# Model Investigator Initiated Study Agreement

### Instruction Pages

* this investigator-led template may be used when NHS organisations sponsor non-commercial research that is led and designed by an NHS-employed Chief Investigator, but is funded and / or supported in-kind by a company. The support in kind may be supply of free product or other non-financial contribution to the research
* this template may be used for single- or multi-centre studies, as applicable
* this template only covers the investigator-led research study; it does not cover continued use of product on compassionate grounds. Such continued use would be subject to separate contractual arrangements
* study specific details to be completed and optional wording to be selected (or deleted where not relevant) are highlighted in yellow. The user will need to insert agreement-specific details in the gaps highlighted in yellow below
* the user should also ensure that the default terms and conditions set out in this template are appropriate for the particular study to which it will apply. Further advice should be sought from the NHS organisation’s R&D department in the case of any doubt. Provisions on recitals and intellectual property are likely to require the most attention on a case by case basis.

### 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 Study (as a preamble to the Agreement, such changes do not constitute modification to the template Agreement).

### Main body of the Agreement

* **Clause 3** – This section can be marked as “Left intentionally blank” if no Products or Samples are being provided.
* **Clause 9.1** – Consider if improvements to Background should be included as part of the Background. You may need to modify the definition of Background accordingly.
* **clause 12** – The highlighted section should be used if the Company is providing a Product for use in the Study. If no Product is provided, then it can be removed. This may need to be negotiated on a case by case basis

### Schedule 1B

* amend this section as necessary to suit the funding provided

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

[**INSERT** full name of the Study]

[**INSERT** Sponsor’s Protocol reference number]

# Investigator Initiated Study Agreement

**Between**

[**Insert** name of NHS organisation] with its main address at [**insert** Institution address]

“**Institution**”

AND

[**Insert** name of company] with its registered address at [**insert** Company address]

“**Company**”

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

### Clause

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Schedule 1A The Product

Schedule 1B Study Budget and Payments Schedule

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Schedule 3 Study Protocol

### Whereas

1. [Company is the owner of all rights in the Product.]
2. Institution wishes to conduct the investigator initiated study entitled “[**insert** study title]” (the “**Study**”) described in the Protocol.
3. Institution has agreed to sponsor the Study and that Institution’s employee (named below) shall act as the Chief Investigator for the Study.
4. [Company wishes to support the Study by providing [supplies of the Product] [and] [funding].]
5. [The NHS Organisation has appointed [insert name of CTU/CRO] as the clinical trial unit /clinical research organisation which will undertake delegated study management activities as set out in the Protocol [and [CTU] [CRO] / sponsor contract]].
6. [insert any other descriptors of the aim of the Agreement].

Now therefore, in consideration of the above premises and subject to the terms and conditions stated herein, the Parties agree as follows:

## Definitions

* 1. It is therefore, agreed that the following terms and conditions shall apply to the performance of the Parties’ obligations under this Agreement (as further defined below):
* **Background**

means Intellectual Property Rights and Know-How that are provided by one Party to the other Party for use in the Study (whether before or after the date of this Agreement) that do not themselves arise from the Study;

* **Chief Investigator or CI**

means [Insert name and title of CI], an employee of the Institution who will act as the Chief Investigator for the Study;

* **Confidential Information**

all information disclosed, (whether in writing, orally or by another means and whether directly or indirectly) by a Party ("Disclosing Party") to another Party ("Receiving Party") directly relating to the Study including, but not limited to information, the release of which is likely to prejudice the commercial business interests of the Disclosing Party, or which is a trade secret, including Know-How and shall also include any data disclosed which is Personal Data and / or special category Personal Data, all as defined in the Data Protection Legislation, and / or information that is otherwise confidential patient information;

* **Data Protection Laws**

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;

* **Effective Date**

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

* **Force Majeure Event**

means any event beyond the reasonable control of the Party claiming to be subject to the Force Majeure Event including, without limitation, strikes, lock-outs, labour or industrial disputes, acts of God, war, riot, civil commotion, pandemics, epidemics, malicious damage, compliance with any law or governmental order, rule, regulation or direction, accident, breakdown of plant or machinery, fire, flood or storm;

* **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;

* **Good Manufacturing Practice or 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;

* **Intellectual Property Rights**

means patents, trademarks, trade names, service marks, domain names copyrights, 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;

* **Inventions**

means new inventions and discoveries and intellectual property rights therein generated by or on behalf of the Institution in the conduct of the Study;

* **Know-How**

means all technical and other information which is not in the public domain, including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, manufacturing data and information contained in submissions to regulatory authorities;

* **[Product**

means device / drug / nutritional supplement **[insert** name of device / drug / placebo / nutritional supplement] as described in Schedules 1 and 2;]

* **Protocol**

means the full description of the Study, together with any amendments thereof, and incorporated into this Agreement by reference;

* **Publication**

means any publications relating to the Study, including but not limited to peer reviewed papers, dissertations, lectures, and scientific posters;

* **Qualified Designee**

means a duly qualified study sub-investigator;

* **Regulatory Authority**

means any regulatory authority responsible for the review and approval of the Study [and the use of the Product];

* **Research Results**

means the research findings produced in the Study which are to be published by the Sponsor and the Chief Investigator, in compliance with the Protocol and applicable law;

* **Samples**

means biological samples collected from Study Participants under the Protocol, including but not limited to [blood] [serum] samples;

* **Sponsor**

means as defined in the UK Policy Framework for Health and Social Care Research [and the Medicines for Human Use (Clinical Trials) Regulations 2004];

* **Study**

has the meaning given in the recitals above;

* **Study Data**

means [anonymized] [pseudonymized] data that is collected under the Protocol such as demographics, primary and secondary outcomes, questionnaires, scans, but excluding personal data as defined under the Data Protection Laws;

* **Study Participant**

means any person who consents (where consent is necessary) and is enrolled to take part in the Study.

## Sponsorship of the Study

* 1. Institution shall conduct the Study in accordance with the Protocol attached hereto at Schedule 3 and identified as Study, and in accordance with the terms of this Agreement, the terms of all relevant regulatory permissions and approvals including the conditions of the favourable opinion given by the relevant NHS research ethics committee, the Clinical Trials Authorisation (CTA) granted by the Medicines and Healthcare products Regulatory Agency (the "MHRA"), the letter of no objection from the MHRA for the clinical investigation of a non-CE marked medical device or a CE marked medical device being used for a new purpose (if applicable), and all applicable laws, regulations, professional standards and principles of Good Clinical Practice. Company shall review, and comment on the Protocol.
  2. Institution, not Company, is the Sponsor of the Study. Institution will not represent to any third party, including Study Participant, that Company is a Sponsor.
  3. Institution is responsible for safety reporting and regulatory obligations associated with the conduct of the Study in the UK.
  4. Institution shall obtain the express consent or approval required by the MHRA and / or other applicable regulatory authorities and ethics committees, prior to the commencement of the Study.
  5. Institution will provide Company with a reasonable opportunity to review and comment upon the Protocol and, any proposed changes to the Protocol. However, Institution shall have the full and final discretion over the Protocol and will notify Company when the Protocol or any changes have been finalised.
  6. In the event that the Study is a multicentre clinical study, the Sponsor will ensure that each site enters into a site agreement with the Sponsor regarding its participation in the Study prior to beginning recruitment of Study Participants.
  7. [Institution shall notify Company as soon as reasonably practical in writing of any adverse effects to Study Participants from use of the Product during the Study, as set out in the Technical / Quality Schedule 2].

## Study Materials

* 1. Company will provide the Institution with the Product in quantity stated in Schedule 1 and in accordance with the Protocol to facilitate the Study[, together with all other materials and substances required by this Agreement, the Protocol, or as otherwise agreed between the Parties and defined in Schedule 1].
  2. The Institution shall use the Product solely for the purpose of conducting the Study. Institution shall not disassemble or reverse engineer the Product, nor use the same for any commercial purpose nor permit any third party so to do. In particular, the Institution shall not invoice any Study Participant or the insurer of any Study Participant for the use of the Product.
  3. Institution will handle Product according to the Protocol and investigator brochure and in accordance with any instructions for use provided by the Company.
  4. **Storage of Product**. The Institution shall ensure that the Product is stored in accordance with the Protocol and [the investigator brochure if appropriate.
  5. **Return of Product**. CI will return all used and unused Product, including containers, to Company or designated Product supply vendor upon expiration or termination of the Study or at such times as Company may direct. Company shall pay shipping expenses for such returns.
  6. Institution shall not grant any security interests in, assign or otherwise dispose of the Products. The Product shall remain free of any lien, charge, security interest, encumbrance or claim.
  7. Without prejudice to Clauses 3.1 to 3.7, details regarding the Parties’ responsibilities, use, storage and distribution of the Product are specified in a Technical / Quality Agreement attached at Schedule 2.
  8. [Institution shall supply Samples to Company as required under the Protocol and agrees that Company may transfer Samples to third party laboratories [**insert** names of labs] under subcontracts on terms which are consistent with this Agreement for the purposes set out in the Protocol and Technical Agreement at Schedule 2. Company will, and will ensure that any subcontractors will:
     1. use the Samples only for the Study;
     2. keep the Samples secure at the Location and protected against loss, damage and contamination;
     3. keep the Samples clearly labelled as the property of the Institution at all times;
     4. maintain complete and accurate written records to ensure that the Samples can be traced at all times and that details of all uses to which the Materials are put and any processes that are applied to them are documented;
     5. ensure that no one other than the Company’s personnel, agents and subcontractors have access to the Samples and that they are suitably qualified and trained to handle the Samples;
     6. ensure that it has in place all necessary safety procedures and practices to handle the Samples and that the Company’s personnel, agents and subcontractors comply with all safety requirements applicable to the Samples necessary for their well-being and that of others;
     7. ensure that all transportation, keeping, use and disposal of the Samples is in accordance with the appropriate containment level; and
     8. ensure that all use of the Samples is within the scope of the Study Participant consent and ethical approval obtained for the Study].

## Chief Investigator

* 1. The CI shall have day to day control of the Study and shall conduct of the Study in accordance with the Protocol and the terms and conditions of this Agreement.
  2. If the CI is unable or unwilling to conduct the Study at any time, the Institution shall promptly notify Company and Institution and shall consult with Company as to the appointment of a replacement CI. If a suitable candidate to act as CI cannot be identified or agreed upon by both Parties, acting reasonably and without undue delay or a replacement CI cannot be recruited, all recruitment of Study Participants shall cease immediately and this Agreement shall be terminated in accordance with Clause 14.2.

## Compliance with Law

* 1. To the extent applicable to each, the Parties shall comply with, all relevant laws in the performance of this Agreement including but not limited to:
     1. The Human Rights Act 1998;
     2. The Data Protection Laws;
     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 Institution;
     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
     10. the World Medical Association Declaration of Helsinki, titled “Ethical Principles for Medical Research Involving Human Subjects”.
  2. In terms of compliance with the reference to the Data Protection Laws as set out in Clause 5.1, the Parties agree that, if personal data (as defined in the Data Protection Laws) of Study Participants is to be exchanged for purposes other than those set out in the Protocol, the Parties will enter into a data sharing agreement.

## Study Data, Research Results, Records and Audits

* 1. Any Study Data, Research Results and Study reports shall be owned by the Institution. Before the first publication of the Research Results by the Institution and / or CI, the Company may use the final Study report for internal purposes only. After the first publication of the Research Results by the Institution and / or CI, Company may use the final study report for the sole purpose of research and development, marketing, or future regulatory submissions. However, for marketing and future regulatory submissions Company will require the Institution’s consent. Acknowledgements of the Institution’s sponsorship of the Study must always be made by Company in accordance with academic, commercial and regulatory standards.
  2. Institution shall maintain the Research Results, Study Data in accordance with good clinical practice and applicable law and shall retain Research Results and Study Data for such period of time as may be required by applicable law. Each Party shall allow an independent auditor, appointed by mutual written agreement of the Party, during normal working hours and upon reasonable written notice to inspect that portion of its facilities and records [solely for the purpose of auditing the respective Party’s [financial management] [the manufacture and supply of the Product (in case of Company) and / or] the conduct of the Study (in case of Institution)]. No access will be granted to Company’s auditor to Study Participant’s personal data including medical records. Any such auditor shall be accompanied by personnel of the audited Party at all times, shall be qualified to conduct such audits and shall comply with all applicable rules and regulations relating to facility security and health and safety.
  3. Each Party shall make its facilities and records available for inspection by representatives of any regulatory authority in compliance with all applicable laws. A Party shall notify the other Party within five (5) days of its receipt of any correspondence, notice or any other indication whatsoever of Regulatory Authority inspection, investigation or other inquiry, or other notice or communication from any Regulatory Authority of any type, that could reasonably be expected to affect the manufacture and supply of the Product and / or conduct of the Study in a material way.
  4. [To the extent that any inspection, investigation or other inquiry concerns [the manufacture and supply of the Product and / or] the conduct of the Study the affected Party shall provide copies of all relevant documents to the other Party. The affected Party shall consult with the other Parties with respect to any response to observations and notifications received in connection with any such inspection, investigation or other inquiry and will give the other Party an opportunity to comment upon (which comments shall be considered by the affected Party in good faith) any proposed response before it is submitted].

## Publication of Results of Publicity

* 1. The Parties recognise that the UK Policy Framework for Health and Social Care Research places an obligation on NHS organisations carrying out health and social care research to publish Study Research Results.
  2. Any publications relating to the Study, including but not limited to publications, dissertations, lectures, and scientific posters, (“Publication”) shall comply with applicable laws and guidelines, including the recommendations of the International Committee of Medical Journal Editors in its most current versions. In the event of any intended Publication, Institution and CI agree to provide to Company the manuscript in its near final form at least 30 (thirty) days prior to submission for obtaining Company’s scientific review.
  3. Institution shall not use, nor authorise others to use, the name or logo of Company in any publicity without the prior written approval from Company.
  4. The Company shall not use, nor authorise others to use, the name or logo of Institution in any publicity without the prior written approval from Institution.
  5. The contents of any forms of publicity resulting from this Agreement, including but not limited to all press releases, reports, presentations, shall be agreed upon by both Parties before submission to publication. According to applicable laws, regulations, codes, and guidelines, Company’s support of the Research shall be disclosed in any Publication.

## Payment and Transparency

* 1. **(Option 1, delete if not applicable)** [Company shall pay the Institution the amounts laid out in the budget at Schedule 1 subject to the Institution meeting the milestones laid out in Schedule 1 and receipt by Company of an invoice from the Institution.
  2. Institution acknowledges that Company may be required to publicly disclose the existence and limited terms of this Agreement, including any payments, transfer or exchange of value in cash or kind made by the Company hereunder, and Institution assents to Company making such disclosure to the extent required under applicable law.]

**OR**

* 1. **(Option 2, delete if not applicable)** [No financial payments are due under this Agreement and each Party shall fund its own costs under the Study.]

## Inventions and Patent Rights

* 1. It is recognised and acknowledged that Background is the separate property of Institution and Company, and is not affected by this Agreement, and neither of the Parties shall have any claims or rights in such separate Intellectual Property Rights of the other Party. Subject to clause 9.3 each Party grants to the other Party a non-exclusive, worldwide, royalty-free licence to use its Background solely for use within the Study to the extent necessary for the other Party to perform its obligations under this Agreement. The licence granted under this Clause 9.1 shall be sub-licensable solely to the extent necessary for the conduct of the Study in accordance with this Agreement.
  2. Institution shall use its reasonable endeavours to promptly disclose to Company any improvements or modification to the Company’s Background made by the Institution in the performance of the Study. For purposes of this Agreement, any Inventions, whether or not patentable, shall be owned exclusively by Institution. Company agrees to assign, and hereby does assign, and shall ensure that its personnel assign, to Institution all of their rights and interests in and to all such Inventions, and shall cooperate with Institution, at Institution’s reasonable expense, in all reasonable respects to assure that ownership of all such Inventions accrues to Institution, including, but not limited to, execution of any and all lawful documentation which may be deemed necessary by Institution for the filing and prosecution of applications and for assignment of the same to Institution, including all declarations, oaths, specifications, and instruments of assignments for filing and registering in the United Kingdom and foreign patent offices, or other necessary or similar documents.
  3. The Company shall grant to Institution an irrevocable, non-exclusive, royalty-free licence to use its Background for the purpose of using and receiving the benefit associated with any Inventions or to derive the benefits and value from the Study.
  4. Company and its personnel and representatives involved in the conduct of the Study shall have the irrevocable right in perpetuity to use any and all Inventions for its internal, research and development purposes only.
  5. Institution grants to Company an exclusive option to first negotiate an exclusive, worldwide, royalty-bearing license to use Invention(s) [directly related to the Product]. Any license to the Company shall be subject to the Institution’s rights to use any intellectual property for its educational and research purposes. The option shall last for 6 months after the completion of the Study. Upon the Company’s exercise of the option, the Parties shall negotiate in good faith for an exclusive license. If despite good faith negotiation the Parties do not reach an agreement within six (6) months after the start of such negotiation, Company’s rights under the option shall expire, and the Institution shall be free to grant a license under Inventions to a third party.

## Warranties

* 1. Each Party warrants that it has the right and authority to enter into this Agreement and that it has the capability and capacity to fulfil its obligations under this Agreement.
  2. Institution warrants that neither it nor any of its respective personnel engaged by it to perform the Study under this Agreement has been debarred or disqualified, is under investigation by competent authorities for a debarment action or is presently debarred pursuant to applicable laws.
  3. **Fair Market Value**. Each Party acknowledges that this Agreement has been negotiated in an arm’s-length transaction and has not been determined in any manner with regard to any implicit or explicit agreement to provide favourable procurement decisions with regard to Company’s products, or to the value or volume of any business or referrals generated between the Parties.
  4. Institution makes no representation or warranty to the Company that any advice or information given by it or any of its employees or students who work or have worked on the Study, or the content or use of any Study Data, Research Results, Study reports and publications works or information provided in connection with the Study, will not constitute or result in any infringement of third-party rights.
  5. No Party to this Agreement makes any representation or gives any warranty to any other Party with regards to the guarantee of a result from the research.
  6. [Company warrants that the Product has been or will be manufactured in accordance with Good Manufacturing Practices and meet the specification document accompanying it on delivery to Institution‘s premises and is fit for its intended purpose. Company hereby expressly excludes from this Agreement any other express, implied and statutory warranties.]

## Confidentiality

* 1. A Party (the “**Receiving Party**”) receiving Confidential Information of the other Party (the “**Disclosing Party**”) under this Agreement shall not disclose the Confidential Information to any third party nor use the Confidential Information for any purpose other than exclusively in accordance with this Agreement and the Protocol without the prior written authorisation of the Disclosing Party or as permitted under this Clause 11.
  2. The Receiving Party may disclose the Confidential Information of the Disclosing Party to those of their research and clinical personnel and those employees who have a reasonable need to know it solely for the performance of the Study on the pre-conditions that such personnel are made aware of the confidential and proprietary nature of such Confidential Information before disclosure. The Receiving Party shall at all times be responsible for those personnel’s compliance with the obligations set out in this Agreement.
  3. Confidential Information shall not include any information which:
     1. is lawfully in the possession of the Receiving Party, free of any obligation of confidentiality to any third party, as shown by the Receiving Party’s contemporaneous written records.
     2. is or becomes generally available to the public other than by a breach of this Clause 11 by the Receiving Party.
     3. is subsequently disclosed to the Receiving Party without restriction as to confidentiality or use, by a third party lawfully entitled to possession of such information and whom the Receiving Party has no reason to believe that third party is bound by a duty of confidentiality to the Disclosing Party.
     4. as shown by the contemporaneous written records of the Receiving Party, is independently developed by or on behalf of the Receiving Party by personnel who have not had access to such Confidential Information.
  4. Information shall not be deemed generally available to the public by reason only that it is known to a few of those persons to whom it would be of special scientific or commercial interest; and a combination of two or more portions of Confidential Information shall not be deemed generally available to the public by reason only of each separate being available.
  5. The Receiving Party may disclose the Disclosing Party’s Confidential Information to the extent such Confidential Information is specifically required to be disclosed by law, by any governmental or regulatory authority, or pursuant to the order of a court or other authority of competent jurisdiction; provided that, to the extent it is legally permitted to do so, it promptly notifies the Disclosing Party of this disclosure and, where possible, takes into account the reasonable requests of the Disclosing Party in relation to the content of such disclosure. The provisions of this Clause 11.5 shall apply to any disclosure the Receiving Party is required to make to an ethics committee or regulatory authority. The Parties acknowledge that there is a general understanding that any such ethics committee and regulatory authority will keep information submitted to it confidential, and the Receiving Party shall mark any of the disclosing Party’s Confidential Information disclosed in accordance with this Clause 11.5 as “confidential”, but each Party accepts that the Receiving Party would be unable to impose any specific obligations upon such bodies.
  6. Each Party shall keep the Confidential Information secure to the same standard as it would its own confidential information and to no less than a reasonable standard.
  7. The obligations of confidentiality and non-use under this Agreement shall last for a period of five (5) years from the date of expiration or earlier termination of this Agreement for whatever reason.
  8. The Institution is subject to the Environmental Information Regulations 2004 (EIR) or the Environmental Information (Scotland) Regulations 2004 (EI(S)R) and the Freedom of Information Act 2000 (FOIA) or the Freedom of Information (Scotland) Act 2002 (FOI(S)A) and may receive a request under EIR, EI(S)R, FOIA or FOI(S)A to disclose any information that belongs to the Company shall notify and consult the Company, as soon as reasonably practicable, and in any event, not later than seven (7) working days after receiving the request.
  9. The Company acknowledge and agrees that the decision on whether any exemption applies to a request for disclosure of recorded information under EIR, FOIA or FOI(S)A is a decision solely for the Institution responding to the request.
  10. Where the Institution determines that it will disclose information it will notify the Company in writing, giving at least four (4) working days’ notice of its intended disclosure.
  11. [Institution accepts responsibility for ensuring that the Study Data is collected and provided in accordance with all applicable consents, approvals and regulations.
  12. The Company undertakes:
      1. to restrict access to the Study Data to only those personnel having a reasonable need to know, and to ensure that those personnel are aware of and comply with the terms of this Clause 11;
      2. to keep the Study Data confidential and not sub-license, transfer, disclose or otherwise make available the Study Data in whole or part to any third party except with specific prior written consent from the Institution;
      3. to keep the Study Data secure by implementing organisational and technological measures appropriate to the nature and sensitivity of the data to prevent the unauthorised or accidental access, use or disclosure of the Study Data;
      4. to notify the Institution as soon as reasonably practicable after becoming aware of any unauthorised or accidental access, use or disclosure of the Study Data, and to co-operate with any investigation made by the Institution in connection with the unauthorised or accidental access, use or disclosure of the Study Data;
      5. not attempt to re-identify any individual from the Study Data or communicate with any individual re-identified from the Study Data, nor to link or attempt to link the Study Data to other data or information except with specific prior written consent from the Provider;
      6. to process the Study Data in accordance with all applicable laws and regulations and the Protocol.
  13. The Study Data is supplied by the Institution in pseudonymised form without the pseudonymisation key (which shall be kept securely by the Institution) or other means for the Company to re-identify individuals from the Study Data. Therefore the Study Data transferred by the Institution to the Company is in effect anonymous. The Parties anticipate that the Study Data may be identifiable personal data in respect of the Institution’s processing but not likely to be identifiable personal data in respect of the Company’s processing, but that this is a question of fact determined by the nature of the Study Data, the arrangements between the Parties, and any other means available to the Company (whether publicly available or otherwise) to re-identify individuals form the Study Data.
  14. In the event that the Study Data is or becomes identifiable personal data when held or processed by a Company, the Parties agree that the Institution and Company shall each be a controller in respect of its own processing of the Study Data, and shall be solely responsible and liable for its own processing of the Study Data including (without limitation) the lawful basis for that processing and ensuring that the Study Data is processed in compliance with the Data Protection Laws.]

## Limitation of Liability; Indemnification

* 1. [Subject to Clause 12.2, Institution agrees to indemnify the Company, its directors, officers, agents and employees and CI (“**Company Indemnitees**”) against any liability, damage, loss or expense incurred to or imposed upon them by a Study Participant or their dependents arising out of any negligent act or omission relating to any clinical intervention or procedure provided for or required by the Protocol to which the Study Participant would not otherwise have been exposed but for their participation in the Study which results in personal injury, including death, to a Study Participant, except to the extent the same is caused by the negligent or wrongful acts or omissions or breach of statutory duty of the Company Indemnitees or a breach of any of their obligations and warranties under this Agreement.]
  2. In the event of any claim or proceeding in respect of personal injury and death being made or brought against the Company by a Study Participant, the Institution shall indemnify the Company and its staff against any claims, proceedings and related costs, expenses, losses and damages arising from the Institution’s negligent performance of the management, design or conduct of the Study, save to the extent that they were caused, or contributed to, by the negligence, wrongful acts, omissions, or breach of statutory duty of the Company or its Staff.
  3. [Company shall indemnify the Institution, [the Study sites] its directors, officers, employees and agents of the (“**Institution Indemnitees**”), from and against any and all liability, damages, loss, costs and expenses (including any settlements or ex gratia payments made with the consent of Company and) incurred by any such Institution Indemnitee person in connection with any claim made or brought (whether successfully or otherwise) by a Study Participant (or their dependants) that result from the Product and its failure to comply with any requirement or warranty of this Agreement, GMP and / or applicable law, except to the extent that the same is caused by the negligence, wrongful acts or omissions or breach of statutory duty of the Institution Indemnitees.
  4. Each Company Indemnitee will promptly notify Institution of any injuries and claims of which it is made aware, provided that Company may provide one notice to Institution on behalf of all the Company Indemnitees and Institution as the case may be may provide one notice to Company on behalf of all the Institution Indemnitees.
  5. The [indemnity in Clause 12.1] [indemnities in Clauses 12.1 and 12.2] (**delete** as applicable) shall not apply to any such claim or proceedings: (a) unless as soon as reasonably practicable following receipt of notice of such claim or proceedings, the indemnified person shall have notified the indemnifying Party in writing of it and shall, upon the indemnifying Party’s request and at that indemnifying Party’s cost, have permitted the indemnifying Party to have full care and control of the claim or proceedings using legal representation of its own choosing; or (b) if the indemnified person shall have made any admission in respect of such claim or proceedings or taken any action relating to such claim or proceedings prejudicial to the defence of it without the written consent of the indemnifying Party (such consent not to be unreasonably withheld or delayed), provided that no indemnified person shall be deemed to be in breach of this condition by any statement properly made by the indemnified person in connection with the operation of the indemnified person’s internal complaint procedures, accident reporting procedures, or disciplinary procedures, or where such a statement is required by law.
  6. The indemnifying Party, in relation to [Clause 12.1] [Clauses 12.1 and 12.2] (**delete** as applicable) shall: (a) keep the indemnified person fully informed of the progress of any claim or proceedings, (b) consult fully with the indemnified person on the nature of any defence to be advanced; and (c) not, without the prior written consent of the indemnified person (such consent not to be unreasonably withheld or delayed), enter into any settlement or compromise of such claim or proceedings which: (i) would result in injunctive or other relief being imposed against an indemnified person; or (ii) does not include as an unconditional term the giving by the claimant to all applicable indemnified persons of a release from liability in relation to such claim or proceedings.
  7. Each Party shall give to the indemnifying Party such assistance as it may reasonably require for the conduct and prompt handling of any such claim or proceedings. Nothing in this Clause 12 shall restrict or limit an indemnified person’s general obligation at law to mitigate a loss it may suffer or incur as a result of an event that gives rise to a claim under [Clause 12.1] [Clauses 12.1 and 12.2] (**delete** as applicable). The benefit conferred by this Clause 12 is intended to be enforceable by the persons referred to in it.]
  8. No Party shall be liable to the other for indirect, special or consequential loss, nor for any loss of revenue, goodwill, reputation, turnover, business, bargain
  9. Nothing in this Agreement shall limit or exclude the liability of a Party to the other Party for:
     1. death or personal injury caused by the negligence of that Party; and
     2. fraud committed by or on behalf of that Party.
     3. a breach by that Party of the Data Protection Laws and
     4. any other liabilities which cannot be excluded or limited by applicable laws.
  10. Subject to Clause 12.8 (**update** clause reference accordingly only if optional clauses above removed), the Institution’s liability under this Agreement whether in contract, tort (including, without limitation, negligence or breach of statutory duty) or howsoever arising shall not exceed [Insert liability cap] [the value of the sums paid to Institution by Company under this Agreement].
  11. In the case of equipment loaned to the Institution by the Company for the purposes of the Study, the Institution’s liability arising from its negligence shall exclude fair wear and tear and shall not exceed the value of the equipment.

## Insurance

* 1. Institution confirms that it is a member of and throughout the duration of this Study shall maintain its membership of the NHS Resolution Clinical Negligence Scheme for Trusts.

## Term and Termination

* 1. This Agreement shall commence on the Effective Date and shall continue in force until the earlier of:
     1. Completion of the Study in accordance with the Study Protocol; or
     2. Earlier termination in accordance with this Agreement.
  2. This Agreement may be terminated by any Party prior to its natural expiration under Clause 14.1 in the following circumstances:
     1. Should a Party commit any breach or default under the terms of this Agreement, and fail to remedy such breach or default within thirty (30) days after receipt of written notice thereof from the non-breaching Party, the Party giving notice may, at its option and in addition to any other remedies which it may have in law or in equity, terminate this Agreement by sending notice of termination to the other Party, and the termination shall be effective immediately on service of such notice.
     2. If the other Party becomes insolvent, or if an order is made or a resolution is passed for its winding up (except for the purpose of solvent amalgamation or reconstruction), or if an administrator, administrative receiver or receiver is appointed over the whole or any part of the other Party’s assets, or if the other Party makes an arrangement with its creditors.
     3. Institution may terminate this Agreement without cause at any time by giving at least three (3) months prior written notice of such termination to the Company or with immediate effect on written notice to the Company if:
        1. it has reasonable and substantial grounds for believing the Study should cease to protect the safety, rights or welfare of Study Participants; or
        2. the ethics committee opinion and / or regulatory authority approval is rejected or suspended, revoked or otherwise terminated and there is no possibility of appeal against such suspension, revocation or termination;
        3. the Chief Investigator ceases employment with the Institution or becomes unable to carry out role of Chief Investigator and a replacement cannot be found and mutually agreed.
  3. If this Agreement is terminated before its natural completion, for any reason whatsoever, the Parties shall work together in good faith to ensure a safe wind-down of the Study and to ensure that Study Participants’ best interests in respect of the Study are carefully considered.

## Notices

* 1. Any notice or other communication required or permitted under this Agreement shall be in writing and (a) delivered by hand or by courier; (b) sent by pre-paid recorded (i.e. signed for) post; or (c) sent by email, to the addresses set out below or such addresses or numbers as may be notified to the other Party from time to time. Notices sent in accordance with this Clause are to be deemed to have been received (i) if delivered by hand or by courier, when left at the address referred to above; (ii) if sent by post, three working days after posting; (iii) if sent by email, when transmitted provided the sender has not received an electronic confirmation of non-delivery. Notice shall be given to the Parties at the addresses listed below:

**COMPANY**

[insert contact details]

**INSTITUTION**

[insert contact details]

## Waiver, Modification, Amendment

* 1. Any waiver, alteration, modification, or amendment of this Agreement must be in writing and signed by both Parties. No waiver of any term, provision or condition of this Agreement, whether by conduct or otherwise in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

## Independent Contractor

* 1. The relationship of Company and Institution under this Agreement shall be that of independent contractors and not agents, joint venturers or partners. No Party shall have any right, power, or authority to assume, create, or incur any expense, liability, or obligation, expressed or implied, on behalf of the other Party, except as expressly provided herein.
  2. Nothing in this Agreement obligates Institution to purchase, lease or order (or arrange for or recommend the same) any Product from Company.

## Assignment

* 1. This Agreement may not be assigned by any Party without the prior written consent of the other Party. This Agreement shall inure to the benefit of and be binding upon each Party, its successors and assigns. No assignment shall relieve either Party of the performance of any accrued obligation.

## Force Majeure

* 1. The obligations of each Party under this Agreement shall be suspended during the period and to the extent that that Party is prevented or hindered from complying with them by a Force Majeure Event.
  2. In the event of a Party being so hindered or prevented, the Party concerned shall give notice of suspension as soon as reasonably possible to the other Party stating the date and extent of the suspension and its cause, and the omission to give such notice shall forfeit the rights of that Party to claim suspension. A Party whose obligations have been suspended as aforesaid shall resume the performance of those obligations as soon as reasonably possible after the removal of the cause and shall so notify the other Party. In the event that the cause continues for more than sixty (60) days, a Party may terminate this Agreement on thirty (30) days written notice to the other Party.

## Governing Law; Jurisdiction

* 1. This Agreement shall be governed by and construed and enforced in accordance with the laws of [England and Wales] [Scotland] [Northern Ireland]. All disputes with respect to this Agreement shall be subject to the exclusive jurisdiction of the courts of [England and Wales] [Scotland] [Northern Ireland].

## Dispute Resolution

* 1. In the event of any dispute or difference between the Parties arising in connection with this Agreement, the authorised representatives of the Parties will discuss and meet as appropriate to try to resolve the dispute within seven (7) calendar days of being requested in writing by any Party to do so. If the dispute remains unresolved, it will then be referred to the senior manager from each of the Parties who will use all reasonable endeavours to resolve the dispute within a further fourteen (14) calendar days.
  2. Where the Parties are unable to resolve a dispute in accordance with Clause 21.1, the Parties will attempt to resolve the dispute in accordance with the relevant subclause 21.2.1, 21.2.2 or 21.2.3, determined in accordance with Clause 20:
     1. in England or Wales Parties will refer the dispute to mediation in accordance with the Centre for Effective Dispute Resolution Model Mediation Procedure; or
     2. in Scotland Parties will refer the dispute to an independent third party to act as a mediator between the Parties. If the Parties are unable to agree on the identity of the third party, the Parties will ask the President of the Law Society of Scotland to appoint a suitable individual to consider the matter. The person so appointed will act as an expert mediator and not as an arbiter; or
     3. in Northern Ireland Parties will refer the dispute to a mediator agreed by the Parties. Where the Parties are unable to agree on the identity of a mediator, the Parties will ask the President of the Law Society of Northern Ireland to appoint a suitable mediator.
  3. Each Party shall each bear its own costs in relation to the settlement of any disputes and the parties shall share equally the costs of any independent third party involved to assist in the resolution of the dispute unless the independent third party directs that costs be apportioned differently.
  4. Any decision reached in accordance with this Clause 21 shall be final and binding upon the Parties.

## Precedence

* 1. Should there be any inconsistency between the Protocol and the other terms of this Agreement, or any document incorporated therein, the terms of the Protocol shall prevail to the extent of such inconsistency except insofar as the inconsistency relates to Clauses 7, 9, 11 and 12 of this Agreement where these terms of the Agreement shall prevail.

## Entire Agreement; Severability

* 1. This Agreement and its Schedules, together with the Protocol set forth the entire agreement between the Parties. In the event a court of competent jurisdiction holds any provision of this Agreement to be invalid, such holding shall have no effect on the remaining provisions of this Agreement, and they shall continue in full force and effect.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Agreement to come into force on the Effective Date.

|  |  |
| --- | --- |
| Signed for and on behalf of:  [**INSERT** NAME OF INSTITUTION]  Signature:  Print name:  Title:  Date: | Signed for and on behalf of:  [**INSERT** NAME OF COMPANY]  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.*

## Schedule 1

## A. The Product

(**Option 1**, delete option 2) [Company has agreed to provide free of charge the following Product(s) whose total market value amounts to GBP [add amount] to Institution for the duration of the Study:

| **Product** | **Quantity** |
| --- | --- |
|  |  |
|  |  |

[Upon completion of the Study or earlier termination in accordance with the terms of this Agreement, Institution and CI shall promptly return to Company all Product(s) as per Company’s instructions in writing at [Company’s] [Institution’s] cost.]]

**Or**

(**Option 2**, delete option 1) [No Product shall be provided under this Agreement.]

## B. Study Budget and Payments Schedule

The Company shall pay the Institution the fees (plus VAT if applicable) on the basis set out below. Such sums shall be payable following receipt by the Company of a valid invoice from the Institution.

For the avoidance of doubt, the Institution shall be responsible for its own taxation and related financial matters.

The Institution shall send its invoices alongside appropriate supporting documentation to the Company at:

[*Insert Invoice address*]

The Company undertakes to authorise the Institution’s invoices for payment (or any undisputed part, if applicable) within 30 days of receipt of an invoice, provided that such invoice has been properly submitted in accordance with the terms of this Agreement; and

Final Invoices will be sent to the Company within 60 days of end of the Study.

Invoices shall be made [Quarterly in arrears / Insert Regularity]. All values are [inclusive / exclusive] of VAT [which will be added if applicable].

The Institution shall quote the reference "[Insert Reference]" on each invoice which it submits under this Agreement.

### Payment Schedule and fees

| **Study Milestone Achieved** | **Amount to be paid (£)** | **Due date for payment** |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

## Schedule 2: [Technical / Quality Agreement] Roles and Responsibilities

[Attach Technical / Quality Agreement]

Or

[Not applicable]

Or

[Roles and Responsibilities table]

## Schedule 3: Study Protocol

Study Protocol including amendments as approved by the relevant Research Ethics Committee incorporated by reference.