MODEL AGREEMENT FOR NON-COMMERCIAL RESEARCH IN THE HEALTH SERVICE

This Agreement dated [Insert DATE] is between

[Insert NAME AND ADDRESS OF NHS BODY], (referred to as "the NHS Organisation")

AND

[Insert NAME AND ADDRESS OF SPONSOR],

[AND [Insert NAMES AND ADDRESSES OF ADDITIONAL SPONSOR(S) if any]]

(referred to as "the Sponsor")

Which are collectively referred to as the "Parties" or individually referred to as a "Party"

The above Parties agree to the following obligations, terms and conditions when carrying out the clinical research study entitled [Insert FULL TITLE].

1. DEFINITIONS

1.1. The following words and phrases have the following meanings:

1.1.1. Chief Investigator	The person who takes overall responsibility for the design, conduct and reporting of the Study; or if a Multi-Site Study, the person who takes primary responsibility for the design, conduct and reporting of the entire Multi-Site Study, whether or not the person is an investigator at any particular site.
1.1.2. Multi-Site Study	Where the Study is part of a study being carried out by or on behalf of the Sponsor at different sites.
1.1.3. NHS Organisation	The NHS contracting body carrying out the research, including Health and Social Care (HSC) Organisations established in Northern Ireland.
1.1.4. Principal Investigator	The leader responsible for a team of individuals conducting the Study.
1.1.5. Participant	Patient, service user, carer, relative of the deceased, professional carer, employee, or member of the public, who consents to take part in the Study. All references to Participants refer to those recruited at or through the Site.
1.1.6. Protocol	The description of the Study as contained in Schedule 1 and all amendments thereto. Such amendments will form part of this Agreement.
1.1.7. Results	All discoveries, data, information, theories, methods, computer programs, format of presentations and applications of the same and all manifestations or expressions of the same in physical, chemical, biological, molecular, electronic or written form.
1.1.8. Site	Any premises occupied by the NHS Organisation in which or through which the Study will be conducted.
1.1.9. Study	The clinical research study being carried out by the NHS Organisation at the Site.

2. STUDY GOVERNANCE

2.1. The Parties agree to comply with all relevant laws, regulations and codes of practice applicable to this Agreement including to the performance of the Study. The Parties agree to comply with the following relevant guidance:

2.1.1. The World Medical Association Declaration of Helsinki, titled “Ethical Principles for Medical Research Involving Human Subjects”.

2.1.2. The Research Governance Framework for Health and Social Care, Second Edition, April 2005, or the Research Governance Framework for Health and Social Care in Wales, November 2001 or the Scottish Executive Health Department Research Governance Framework for Health and Community Care, Second Edition, February 2006 or the Research Governance Framework for Health and Social Care in Northern Ireland, December 2006 or the latest version of the relevant Research Governance Framework should it be revised and reissued.

2.2. 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 consistency relates to clauses 4, 5, 7 and/or 8 of this Agreement where these terms of the Agreement shall prevail.

3. OBLIGATIONS OF THE PARTIES

3.1. The Parties shall conduct the Study in accordance with:

3.1.1. The current version of the Protocol. Substantial amendments to the Protocol shall form part of this Agreement following confirmation in writing by the Parties.

3.1.2. The terms of all relevant regulatory permissions and approvals. These may include, but are not limited to:

3.1.2.1. The Clinical Trials Authorisation (CTA) granted by the Medicines and Healthcare products Regulatory Agency (MHRA).

3.1.2.2. The terms and conditions of the favourable opinion given by the relevant NHS Research Ethics Committee.

3.1.2.3. 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.

3.1.2.4. The permission given by or on behalf of the Site R&D management (NHS permission).

3.2. The Parties shall carry out their respective responsibilities in accordance with this Agreement including those set out in the Schedules. Each Party shall on the giving of reasonable written notice to the other Party have the right to audit the other Party's compliance with this Agreement. Such right shall include access to all relevant documents and other information relating to the Study.

4. LIABILITIES AND INDEMNITY

4.1. Nothing in this clause 4 shall operate so as to restrict or exclude the liability of any Party in relation to death or personal injury caused by the negligence of that Party or its employees, students, consultants and subcontractors, including researchers, or to restrict or exclude any other liability of any Party which cannot be so restricted in law.

4.2. Subject to clauses 4.3, 4.4, 4.5, 4.6, 4.7 and 4.8 the Sponsor shall indemnify and keep the NHS Organisation and its employees, students, consultants and subcontractors, including researchers, indemnified against any claims, proceedings and related costs, expenses, losses, damages and demands to the extent they arise or result from the NHS Organisation:

4.2.1. Undertaking the Study in accordance with the Protocol; and/or

4.2.2. Preparing, manufacturing or assembling any medicinal product, medical device or other equipment in accordance with the Protocol or other written instructions of the Sponsor, where such instructions differ from the instructions of the manufacturer.

4.3. The indemnity shall only apply if the NHS Organisation:

4.3.1 Informs the Sponsor in writing as soon as reasonably practicable following receipt of notice of such claim or proceeding;

4.3.2 Upon the Sponsor's request and at the Sponsor's cost gives the Sponsor full control of the claim or proceedings and provides all reasonable assistance; and

4.3.3 Makes no admission in respect or such claim or proceedings other than with the prior written consent of the Sponsor.

4.4. The indemnity shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages and demands arise or result from:

4.4.1 The wrongful acts or omissions or negligence or breach of statutory duty of the NHS Organisation or its students, consultants and subcontractors, including researchers; or

4.4.2 A treatment or procedure routinely undertaken as part of NHS treatment.

4.5. If a Party incurs any loss or damage (including costs and expenses) ("Loss") arising or resulting from this Agreement and:

4.5.1. All Parties are NHS bodies as defined in Section 9(4) of the National Health Service Act 2006 or Section 17 of the National Health Service (Scotland) Act 1978 or Articles 16 and 26 of the Health and Personal Social Services (Northern Ireland) Order 1972, which established the Boards and Central Services Agency respectively and Article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991: which established Trusts in Northern Ireland as appropriate; or

4.5.2. One or more Party is a NHS body and the other Party (ies) is a NHS Foundation Trust; or

4.5.3. All Parties are NHS Foundation Trusts;

Then clauses 4.6, 4.7 and 4.8 shall apply.

4.6. If all Parties are NHS bodies / NHS Foundation Trusts in England, Wales or Northern Ireland and are indemnified by the same Indemnity Scheme (being one of the NHS Litigation Authority clinical negligence or the Welsh Risk Pool or the Clinical Negligence Fund in Northern Ireland) and the Party incurring any loss can recover such loss under one of the Indemnity Schemes, then such Party shall rely on the cover provided by the Indemnity Scheme and not seek to recover the Loss from the other Party (ies). Where the other Party (ies) caused or contributed to the Loss, it undertakes to notify the relevant Indemnity Scheme(s) to take this into account in determining the future levies of all Parties in respect of the indemnity schemes.

4.7. If:

4.7.1. The Parties are members of the same Indemnity Scheme in England, Wales or Northern Ireland and the Party incurring the Loss is not indemnified for that Loss by its Indemnity Schemes; or

4.7.2. All Parties are NHS bodies in Scotland; or

4.7.3. The Parties are NHS bodies/Foundation Trusts established in different jurisdictions within the United Kingdom;

Then the Parties shall apportion such Loss between themselves according to their respective responsibility for such Loss. Should the Parties be unable to agree the apportionment the matter shall be resolved in accordance with clause 16.5.

4.8. If one or more Parties are NHS Foundation Trusts and the Party incurring the Loss is not responsible for all or part of the Loss and is not indemnified in respect of the Loss by one of the Indemnity Schemes then the Party incurring the Loss shall be entitled to recover the Loss from the other Party (ies) pursuant to the provisions of this Agreement.

4.9. The liability of the NHS Organisation to the Sponsor in respect of any contractual liability the Sponsor may or does incur to a third party arising or resulting from this Agreement shall be limited to all fees payable by the Sponsor to the NHS Organisation in accordance with clause 9.

4.10. No Party shall be liable to another in contract, tort, breach of statutory duty or otherwise for any loss of profits, revenue, reputation, business opportunity, contracts, or any indirect, consequential or economic loss arising directly or indirectly out of or in connection with this Agreement.

5. CONFIDENTIALITY, DATA PROTECTION AND FREEDOM OF INFORMATION

5.1. Medical confidentiality

5.1.1. The Parties agree to adhere to the principles of medical confidentiality in relation to Participants. The Parties shall comply with the requirements of the common law of confidentiality, the Data Protection Act 1998 and, as appropriate, the NHS Confidentiality Code of Practice or the Scottish Executive Health Department NHS Code of Practice on Protecting Patient Confidentiality or the Confidentiality: Code of Practice for Health and Social Care in Wales or the Code of Practice on Protecting the Confidentiality of Service Users in Northern Ireland, (when implemented).

5.1.2. Personal data shall not be disclosed to the Sponsor by the NHS Organisation, save where this is required directly or indirectly to satisfy the requirements of the Protocol, or for the purpose of monitoring or reporting adverse events.

5.1.3. Neither the Sponsor nor the NHS Organisation shall disclose the identity of Participants to third parties without the prior written consent of the Participant except in accordance with the Data Protection Act 1998 or, as appropriate, the NHS Confidentiality Code of Practice or the Scottish Executive Health Department NHS Code of Practice on Protecting Patient Confidentiality or the Confidentiality; Code of Practice for Health and Social Care in Wales or the Code of Practice on Protecting the Confidentiality of Service Users in Northern Ireland, (when implemented).

5.2. Freedom of Information

5.2.1. Parties to this Agreement which are subject to the Freedom of Information Act 2000 (FOIA) or the Freedom of Information (Scotland) Act 2002 (FOI(S)A) and which receive a request under FOIA or FOI(S)A to disclose any information that belongs to another Party shall notify and consult that Party in accordance with clause 14, as soon as reasonably practicable, and in any event, not later than five working days after receiving the request.

5.2.2. The Parties acknowledge and agree that the decision on whether any exemption applies to a request for disclosure of recorded information under FOIA or FOI(S)A is a decision solely for the Party responding to the request.

5.2.3. Where the Party responding to an FOIA or FOI(S)A request determines that it will disclose information it will notify the other Party in writing, giving at least two working days notice of its intended disclosure.

5.3. Confidential information

5.3.1. Each Party agrees to ensure that information supplied to them under this Agreement and belonging to or licensed to the other Party and marked as confidential is treated as confidential.

5.3.2. The NHS Organisation agrees to treat the Results of the Study as confidential.

5.3.3. Each Party agrees:

5.3.3.1. To ensure that any of their employees, students, consultants or sub-contractors who participate in the operation of the Study are made aware of, and abide by, the requirement of clause 5.3.

5.3.3.2. To use the confidential information solely in connection with the operation of the Agreement and not otherwise.

5.3.3.3. Not to disclose the confidential information in whole or in part to any person without the other Party's written consent.

5.3.4. The provision of clause 5.3 shall not apply to the whole or any part of the confidential information that is:

5.3.4.1. Lawfully obtained free of any duty of confidentiality.

5.3.4.2. Already in the possession of the Party receiving such information and which they can show from written records (other than as a result of a breach of clause 5.3.1 or 5.3.2).

5.3.4.3. In the public domain (other than as a result of a breach of clause 5.3.1 or 5.3.2).

5.3.4.4. Necessarily disclosed pursuant to a statutory obligation.

5.3.4.5. Disclosed with prior written consent of the other Party.

5.3.4.6. Necessarily disclosed by a Party by virtue of its status as a public authority in terms of the Freedom of Information Act 2000 or the Freedom of Information (Scotland) Act 2002.

5.4. The restrictions contained in clause 5.3 shall continue to apply after the termination of this Agreement for 10 years.

6. PUBLICITY

6.1. No Party shall use the name, logo or registered image of the other Party(ies) or their employees in any publicity, advertising or press release without the prior written approval of an authorised representative of that Party.

6.2. The content and timing of any publicity, advertising or press release shall be agreed by all Parties involved; such agreement not to be unreasonably withheld.

7. PUBLICATION

7.1. The Parties recognise that the Research Governance Framework referenced in clause 2 of this Agreement places an obligation on NHS Organisations carrying out health and social care research to publish their work. The Parties agree that this clause 7 should be interpreted in light of such obligation.

7.2. Following completion of the Study, the Sponsor shall use all reasonable endeavours to ensure the appropriate publication or other dissemination of the conclusions of the Study. Should the Study form part of a study being undertaken at a number of separate sites this obligation shall arise following completion of the entire Multi-Site Study.

7.3. The NHS Organisation shall not publish or otherwise disseminate the conclusions of the Study, including all or any part of the Results of the Study without the prior written consent of the Sponsor, such consent not to be unreasonably withheld or delayed. Any publication or other dissemination of the conclusions of the Study by the NHS Organisation shall not occur until the Sponsor has

published the conclusions of the Study in accordance with clause 7.2 and shall refer to publication by the Sponsor in such form as the Sponsor may reasonably direct.

8. INTELLECTUAL PROPERTY RIGHTS

8.1. All background intellectual property rights (including licences) and know-how used in connection with the Study shall remain the property of the Party introducing the same and the exercise of such rights for purposes of the Study shall not infringe any third party's rights.

8.2. All intellectual property rights and know-how in the Protocol and in the Results arising directly from the Study, but excluding all improvements thereto or clinical procedures developed or used by the NHS Organisation, shall belong to the Sponsor. The NHS Organisation hereby assigns all such intellectual property rights ("IPR"), and undertakes to disclose all such know-how, to the Sponsor.

8.3. Subject to clause 8.1 and 8.2, all property rights in any material (whether tissue, cellular, genetic, biochemical or otherwise) deriving or arising from biological material or any derivations provided to the Sponsor by the NHS Organisation shall belong to the Sponsor.

8.4. The NHS Organisation shall at the request and expense of the Sponsor execute all such documents and do all acts necessary to fully vest the IPR in the Sponsor. To give effect to this clause 8.4, the NHS Organisation shall ensure that persons involved in the Study assign such IPR, and disclose such know-how to the NHS Organisation.

8.5. Nothing in this clause 8 shall be construed so as to prevent or hinder the NHS Organisation from using know-how gained during the performance of the Study in the furtherance of its normal activities of providing or commissioning clinical services, teaching and research to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual property right of the Sponsor. This clause 8.5 does not permit the disclosure of any of the Results of the Study, all of which remain confidential.

9. FINANCIAL AND SUPPLIES ARRANGEMENTS

9.1. The Parties agree to financing of the Study as set out in Schedule 3. In the event that amendments to the Protocol require changes to the financial arrangements, an amended financial schedule will be signed by the Parties and attached at Schedule 3 of this Agreement.

9.2. Where payments are agreed:

9.2.1. The Parties agree that prior to payment the NHS Organisation shall submit an invoice setting out the costs incurred and payment claimed.

9.2.2. Payment by the Sponsor shall be without prejudice to any claims or rights which the Sponsor may have against the NHS Organisation and shall not constitute any admission by the Sponsor as to the performance by the NHS Organisation of its obligations under this Agreement.

9.3. The Parties agree to the procurement and provision of any medicine, equipment, materials, consumables software or other items necessary for the Study as set out in Schedule 3. Any such items provided by the Sponsor or on behalf of the Sponsor to the NHS Organisation shall be used by the NHS Organisation only for the Study and in accordance with the Protocol.

9.4. The Sponsor shall use any tissue, sample, data, material or other information provided by or derived from a Participant and provided by or on behalf of the NHS Organisation to the Sponsor in accordance with the consent provided by the Participant.

10. TERM

10.1. This Agreement shall commence on the date the final signatory signed the Agreement and shall remain in effect until completion of the Study as specified in the Protocol, or until earlier termination in accordance with this Agreement. If the Protocol does not specify when the Study is complete, then it shall be deemed to be when all Parties have completed their respective obligations as described in the Protocol and in Schedule 2.

11. SUSPENSION OR EARLY TERMINATION

11.1. Either Party may suspend their involvement in the Study pending the outcome of an investigation of a serious adverse event or otherwise on grounds of Participant safety.

11.2. This Agreement may be terminated immediately by notice in writing by any Party if another Party is:

11.2.1. In material or continuing breach of any of its obligations under this Agreement and fails to remedy the breach (if capable of remedy) for a period of 30 days after written notice by the non-breaching Party; or

11.2.2. Declared insolvent or has an administrator or receiver appointed over all or any part of its assets or ceases or threatens to cease to carry on its business or, in the case of the NHS Organisation, if it is a NHS Foundation Trust listed in the register of NHS Foundation Trusts maintained pursuant to Section 39 of the National Health Service Act 2006, any step or proceedings is taken against the NHS Organisation by the Independent Regulator under Sections 52-55 of that Act; or if not and the Secretary of State makes an order under either the National Health Service Act 2006 Section 70 or the National Health Service (Residual Liabilities) Act 1996 Section 2 in respect of the NHS Organisation transferring its property rights and liabilities to one of the bodies referred to in Section 70(2) National Health Service Act 2006 or Section 2(2) National Health Service (Residual Liabilities) Act 1996 as applicable.

11.3. The Sponsor may terminate this Agreement by notice in writing and without liability for such termination:

11.3.1. If the regulatory permissions and approvals previously granted to perform the Study are withdrawn.

11.3.2. If funding is withdrawn or terminated for any reason or if it has been agreed that there are insufficient funds available to continue the Study.

11.3.3. If the Principal Investigator becomes unavailable to continue his/her supervision of the Study for any reason and a replacement acceptable to all Parties is not found.

11.3.4. If (including but not limited to): insufficient numbers of Participants are being recruited by the NHS Organisation to the Study; insufficient numbers of Participants are being recruited to the Study across all the study centres; interim analysis of the data from this Study or the results of another study supersede the necessity for completion of this Study; following 30 days prior written notice of termination to the NHS Organisation.

11.3.5. In the event of cessation of supply of medicinal product, medical device or information or materials critical to the Study.

11.4. The NHS Organisation may terminate this Agreement on one month's notice in writing to the Sponsor. Prior to so terminating this Agreement, the NHS Organisation shall discuss with the Sponsor the reasons for wishing to terminate and explore alternative arrangements to termination.

11.5. In the event of termination of this Agreement under clause 11 the following provisions shall apply:

11.5.1 The Sponsor(s) shall, subject to the prior compliance of the NHS Organisation with its obligations on termination, upon receipt of a valid invoice, pay the NHS Organisation any outstanding monies due to the NHS Organisation as at the date of termination.

11.5.2 The NHS Organisation shall ensure that there is prompt refund to the Sponsor of the amount, if any, by which the cumulative cost paid by the Sponsor to the NHS Organisation under this Agreement exceeds the actual commitments incurred by the NHS Organisation up to the date of termination and any other costs in accordance with Schedule 3.

11.5.3 The NHS Organisation shall provide to the Sponsor all Results of the Study and other relevant information or data relating to work undertaken by the NHS Organisation prior to the date of termination and co-operate with all reasonable requests from the Sponsor at the cost and expense of the Sponsor including any continued monitoring of Participants.

11.5.4 The NHS Organisation shall ensure that all instructions by the Sponsor as regards the return or disposal of all unused supplies, or medical devices or other equipment or items previously furnished to the NHS Organisation for the purposes of the Study are complied with.

11.5.5 The NHS Organisation shall ensure that the instruction of the Sponsor regarding the transfer or storage of all information, material or data relating to the Study collected by the NHS Organisation in the course of carrying out the Study are complied with.

11.5.6 Unless otherwise agreed in writing with the Sponsor, the Sponsor shall pay the costs and expenses of returning, dispatching, transferring or storing items in accordance with clauses 11.5.4 and 11.5.5.

11.6 Any termination of this Agreement under this clause 11 will be without prejudice to any other rights or remedies of any Party under this Agreement or at law, and will not affect any accrued rights or liabilities of any Party at the date of termination shall survive the expiry or termination of this Agreement.

12 AGREEMENT, MODIFICATION AND AUTHORITY OF CO-SPONSORS

12.1 Any amendments to this Agreement shall be valid only if made in writing, agreed and signed by the Parties.

12.2 Where there is more than one Sponsor, each Sponsor has the authority to act on behalf of all co-Sponsors. Any amendments to this Agreement signed by one Sponsor shall be valid and binding on all co-Sponsors and any instructions or consent given by one Sponsor is deemed to be given on behalf of all co-Sponsors.

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

13 FORCE MAJEURE

13.1 No Party shall be liable for any delay in performance or failure to perform its obligations under this Agreement if such delay or failure is due to an occurrence beyond its reasonable control. The Party affected by such occurrence shall promptly notify the other Party. If the circumstances causing the

delay or failure to perform continue for longer than 30 working days the other Party(ies) shall be entitled to terminate this Agreement by notice in writing with immediate effect.

14 NOTICES

14.1 Any notice under this Agreement shall be in writing, signed by the relevant Party to the Agreement and delivered personally, by courier, by recorded delivery post, or by facsimile, providing evidence of receipt, but not by e-mail.

14.2 Notices to the Sponsor and to the NHS Organisation shall be delivered to the person and at the address specified in Schedule 3.

15 ASSIGNMENT AND SUBLETTING

15.1 No Party shall novate, assign, or subcontract all or any part of their rights or obligations under this Agreement without the prior written consent of the other Parties.

16 DISPUTE RESOLUTION

16.1 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 7 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 14 days.

16.2 If the Parties are unable to resolve a dispute using the procedure outlined in clause 16.1, the Parties will attempt to resolve the dispute by the appropriate method of:

16.2.1 In England or Wales Parties will refer the dispute to mediation in accordance with the Centre for Effective Dispute Resolution Model Mediation Procedure; or

16.2.2 In Scotland Parties will refer the dispute to an independent third party. 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 and not as an arbiter; or

16.2.3 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.

16.3 The Parties shall each bear their own costs in relation to the settlement of any disputes and 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.

16.4 Any decision reached in accordance with this clause 16 shall be final and binding upon the Parties.

16.5 Notwithstanding the provisions of clauses 16.2 to 16.4, where the Agreement is an NHS Contract as defined in Section 9(4) National Health Service Act 2006 or Section 17 National Health (Scotland) Act 1978 or a HSS contract (now HSC contract) as defined in Article 8 of the Health and Personal Social Service (Northern Ireland) Order 1991 as applicable, any dispute between the Parties shall be referred for determination by:

16.5.1 The Secretary of State for Health if both Parties are NHS Organisations in England or Wales;

16.5.2 The Scottish Ministers if both Parties are NHS Organisations in Scotland;

16.5.3 The Secretary of State and the Department of Health, Social Services and Public Safety acting jointly if both Parties are NHS Organisations in Northern Ireland; or

16.5.4 Where one Party is an NHS Organisation in one jurisdiction and one Party is an NHS Organisation in another jurisdiction by the appropriate representative bodies in both jurisdictions specified in clauses 16.5.1, 16.5.2 or 16.5.3 acting jointly.

17 GENERAL

17.1 No failure or delay by any Party to exercise any right under this Agreement will operate as a waiver of it, nor will any partial exercise preclude any future exercise of the same.

17.2 If any clause or part of this Agreement is found by any court, tribunal, administrative body or authority of competent jurisdiction to be illegal, invalid or unenforceable then that provision shall, to the extent required, be severed from this Agreement and shall be effective without, as far as possible, modifying any other clause or part of this Agreement and shall not affect any other provisions of this Agreement which shall remain in full force and effect.

17.3 Nothing in this Agreement shall confer or purport to confer on any third party any benefit or any right to enforce any term of this Agreement.

18 SURVIVAL OF CLAUSES

18.1 The following clauses shall survive the termination or expiry of this Agreement: clauses 1, 4, 5, 7, 8 and 19.

19 GOVERNING LAW

19.1 Subject to clause 19.2:

19.1.1 If the Site is located in England or Wales, this Agreement is deemed made and shall be interpreted in accordance with the laws of England and Wales and the Parties submit to the exclusive jurisdiction of the English and Welsh Courts.

19.1.2 If the Site is located in Scotland this Agreement is deemed made and shall be interpreted in accordance with the laws of Scotland and the Parties submit to the exclusive jurisdiction of the Scottish Courts.

19.1.3 If the Site is located in Northern Ireland this Agreement is deemed made and shall be interpreted in accordance with the laws of Northern Ireland and the Parties submit to the exclusive jurisdiction of the Northern Irish Courts.

19.2 The Parties may agree to override clause 19.1.1, 19.1.2 and 19.1.3 and nominate the English and Welsh or Scottish or Northern Irish laws and court jurisdiction to apply to this Agreement irrespective of the location of the Site or Sites. Any such nomination must be in writing and signed by all Parties.

SIGN OFF

Signed by the duly authorised representatives of the Parties on the date stated at the beginning of this Agreement

Study Title: [Insert SHORT TITLE OF STUDY]
Reference: [Insert REFERENCE NUMBER e.g. EUDRACT NUMBER OR SIMILAR REFERENCE]

SIGNED ON BEHALF OF THE SPONSOR

……	……	……	……
Name	Position	Signature	Date

[REPEAT AS NECESSARY FOR ADDITIONAL SPONSORS]

SIGNED ON BEHALF OF NHS ORGANISATION

……	……	……	……
Name	Position	Signature	Date

SCHEDULE 1

STUDY PROTOCOL

Note 1: The Protocol must set out the objectives, design, methodology, statistical and organisational arrangements.

Note 2: The Parties should check that there are no conflicts between Agreement clauses and Protocol. Any conflicts that are identified must be resolved prior to signing this Agreement.

Note 3: Should there be any inconsistency between the Protocol and the other terms of this Agreement, or any document incorporated therein, clause 2.2 of this Agreement shall apply.

Summary of Management Arrangements

Funder(s)……..[Insert NAME and ADDRESS]
Sponsor(s)…… .[Insert NAME and ADDRESS] (State if co-sponsorship or joint sponsorship)
Chief Investigator for the Study….[Insert NAME and ADDRESS]……Employer….[Insert NAME and ADDRESS]……..
Principal Investigator….[Insert NAME and ADDRESS]……Employer…….[Insert NAME and ADDRESS]……
Study coordinating organisation…….[Insert NAME and ADDRESS]……
Others organisations (specify)

Number of Participants to be recruited at the Site ……[Insert NUMBER, AS APPROPRIATE]……
Number of samples/ records to be provided by the Site……[Insert NUMBER AS APPROPRIATE]…….

Timelines:

Milestone	Target date
Provision of materials for Ethics Committee submission	[Insert DATE]
Ethics Committee submission	[Insert DATE]
First Participant recruited	[Insert DATE]
Last Participant recruited	[Insert DATE]
[Insert other milestones as applicable]	[Insert DATE]

[Insert PROTOCOL]

SCHEDULE 2

DIVISION OF RESPONSIBILITIES

The Parties collaborating in the [Insert NAME OF STUDY] will undertake responsibilities as attributed in the table below.

Note 1: Parties should set out the agreed division and/or delegation of responsibilities in the table below. Where there is more than one Sponsor, the name of the Sponsor responsible for each activity should be given. Some responsibilities are only applicable to particular types of study. Where a particular responsibility is not applicable to the Study, "not applicable" should be entered in the column designating "Responsible Party". Any additional responsibilities to those set out in this table should be added at the end to preserve the numbering of the standard list and navigation of the contents.

Note 2: Where both the Sponsor and NHS Organisation are named in respect of a particular responsibility, liability for such responsibility is not joint and several. Their respective responsibility shall be as laid down in applicable legislation, guidance and the governance arrangements for the Study or as is otherwise applicable to their respective roles in the Study.

Note 3: All references to Participants refer to those recruited at or through the Site.

Note 4: All capitalised terms used in the Schedule but not otherwise defined in the Agreement shall have the meaning ascribed to them in the Medicines for Human Use (Clinical Trials) Regulations 2004

	Responsibility to:	Responsible Party:	If Responsibility is delegated, name the body / individual that it is delegated to:
1. Study preparation (All studies)	a) Ensure that insurance or indemnity arrangements are in place to cover liabilities.	Sponsor	
	b) Secure and administer funding for the Study.	Sponsor	
	c) Secure and contract for the supply of resources including medicinal products / devices / Contract Research Organsation services.	Sponsor	
	d) Ensure that the appropriate contracts and agreements are in place for the Study.	Sponsor	
	e) Notify the substantive employers of investigators in writing, in advance of the Study commencing, of their participation in the Study.	NHS Organisation	
2. Applications and Registration (All studies)	a) Ensure that the Protocol has undergone independent scientific and statistical review and is compliant with the relevant regulations/ guidelines.	Sponsor	

	Responsibility to:	Responsible Party:	If Responsibility is delegated, name the body / individual that it is delegated to:
	b) Prepare Participant information sheet and consent form, including where appropriate consent to providing Participant tissue, sample, medical data or other material to the Sponsor and other relevant documents prior to ethics submission.	Sponsor	
	c) Prepare and submit ethics application.	Sponsor	
	d) Register the Study with an appropriate protocol registration scheme.	Sponsor	
	e) Obtain NHS permission.	Sponsor	
	f) [Insert ANY ADDITIONAL PERMISSIONS APPROVALS TO BE SOUGHT]		
3. Protocol Amendments (All studies)	a) Prepare and submit proposed substantial amendments of the Protocol to the regulatory authority(ies), relevant ethics committee and NHS Site.	Sponsor	
	b) Ensure all investigators are aware of dates of approval and implementation of all such amendments.	Sponsor and NHS Organisation	
4. Study Conduct (All studies)	a) Ensure that legislation in relation to research is followed within the Site	NHS Organisation	
	b) Ensure that the Study Site team members are appropriately qualified and experienced to undertake the conduct of the Study and that they have current substantive or honorary employment contracts in place, where required.	NHS Organisation	
	c) Ensure that no Participant is recruited until a favourable ethical opinion has been provided	Sponsor and NHS Organisation	
	d) Ensure that no Participant is recruited to the Study until satisfied that all relevant regulatory permissions and approvals have been obtained.	Sponsor and NHS Organisation	
	e) Put and keep in place arrangements to allow all investigators to conduct the Study in accordance with the Protocol and clause 2 of this Agreement	Sponsor and NHS Organisation	
	f) Ensure that the Study is managed, monitored and reported as agreed in the Protocol.	Sponsor and NHS Organisation	

	Responsibility to:	Responsible Party:	If Responsibility is delegated, name the body / individual that it is delegated to:
	g) Ensure that the rights of individual Participants are protected and that they receive appropriate medical care whilst participating in the Study.	NHS Organisation	
	h) Maintain and archive Study documentation at the Site.	NHS Organisation	
	i) Ensure that all data and documentation are available for the purposes of monitoring, inspection or audit and that the appropriate consent has been provided by the Participant.	NHS Organisation	
	j) Inform appropriate health or social care professionals if their patient is a Participant in the Study in accordance with the Research Governance Framework.	NHS Organisation	
	k) Ensure adequate facilities, resources and support are available to conduct the Study at the Site.	NHS Organisation	
	l) Report suspected research misconduct.	Sponsor and NHS Organisation	
	m) Notify the regulatory authority(ies) of the end of the Study.	Sponsor	
	n) Notify the regulatory authority(ies) and relevant ethics committee if the Study is terminated early.	Sponsor	
5. Adverse events (All studies)	a) Maintain detailed records of all adverse events as specified in the Protocol.	Sponsor and NHS Organisation	
	b) Report adverse events as agreed in the Protocol and to legal requirements and in accordance with NHS Organisation policy.	Sponsor and NHS Organisation	
	c) Ensure that procedures are in place for emergency unblinding of the randomisation code.	Sponsor	
	d) Promptly inform regulatory authorities, ethics committees and investigators of any urgent safety measures taken to protect Participants in the Study.	Sponsor	

	Responsibility to:	Responsible Party:	If Responsibility is delegated, name the body / individual that it is delegated to:
	e) Ensure that annual safety reports and end of Study reports are generated and submitted to the regulatory authority and relevant ethics committee within the required timeframes.	Sponsor	
	f) Ensure that all investigators are, at all times, in possession of the current relevant safety information for the Study.	Sponsor	
6. Data Management (All studies)	a) Design of case report forms and database.	Sponsor	
	b) Ensure appropriate analysis of data.	Sponsor	
7. Publication (All studies)	a) Initiate and coordinate review and submission of abstracts, posters and publications.	Sponsor	
8. Archiving (All studies)	a) Ensure that all Study records are archived appropriately on conclusion of the Study and retained for [insert PERIOD e.g. 10 years]	Sponsor	
9. Clinical Trials involving Medicinal Products	a) Ensure that the Study is conducted in accordance with the principles of Good Clinical Practice (GCP).	Sponsor	
	b) Request Clinical Trials Authorisation from the regulatory authority (MHRA in the UK).	Sponsor	
	c) Ensure that Investigational Medicinal Product (IMP) is not used for any purposes other than the conduct of the Study and is used in strict accordance with the Protocol.	NHS Organisation	
	d) Ensure that all Serious Adverse Events (SAE), other that those specified in the Protocol as not requiring immediate reporting, are promptly assessed as regards the requirement for expedited reporting to the regulatory authority and relevant ethics committee.	Sponsor	
	e) Ensure that SAEs are reviewed by an appropriate committee for the monitoring of trial safety.	Sponsor	
	f) Ensure that all Suspected Unexpected Serious Adverse Reactions (SUSAR) are identified and fully reported to the regulatory authority and relevant ethics committee within the required timelines.	Sponsor	

	Responsibility to:	Responsible Party:	If Responsibility is delegated, name the body / individual that it is delegated to:
	g) Ensure that investigators are aware of any SUSARs occurring in relation to the Investigational Medicinal Product (IMP).	Sponsor	
	h) Ensure IMP is provided and labelled in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004.	Sponsor	
	i) Ensure that IMP is stored in appropriate and secure conditions and that detailed records are maintained regarding its movement from delivery to return/destruction.	NHS Organisation	
10. Studies involving CE marked medical devices for new purpose or non-CE marked Medical Device	a) Ensure that sufficient product is available for the planned number of Participants.	Sponsor	
	b) Ensure that investigational medical devices are not used for any purposes other than the conduct of the Study.	NHS Organisation	
	c) Obtain a letter of no objection from the Medicines and Healthcare products Regulatory Agency for the clinical investigation of a non-CE marked medical device or a CE marked medical device being used for a new purpose	Sponsor	
	d) Ensure that adverse events are reported to the Medicines and Healthcare products Regulatory Agency.	Sponsor	
	e) Ensure that investigational medical devices are stored in appropriate, secure conditions and returned as instructed by Sponsor. Further to ensure that detailed records are maintained regarding its movement from delivery to return/destruction.	NHS Organisation	
11. [Insert other responsibilities, if necessary]	a) [Insert additional responsibilities if necessary e.g. regarding storage and use of tissue samples.]		

SCHEDULE 3

FINANCIAL ARRANGEMENTS

	Area of Cost	Payment (£ Sterling)
1		
2		
3		
4		
5		
6		
7		

If VAT is payable, then the Sponsor shall pay the VAT in addition to the payment on presentation of a VAT invoice. If VAT is not payable, then the Sponsor shall issue a VAT exemption certificate.

Schedule of payments and details of payment arrangements

Invoices to be submitted [Insert FREQUENCY OR INTERVAL e.g. quarterly] to:

[Insert JOB TITLE, NAME OF BODY & ADDRESS]

Payment to be made by cheque payable to:

[Insert NAME OF NHS ORGANISATION]

and remitted to:

[Insert JOB TITLE/POSITION]

[Insert ADDRESS]

Or arrange BACS Transfer to: [Insert BANK NAME].

Sort code: [Insert SORT CODE]

Account: [Insert ACCOUNT NUMBER]

And send the relevant paper work to [Insert ADDRESSEE FOR PAPERWORK] at the above address

Where no payments are to be made tick this box ☐

SUPPLIES ARRANGEMENTS

Any medicine, equipment, materials, consumables, software or other items ("Items") being provided by the Sponsor or procured by the NHS Organisation for use in the Study shall be specified below.

Note 1: Parties should complete the table below. If the NHS Organisation is to procure any Items and is to be reimbursed by the Sponsor this should be specified in this Schedule. Similarly if the NHS Organisation is to pay the Sponsor for any Items provided to the NHS Organisation by or on behalf of the Sponsor this should be specified in this Schedule.

Note 2: Parties should specify in this Schedule, as appropriate, arrangements for:

- Ownership of items
- Insurance
- Storage instructions
- Instructions for use, return and/or destruction
- Any training to be provided
- Maintenance of equipment

Item	Quantity	Frequency of supply	Responsibility to supply/procure (either Sponsor or NHS Organisation)

Where no Items are to be provided or procured tick this box ☐

NOTICES

Notices to the Sponsor shall be addressed to:

[Insert JOB TITLE OR POSITION]

[Insert NAME OF ORGANISATION]

[Insert ADDRESS]

(Repeat as necessary for Additional Sponsors)

Notices to the NHS Organisation shall be addressed to:

[Insert JOB TITLE OR POSITION]

[Insert NAME OF NHS BODY]

[Insert ADDRESS]