in accordance with the Sponsor / Affiliate’s policy and generally accepted standards for authorship. If the Investigator or other representatives of the Trust is a named author of the multi-centre publication, such person shall have access to the Clinical Trial data from all Clinical Trial sites as necessary to participate fully in the development of the multi-centre publication.

## During the period for review of a proposed publication referred to in clause 8.2 above, the Sponsor / Affiliate shall be entitled to make a reasoned request to the Trust that publication be delayed for a period of up to six (6) months from the date of first submission to the Sponsor / Affiliate in order to enable the Sponsor / Affiliate to take steps to protect its proprietary information and/or Intellectual Property Rights and Know How and the Trust shall not unreasonably withhold its consent to such a request. The Trust shall not unreasonably withhold or delay its consent to a request from the Sponsor / Affiliate for an exceptional additional delay if, in the reasonable opinion of the Sponsor / Affiliate, the Sponsor / Affiliate’s proprietary information and/or Intellectual Property Rights and Know How might otherwise be compromised or lost.

# INTELLECTUAL PROPERTY

## All Intellectual Property Rights and Know How owned by or licensed to the Sponsor / Affiliate 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 / Affiliate.

## All Intellectual Property Rights and Know How owned by or licensed to the Trust 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 Trust.

## All Intellectual Property Rights and Know How arising from and relating to the Clinical Trial, the Investigational Medicinal Product (including but not limited to its formulation and use alone or in combination with other drugs) or the Protocol, but excluding any clinical procedure and improvements thereto that are clinical procedures of the Trust, shall vest in the Sponsor / Affiliate in accordance with clauses 9.4 and 9.5 below.

## In accordance with clause 9.3 above, the Trust hereby assigns, and shall procure that the Investigator assigns, its rights in relation to all Intellectual Property Rights and in all Know How, falling within 9.3 above, to the Sponsor / Affiliate and at the request and expense of the Sponsor / Affiliate, the Trust shall execute, and shall procure that the Investigator executes, all such documents and do all such other acts as the Sponsor / Affiliate may reasonably require in order to vest fully and effectively all such Intellectual Property Rights and Know How in the Sponsor / Affiliate or its nominee.

## The Trust and the Investigator shall promptly disclose to the Sponsor / Affiliate any Know How generated pursuant to this Agreement and falling within clause 9.3 above and undertake not to use or disclose such Know How other than for the purposes of this Agreement.

## Nothing in this clause 9 shall be construed so as to prevent or hinder the Trust from using Know How gained during the performance of the Clinical Trial in the furtherance of its normal activities, to the extent such use does not result in the disclosure or misuse of Confidential Information or the infringement of any Intellectual Property Right of the Sponsor / Affiliate.

# FINANCIAL ARRANGEMENTS

## Arrangements relating to the financing of this Clinical Trial by the Sponsor / Affiliate are set out in Appendix 4 hereto.

## In the event that amendments to the Protocol require changes to the Trial financing arrangements, an amended financial schedule will be signed by the Parties pursuant to clause 14.2 below and attached at Appendix 4 of this Agreement.

## All payments will be made according to the schedule contained in Appendix 4 on presentation of a VAT invoice to the Sponsor / Affiliate by the Trust.

## The Trust agrees that the Sponsor / Affiliate may make public the amount of funding provided to the Trust by the Sponsor / Affiliate for the conduct of the Clinical Trial and may identify the Trust and the Investigator as part of this disclosure.  The Trust represents that it has obtained the Investigator’s consent to this disclosure

## The Sponsor / Affiliate shall promptly respond to any reasonable request for invoicing data received from the Trust within forty five (45) days of the close-out of the Trial Site. The Trust will send its final invoice, (or, as the case may be, issue a credit note and make repayment of any monies previously paid for work not completed), to the Sponsor / Affiliate as soon as possible and, in any event, within forty five (45) days of receipt of the said data where such a request has been made, or within forty five (45) days of Trial close-out in all other circumstances unless there is a written agreement between the Trust and the Sponsor / Affiliate to extend these periods.

## The Sponsor / Affiliate shall make payment within forty five (45) days of the date of receipt of the invoice mentioned in Clause 10.3 above. The Sponsor / Affiliate will notify the Trust, via the contact detailed in the notices section [insert clause number], when the Clinical Trial is considered completed, closed or terminated for the Trust to trigger the generation of the final invoice.  All outstanding payments detailed in the final invoice from the Trust will be provided to the Sponsor / Affiliate within 60 calendar days from the date the Trust is notified of the end of the Clinical Trial or the date of site close out visit, whichever is later.   After this date, any further invoices received in relation to the closed Clinical Trial are not required to be paid by the Sponsor / Affiliate.

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

# TERM

This Agreement will remain in effect until completion of the Clinical Trial, close-out of the Trial Site and completion of the obligations of the Parties under this Agreement or earlier termination in accordance with this Agreement.

# EARLY TERMINATION

## Either the Sponsor / Affiliate or the Trust (the “Terminating Party”) may terminate this Agreement with immediate effect at any time if the other Party or the Investigator (the “Defaulting Party”) is:

### 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) days of a written notice from the Terminating Party specifying the breach and requiring its remedy;

### 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 Trust, 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 Trust 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 Trust transferring its liabilities to one of the bodies referred to in Section 70 of that Act.

## 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.

## The Sponsor / Affiliate may terminate this Agreement on notice to the Trust if the Investigator is no longer able (for whatever reason) to act as Investigator and no replacement mutually acceptable to the Trust and the Sponsor / Affiliate can be found.

## The Sponsor / Affiliate may terminate this Agreement immediately upon notice in writing to the Trust for reasons not falling within clauses 12.1, 12.2 or 12.3 above. In all such circumstances the Sponsor / Affiliate shall confer with the 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.

## In the event of early termination of this Agreement by the Sponsor / Affiliate, pursuant to clauses 12.1, 12.2, 12.3 and 12.4 and subject to an obligation on the Trust and the Investigator to mitigate any loss, the Sponsor / Affiliate 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 bytheTrust for the performance of the Clinical Trial prior to the date of termination, and agreed with the Sponsor / Affiliate.

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

## At close-out of the Trial Site following termination or expiration of this Agreement the Trust shall immediately deliver, and shall make sure that the Investigator delivers, to the Sponsor / Affiliate all Confidential Information and any other unused materials provided to the Trust and/or the Investigator pursuant to this Agreement.

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

# RELATIONSHIP BETWEEN THE PARTIES

## 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, and 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.

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

# AGREEMENT AND MODIFICATION

## 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.

14.2 Any amendment to the Protocol pursuant to clause 4.7 (“Protocol Amendment”) shall be managed by means of the change control procedure set out in this clause 14.2

14.2.1 For the purposes of this Agreement, a “change request” is a request to change the obligations of the Parties arising from a Protocol Amendment.

14.2.2 Where the Sponsor / Affiliate originates a change request, the Trust shall provide the Sponsor / Affiliate, 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.

* + 1. 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 both Parties.
		2. An amended financial schedule shall be signed and appended to this Agreement according to clause 10.2 above.

## This Agreement including its Appendices contains the entire understanding between the Parties and supersedes all other agreements, negotiations, representations and undertakings, whether written or oral, of prior date between the Parties relating to the Clinical Trial, which is the subject of this Agreement. Nothing in this Agreement will, however, operate to limit or exclude any liability for fraud.

# FORCE MAJEURE

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.

# NOTICES

Any notices under this Agreement shall be in writing, signed by the relevant Party to this Agreement and delivered personally, by courier or by recorded delivery post.

Notices to the Sponsor / Affiliate shall be addressed to:

 [….insert address….]

Notices to the Trust shall be addressed to:

 [….insert address….]

 [The email address to which requests for destruction of Trial records should be sent is:

 [….insert address….] ]

# 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"). Any right or remedy of a third Party which 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.

# 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.

# DISPUTE RESOLUTION

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

## 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.

* + 1. 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 he shall be nominated by the President for the time being of the British Medical Association. The mediation will start no later than twenty (20) days after the date of the ADR Notice.
	1. 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.
	2. Nothing in this Agreement shall prevent either Party from seeking an interim injunction 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.

# SURVIVAL OF CLAUSES

The following clauses shall survive the termination or expiry of this Agreement:-

1 Definitions

3.2 to 3.7 (inclusive) Clinical Trial Governance

4.3, 4.4, 4.13, 4.14 4.17 Obligations of the Parties and the Investigator

4.17 Liabilities and Indemnity

6 Data Protection, Freedom of Information, and Confidentiality,

7 Publicity

8 Publication

9 Intellectual Property

12 Early Termination

13 to 21 (inclusive) Miscellaneous provisions

Subject to clause 6.3 (Confidential Information) shall survive the termination or expiry of this Agreement for a period of ten (10) years commencing on the date of such termination or expiry.

# GOVERNING LAW

This Agreement shall be governed and construed in accordance with the laws of England and Wales.

# COUNTERPARTS

## 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.

## 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 on behalf of the:

**SPONSOR / AFFILIATE**:

 ...........................................................

D D

D

M

M

M

Y

Y

Y

Y

........................................................... Date:

.....................................……………….

(Print name and position of authorised signatory)

Signed on behalf of the:

**TRUST**: ...........................................................

D D

D

M

M

M

Y

Y

Y

Y

........................................................... Date:

.....................................……………….

(Print name and position of authorised signatory)

Authorised signatory (Chief Executive, Director of R&D, Finance Director, or equivalent)

Appendix 1

**Clinical Trial Conduct at the Trust**

**DIVISION OF RESPONSIBILITIES AND DELEGATION OF ACTIVITIES**

(Although some **RESPONSIBILITIES** cannot be delegated this schedule does allow delegation of **ACTIVITIES** – e.g. to Chief Investigator, CTU or CRO – to be detailed)

The Parties collaborating in the Study will undertake responsibilities as attributed in the table below.

Note 1: Parties should set out any agreed delegation of **ACTIVITIES** in the table below.

Note 2: Some responsibilities are only applicable to particular types of study. Where a particular activity is not applicable to the Study N/A should be entered for the activity.

Note 3: Any additional responsibilities to those set out in this table should be added at the end of the table to preserve the numbering of the standard list and navigation of the contents.

Note 4: All references to Participants refer to those under the care of the Trust.

Note 5: All capitalised terms used in the Schedule but not otherwise defined in the Agreement shall have the meaning ascribed to them in relevant legislation.

|  | **RESPONSIBILITY to:** | **Sponsor / Affiliate** | **Trust** | **If ACTIVITY is delegated, name the body / individual delegated to:** |
| --- | --- | --- | --- | --- |
| 1. **Study preparation**

**(All studies)** | 1. Ensure that the Study and its Protocol have received robust and favourable scientific and, where applicable, statistical peer review
 | ✓ |  |  |
| 1. Ensure appropriate clinical trials insurance is in place for the design and management of the Study
 | ✓ |  |  |
| 1. Ensure that indemnity arrangements are in place to cover Trust liabilities
 |  | ✓ |  |
| 1. Ensure that insurance or indemnity arrangements are in place to cover Sponsor liabilities
 | ✓ |  |  |
| 1. Secure and administer funding for the research costs of the Study
 | ✓ |  |  |
| 1. Secure and contract for the supply of resources, where applicable, including medicinal products / devices / Contract Research Organisation services
 | ✓ |  |  |
| 1. Ensure that the appropriate contracts and agreements are in place for the Study
 | ✓ |  |  |
| 1. Ensure adequate facilities, resources and support (capacity and capability) are available to conduct the Study at the Trust
 |  | ✓ |  |
| 1. **Applications, authorisations and registration**

**(All studies)** | * 1. Ensure that the Protocol is compliant with the relevant regulations/ guidelines
 | ✓ |  |  |
| * 1. Prepare Participant information sheet and consent form (and assent form where applicable), including, where appropriate, consent to: provision of Material(s) and Personal Data, Clinical Data or other data, as required, to the Sponsor
 | ✓ |  |  |
| * 1. Register the Study on an appropriate trial register
 | ✓ |  |  |
| * 1. Obtain approvals from relevant Ethics Committee(s)
 | ✓ |  |  |
| * 1. Obtain HRA Approval (for NHS sites in England)
 | ✓ |  |  |
| * 1. ensure that all relevant departments at The Trust are aware of and, where necessary, have agreed to their role in the study
 |  | ✓ |  |
| * 1. Obtain a Clinical Trials Authorisation for a CTIMP from the regulatory authority (MHRA in the UK)
 | ✓ |  |  |
| * 1. Obtain a Letter of no objection for the clinical investigation of a non-CE marked medical device from the regulatory authority (MHRA in the UK)
 | ✓ |  |  |
| * 1. [Insert ANY ADDITIONAL PERMISSIONS APPROVALS TO BE SOUGHT]
 | ✓ |  |  |
| 1. **Protocol Amendments**

**(All studies)** | 1. Prepare and submit proposed substantial (and, for studies of investigational medical devices, non-substantial) amendments to all relevant ethics committee(s) and, if appropriate, regulatory authority(ies)
 | ✓ |  |  |
|  | 1. Ensure the Principal Investigator is informed of all amendments requiring implementation at Site, including the date on which the amendment should be implemented
 | ✓ |  |  |
|  | 1. Ensure all amendments of which the site is notified and that require local implementation are implemented at Trust
 |  | ✓ |  |
|  |
| 1. **Study Conduct**

**(All studies)** | 1. Ensure that the Study is managed according to GCP (as defined in the Protocol), all relevant legislation, and the Protocol
 | ✓ |  |  |
| 1. Ensure that the Study is conducted locally according to GCP, all relevant legislation, and the Protocol
 |  | ✓ |  |
| 1. Submit all Study Data and Materials required for the Study, in accordance with the Protocol and any Study specific manuals provided by the Sponsor
 |  | ✓ |  |
| 1. Ensure that the Trust team members are appropriately qualified and experienced to undertake the conduct of the Study and that they have current substantive or honorary employment contracts in place, where required
 |  | ✓ |  |
| 1. Ensure that no Participant is recruited at Site until the Trust has been activated by the Sponsor
 |  | ✓ |  |
|  |  |
| 1. Ensure that the Study is managed, monitored and reported as agreed in the Protocol
 | ✓ |  |  |
|  |  |
| 1. Maintain Investigator Site File (and Pharmacy Site File, where relevant) at Trust, ensuring compliance with Sponsor requirements and applicable guidance/legislation
 |  | ✓ |  |
| 1. Maintain Trial Master File, ensuring compliance with applicable guidance/ legislation
 | ✓ |  |  |
| 1. Assess capability of Participants to give informed consent
 |  | ✓ |  |
|  |  |  |  |
| 1. Ensure no Study procedure is carried out on a Participant until consent (where required) is obtained in accordance with the Protocol
 |  | ✓ |  |
| 1. Ensure that the rights of individual Participants are protected and that they receive appropriate medical care whilst participating in the Study.
 |  | ✓ |  |
| 1. Ensure that all Clinical Data and documentation are available for the purposes of monitoring, inspection or audit
 |  | ✓ |  |
| 1. Inform appropriate health or social care professionals if their patient is a Participant in the Study, if required
 |  | ✓ |  |
| 1. Ensure relevant Protocol deviations, and all serious breaches of Study conduct and/or GCP are reported to the Sponsor
 |  | ✓ |  |
| 1. Report serious breaches of Study conduct and/or GCP to relevant ethics committees and regulatory authority(ies) (as applicable)
 | ✓ |  |  |
| 1. Report suspected research misconduct, identified by the Sponsor, to the Trust
 | ✓ |  |  |
| 1. Report suspected research misconduct, identified by the Trust, to the Sponsor
 |  | ✓ |  |
|  |  |
| 1. Notify the relevant ethics committee(s) and, if applicable, regulatory authority(ies) of the end of the Study
 | ✓ |  |  |
| 1. Notify the relevant ethics committee(s) and, if applicable, regulatory authority(ies) if the Study is terminated early
 | ✓ |  |  |
| 1. **Adverse events**

**(All studies)** | 1. Maintain detailed records of all adverse events as specified in the Protocol
 |  | ✓ |  |
|  |  |
| 1. Report adverse events as defined in the Protocol and to legal requirements and in accordance with Trust policy
 |  | ✓ |  |
|  |  |
| 1. Ensure that procedures are in place for emergency unblinding of the randomisation code. (If applicable)
 | ✓ |  |  |
| 1. Promptly notify the Sponsor of any urgent safety measure taken to protect Participants at Site
 |  | ✓ |  |
| 1. Promptly inform relevant ethics committee(s), regulatory authority(ies) (if applicable), and all Principal Investigators of any urgent safety measures taken to protect Participants in the Study
 | ✓ |  |  |
| 1. Ensure that all Serious Adverse Events (SAE) are reported to the Sponsor, as specified in the Protocol
 |  | ✓ |  |
| 1. Ensure all SAEs are promptly assessed, and expedited reporting to the relevant ethics committee(s) and regulatory authority (if applicable) is undertaken where necessary
 | ✓ |  |  |
| 1. Ensure that SAEs are reviewed by an appropriate committee for the monitoring of Study safety
 | ✓ |  |  |
| 1. Ensure that annual safety/progress reports and final Study report are generated and submitted to relevant ethics committee(s) and regulatory authority(ies) (e.g. Development Safety Update Reports, if applicable), within the required timeframes
 | ✓ |  |  |
| 1. Ensure that the Principal Investigator is, at all times, in possession of the current relevant safety information for the Study
 | ✓ |  |  |
| 1. **Data Management**

**(All studies)** | 1. Design of case report forms (eCRFs/CRFs) and database
 | ✓ |  |  |
| 1. Complete eCRFs/CRFs fully, accurately, and submit in a timely manner and in accordance with the Protocol
 |  | ✓ |  |
| 1. Respond to the Sponsor’s requests for data clarification
 |  | ✓ |  |
| 1. Process and code Study Data
 | ✓ |  |  |
| 1. Ensure appropriate analysis of Study Data
 | ✓ |  |  |
| 1. **Publication**

**(All studies)** | 1. Prepare and submit abstracts, posters and publications of the Study endpoints
 | ✓ |  |  |
| 1. **Archiving**

**(All studies)** | 1. Ensure that the Trial Master File is archived appropriately on conclusion of the Study and retained as required by the Protocol
 | ✓ |  |  |
| 1. Ensure that all Study records held at Site are archived appropriately when notified by the Sponsor and retained as required by the Protocol
 |  | ✓ |  |
| 1. **Clinical Trials involving Investigational Medicinal Products**
 | 1. Ensure appropriate arrangements are defined for the supply, labelling, storage and destruction of Study drug(s)
 | ✓ |  |  |
| 1. Ensure ability to comply with the arrangements for the Study drug
 |  | ✓ |  |
| 1. Ensure that Study Drug(s) supplied for specific use in the Study is/are used in strict accordance with the Protocol and is/are not used for any other purpose
 |  | ✓ |  |
| 1. Ensure that Study Drug(s) is/are stored in appropriate and secure conditions
 |  | ✓ |  |
| 1. Ensure approvals are in place and issue regulatory ‘green light’ for release of Study Drug(s)
 | ✓ |  |  |
| 1. Ensure that appropriate accountability and destruction records are maintained, as required by the Sponsor
 |  | ✓ |  |
| 1. **Studies involving CE marked medical devices for new purpose or non-CE marked Medical Device**
 | 1. Ensure that the site is provided with the a sufficient number of investigational medicinal devices/disposables required for proper functioning of the device for the planned number of Participants
 | ✓ |  |  |
| 1. Ensure that investigational medical devices are not used for any purposes other than the conduct of the Study, unless Sponsor permits continued intended use for CE marked device after conclusion of the Study
 |  | ✓ |  |
| 1. Ensure that investigational medical devices are stored in appropriate, secure conditions and returned as instructed by Sponsor. Further to ensure that detailed records are maintained regarding its movement from delivery to return/destruction.
 |  | ✓ |  |
| 1. **[Insert other responsibilities, if necessary]**
 | 1. [Insert additional Study specific responsibilities, not covered elsewhere, if necessary.]
 |  |  |  |

**Appendix 2**

**CLINICAL TRIAL COMPENSATION GUIDELINES 2015**

**PHASE I COMPENSATION GUIDELINES**

**Background**

The Association of the British Pharmaceutical Industry requires member companies that Sponsor / Affiliate 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 Clinical Trial.

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 / Affiliate 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 Sponsor / Affiliate 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 Clinical Trial 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 [Sponsor / Affiliate] sponsoring the Clinical Trial confirms that:

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

**PHASE II, III AND IV CLINICAL TRIAL COMPENSATION GUIDELINES**

**Background**

The Association of the British Pharmaceutical Industry 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 [Sponsor / Affiliate] 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 by the Sponsor / Affiliate 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 d 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 [Sponsor / Affiliate] 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.

**Appendix 3**

**FORM OF INDEMNITY**

1. The Sponsor / Affiliate indemnifies and holds harmless the Trust 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 Trust 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 Trust, 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 / Affiliate 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 Trust, its employees or Agents;

2.2 to the extent that such personal injury (including death) is caused by the failure of the Trust*,* 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 Trustshall have notified the Sponsor / Affiliate in writing of it and shall, upon the Sponsor / Affiliate’s request, and at the Sponsor / Affiliate’s cost, have permitted the Sponsor / Affiliate to have full care and control of the claim or proceeding using legal representation of its own choosing;

2.4 if the Trust, 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 / Affiliate such consent not to be unreasonably withheld provided that this condition shall not be treated as breached by any statement properly made by the Trust, its employees or Agents in connection with the operation of the Trust’s internal complaint procedures, accident reporting procedures or disciplinary procedures or where such a statement is required by law.

3. The Sponsor / Affiliate shall keep the Trust and its legal advisors fully informed of the progress of any such claim or proceeding, will consult fully with the Trust on the nature of any defence to be advanced and will not settle any such claim or proceeding without the written approval of the Trust (such approval not to be unreasonably withheld).

4. Without prejudice to the provisions of paragraph 2.3 above, the Trust will use its reasonable endeavours to inform the Sponsor / Affiliate 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 / Affiliate reasonably informed of developments in relation to any such claim or proceeding even where the Trust decides not to make a claim under this indemnity. Likewise, the Sponsor / Affiliate shall use its reasonable endeavours to inform the Trust of any circumstances and shall keep the Trust reasonably informed of developments in relation to any such claim or proceeding made or brought against the Sponsor / Affiliate alone.

5. The Trust and the Sponsor / Affiliate will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding by or on behalf of Clinical Trial Subjects (or their dependants) or concerning such a declaration as is referred to in paragraph 1.2 above.

6. Without prejudice to the foregoing if injury is suffered by a Clinical Trial Subject while participating in the Clinical Trial, the Sponsor / Affiliate 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 Investigator to make clear to the Clinical Trial Subjects that the Clinical Trial is being conducted subject to the Association Guidelines.

7. For the purpose of this indemnity, the expression “Agents” shall be deemed to include without limitation any nurse or other health professional providing services to the Trust under a contract for services or otherwise and any person carrying out work for the Trust under such a contract connected with such of the Trust*’s* facilities and equipment as are made available for the Clinical Trial.

**Appendix 4**

**FINANCIAL ARRANGEMENTS**

**FINANCIAL ARRANGEMENTS APPENDIX SUGGESTED WORDING INSTRUCTIONS**

[*Please delete instruction text upon completion of this template*]:

* *This Financial Arrangements Appendix suggested layout is designed for use with the model agreement to support the standard contractual terms.*
* *Based on costing template versions 2.3 (Financial year 15/16).*
* *The wording proposed is guidance only and may be amended as required by the contracting Parties to suit the Clinical Trial requirements.*
* *All red text is designed to be replaced by Clinical Trial or Agreement specific information or removed. Red Italic text is instructional text which should be removed on completion of the document.*
* *Where possible, include any anticipated costs (estimated numbers of screen failures, requirement for optional procedures or additional cycles) to provide an estimate value for all possible or foreseeable costs based on reasonable assumptions (which should be detailed in this Appendix where necessary). Where cost is known to be incurred but a total cannot be calculated, this is covered with by the supporting text in the ‘Total Cost Summary’ section*

**Payments**

This Appendix specifies all payments to be made by the Sponsor / Affiliate to the Trust under the Financial Arrangement clause 10 *[amend ref number as applicable]* and Early Termination Clause 12 *[amend ref number as applicable]* of this Agreement for the Clinical Trial named above based on the final agreed Industry Costing Template referenced herein and includes all Clinical Trial related costs.

Any changes to the values or payments must be made by official written notice to the other Party in accordance with the Notice clause 16 *[amend ref number as applicable]* of this Agreement. In accordance with the Obligations of the Parties and the Investigator in clauses 4.11 and 4.12 *[amend ref numbers as applicable]* of this Agreement any payment adjustments for Clinical Trial Subject recruitment (over or under recruitment) will be made according to the values specified in this Appendix. Sponsor / Affiliate reserves the right to decrease or increase the recruitment target defined in this Agreement at any time during the Clinical Trial without renegotiating the per patient costs in this Appendix. The Clinical Trial costs may be adjusted where necessary as a result of a protocol amendment or any other change to the Clinical Trial which impacts on the original cost assumptions for the delivery of the Clinical Trial.

Payments will be made in accordance with this Agreement upon presentation of a valid invoice from the Trust with a breakdown of payments covering:

1. Set-up and Close-down fees
2. Clinical Trial Subject visit Fees
3. All other Fees

**Invoicing and Value Added Tax (VAT)**

Invoices will be based on the services performed or data monitored which, where possible, have been confirmed by *[provided by]* the Sponsor / Affiliate as complete and evaluable for the invoice period in a timely fashion prior to the raising of the invoice. No payment should be made by the Sponsor / Affiliate *[amend as applicable]* until a valid invoice for the amount payable has been received or raised when using a self-invoicing system to enable the Sponsor / Affiliate to raise the invoice on behalf of the Trust.

Invoices will be raised by [EITHER] the Trust following content approval by the Sponsor / Affiliateon a quarterly basis [include alternative invoicing intervals as required] [OR] the Sponsor / Affiliate on behalf of the Trust when utilising a self-invoicing system.

Upon termination of the Clinical Trial, due to completion of the Clinical Trial (defined as (i) completion of the close-out visit, (ii) receipt of all completed and corrected case report forms and queries, (iii) receipt of the Investigator’s final report in a form acceptable to Sponsor / Affiliate as per relevant standards/requirements and (iv) provided all unused Clinical Trial drug has been accounted for) or for any other cause, all remaining amounts due for Clinical Trial Subject visits completed in full or in part shall be invoiced as per the terms detailed in this Financial Arrangements Appendix of this Agreement.

The final Clinical Trial invoice payment may be held by the Sponsor / Affiliate until all outstanding queries for the Clinical Trial site have been resolved.

All figures are INCLUSIVE of all overheads, capacity building and Market Forces Factor where applicable. All figures are EXCLUSIVE of VAT. VAT will not be added to invoices issued in connection with this Agreement/ VAT will be applied at the current United Kingdom rate at the time of invoicing *[amend as applicable to reflect Trust policy on the application of VAT for clinical trial or investigations based on advice from HM Revenue and Customs (HMRC) or Trust VAT advisor]*

**Pass-through Payments**

[Include the following text when Investigator is not employed by the Trust] It shall be the responsibility of the Trust to make the appropriate agreed pass-through payments to the Investigator’s principal employer as described in this Appendix.

**Inflation**

[Include the following text when a Clinical Trial is likely to run longer than two years (twenty-four consecutive months)] An inflationary price review can be addressed a minimum of two years (24 consecutive months) from the date of Clinical Trial contract signature. The rate of inflation to be applied will be agreed by the Sponsor / Affiliateand the NHS Organisation at the time of the inflationary review and will be applied to all remaining Clinical Trial costs, excluding previously invoiced costs, for the duration of the Clinical Trial. The agreed inflation rate applied and resultant cost changes will be documented in a model Clinical Trial Agreement amendment which all Parties of the original model Clinical TrialAgreement will sign and subsequent invoices will reflect the agreed change(s).

1. **SET-UP AND CLOSE-DOWN FEES**

The one-off payments described in the following table are non-refundable and will be payable upon execution of the Agreement:

*[Include the following table for a Secondary Care site only]*

|  |  |
| --- | --- |
| **Fee** | **Total Value (inclusive of all overheads and MFF)** |
| R&D management fees | £[*insert value*] |
| *[Insert department name]* Support Department Set-up fee  | £[*insert value or* ‘Not applicable’] |
| Site initiation fees  | £[*insert value or ‘Not applicable’*] |
| Chief Investigator fee  | £[*insert value or* ‘Not applicable’] |
| Clinical Research Set-up fee | £[*insert value or* ‘Not applicable’] |
| Pharmacy Set-up & Close down fee  | £[*insert value or* ‘Not applicable’] |

*[***SECTION A SUB-TOTAL : Set-up and Close-down Fees**

|  |  |  |
| --- | --- | --- |
| **SUB TOTAL** | £ [*insert subtotal value*] | Based on the following assumptions:*[*Not applicable *or insert relevant assumptions]* |

1. **CLINCIAL TRIAL SUBJECT VISIT FEES**

Payments will be made on a pro-rata basis according to the visit and investigation payment schedule below and include all overhead and applicable Market Forces Factor.

[*insert both visit table from summary worksheet of Industry Costing Template or from the per patient tab if preferable to the parties*]

[*insert investigation table from summary worksheet of Industry Costing Template or from the per patient tab if preferable to the parties*]

|  |  |  |
| --- | --- | --- |
| **Total per clinical Trial****Subject budget (EXCLUDING PHARMACY):** | **£**[*insert value from costing template per patient section*] | *[insert any assumptions e.g. including all visit scheduled investigations]* |

[*insert per patient costs (dispensing related) table from Pharmacy Services worksheet of Industry Costing Template if applicable*]

NOTE: The prescription charge included in this table reflects the charge value at the time of cost agreement. The NHS prescription charge can change on an annual basis (~April) and will be adjusted as necessary at the time of invoicing to reflect the applicable charge.

|  |  |  |
| --- | --- | --- |
| **Pharmacy Services per clinical Trial****Subject budget (dispensing related) fees** | **£**[*insert value from costing template Pharmacy section if applicable*] | *[insert any assumptions as per the costing template section on the Pharmacy tab]* |

**Payment for screen failure and discontinuation**

For the purpose of this Appendix, a ‘Screen Failure’ is defined as a Clinical Trial Subject who is eligible with respect to Protocol defined eligibility criteria to enter the screening process, gave informed consent but are found to be ineligible for treatment allocation. All costs associated with each Clinical Trial Subject Screen Failure are payable by the Sponsor / Affiliate on a pro rata basis as per the individual task price agreed in the Industry Costing Template referenced herein. Sponsor / Affiliate is not expected to pay for recruited Clinical Trial Subjects who did not meet the initial eligibility criteria to enter the screening process, or where there are significant deviations from the Protocol. [If required] Estimations of screen failures rates that may impact the screen failure payment are detailed here [add details of any agreed screen failure payment restrictions or estimations]

A Clinical Trial Subject, who for the purposes of this Appendix is defined as eligible with respect to Protocol defined eligibility criteria and gave informed consent, who discontinues from the Clinical Trial prior to completion of all the Protocol defined visits and assessments because of adverse events, inefficacy of Clinical Trial medication, coexistent disease, as a result of a decision made by the Principle Investigator (PI), non-compliance or non-attendance, will be considered evaluable and payment will be made on a pro-rata basis. The value of payment will be based on completion of visits, procedures and investigations as defined in the Clinical Trial Subject table in this section B of this Appendix to cover all relevant costs and pass-through expenses in respect of such Clinical Trial Subject, provided that the data relating to such Clinical Trial Subject are adequately recorded in the Case Report Forms up to the time of discontinuation.

Clinical Trial Subjects who are entered into the Clinical Trial but who do not satisfy the Protocol eligibility criteria at the time of entry must be either discontinued from the Clinical Trial or dealt with as outlined in the Protocol. Appropriate payment, if applicable, will be agreed on a case by case basis between the Sponsor / Affiliate and Trust at the time of occurrence in respect of such Clinical Trial Subjects.

**Unscheduled Visits**

Unscheduled visits will be paid at the agreed price for the procedures and investigations within the Industry Costing Template referenced herein which are performed at the unscheduled visit.

**Central Laboratory Costs**

Any central laboratory costs will be paid for by the Sponsor / Affiliate and have been excluded from these costs and Agreement.

**SECTION B SUB-TOTAL : Clinical Trial Subject Visit Fees**

|  |  |  |
| --- | --- | --- |
| **SUB TOTAL**  | £ [*insert subtotal value*] | Based on the following assumptions:*[*Not applicable *or insert relevant assumptions e.g. X number Subjects as per the Agreement, X number of screen failures]* |

1. **ALL OTHER FEES**

All other remaining fees associated with the conduct of the Clinical Trial not previously listed are detailed in this Appendix are included in this section.

**Additional itemised costs**

[*insert additional itemised cost table from Additional itemised cost worksheet of Industry Costing Template if applicable and if not entirely covered in the investigations table from the summary sheet as shown in section A*]

**Pharmacy**

|  |  |  |
| --- | --- | --- |
| IMP Management Fee | £[*insert value*] | Annually invoiced on a pro rata basis from month of site initiation to month of site close out, which for this Clinical Trial is estimated to be [*insert number of months for the cost calculation*] months |

All other Pharmacy tasks to be invoiced as required following written Sponsor / Affiliate approval of time allocated and confirmation of conduct as detailed below:

[*Insert Variable Costs table from Pharmacy tab in template*]

[*Insert Additional Costs table from Pharmacy tab in template*]

**Review and approval of Category A or B amendments**

|  |  |
| --- | --- |
| £[*insert value*] | Payable to the Trust for the review and approval per each Category A or B Amendment requiring a change in documentation or process to conduct the Clinical Trial and the value includes the generation of a revised Industry Costing Template and change request as defined in the model agreement in the Agreement and Modification clause 16 *[amend ref number as applicable]* to reflect any changes to costs and/or contract terms as a result of the amendment.A per Clinical Trial Subject re-consent fee may be payable following amendments and will be agreed between the Sponsor / Affiliate/CRO [amend as applicable] and documented in the change request. |

**Clinical Trial****Subject related expenses and allowances**

The Sponsor / Affiliate have agreed to reimburse reasonable travelling and other expenses which occur as a direct result of participation in this Clinical Trial as follows:

|  |  |  |  |
| --- | --- | --- | --- |
| Travel costs | £[*insert value*]  | maximum per visitThis includes standard class rail travel, underground/bus fares and use of a private vehicle at 40p per mile.TrialSite Personnel will maintain a record of claims, supported by receipts where possible, for inspection by the Sponsor / Affiliate upon requestHigher values required to receive written approval from Sponsor / Affiliate PRIOR to Clinical Trial Subject travel [OR] Not Applicable | £ [*insert total value*] based on [*insert estimated number*] of visits for [*insert estimated number of*] patients |
| Refreshment costs | £[*insert value*]  | maximum per visit[OR] Not Applicable | £ [*insert total value*] based on [*insert estimated number*] of visits for [*insert estimated number of*] Clinical Trial/Investigation *[amend as applicable]* Subjects |
| Inconvenience payment costs (as approved by the ethics committee) | £[*insert value*]  | maximum per visit [OR] Not Applicable | £ [*insert total value*] based on [*insert estimated number*] of visits for [*insert estimated number of*] Clinical Trial Subjects |

[INCLUDE EITHER]

Clinical Trial Subjects should submit receipts or other appropriate documentation to Trust where available to support the expenditure. The Trust will reimburse Clinical Trial Subjects directly for travel and other expenses incurred. The Investigator and Trial Site Personnel will maintain records, supported by receipts of the expenditures where possible, and make de-identified copies available at site monitoring visits, if requested by the Sponsor / Affiliate. The Sponsor / Affiliate will reimburse the Trust for all such payments upon confirmation of spend and itemised inclusion in the quarterly *[or include other invoicing interval if adjusted from quarterly]* invoice.

[OR IF USING A FLOAT FOR EXPENSES] The Sponsor / Affiliate will provide a float of £[*insert value*] on execution of Agreement for direct reimbursement of Clinical Trial Subject expenses. The Investigator and Trial Site Personnel will maintain records, supported by receipts of the expenditures where possible, and make de-identified copies available at site monitoring visits, if requested by the Sponsor / Affiliate. The float fund value will be kept under review by the Investigator and/or the Trial Site Personnel . Any subsequent additions or float replenishment will be made by the Sponsor / Affiliateupon receipt of invoice from the Trust. Any balance remaining in the float at the end of the Clinical Trial will be refunded to the Sponsor / Affiliate or deducted from the final Clinical Trial payment.

**Archiving of Clinical Trial documents**

|  |  |
| --- | --- |
| £[*insert value or* ‘Not Applicable’] | EITHERInclusive cost covering transport, box provision and destruction fee for the Clinical Trial [*insert assumptions as required e.g. 15 year term*]. This value includes all preparation and retrieval fees relating to any reasonable request to access the Clinical Trial documentation after it has gone into storage. The Trust will make arrangements for the Clinical Trial documentation to be archived off-site upon Clinical Trial closure as per Medical Research Council (MRC) guidelines and invoiced in full at Clinical Trial closure.[OR]Not applicable - Independent, secure archiving of Clinical Trial documentation (including but not limited to Investigator files) will be arranged and funded by the Sponsor / Affiliate at the end of the Clinical Trial. Instructions for accessing the archived materials will be provided to the Trial Site Personnel. [*amend reason as required*] |

**Primary Care Referral – Patient Identification Centre Costs [*Include if applicable*]**

[*insert number*] (maximum number) Primary Care Patient Identification Centres will receive the following payments:

[Insert Primary Care Referral table from Pharmacy tab in template]

Additional Primary Care Patient Identification Centres may be included at any time throughout the duration of the Clinical Trial receiving the same payment following provision of written permission from the Sponsor / Affiliate.

It is noted that a sub-agreement for the purposes of financial transfer only may be put in place between the Trust receiving the payment for such referrals and the referring Primary Care site in order to transfer the payments of the values detailed above.

**SECTION C SUB-TOTAL : All Other costs**

|  |  |  |
| --- | --- | --- |
| **SUB TOTAL** | £ [*insert subtotal value*] | Based on the following assumptions:*[*Not applicable *or insert relevant assumptions e.g. excluding amendment costs which are charged as incurred]* |

**MAXIMUM COST SUMMARY**

Inclusive of all costs listed above and where possible based on estimated total number of Clinical Trial Subjects detailed in this Agreement assuming all Subjects have completed all Protocol specified interventions.

The Sponsor / Affiliate will reimburse any costs additional to those described in this Appendix, if properly incurred by the Trust in pursuance of the Clinical Trial, and supported by complete and agreed Case Report Forms, Travel Receipts, or other relevant documentation via the invoicing, approval and payment system set-up for this Clinical Trial.

|  |  |
| --- | --- |
| **Sections** | **Total Value****including all overheads and MFF** |
| TOTAL A. Set-up and Close-down Fees | £[*insert value*] |
| TOTAL B. Clinical Trial Subject’s visit Fees | £[*insert value*] |
| TOTAL C. All other Fees EXCLUDING additional itemised costs, Pharmacy additional costs and amendment fees as tabulated above which are charged ‘as incurred’ | £[*insert value*] |
| **Grand Total for the Clinical Trial** | £[*insert value*] |

**Payment Details**

Following confirmation of invoice content from Sponsor / Affiliate prior to invoice generation, invoices should be sent to the following invoice address:

|  |  |
| --- | --- |
| Name:  | *[Sponsor / Affiliate to insert relevant details]* |
| Job title: | *[Sponsor / Affiliate to insert relevant details]* |
| Address: | *[Sponsor / Affiliate to insert relevant details]* |
| Reference on Invoice: | *[Sponsor / Affiliate to insert relevant details]* |
| Telephone No:  | *[Sponsor / Affiliate to insert relevant details]* |
| Fax no: | *[Sponsor / Affiliate to insert relevant details]* |
| Email: | *[Sponsor / Affiliate to insert relevant details]* |

*[Insert following table if Sponsor / Affiliate has an alternative address at which to receive invoices which is different to the invoice address (i.e. the legal entity) above]*

The invoice referencing the invoice address in the table above should be sent to the following recipient for processing:

|  |  |
| --- | --- |
| Name:  | *[Sponsor / Affiliate to insert relevant details]* |
| Job title: | *[Sponsor / Affiliate to insert relevant details]* |
| Address: | *[Sponsor / Affiliate to insert relevant details]* |
| Reference on Invoice: | *[Sponsor / Affiliate to insert relevant details]* |
| Telephone No:  | *[Sponsor / Affiliate to insert relevant details]* |
| Fax no: | *[Sponsor / Affiliate to insert relevant details]* |
| Email: | *[Sponsor / Affiliate to insert relevant details]* |

Invoicing queries should be sent to:

|  |  |
| --- | --- |
| Name:  | *[*Trust *to insert relevant details]* |
| Job title: | *[*Trust *to insert relevant details]* |
| Address: | *[*Trust *to insert relevant details]* |
| Reference on Invoice: | *[*Trust *to insert relevant details]* |
| Telephone No:  | *[*Trust *to insert relevant details]* |
| Fax no: | *[*Trust *to insert relevant details]* |
| Email: | *[*Trust *to insert relevant details]* |

Payments by the Sponsor / Affiliate will be made with reference *[insert* Trial *identifier reference for inclusion on invoice]* by BACS to:

|  |  |
| --- | --- |
| Bank | *[*Trust *to insert relevant details]* |
| Address | *[*Trust *to insert relevant details]* |
| Account Name | *[*Trust *to insert relevant details]* |
| Account No | *[*Trust *to insert relevant details]* |
| Sort Code | *[*Trust *to insert relevant details]* |
| Swift Code | *[*Trust *to insert relevant details]* |
| IBAN No | *[*Trust *to insert relevant details]* |
| VAT Code | *[*Trust *to insert relevant details if applicable or mark as Not Applicable]* |

**Appendix 5**

**CONDITIONS APPLICABLE TO THE INVESTIGATOR**

The Trust represents and warrants the following.

(a) he 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 which might prevent or restrict his performance of the obligations detailed in this Agreement.

1. where the Trust is not the Investigator’s principal employer, he has notified his principal employer of his proposed participation in the Clinical Trial and, where relevant, his supervision of Trial Site Personnel. He has obtained all necessary consents from his principal employer relating to this.
2. he is not involved in any regulatory or misconduct litigation or investigation by the Food and Drug Administration, the Medicines and Healthcare products Regulatory Agency, the European Medicines Agency, the General Medical Council or other regulatory authorities. No data produced by him in any previous clinical Clinical Trial has been rejected because of concerns as to its accuracy or because it was generated by fraud.
3. he has considered, and is satisfied that, facilities appropriate to the Clinical Trial are available to him at the Trial Site and that he is supported, and will continue to be supported, by medical and other staff of sufficient number and experience to enable the Trust to perform the Clinical Trial efficiently and in accordance with its obligations under the Agreement.
4. he is employed by, or has a contract for services (commonly known as an honorary contract) with, the Trust, which is a member of the Clinical Negligence Scheme for Trusts (CNST).

1. during the Clinical Trial, he will not serve as an investigator or other significant participant in any clinical trial for another Sponsor / Affiliate if such activity might adversely affect his ability to perform his obligations under this Agreement.
2. where the Trust is not a member of the NHLA CNST, he/she carries medical liability insurance (or the Trust carries medical liability insurance covering him) and details and evidence of the coverage will be provided to Sponsor / Affiliate upon request.
3. neither he/her, nor his/her spouse nor any dependent children, have entered into and will not enter into any financial arrangements with the Sponsor / Affiliate to hold financial interests in the Sponsor / Affiliate that are required to be disclosed pursuant to any applicable laws, namely (i) any financial arrangement whereby the value of the compensation paid in respect of the performance of the Clinical Trial could be influenced by the outcome of the Clinical Trial, (ii) any proprietary interest in the product being tested, (iii) any significant equity interest in the Sponsor / Affiliate and (iv) any significant payments from the Sponsor / Affiliate such as grants to fund on-going research, compensation in the form of equipment, retainers for on-going consultation or honoraria. In the case of subparagraphs (iii) and (iv) the Investigator understands that such prohibitions relate to the period that the Investigator is carrying out the Clinical Trial and for 1 year following completion of the Clinical Trial.

**Appendix 6**

**MATERIAL TRANSFER PROVISIONS\***

1. Where the Protocol requires the Trust to supply Material to the Sponsor / Affiliate, this Appendix 6 shall apply.
2. In accordance with the Protocol, the Trust shall send Material to the Sponsor / Affiliate or, in accordance with provision 8 below, to a third party nominated by the Sponsor / Affiliate.
3. The Trust 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 or the Human Tissue Act (Scotland) Act 2006 (as the case may be) and as required by the Protocol.
4. Subject to provision 3 above, the Materials are supplied without any warranty, expressed or implied, including as to their properties, merchantable quality, fitness for any particular purpose, or freedom from infection.
5. The Sponsor / Affiliate shall ensure, or procure through an agreement with the Sponsor’s / Affiliate’s nominee as stated in provision 2 above that:

5.1 the Material is used in accordance with the Protocol, the consent of the Participant, and the ethics approval for the Study;

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

5.3 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 studies approved by an appropriate ethics committee and in accordance with the Participant’s consent; and

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

1. The Parties shall comply with all relevant laws, regulations and codes of practice governing the research use of human biological material.
2. The Trust and the Sponsor / Affiliate shall each be responsible for keeping a record of the Material that has been transferred according to this Appendix 6.
3. To the extent permitted by law the Trust and its staff shall not be liable for any consequences of the supply to or the use by the Sponsor / Affiliate of the Material or of the supply to or the use by any third party to whom the Sponsor / Affiliate subsequently provides the Material or the Sponsor’s nominee as stated in provision 2 above, save to the extent that any liability which arises is a result of the negligence of the Trust.
4. The Sponsor / Affiliate undertakes that, in the event that Material is provided to a third party in accordance with provision 2 above, it shall require that such third party shall undertake to handle any Material related to the Study 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.
5. Unless otherwise agreed, any surplus Material that is not returned to the Trust or retained for future research shall be destroyed in accordance with the Human Tissue Act.

\*These provisions do not remove the need for the Sponsor to clearly lay out in their Protocol (and to potential Participants in the patient information sheet/s) at a minimum the following information for all Material taken: 1) The nature of the Materials, 2) The reason that the Material is being taken, 3) where the Material is to be sent and, 4) what will happen to any remaining Material once it has been processed/analysed, etc. for the purposes of this Study (e.g. return, retention or destruction). Detailed guidance on what information should be included in a protocol may be found on the HRA website: [www.hra.nhs.uk](http://www.hra.nhs.uk)