# Contract Research Organisation Model Commercial Chief Investigator Agreement

**Scope and details of the agreement**

This agreement is developed for use between Sponsors of commercial health and care research, their Contract Research Organisation (CRO) and either of the following:

* NHS / Health and Social Care (HSC) organisations employing an individual who will be undertaking the role of Chief Investigator during their time as NHS- / HSC-employed staff. This includes individuals who have an honorary research contract with the NHS but are substantively employed by another organisation, for example a university.
* Independent primary care contractors providing NHS / HSC services which either employ the person who will be undertaking the role of Chief Investigator, or have a partner who will be undertaking the role of Chief Investigator, during their time as an employee or partner of the independent primary care contractor.

It has not been developed for use when the Chief Investigator (CI) is acting in a personal capacity or where they are doing chief investigator activities on behalf of another employer.

The agreement is designed for use when the research study is a Clinical Trial of an Investigational Medicinal Product (CTIMP). It can be used when the Chief Investigator is acting as CI for the UK only, or where they are also providing CI Services to other countries.

It is not designed for use in non-CTIMP studies or in combined CTIMP and investigational medical device studies.

This agreement is still needed when the NHS CI Employer is exploring whether to or intends to participate in the Clinical Trial as a trial site and whether or not the person acting as Chief Investigator will also act as a Principal Investigator. This is because the roles and responsibilities of the two positions are different, and the management of various aspects of the roles and responsibilities are different, including indemnity, payment, records management, and confidentiality obligations.

This agreement does not include data processing or transfer clauses relating to Participant Personal Data. It is expected that information about Participants which is shared with the Chief Investigator is minimised to such an extent that it is no longer considered Personal Data under UK GDPR.

It is expected that this Agreement is in place before any CI Services are provided - and usually no later than the IRAS submission is made to regulatory authorities – to ensure that there is clarity between CI, NHS CI Employer and Sponsor as to the CI Services to be provided prior to the CI authorising the IRAS submission. By exception, this Agreement may be agreed after IRAS submission, where there is otherwise a risk of delay to the IRAS submission.

You can use this template in situations it is not designed for where there is no alternative model agreement available, however, you do so at your own risk and may need to modify the template accordingly to fit your situation.

**Details of specific clauses**

Clause 4.6 specifies that any use of another Party’s Confidential Information using AI Tools must receive consent from that Party before doing so. The exception to this is that Sponsor or CRO may use NHS CI Employer’s Confidential Information in the Sponsor’s or CRO’s Secured, Dedicated Cloud-Based Environments. As with other uses of the NHS CI Employer’s Confidential Information by the Sponsor or CRO, any use outside of the Secured, Dedicated Cloud-Based Environments would require the NHS CI Employer’s consent.

This Agreement states in Clause 6 that the Sponsor and NHS CI Employer are independent data Controllers under GDPR. This is because the Sponsor is not instructing the NHS CI Employer on what data it needs to process or how it needs to be processed; the NHS CI Employer makes its own decisions about what CI Personal Data it processes and for what purposes. In contrast, the site agreements (such as the model Clinical Trial Agreement, or mCTA) name the Sponsor as the data Controller and the participating organisation as its Processor. This is because the Sponsor determines what Participant Personal Data is processed, how it is processed and why; the participating organisation follows the instructions of the Sponsor. This contract does not take any position on the Controller or Processor status of the CRO in relation to the Sponsor, but it does confirm that there is no Controller-Processor relationship between the CRO and NHS CI Employer. The site agreements do not include data processing clauses regarding the Personal Data of the participating organisation’s employees.

Clause 9 details audit and inspection visits by the Sponsor, its Agent, or regulatory authorities. This agreement specifically manages requirements related to the performance of CI Services. It is up to the Sponsor whether and how to audit the provision of services in line with this Agreement. Regulatory authorities, including the MHRA, may inspect the provision of CI Services or other compliance with applicable legislation. Where the Chief Investigator is also acting as Principal Investigator, any requirements related to monitoring, audit or inspection of Principal Investigator services and site activities will be managed separately through the site agreement.

Clause 12 of this Agreement limits the liability of the NHS CI Employer and / or the CI, where possible, in relation to clinical negligence only. The purpose of this Agreement is only to attain the expertise and knowledge of the Chief Investigator. Site agreements such as the mCTA are based on a different relationship which is why they include more detailed insurance and indemnity provisions to cover design and management of the Clinical Trial by Sponsor, and conduct by the Trial Site.

**Instruction Pages**

The information set out below provides a checklist of information that needs to be included in this Agreement in preparation for execution by the Parties. Complete only the fields highlighted in yellow. Read and delete the drafting notes in square brackets throughout the Agreement, tailoring the Agreement as needed in line with the instructions.

It is the Sponsor and CRO’s responsibility to provide the required information for review by the NHS CI Employer.

### Footers

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

### Front page

Complete all of the required information.

### Recitals

Add, remove and / or update recitals as applicable to the Clinical Trial and the CI Services (as a preamble to the Agreement, such changes do not constitute modification to the template Agreement). Recital E should be completed where a corporate Affiliate of the Sponsor, or other party, 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

**Clauses 6.3.2a, 6.3.2b and 6.3.2c** – Insert e-mail addresses for Personal Data Breach contacts of the Parties. The Sponsor contact for breaches should be entered into 6.3.2a, whether this is the Sponsor acting on its own behalf or the CRO acting on behalf of the Sponsor. Where the CRO will be a contact for data breaches as an independent data controller in its own right, its details should be included in 6.3.2c; otherwise this clause should be deleted.

**Clause 8.1** – Insert the appropriate number of years and working days.

**Clause 8.1.b** – Insert e-mail address for NHS CI Employer archiving contact.

**Clause 11.5.1** – Delete the highlighted text if this Clinical Trial is not a trial of an advanced therapy medicinal product (ATMP). If this Clinical Trial is of an ATMP, keep the highlighted yellow text.

**Clause 11.5.2** – Delete the highlighted text if this Clinical Trial is not a trial of an ATMP. If this Clinical Trial is of an ATMP, keep the highlighted yellow text.

**Clause 11.5.4** – Check that this Clause references the version of the Declaration of Helsinki applicable to this Clinical Trial and update where needed.

**Clause 11.5.7** – Delete if the Clinical Trial does not involve transplantation of human cells, tissue or organs.

**Clause 12.2** – Two options for this clause are provided. The first option describes liability arrangements where the NHS CI Employer can accept liability for the Chief Investigator’s clinical negligence. This option applies when the NHS CI Employer provides secondary or tertiary care, or where they are an independent primary care contractor in England (for example, a general practice). This option may also apply for independent primary care contractors in Wales, but you should check this with them directly. Delete this option when the NHS CI Employer will not accept liability for the CI’s negligence.

The second option describes liability arrangements when the CI must have their own indemnity in place for clinical negligence because the NHS CI Employer does not indemnify them for this itself. This option applies when the NHS CI Employer is an independent primary care contractor in Northern Ireland or Scotland. This option may also apply for independent primary care contractors in Wales, but you should check this with them directly. Delete this option when the NHS CI Employer will accept liability for the CI’s negligence.

**Clauses 19.3, 19.4 and 19.5** – Complete the full names, addresses (and e-mail addresses, as applicable) for contact persons for notices to the Parties.

### Signature page

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

### Appendix 1

Detailed guidance for completion of this Appendix is included within the Financial Arrangements Appendix itself.

### Appendix 2

The Chief Investigator should be provided with this Appendix and sign the declaration at the end of the Appendix. Ensure that the CI has signed this Appendix before the Agreement is executed. If the CI does not sign the declaration to acknowledge the intended Processing of their Personal Data, another individual should be sought to act as CI.

### Appendix 3

The Chief Investigator should be provided with and complete this Appendix in full. The Parties should work with the CI to complete this Appendix, and both Parties should review the information included before the Agreement is executed to make sure that they are content with the interests declared (if any). Where there are interests to declare, the CI should list these in the table in the section “Interests related to this Agreement” and indicate whether it is agreed that they are actual, potential or perceived. Ensure that the CI has completed and signed this Appendix before the Agreement is executed.

### Appendix 4

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

Check the box at Appendix 4 if it is not relevant to the specific Clinical Trial.

### Appendix 5

Clearly set out which Sponsor responsibilities for Chief Investigator management will be performed by the CRO.

Check the box at Appendix 5 if the Sponsor has not delegated any duties or functions under ICH-GCP to the CRO for the specific Clinical Trial.

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

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

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

# Contract Research Organisation Commercial Chief Investigator Agreement

**Between**

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

**“Sponsor”**

AND

[**INSERT** NAME AND REGISTERED ADDRESS OF NHS CI EMPLOYER]

**“NHS CI Employer”**

AND

[INSERT NAME OF CRO AND REGISTERED ADDRESS OF CRO]

**“CRO”**

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

# Contract Research Organisation Commercial Chief Investigator Agreement

### Clause

1. Definitions
2. Chief Investigator Services
3. Intellectual Property
4. Confidential Information
5. Freedom of Information
6. Data Protection
7. Publications
8. Record Retention
9. Quality Assurance Audit
10. Publicity
11. Governance
12. Liability
13. Payment Terms
14. Term and Termination
15. Force Majeure
16. Dispute Resolution
17. Miscellaneous
18. Relationship between the Parties
19. Notices
20. Counterparts and Signatures

Appendix 1 Financial Arrangements

Appendix 2 Chief Investigator Data Processing Notice and Declaration

Appendix 3 Chief Investigator Declaration

Appendix 4 Formal Delegation of Authority to a Corporate Affiliate of the Sponsor or Other Party to Contractually Bind Sponsor

Appendix 5 Sponsor’s Clinical Trial Related Duties and Functions Under ICH-GCP to be Performed by CRO

**WHEREAS**

1. Sponsor wishes to fulfil Sponsor obligations in accordance with the UK Policy Framework and the Regulations, including appointment of a chief investigator for the Clinical Trial in the UK.
2. Sponsor has entered into an agreement with the CRO, which is a Contract Research Organisation.
3. [insert name of CI] is [**OPTION if CI is an employee**: an employee (by virtue of a substantive, joint academic appointment, or other relevant contract type) of the NHS CI Employer] [**OPTION if CI is a GP Partner**: a general practitioner partner of the NHS CI Employer] and [insert name of CI], on behalf of the NHS CI Employer, is qualified (by registration as an authorised health professional, education, training and experience) and willing to provide the CI Services required by the Sponsor.
4. This Agreement is between the Sponsor, CRO and the NHS CI Employer, whereby the [Sponsor] [CRO] **(delete as appropriate)** has satisfied itself as to the suitability of the CI for their functions and procures the CI Services through the NHS CI Employer, which agrees to provide reasonable support to Sponsor, CRO and CI in the execution of the CI Services.
5. References throughout this Agreement to Sponsor shall be construed to include reference to [insert name of Affiliate, or other party], as Affiliate (or other party) empowered by the Sponsor to legally bind the Sponsor to this Agreement and to act on its behalf, in accordance with Appendix 4.
6. The NHS CI Employer represents that the CI, not being a Party to this Agreement, understands and agrees to discharge their duties under it, as an employee of the NHS CI Employer.

It is therefore, agreed that the following terms and conditions shall apply to the CI Services (as 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 or CRO, save where there are contractual arrangements in place to exclude such affiliate. For the purposes of this definition, a business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity, by contract or otherwise;

* **Agent**

shall include but is not limited to, any person providing services to the NHS CI Employer 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 NHS CI Employer and / or any contracted third party providing services to a Party under a contract for services or otherwise;

* **Agreement**

means this Agreement comprising its clauses, schedules and any appendices attached to it and any variations made thereto in accordance with Clause 17.2;

* **Chief Investigator or CI**

means the individual providing the CI Services described in this Agreement;

* **CI Services**

means the legislative and policy responsibilities of the Chief Investigator under The Regulations, the UK Policy Framework, and this Agreement, including the CI services set out in Appendix 1;

* **Clinical Trial**

means the investigation to be conducted in the UK according to the Protocol;

* **Clinical Trial Data**

means the data from the Clinical Trial, stored separately to any source data or Personal Data, which is used to create the Results;

* **Confidential Information**

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

* business, affairs, plans, intentions or market opportunities
* operations, processes, product information, designs, trade secrets or Know-How
* any information developed by the Parties in connection with the Clinical Trial in the course of carrying out this Agreement
* the Protocol, the investigator brochure(s) relating to the Clinical Trial and Appendix 1 to this Agreement (‘Financial Arrangements’);
* **Controller**

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

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

* **EIR**

means either the Environmental Information Regulations 2004 or the Environmental Information (Scotland) Regulations 2004, as applicable to the place of constitution of the NHS CI Employer;

* **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 NHS CI Employer;

* **GDPR**

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

* **GMP**
means the principles and guidelines of good manufacturing practice for medicinal products for human use and for investigational medicinal products for human use laid down in Commission Directive 2003/94/EC, as modified by Schedule 2A to the Human Medicines Regulations 2012, or if Regulations have been made under the powers in regulation B17(1) of the 2012 Regulations, and have come into force, those Regulations, and, in the case of Northern Ireland, any applicable EU standard;
* **GVP**
means any appropriate national UK regulations or standards on good pharmacovigilance practices and in the case of Northern Ireland any applicable EU requirement
* **ICH-GCP**
means the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95); together with such other Good Clinical Practice requirements as may apply within the UK from time to time, including the requirements of any regulations made under regulation 57 of the Medicines for Human Use (Clinical Trials) Regulations 2004/1031 (as amended by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019) and any relevant guidance issued under those Regulations and, in the case of Northern Ireland, any applicable EU requirement;
* **Intellectual Property Rights**

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

* **Investigational Drugs**
means the Investigational Medicinal Product (as defined below) together with control material (for example, placebo, comparator drug, concomitant drug) as detailed in the Protocol;
* **Investigational Medicinal Product or IMP**
means the Sponsor product that is being studied as detailed in the Protocol;
* **Joint Position**

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

* **Know-How**

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

* **Participant**

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

* **Personal Data**

means any and all information, data and material of any nature received or obtained by any Party in connection with this Agreement which is personal data as defined in the Data Protection Laws and Guidance;

* **Principal Investigator**

means the individual responsible to the Chief Investigator for the conduct of the Clinical Trial at a site;

* **Process**

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

* **Processor**

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

* **Protocol**

means the full description of the Clinical Trial with the reference number set out on the front page of this Agreement, together with any amendments thereof;

* **Regulatory Authority**

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

* **Retention Period**

means the time period in which the documents, records and correspondence relating to this Agreement are retained by the NHS CI Employer after the completion of the CI Services, as specified in Clause 8;

* **Results**
means the research findings produced in the Clinical Trial;
* **Secured, Dedicated Cloud-Based Environment**

means infrastructure in which the use of the Confidential Information is access controlled, encrypted, and segregated from publicly accessible artificial intelligence (AI) models and platforms, and is governed by the Sponsor’s or CRO’s internal confidentiality, security, and compliance protocols;

* **The Regulations**

means The Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended);

* **UK Policy Framework**

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

* 1. Any reference to a statutory provision, code or guidance shall be deemed to include reference to any subsequent modification or re-enactment of it, provided that the provisions of the Declaration of Helsinki relating to post-trial supply of IMP (as further defined herein) shall be those that are explicitly indicated in this Agreement. All subsequent modifications to or re-enactments of the Declaration of Helsinki, whether set out in a modification or amendment or otherwise, shall not apply to this Agreement.
	2. The headings to clauses are inserted for convenience only and shall not affect the interpretation or construction of this Agreement.
	3. Where appropriate, words denoting the singular shall include the plural and vice versa.
	4. Where the NHS CI Employer 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, including its appendices, 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.

## Chief Investigator Services

* 1. The NHS CI Employer shall provide, through the Chief Investigator, the CI Services.
		1. Where the NHS CI Employer is not the Chief Investigator’s substantive employer it will notify the Chief Investigator’s substantive employer in a timely way of their proposed involvement in the Clinical Trial. Any financial or other arrangements relating to the Chief Investigator’s involvement in the Clinical Trial as CI will be agreed directly between the NHS CI Employer and the Chief Investigator’s substantive employer.
	2. The CI Services provided under this Agreement shall fulfil the responsibilities of a Chief Investigator, as set out in the UK Policy Framework and as amended from time to time, including that the CI shall:
		1. satisfy themself that the Protocol takes into account any relevant systematic reviews, other research evidence and research in progress (research studies may replicate previous research, but should acknowledge the reason for doing so), that it makes effective use of patient, service user and public involvement where appropriate and that it is scientifically sound, safe (i.e. that the risk of harm has been minimised as much as possible and is not expected to outweigh the benefits), ethical, legal and feasible and remains so for the duration of the Clinical Trial, taking account of developments while the Clinical Trial is ongoing;
		2. satisfy themself that the Protocol has been submitted for appropriate independent expert (‘peer’) review and revised in light of that review;
		3. satisfy themself that, if expected or required, the Protocol has been submitted for review by and obtained approval from a research ethics committee and any other relevant approval bodies;
		4. satisfy themself that everyone involved in the conduct of the Clinical Trial is qualified by education, training (training should be appropriate and proportionate to the type of research undertaken, and should cover the responsibilities of researchers set out in relevant legislation and standards) and experience, or otherwise competent, to discharge their roles in the Clinical Trial. For multi-site projects, this applies to satisfying themself as to each Principal Investigator’s suitability. Assessing the suitability of individuals within each Principal Investigator’s local team will be delegated by the CI to each Principal Investigator for their respective site;
		5. satisfy themself that the information to be given to potential Participants is in a suitable format and is clear and relevant to the potential Participants’ participation in the Clinical Trial and, where consent is required, to potential Participants’ decision-making about taking part in the Clinical Trial;
		6. adhere to the agreed arrangements for making information about the Clinical Trial publicly available before it starts (unless a deferral is agreed by or on behalf of the research ethics committee);
		7. adhere to the agreed arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after the Clinical Trial has finished;
		8. start the Clinical Trial only once the [Sponsor] [CRO] **(delete as appropriate)** has confirmed that everything is ready for it to begin;
		9. adhere to the agreed procedures and arrangements for reporting (for example safety reports) and for monitoring the Clinical Trial, including its conduct, the Participants’ safety and well-being and the ongoing suitability of the approved Protocol in light of adverse events or other developments; and
		10. adhere to the agreed arrangements for making information about the findings of the Clinical Trial available, including, where appropriate to Participants.
	3. The NHS CI Employer acknowledges that to assume the function of a CI it is necessary for the CI to:
		+ 1. have previous clinical trial experience
			2. have sufficient time available to commit to the CI Services
			3. be contactable by the Sponsor, CRO and, where applicable, by Principal Investigators
			4. have commitment to the Clinical Trial.
	4. The NHS CI Employer shall notify the Sponsor and CRO if the CI ceases to be employed by or associated with the NHS CI Employer, is erased from the medical register (or equivalent UK professional register where the CI is not a medical doctor) or is otherwise sanctioned by an applicable regulatory or other governmental authority, or is otherwise unavailable to continue as CI. The NHS CI Employer shall use all reasonable endeavours to find a replacement acceptable to all Parties, subject to the NHS CI Employer’s overriding obligations in relation to individual patient care. If no mutually acceptable replacement can be found the Sponsor or CRO may terminate this Agreement pursuant to Clause 14.

## Intellectual Property

* 1. All Intellectual Property Rights and Know-How owned by or licensed to the Sponsor or Affiliate(s) prior to and after the date of this Agreement, other than any Intellectual Property Rights and Know-How arising from the Clinical Trial, are and shall remain the property of the Sponsor.
	2. All Intellectual Property Rights and Know-How owned by or licensed to the CRO prior to and after the date of this Agreement other than any Intellectual Property Rights and Know-How arising from the Clinical Trial are and shall remain the property of the CRO.
	3. All Intellectual Property Rights and Know-How owned by or licensed to the NHS CI Employer prior to and after the date of this Agreement, other than any Intellectual Property Rights and Know-How arising from the Clinical Trial, are and shall remain the property of the NHS CI Employer.
	4. All Intellectual Property Rights and Know-How arising from and relating to the Clinical Trial, the IMP (including but not limited to its formulation and use alone or in combination with other drugs), and / or the Protocol, but excluding any clinical procedure and improvements thereto that are clinical procedures of the NHS CI Employer, shall vest in the Sponsor in accordance with Clauses 3.5 and 3.6 of this Agreement.
	5. In accordance with Clause 3.4, the NHS CI Employer hereby assigns, and shall procure that CI and any other of its Agents assign, its rights in relation to all Intellectual Property Rights and Know-How, falling within Clause 3.4, to the Sponsor or its nominee. At the request and expense of the Sponsor, the NHS CI Employer shall execute, and shall procure that the CI and any other of its Agents shall execute, all such documents and do all such other acts as the Sponsor may reasonably require in order to vest fully and effectively all such Intellectual Property Rights and Know-How in the Sponsor or its nominee.
	6. The NHS CI Employer shall, and will ensure that the CI shall, promptly disclose to the Sponsor and CRO any Know-How generated pursuant to this Agreement and falling within Clause 3.4 and undertakes not to use or disclose such Know-How other than for the purposes of this Agreement.
	7. Nothing in this Clause 3 shall be construed so as to prevent or hinder the NHS CI Employer from using its Know-How generated during the performance of the CI Services 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.

## Confidential Information

* 1. Each Party may only disclose Confidential Information to their own officers, Agents and employees (and in the case of the Sponsor or CRO, those of its Affiliates and, if applicable, other parties who may have contractual rights in the Results or to develop the IMP (for example, through a 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 another Party, save where disclosure is required by a Regulatory Authority or by law (including any disclosure required to ensure compliance, by the NHS CI Employer, with the FOIA or EIR in accordance with Clause 5 of this Agreement). The Party required to make the disclosure shall inform the other Parties, within a reasonable time prior to being required to make the disclosure (and, where appropriate, in accordance with Clause 5), of the requirement to disclose and the information required to be disclosed. Each Party undertakes not to make use of any Confidential Information of the other Parties, other than in accordance with this Agreement, without the prior written consent of the relevant Party.
	2. For the avoidance of doubt, nothing in this Clause 4 shall be construed as intended to prevent any Party, or the CI, from sharing Confidential Information, for the purpose of the CI Services, with any prospective trial site or trial site in the Clinical Trial that has in place a model confidential disclosure agreement or model clinical trial agreement in relation to the Clinical Trial. The NHS CI Employer warrants that it shall require the CI to seek confirmation from the [Sponsor] [CRO] (**delete** as applicable) that any prospective trial site has a model confidential disclosure agreement in place with the Sponsor or its Agent before the first disclosure of any Confidential Information related to the Clinical Trial. The Sponsor acknowledges that the CI can share Confidential Information related to the Clinical Trial with trial sites which have entered into a model clinical trial agreement in relation to the Clinical Trial with the Sponsor without its prior confirmation that a model clinical trial agreement is in place.
	3. 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;
	4. In the event of a Party visiting the establishment of another Party, the visiting Party undertakes that any further Confidential Information that may come to the visiting Party’s knowledge as a result of any such visit, shall be treated as Confidential Information in accordance with this Clause 4.
	5. This Clause 4 shall remain in force for the time period for which the NHS CI Employer retains records related to this Agreement as set out in Clause 8 (Record Retention) (subject to the permitted uses set out in this agreement). Save as aforesaid, and unless otherwise expressly set out in this Agreement, this Clause 4 shall remain in force for a period of ten (10) years after the termination or expiry of this Agreement.
	6. The NHS CI Employer will not use or employ, and will not cause any third party to use or employ, Sponsor or CRO Confidential Information in any generative or other artificial intelligence algorithms, models, software, tools, technologies, or systems, including but not limited to, natural language processing, deep learning models, or machine learning (collectively, "**AI Tools**"), unless Sponsor and / or CRO (as applicable) provides express consent in writing. The Sponsor and CRO will not use or employ, and will not cause any third party to use or employ, NHS CI Employer Confidential Information in any AI Tool, unless NHS CI Employer provides express consent in writing except that Sponsor and CRO may each, on the basis of this Agreement and without additional NHS CI Employer’s consent, use NHS CI Employer’s Confidential Information within their own Secured, Dedicated Cloud-Based Environment and / or local AI Tool instance subject to Sponsor’s and CRO’s confidentiality, security and non-use obligations herein. The Sponsor and CRO each warrant that any Confidential information used within its Secured, Dedicated Cloud-Based Environment will not be used to train, fine-tune, or otherwise improve the performance of any underlying AI models.

## Freedom of Information

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

## Data Protection

* 1. The Parties acknowledge that the CI has accepted the terms of the Chief Investigator Data Processing Notice and Declaration at Appendix 2 and that the Parties may process the Personal Data of the CI in accordance with this Agreement.
	2. The Parties acknowledge that the CI will not have access to the Personal Data of Clinical Trial Participants, in their role as CI, and that for the purpose of this Agreement, Sponsor and NHS CI Employer are assumed to be a separate and independent Controller of any Personal Data that is processed in association with the Agreement and the CI Services. This means that Sponsor and NHS CI Employer will assume full responsibility for the Personal Data it collects, processes, or otherwise handles within its own systems and under its own control. This Agreement does not form a Controller-Processor relationship or agreement between the CRO and NHS CI Employer. The relationship between CRO and Sponsor in relation to Personal Data is not the subject of this Agreement.
	3. The Parties agree:
		1. to comply with all Data Protection Laws and Guidance in Processing the Personal Data of the CI and of any Agents of another Party, including by implementing and maintaining appropriate technological and organisational measures to protect such Personal Data under its control. Each Party will take appropriate operational measures to safeguard any such Personal Data against any unauthorised access, deletion or modification. 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 the other Party via email in the event of any Personal Data Breach that relates to that Personal Data using the following contacts:
			1. Sponsor contact: [insert email address]
			2. NHS CI Employer contact: [insert email address]
			3. (**DELETE** if not applicable) CRO contact: [insert email address]
		3. to cooperate with each other in relation to the processing of Personal Data. This includes sharing information necessary for compliance with Data Protection Laws and Guidance and addressing any concerns related to the handling of Personal Data.

## Publications

* 1. The Sponsor shall ensure that the Results of the Clinical Trial are published on a free, publicly accessible clinical trial Results database in accordance with the principles of the Joint Position within one (1) year after the IMP is first approved and made commercially available in any country or, if the Clinical Trial is a post-approval clinical trial, within one (1) year of completion of the Clinical Trial. In respect of a clinical trial that is under review by peer reviewed journals that prohibit disclosure of results pre-publication, the Results will be posted at the time of publication.
		1. The NHS CI Employer acknowledges that nothing in this Agreement prevents the Sponsor and / or CRO (nor any person with whom they share the methods and Results of the Clinical Trial) from presenting at symposia, national or regional professional meetings, publishing in journals, theses or dissertations or otherwise of their own choosing, the methods and results of the Clinical Trial and in particular, but without limiting the foregoing, post a summary of the Clinical Trial results in an on-line clinical trials register(s) before or after publication by any other method.
		2. The participation of the CI as named author of published Results shall be determined in accordance with the Sponsor’s or CRO’s policy and generally accepted standards for authorship. The CI shall have access to the Clinical Trial Data from all sites involved in the Clinical Trial, as necessary to participate fully in the development of the publication.
	2. The Sponsor recognises that the NHS CI Employer and CI have a responsibility under the UK Policy Framework to ensure that Results of scientific interest arising from the Clinical Trial are appropriately published and disseminated.
	3. The Sponsor agrees that the CI shall be permitted to present at symposia, national and regional professional meetings and to publish in journals, theses or dissertations, or otherwise of their own choosing, the methods and Results of the Clinical Trial, subject to this Clause 7 and any publication policy described in the Protocol, provided any such policy is consistent with the Joint Position.
	4. Upon completion of the Clinical Trial at all sites, and any prior publication by the Sponsor of Results, or when the Clinical Trial Data are adequate (in the Sponsor’s reasonable judgment), the NHS CI Employer may prepare the data derived from the Clinical Trial for publication. Such data will be submitted to the Sponsor for review and comment prior to publication.
		1. In order to ensure that the Sponsor will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to the Sponsor for review at least sixty (60) days (or the time specified in the Protocol if longer) prior to submission for publication, public dissemination, or review by a publication committee.
		2. The NHS CI Employer agrees and shall ensure that the CI agrees that all reasonable comments made by the Sponsor in relation to a proposed publication by the NHS CI Employer will be incorporated into the publication.
		3. Subject to Clause 4 regarding Confidential Information, the NHS CI Employer will accurately describe and will ensure that the CI will accurately describe the financial support of the Sponsor for the Clinical Trial in all publications and presentations.
		4. During the period for review of a proposed publication referred to in Clause 7.4.1, the Sponsor shall be entitled to make a reasoned request to the NHS CI Employer that publication be delayed for a period of up to six (6) months from the date of first submission to the Sponsor in order to enable the protection of proprietary information and / or Intellectual Property Rights and Know-How and the NHS CI Employer shall not unreasonably withhold or delay its consent to such request. The NHS CI Employer 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.

## Record Retention

* 1. The NHS CI Employer will archive all documents, records and correspondence related to this Agreement in accordance with the MRC Principles and Guidelines for Good Research Practice. The NHS CI Employer shall retain all such records for a period of [INSERT NUMBER] years after the completion of all Protocol required activities for all enrolled Participants in all locations where the Sponsor (or any Affiliate of the Sponsor) is carrying out the Clinical Trial or the completion of the CI Services, whichever is later. Upon the expiry of the Retention Period the NHS CI Employer shall transfer such records to the Sponsor or CRO if requested by the Sponsor or CRO, and shall not destroy any records without the [Sponsor’s] [CRO’s] (**delete as appropriate**) 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 or CRO within [INSERT NUMBER] working days of receipt by the [Sponsor] [CRO] (**delete as appropriate**) of a written request by the NHS CI Employer for approval to destroy such records, the NHS CI Employer may proceed to destroy the records and such destruction shall not be in breach of this Agreement.

a. The NHS CI Employer will archive the records either in line with its usual archiving arrangements or will collaborate with the Sponsor or CRO to arrange appropriate archiving outside usual NHS CI Employer practice.

b. All arrangements for access to documents at the NHS CI Employer should be made with the NHS CI Employer’s responsible person for archiving: [insert email address] **(recommend using a generic email address)**.

c. In the event that costs of archiving are to be incurred by the NHS CI Employer, including all preparation and retrieval costs relating to any reasonable request to access the documentation, the Sponsor warrants and confirms that it or its Agents, or CRO, will pay all such costs as provided by the NHS CI Employer as a one-off payment [**DELETE ONE OPTION AND RETAIN THE OTHER**] [for archiving physical records at the completion of the CI Services 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 the completion of the CI Services] [of £750 (inclusive of all overheads but exclusive of VAT, where applicable) for the establishment of the NHS CI Employer’s electronic filing of records relating to this Agreement, including the arrangements for the archiving of the same, following commencement of this Agreement]. In the event that the records are archived offsite by the Sponsor and the NHS CI Employer does not incur any costs, no amounts will be payable to the NHS CI Employer.

d. Notwithstanding the foregoing, the NHS CI Employer will retain responsibility for the records and access thereto.

## Quality Assurance Audit

* 1. The activities and records of the NHS CI Employer, and the CI, under this Agreement may upon reasonable notice be audited by the Sponsor, CRO, or their Agents, in order to assess compliance with the responsibilities and obligations of the CI within the CI Services, ICH-GCP and GVP, subject to compliance with the Data Protection Laws and Guidance. The NHS CI Employer agrees, following reasonable written notification, to allow an independent audit of all documentation relevant to this Agreement.
	2. The NHS CI Employer acknowledges that Regulatory Authorities may inspect its, and the Chief Investigator’s, activities and records related to the Clinical Trial, subject to compliance with Data Protection Laws and Guidance.

## Publicity

* 1. Subject to Clauses 7.1.2, 7.4.3 and 13.3, the Sponsor and CRO will not, and will ensure that their Affiliates and Agents do not, use the name of the NHS CI Employer or the CI in any publicity, advertising or news release without prior written approval from the NHS CI Employer and / or the CI (as applicable), such approval not to be unreasonably withheld.
	2. For the avoidance of doubt, nothing in this Agreement will prohibit the Sponsor or CRO from publishing the identity and contact information of the CI for the purpose of registering the Clinical Trial in a publicly available clinical trials database or otherwise as may be required by applicable law.
	3. The NHS CI Employer will not, and will ensure that the CI and its Agents do not, use the name of the Sponsor or CRO, or the name(s) of any of their employees, nor the name of the Clinical Trial, nor the IMP in any publicity, advertising or news release without the prior written approval of the Sponsor and / or CRO as appropriate, such approval not to be unreasonably withheld. The provisions of this Clause 10.3 shall also apply to the NHS CI Employer’s use of the name, trademark, service mark, and / or logo of any third parties collaborating with the Sponsor or CRO on the Clinical Trial and / or the investigational medicinal product (“**Sponsor or CRO Collaborators**”) provided that the NHS CI Employer has been notified of the identity of the Sponsor or CRO Collaborators.

## Governance

* 1. The NHS CI Employer represents that neither it nor, to the best of its knowledge arrived at after reasonable due diligence, the CI is restricted or prevented under any law from taking part in clinical research. During the term of this Agreement and for one (1) year after its termination or expiry, the NHS CI Employer will notify the Sponsor and CRO if the NHS CI Employer becomes aware of any restriction or prevention being applied to the CI.
	2. The NHS CI Employer represents that it and, to the best of its knowledge arrived at after reasonable due diligence, the CI are not the subject of any past or pending government or regulatory investigation, inquiry, warning or enforcement action (collectively “**Agency Action**”) related to their conduct of research that has not previously been disclosed to the Sponsor and CRO. The NHS CI Employer will promptly notify the Sponsor and CRO if it becomes aware of any Agency Action regarding compliance with ethical, scientific or regulatory standards for the conduct of research, if the Agency Action relates to events or activities that occurred prior to or during the period in which the Clinical Trial is conducted.
	3. The NHS CI Employer represents that it is not aware of any actual, potential or perceived interest that the CI may have, other than any that are disclosed in Appendix 3. The NHS CI Employer shall ensure that the CI shall disclose any change of interests during the term of this Agreement using the declaration of interests in Appendix 3.
	4. To the extent applicable to each, the Parties shall comply with, and the NHS CI Employer shall ensure that the CI complies 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 NHS CI Employer;
		4. The Medicines Act 1968;
		5. The Human Medicines Regulations 2012;
		6. The Medicines for Human Use (Clinical Trial) Regulations 2004;
		7. The Bribery Act 2010;
		8. Relevant law having effect by virtue of ss2-4 of the European Union (Withdrawal) Act 2018;
		9. (In Northern Ireland) laws of the European Union having effect as a result of the protocol on Ireland / Northern Ireland.
	5. The Parties shall comply with, and the NHS CI Employer shall ensure that the CI complies with, all relevant guidance relating to medicines and clinical trials from time to time in force, including but not limited to:
		1. the ICH-GCP [**delete** if Clinical Trial is not an ATMP] including the European Commission Guidelines on Good Clinical Practice specific to Advanced Therapy Medicinal Products;
		2. GMP [**delete** if Clinical Trial is not an ATMP] including the European Commission Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products;
		3. GVP;
		4. the World Medical Association Declaration of Helsinki entitled, “Ethical Principles for Medical Research Involving Human Subjects (1996)”;
		5. the UK Policy Framework;
		6. the UK Research and Innovation policies and principles entitled, “[Human Biological Samples](https://www.ukri.org/about-us/policies-standards-and-data/good-research-resource-hub/human-biological-samples/)”;
		7. [**DELETE IF NOT APPLICABLE** – the ethical principles endorsed by [WHA63.22](https://apps.who.int/iris/handle/10665/341814) with regard to the Clinical Trial.]
	6. The NHS CI Employer shall ensure that the CI delivers and / or undertakes any such appropriate training as the Sponsor or CRO may consider necessary for the provision of CI Services, including but not limited to the training and provision of information given during investigator meetings.
	7. **Anti-Bribery and Corruption**
		1. Each Party warrants and represents that it has not committed, and that it has not induced the CI to commit, 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 any other Party any gift or consideration of any kind, as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this Agreement or any other agreement with any other Party or for showing or not showing favour or disfavour to any person in relation to this Agreement or any other agreement with any other Party; or
			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 any other Party.
		2. In addition to the above, the NHS CI Employer warrants and represents that the Chief Investigator has not and will not commit any Prohibited Acts.
		3. If any Party or the Chief Investigator has committed or commits any of the Prohibited Acts in relation to this Agreement, then any other Party shall be entitled to terminate this Agreement in accordance with Clause 14, in addition to any other remedy available, taking into consideration the potential effects of termination on the health of Participants.

## Liability

* 1. Nothing in this Clause 12 shall operate so as to restrict or exclude the liability of any Party in relation to death or personal injury caused by the negligence or wilful misconduct of that Party or its Agents or employees, or to restrict or exclude any other liability of any Party that cannot be so restricted or excluded in law.
	2. [**DELETE** if **Chief Investigator** will provide their own indemnity] Whilst the NHS CI Employer will use all reasonable endeavours to ensure that the CI undertakes their responsibilities and obligations under this Agreement, the NHS CI Employer makes no warranty, express or implied, as to the advice provided by the CI to the Sponsor, CRO, or any site in the Clinical Trial and will not be held responsible for any consequence arising out of any inaccuracies or omissions unless such inaccuracies or omissions are the result of clinical negligence on the part of the CI. Subject to Clause 17.3 (Survival of Clauses), it is agreed by the Parties to this Agreement that the obligations of the NHS CI Employer and the CI shall cease upon completion of the CI Services, or earlier termination in accordance with this Agreement. No liability whatsoever either direct or indirect shall be accepted by the NHS CI Employer and / or the CI for the effects of any product or process that may be produced or adopted by the Sponsor or CRO or any other party, notwithstanding that the formulation of such product or process may be based in whole or in part upon this Agreement.
	3. [**DELETE** if **NHS CI Employer** will provide indemnity] Whilst the NHS CI Employer will use all reasonable endeavours to ensure that the CI undertakes their responsibilities and obligations under this Agreement, the NHS CI Employer makes no warranty, express or implied, as to the advice provided by the CI to the Sponsor, CRO, or any site in the Clinical Trial and will not be held responsible for any consequence arising out of any inaccuracies or omissions. The NHS CI Employer represents that the Chief Investigator shall have adequate insurance or indemnity arrangements in place to cover against any consequence arising from inaccuracies or omissions that are the result of clinical negligence on the part of the CI. Subject to Clause 17.3 (Survival of Clauses), it is agreed by the Parties to this Agreement that the obligations of the NHS CI Employer and the CI shall cease upon completion of the CI Services, or earlier termination in accordance with this Agreement. No liability whatsoever either direct or indirect shall be accepted by the NHS CI Employer and / or the CI for the effects of any product or process that may be produced or adopted by the Sponsor or CRO or any other party, notwithstanding that the formulation of such product or process may be based in whole or in part upon this Agreement.
	4. The CRO expressly disclaims any liability in connection with Investigational Drugs caused by or allegedly caused by the use or misuse of the Investigational Drugs other than liability for death, personal injury or loss of or damage to property which liability is the result of negligence on the part of the CRO.

## Payment Terms

* 1. Payment for CI Services will be made in accordance with Appendix 1 of this Agreement.
		1. In addition, the [Sponsor] [CRO] **(delete as appropriate)** or its Agent, will reimburse all reasonable travel and other reasonable out-of-pocket expenses incurred by the CI in connection with the CI Services which have the prior approval of the [Sponsor] [CRO] **(delete as appropriate)**, subject to the [Sponsor] [CRO] **(delete as appropriate)**or their Agent, receiving a completed reimbursement claim form (to be provided, if applicable, by the [Sponsor] [CRO] **(delete as appropriate)**or their Agent) or invoice and accompanying proof of purchases (e.g. receipts) for each expense being claimed within forty-five (45) days of completion of the responsibilities in order to enable the [Sponsor] [CRO] **(delete as appropriate)**to comply with its obligations arising under the ABPI Code of Practice for the Pharmaceutical Industry (“**ABPI Code**”) and any other applicable law, code or regulation, with regards to transparency from time to time. It is further agreed that any such expenses will be paid at the rate of fair market value (in line with the ABPI Code) and subject to the documentation evidencing the expenses being in sufficient detail for the [Sponsor’s] [CRO’s] **(delete as appropriate)** financial reporting purposes, provided that the required detail does not impose an unreasonable administrative burden upon the NHS CI Employer. Such expenses may be publicly reportable.
	2. The [Sponsor] [CRO] **(delete as appropriate)** acknowledges that the NHS CI Employer can defer funds paid under this Agreement to build research capacity in future financial years. All Parties acknowledge that there is no obligation under this Agreement on the NHS CI Employer to either spend funds paid under the Agreement within the same financial year, or to refund the [Sponsor] [CRO] **(delete as appropriate)** with any sums not spent within the same financial year.
	3. The NHS CI Employer agrees that the Sponsor and / or CRO may make public the financial support provided to the NHS CI Employer by the Sponsor and / or CRO for the conduct of the CI services and may identify the NHS CI Employer and CI as part of the disclosure.

## Term and Termination

* 1. This Agreement will commence on the date of last signature and will continue until completion of the CI Services, unless terminated earlier in accordance with the conditions of this Agreement.
	2. The Sponsor, CRO or the NHS CI Employer (the “**Terminating Party**”) may terminate this Agreement with immediate effect at any time if another Party or the Chief 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 (20) working 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.
	3. The Sponsor or CRO may terminate this Agreement on notice to the NHS CI Employer if the Chief Investigator is no longer able (for whatever reason) to act as Chief Investigator and no replacement mutually acceptable to the Parties can be found.
	4. The Sponsor may terminate this Agreement immediately upon notice in writing to the NHS CI Employer for reasons not falling within Clauses 14.2 or 14.3. In all such circumstances, the Sponsor shall confer with the Chief Investigator and use its best endeavours to minimise any inconvenience or harm to Participants caused by the premature termination of the Clinical Trial and / or this Agreement.
	5. In the event of early termination of this Agreement by the Sponsor or CRO, pursuant to Clauses 14.2, 14.3, or by the Sponsor pursuant to Clause 14.4 and subject to an obligation on the NHS CI Employer and the Chief Investigator to mitigate any loss, the Party making payment shall pay all costs incurred and falling due for payment up to the date of termination, and also all non-cancellable expenditure falling due for payment after the date of termination that arises from commitments reasonably and necessarily incurred by the NHS CI Employer for the performance of the CI Services prior to the date of termination, and agreed with the Party making payment.
	6. On the expiry or termination of this Agreement (for whatever reason), the NHS CI Employer shall [destroy, and shall ensure that the Chief Investigator shall destroy,] [promptly deliver, and shall ensure that the Chief Investigator delivers, to the Sponsor or CRO] (**delete** one option) any Confidential Information received by NHS CI Employer and / or the CI (and copies thereof) disclosed or supplied pursuant to or in relation to this Agreement, save one copy that shall be retained by the NHS CI Employer in accordance with Clause 4.4 and Clause 8 (Record Retention). 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 NHS CI Employer’s information technology systems procedures, provided that such copies are maintained in strict confidence and the NHS CI Employer shall make no further use of those copies other than as permitted in the Agreement. Retention of Confidential Information on backup computer systems shall not relieve the Parties of non-disclosure and non-use obligations.

## Force Majeure

* 1. No Party shall be liable to any other Party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, terrorist activity, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstances shall promptly notify the other Parties in writing when such circumstances cause a delay or failure in performance 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 Parties shall have the right to terminate this Agreement immediately by notice in writing to the other Parties.

## Dispute Resolution

* 1. In the event of a dispute arising under this Agreement, authorised representatives of the Parties will discuss and meet as appropriate to try to resolve the dispute within seven (7) days of being requested in writing by any Party to do so. If the dispute remains unresolved, it will then be referred to a senior manager from each of the Parties who will use all reasonable endeavours to resolve the dispute within a further fourteen (14) days.
	2. If the NHS CI Employer is constituted in England or Wales then, in the event of failure to resolve the dispute through the steps set out in Clause 16.1, the Parties agree to attempt to settle it by mediation in accordance with the Centre for Effective Dispute Resolution Model Mediation Procedure. To initiate a mediation, a Party shall give notice in writing (“**ADR Notice**”) to the other Parties requesting mediation in accordance with this Clause 16.2. The Parties shall seek to agree the nomination of the mediator, but in the absence of agreement the mediator shall be nominated by the President for the time being of the British Medical Association. The person so appointed will act as an expert and not as an arbitrator. The mediation will start no later than twenty (20) days after the date of the ADR Notice. The Parties shall each bear their own costs and expenses in relation to settlement of any disputes in terms of this Clause 16 and shall share equally the costs of the independent third party. If the dispute is not resolved within thirty (30) days of the ADR Notice, a Party shall be entitled to submit to the exclusive jurisdiction of the courts of England and Wales.
	3. If the NHS CI Employer is constituted in Scotland, then in the event of failure to resolve the dispute through the steps set out in Clause 16.1, 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 16 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 16.1 and 16.2, a Party shall be entitled to submit to the exclusive jurisdiction of the Scottish courts.
	4. If the NHS CI Employer is constituted in Northern Ireland, then in the event of failure to resolve the dispute through the steps set out in Clause 16.1, the Parties agree to attempt to resolve the dispute by mediation. To initiate a mediation, a Party will give notice in writing to the other Parties requesting mediation in accordance with this Clause 16.4. 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 16.1 and 16.2, a Party shall be entitled to submit to the exclusive jurisdiction of the courts of Northern Ireland.
	5. Nothing in this Agreement shall prevent any Party from seeking an interim injunction (if the NHS CI Employer is constituted in England or Wales or Northern Ireland) or interdict (if the NHS CI Employer 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 any of the Parties is entitled to an interim injunction or interdict as applicable.

## Miscellaneous

* 1. This Agreement contains the entire understanding between the Parties. This Agreement supersedes all other agreements, negotiations, representations and undertakings, whether written or oral, of prior date between the Parties relating to the CI Services which are the subject of this Agreement.
	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. The Parties warrant that the [Sponsor] [CRO] **(delete as applicable)** and the NHS CI Employer will inform the Chief Investigator of any changes which affect the provision of the CI Services before they vary the Agreement.
	3. **Survival of Clauses**

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

**Clause 1** Definitions

**Clause 3** Intellectual Property

**Clause 4** Confidential Information

**Clause 5** Freedom of Information

**Clause 6** Data Protection

**Clause 7** Publications

**Clause 8** Record Retention

**Clause 9** Quality Assurance Audit

**Clause 10** Publicity

**Clause 11** Governance

**Clause 12** Liability

**Clause 14** Term and Termination

**Clause 15** Force Majeure

**Clause 16** Dispute Resolution

**Clause 17** Miscellaneous

**Clause 18** Relationship of the Parties

 **Clause 19** Notices

* 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 NHS CI Employer is constituted in Scotland (each being a "**Third Party Rights Act**"). Any right or remedy of a third party that existed or is available apart from the relevant Third Party Rights Act is not affected; in particular, without limitation, any right of any Participant to claim compensation.

* 1. **Governing Law and Jurisdiction**

Where the NHS CI Employer 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 NHS CI Employer 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 NHS CI Employer 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 NHS CI Employer 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. **Waiver**

No failure, delay, relaxation or indulgence by any Party in exercising any right conferred on such Party by this Agreement shall operate as a waiver of such right, nor shall any single or partial exercise of any such right nor any single failure to do so, preclude any other or future exercise of it, or the exercise of any other right under this Agreement.

## Relationship between the Parties

* 1. CRO may assign or otherwise transfer this Agreement, in whole including all prior rights and responsibilities but not in part or otherwise, to the Sponsor or another party subject to the consent of the Sponsor. The CRO shall promptly inform the NHS CI Employer of any such transfer and provide the NHS CI Employer with a copy of the assignment or other transfer agreement duly executed by the CRO and the Sponsor or other party and a copy of the Sponsor’s written consent thereto.
	2. Except as provided in Clause 18.1, no Party may assign its rights under this Agreement or any part thereof without the prior written consent of the other Parties, such consent not to be unreasonably withheld or delayed, except that the Sponsor and / or CRO may assign this Agreement at any time to a successor to all or substantially all of its business or assets to which this Agreement relates, whether by way of merger, consolidation, sale of stock, sale of assets, operation of law or otherwise, upon written notice to the NHS CI Employer. The Sponsor, and / or CRO, shall inform the NHS CI Employer in good time in writing about the aforementioned assignment / assignation.
	3. No Party may sub-contract the performance of all or any of its obligations under this Agreement without the prior written consent of the other Parties, such consent not to be unreasonably withheld or delayed. In the event that any Party sub-contracts its responsibilities under this Agreement, it shall be responsible for the acts and omissions of its sub-contractors as though they were its own. Any Party who so sub-contracts shall be responsible for pass-through of payments to its sub-contractors.
	4. The Sponsor shall use all reasonable endeavours to procure the punctual, true and faithful performance and observance by the CRO of its obligations under this Agreement. In the event of any material breach of the obligations of the CRO under this Agreement, and on receipt of notice from the NHS CI Employer to do so, the Sponsor shall from the date of such notice assume all rights and obligations of the CRO under this Agreement and at its own expense perform or, subject to the agreement of the NHS CI Employer (such agreement not to be unreasonably withheld or delayed), take whatever steps may be necessary to procure the performance of the obligations of the CRO under this Agreement by another party.
	5. In the event that the CRO passes a resolution or the court makes an order that the CRO be wound up otherwise than for the purpose of bona fide reconstruction or amalgamation, or a receiver, manager or administrator on behalf of a creditor is appointed in respect of the CRO’s business or any part thereof, or the CRO is unable to pay its debts within the meaning of Section 123 of the Insolvency Act 1986 then, on receipt of notice from the NHS CI Employer to do so, the Sponsor shall from the date of such notice assume all the rights and obligations of the CRO under this Agreement and at its own expense perform or, subject to the agreement of the NHS CI Employer (such agreement not to be unreasonably withheld or delayed), take whatever steps may be necessary to procure the performance of the obligations of the CRO under this Agreement by another party.
	6. Nothing in this Agreement shall be construed as creating a joint venture, partnership, contract of employment or relationship of principal and agent between any of the Parties.

## Notices

* 1. Any notice required to be given by any Party shall be in writing quoting the date of the Agreement and shall be delivered by hand or sent by pre-paid first-class recorded delivery or by e-mail to the contact persons listed below, as per the contact details listed below, or such other person as one Party may inform the other Parties in writing from time to time.
	2. 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.
	3. Notices to the Sponsor shall be addressed to:

[Insert contact name and address – include email address as applicable]

* 1. Notices to the CRO shall be addressed to:

[Insert contact name and address – include email address as applicable]

* 1. Notices to the NHS CI Employer shall be addressed to:

[Insert contact name and address – include email address as applicable]

## 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 another Party shall take effect as delivery of an executed counterpart of this Agreement. If either method of delivery is adopted, without prejudice to the validity of the Agreement thus made, each Party shall provide the others with the original of such counterpart as soon as reasonably possible thereafter. No counterpart shall be effective until each Party has executed and delivered at least one counterpart.

|  |  |  |
| --- | --- | --- |
| Signed for and on behalf of:[**INSERT** NAME OF SPONSOR]OrSigned by [**INSERT** name of company] for and on behalf of [**INSERT** NAME OF SPONSOR], as duly authorised under Appendix 4Signature:Print name:Title: Date: | Signed for and on behalf of:[**INSERT** NAME OF CRO]Signature:Print name:Title: Date: | Signed for and on behalf of:[**INSERT** NAME OF NHS CI EMPLOYER]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: Financial Arrangements

[**[DELETE this guidance before providing agreement to NHS CI Employer]**

**Clause 1.2:** Four options to describe the frequency of invoicing are provided to the Sponsor or CRO. A single option should be selected. If the final option is selected (another frequency to be agreed by the Parties) this should be based on a calendar frequency (for example twice annually), not Clinical Trial or NHS CI Employer milestones (for example, upon completion of 2 investigator meetings).

**Clause 1.3:**Five options to describe the arrangements for raising invoices for the CI Services are provided to the Sponsor or CRO. A single option should be selected.

**Clause 2.1:** The Sponsor or CRO should provide here the contact details to which invoices should be sent by the NHS CI Employer. The Sponsor or CRO 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 2.2:** The contact details for invoice requests and invoice queries to be sent to the NHS CI Employer should be completed by the Sponsor or CRO following discussion with the NHS CI Employer and prior to sharing the Agreement with the NHS CI Employer. Whether the NHS CI Employer chooses to receive the invoice requests or queries to its physical address or by email should be specified here.

**Clause 2.3:**Payment details for the NHS CI Employer should be completed by the Sponsor or CRO following discussion with the NHS CI Employer and prior to sharing the Agreement with the NHS CI Employer.

**Clause 3.1:** Find the [market forces factor](https://www.nihr.ac.uk/how-interactive-costing-tool-ict-calculates-costs-studies-sites) (MFF) specific to the NHS CI Employer within the Overheads tab of the iCT tariff data spreadsheet on the NIHR website. Cross-reference this with the table here, and use the information in this table to replace the highlighted text in this clause with the relevant number.

| **Market Forces Factor specified in the interactive Costing Tool Tariff Data** | **Total Medical Staff hourly cost 2025/26 (direct cost + indirect cost + capacity build + MFF)** | **Market Forces Factor percentage** | **Market Forces Factor hourly cost** |
| --- | --- | --- | --- |
| 1.03 | £243.08 | 3.0% | £7.08 |
| 1.04 | £245.44 | 4.0% | £9.44 |
| 1.05 | £247.80 | 5.0% | £11.80 |
| 1.055 | £248.98 | 5.5% | £12.98 |
| 1.06 | £250.16 | 6.0% | £14.16 |
| 1.065 | £251.34 | 6.5% | £15.34 |
| 1.07 | £252.52 | 7.0% | £16.52 |
| 1.08 | £254.88 | 8.0% | £18.88 |
| 1.09 | £257.24 | 9.0% | £21.24 |
| 1.1 | £259.60 | 10.0% | £23.60 |
| 1.11 | £261.96 | 11.0% | £25.96 |
| 1.12 | £264.32 | 12.0% | £28.32 |
| 1.13 | £266.68 | 13.0% | £30.68 |
| 1.14 | £269.04 | 14.0% | £33.04 |
| 1.15 | £271.40 | 15.0% | £35.40 |
| 1.16 | £273.76 | 16.0% | £37.76 |
| 1.17 | £276.12 | 17.0% | £40.12 |
| 1.18 | £278.48 | 18.0% | £42.48 |
| 1.19 | £280.84 | 19.0% | £44.84 |
| 1.2 | £283.20 | 20.0% | £47.20 |
| 1.21 | £285.56 | 21.0% | £49.56 |
| 1.22 | £287.92 | 22.0% | £51.92 |
| 1.23 | £290.28 | 23.0% | £54.28 |
| 1.24 | £292.64 | 24.0% | £56.64 |
| 1.25 | £295.00 | 25.0% | £59.00 |
| 1.26 | £297.36 | 26.0% | £61.36 |
| 1.27 | £299.72 | 27.0% | £63.72 |
| 1.29 | £304.44 | 29.0% | £68.44 |
| 1.32 | £311.52 | 32.0% | £75.52 |
| 1.33 | £313.88 | 33.0% | £77.88 |
| 1.36 | £320.96 | 36.0% | £84.96 |

**Clause 3.2**: complete the table with services which will be provided to set up the Clinical Trial. Examples of services which might be provided by the Chief Investigator to set up the Clinical Trial have been included.

* The example services are not definitive or exhaustive – you can add and remove services as required and as agreed between the Sponsor and / or CRO and NHS CI Employer. You can also add and remove rows to this table as needed.
* The time required for the example services to be provided in this clause is the minimum time it is expected that these activities will take. The amount of time contracted for these services cannot be less than that specified in the template, but if more time is needed this can be added before the contract is executed if the Parties agree to this.
* The cost per hour is fixed at the hourly Medical Staff rate in the interactive Costing Tool – it is not negotiable. Use the hourly cost you included in Clause 3.1 to calculate the total cost for each activity based on the number of hours agreed between the Parties. The example includes indicative costs for these activities, excluding MFF which would need to be added. The cost represents fair market value.

**Clause 3.3**: complete the table with any services the Chief Investigator will provide after the initial set-up of the Clinical Trial. Examples of services which might be provided by the Chief Investigator have been included.

* The example services are not definitive or exhaustive – you can add and remove services as required and as agreed between the Sponsor and / or CRO and NHS CI Employer. You can also add and remove rows to this table as needed.
* The time required for the example services to be provided in this clause is the minimum time for each example service and is subject to negotiation.
* The cost per hour is fixed at the hourly Medical Staff rate in the interactive Costing Tool – it is not negotiable. Use the hourly cost you included in Clause 3.1 to calculate the total cost for each activity based on the number of hours agreed between the Parties. The example includes indicative costs for these activities, excluding MFF which would need to be added. The cost represents fair market value.

**Clause 3.6:** Include the number of hours for initial set-up activities agreed in Clause 3.2, plus the number of maintenance hours for every year it is anticipated the CI Services will be required. Using this number of hours, multiply this by the hourly Medical Staff cost included in Clause 3.1.]

## Invoicing and Value Added Tax (VAT)

* 1. Invoices will be based on the CI Services performed. No payment will be made (unless an automatic payment has been arranged) by or on behalf of the [Sponsor] [CRO] **(delete as appropriate)** until a valid invoice for the amount payable has been received.
	2. Invoices will be raised on a [monthly] [quarterly] [ad hoc] [other: insert as agreed between the Parties] **(DELETE THREE AND RETAIN ONE OPTION)** basis after contract execution, with the final invoice raised in accordance with Clause 1.10 of this Appendix.
	3. The Parties agree to use the following method to manage invoicing:

**[****OPTION 1 (delete if not applicable)**: The [Sponsor] [CRO] **(delete as appropriate)**, or its Agent, will issue invoice requests. The NHS CI Employer shall invoice the [Sponsor] [CRO] **(delete as appropriate)** or its Agent in arrears upon receipt of an invoice request.]

**[OPTION 2 (delete if not applicable)**: The [Sponsor] [CRO] **(delete as appropriate)** or its Agent will liaise with the NHS CI Employer to agree the value and content of invoices to be raised]

**[OPTION 3 (delete if not applicable)**: The [Sponsor] [CRO] **(delete as appropriate)** or its Agent will use a self-invoicing system to raise invoices on behalf of the NHS CI Employer]

**[OPTION 4 (delete if not applicable)**: The [Sponsor] [CRO] **(delete as appropriate)** or its Agent will use an automated payment system to pay the NHS CI Employer. The NHS CI Employer shall be paid according to the evidence provided within the automated payment system of costs incurred.]

**[OPTION 5 (delete if not applicable)**: The [Sponsor] [CRO] **(delete as appropriate)** or its Agent will delegate responsibility to manage invoicing to the NHS CI Employer. The NHS CI Employer will invoice the [Sponsor] [CRO] **(delete as appropriate)**, or its Agent, in arrears.]

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 1.7 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 NHS CI Employer shall:
		1. be valid tax invoices for the purposes of VAT legislation;
		2. identify the NHS CI Employer and IRAS ID;
		3. contain a breakdown of prices per activity covering:
			1. set-up prices;
			2. maintenance prices;
			3. expenses incurred (where applicable).
		4. clearly state the corresponding period being invoiced for;
		5. identify the purchase order number (if applicable) assigned to the CI Services; and
		6. be sent to the [Sponsor] [CRO] **(delete as appropriate)** or its Agent at the email address provided below.
	2. The NHS CI Employer’s failure to comply with the above invoice requirements may result in a delay in payment.
	3. Any delay in the payment of the payee invoices by or on behalf of the [Sponsor] [CRO] **(delete as appropriate)** 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.
	4. If the [Sponsor] [CRO] **(delete as appropriate)** or its Agent disputes any invoice, or part of any invoice, or receives an invoice in respect of CI Services not provided in accordance with this Agreement, or which the [Sponsor] [CRO] **(delete as appropriate)** believes (acting reasonably) have not been properly provided, then the [Sponsor] [CRO] **(delete as appropriate)** or its Agent will make contact in a timely manner with the NHS CI Employer’s finance team as per Clause 2.2 of this Appendix to resolve the query. If the query is not resolved, then the [Sponsor] [CRO] **(delete as appropriate)** 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 NHS CI Employer shall issue the [Sponsor] [CRO] **(delete as appropriate)** or its Agent with a credit note for the disputed amount and the [Sponsor] [CRO] **(delete as appropriate)** or its Agent will pay the undisputed amount in accordance with the Payment Terms clause of this Agreement, or;
		2. Reject the NHS CI Employer’s invoice and request that the NHS CI Employer submit a new invoice for the undisputed amount. On receipt of the new valid invoice, the [Sponsor] [CRO] **(delete as appropriate)** or its Agent shall pay the new invoice in accordance with the Payment Terms clause of this Agreement.
	5. Any outstanding dispute remaining in relation to Clause 1.7 of this Appendix will be resolved in accordance with Clause 16 (Dispute Resolution) of this Agreement.
	6. The [Sponsor] [CRO] **(delete as appropriate)** or its Agent will notify the NHS CI Employer of the completion of CI Services, or early termination of this Agreement, in order to trigger the generation of a final invoice. Notification will be made to: [insert email address].
	7. Upon completion of the CI Services, or early termination of this Agreement, all remaining amounts due shall be invoiced as per the terms detailed in this CI Services Appendix, subject to receipt of the Chief Investigator’s final report, where applicable, in a form acceptable to the [Sponsor] [CRO] **(delete as appropriate)** as per relevant standards / requirements.
	8. The Sponsor and / or CRO or its Agent shall promptly respond to any reasonable request for invoicing data received from the NHS CI Employer for the purposes of the final invoice, provided that the request is received within forty-five (45) calendar days of the notification of the completion of CI Services or early termination of the Agreement.
	9. **Longstop Dates**
	It is agreed that the [Sponsor] [CRO] **(delete as appropriate)** shall not be required to make payment for any amounts that the NHS CI Employer fails to notify the [Sponsor] [CRO] **(delete as appropriate)** of within sixty (60) calendar days of the [Sponsor] [CRO] **(delete as appropriate)** providing the final invoicing information (if requested), in accordance with Clause 1.11 of this Appendix, or sixty (60) calendar days from completion of the CI Services, 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 2.1, and it is not an obligation for the Sponsor or CRO 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 1.7 to 1.8 of this Appendix is resolved.
	10. The final invoice payment may be held by the [Sponsor] [CRO] **(delete as appropriate)** or its Agent until all outstanding queries have been resolved.
	11. All figures in the Finance Schedule are INCLUSIVE of all indirect costs, capacity building and NHS CI Employer specific multipliers. All figures include all relevant taxes EXCEPT VAT which should be added to invoices where applicable.

## 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 NHS CI Employer 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] [CRO] **(delete as appropriate)** 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 2.2) | *[insert relevant details]* |

## CI Services and Finance Schedule

* 1. The Chief Investigator Services will be charged at the hourly Medical Staff rate in the interactive Costing Tool of £[236 + Market Forces Factor]. This hourly cost is inclusive of £124 per hour direct costs, plus 70% indirect costs (£87), 20% capacity build (£25) and [insert NHS CI Employer-specific market forces factor]% Market Forces Factor (£[insert NHS CI Employer-specific market forces factor price]).
	2. The Chief Investigator’s services to the Sponsor and CRO under this Agreement relating to the initial set-up of the Clinical Trial are:

| **Service to the Sponsor and CRO** | **Time required** | **Cost (subject to Clause 3.6 of this Appendix)** |
| --- | --- | --- |
| Advise on the development of the Protocol and Participant facing information, including through engagement with other professional experts and representatives of patient and Participant groups | 5 hours | £1180.00 + NHS CI Employer-specific MFF |
| Support regulatory (for example MHRA and REC) submissions | 2 hours | £472.00+ NHS CI Employer-specific MFF |
| Support completion of the iCT as part of National Contract Value Review (NCVR) | 1 hour | £236.00 + NHS CI Employer-specific MFF |
| Virtual attendance at REC meetings and providing feedback | 2 hours | £472.00 + NHS CI Employer-specific MFF |
| Review of responses to RECs | 2 hours | £472.00 + NHS CI Employer-specific MFF |
| Assist the [Sponsor] [CRO] **(delete as appropriate)** with identifying new sites if required and advise the [Sponsor] [CRO] **(delete as appropriate)** on suitability for the conduct of the Clinical Trial, or local Principal Investigators and their site facilities | 4 hours | £944.00 + NHS CI Employer-specific MFF |
| Support the development of training materials for site staff | 3 hours | £708.00 + NHS CI Employer-specific MFF |

* 1. The Chief Investigator will deliver the following ongoing maintenance services to the Sponsor and CRO on an annual basis:

| **Service to the Sponsor and CRO** | **Time required per year** | **Cost per year (subject to Clause 3.6 of this Appendix)** |
| --- | --- | --- |
| Communication (both written and verbal) with the Sponsor and / or CRO (as applicable) | 1 hour | ££236.00 + NHS CI Employer-specific MFF |
| Ongoing updates and communication to / from participating sites | 1 hour | ££236.00 + NHS CI Employer-specific MFF |
| Responding to issues arising with Clinical Trial set-up and logistics | 1 hour | ££236.00 + NHS CI Employer-specific MFF |
| Provide input to and chair investigator meetings | 1 hour | ££236.00 + NHS CI Employer-specific MFF |
| Ongoing development and maintenance of the Protocol and Participant-facing information, including through engagement with other professional experts and representatives of patient and Participant groups | 1 hour | ££236.00 + NHS CI Employer-specific MFF |
| Review of interim safety data | 1 hour | ££236.00 + NHS CI Employer-specific MFF |

* 1. If the NHS CI Employer is audited or inspected by the Sponsor and / or CRO, its Agents or any Regulatory Authorities in line with Clause 9 of this Agreement, the [Sponsor] [CRO] **(delete as appropriate)** warrants that it will reimburse the NHS CI Employer a minimum of £[1,770.00 + NHS CI Employer-specific MFF] (7.5 hours) for the completion of each audit or inspection visit. Any additional time required by the NHS CI Employer to support the audit or inspection visit will be charged at the hourly Medical staff rate in force from time to time. For the avoidance of doubt, the [Sponsor] [CRO] **(delete as appropriate)** will not reimburse the NHS CI Employer for any inspections by Regulatory Authorities which are triggered by the actions of the NHS CI Employer which are outside of the Sponsor's and CRO’s control.
	2. The total time spent on these services will not exceed a total of [insert number of hours] hours. The total potential value of this Agreement, at the point of contract execution and without further amendment, is therefore no greater than £[insert value].
	3. The cost per hour for the services provided under Clauses 3.3 and 3.4 of this Appendix will update every year on 1 April to be in line with the current Medical Staff rate in the interactive Costing Tool. In addition, if the Medical Staff rate is updated in the interactive Costing Tool part way through the year, the cost per hour in Clauses 3.3 and 3.4 of this Appendix will uplift on the same day. For the avoidance of doubt, these updates in the cost per hour to account for inflation will be appended to the Agreement as soon as possible after they take effect for clarity, but will **not** be a variation to this Agreement.
	4. If additional CI time or activities are required this will be by prior agreement between the Parties and with the consent of the CI, in accordance with Clause 17.2 of this Agreement, with the cost calculated using the above interactive Costing Tool derived hourly rate from time to time in force.

# Appendix 2: Chief Investigator Data Processing Notice and Declaration

We, the Sponsor, being a commercial company with a legitimate interest in conducting health care research, will process your Personal Data (including CV, training certificates and so forth, as well as other data about you obtainable from public sources, or provided to us by you or the NHS CI Employer relating to the conduct of this Clinical Trial) as necessary to fulfil our purposes in relation to the Clinical Trial and future research purposes, on the basis of our legitimate interest in so doing (that is, the legal basis for the processing of your Personal Data by and on behalf of us as data Controller is our legitimate interest). Your Personal Data processed for the purpose of this Clinical Trial (or for future research purposes) will not include Sensitive Personal Data, as defined in the Data Protection Laws and Guidance.

Our overarching purpose in processing your Personal Data in relation to the Clinical Trial is the exercise of our oversight responsibilities as Sponsor, as defined in The UK Policy Framework for Health and Social Care Research (and in The Regulations as and where applicable). Copies of the documents containing your Personal Data may be taken by our Agents to be provided to us and / or sent to us by the NHS CI Employer, as we require and as appropriate for the maintenance of our oversight of the CI Services under this Agreement. In addition, we may process your Personal Data for the purposes of determining the feasibility of future research (for example, in considering your suitability to act as CI for future studies).

We will only process your Personal Data as required to fulfil our purposes in relation to the Clinical Trial and future research purposes, including processing only that data which is necessary for our purposes and retaining your Personal Data only for as long as required for our purposes (including, but not limited to, adhering to any legal or best practice requirements on the duration of retention of documents that comprise the trial master file). Your Personal Data will be securely transferred to us, and held by us, in accordance with our data security policies, access to, or copies of which, will be provided upon request.

We may share your Personal Data with the following types of organisation to support fulfilment of the CI Services:

* Regulatory Authorities
* the CRO
* [Sponsor to specify other organisation types in a list, such as Sponsor Affiliates, public registries etc ]

Your Personal Data may be transferred to a country outside of the UK, where the protections afforded by data protection legislation may be less than in the UK. We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following **[delete as applicable]**:

* [some of] the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
* we use specific contracts approved for use in the UK which give personal data a similar level of protection it has in the UK. For further details visit the Information Commissioner’s Office (ICO) website: <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/>
* we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
* we will ensure other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
* we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: <https://ico.org.uk/for-organisations/report-a-breach>
* **[insert other ways data stays safe outside the UK]**

In undertaking our obligations as a Sponsor of research, we may make available your Personal Data to regulatory bodies or other parties with a legal duty, public duty or other legitimate interest in the oversight of healthcare research and the licensing, commissioning, etc. of healthcare interventions.

You have the following rights regarding your personal data:

* To be informed – you can ask us what Personal Data we are processing about you and why.
* To access – you can ask to see the Personal Data that we hold about you and obtain a copy.
* Rectification – you can ask us to correct any inaccurate information that we hold about you.
* Erasure – you can ask us to delete Personal Data we hold about you, which we must do unless we are able to demonstrate overriding legitimate grounds for continued processing, or we are required to continue to process your data in order to comply with The Regulations, or other UK law.
* Restriction – you can ask us not to process information about you if the information is inaccurate, processed unlawfully, or no longer needed for the stated purpose.
* To object – you can ask that we cease our processing of your Personal Data, which we must do unless we are able to demonstrate compelling legitimate grounds for the processing which overrides your interests, rights and freedoms or that our processing is necessary for the establishment, exercise or defence of legal claims

Please note that if in exercising these rights you compromise our ability to fulfil our stated purposes, you may be removed from your role in this Clinical Trial.

If you want to exercise your rights, or have any other questions or complaints about how we have handled your Personal Data, you can contact us at any time via **[insert contact details]**. Should you wish to directly contact our Data Protection Officer you may do so via **[insert contact details]**.

If you are not satisfied with the response you receive to any questions in relation to your Personal Data or any requests that you make in order to exercise your rights in relation to your Personal Data, or if you believe that your Personal Data is being processed in a way that is not lawful, you can complain to the Information Commissioner’s Office (ICO).

**I hereby confirm that I have read and understood this CI data processing notice and declaration, made by the Sponsor as to their processing of my Personal Data for the purposes of this Agreement and for other purposes related to future research projects.**

**I also acknowledge and accept the obligations as CI, as set out throughout this Agreement:**

|  |  |
| --- | --- |
| CI Print name: |  |
| CI Signature: |  |
| Date: |  |

# Appendix 3: Chief Investigator Declaration

I understand my role as CI for the Clinical Trial under this Agreement and I make this declaration in good faith. These are my interests from the last 3 years.

### No Interests related to this Agreement

|  |  |
| --- | --- |
| I have no interests which are actual, potential or perceived conflicts of interest in relation to this Agreement, including in relation to the Clinical Trial and the medicinal products to be tested or to the Sponsor, the CRO or any of their Agents or Affiliates known to me. I undertake to carry out my duties with the highest degree of objectivity and integrity. | [insert initials if this box is applicable, otherwise state “not applicable”] |

### Interests related to this Agreement

In this Appendix, “Close Family Member” means in relation to you:

* + - 1. your spouse or civil partner;
			2. your children and step-children, your parents and step-parents, your brothers and sisters and your step-brothers and step-sisters;
			3. the spouse or civil partner of any of the family members listed in (b).

This meaning is in line with The Financial Services and Markets Act 2000 (Regulated Activities) Order 2001 and The Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended from time to time.

In this Appendix, financial interests include but are not limited to, paid advisory roles, shareholding, paid consultancy and input to scientific advisory panel

**Actual**: This is an existing interest, for example: you hold, or a Close Family Member holds, a financial interest in the Sponsor, CRO, their Agents or Affiliates, or you otherwise have a relationship with the medicinal product(s) to be tested from which you or a close family member might make financial gain.

**Potential**: This is an interest that is about to happen or could happen, for example: you or a Close Family Member is in the process of being hired by, or obtaining a financial interest in the Sponsor, CRO, their Agents or Affiliates or the medicinal product(s) to be tested.

**Perceived**: This is an interest which might be reasonably perceived by others as compromising a person’s objectivity, for example: you or a Close Family Member have a close personal friendship with a director of the Sponsor, CRO, their Agents or Affiliates and / or an entity providing the medicinal product(s) to be tested. A perceived conflict of interest might also arise from non-paid advisory roles with the Sponsor, CRO, their Agents or Affiliates or an entity providing the medicinal product to be tested.

| **Type of interest (actual, potential or perceived)** | **Details of interest** |
| --- | --- |
| [Add details and rows as needed. If there are no interests, state “not applicable”] |  |
|  |  |
|  |  |

I confirm that this is a true statement of my interests. If there is anything in the course of the provision of CI Services which changes these declarations, I confirm that I will update this declaration.

|  |  |
| --- | --- |
| CI Print name: |  |
| CI Signature: |  |
| Date: |  |

# Appendix 4: Formal Delegation of Authority to a Corporate Affiliate or Other Party to Contractually Bind Sponsor

[ ]  If this box is checked, this Appendix 4 (Formal Delegation of Authority to a Corporate Affiliate or Other Party to Contractually Bind Sponsor) is not used.

# Appendix 5: Sponsor’s Clinical Trial Related Duties and Functions Under ICH-GCP to be Performed by CRO

[ ]  If this box is checked, this Appendix 5 (Sponsor’s Clinical Trial Related Duties and Functions Under ICH-GCP to be Performed by CRO) is not used.

**FINAL PAGE**