# Model Non-Interventional Study Agreement

**The information set out below provides a checklist of information that needs to be included in the model Non-Interventional Study Agreement (mNISA) in preparation for execution by the Parties.**

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

### Footers

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

### Front page

Complete all of the required information.

### Recitals

Add, remove and / or update recitals as applicable to the Non-Interventional Study (as a preamble to the Agreement, such changes do not constitute modification to the template Agreement). Recital D should be completed where a corporate Affiliate of the Sponsor is formally empowered by the Sponsor to sign the Agreement on behalf of the Sponsor thereby binding the Sponsor as Party to the Agreement (and should be removed where this is not the case).

**Main Body of the Agreement**

**Clause 4.11** – Delete either the option for enrolment of Participants or use of Personal Data / Material only. Insert target number for the Participating Organisation.

**Clause 4.12** – Amend this clause accordingly depending on whether Participants will be enrolled or only their Personal Data / Material.

**Clause 4.13.9** – Insert the appropriate number of years and working days.

**Clause 4.13.9.b** – Insert e-mail address for Participating Organisation archiving contact.

**Clause 4.13.9.c** – Choose one option either for physical or electronic archiving to be used.

**Clauses 4.13.10** and **4.13.11** – Delete either or both clauses depending upon whether Material will be analysed locally, centrally or if no Material will be analysed.

**Clause 4.15** – Delete if no equipment or resources are provided by the Sponsor.

**Clause 5.4** – Delete yellow highlighted text if not applicable.

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

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

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

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

### Signature page

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

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

### Appendix 1

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

### Appendix 2

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

### Appendix 4

Check the box at Appendix 4 if it is not relevant to the specific Non-Interventional Study.

### Appendix 5

Complete details of any equipment and / or resources being supplied to the Participating Organisation for the Non-Interventional Study. Clearly indicate whether liability will be determined in accordance with the main body of the Agreement, or pursuant to an MIA (N.B. cover cannot be provided pursuant to an MIA for any Participating Organisations in England or Northern Ireland, or NHS primary care independent contractor Participating Organisations in Scotland or Wales).

Where no equipment and / or resources is / are being provided, check the box at Appendix 5 to indicate the Appendix is not used.

### Appendix 6

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

Check the box at Appendix 6 if it is not relevant to the specific Non-Interventional Study.

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

[**INSERT** FULL NAME OF THE NON-INTERVENTIONAL STUDY]

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

# Non-Interventional Study Agreement

**Between**

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

**‘Participating Organisation’**

AND

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

**the ‘Sponsor’**

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

# Non-Interventional Study Agreement

**Clause**

1 Definitions

2 Principal Investigator and Personnel

3 Non-Interventional Study Governance

4 Obligations of the Parties and the Principal Investigator

5 Liabilities and Indemnities

6 Data Protection

7 Freedom of Information

8 Confidential Information

9 Publicity

10 Publications

11 Intellectual Property

12 Finances

13 Term

14 Termination

15 Relationship of the Parties

16 Agreement and Modification

17 Force Majeure

18 Notices

19 Dispute Resolution

20 Miscellaneous

Appendix 1 Timelines and Responsibilities of the Parties

Appendix 2 Financial Arrangements

Appendix 3 Conditions Applicable to the Principal Investigator

Appendix 4 Material Transfer Provisions

Appendix 5 Equipment and Resources

Appendix 6 Formal Delegation of Authority to a Corporate Affiliate of the Sponsor to Contractually Bind Sponsor

**Whereas**

1. The Sponsor is a [insert type of company e.g. pharmaceutical, medical device etc] company involved in [insert company’s interests e.g. post marketing surveillance etc].
2. The Participating Organisation is concerned with the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare.
3. The Sponsor wishes to contract with the Participating Organisation to undertake a Non-Interventional Study.
4. References throughout this Agreement to Sponsor shall be construed to include reference to [Insert name of Affiliate], as Affiliate empowered by the Sponsor to legally bind the Sponsor to this Agreement and to act on its behalf, in accordance with Appendix 6.
5. The study is an [IRAS STUDY TYPE].

It is therefore, agreed that the following terms and conditions shall apply to the conduct of the Non-Interventional Study (as further defined below):

## Definitions

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

**Affiliate**
means any business entity that controls, is controlled by, or is under the common control with the Sponsor, save where there are contractual arrangements in place to exclude such affiliate. For the purposes of this definition, a business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity, by contract or otherwise;

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

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

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

**Code of Practice**
means the most recent editions of the Code of Practice for the Pharmaceutical Industry, issued by the ABPI or the Code of Ethical Business Practice, issued by the ABHI, from time to time;

**Confidential Information**
means all confidential information (however recorded or preserved) disclosed by a Party and / or its Affiliate to the other Party, in connection with the Non-Interventional Study, which is information that would be regarded as confidential by a reasonable business person, including (but not limited to):

* business, affairs, plans, intentions or market opportunities
* operations, processes, product information, designs, trade secrets or Know-How
* any information developed by the Parties in connection with the Non-Interventional Study in the course of carrying out this Agreement
* the Protocol and Appendix 2 to this Agreement (‘Financial Arrangements’);

**Confidential Participant Information**

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

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

**Data Protection Laws and Guidance**
means the GDPR, the Data Protection Act 2018, the Privacy and Electronic Communications (EC Directive) Regulations 2003, as well as any legally enforceable NHS requirements, Codes of Practice or Guidance issued by the Information Commissioner’s Office, in each case in force from time to time in England, Northern Ireland, Scotland and / or Wales;

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

**EEA**
means the European Economic Area comprising the countries of the European Union as well as Iceland, Liechtenstein and Norway;

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

**EIR**

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

**Ethically-Approved Participant Payments**

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

**Expenses**

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

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

**GDPR**

means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of Personal Data and on the free movement of such data, as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019;

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

**Know-How**
means all technical and other information that is not in the public domain (other than as a breach of confidence) including, but not limited to, information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data and manufacturing data whether or not protected by Intellectual Property Rights or any applications for such rights;

**Localised Online iCT**
means the localised, Participating Organisation-specific output from the online interactive Costing Tool (iCT), which is used by the Sponsor to agree the prices for the conduct of the Non-Interventional Study, together with any amendments thereof made in accordance with Clause 12.2 of this Agreement and Clause 4 of Appendix 2 of this Agreement, as agreed between the Parties and incorporated into this Agreement by reference;

**Material**
means any clinical biological sample, or portion thereof, derived from Non-Interventional Study Subjects, including information related to such Material, analysed by the Participating Organisation in accordance with the Protocol, or otherwise supplied under Appendix 4 (where applicable) to the Sponsor or its nominee;

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

**Multi-Centre Study**
means a Non-Interventional Study where at least one other institution is participating in the Non-Interventional Study;

**Non-Interventional Study**

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

**Participant**
means a person [enrolled to participate] [whose Personal Data and/or Material is being used] (**delete as applicable**) in the Non-Interventional Study according to criteria detailed in the Protocol;

**Personal Data**
means any and all information, data and material of any nature received or obtained by either Party in connection with this Agreement which is personal data as defined in the Data Protection Laws and Guidance and which relates to a Participant (or potential Participant) and / or their treatment or medical history;

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

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

**Principal Investigator**
means the person who will take primary responsibility for the conduct of the Non-Interventional Study at the Site on behalf of the Participating Organisation;

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

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

**Protocol**
means the full description of the Non-Interventional Study with the reference number set out on the front page of this Agreement, together with any amendments thereof made in accordance with Clause 16.3 and incorporated into this Agreement by reference;

**Pseudonymised Data**
means individual-level data relating to a natural person (as opposed to aggregated data) who is made no longer identified or identifiable from that data by virtue of the replacement of personal identifiers with a code, or equivalent, and which is safeguarded as non-identifiable in accordance with this Agreement;

**Regulatory Authority**

means any regulatory authority responsible for the review and approval of the Non-Interventional Study, including, for the purposes of this definition, the NHS / HSC research ethics committee;

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

**Results**
means the research findings produced in the Non-Interventional Study;

**Retention Period**

means the time period in which the Non-Interventional Study records are retained by the Participating Organisation after Study Completion, as specified in Clause 4.13.9;

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

**Site File**
means the file maintained by the Principal Investigator in line with scientific good practice and governance principles;

**Site Study Completion**
means the conclusion of all Protocol required activities for all [enrolled] Participants at the Site;

**Sponsor File**

 means the file maintained by the sponsor in line with scientific good practice and governance principles;

**Study Completion**
means the conclusion of all Protocol required activities for all [enrolled] Participants in all locations where the Sponsor (or any Affiliate of the Sponsor) is carrying out the Non-Interventional Study described in the Protocol;

**Study Monitor**
means one or more persons appointed by the Sponsor, or Affiliate, to monitor compliance of the Non-Interventional Study with Sponsor requirements and to conduct source data verification;

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

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

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

* 1. Any reference to a statutory provision, code or guidance shall be deemed to include reference to any subsequent modification or re-enactment of it.
	2. The headings to clauses are inserted for convenience only and shall not affect the interpretation or construction of this Agreement.
	3. Where appropriate, words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders.
	4. Where the Participating Organisation is a Health and Social Care (HSC) organisation in Northern Ireland, references throughout this document to the NHS should be construed to include HSC as applicable.
	5. A reference to this Agreement or to any other agreement or document referred to in this Agreement is a reference to this Agreement or such other agreement or document as amended, varied or novated (in each case other than in breach of the provisions of this Agreement) from time to time.
	6. If any Clause or part of this Agreement is found by any court, tribunal, administrative body or authority of competent jurisdiction to be illegal, invalid or unenforceable then that provision shall, to the extent required, be severed from this Agreement and shall be ineffective without, as far as possible, modifying any other clause or part of this Agreement and shall not affect any other provisions of this Agreement which shall remain in full force and effect.

## Principal Investigator and Personnel

* 1. The Participating Organisation represents that it is entitled to procure, and the Participating Organisation will procure the services of the Principal Investigator, any and all Sub-Investigators and other Personnel, to fulfil these functions and shall ensure the performance of the obligations of the Principal Investigator, any and all Sub-Investigators and other Personnel set out in Appendix 3 and elsewhere in this Agreement.
		1. Where the Participating Organisation is not the Principal Investigator’s substantive employer it will notify the Principal Investigator’s substantive employer in a timely way of the Principal Investigator’s proposed involvement in the Non-Interventional Study. Any financial or other arrangements relating to the Principal Investigator's involvement in the Non-Interventional Study as Principal Investigator will be agreed directly between the Participating Organisation and the Principal Investigator’s substantive employer.
	2. The Participating Organisation represents that the Principal Investigator holds the necessary registration and has the necessary expertise, time and resources to perform the Non-Interventional Study and will ensure that the Principal Investigator is made aware of and acknowledges the obligations applicable to the Principal Investigator set out in this Agreement, including but not limited to those set out in Appendix 3.
	3. The Participating Organisation shall notify the Sponsor if the Principal Investigator ceases to be employed by or associated with the Participating Organisation, is erased from the medical register (or equivalent UK professional register where the Principal Investigator is not a medical doctor) or is otherwise sanctioned by an applicable regulatory or other governmental authority, or is otherwise unavailable to continue as Principal Investigator. The Participating Organisation shall use all reasonable endeavours to find a replacement acceptable to both the Sponsor and the Participating Organisation, subject to the Participating Organisation’s overriding obligations in relation to Participants and individual patient care. If no mutually acceptable replacement can be found the Sponsor may terminate this Agreement pursuant to Clause 14.3.
	4. The Participating Organisation shall procure, and shall ensure that the Principal Investigator procures, the performance of the obligations of the Personnel as set out in this Agreement.
	5. The Principal Investigator and / or Personnel shall attend any meetings regarding the Non-Interventional Study as reasonably requested by the Sponsor (“**Investigator Meetings**”). Such meetings to be conducted by the Sponsor to convey or exchange information with the Principal Investigator, all Sub-Investigators or other Personnel to support the effective conduct or close-out of the Non-Interventional Study. The Participating Organisation agrees that no additional compensation shall be due hereunder for Principal Investigator’s or any other Personnel’s respective participation in Investigator Meetings. The Sponsor shall reimburse or pay for reasonable pre-approved expenses for attendance at the Investigator Meetings upon receipt of documentation. It is further agreed that any such expenses will be paid at the rate of fair market value (as detailed in the applicable Code of Practice) and subject to the documentation evidencing the expenses being in sufficient detail for the Sponsor’s financial reporting purposes, provided that the required detail does not impose an unreasonable administrative burden upon the Participating Organisation. Such expenses may be publicly reportable.
	6. The Participating Organisation represents that it will support the Principal Investigator to make good faith diligent efforts to ensure the completion of all case report forms, where applicable, in a timely manner.

## Non-Interventional Study Governance

* 1. If applicable, the Sponsor shall inform the Participating Organisation and the Principal Investigator of the name and telephone number of the Study Monitor and the name of the person who will be available as a point of contact.
	2. To the extent applicable to each, the Parties shall comply with, and the Participating Organisation shall ensure that the Principal Investigator and all Personnel who are providing any manner of service related to the Non-Interventional Study comply with, all relevant laws, including but not limited to:
		1. The Human Rights Act 1998.
		2. The Data Protection Laws and Guidance.
		3. The Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006, to be determined in accordance with the place of constitution of the Participating Organisation.
		4. The Bribery Act 2010.
		5. Relevant law having effect by virtue of ss2-4 of the European Union (Withdrawal) Act 2018.
		6. (In Northern Ireland) laws of the European Union having effect as a result of the protocol on Ireland / Northern Ireland.
	3. The Parties shall comply with, and the Participating Organisation shall ensure that the Principal Investigator and all Personnel who are providing any manner of service related to the Non-Interventional Study comply with, all relevant guidance relating to clinical research from time to time in force including but not limited to:
		1. the World Medical Association Declaration of Helsinki entitled, ‘Ethical Principles for Medical Research Involving Human Subjects’.
		2. the UK Policy Framework.
		3. if applicable, the UK Research and Innovation policies and principles entitled, “[Human Biological Samples](https://www.ukri.org/about-us/policies-standards-and-data/good-research-resource-hub/human-biological-samples/)”.
	4. The Participating Organisation shall ensure that the Principal Investigator, Sub-Investigators and any Sub-Investigators joining the Non-Interventional Study following the initiation of the Non-Interventional Study, undertake any such appropriate training as the Sponsor may consider necessary for the conduct of the Non-Interventional Study, including but not limited to the training and provision of information given during Investigator Meetings.
	5. **Location of the Non-Interventional Study**
	The Parties acknowledge that the Participating Organisation might have responsibility for several hospitals that may have the potential to be involved in the Non-Interventional Study. It is agreed however, that only those Sites that have been agreed between the Parties shall participate in the Non-Interventional Study.
	6. **Anti-Bribery and Corruption**
		1. Each Party warrants and represents that it has not committed any of the following acts (“**Prohibited Acts**”):
1. an offence under the Bribery Act 2010; or
2. other than in accordance with applicable laws, valid agreements and the provisions of this Agreement, offered, given or agreed to give any officer or employee of the other Party any gift or consideration of any kind, as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this Agreement or any other agreement with the other Party or for showing or not showing favour or disfavour to any person in relation to this Agreement or any other agreement with the other Party; or
3. in connection with this Agreement, paid or agreed to pay any commission other than a payment in accordance with this Agreement that has not otherwise been disclosed in writing to the other Party.
	* 1. If either Party has committed or commits any of the Prohibited Acts in relation to this Agreement, the other Party shall be entitled to terminate this Agreement in accordance with Clause 14, in addition to any other remedy available.

## Obligations of the Parties and the Principal Investigator

* 1. Each Party represents and warrants that it has the right and authority to enter into this Agreement and that it has the capability and capacity to fulfil its obligations under this Agreement.
	2. The Parties agree to adhere to the principles of medical confidentiality in relation to Participants involved in the Non-Interventional Study.
	3. Where required, the Sponsor shall be responsible for obtaining and maintaining a Regulatory Authority approval, and any other approvals needed for the conduct of the Non-Interventional Study.
	4. The Principal Investigator shall be responsible for:
		1. ensuring that where required, the appropriate informed consent form, approved by the Sponsor and the relevant research ethics committee, is signed by or on behalf of each Participant before the first Non-Interventional Study related procedure starts for that Participant
		2. making any necessary disclosures of financial interests and arrangements, as defined and requested by the Sponsor, provided that such disclosures may be made prior to the commencement of work activities associated with the Non-Interventional Study as well as subsequent to Site Study Completion, and that the Principal Investigator, (all) Sub-investigator(s) and Personnel shall update such disclosures as necessary to maintain their accuracy and completeness during the term of this Agreement and for any other period required by applicable law.
	5. As detailed in the applicable Code of Practice, the Sponsor shall submit the Non-Interventional Study for listing in a free, publicly accessible registry within forty-two (42) calendar days of initiation of the Non-Interventional Study by [enrolment] [access to the Personal Data and / or Material] (**delete** as applicable) of the first Participant. The Participating Organisation agrees that such listing may include a summary of the Protocol, the name of the Participating Organisation and the details of the Site(s) where the Non-Interventional Study is being conducted. Subject to Clause 6 of this Agreement, in the event that the Sponsor intends to publish the name of the Principal Investigator on a publicly accessible registry, the Sponsor shall be responsible for obtaining the written permission of the Principal Investigator for the use of the Principal Investigator’s name (and any other personal information) in such a publication.
	6. The Parties shall conduct the Non-Interventional Study in accordance with the terms of this Agreement (including the incorporated Protocol) and, where required, the terms and conditions of the favourable opinion of the research ethics committee.
	7. Until the Sponsor has obtained approval from the research ethics committee (if required) and any other necessary approvals, it shall not commence the Non-Interventional Study at the Participating Organisation, nor shall it authorise the Participating Organisation to commence the Non-Investigational Study at the Participating Organisation. The Participating Organisation shall ensure that no activity mandated by the Protocol takes place in relation to any Participant until it is satisfied that all relevant approvals have been obtained.
	8. In the event of any substantial amendments being made to the Protocol, the amendments shall be signed by the Principal Investigator and shall be implemented by the Personnel as required by the Sponsor. The Sponsor shall initiate simultaneously the change control procedures set out in Clause 16.3 of this Agreement.
	9. The Sponsor shall make the Protocol available to the Principal Investigator and provide evidence of the approvals set out in Clause 4.6 and the Principal Investigator shall include such documents in the Site File. The Sponsor shall ensure that any and all information of which the Sponsor is aware, or which comes to the attention of the Sponsor from time to time, and which may, in the reasonable opinion of the Sponsor, be materially relevant to the conduct of the Non-Interventional Study, will also be provided to the Principal Investigator for inclusion in the Site File.
	10. Subject to the Participating Organisation’s and the Principal Investigator’s overriding obligations in relation to Participants and individual patient care, the Participating Organisation shall ensure that neither it nor the Principal Investigator, nor the Personnel shall during the term of this Agreement conduct any other Research that might hinder the Participating Organisation’s or Principal Investigator’s ability to [enrol and] study the required cohort of Participants.
	11. The Participating Organisation shall use its best endeavours to ensure that the Principal Investigator [enrols] [includes the Personal Data and / or Material] **(delete option not applicable)** [a minimum of] **(DELETE if not applicable)** [**INSERT NUMBER**] Participant(s), to participate in the Non-Interventional Study and the Parties shall conduct the Non-Interventional Study in accordance with the Timelines.
	12. In the event that the Non-Interventional Study is part of a Multi-Centre Study, the Sponsor may amend the number of Participants to be [enrolled] [included] (delete as applicable) pursuant to the Protocol as follows:
		1. If in the reasonable opinion of the Sponsor, [enrolment] [inclusion] (delete as applicable) of the Participants at the Participating Organisation is proceeding at a rate below that required to enable the Timelines to be met, and upon the Sponsor’s request to increase [the enrolment rate] [the rate of Personal Data records being Processed and / or Material samples being processed] (delete as applicable), the Participating Organisation is unable to comply, the Sponsor may by reasonable notice to the Participating Organisation, require the Participating Organisation to cease [enrolment] [inclusion] (delete as applicable) of Participants.
		2. If with respect of the Non-Interventional Study, the global [enrolment] [inclusion] (delete as applicable) target has been reached, upon receipt of a notice, the Participating Organisation shall ensure that the Principal Investigator shall immediately stop the [enrolment] [inclusion] (delete as applicable) of Participants and the terms and conditions of this Agreement shall not apply to individuals who at the time of receipt of such notice have not signed informed consent, where required, and have not been [enrolled] [included] (delete as applicable) in the Non-Interventional Study. Payments shall be made according to the number of Participants [enrolled] [included] (delete as applicable) up to the date of receipt of the notice.
		3. If [enrolment] [inclusion] (delete as applicable) of Participants is proceeding at a rate above that which is required to meet the Timelines, the Sponsor may, with the written agreement of the Participating Organisation, increase the number of Participants to be [enrolled] [included] (delete as applicable) at the Site and the payment to be made will be adjusted in accordance with Clause 16.2.
	13. **Access, Research Misconduct and Regulatory Authorities**
		1. The Participating Organisation represents that neither it nor, to the best of its knowledge arrived at after reasonable due diligence, any of the Personnel, including the Principal Investigator, are restricted or prevented under any law from taking part in clinical research and the Participating Organisation will not knowingly use in any capacity the services of any person who is so restricted or prevented under any such laws with respect to the services to be performed under this Agreement. During the term of this Agreement and for one (1) year after its termination or expiry, the Participating Organisation and the Principal Investigator will notify the Sponsor if the Participating Organisation and / or the Principal Investigator, becomes aware of any restriction or prevention being applied to it, the Principal Investigator or any of the Personnel.
		2. The Participating Organisation represents that it and, to the best of its knowledge arrived at after reasonable due diligence, the Principal Investigator or any of the Personnel, are not the subject of any past or pending government or regulatory investigation, inquiry, warning or enforcement action (collectively “**Agency Action**”) related to its conduct of research that has not previously been disclosed to the Sponsor. The Participating Organisation will promptly notify the Sponsor if it becomes aware of any Agency Action regarding compliance with ethical, scientific or regulatory standards for the conduct of research, if the Agency Action relates to events or activities that occurred prior to or during the period in which the Non-Interventional Study is conducted.
		3. Each Party shall inform the other immediately upon becoming aware of any Serious Breach of the Protocol and / or any other rules, principle or guidance, relating to the Non-Interventional Study at the Site. The Sponsor shall, at its discretion, inform other sites that a Serious Breach has occurred but shall not be under any obligation to do so. For the purposes of this Clause 4.13.3, a “**Serious Breach**” is a breach that is likely to affect, to a significant degree:
1. the safety or physical or mental integrity of the Participants; or
2. the scientific value of the Non-Interventional Study.
	* 1. If applicable, the Participating Organisation shall permit the Study Monitor and any Auditor or Inspector access to all relevant clinical data of the Participants for monitoring and source data verification, such access (be it on site, or via remote means) to be arranged at mutually convenient times and on reasonable notice. The monitoring may take such form as the Sponsor reasonably thinks appropriate, including the right to inspect any facility being used for the conduct of the Non-Interventional Study and to examine, in-person or by remote means, any procedures or records relating to the Non-Interventional Study, subject to compliance with Data Protection Laws and Guidance. The Sponsor will alert the Participating Organisation, promptly in accordance with Clause 18.3, of significant issues (in the opinion of the Sponsor) relating to the conduct of the Non-Interventional Study.
		2. In the event that the Sponsor reasonably believes that there has been research misconduct in relation to the Non-Interventional Study, the Participating Organisation shall, and shall ensure that the Principal Investigator shall, provide all reasonable assistance to any investigation undertaken by or on behalf of the Sponsor into any alleged research misconduct. The results of the investigation shall, subject to any obligations of confidentiality, be communicated to the Participating Organisation. In the event that the Participating Organisation reasonably believes that there has been research misconduct in relation to the Non-Interventional Study, the Sponsor shall provide all reasonable assistance to any investigation undertaken by or on behalf of the Participating Organisation into any alleged research misconduct. The results of the investigation shall, subject to any obligations of confidentiality, be communicated to the Sponsor.
		3. Participating Organisation shall promptly inform the Sponsor of any intended or actual inspection, written enquiry and / or visit to the Site by any Regulatory Authority, in connection with the Non-Interventional Study, and forward to the Sponsor copies of any correspondence from any such Regulatory Authority relating to the Non-Interventional Study. The Participating Organisation will use reasonable endeavours to procure that the Sponsor may have a representative present during any such visit or inspection and the opportunity to review and comment on the Participating Organisation’s response to the visit or inspection by a Regulatory Authority in connection with the Non-Interventional Study. The Parties further acknowledge that inspections and written enquiries by Regulatory Authorities may also occur after the conclusion of the Non-Interventional Study and both Parties shall cooperate with any such inspection or written enquiry.
		4. The Participating Organisation will permit the Sponsor to examine the conduct of the Non-Interventional Study and the Site upon reasonable advance notice during regular business hours to determine that the Non-Interventional Study is being conducted in accordance with the Protocol. The Parties agree that the Sponsor shall have the right to audit Non-Interventional Study records during, and subsequent to, the Non-Interventional Study.
		5. Upon Site Study Completion (whether prematurely or otherwise), the Principal Investigator shall co-operate with the Sponsor in producing a report of the Non-Interventional Study detailing the methodology, Results and containing an analysis of the Results and drawing appropriate conclusions.
		6. The Participating Organisation will archive Non-Interventional Study records following Site Study Completion, in accordance with the MRC Principles and Guidelines for Good Research Practice. The Participating Organisation shall retain all Non-Interventional Study records for a Retention Period of [**INSERT NUMBER**] years after Study Completion. Upon the expiry of the Retention Period the Participating Organisation shall transfer such records to the Sponsor if requested by Sponsor, excluding any Confidential Participant Information, and shall not destroy any records without Sponsor’s prior written approval, such approval not to be unreasonably withheld or delayed. Notwithstanding the foregoing, in the event that no response is received from the Sponsor within **[INSERT NUMBER]** workingdays of receipt by the Sponsor of a written request by the Participating Organisation for approval to destroy such records, the Participating Organisation may proceed to destroy the records and such destruction shall not be in breach of this Agreement.
3. The Participating Organisation will archive the Non-Interventional Study records either in line with its usual archiving arrangements, or will collaborate with the Sponsor to arrange appropriate archiving outside usual Participating Organisation practice.
4. All arrangements for access to documents at the Participating Organisation should be with the Participating Organisation’s responsible person for archiving: [insert email address] **(recommend using a generic email address).**
5. In the event that costs of archiving are to be incurred by the Participating Organisation, including all preparation and retrieval costs relating to any reasonable request to access the Non-Interventional Study documentation, the Sponsor warrants and confirms that it or its Agent will pay all such costs as provided by the Participating Organisation as a one-off payment at [**DELETE** ONE OPTION AND RETAIN THE OTHER] [for archiving physical records close-down of the Non-Interventional Study at the rate applicable at the time. The minimum price for the archiving of physical records will be £750 per box (inclusive of all overheads but exclusive of VAT, where applicable), subject to the prevailing cost of the NHS provider service at Site Study Completion] [of £750 (inclusive of all overheads but exclusive of VAT, where applicable) for the establishment of the Participating Organisation’s electronic Site File, including the arrangements for the archiving of the same, following commencement of this Agreement]. In the event that the Non-Interventional Study records are archived offsite by the Sponsor and the Participating Organisation does not incur any costs, no amounts will be payable to the Participating Organisation.
6. Notwithstanding the foregoing, the Participating Organisation will retain responsibility for the Site File and access thereto. The Site File shall be archived separately to the Sponsor File.
	* 1. [**DELETE IF NOT APPLICABLE**] Where the Participating Organisation is responsible for analysis of Material during the course of the Non-Interventional Study it shall ensure that such analysis is conducted at a laboratory approved by the Sponsor or, in the case of point of care analysis, by methodology and using equipment that is acceptable to, or provided by, the Sponsor. The Participating Organisation shall ensure that analysis of Material is undertaken in accordance with the Protocol and any other document agreed between the Sponsor and the Participating Organisation (including the provisions of Appendix 4).
		2. [**DELETE IF NOT APPLICABLE**] Where the Sponsor undertakes the analysis of Material and / or has contracted with a third-party laboratory (“**Central Laboratory**”) to undertake the analysis of Material, the Sponsor shall comply, and shall ensure the Central Laboratory shall comply, with the terms of Appendix 4 herein that are expressed to be the responsibility of the Sponsor.
	1. **Updating Contact Details, Including for Notices and Payments**

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

* 1. **[DELETE IF NOT APPLICABLE]** **Equipment and Resources**
	The Parties agree that the Sponsor shall arrange for the provision of the equipment and resources to the Participating Organisation, pursuant to the terms set out in Appendix 5.

## Liabilities and Indemnities

* 1. The Sponsor shall indemnify the Participating Organisation and its Agents, against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands to the extent they arise or result from the negligent acts or omissions of, or the wilful misconduct of the Sponsor, and / or contracted third party, in its performance of this Agreement or in connection with the Non-Interventional Study.
	2. The Sponsor shall maintain all proper insurance arrangements to cover liabilities arising from its conduct in the Non-Interventional Study, in respect of any claims brought by or on behalf of a Participant. The Sponsor shall provide the Participating Organisation such evidence of its insurance maintained pursuant to Clause 5.1 as the Participating Organisation shall from time to time reasonably request.
	3. In no circumstances shall either Party be liable to the other Party in contract, tort or delict (if the Participating Organisation is constituted in Scotland) (including negligence or breach of statutory duty) or otherwise howsoever arising or whatever the cause thereof, for any loss of profit, business, reputation, contracts, revenues or anticipated savings or for any special, indirect or consequential damage of any nature, which arises directly or indirectly from any default on the part of the other Party.
	4. Subject to Clauses 5.5 and 5.6 the Participating Organisation’s liability to the Sponsor arising out of or in connection with any breach of this Agreement or any act or omission of the Participating Organisation in connection with the performance of the Non-Interventional Study shall in no event exceed the fees payable by the Sponsor to the Participating Organisation under this Agreement. For clarity, the “fees payable” are the total sum of the amounts specified in Appendix 2 based on the full enrolment of Participants for the full period of the Non-Interventional Study. **[DELETE IF NOT APPLICABLE]** In the case of equipment loaned to the Participating Organisation for the purposes of the Non-Interventional Study, the Participating Organisation’s liability for loss or damage to this equipment arising from its negligence shall exclude fair wear and tear and shall not exceed the value of the equipment.
	5. In respect of any wilful and / or deliberate breach by the Participating Organisation, or any breach of Clauses 6, 8, 10 or 11 the Participating Organisation’s liability to the Sponsor arising out of or in connection with the breach shall not exceed two times the value of the Agreement. For clarity, the “value of the Agreement” is the total sum of the amounts specified in Appendix 2 based on the full enrolment of Participants for the full period of the Non-Interventional Study.
	6. Nothing in this Clause 5 shall operate so as to restrict or exclude the liability of either Party in relation to death or personal injury caused by the negligence or wilful misconduct of that Party or its Agents or employees, or to restrict or exclude any other liability of either Party that cannot be so restricted or excluded in law.
	7. Nothing in this Agreement will operate to limit or exclude any liability for fraud.

## Data Protection

* 1. The Parties agree:
		1. To comply with all Data Protection Laws and Guidance in Processing the Personal Data of actual and potential Participants. This Clause 6 is in addition to and does not replace, relieve or remove a Party’s obligations or rights under the Data Protection Laws and Guidance.
		2. When one Party is Processing Personal Data, as Controller, for which the other Party is at that time a separate and independent Controller, to promptly and without undue delay, notify and inform that other Party in the event of any Personal Data Breach that relates to that Personal Data.
	2. **Processing of Participant Personal Data**
		1. For the purpose of the Data Protection Laws and Guidance, the Sponsor is the Controller and the Participating Organisation is the Sponsor’s Processor of Personal Data which the Participating Organisation Processes for the purpose of the Non-Interventional Study.
		2. The Participating Organisation’s Processing of Personal Data, as a Processor of the Sponsor, shall be governed by this Agreement, including the Protocol, which sets out the subject matter, duration, nature and purpose of the Processing, the type of Personal Data and the categories of Data Subjects, and obligations and rights of the Sponsor as Controller.
		3. The Participating Organisation is the Controller of Personal Data Processed for purposes other than the Non-Interventional Study, for example the provision of medical care.
		4. The Participating Organisation, in its role as Processor of the Personal Data under Clause 6.2.1, agrees to only Process Personal Data for and on behalf of the Sponsor in accordance with the documented instructions of the Sponsor, including with regard to transfers of Personal Data to a third country or an international organisation. If the Participating Organisation is required by law to otherwise Process the Personal Data, the Participating Organisation shall notify the Sponsor before undertaking the Processing, or as soon as possible thereafter, unless such notification is prohibited on important grounds of public interest in accordance with GDPR Article 28(3)(a). In the case of such prohibition, the Participating Organisation shall notify the Sponsor as soon as possible once the prohibition is lifted, if it is lifted.
		5. The Participating Organisation agrees to comply with the obligations applicable to Processors described by Article 28 of the GDPR, as well as those additional obligations required by the Sponsor pursuant to this Agreement, including but not limited to the following:
1. implementing and maintaining appropriate technical and organisational security measures for Personal Data Processed in its systems, in keeping with its obligations as an NHS organisation, thereby providing guarantee to the Sponsor pursuant to GDPR Article 28(1);
2. ensuring that Personnel authorised to Process Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality (Article 28(3)(b));
3. taking all measures required by GDPR Article 32 in relation to the security of Processing (GDPR Article 28(3)(c));
4. subject to Clause 6.2.6 complying with the conditions described in GDPR Article 28(2) and (4) for engaging another Processor (GDPR Article 28(3)(d));
5. taking into account the nature of the Processing, assist the Sponsor, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising Data Subjects’ rights (GDPR Article 28(3)(e));
6. assisting the Controller, to ensure compliance with the obligations pursuant to GDPR Articles 32 to 36, taking into account the nature of the Processing and the information available to the Participating Organisation (GDPR Article 28(3)(f));
7. maintaining a record to demonstrate compliance with this Clause and Data Protection Laws and Guidance, including the records required pursuant to GDPR Article 30(2);
8. in the event of any Personal Data Breach by the Participating Organisation as a Processor of the Sponsor, the Participating Organisation shall:
9. promptly and without undue delay following discovery of such Personal Data Breach, send written notice of the incident via e-mail to [**insert**];
10. not make any statements or notifications about the Personal Data Breach (as it relates to the Processing for the purpose of the Non-Interventional Study) to any individual affected by the incident, the public or any third party without Sponsor’s prior written approval; and
11. immediately take steps to investigate and mitigate the Personal Data Breach and reasonably cooperate with the Sponsor.
	* 1. In furtherance of its obligations under Article 28 GDPR, the Participating Organisation agrees that it will not engage another Processor for the purpose of the Non-Interventional Study without prior written authorisation of the Sponsor (GDPR Article 28(2)), excepting where that other Processor is a Participant Identification Centre (PIC), in which case Clause 6.2.6 (a) shall apply;
12. In accordance with GDPR Article 28(2) the Participating Organisation may appoint PICs, on the basis of an unmodified template data processing agreement agreed in advance with the Sponsor, by notifying the Sponsor that they intend to contract the PIC. The Sponsor will be considered to have authorised this sub-processing if it does not notify the Participating Organisation to the contrary within [**INSERT NUMBER**, FOR EXAMPLE, FIVE (5)] working days.
	* 1. At the expiry or lapse of this Agreement, the Participating Organisation shall, at the choice of the Sponsor, destroy or return all Personal Data to the Sponsor unless there is a legal requirement for retention and storage (GDPR Article 28(3)(g)), and / or where that Personal Data is held by the Participating Organisation as Controller for its own purpose(s).
		2. The Participating Organisation will:
13. ensure that its Personnel and the Principal Investigator, do not Process Personal Data except in accordance with the Protocol and this Agreement;
14. take all reasonable steps to ensure the reliability and integrity of the Principal Investigator and any of its Personnel who have access to the Personal Data and will ensure that the Principal Investigator and the Personnel:
15. are aware and comply with the Participating Organisation’s duties under this Clause 6 (Data Protection);
16. are subject to mandatory training in their information governance responsibilities and have appropriate contracts, including sanctions, including for breach of confidence or misuse of Personal Data; and;
17. are informed of the confidential nature of the Personal Data and understand their responsibilities for information governance, including their obligation to Process Personal Data securely and to only disseminate or disclose it for lawful and appropriate purposes.
	* 1. The Participating Organisation agrees to:
18. Provide the Sponsor with evidence of its compliance with the obligations set out in this Agreement, and / or, at the Sponsor’s discretion and on reasonable notice, to allow the Sponsor, or a third party appointed by the Sponsor, to audit the Participating Organisation’s compliance with the obligations described in this Agreement, Data Protection Laws and Guidance (including but not limited to Article 28 GDPR), subject to the Sponsor, or its appointed third party, complying with all relevant health and safety and security policies of the Participating Organisation.
19. Obtain prior written agreement of the Sponsor to Process Personal Data outside of the UK and the EEA.
	* 1. In addition to the Participating Organisation’s obligations under Clause 6.2.9(b), where the Participating Organisation, acting as the Sponsor’s Processor, Processes Personal Data outside of the UK and the EEA, the Participating Organisation warrants that it does so in compliance with the Data Protection Laws and Guidance.
	1. **Sharing of Personal Data and / or Participant Pseudonymised Data**
		1. Neither Personal Data nor Pseudonymised Data of Participants shall be transferred by the Participating Organisation to the Sponsor unless this is required directly or indirectly to satisfy the purposes of this Agreement, or for the purposes of monitoring and reporting of events or in relation to a claim or proceeding brought by a Participant in connection with the Non-Interventional Study or is otherwise required by applicable law.
		2. The Sponsor agrees not to pass Personal Data or Pseudonymised Data of Participants provided under this Agreement to a third party, unless that third party is bound by contractual obligations at least as stringent as in this Clause 6.
		3. The Sponsor agrees to use Personal Data and / or Pseudonymised Data of Participants for the purpose of the Non-Interventional Study or otherwise as permitted in the approved consent form and in all circumstances for no purpose which is incompatible with the Non-Interventional Study purpose. The Sponsor further agrees not to disclose the Personal Data or Pseudonymised Data of Participants to any person except as required or permitted by law or applicable guidance.
		4. The Sponsor agrees to comply with the obligations placed on it as a Controller pursuant to Data Protection Laws and Guidance, including but not limited to demonstrating compliance with the principles relating to Processing of Personal Data (Article 5 GDPR).
		5. The Sponsor agrees to ensure persons Processing Personal Data and / or processing Pseudonymised Data of actual or potential Participants under this Agreement are equipped to do so respectfully and safely. In particular:
20. to ensure any such persons (excluding employees, honorary employees, students, researchers, consultants and sub-contractors of the Participating Organisation) understand the responsibilities for information governance, including their obligation to Process Personal Data and / or Pseudonymised Data of Participants securely and to only disseminate or disclose for lawful and appropriate purposes;
21. to ensure any such persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Participating Organisation) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable Personal Data Breaches.
	* 1. The Sponsor agrees to take reasonable steps to proactively prevent Personal Data Breaches, and / or equivalent breaches relating to Pseudonymised Data of Participants, and to respond appropriately to incidents or near misses. In particular:
22. to ensure that Personal Data and / or Pseudonymised Data of Participants are only accessible to persons who need it for the purposes of the Non-Interventional Study and to remove access as soon as reasonably possible once it is no longer needed;
23. to ensure all access to Personal Data and / or Pseudonymised Data of Participants on IT systems Processed for Non-Interventional Study purposes can be attributed to individuals.
24. to review processes to identify and improve processes which have caused Personal Data Breaches or near misses, or which force persons Processing Personal Data and / or processing Pseudonymised Data of Participants to use workarounds which compromise data security.
25. to adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice.
26. to take action immediately following a Personal Data Breach or near miss.
	* 1. The Sponsor agrees to ensure Personal Data and / or Pseudonymised Data of Participants are Processed / processed using secure and up-to-date technology. In particular:
27. to ensure no unsupported operating systems, software or internet browsers are used to support the Processing of Personal Data and / or processing of Pseudonymised Data of Participants for the purposes of the Non-Interventional Study.
28. to put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework.
29. to ensure IT suppliers are held accountable via contracts for protecting Personal Data and / or Pseudonymised Data of Participants that they Process / process and for meeting all relevant information governance requirements.

## Freedom of Information

* 1. The Sponsor acknowledges that the Participating Organisation is subject to the applicable FOIA and EIR and associated guidance and codes of practice.
	2. If the Participating Organisation or its Agent(s) receive a request under the FOIA or EIR to disclose information related to this Agreement, it will notify the Sponsor as soon as is reasonably practicable, and in any event, no later than five (5) working days after receiving the request. The Participating Organisation will consult with the Sponsor in accordance with all applicable guidance.
	3. The Sponsor acknowledges that the decision on whether any exemption applies to a request for disclosure of recorded information under the FOIA or EIR is a decision solely for the Participating Organisation.
	4. The Sponsor shall cooperate with the Participating Organisation and shall use its reasonable endeavours to respond within ten (10) working days of the Participating Organisation’s reasonable request for assistance.
	5. Where the Participating Organisation determines that it will disclose information, notwithstanding any objections from the Sponsor, it will notify the Sponsor in writing, giving at least two (2) working days’ notice of its intended disclosure.

## Confidential Information

* 1. The Participating Organisation and the Sponsor may only disclose Confidential Information to those of its officers, Agents and employees (and in the case of the Sponsor, those of its Affiliates and (if applicable) other parties who may have contractual rights in the Results (for example, through a licence, collaborative agreement, Co-Promotion Agreement, Co-Development Agreement, etc. with Sponsor) that are directly concerned with the carrying out of this Agreement. Each Party undertakes to treat as strictly confidential and not to disclose to any third party any Confidential Information of the other Party, save where disclosure is required by law (including any disclosure required to ensure compliance by the Participating Organisation, with the FOIA or EIR in accordance with Clause 7 of this Agreement). The Party required to make the disclosure shall inform the other within a reasonable time prior to being required to make the disclosure (and, where appropriate, in accordance with Clause 7) of the requirement to disclose and the information required to be disclosed. Each Party undertakes not to make use of any Confidential Information of the other Party other than in accordance with this Agreement, without the prior written consent of the other Party.
	2. The obligations of confidentiality set out in this Agreement, shall not apply to information that is:
		1. published or becomes generally available to the public other than as a result of a breach of this Agreement by the receiving Party.
		2. in the possession of the receiving Party prior to its receipt from the disclosing Party, as evidenced by contemporaneous written evidence, and is not subject to a duty of confidentiality.
		3. independently developed by the receiving Party, as evidenced by contemporaneous written evidence and is not subject to a duty of confidentiality.
		4. obtained by the receiving Party from a third party that is not subject to a duty of confidentiality.
	3. In the event of a Party visiting the establishment of the other Party, the visiting Party undertakes that any further Confidential Information that may come to the visiting Party’s knowledge as a result of any such visit, shall be treated as Confidential Information in accordance with this Clause 8.
	4. This Clause 8 shall remain in force (i) without limit in time in respect of Personal Data and any other information which relates to a patient, their treatment and / or medical records (ii) for information not falling under the aforementioned, the time period for which the Participating Organisation retains Non-Interventional Study records as set out in Section 4.13.9 (subject to the permitted uses set out in this Agreement). Save as aforesaid, and unless otherwise expressly set out in this Agreement, this Clause 8 shall remain in force for a period of ten (10) years after the termination or expiry of this Agreement.

## Publicity

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

## Publications

* 1. The Sponsor recognises that the Participating Organisation and Principal Investigator have a responsibility under the UK Policy Framework to ensure that results of scientific interest arising from the Non-Interventional Study are appropriately published and disseminated.
		1. The Sponsor agrees that employees of the Participating Organisation and the Principal Investigator shall be permitted to present at symposia, national and regional professional meetings and to publish in journals, theses or dissertations, or otherwise of their own choosing, the methods and Results of the Non-Interventional Study, subject to this Clause 10 and any publication policy described in the Protocol provided any such policy is consistent with Clause 10.4.
		2. If the Non-Interventional Study is a Multi-Centre Study, any publication based on the results obtained at any one Site (or group of Sites) shall not be made before the first Multi-Centre Study publication.
		3. If a publication concerns the analyses of sub-sets of data from a Multi-Centre Study, the publication must make reference to the relevant Multi-Centre Study publication.
	2. Upon Site Study Completion, and any prior publication by the Sponsor of Multi-Centre Study data or when the Non-Interventional Study data are adequate (in the Sponsor’s reasonable judgment), the Participating Organisation and or the Principal Investigator may prepare the data derived from the Site(s) for publication. Such data will be submitted to the Sponsor for review and comment prior to publication.
		1. In order to ensure that the Sponsor will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to the Sponsor for review at least forty (40) working days (or the time specified in the Protocol if longer) prior to submission for publication, public dissemination, or review by a publication committee.
	3. The Participating Organisation agrees and shall ensure that the Principal Investigator agrees that all reasonable comments made by the Sponsor in relation to a proposed publication by the Participating Organisation and / or the Principal Investigator will be incorporated into the publication.
	4. The Sponsor shall ensure that the Results of the Non-Interventional Study are published within one (1) year of Study Completion. In respect of a Non-Interventional Study that is under review by peer reviewed journals that prohibit disclosure of Results pre-publication, the Results will be posted at the time of publication.
		1. The Participating Organisation acknowledges that nothing in this Agreement prevents the Sponsor (nor any person with whom they share the methods and Results of the Non-Interventional Study) from presenting at symposia, national or regional professional meetings, publishing in journals, theses or dissertations or otherwise of their own choosing, the methods and Results of the Non-Interventional Study and in particular, but without limiting the foregoing, post a summary of the Non-Interventional Study Results in a publicly accessible registry before or after publication by any other method.
	5. Subject to Clause 8 regarding Confidential Information, the Participating Organisation will accurately describe and will ensure that the Principal Investigator will accurately describe the financial support of the Sponsor for the Non-Interventional Study in all publications and presentations.
	6. In the event that the Sponsor coordinates a Multi-Centre Study publication, the participation of the Principal Investigator or Personnel as named authors shall be determined in accordance with the Sponsor’s policy and generally accepted standards for authorship. If the Principal Investigator or other Personnel are to be named as authors of the Multi-Centre Study publication, such person(s) shall have access to the Non-Interventional Study data from all sites involved in the Non-Interventional Study, as necessary to participate fully in the development of the Multi-Centre Study publication.
	7. During the period for review of a proposed publication referred to in Clause 10.2.1 above, the Sponsor shall be entitled to make a reasoned request to the Participating Organisation that publication be delayed for a period of up to one hundred and eighty (180) calendar days from the date of first submission to the Sponsor in order to enable the protection of proprietary information and / or Intellectual Property Rights and Know-How and the Participating Organisation shall not unreasonably withhold or delay its consent to such request. The Participating Organisation shall not unreasonably withhold or delay its consent to a request from the Sponsor for an exceptional additional delay if, in the reasonable opinion of the Sponsor, proprietary information and / or Intellectual Property Rights and Know-How might otherwise be compromised or lost.

## Intellectual Property

* 1. All Intellectual Property Rights and Know-How owned by or licensed to the Sponsor or Affiliate(s) prior to and after the date of this Agreement other than any Intellectual Property Rights and Know-How arising from the Non-Interventional Study are and shall remain the property of the Sponsor.
	2. All Intellectual Property Rights and Know-How owned by or licensed to the Participating Organisation prior to and after the date of this Agreement other than any Intellectual Property Rights and Know-How arising from the Non-Interventional Study are and shall remain the property of the Participating Organisation.
	3. All Intellectual Property Rights and Know-How arising from and relating to the Non-Interventional Study and / or the Protocol, but excluding any clinical procedure and improvements thereto that are clinical procedures of the Participating Organisation, shall vest in the Sponsor in accordance with Clauses 11.4 and 11.5 of this Agreement.
	4. In accordance with Clause 11.3, the Participating Organisation hereby assigns, and shall procure that its Agents assign, its rights in relation to all Intellectual Property Rights and Know-How, falling within Clause 11.3, to the Sponsor or its nominee. At the request and expense of the Sponsor, the Participating Organisation shall execute, and shall procure that its Agents shall execute, all such documents and do all such other acts as the Sponsor may reasonably require in order to vest fully and effectively all such Intellectual Property Rights and Know-How in the Sponsor or its nominee.
	5. The Participating Organisation shall and will ensure that the Principal Investigator promptly disclose to the Sponsor any Know-How generated pursuant to this Agreement and falling within Clause 11.3 and undertakes not to use or disclose such Know-How other than for the purposes of this Agreement.
	6. Nothing in this Clause 11 shall be construed so as to prevent or hinder the Participating Organisation from using Know-How gained during the performance of the Non-Interventional Study in the furtherance of its normal activities, to the extent that such use does not result in the disclosure or misuse of Confidential Information or the infringement of any Intellectual Property Right or Know-How of the Sponsor.

## Finances

* 1. Arrangements relating to the financing of this Non-Interventional Study by the Sponsor are set out in Appendix 2 All payments will be made according to Appendix 2.
	2. In the event that any change to the Protocol results in amendment to the financial arrangements set out at Appendix 2, it is agreed that the Parties will vary Appendix 2 in accordance with Clause 16.2.
	3. Subject to Clauses 4.12 and 12.2, changes to the recruitment target set out at Clause 4.11 will be made without renegotiating the per capita payments in Appendix 2.
	4. In accordance with Clause 4.12, any payment adjustments for recruitment (over or under recruitment) will be made according to the per capita payments and other values specified in Appendix 2, including (as applicable) any inflationary uplifts in accordance with Clause 4 of Appendix 2.
	5. The Participating Organisation agrees that the Sponsor may make public the financial support provided to the Participating Organisation by the Sponsor for the conduct of the Non-Interventional Study and may identify the Participating Organisation as part of this disclosure.

## Term

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

## Termination

* 1. Either the Sponsor or the Participating Organisation (the “**Terminating Party**”) may terminate this Agreement with immediate effect at any time if the other Party or the Principal Investigator (the “**Defaulting Party**”) is:
		1. in breach of any of the Defaulting Party’s obligations hereunder (including a failure without just cause to meet a timeline set out in this Agreement or the Protocol) and fails to remedy such breach where it is capable of remedy within twenty-eight (28) calendar days of a written notice from the Terminating Party specifying the breach and requiring its remedy;
		2. declared insolvent or has an administrator or receiver appointed over all or any part of its assets or ceases or threatens to cease to carry on its business.
	2. Either Party may terminate this Agreement on notice to the other Party with immediate effect if it is reasonably of the opinion that the Non-Interventional Study should cease in the interests of the health of Participants involved in the Non-Interventional Study.
	3. The Sponsor may terminate this Agreement on notice to the Participating Organisation if the Principal Investigator is no longer able (for whatever reason) to act as Principal Investigator and no replacement mutually acceptable to the Participating Organisation and the Sponsor can be found. In the event that a Sub-Investigator is no longer able (for whatever reason) to act as a Sub-Investigator and no suitable replacement Sub-Investigator acceptable to the Participating Organisation and Sponsor can be found, the Sponsor may terminate this Agreement on notice to the Participating Organisation.
	4. Either Party may terminate this Agreement immediately upon notice in writing to the other Party for reasons not falling within Clauses 14.1.1, 14.2 or 14.3 above.
	5. In the event of early termination of this Agreement by the Sponsor, pursuant to Clauses 14.1, 14.2, 14.3 or 14.4 and subject to an obligation on the Participating Organisation and the Principal Investigator to mitigate any loss, the Sponsor shall pay all costs incurred and falling due for payment up to the date of termination, and also all non-cancellable expenditure falling due for payment after the date of termination that arises from commitments reasonably and necessarily incurred by the Participating Organisation for the performance of the Non-Interventional Study prior to the date of termination, and agreed with the Sponsor.
	6. At Site Study Completion, the Participating Organisation shall [destroy, and shall ensure that the Principal Investigator shall destroy,] [promptly deliver, and shall ensure that the Principal Investigator delivers, to the Sponsor] (**delete** one option) all Confidential Information and any other unused materials provided to the Participating Organisation and / or the Principal Investigator pursuant to this Agreement, excepting such Confidential Information and other information that forms the Study File, and other documents as agreed between Participating Organisation and Sponsor or that are otherwise required by applicable legislation to be retained by the Participating Organisation, which will be retained in accordance with 4.13.9. Any obligation to destroy or return Confidential Information or copies thereof does not extend to automatically generated computer back-up or archival copies generated in the ordinary course of the Participating Organisation’s information technology systems procedures, provided that the Participating Organisation shall make no further use of those copies.
	7. Termination of this Agreement will be without prejudice to the accrued rights and liabilities of the Parties under this Agreement.

## Relationship of the Parties

* 1. 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, except that the Sponsor may assign this Agreement at any time to a successor to all or substantially all of its business or assets to which this Agreement relates, whether by way of merger, consolidation, sale of stock, sale of assets, operation of law or otherwise, upon written notice to the Participating Organisation. The Sponsor shall inform the Participating Organisation in good time in writing about the aforementioned assignment / assignation.
	2. 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. In the event that either Party sub-contracts its responsibilities under this Agreement, it shall be responsible for the acts and omissions of its sub-contractors as though they were its own. Any Party who so sub-contracts shall be responsible for pass-through of payments to its sub-contractors.
	3. Nothing in this Agreement shall be construed as creating a joint venture, partnership, contract of employment or relationship of principal and agent between the Parties.

## Agreement and Modification

* 1. **Order of Precedence**
	Should there be any inconsistency between the Protocol and the terms of this Agreement or any other document incorporated herein, the terms of the Protocol shall prevail to the extent of any inconsistency except insofar as the inconsistency relates to Clauses 5, 6, 7, 8, 10, 11 and 16 of this Agreement, whereby the terms of this Agreement shall prevail.
	2. Any change in the terms of this Agreement shall be valid only if the variation is made in writing, agreed and signed by the Parties.
	3. Any amendment to the Protocol (“**Protocol Amendment**”) shall be managed by means of the change control procedure set out in this Clause.
		1. For the purposes of this Agreement, a “**Change Request**” is a request to change the obligations of the Parties arising from a Protocol Amendment.
		2. Where the Sponsor originates a Change Request, the Participating Organisation shall provide the Sponsor, within ten (10) working days of receiving the Change Request, details of the impact that the proposed Protocol Amendment will have upon the costs of carrying out the Non-Interventional Study and the other terms of this Agreement.
		3. A Change Request shall become a “**Change Order**” when the requirements of the change control procedure have been satisfied and any necessary change to this Agreement is signed by the authorised representatives of the Parties.
		4. An amended financial appendix shall be signed and appended to this Agreement according to Clause 12.2 above.
	4. This Agreement contains the entire understanding between the Parties and supersedes all other agreements, negotiations, representations and undertakings, whether written or oral, of prior date between the Parties relating to the conduct of the Non-Interventional Study (as overseen by the Principal Investigator) that is the subject of this Agreement.

## Force Majeure

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

## Notices

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

## Dispute Resolution

* 1. In the event of a dispute arising under this Agreement, authorised representatives of the Parties will discuss and meet as appropriate to try to resolve the dispute within five (5) working days of being requested in writing by either Party to do so. If the dispute remains unresolved, it will then be referred to a senior manager from each of the Parties who will use all reasonable endeavours to resolve the dispute within a further ten (10) working days.
	2. If the Participating Organisation is constituted in England or Wales, then in the event of failure to resolve the dispute through the steps set out in Clause 19.1 the Parties agree to attempt to settle it by mediation in accordance with the Centre for Effective Dispute Resolution Model Mediation Procedure. To initiate a mediation, either Party shall give notice in writing (“**ADR Notice**”) to the other Party requesting mediation in accordance with this Clause 19.2. The Parties shall seek to agree the nomination of the mediator, but in the absence of agreement the mediator shall be nominated by the President for the time being of the British Medical Association. The person so appointed will act as an expert and not as an arbitrator. The mediation will start no later than fifteen (15) working days after the date of the ADR Notice. The Parties shall each bear their own costs and expenses in relation to settlement of any disputes in terms of this Clause 19 and shall share equally the costs of the independent third party. If the dispute is not resolved within twenty (20) working days of the ADR Notice, either Party shall be entitled to submit to the exclusive jurisdiction of the courts of England and Wales.

If the Participating Organisation is constituted in Scotland, then in the event of failure to resolve the dispute through the steps set out in Clause 19.1, the same may be referred to an independent third party for resolution. In the event that the Parties cannot mutually agree on the identity of an independent third party, the Parties will ask the President for the time being of the Law Society of Scotland to appoint a suitable individual to consider the matter in dispute. The person so appointed will act as an expert and not as an arbiter. The Parties shall each bear their own costs and expenses in relation to settlement of any disputes in terms of this Clause 19 and shall share equally the costs of the independent third party. If the Parties are unable to resolve a dispute arising out of or in connection with this Agreement in accordance with Clause 19.1 and 19.2, either Party shall be entitled to submit to the exclusive jurisdiction of the Scottish courts.

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

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

## Miscellaneous

* 1. **Rights of Third Parties**
	Nothing in this Agreement is intended to confer on any person any right to enforce any term of this Agreement which that person would not have had but for the Contracts (Rights of Third Parties) Act 1999, or the Contract (Third Party Rights) (Scotland) Act 2017 where the Participating Organisation is constituted in Scotland (each being a “**Third Party Rights Act**”). Any right or remedy of a third party that existed or is available apart from the relevant Third Party Rights Act is not affected
	2. **Waiver**
	No failure, delay, relaxation or indulgence by either Party in exercising any right conferred on such Party by this Agreement shall operate as a waiver of such right, nor shall any single or partial exercise of any such right nor any single failure to do so, preclude any other or future exercise of it, or the exercise of any other right under this Agreement.
	3. **Survival of Clauses**
	The following clauses shall survive the termination or expiry of this Agreement:

**Clause 1** Definitions

**Clause 3.2 to 3.6**  Non-Interventional Study Governance

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

**Clause 4.14** Updating Contact Details, Including for Notices and Payments

**Clause 5** Liabilities and Indemnities

**Clause 6** Data Protection

**Clause 7** Freedom of Information

**Clause 8** Confidential Information

**Clause 9** Publicity

**Clause 10** Publications

**Clause 11** Intellectual Property

**Clause 14** Termination

**Clause 15** Relationship of the Parties

**Clause 16** Agreement and Modification

**Clause 17** Force Majeure

**Clause 18** Notices

**Clause 19** Dispute Resolution

**Clause 20** Miscellaneous

* 1. **Governing Law and Jurisdiction**
	Where the Participating Organisation is constituted in England then this Agreement shall be governed and construed in accordance with the laws of England and Wales and the courts of England and Wales shall have exclusive jurisdiction to hear any dispute relating to this Agreement.

Where the Participating Organisation is constituted in Wales then this Agreement shall be governed and construed in accordance with the laws of England and Wales as applied in Wales and the courts of England and Wales shall have exclusive jurisdiction to hear any dispute relating to this Agreement.

Where the Participating Organisation is constituted in Scotland, this Agreement shall be governed and construed in accordance with the laws of Scotland and the courts of Scotland shall have exclusive jurisdiction to hear any dispute relating to this Agreement.

Where the Participating Organisation is constituted in Northern Ireland, then this Agreement shall be governed and construed in accordance with the laws of Northern Ireland and the Courts of Northern Ireland shall have exclusive jurisdiction to hear any dispute relating to this Agreement.

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

|  |  |
| --- | --- |
| Signed for and on behalf of:[**INSERT** NAME OF SPONSOR]OrSigned by [**INSERT** name of company] for and on behalf of [**INSERT** NAME OF SPONSOR], as duly authorised under Appendix 6Signature:Print name:Title: Date: | Signed for and on behalf of:[**INSERT** NAME OF PARTICIPATING ORGANISATION]Signature:Print name:Title:Date |

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

**Appendix 1: Timelines and Responsibilities of the Parties**

The milestones and division of responsibility set out below are provided as examples only. The milestones for each Non-Interventional Study are to be agreed between the Sponsor and the Participating Organisation in accordance with the specific Non-Interventional Study arrangements that are applicable at each Site. Please remove this text once the document has been agreed for the Non-Interventional Study.

|  |  |  |  |
| --- | --- | --- | --- |
| **Milestone** | **Sponsor responsibility** | **Participating Organisation responsibility** | **Target date for completion at Site** |
| Site Initiation visit | Yes | Yes | [ENTER DATE] |
| First Participant enrolled | No | Yes | [ENTER DATE] |
| Last Participant enrolled | No | Yes | [ENTER DATE] |
| All Case Report Form queries submitted | Yes | No | [ENTER DATE] |
| All Case Report Form queries completed | No | Yes | [ENTER DATE] |

**Appendix 2 – Financial Arrangements**

### [Financial Arrangements Appendix Instructions

*Please delete instruction text prior to sharing the Agreement with the Participating Organisation.*

* **Clause 2.2:** Four options to describe the frequency of invoicing are provided to the Sponsor, or party acting on its behalf. A single option should be selected. If the final option is selected (another frequency to be agreed by the Parties) this should be based on a calendar frequency (for example twice annually), not Non-Interventional Study or Participating Organisation milestones (for example, upon recruitment of 10 Participants).
* **Clause 2.3:**Five options, to describe the arrangements for raising invoices for this Non-Interventional Study, are provided to the Sponsor or its Agent. The Parties can agree that more than one option may be appropriate to include in the Agreement; only the relevant option(s) should be retained. Where multiple options are chosen, the sub-option within each retained clause should also be retained and detail added. At least one option must be chosen. If only a single option is chosen, the sub-option should be removed.
* **Clause 6.3:** The Sponsor, or its Agent, should include the proposed caps for the payment of Expenses (without further authorisation) within the table prior to sharing the Agreement with the Participating Organisation. The template table includes examples of Expenses that may be entered here, and under which basis the cap applies. The examples can be modified, added to and / or removed as needed to reflect the Non-Interventional Study specific arrangements. Rows should be deleted or added to the table as needed. The Sponsor, or its Agent, may need to discuss the appropriateness of the cap with the Participating Organisation to accommodate the time commitment for Non-Interventional Study visits, the distance Participants (and, as applicable, parents, carers or others who may reasonably be expected to accompany them) need to travel to the Participating Organisation, and any other factors which may impact on the cap.

If there will be no Expenses paid, enter “not applicable” as the pass-through cost, and enter the cap as £0.00.

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

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

If the Sponsor has not designed the Non-Interventional Study to require out of hours working, enter “not applicable” as the out of hours cost, and enter the cost as £0.00.

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

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

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

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

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

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

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

## Payments

* 1. This Appendix specifies all payments to be made by, or on behalf of, the Sponsor, to the Participating Organisation, under the Financial Arrangements and Termination Clauses within this Agreement.
	2. Non-Interventional Studies that are subject to [National Contract Value Review](https://www.england.nhs.uk/aac/what-we-do/embedding-research-in-the-nhs/national-contract-value-review/) must use an unmodified version of the Finance Schedule generated by the interactive Costing Tool (iCT). Changes, by either Party, to the Finance Schedule, prior to the Effective Date of this Agreement, are not permitted under the terms of the [National Directive on Commercial Contract Research Studies](https://www.england.nhs.uk/publication/national-directive-on-commercial-contract-research-studies/), in England, and equivalent policy positions in each of the devolved administrations.
		1. In accordance with the above, the Sponsor represents and warrants that the Finance Schedule, incorporated into this Appendix by or on behalf of the Sponsor, is an unmodified version of the Finance Schedule generated by the Localised OnlineiCT for this Non-Interventional Study, following the conclusion of the study resource review.
		2. In accordance with the above, the Participating Organisation represents and warrants that prior to execution of this Agreement, no alterations have been made to the Financial Arrangements Appendix, including the Finance Schedule, provided by or on behalf of the Sponsor.
	3. Subject to Clause 9 of this Appendix, the Sponsor reserves the right to withhold payments to Participating Organisation for activities conducted which were:
		1. not required by the Protocol; and / or
		2. conducted in breach of the Protocol.
	4. The Sponsor acknowledges that the Participating Organisation can defer funds under this Agreement to build research capacity in future financial years. Both Parties acknowledge that there is no obligation under this Agreement on the Participating Organisation to either spend funds paid under the Agreement within the same financial year, or to refund the Sponsor with any sums not spent within the same financial year.

## Invoicing and Value Added Tax (VAT)

* 1. Invoices will be based on the services performed and / or data monitored. Where possible, data will be confirmed as complete and evaluable in a timely manner by (or on behalf of) the Sponsor for the invoice period, prior to the raising of the invoice. No payment will be made (unless an automatic payment has been arranged) by or on behalf of the Sponsor until a valid invoice for the amount payable has been received.
	2. The first invoice is to be raised after contract execution. Subsequent invoices will be raised on a [monthly] [quarterly] [ad hoc] [other: insert as agreed between the Parties] **(DELETE THREE AND RETAIN ONE OPTION)** basis, with the final invoice raised in accordance with Clause 2.10 of this Appendix.
	3. The Parties agree to use the following method(s) to manage invoicing:
		1. **[****OPTION 1 (delete if not applicable)**: The Sponsor, or its Agent, will issue invoice requests, detailing visits and any additional procedures completed. The Participating Organisation shall invoice the Sponsor or its Agent in arrears upon receipt of an invoice request. **[Sub-Option (delete if not applicable):** This Clause is effective for invoicing relating to [**insert activities which will be invoiced using this method**]].]
		2. **[OPTION 2 (delete if not applicable)**: The Sponsor or its Agent will liaise with the Participating Organisation to agree the value and content of invoices to be raised. **[Sub-Option (delete if not applicable)**: This Clause is effective for invoicing relating to [**insert activities which will be invoiced using this method**]].]
		3. **[OPTION 3 (delete if not applicable)**: The Sponsor or its Agent will use a self-invoicing system to raise invoices on behalf of the Participating Organisation **[Sub-Option (delete if not applicable)**: This Clause is effective for invoicing relating to [**insert activities which will be invoiced using this method**]].]
		4. **[OPTION 4 (delete if not applicable)**: The Sponsor or its Agent will use an automated payment system to pay the Participating Organisation. The Participating Organisation shall be paid according to the evidence provided within the automated payment system of costs incurred. [**Sub-Option (delete if not applicable)**: This Clause is effective for invoicing relating to [**insert activities which will be invoiced using this method**]].]
		5. **[OPTION 5 (delete if not applicable)**: The Sponsor or its Agent will delegate responsibility to manage invoicing to the Participating Organisation. The Participating Organisation will invoice the Sponsor, or its Agent, in arrears. [**Sub-Option (delete if not applicable)**: This Clause is effective for invoicing relating to **[insert activities which will be invoiced using this method**]].**]**

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

* 1. Valid invoices (and, if required due to a limit being in place on the amount of information able to be included on the invoice, supporting documents sent alongside the invoice to detail any further information required by this Clause) issued by the Participating Organisation shall:
		1. be valid tax invoices for the purposes of VAT legislation;
		2. identify the Participating Organisation and IRAS ID;
		3. contain a breakdown of prices per activity covering:
1. set-up and close-down prices;
2. Per Participant fees, clearly identifying the correct Participant identification number(s), and;
3. all other prices.
	* 1. clearly state the corresponding period being invoiced for any periodic prices;
		2. identify the purchase order number (if applicable) assigned to the Participating Organisation; and
		3. be sent to the Sponsor or its Agent at the email address provided below.
	1. The Participating Organisation’s failure to comply with the above invoice requirements may result in a delay in payment.
	2. Any delay in the payment of the payee invoices by or no behalf of the Sponsor will incur an interest charge on any undisputed amounts overdue of two (2) per cent per month above the National Westminster Bank plc base rate prevailing on the date the payment is due.
	3. If the Sponsor or its Agent disputes any invoice, or part of any invoice, or receives an invoice in respect of activities not provided in accordance with this Agreement, or which the Sponsor believes (acting reasonably) have not been properly provided, then the Sponsor or its Agent will make contact in a timely manner with the Participating Organisation’s finance team as per Clause 12.2 of this Appendix to resolve the query. If the query is not resolved, then the Sponsor or its Agent may either:
		1. withhold payment of the disputed part of the invoice in respect of the disputed amounts and / or activities, including an explanation as to why payment is withheld, in which case the Participating Organisation shall issue the Sponsor or its Agent with a credit note for the disputed amount and the Sponsor or its Agent will pay the undisputed amount in accordance with the Finances clause of this Agreement, or;
		2. reject the Participating Organisation’s invoice and request that the Participating Organisation submit a new invoice for the undisputed amount. On receipt of the new valid invoice, the Sponsor or its Agent shall pay the new invoice in accordance with the Finances clause of this Agreement.
	4. Any outstanding dispute remaining in relation to Clause 2.7 of this Appendix will be resolved in accordance with Clause 19 of this Agreement.
	5. The Sponsor or its Agent will notify the Participating Organisation of Site Study Completion, or early termination of this Agreement, in order to trigger the generation of a final invoice. Notification will be made to: [insert email address].
	6. Upon Site Study Completion, or early termination of this Agreement, all remaining amounts due shall be invoiced as per the terms detailed in this Financial Arrangements Appendix, subject to the following:
		1. completion of the close-out visit, where applicable;
		2. receipt of all completed and corrected case report forms and queries;
		3. receipt of the Principal Investigator’s final report, where applicable, in a form acceptable to the Sponsor as per relevant standards / requirements, and;
		4. provided any applicable Sponsor or Vendor Resources or Equipment has been accounted for and returned, retained or destroyed in accordance with Sponsor instructions.
	7. The Sponsor or its Agent shall promptly respond to any reasonable request for invoicing data received from the Participating Organisation for the purposes of the final invoice, provided that the request is received within forty-five (45) calendar days of the notification of Site Study Completion or early termination of the Agreement.
	8. **Longstop Dates**
	It is agreed that the Sponsor shall not be required to make payment for any amounts that the Participating Organisation fails to notify the Sponsor of within sixty (60) calendar days of the Sponsor providing the final invoicing information (if requested), in accordance with Clause 2.11 of this Appendix, or sixty (60) calendar days from Site Study Completion, or early termination of this Agreement, if invoicing information is not requested (“**Longstop Dates**”). For the avoidance of doubt these notifications should be in accordance with table 12.1, and it is not an obligation for the Sponsor to pay invoices dated after the Longstop Date. Notwithstanding the above, this Clause does not take effect until any dispute regarding invoicing in line with Clauses 2.7 to 2.8 of this Appendix is resolved.
	9. The final invoice payment may be held by the Sponsor or its Agent until all outstanding queries have been resolved.
	10. All figures in the Finance Schedule are INCLUSIVE of all indirect costs, capacity building and Participating Organisation specific multipliers. All figures include all relevant taxes EXCEPT VAT which should be added to invoices where applicable.

## Pass-through Payments

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

## Inflation

* 1. Adjustment to the Finance Schedule to account for inflation (**“Adjustment”**) may be undertaken, at Participating Organisation request or as initiated by the Sponsor, a minimum of two years (twenty-four consecutive months) from the Effective Date of the Agreement and thereafter every twelve months.
		1. The prices presented in the revised Finance Schedule, accounting for inflation, will be the prices generated by the Localised OnlineiCT on the day agreed by the Parties, and the revised prices will be applied to all Non-Interventional Study payments made as a result of the first and any subsequent invoices following execution of contract variation.
		2. The revised Localised OnlineiCT Finance Schedule generated on the day agreed, will be provided by the Sponsor to the Participating Organisation and incorporated into this Agreement, with subsequent invoices reflecting the uplifted Finance Schedule, subject to Clause 4.1.1 of this Appendix.
		3. For the avoidance of doubt, a contract variation in line with Clause 16.2 of this Agreement is required to update the prices in the Finance Schedule to take account of inflation.

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

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

## Expenses and Other Pass-through Costs

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

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

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

| **Out of hours cost** | **Cap (£)** | **Basis of cap** |
| --- | --- | --- |
| [Nurse time for out of hours study visits] |  | [Total out of hours costs incurred over the Non-Interventional Study] |

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

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

* 1. The Parties agree to use the following method(s) to manage the payment of Expenses:
		1. [**OPTION 1 (delete if not applicable):** Receipts, or other appropriate documentation, where available, will be submitted to the Participating Organisation to support the expenditure. The Participating Organisation will pay Expenses directly to those who have incurred Expenses. **[Sub-Option (delete if not applicable):** This Clause is effective for the payment of Expenses relating to [**insert activities which will be paid for using this method**].]]
		2. [**OPTION 2 (delete if not applicable):** Receipts, or other appropriate documentation, where available, will be submitted to the Sponsor or its Agent to support the expenditure. The Sponsor or its Agent will pay Expenses directly to those who have incurred Expenses. **[Sub-Option (delete if not applicable):** This Clause is effective for the payment of Expenses relating to [**insert activities which will be paid for using this method**].]]
		3. [**OPTION 3 (delete if not applicable)**: Expenses will be paid through an automated payment system (which may include provision of a pre-payment card) by the **[Sponsor] [Sponsor’s Agent] [Participating Organisation]. [Sub-Option (delete if not applicable):** This Clause is effective for the payment of Expenses relating to [**insert activities which will be paid for using this method**].]]
	2. The Parties agree to use the following method(s) to manage the payment of Ethically-Approved Participant Payments:
		1. [**OPTION 1 (delete if not applicable):** The Participating Organisation will make Ethically-Approved Participant Payments directly to Participants.]
		2. [**OPTION 2 (delete if not applicable):** The Sponsor or its Agent will make Ethically-Approved Participant Payments directly to Participants.]
		3. [**OPTION 3 (delete if not applicable):** There are no Ethically-Approved Participant Payments to be made for this Non-Interventional Study.]
	3. If the Participating Organisation receives payment from the Sponsor or its Agent for pass-through-related costs and Expenses, the Participating Organisation shall ensure that the Principal Investigator and Personnel will maintain records, supported by receipts of the expenditures where possible, and make available de-identified copies, if possible, at monitoring visits, if requested. The Sponsor or its Agent will reimburse the Participating Organisation for all such payments upon confirmation of spend and itemised inclusion in the invoice.
	4. [**DELETE IF NOT APPLICABLE** - An Expenses float of £[XX.XX] will be provided and replenished as necessary by the Sponsor or its Agent upon receipt of invoice from the Participating Organisation. Any balance remaining in the float at the end of the Non-Interventional Study will be refunded to the Sponsor or its Agent.]

## Participant Visit Fees

* 1. Payments will be made according to the visit and investigation payments set out in Clause 13.2 of this Appendix (Participant Visit Fees) and include all indirect prices, capacity building and applicable Participating Organisation specific multipliers.
	2. Please note that tables may have been added below, as a result of the study resource review, for planned unscheduled activities that may occur for selected Participants only in line with Clause 9.1 of this Appendix. This table will indicatively state the additional visit prices applicable for those selected Participants.

## Payment for screen failure and discontinuation

* 1. For the purpose of this Appendix, a “Screen Failure” is defined as a Participant who is eligible with respect to Protocol defined eligibility criteria to enter the screening process, gave informed consent but is found to be ineligible for the Non-Interventional Study.
		1. The Participating Organisation will receive payment per Screen Failure [**DELETE** ONE OPTION AND RETAIN THE OTHER] [for all Screen Failures, provided that it was not evident from information available to the Participating Organisation at the time of screening that the potential Participant could not be eligible] [for an initial [X] Screen Failures. Payment for any Screen Failures at the Participating Organisation after this cap is reached requires approval from the Sponsor or its Agent, and if given will be based on payment for [X] Screen Failures per [X] Participants [enrolled] [Included] **(delete options not selected in Clause 4.11 of the main Agreement)**] at the Participating Organisation.
		2. All costs associated with each Screen Failure are payable by the Sponsor or its Agent on a pro rata basis as per the individual task price set out in the list of screening activities present for the screening visit in the Localised OnlineiCT.
	2. A Participant who discontinues from the Non-Interventional Study, prior to completion of all the Protocol defined visits and assessments, because of adverse events, disease progression, coexistent disease, as a result of a decision made by the Principal Investigator, withdrawal of participation by Participant, and / or non-compliance or non-attendance, will be considered evaluable and payment will be made on a pro-rata basis.
	3. The value of payments under Clause 8.2 of this Appendix will be based on completion of visits, procedures and investigations as defined in the Participant table in this Appendix to cover all relevant costs and pass-through expenses in respect of such Participants, provided that the data relating to such Participants are adequately recorded in the Case Report Forms up to the time of discontinuation.
	4. Participants who are entered into the Non-Interventional Study but who do not satisfy the Protocol eligibility criteria at the time of entry must be either discontinued from the Non-Interventional Study or dealt with as outlined in the Protocol. Appropriate payment, if applicable, will be agreed on a case by case basis between the Sponsor or its Agent and Participating Organisation at the time of occurrence in respect of such Participants.

## Unscheduled Visits

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

## Central Laboratory Costs

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

## All Other Fees

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

## Payment Details

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

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

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

* 1. Invoicing requests and invoicing queries to the Participating Organisation should be sent to:

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

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

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

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

## Finance Schedule

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

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

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

* 1. **Participant Visit Fees**

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

* 1. **All Other Fees**

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

**Appendix 3 – Conditions Applicable to the Principal Investigator**

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

**Appendix 4 – Material Transfer Provisions**

 [ ]  If this box is checked, this Appendix 4 (Material Transfer Provisions) is not used.

Where the Protocol requires the Participating Organisation to supply Material to the Sponsor this Appendix 4 shall apply.

1. In accordance with the Protocol, the Participating Organisation shall send Material to the Sponsor or, in accordance with Section 7 below, to a third party nominated by the Sponsor;
2. The Participating Organisation warrants that all Material has been collected with appropriate informed consent and has been collected and handled in accordance with applicable law (including, without limitation, the Human Tissue Act 2004) and as required by the Protocol;
3. Subject to Section 2 above, the Material is supplied without any warranty, expressed or implied, including as to its properties, merchantable quality, fitness for any particular purpose, or freedom from infection;
4. The Sponsor shall ensure, or procure through an agreement with the Sponsor’s nominee as stated in Section 1 above, that:
	1. the Material is used in accordance with the consent of the Participant and the approval of all Regulatory Authorities for the Non-Interventional Study and the Protocol;
	2. the Material is handled and stored in accordance with applicable law;
	3. the Material shall not be redistributed or released to any person other than in accordance with the Protocol or for the purpose of undertaking other research approved by an appropriate ethics committee, where such approval is required, and provided it is in accordance with the Participant’s consent.
5. The Parties shall comply with all relevant laws, regulations and codes of practice governing the Non-Interventional Study and the use of Material;
6. The Participating Organisation and the Sponsor shall each be responsible for keeping a record of the Material that has been transferred according to this Appendix 4;
7. To the extent permitted by law, the Participating Organisation and its Personnel shall not be liable for any consequences of the supply to or the use by the Sponsor of the Material, or of the supply to or the use by any third party to whom the Sponsor subsequently provides the Material, or the Sponsor’s nominee as stated in Section 1 above, save to the extent that any liability that arises is a result of the negligence, wrongful acts or omissions or breach of statutory duty of the Participating Organisation or its Personnel, or their failure to comply with the terms of this Agreement;
8. The Sponsor undertakes that, in the event that Material is provided to a third party in accordance with Section 1 above, it shall require that such third party shall undertake to handle any Material related to the Non-Interventional 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 4;
9. Unless otherwise agreed, any surplus Material that is not returned to the Participating Organisation or retained for future research shall be destroyed in accordance with the Human Tissue Act 2004.

**Appendix 5 – Equipment and Resources**

[ ]  If this box is checked, this Appendix 5 (Equipment and Resources) is not used

1. **Sponsor-Provided Equipment**

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

* 1. Sponsor will provide the CE- / UKCA- / UKNI-Marked equipment identified below (“**Sponsor Equipment**”) for use by the Participating Organisation in the conduct or reporting of the Non-Interventional Study:

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

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

1. **Sponsor-Provided Resources**

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

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

**Alternative #1 – Return to Sponsor (DELETE ENTIRE ALTERNATIVE IF NOT APPLICABLE)**

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

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

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

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

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

**Alternative #3 – Return of Sponsor Resources to Sponsor and purchase of Sponsor Equipment by Participating Organisation. (DELETE ENTIRE ALTERNATIVE IF NOT APPLICABLE)**

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

After completion of the Non-Interventional Study at the Site, Sponsor will make Sponsor Equipment available for purchase by the Participating Organisation at its then depreciated value. If Non-Interventional Study conduct is completed significantly earlier or later than originally estimated, the depreciated value identified in the table above will be adjusted accordingly. The Sponsor will ensure that any transfer of ownership is documented in writing.

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

1. **Vendor-Provided Equipment or Resources**

[ ]  Please check this box if no Equipment or Resources will be provided by a Vendor

* 1. **The Sponsor** will arrange for a vendor to provide the following equipment or proprietary materials (“**Vendor Property**”) for use in this Non-Interventional Study:

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

**Permitted Uses of Vendor Property**

**[OPTION 1 (delete if not applicable)**:The Participating Organisation will use Vendor Property only for purposes of this Non-Interventional Study.**]**

**[OPTION 2 (delete if not applicable)**: **Specify permitted uses.]**

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

**Alternative #1 – indemnity provided by this Appendix 7 (DELETE ENTIRE ALTERNATIVE IF NOT APPLICABLE) [N.B. THIS OPTION MUST BE SELECTED FOR ALL PARTICIPATING ORGANISATIONS IN ENGLAND OR NORTHERN IRELAND, AND PARTICIPATING ORGANISATIONS IN SCOTLAND OR WALES WHICH ARE NHS PRIMARY CARE INDEPENDENT CONTRACTORS]**

The Sponsor has no liability for damages of any sort, including personal injury or property damage resulting from the use of [**Sponsor Equipment**], [**Sponsor Resources**] [or] [**Vendor Property**] except to the extent that such damages were caused by the wilful misconduct, negligent acts or omissions of Sponsor or the Vendor.

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

Subject to Clause 5.4 of the Agreement, the Participating Organisation shall be liable for any damage, loss or destruction of the [**Sponsor Equipment**], [**Sponsor Resources**] or [**Vendor Property**] and for any losses attributable to the [**Sponsor Equipment**], [**Sponsor Material**] [or] [**Vendor Property**] caused by the Participating Organisation’s wilful misconduct, negligent acts or omissions. Under no circumstances shall the Participating Organisation be liable for any damage caused as a result of using the equipment per instructions or due to normal wear and tear. To avoid doubt, the Participating Organisation shall not insure the [**Sponsor Equipment**], [**Sponsor Material**] or [**Vendor Property**].

**Alternative #2 – Equipment is supplied under an MIA (DELETE ENTIRE ATERNATIVE IF NOT APPLICABLE) [N.B. THIS OPTION IS ONLY AVAILABLE FOR PARTICIPATING ORGANISATIONS IN SCOTLAND OR WALES WHICH ARE NOT NHS PRIMARY CARE INDEPENDENT CONTRACTORS]**

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

**Appendix 6 – Formal Delegation of Authority to a Corporate Affiliate to Contractually Bind Sponsor**

 [ ]  If this box is checked, this Appendix 6 (Formal Delegation of Authority to a Corporate Affiliate to Contractually Bind Sponsor) is not used.

**FINAL PAGE**