**[Complete only the fields highlighted in yellow. Read & delete the drafting notes highlighted in red text before sharing with NHS / HSC CI Employer]**

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

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

**“Clinical Trial”**

# 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”**

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

**WHEREAS** Sponsor wishes to fulfill Sponsor obligations in accordance with the Research Governance Framework and the Regulations, including appointment of a Chief Investigator (CI) for the Clinical Trial in the UK.

**WHEREAS** [insert CI] is an employee (by virtue of a substantive, joint academic appointment, or other relevant contract type) of the NHS CI Employer and [insert CI], on behalf of the NHS CI Employer, is qualified (by education, training and experience) and willing to provide the CI services required by the Sponsor.

**WHEREAS** This Agreement is between the Sponsor and the NHS CI Employer, whereby the Sponsor confirms the suitability of the CI for their functions and procures the services of the NHS CI Employer, which agrees to provide reasonable support to both Sponsor and CI in the execution of the CI’s duties.

**WHEREAS** The CI, not being a Party to this Agreement, represents that they understand and agree 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 further defined below):

## Definitions

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

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

* **Agent**

shall include but is not limited to, any person 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 17.1;

* **Chief Investigator**

means the individual providing the CI services described in this Agreement, and who has overall responsibility for the conduct of the Clinical Trial in accordance with the Research Governance Framework. In a multi-site study, the CI has co-ordinating responsibility for research conducted by all Principal Investigators for the Clinical Trial;

* **Confidential Information**

means all confidential information (however recorded or preserved) disclosed by a Party and / or its Affiliate to the other Party, in connection with the 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 and the Investigator Brochure(s) relating to the Clinical Trial;
* **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;

* **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;

* **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;

* **Principal Investigator**

means the individual responsible for research activities at an investigator site, under the Chief Investigator’s oversight;

* **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;

* **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;

* **The Regulations**

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

* **Research Governance 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, however, that the provisions of the Declaration of Helsinki relating to post-trial supply of IMP (as further defined herein) shall be those that are explicitly indicated in this Agreement and all subsequent modifications to or re-enactments of the Declaration of Helsinki, whether set out in a modification or amendment or otherwise, shall not apply to this Agreement.
  2. The headings to clauses are inserted for convenience only and shall not affect the interpretation or construction of this Agreement.
  3. Where appropriate, words denoting the singular shall include the plural and vice versa.
  4. 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.

## Chief Investigator Services

* 1. The Sponsor engages the NHS CI Employer to provide, through their employee (the CI), the services set out in this Agreement, including those listed in Appendix 1 of this Agreement.
  2. The CI services provided under this Agreement shall fulfil the responsibilities of a chief investigator, as set out in The Research Governance Framework, 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 is delegated to each Principal Investigator for their respective research site;
     5. satisfy themself that the information to be given to potential participants is in a suitable format and is clear and relevant to their participation in the Clinical Trial and, where consent is required, to their 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 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 time available to commit to the role
       3. be contactable by the Sponsor and, where applicable, by Principal Investigators
       4. have commitment to the Clinical Trial

## 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 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.
  3. All Intellectual Property Rights and Know-How arising from and relating to the Clinical Trial, the IMP (including but not limited to its formulation and use alone or in combination with other drugs), and / 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 3.4 and 3.5 of this Agreement.
  4. In accordance with Clause 3.3, 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 3.3, 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.
  5. The NHS CI Employer shall, and will ensure that the CI shall, promptly disclose to the Sponsor any Know-How generated pursuant to this Agreement and falling within Clause 3.3 and undertakes not to use or disclose such Know-How other than for the purposes of this Agreement.
  6. 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 Clinical Trial in the furtherance of its normal activities, to the extent that such use does not result in the disclosure or misuse of Confidential Information or the infringement of any Intellectual Property Right or Know-How of the Sponsor.

## Confidentiality

* 1. The Parties may only disclose Confidential Information to their own officers, Agents and employees (and in the case of the Sponsor, those of its Affiliates and, if applicable, other parties who may have contractual rights in the Results 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. Both Parties undertake to treat as strictly confidential and not to disclose to any third party any Confidential Information of the other Party, save where disclosure is required by a Regulatory Authority or by law (including any disclosure required to ensure compliance, by the 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 Party, 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. Both Parties undertake not to make use of any Confidential Information of the other Party, other than in accordance with this Agreement, without the prior written consent of the other Party.
  2. The obligations of confidentiality set out in this Agreement, shall not apply to information that is:
     1. published or becomes generally available to the public other than as a result of a breach of this Agreement by the receiving Party;
     2. in the possession of the receiving Party prior to its receipt from the disclosing Party, as evidenced by contemporaneous written evidence, and is not subject to a duty of confidentiality;
     3. independently developed by the receiving Party, as evidenced by contemporaneous written evidence and is not subject to a duty of confidentiality;
     4. obtained by the receiving Party from a third party that is not subject to a duty of confidentiality.
  3. In the event of a Party visiting the establishment of the other Party, the visiting Party undertakes that any further Confidential Information that may come to the visiting Party’s knowledge as a result of any such visit, shall be treated as Confidential Information in accordance with this Clause 4.
  4. This Clause 4 shall remain in force for a period of ten (10) years after the termination or expiry of this Agreement.
  5. Sponsor Confidential Information shall not be utilized or employed 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 provides express consent in writing. NHS CI Employer Confidential Information shall not be utilized or employed in any AI Tool, unless NHS CI Employer provides express consent in writing; except that Sponsor may, without NHS CI Employer’s consent, use NHS CI Employer’s Confidential Information within a secured, dedicated cloud-based and/or local AI Tool instance subject to Sponsor’s confidentiality, security and non-use obligations herein.

## Freedom of Information

* 1. The Sponsor acknowledges 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, Investigational Drugs (or their manufacturers), or the Clinical Trial), it will notify the Sponsor as soon as is reasonably practicable, and in any event, no later than five (5) working days after receiving the request. The NHS CI Employer will consult with the Sponsor in accordance with all applicable guidance.
  3. The Sponsor acknowledges that subject to Clause 5.3.1, 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.
     1. The Sponsor shall cooperate with the NHS CI Employer and shall use its reasonable endeavours to respond within ten (10) working days of the NHS CI Employer’s reasonable request for assistance.
  4. Where the NHS CI Employer determines that it will disclose information, notwithstanding any objections from the Sponsor, it will notify the Sponsor in writing, giving at least two (2) working days’ notice of its intended disclosure.

## Data Protection

* 1. The Parties acknowledge that the CI has accepted the terms of the Data Processing Notice at Appendix 2 and that the Parties may process the Personal Data of the CI in accordance with this Agreement, including its appendices.
  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, each Party is assumed to be a separate and independent Controller of any Personal Data that is processed in association with the Agreement and the CI services set out within it. This means that each Party will assume full responsibility for the Personal Data it collects, processes, or otherwise handles within its own systems and under its own control.
  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 either 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 and inform that other Party in the event of any Personal Data Breach that relates to that Personal Data.
     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 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 (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 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 Research Governance 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, and any prior publication by the Sponsor of Clinical Trial data, 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. 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 above, 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. Each Party will retain at least one copy of all documents, records and correspondence relating to this Agreement either:
     + 1. for at least twenty-five (25) years, or
       2. until at least two (2) years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least two (2) years have elapsed since the formal discontinuation of clinical development of the Clinical Trial medication whichever is the longer.
  2. The Sponsor must be informed in advance in writing of any change of address or relocation of the records retained under this Agreement. The Sponsor will inform the NHS CI Employer when it is no longer necessary to retain these records.

## Quality Assurance Audit

* 1. The activities and records of the NHS CI Employer, and the CI, under this Agreement may upon reasonable notice be monitored and audited by the Sponsor, or inspected by governmental regulatory bodies, in order to assess compliance with The Regulations and the associated responsibilities and obligations of the CI The NHS CI Employer agrees, following reasonable written notification, to allow an independent audit of all documentation relevant to this Agreement.

## Publicity

* 1. Neither Party will use the name of the other Party, and the Sponsor will not use the name of the CI, in any publicity, advertising or news release without prior written approval from the other Party, such approval not to be unreasonably withheld.
  2. The Sponsor will 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
  3. The NHS CI Employer will not, and will ensure that the CI and its Agents do not, use the name of the Sponsor, the Sponsor’s employees, nor the name of the Clinical Trial, nor the investigational medicinal product in any publicity, advertising or news release without the prior written approval of the Sponsor, such approval not to be unreasonably withheld. The provisions of this Clause 10.2 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 on the Clinical Trial and / or the investigational medicinal product (“Sponsor Collaborators”) provided that the NHS CI Employer has been notified of the identity of the Sponsor Collaborators.

## Governance

* 1. The NHS CI Employer represents that the CI is not 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 if the NHS CI Employer becomes aware of any restriction or prevention being applied to the CI.
  2. The NHS CI Employer represents that the CI is 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. The NHS CI Employer will promptly notify the Sponsor if it becomes aware of any Agency Action regarding compliance with ethical, scientific or regulatory standards for the conduct of research, if the Agency Action relates to events or activities that occurred prior to or during the period in which the Clinical Trial is conducted.
  3. The NHS CI Employer represents that it is not aware of any actual, potential or perceived conflicts of interest that the CI may have, other than any that are disclosed 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;
     2. GMP;
     3. GVP;
     4. the World Medical Association Declaration of Helsinki entitled, “Ethical Principles for Medical Research Involving Human Subjects (1996)”;
     5. the Research Governance Framework;
     6. the UK Research and Innovation policies and principles entitled, “Human Biological Samples”;
     7. [**DELETE IF NOT APPLICABLE** – the ethical principles endorsed by WHA63.22 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 may consider necessary for the conduct of the Clinical Trial, including but not limited to the training and provision of information given during investigator meetings.

## Liability

* 1. Nothing in this Clause 12 shall operate so as to restrict or exclude the liability of either Party in relation to death or personal injury caused by the negligence or wilful misconduct of that Party or its Agents, or to restrict or exclude any other liability of either Party that cannot be so restricted or excluded in law.
  2. 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 advice provided by the CI to the Sponsor 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. 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 Clinical Trial, 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 any other party, notwithstanding that the formulation of such product or process may be based in whole or in part upon this Agreement.

## Payment Terms

* 1. Payment for CI services will be made in accordance with Appendix 1 of this Agreement.
     1. In addition, the Sponsor, or their Agent, will reimburse all reasonable travel and other reasonable out-of-pocket expenses incurred by the CI in connection with the responsibilities which have the prior approval of the Sponsor, subject to the Sponsor, or their Agent, receiving a completed reimbursement claim form (to be provided by the Sponsor, or their Agent) 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 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.
  2. The fees are exclusive of any VAT, which will be paid in addition if applicable on production of VAT invoices by the NHS CI Employer.
  3. Payments will be made within forty-five (45) days of receipt of a VAT compliant invoice or completed reimbursement claim form and accompanying proof of purchases. The VAT compliant invoice must reference the Clinical Trial protocol and unique Purchase Order number to identify the appropriate Clinical Trial related contacts.

**Invoices and completed reimbursement claim form should be sent electronically to:** [Insert appropriate email address for Sponsor, or their Agent]

**or by post to:**

[Insert appropriate postal address for Sponsor, or their Agent]

**Details to be included on the invoice:**

Protocol number / Investigator: [enter details]

Unique purchase order number: To be provided upon Agreement execution

Account number: [enter details]

Sort code: [enter details]

Bank name: [enter details]

Account holder: [enter details]

Bank address: [enter details]

IBAN: [enter details]

## Term and Termination

* 1. This Agreement will commence on the date of last signature and will continue until completion of the Clinical Trial, unless terminated earlier in accordance with the conditions of this Agreement.
  2. Either Party may terminate this Agreement for any reason by giving three (3) months’ written notice to the other Party. Where either party has terminated this Agreement under this paragraph Sponsor shall reimburse for any activities completed up to and including the effective date of termination.
  3. Either Party may immediately terminate this Agreement at any time if either Party:
     + 1. commits a material breach of any of its obligations under this Agreement which is incapable of remedy, in the opinion of the Party not in breach; or
       2. fails to remedy, where it is capable of remedy, any breach of any of its obligations under this Agreement after having been required in writing to remedy such breach within a period of fourteen 14(14) days.
  4. On the expiry or termination of this Agreement (for whatever reason) the following provisions shall apply:
     + 1. Any provision which is expressly intended to come into or remain in force on or after termination shall continue in full force and effect.
       2. Any Confidential Information (as defined in paragraph 4 (above) received by NHS CI Employer and/or the CI (and copies thereof) disclosed or supplied pursuant to or in relation to this Agreement shall be promptly returned to the Sponsor or disposed of in accordance with Sponsor’s reasonable instructions, save one copy that shall be retained by the NHS CI Employer in accordance with Clause 6.1.

## Force Majeure

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

## 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 either Party to do so. If the dispute remains unresolved, it will then be referred to a senior manager from each of the Parties who will use all reasonable endeavours to resolve the dispute within a further fourteen (14) days.
  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, either Party shall give notice in writing (“**ADR Notice**”) to the other Party 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, either 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, either 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, either Party will give notice in writing to the other Party 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 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, either Party shall be entitled to submit to the exclusive jurisdiction of the courts of Northern Ireland.
  5. Nothing in this Agreement shall prevent either 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 Clause shall amount to an agreement that either of the Parties is entitled to an interim injunction or interdict as applicable.

## Miscellaneous

* 1. 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 and noted by the CI.
  2. **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. This Agreement is intended to be legally binding and shall be governed by the laws of [England and Wales] [Scotland] [Northern Ireland] and all disputes or claims thereof shall be subject to the exclusive jurisdiction of the [English and Welsh] [Scottish] [Northern Irish] courts.
  2. **Waiver**

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

## Relationship between the Parties

* 1. Neither Party may assign its rights under this Agreement or any part thereof without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, except that the Sponsor may assign this Agreement at any time to a successor to all or substantially all of its business or assets to which this Agreement relates, whether by way of merger, consolidation, sale of stock, sale of assets, operation of law or otherwise, upon written notice to the NHS CI Employer. The Sponsor shall inform the NHS CI Employer in good time in writing about the aforementioned assignment / assignation. Neither Party may sub-contract the performance of all or any of its obligations under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed. In the event that either Party sub-contracts its responsibilities under this Agreement, it shall be responsible for the acts and omissions of its sub-contractors as though they were its own. Any Party who so sub-contracts shall be responsible for pass-through of payments to its sub-contractors.
  2. Nothing in this Agreement shall be construed as creating a joint venture, partnership, contract of employment or relationship of principal and agent between the Parties.

## Notices

* 1. Any notice required to be given by either Party shall be in writing quoting the date of the Agreement and shall be delivered by hand or sent by pre-paid first-class recorded delivery or by e-mail to the contact persons listed below, as per the contact details listed below, or such other person as one Party may inform the other Party in writing from time to time.
  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 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 the other Party shall take effect as delivery of an executed counterpart of this Agreement. If either method of delivery is adopted, without prejudice to the validity of the Agreement thus made, each Party shall provide the others with the original of such counterpart as soon as reasonably possible thereafter. No counterpart shall be effective until each Party has executed and delivered at least one counterpart.

|  |  |
| --- | --- |
| Signed for and on behalf of:  [**INSERT** NAME OF SPONSOR]  Or  Signed by [**INSERT** name of company] for and on behalf of [**INSERT** NAME OF SPONSOR], as duly authorised under Appendix 4  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: Chief Investigator Services

[**[DELETE this guidance before providing agreement to NHS CI Employer]** The specific services and time allocated to each in the below table are provided as a guide to what might be included by the Sponsor in this appendix. The specific services required by Sponsor and the exact timings allocated to each are a matter for Sponsor determination and negotiation with NHS CI Employer, on behalf of the CI.]

The Chief Investigator’s services to the Sponsor under this Agreement are:

### For Payment Upon Execution of Agreement

| **Service to the Sponsor** | **Time Required** | **Cost** |
| --- | --- | --- |
| Advise on the development and maintenance of the Protocol and participant facing information, including through engagement with other professional experts and representatives of patient and participant groups | 7 hours | £1358.00 |
| Support regulatory (for example MHRA and REC) submissions | 2 hours | £388.00 |
| Virtual attendance at REC meetings and providing feedback | 2 hours | £388.00 |
| Review of responses to RECs | 2 hours | £388.00 |
| Assist the Sponsor with identifying new sites if required and advise the Sponsor on suitability, for the conduct of the Clinical Trial, or local Principal Investigators and their site facilities | 4 hours | £776.00 |
| Support the development of training materials for site staff | 3 hours | £582.00 |

### For Payment Annually or Upon Completion of Termination of the Agreement

| **Service to the Sponsor** | **Time Required** | **Cost** |
| --- | --- | --- |
| Communication (both written and verbal) with the Sponsor / CRO (as applicable) | 7 hours | £1358.00 |
| Ongoing updates and communication to / from participating sites | 7 hours | £1358.00 |
| Responding to issues arising with Clinical Trial set-up and logistics | 7 hours | £1358.00 |
| Provide input to and chair investigator meetings | 4 hours | £776.00 |

The total time spent on these services will not exceed a total of [**45 hours] (**charged at the Interactive Costing Tool rate of £194 per hour – that is £102 per hour direct costs, plus 70% indirect costs and 20% capacity build). The total value of this Agreement, without further amendment, is therefore [**£8,730.00]**.

If additional CI time is required this will be by prior agreement between the Parties and with the consent of the CI, in accordance with Clause 17.1, with the cost calculated using the above iCT derived hourly rate of £194.

# Appendix 2: Chief Investigator Data Processing Notice and Declaration

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 them by the NHS CI Employer or yourself relating to the conduct of this Clinical Trial) as necessary to fulfil its purposes in relation to the Clinical Trial and future studies, on the basis of their legitimate interest in so doing (i.e. the legal basis for the processing of your Personal Data by and on behalf of the Sponsor as data Controller is their legitimate interest). Your Personal Data processed for the purpose of this Clinical Trial (or for future studies, as below) will not include Sensitive Personal Data, as defined in the Data Protection Laws and Guidance.

The overarching purpose of the Sponsor in processing your Personal Data in relation to the Clinical Trial is the exercise of its 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 agents of the Sponsor to be provided to the Sponsor and / or sent to the Sponsor by the NHS CI Employer, as required by the Sponsor and as appropriate for the maintenance of its Sponsor oversight of the CI services under this Agreement. In addition, the Sponsor may process your Personal Data for the purposes of determining the feasibility of future research (e.g. in considering your suitability to act as CI for future studies).

The Sponsor will only process your Personal Data as required to fulfil its purposes in relation to the Clinical Trial and future studies (as described above), including processing only that data which is necessary for its purpose/s and retaining your personal data only for as long as required for its 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 the Sponsor, and held there, in accordance with the data security policies of the Clinical Trial Sponsor, access to, or copies of which, will be provided upon request.

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. This may compromise your ability to fully exercise all of your rights in relation to that personal data, as well as compromising its security, although the Sponsor commits to acting in good faith to protect your Personal Data and associated rights to the best of its ability.

In undertaking its obligations as a Sponsor of research, the Clinical Trial Sponsor 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 the Clinical Trial Sponsor what Personal Data they are processing about you and why.
* To access – you can ask the Clinical Trial Sponsor to see the Personal Data that they hold about you and obtain a copy.
* Rectification – you can ask the Clinical Trial Sponsor to correct any inaccurate information that they hold about you.
* Restriction – you can ask the Clinical Trial Sponsor 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 the Clinical Trial Sponsor ceases its processing of your Personal Data, which it must do unless it is able to demonstrate compelling legitimate grounds for the processing which overrides your interests, rights and freedoms or that its processing is necessary for the establishment, exercise or defence of legal claims

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

If you want to ask about your rights, or have any other questions or complaints about how the Sponsor has handled your Personal Data, you can contact the Sponsor at any time via **[xxxxxxx]**. Should you wish to contact the Data Protection Officer of the Sponsor you may do so via **[xxxxxxx]**.

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, understood and accept this CI data processing statement, 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:**

|  |  |
| --- | --- |
| Print name: |  |
| 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. *Initial against one of the following options:*

### No conflict of interest

|  |  |
| --- | --- |
| I have no actual, potential or perceived conflict of interest in relation to this Agreement, including in relation to the Clinical Trial and the medicinal products to be tested or the Sponsor or any of its Agents or Affiliates known to me. I undertake to carry out my duties with the highest degree of objectivity and integrity. |  |

### Conflict of interest

|  |  |
| --- | --- |
| **Actual**: This is an existing conflict of interest, for example: you hold, or a close family member holds, a financial interest in the Sponsor, their Agent or Affiliate, 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 a conflict of interest that is about to happen or could happen, for example: you or a close relative is in the process of being hired by, or obtaining a financial interest in the Sponsor, their Agent or Affiliate or the medicinal product(s) to be tested. |  |
| **Perceived**: This is a conflict of interest which might be reasonably perceived by others as compromising a person’s objectivity, for example: you have a close personal friendship with a director of the Sponsor, their Agent or Affiliate 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, their Agent or Affiliate or an entity providing the medicinal product to be tested. |  |

|  |  |
| --- | --- |
| Describe the circumstances giving rise to the conflict of interest: |  |

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

# Appendix 4: Formal Delegation of Authority to a third partyto Contractually Bind Sponsor

**[DELETE if not applicable]**