# MODEL AGREEMENT FOR NON-COMMERCIAL RESEARCH

The University of Birmingham, Edgbaston, Birmingham, B15 2TT

(referred to as “the Sponsor”)

AND

[Insert NAME AND ADDRESS OF TRIAL SITE]

(referred to as “the Trial Site”)

Which are collectively referred to as the “**Parties**” or individually referred to as a “**Party**”

**NOW**

**WHEREAS** the Sponsor is a University

**WHEREAS** the Study is coordinated on behalf of the Sponsor by Birmingham Clinical Trials Unit (BCTU) which is a Clinical Trials Unit

**WHEREAS** the Funder is The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme, which is a Government Funding Stream

**WHEREAS** the Study is Multi-Centre, having more than one Investigator Site

**WHEREAS** the Trial Site is a Lead Trial Site in an Investigator Site comprising of more than one legal entity;

**WHEREAS** the Study is a clinical trial of an Investigational Medicinal Product (CTIMP)

# MODEL AGREEMENT FOR NON-COMMERCIAL RESEARCH

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In respect of the clinical research Study entitled “A randomised controlled trial of STeroid Administration Routes For Idiopathic Sudden sensorineural Hearing loss” the above Parties HEREBY AGREE AS FOLLOWS:

## DEFINITIONS

* 1. The following words and phrases have the following meanings:

**Agent(s)**
includes, but shall not be limited to, any person undertaking a function in connection with this Agreement (including the Principal Investigator, any nurse or other health professional), any such person’s principal employer in the event it is not the Trial Site and where such person is providing services to a Party under a contract for services or otherwise (including clinical academics), and/or any contracted third party providing services to a Party under a contract for services or otherwise;

**Agreement**
this Agreement, together with the schedules annexed hereto;

**Background**
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**

the person, named in Schedule 1, who takes overall responsibility for the design, conduct and reporting of the Study or if a Multi-Centre study, the person who takes primary responsibility for the design, conduct and reporting of the entire Multi-Centre Study, whether or not the person is a Principal Investigator;

**Clinical Data**

any data which relate to a specific actual or potential Participant, which may include, without limitation, medical records, medical imaging data, scans, questionnaires, readouts of individual biomedical or genetic analysis;

**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;

**Controller**

shall have the meaning set out in the Data Protection Legislation (and "Controllership” shall be construed accordingly);

**Data Protection Legislation**

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

**Data Subject**

as defined in the Data Protection Legislation;

**Funder**

the organisation(s) detailed in Schedule 1 that is/are providing support to the Study;

**GDPR**

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

**Intellectual Property Rights**

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;

**Investigator Site**

the activities conducted under this Agreement overseen by one Principal Investigator, regardless of the location of those activities;

**Know-How**

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;

**Lead Trial Site**

Where the Principal Investigator has oversight of Study activities at the Lead Trial Site and at an Other Trial Site(s), the Trial Site is the Lead Trial Site, being the ‘hub’ in a ‘hub and spoke’ delivery model;

**Material**

any clinical biological sample or portion thereof, derived from Participants, including any information related to such material, supplied by the Trial Site to the Sponsor or its nominee under Schedule 4;

**Multi-Centre**

A study that involves more than one Investigator Site;

**NHS Indemnity Scheme**

one of the NHS Resolution Clinical Negligence Scheme for Trusts (CNST), or Clinical Negligence Scheme for General Practice (CNSGP) in England; the Clinical Negligence Fund in Northern Ireland; the Clinical Negligence and other Risks Indemnity Scheme (CNORIS) in Scotland; or the Welsh Risk Pool Service (WRPS) in Wales;

**Other Trial Site(s)**

a legal entity (or entities) subcontracted by the Trial Site to undertake Study related activity for which the Principal Investigator is responsible;

**Participant**

any person who consents (where consent is necessary) and is enrolled to take part in the Study. All references to Participants in this Agreement refer to those recruited by or under the care of the Trial Site for the purpose of the Study;

**Personal Data**

any and all information, data and material of any nature received or obtained by any Party in connection with this Agreement which is personal data as defined in the Data Protection Legislation and which relates to any actual or potential Participant or their treatment or medical history;

**Principal Investigator (PI)**

the leader responsible for a team of individuals conducting the Study at the Investigator Site and who has signed the declaration at Schedule 5;

**Process**
as defined in the Data Protection Legislation (and "Processing" and "Processed" shall be construed accordingly);

**Processor**
shall have the meaning set out in the Data Protection Legislation;

**Protocol**
the full description of the Study with the reference number set out on the front page of this Agreement, together with any amendments thereof, and incorporated into this Agreement by reference. For Clinical Investigations of Medical Devices, Protocol will be construed to include the clinical investigation plan for the Study;

**Pseudonymised Data**

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

**Results**

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;

**Sponsor**

the individual, company, institution or organisation that is (or the institutions or organisations, where there is more than one sponsor under a co-sponsorship or joint-sponsorship arrangement, that are) Party to this Agreement, that takes responsibility for the initiation, management and financing (or arranging the financing) of the Study;

**Study**

the clinical research study that is the subject of this Agreement;

**Study Data**

all discoveries, data, information, theories, methods, computer programmes, 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 arising from the performance of the Study;

**Study Drug**

the investigational medicinal product (IMP) / investigational medicinal product(s) (IMPs) specified in the Protocol (including, where applicable, placebo).

* 1. Any reference to a statutory provision, code or guidance shall be deemed to include reference to any subsequent modification or re-enactment of it.

## Obligations of the Parties

* 1. To the extent applicable to each, the Parties shall comply with, and the Trial Site shall ensure that the Principal Investigator and all personnel who are providing any manner of service related to the Study comply with, all relevant laws and codes of practice, which may include but not be limited to:
		1. The Human Rights Act 1998;
		2. The Data Protection Legislation;
		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 Trial Site;
		4. Where the Study is not a Clinical Trial of an Investigational Medicinal Product, the Mental Capacity Act 2005 (or a combined Clinical Trial of a Medicinal Product and Clinical Investigation of a Medical Device), the Adults with Incapacity (Scotland) Act 2000 or The Mental Capacity (Northern Ireland) Act 2016, to be determined in accordance with the place of constitution of the Trial Site;
		5. The Medicines Act 1968;
		6. The Human Medicines Regulations 2012;
		7. The Medicines for Human Use (Clinical Trial) Regulations 2004;
		8. The Bribery Act 2010;
		9. Relevant law having effect by virtue of ss2-4 of the European Union (Withdrawal) Act 2018;
		10. (In Northern Ireland) laws of the European Union having effect as a result of the Protocol on Ireland/Northern Ireland;
		11. the World Medical Association Declaration of Helsinki, titled “Ethical Principles for Medical Research Involving Human Subjects”;
		12. the UK Policy Framework for Health and Social Care Research.
	2. The Parties shall conduct the Study in accordance with:
		1. the Protocol;
		2. the terms of all relevant regulatory permissions and approvals. These may include, but are not limited to:
1. the terms and conditions of the favourable opinion given by the relevant NHS Research Ethics Committee;
2. the Clinical Trials Authorisation (CTA) granted by the Medicines and Healthcare products Regulatory Agency (the "MHRA");
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.
	1. The Parties shall carry out their respective responsibilities in accordance with this Agreement.
	2. The Sponsor shall, on the giving of reasonable prior written notice to the Trial Site, have the right to audit, on-site or by remote means, the Trial Site’s compliance with this Agreement. The Sponsor may appoint an auditor to carry out such an audit. Such right to audit shall include access, during normal working hours to the Trial Site's premises and/or to all relevant documents and other information relating to the Study.
	3. The Trial Site shall use reasonable endeavours to recruit Participants to participate in the Study as set out in Schedule 1 hereto.
	4. The Trial Site shall:
		1. promptly notify the Sponsor should any responsible body, such as, but not limited to, the MHRA, conduct or give notice of intent to conduct any inspection at the Trial Site in relation to the Study;
		2. allow the Sponsor to support the preparations for such inspection; and
		3. following the inspection, provide the Sponsor with the results of the inspection relevant to the Study. The Sponsor will be responsible for sharing such results with the Funder if required.
	5. In accordance with Participant consent, the Trial Site shall permit the Sponsor’s appointed representatives and any appropriately appointed monitor access to all relevant Clinical Data for monitoring, source data verification and adverse event reporting or investigation as appropriate. The Parties agree that such access will be arranged at mutually convenient times and on reasonable notice. Such monitoring may take such form as the Sponsor reasonably thinks appropriate, in on-site or remote form, including the right to inspect any facility being used for the conduct of the Study, reasonable access to relevant members of staff at the Trial Site and the right to examine any procedures or records relating to the Study, subject at all times to Clause 4 of this Agreement. The Sponsor will alert the Trial Site promptly to significant issues (in the opinion of the Sponsor) relating to the conduct of the Study.

**Anti-Bribery and Corruption**

* 1. Each Party warrants and represents that:
		1. It has not committed any offence under the Bribery Act 2010 or any of the following acts (“Prohibited Acts”):
			1. other than in accordance with applicable laws, valid agreements and the provisions of this Agreement, offered, given or agreed to give any Agent of the other Party any gift or consideration of any kind, as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this Agreement or any other agreement with the other Party or for showing or not showing favour or disfavour to any person in relation to this Agreement or any other agreement with the other Party; or
			2. in connection with this Agreement, paid or agreed to pay any commission other than a payment in accordance with this Agreement that has not otherwise been disclosed in writing to the other Party.
	2. If either Party has committed or commits any of the Prohibited Acts or has committed or commits any offence under the Bribery Act 2010 in relation to this Agreement, the other Party shall be entitled to terminate this Agreement in accordance with Clause 10, in addition to any other remedy available, taking into consideration the potential effects of termination on the health of Participants.

## Liabilities and Indemnity

* 1. Nothing in this Clause 3 shall operate so as to restrict or exclude the liability of a Party in relation to statutory or regulatory liability (including but not limited to breach of the Data Protection Legislation), death or personal injury caused by the negligence or wilful misconduct of that Party or its Agent(s), fraud or fraudulent misrepresentation or to restrict or exclude any other liability of a Party which cannot be so restricted or excluded in law.
	2. Where a Party is a non-NHS organisation, or an NHS organisation that is not covered by an NHS Indemnity Scheme, then that Party shall maintain all proper insurance or equivalent indemnity arrangements to cover liabilities arising from its participation in the Study, in respect of any claims brought by or on behalf of a Participant. Where the Party is covered by an NHS Indemnity Scheme, it shall maintain its cover therein or otherwise ensure it has appropriate cover against claims arising as a result of clinical negligence by the Party and/or its Agents brought by or on behalf of the Participants. Each Party shall provide to the other such evidence of their insurance or equivalent indemnity cover maintained pursuant to Clause 3.2 as the other Party shall from time to time reasonably request, such evidence might comprise confirmation that an NHS organisation is a member of, or otherwise covered by, one of the NHS Indemnity Schemes.
	3. Subject to Clauses 3.4, 3.5, 3.6, 3.7 and 3.8, the Sponsor shall indemnify the Trial Site and its Agents, against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands (“**Claims**”) to the extent they arise or result from the negligent acts or omissions of, or the wilful misconduct of the Sponsor, and/or contracted third party, in its performance of this Agreement or in connection with the Study.
	4. Subject to Clauses 3.3, 3.5, 3.6 and 3.8, the Trial Site shall indemnify the Sponsor and its respective Agents, against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands to the extent they arise or result from the negligent acts or omissions of, or the wilful misconduct of the Trial Site, or its Agents, in its performance of this Agreement or in connection with the Study.
	5. An indemnity under Clauses 3.3 or 3.4 shall only apply if the indemnified Party:
		1. informs the Party providing the indemnity in writing as soon as reasonably practicable following receipt of notice of the claim or proceedings;
		2. upon the indemnifying Party’s request and at the indemnifying Party’s cost gives the indemnifying Party full control of the claim or proceedings and provides all reasonable assistance; and
		3. makes no admission in respect of such claim or proceedings other than with the prior written consent of the indemnifying Party.
	6. Any indemnity under Clauses 3.3 or 3.4 shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages or demands arise or result from the negligent acts or omissions or wilful misconduct or breach of statutory duty of the indemnified Party, or its Agent(s).
	7. The indemnity under Clause 3.3 shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages or demands arise or result from:
		1. Trial Site, or its Agent(s), carrying out a treatment or procedure that would be routinely undertaken at or for that Trial Site as part of National Health Service treatment; or
		2. Trial Site, or its Agent(s), preparing, manufacturing or assembling any medicinal product, medical device or other equipment which is not done in accordance:
1. with the Protocol; or
2. with written instructions of the manufacturer; or
3. (where such instructions differ from the instructions of the manufacturer) other written instructions of the Sponsor.
	1. No Party shall be liable to another in contract, tort/delict, 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.
	2. If a Party incurs any loss or damage (including costs and expenses) (“**Loss**”) arising or resulting from this Agreement and:
		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 Section 7 (4) of the NHS (Wales) Act 2006 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 are otherwise bodies covered by an NHS Indemnity Scheme; or
		2. one or more Party is a NHS body or otherwise covered by an NHS Indemnity Scheme and the other Party(ies) is a NHS Foundation Trust; or
		3. all Parties are NHS Foundation Trusts;

then Clauses 3.10, 3.11 and 3.12 shall apply.

* 1. If all Parties are NHS bodies / NHS Foundation Trusts in England, Wales or Northern Ireland or non NHS bodies and are indemnified by the same Indemnity Scheme (being one of the NHS Resolution clinical negligence schemes 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.
	2. If:
		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
		2. all Parties are covered by the same Indemnity Scheme in Scotland; or
		3. the Parties are NHS bodies/Foundation Trusts established in different jurisdictions within the United Kingdom, or are bodies otherwise covered by different NHS Indemnity Schemes;

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 15.5 of this Agreement.

* 1. 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.
	2. Subject to Clauses 3.1 and 3.7 the liability of the Trial Site to the Sponsor and the liability of the Sponsor to the Trial Site arising out of or in connection with any breach of this Agreement or any act or omission of either Party in connection with the performance of the Study shall not exceed the greater of the amount of fees payable by the Sponsor to the Trial Site under this Agreement, or one hundred thousand (£100,000 GBP) pounds. For the avoidance of doubt, this cap applies also but not exclusively to the indemnities offered under Clauses 3.3 and 3.4.
	3. Notwithstanding Clause 3.13, in the case of equipment loaned by or on behalf of the Sponsor to the Trial Site for the purposes of the Study, the Trial Site’s liability for damage to or loss of that equipment arising from its negligence shall exclude fair wear and tear and shall not exceed the replacement value of the equipment.

## Confidentiality, Data Protection and Freedom of Information

### Data Protection

* 1. Participant Confidentiality
		1. The Parties agree to comply with all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality) in relation to actual and potential Participants.

Data Processing Terms

* + 1. For the purposes of the Data Protection Legislation, the Sponsor is the Controller and the Trial Site is the Sponsor's Processor in relation to all Processing of Personal Data that is Processed for the purpose of this Study and for any future research use under the Controllership of the Sponsor, that would not have taken place but for this Agreement regardless where that Processing takes place.
		2. The Parties acknowledge that whereas the Sponsor is the Controller in accordance with Clause 4.1.2, the Trial Site is the Controller of the Personal Data Processed for the purpose of providing clinical care to the Participants. This Personal Data, Processed for care purposes under the Controllership of the Trial Site, may be the same Personal Data, that is Processed for research purposes under the separate Controllership of the Sponsor in accordance with this Agreement.
		3. Where the Trial Site is the Sponsor's Processor and thus where the Processing is undertaken by the Trial Site for the purposes of the Study, Clauses 4.1.5 to 4.1.9 below will apply. For the avoidance of doubt, such Clauses do not apply where the Trial Site is Processing the Participant Personal Data as a Controller.
		4. The Trial Site agrees only to Process Personal Data for and on behalf of the Sponsor in accordance with the instructions of the Sponsor and for the purpose of the Study and to ensure the Sponsor’s compliance with the Data Protection Legislation.
		5. The Trial Site agrees to comply with the obligations applicable to Processors described by Article 28 GDPR including, but not limited to, the following:
1. to implement and maintain appropriate technical and organisational security measures sufficient to comply at least with the obligations imposed on the Controller by Article 28(1);
2. to not engage another Processor without the prior written authorisation of the Sponsor (Article 28(2));
3. to Process the Personal Data only on documented instructions from the Sponsor unless required to do otherwise by legislation, in which case the Trial Site shall notify the Sponsor before Processing, or as soon as possible after Processing if legislation requires that the Processing occurs immediately, unless legislation prohibits such notification on important grounds of public interest (Article 28(3)(a));
4. to ensure that personnel authorised to Process Personal Data are under confidentiality obligations (Article 28(3)(b));
5. to take all measures required by Article 32 GDPR in relation to the security of processing (Article 28(3)(c));
6. to respect the conditions described in Article 28(2) and (4) for engaging another Processor (Article 28(3)(d));
7. to, taking into account the nature of the Processing, assist the Sponsor, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising Data Subjects’ rights (Article 28(3)(e));
8. to assist the Controller, to ensure compliance with the obligations pursuant to Articles 32 to 36 GDPR taking into account the nature of the Processing and the information available to the Trial Site (Article 28(3)(f));
9. to, at the choice of the Sponsor, destroy or return all Personal Data to the Sponsor at the expiry or early termination of the Agreement, unless storage is legally required (Article 28(3)(g)) or where that Personal Data is held by the Trial Site as Controller for the purpose of clinical care or other legal purposes; and
10. to maintain a record of Processing activities as required by Article 30(2) GDPR.
	* 1. The Trial Site shall ensure that:
11. its Agents do not Process Personal Data except in accordance with this Agreement (and in particular the Protocol);
12. it takes all reasonable steps to ensure the reliability and integrity of any of its Agents who have access to the Personal Data and ensure they:
13. are aware and comply with the Trial Site's duties under this Clause;
14. are subject to mandatory training in their information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data; and
15. are informed of the confidential nature of the Personal Data and understand the responsibilities for information governance, including their obligation to Process Personal Data securely and to only disseminate or disclose for lawful and appropriate purposes.
	* 1. The Trial Site agrees to:
16. allow the Sponsor(s) or another auditor appointed by the Sponsor(s) to audit the Trial Site’s compliance with the obligations described by this Agreement, Data Protection Legislation in general and Article 28 GDPR in particular, on reasonable notice subject to the Sponsor complying with all relevant health and safety and security policies of the Trial Site and/or to provide the Sponsor with evidence of its compliance with the obligations set out in this Agreement; and
17. obtain prior agreement of the Sponsor to store or Process Personal Data outside the UK and the European Economic Area.
	* 1. Where the Trial Site stores or otherwise Processes Personal Data outside of the UK and the European Economic Area as the Sponsor’s Processor, it warrants that it does so in compliance with the Data Protection Legislation.

### Sharing of Personal Data and/or Participant Pseudonymised Data

* + 1. Neither Personal Data nor Pseudonymised Data of actual or potential Participants shall be disclosed to the Sponsor by the Trial Site under this Agreement, 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, or in relation to a claim or proceeding brought by a Participant in connection with the Study.
		2. The Sponsor agrees to use Personal Data and/or Participant Pseudonymised Data supplied under this Agreement solely in connection with the operation of the Agreement, or otherwise for purposes not incompatible with this original purpose (GDPR Article 5(1)(b)), and not otherwise. In particular:
1. not to disclose Personal Data and/or Participant Pseudonymised Data to any person except in accordance with applicable legal requirements and codes of practice.
	* 1. The Sponsor agrees to comply with the obligations placed on a Controller by the Data Protection Legislation. This is not limited to, but includes, being responsible for and able to demonstrate compliance with the principles relating to Processing of Personal Data (GDPR Article 5).
		2. The Sponsor agrees to ensure persons Processing Personal Data and/or processing Participant Pseudonymised Data under this Agreement are equipped to do so respectfully and safely. In particular, to ensure that:
2. any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Trial Site) Processing Personal Data and/or processing Participant Pseudonymised Data understand the responsibilities for information governance, including their obligation to Process Personal Data and/or process Participant Pseudonymised Data securely and to only disseminate or disclose for lawful and appropriate purposes;
3. any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Trial Site) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable data breaches.
	* 1. The Sponsor agrees to proactively prevent data security breaches and to respond appropriately to incidents or near misses. In particular, to:
4. ensure that Personal Data and/or Participant Pseudonymised Data are only accessible to persons who need it for the purposes of the Study, or for other purposes that are not incompatible with that purpose and that are not incompatible with the Participant consent, and to remove access as soon as reasonably possible once it is no longer needed;
5. ensure all access to Personal Data and/or Participant Pseudonymised Data on IT systems processed for Study purposes can be attributed to individuals;
6. review processes to identify and improve processes which have caused breaches or near misses, or which force persons Processing Personal Data and/or processing Participant Pseudonymised Data to use workarounds which compromise data security;
7. adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice;
8. take action immediately following a data breach or near miss.
	* 1. The Sponsor agrees to ensure data are Processed using secure and up to date technology. In particular, to:
9. ensure no unsupported operating systems, software or internet browsers are used to support the Processing of Personal Data and/or processing of Participant Pseudonymised Data for the purposes of the Study;
10. put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework such as Cyber Essentials;
11. ensure IT suppliers are held accountable via contracts for protecting Personal Data and/or Participant Pseudonymised Data they Process (and/or process) and for meeting all relevant information governance requirements.
	1. **Freedom of Information**
		1. Parties to this Agreement which are 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 which receive a request under EIR, FOIA or FOI(S)A to disclose any information that belongs to another Party shall notify and consult that Party in accordance with Clause 13, as soon as reasonably practicable, and in any event, not later than seven (7) working days after receiving the request.
		2. The Parties acknowledge and agree 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 Party responding to the request.
		3. Where the Party responding to an EIR, FOIA or FOI(S)A request determines that it will disclose information it will notify the other Party in writing, giving at least four (4) working days’ notice of its intended disclosure.
	2. **Confidentiality**
		1. Subject to Clause 6 below, the Trial Site agrees to treat the Results, excluding any Clinical Data of the Study, as Confidential Information of the Sponsor and the Sponsor agrees to treat Personal Data, Pseudonymised Participant Data and confidential patient information as Confidential Information.
		2. The Receiving Party agrees:
12. to take all reasonable steps to protect the confidentiality of the Confidential Information and to prevent it from being disclosed otherwise than in accordance with this Agreement;
13. to ensure that any of its employees, students, researchers, consultants or sub-contractors who participate in the operation of the Study are made aware of, and abide by, the requirement of this Clause 4.3.2;
14. to use Confidential Information solely in connection with the operation of the Agreement and not otherwise, except in the case where the Confidential Information is Personal Data and/or confidential patient information, where it may be used solely on the basis of maintaining the common law duty of confidentiality and in accordance with the requirements of the Data Protection Legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose;
15. not to disclose Confidential Information in whole or in part to any person without the Disclosing Party’s prior written consent or, where the Confidential Information is Personal Data and/or confidential patient information, without maintaining the common law duty of confidentiality and in accordance with the requirements of the Data Protection Legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose;
16. That in the event of a Party visiting the establishment of another Party, the visiting Party undertakes that any further Confidential Information that may come to the visiting Party’s knowledge as a result of any such visit, shall be treated as Confidential Information in accordance with this Clause 4.3.
	* 1. The provisions of Clause 4.3.1 and 4.3.2 shall not apply to the whole or any part of the Confidential Information that is:
17. lawfully obtained by the Receiving Party free of any duty of confidentiality;
18. already in the possession of the Receiving Party and which the Receiving Party can show from written records was already in its possession (other than as a result of a breach of Clause 4.3.1 or 4.3.2);
19. in the public domain (other than as a result of a breach of Clause 4.3.1 or 4.3.2);
20. independently discovered by employees of the Receiving Party without access to or use of Confidential Information;
21. necessarily disclosed by the Receiving Party pursuant to a statutory obligation;
22. disclosed with prior written consent of the Disclosing Party;
23. necessarily disclosed by the Receiving Party by virtue of its status as a public authority in terms of the EIR, EI(S)R, FOIA or the FOI(S)A;
24. published in accordance with the provisions of Clause 6.
	* 1. The restrictions contained in Clauses 4.3 shall remain in force without limit in time in respect of Personal Data and any other information which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly set out in this Agreement, these clauses shall remain in force for a period of ten (10) years after the termination or expiry of this Agreement.

## Publicity

* 1. Neither Party shall use the name, logo or registered image of the other Party or the Agents of such other Party in any publicity, advertising or press release, related to this Agreement, without the prior written approval of an authorised representative of that Party.
	2. The content and timing of any publicity, advertising or press release shall be agreed by both Parties, such agreement not to be unreasonably withheld.

## Publication

* 1. In accordance with all relevant laws, regulations and codes of practice, it is agreed that the Sponsor has an obligation to and shall publish the Results of the full Study and that the Trial Site shall not publish any Study Data, including through presentation or submission of an abstract, without the prior permission in writing from the Sponsor (which shall not be unreasonably withheld or delayed).

## Intellectual Property Rights

* 1. All Background Intellectual Property Rights (including licences) and Background Know-How and their improvements 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 knowingly infringe any third party’s rights.
	2. All Intellectual Property Rights and Know-How in the Protocol and other documents and information disclosed by the Sponsor, and in the Study Data, excluding clinical procedures developed or used by the Trial Site independently of the Study, shall belong to the Sponsor. The Trial Site hereby assigns all such Intellectual Property Rights, and undertakes to disclose all such Know-How, to the Sponsor.
	3. Subject to Clauses 7.1 and 7.2, all Intellectual Property Rights deriving or arising from the Material or any derivations of the Material provided to the Sponsor by the Trial Site shall belong to the Sponsor.
	4. At any time within the duration of the Study, the Trial Site shall at the request and expense of the Sponsor execute all such documents and do all acts necessary to fully vest the Intellectual Property Rights in the Sponsor. To give effect to this Clause 7.4, the Trial Site shall ensure that its Agents involved in the Study assign such Intellectual Property Rights falling within Clauses 7.2 and 7.3 and disclose such Know-How to the Trial Site.
	5. Subject to this Clause 7.5 and Clause 7.6, nothing in this Clause 7 shall be construed so as to prevent or hinder the Trial Site from using its own Know-How or Study Data that is Clinical Data gained during the performance of the Study, at its own risk, in the furtherance of its normal activities of providing clinical care 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, or their Funder, or the holder of any Intellectual Property Rights related to the Study Drug. This Clause 7.5 does not permit the disclosure of any of the Study Data, all of which remain confidential until publication of the Results in accordance with clause 6.1. Any Study Data not so published remains the Confidential Information of the Sponsor, or their Funder, or the holder of any Intellectual Property Rights related to the Study Drug.
	6. The Trial Site may, with the prior written permission of the Sponsor (such permission not to be unreasonably withheld), use Study Data gained during the performance of the Study, at its own risk, in the furtherance of its normal activities of 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 or their Funder or the holder of the Intellectual Property Rights of the Study Drug. This Clause 7.6 does not permit the disclosure of any of the Study Data, all of which remain confidential until publication of the Results of the Study in accordance with Clause 6.1.

## Financial and Supplies Arrangements

* 1. The Parties agree to financing of the Study as set out in Schedule 3.
	2. Where payments are agreed:
		1. The Parties agree that prior to receiving payment the Trial Site shall submit an invoice in accordance with Part A of Schedule 3 setting out the costs incurred and payment claimed.
		2. Payment by the Sponsor shall be without prejudice to any claims or rights which the Sponsor may have against the Trial Site and shall not constitute any admission by the Sponsor as to the performance by the Trial Site of its obligations under this Agreement.
	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 Trial Site shall be used by the Trial Site only for the Study and in accordance with the Protocol, or otherwise as agreed in Schedule 3.
	4. The Sponsor shall use any Study Data, Material or other information provided by or derived from a Participant and provided by or on behalf of the Trial Site to the Sponsor in accordance with the consent provided by the Participant and the Protocol, and in respect of Materials also in accordance with Schedule 4.

## Term

* 1. This Agreement will commence on the date the final signatory signed the Agreement and shall remain in effect until completion of the Study (which means the conclusion of all Protocol required activities for all enrolled Participants) and close-out of the Trial Site or earlier termination in accordance with Clause 10 of this Agreement.

## Termination

* 1. This Agreement may be terminated immediately by notice in writing by either Party if the other Party is:
		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 thirty (30) calendar days after written notice by the non-breaching Party; or
		2. declared insolvent or has an administrator or receiver appointed over all or any part of its assets or ceases or threatens to cease to carry on its business.
	2. Subject to Clause 10.4, the Sponsor may terminate this Agreement by notice in writing:
		1. if the regulatory permissions and approvals previously granted to perform the Study are withdrawn;
		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;
		3. if advised to do so by the study management committee/group, trial oversight committee, study oversight group or other similar arrangements as defined in the Protocol;
		4. in the event of cessation of supply of Study Drug, medical device, equipment or similar necessary for the Study, or information or resources critical to the Study.
	3. Subject to Clause 10.4, any Party may terminate this Agreement by notice in writing:
		1. if the Principal Investigator becomes unavailable to continue his/her supervision of the Study for any reason and a replacement acceptable to both Parties is not found.
	4. In the event of termination or expiry of this Agreement, or if the Trial Site chooses to cease Participant recruitment in accordance with Clause 10.6, the following provisions shall apply:
		1. The Parties shall work together to facilitate an orderly cessation of the Study at the Trial Site (or cessation of recruitment of Participants, where the Trial Site has chosen to cease recruiting in accordance with Clause 10.6), taking into account the rights, safety, well-being and continuity of treatment (if appropriate) of the Participants and applicable law.
		2. The Sponsor shall, subject to the prior compliance of the Trial Site with its obligations on termination, upon receipt of a valid invoice submitted in accordance with Schedule 3, pay the Trial Site any outstanding monies due to the Trial Site as at the date of termination.
		3. The Trial Site 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 Trial Site under this Agreement exceeds the actual commitments incurred by the Trial Site up to the date of termination, or cessation of Participant recruitment, and any other costs in accordance with Schedule 3 and, in the event of cessation of recruitment of Participants, where the Trial Site has chosen to cease recruiting in accordance with Clause 10.6, an amendment in writing signed by the Sponsor and the Trial Site shall be made to any payments due under Schedule 3 to reflect the reduction in recruitment numbers.
		4. The Trial Site shall provide to the Sponsor all Study Data and other relevant information and/or data relating to work undertaken by the Trial Site prior to and including the date of termination and co-operate with all reasonable requests from the Sponsor including any continued monitoring of Participants in accordance with Protocol.
		5. Where applicable, the Trial Site shall ensure that all reasonable instructions by the Sponsor as regards the return or disposal of all unused supplies, or medical devices or other equipment or items previously provided to the Trial Site for the purposes of the Study are complied with.
		6. The Trial Site shall ensure that the instructions of the Sponsor regarding the transfer and/or storage of all information, material or data relating to the Study collected by the Trial Site in the course of carrying out the Study are complied with.
		7. Unless otherwise agreed in writing with the Sponsor, the costs and expenses of returning, dispatching, transferring or storing items shall be in accordance with Schedule 3.
	5. Termination under this Clause 10 will be without prejudice to any other rights or remedies of either Party under this Agreement or at law and will not affect any accrued rights or liabilities of either Party at the date of termination.
	6. The Trial Site will notify the Sponsor in accordance with Clause 13 if, for any reason, it elects to cease Participant recruitment.

## Agreement and Modification

* 1. Any amendments to this Agreement shall be valid only if made in writing and signed by authorised signatories of the Parties.
	2. This Agreement, including its Schedules, contains the entire understanding between the Parties. This Agreement supersedes all other agreements, negotiations, representations and undertakings, whether written or oral of prior date between the Parties relating to the Study, other than where a separate Investigator Site within the Trial Site has been contracted, in which case the Agreement does not supersede that agreement.

## Force Majeure

* 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 thirty (30) calendar days, the other Party shall be entitled to terminate this Agreement by notice in writing with immediate effect.

## Notices

* 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 e-mail, providing evidence of receipt.
	2. Notices to the Sponsor and to the Trial Site shall be delivered to the addressee and at the address specified in Schedule 1 or as may be amended by the Parties during the Study.
	3. Notices:
		1. by post will be effective upon the earlier of actual receipt, or seven (7) calendar days after mailing;
		2. by hand will be effective upon delivery; and
		3. by e-mail will be effective when sent in legible form, but only if, following transmission, the sender does not receive a non-delivery message.

## Assignment and Sub-Contracting

* 1. No Party shall novate or assign all or any part of their rights or obligations under this Agreement without the prior written consent of the other Party, notwithstanding the right of the Sponsor to assign its own Intellectual Property Rights.
	2. Except as agreed between the Parties at the commencement of this Agreement and as set out in Schedule 1, the Trial Site shall not sub-contract the performance of all or any of its obligations under this Agreement without the prior written consent of the Sponsor, such consent not to be unreasonably withheld or delayed.
	3. The Sponsor(s) may sub-contract performance of all or any of its obligations under this Agreement at any time during the term. If in so doing it changes any of the arrangements described in Schedule 2 of this Agreement, it will notify the Trial Site of these changes and, where appropriate, agree to vary this Agreement.
	4. In the event that either Party sub-contracts its responsibilities under this Agreement, it shall be responsible for the acts and omissions of its sub-contractors as though they were its own.

## 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 Agreement is an NHS Contract as defined in Section 9(1) National Health Service Act 2006 or Section 17 National Health (Scotland) Act 1978 or Section 7 (1) of the NHS (Wales) Act 2006 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 (“**NHS Contract**”), any dispute between the Parties not resolved in accordance with Clause 15.1 shall be referred for determination by:
		1. The Secretary of State for Health if both Parties are NHS Organisations in England;
		2. 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;
		3. The Scottish Ministers if both Parties are NHS Organisations in Scotland;
		4. The Welsh Ministers if both parties are NHS Organisations in Wales; or
		5. 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 15.2.1, 15.2.2, 15.2.3 or 15.2.4 acting jointly.
	3. Where the Agreement is not an NHS Contract and the Parties are unable to resolve a dispute in accordance with Clause 15.1, the Parties will attempt to resolve the dispute in accordance with the relevant subclause 15.3.1, 15.3.2 or 15.3.3, determined in accordance with Clause 18:
		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.
	4. 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.
	5. Any decision reached in accordance with this Clause 15 shall be final and binding upon the Parties.

## General

* 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 3, 4, 6 and/or 7 of this Agreement where these terms of the Agreement shall prevail.
	2. 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.
	3. If any Clause or part of this Agreement is found by any court, tribunal, administrative body or authority of competent jurisdiction to be illegal, invalid or unenforceable then that provision shall, to the extent required, be severed from this Agreement and shall be ineffective without, as far as possible, modifying any other clause or part of this Agreement and shall not affect any other provisions of this Agreement which shall remain in full force and effect.
	4. Except as expressly stated 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.
	5. Nothing in this Agreement shall be construed as creating a joint venture, partnership, contract of employment or relationship of principal and agent between the Parties.
	6. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together shall constitute one and the same instrument.

## Survival of Clauses

* 1. The following Clauses shall survive the termination or expiry of this Agreement: Clauses 1 (Definitions), 3 (Liabilities and Indemnities), 4 (Confidentiality, Data Protection and Freedom of Information), 5 (Publicity), 6 (Publication), 7 (Intellectual Property Rights), 10.4 and 10.5 (Termination), 17 (Survival of Clauses), 18 (Governing Law) and Schedule 4 (Material Transfer Provisions).

## Governing Law

* 1. By the signing of this Agreement the Parties agree that the conduct of the Study at the Trial Site is governed by and subject to the national laws and regulations of the Trial Site as provided for and as more particularly set out at Clause 2, Clause 3 and Clause 4.
	2. Any other issue, including any issue as to the construction of this Agreement, shall be governed and construed in accordance with the laws governing the country of the United Kingdom in which the Sponsor is established, namely, the laws of England and Wales, as applied in England
		1. Where the Agreement is not an NHS Contract, issues subject to Clause 18.2 and not resolved in accordance with Clause 15 shall be subject to the exclusive jurisdiction of the Courts of the Sponsor. Save, that where both Parties agree, having taken into consideration that it would be more reasonable and expeditious both as to time and costs, in such instance to do so, for the agreed issue pertaining to this Agreement, to be subject to the jurisdiction of the defendant.

## Sign Off\*

Each Party represents that it has ‘redlined’ or otherwise called attention to all changes that it made and sent to the other Party in previously sent drafts of this Agreement, including but not limited to drafts of the schedules.

Signed by the duly authorised representatives of the Parties.

### SIGNED ON BEHALF OF THE SPONSOR

………………………….………………………… ………………………….…………………

Name Position

………………………….………………………… ………………………….…………………

Signature Date

### SIGNED ON BEHALF OF THE TRIAL SITE

………………………….………………………… ………………………….…………………

Name Position

………………………….………………………… ………………………….…………………

Signature Date

\* Duly authorised scanned signatures shall be mutually acceptable and email deemed a valid medium for exchanging signed copies of this Agreement, which may be executed in counterpart.

*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

## Summary of Study Arrangements

**Funder(s):** National Institute for Health Research, The Secretary of State for Health and Social Care, 39 Victoria Street, Westminster, London, SW1H 0EH

**Sponsor(s):** The University of Birmingham, Edgbaston, Birmingham, B15 2TT

**Chief Investigator for the Study:** Dr James R Tysome ENT Department, Box 48, Addenbrookes Hospital, Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge CB2 0QQ

**Substantive Employer:** Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge CB2 0QQ

**Principal Investigator:** [Insert NAME and ADDRESS]

**Substantive Employer:** [Insert NAME and ADDRESS]

NHS [ ]  Other [ ]

If not substantively employed by Trial Site, PI holds honorary/clinical academic contract

Yes [ ]

**Study co-ordinating organisation:** Birmingham Clinical Trials Unit, Institute of Applied Health Research, College of Medical and Dental Sciences, Public Health Building], The University of Birmingham, Edgbaston, Birmingham B15 2TT.

**Other organisations (specify):** HearX SA (PTY) Ltd, Ground Floor Building no 2, Ashley Gardens Office Park, 180 Garsfontein Road, Pretoria 0081, South Africa. HearX have produced a hearDigits product to enable participants to perform self-home hearing tests for use in the sub-study, though this will not impact the participating site directly.

**Sponsor Service Providers** (for use when outsourcing directly impacts on Trial Site, e.g. use of a CRO, CTU, etc.)**:** N/A

## Estimated number of Participants to be recruited at the Trial Site: [Insert NUMBER, PER MONTH, YEAR, DURATION OF THE STUDY – delete as applicable]

## Notices

**Notices to the Sponsor shall be addressed to**:

Director of Research Strategy and Services

The University of Birmingham

Edgbaston

Birmingham B15 2TT

**Notices to the Trial Site shall be addressed to:**

[Insert JOB TITLE OR POSITION]

[Insert NAME OF NHS BODY]

[Insert ADDRESS]

[Insert E-MAIL ADDRESS]

# SCHEDULE 2

## Study Conduct at the Trial Site

### Division of Responsibilities and Delegation of Activities

(Although some **RESPONSIBILITIES** cannot be delegated, because they fall by law or policy upon a specific party, this Schedule does allow for a description of delegated **ACTIVITIES**, e.g. to Chief Investigator, CTU (if legally separate from the Sponsor) or CRO – to be detailed)

The Parties collaborating in the Study will undertake responsibilities and activities as attributed in the table below.

**Note 1:** Parties should set out any agreed delegation of **ACTIVITIES** in the table below.

**Note 2:** Where there are Co-Sponsors, **the name of the Sponsor responsible for each activity should be entered for the activity**.

**Note 3:** Some activities are only applicable to particular types of study. Where a particular activity is not applicable to the Study “N/A” (Not Applicable) should be entered.

**Note 4:** Any additional responsibilities and/or activities to those set out in this table should be added at the end of the table to preserve the numbering of the standard list and navigation of the contents.

**Note 5:** All references to Participants refer to those under the care of the Trial Site (except where explicitly referenced as a delegated activity of an Other Trial Site, contracted by the Trial Site i.e. within the same Investigator Site).

**Note 6:** All capitalised terms used in the Schedule but not otherwise defined in the Agreement shall have the meaning ascribed to them in relevant legislation.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **RESPONSIBILITY to:** | **Sponsor (where Co-Sponsored, name the responsible Party)** | **Lead Trial Site**  | **If ACTIVITY is delegated, name the body / individual delegated to (including, where applicable, Other Trial Sites within the Investigator Site):** |
| 1. Study preparation(All studies)
 | 1. Ensure that the Study and its Protocol have received robust and favourable scientific and, where applicable, statistical peer review
 | Yes |  |  |
|  | 1. Ensure appropriate insurance is in place for the design and management of the Study
 | Yes |  |  |
|  | 1. Ensure that indemnity arrangements are in place to cover Trial Site liabilities
 |  | Yes |  |
|  | 1. Ensure that insurance or indemnity arrangements are in place to cover Sponsor liabilities
 | Yes |  |  |
|  | 1. Secure and administer funding for the research costs of the Study
 | Yes |  |  |
|  | 1. Secure and contract for the supply of resources, where applicable, including supplied medicinal products / devices or Contract Research Organisation services
 | Yes |  |  |
|  |
|  | 1. Ensure that the appropriate contracts and agreements are in place for the Study
 | Yes | Yes |  |
|  | 1. Ensure adequate facilities, resources and support (capacity and capability) are available to conduct the Study at the Trial Site
 |  | Yes |  |
| 1. Applications, authorisations and registration(all studies)
 | 1. Ensure that the Protocol is compliant with the relevant regulations/ guidelines
 | Yes |  |  |
|  | 1. Prepare Participant information sheet and consent form (and assent form where applicable), including, where appropriate, consent for: provision of Material(s) and Personal Data, Clinical Data or other data, as required, to the Sponsor
 | Yes |  |  |
|  | 1. Register the Study on an appropriate clinical trial register
 | Yes |  |  |
|  |
|  | 1. Obtain approvals from relevant Ethics Committee(s)
 | Yes |  |  |
|  | 1. Obtain HRA and HCRW Approval (for research in the NHS in England and/or Wales) and/or equivalent review/approval in Scotland and/or Northern Ireland
 | Yes |  |  |
|  |
|  | 1. Ensure that all relevant departments at the Trial Site are aware of and, where necessary, have agreed to their role in the Study
 |  | Yes |  |
|  | 1. Obtain a Clinical Trials Authorisation for a CTIMP from the regulatory authority (MHRA in the UK)
 | Yes |  |  |
|  | 1. Obtain a Letter of no objection for the clinical investigation of a non-CE marked medical device from the regulatory authority (MHRA in the UK)
 | N/A |  |  |
|  |
|  |
| 1. Protocol Amendments(all studies)
 | 1. Prepare and submit proposed substantial (and, for any Study of investigational medical devices, non-substantial) amendments to all relevant ethics committee(s) and, if appropriate, regulatory authority(ies)
 | Yes |  |  |
|  | 1. Ensure the Principal Investigator is informed of all amendments requiring implementation at the Trial Site, including the date on which the amendment should be implemented
 | Yes |  |  |
|  |
|  | 1. Ensure all amendments of which the Trial Site is notified and that require local implementation are implemented at Trial Site, or that the sponsor is promptly notified that the amendment cannot be implemented and given the reason for this
 |  | Yes |  |
| 1. Study Conduct(all studies)
 | 1. Ensure that the Study is managed according to GCP (as defined in the Protocol) or EN ISO 14155:2020, as applicable, all relevant legislation, and the Protocol
 | Yes |  |  |
|  |
|  | 1. Ensure that the Study is conducted locally according to GCP (as defined in the Protocol) or EN ISO 14155:2020, as applicable, all relevant legislation, and the Protocol
 |  | Yes |  |
|  |
|  | 1. Submit all Study Data and Materials required for the Study, in accordance with the Protocol and any Study specific manuals provided by the Sponsor
 |  | Yes |  |
|  | 1. Ensure that the Trial Site team members are appropriately qualified and experienced to undertake the conduct of the Study and that they have current substantive and/or honorary employment contracts in place, where required
 |  | Yes |  |
|  | 1. Ensure that no Participant is recruited by the Trial Site until the Trial Site has been activated by the Sponsor
 |  | Yes |  |
|  | 1. Ensure that the Study is managed, monitored and reported as agreed in the Protocol and/or agreed monitoring plan.
 | Yes |  |  |
|  | 1. Maintain Investigator Site File (and Pharmacy Site File, where relevant) at Trial Site, ensuring compliance with Sponsor requirements and applicable guidance/ legislation
 |  | Yes |  |
|  | 1. Maintain Trial Master File/Sponsor File, ensuring compliance with applicable guidance/ legislation
 | Yes |  |  |
|  | 1. Assess capability of Participants to give informed consent
 |  | Yes  |  |
|  | 1. Ensure no Study procedure is carried out on a Participant until consent (where required) is obtained in accordance with the Protocol
 |  | Yes |  |
|  | 1. Ensure that the rights of individual Participants are protected and that they receive appropriate medical care whilst participating in the Study.
 |  | Yes |  |
|  |
|  | 1. Ensure that all Clinical Data and documentation are available for the purposes of monitoring, inspection or audit
 |  | Yes |  |
|  |
|  | 1. Inform appropriate health or social care professionals if their patient is a Participant in the Study, if required
 |  | Yes |  |
|  | 1. Ensure relevant Protocol deviations, and all serious breaches of Study conduct and/or GCP (as defined in the protocol), or of EN ISO 14155:2020 as applicable, are reported to the Sponsor
 |  | Yes |  |
|  | 1. Report serious breaches of Study conduct and/or GCP, or EN ISO 14155:2020 as applicable, to relevant ethics committees and regulatory authority(ies) (as applicable)
 | Yes |  |  |
|  | 1. Report suspected research misconduct, identified by the Sponsor, to the Trial Site
 | Yes |  |  |
|  | 1. Report suspected research misconduct, identified by the Trial Site, to the Sponsor
 |  | Yes |  |
|  | 1. Notify the Trial Site, relevant ethics committee(s) and, if applicable, regulatory authority(ies) of the end of the Study
 | Yes |  |  |
|  | 1. Notify the Trial Site, relevant ethics committee(s) and, if applicable, regulatory authority(ies) if the Study is terminated early
 | Yes |  |  |
| 1. Adverse events(all studies)
 | 1. Maintain detailed records of all adverse events as specified in the Protocol
 |  | Yes |  |
|  | 1. Report adverse events as defined in the Protocol and to legal requirements and in accordance with Trial Site policy
 |  | Yes |  |
|  | 1. Ensure that procedures are in place for emergency unblinding of the randomisation code. (If applicable)
 | Yes |  |  |
|  | 1. Promptly notify the Sponsor of any urgent safety measure taken to protect Participants
 |  | Yes |  |
|  | 1. Promptly inform relevant ethics committee(s), regulatory authority(ies) (if applicable), and all Principal Investigators of any urgent safety measures taken to protect Participants in the Study
 | Yes |  |  |
|  | 1. Ensure that all Serious Adverse Events (SAE) are reported to the Sponsor, as specified in the Protocol
 |  | Yes |  |
|  |
|  | 1. Ensure all SAEs are promptly assessed, and expedited reporting to the relevant ethics committee(s) and regulatory authority (if applicable) is undertaken where necessary
 | Yes |  |  |
|  | 1. Ensure that SAEs are reviewed by an appropriate committee for the monitoring of Study safety
 | Yes |  |  |
|  | 1. Ensure that annual safety / progress reports and final Study report are generated and submitted to relevant ethics committee(s) and regulatory authority(ies) (e.g. Development Safety Update Reports, if applicable) within the required timeframes
 | Yes |  |  |
|  |
|  | 1. Ensure that the Principal Investigator is, at all times, in possession of the current relevant safety information for the Study
 | Yes |  |  |
|  |
| 1. Data Management(all studies)
 | 1. Design of case report forms (eCRFs/CRFs) and database
 | Yes |  |  |
|  | 1. Complete eCRFs/CRFs fully, accurately in a contemporaneous manner, and submit in a timely manner and in accordance with the Protocol
 |  | Yes |  |
|  | 1. Respond to the Sponsor’s requests for data clarification
 |  | Yes |  |
|  | 1. Process and code Study Data
 | Yes |  |  |
|  | 1. Ensure appropriate analysis of Study Data
 | Yes |  |  |
| 1. Publication(all studies)
 | 1. Prepare and submit abstracts, posters and publications of the Study endpoints
 | Yes |  |  |
| 1. Archiving(all studies)
 | 1. Ensure that the Trial Master File is archived appropriately on conclusion of the Study and retained as required by the Protocol
 | Yes |  |  |
|  | 1. Ensure that all Study records held by the Trial Site are archived appropriately when notified by the Sponsor and retained as required by the Protocol
 |  | Yes  |  |
| 1. Clinical Trials involving Investigational Medicinal Products
 | 1. Ensure appropriate arrangements are defined for the supply, labelling, storage and destruction of Study Drug(s)
 | Yes |  |  |
|  | 1. Ensure ability to comply with the arrangements for the Study Drug(s)
 |  | Yes |  |
|  | 1. Ensure that Study Drug(s) supplied for specific use in the Study is/are used in strict accordance with the Protocol and is/are not used for any other purpose
 |  | N/A |  |
|  | 1. Ensure that Study Drug(s) is/are stored in appropriate and secure conditions
 |  | N/A |  |
|  | 1. Ensure approvals are in place and issue regulatory ‘green light’ for release of Study Drug(s)
 | N/A |  |  |
|  | 1. Ensure that appropriate accountability and destruction records are maintained, as required by the Sponsor
 |  | N/A |  |
| 1. Studies involving CE-marked medical devices for new purpose or non-CE marked Medical Device
 | 1. Ensure that the Trial Site is provided with a sufficient number of investigational medical devices/ disposables required for proper functioning of the device for the planned number of Participants
 | N/A |  |  |
|  | 1. Ensure that investigational medical devices are not used for any purposes other than the conduct of the Study, unless Sponsor permits continued intended use for CE marked device after conclusion of the Study
 |  | N/A |  |
|  | 1. 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.
 |  | N/A |  |
|  |
|  |
| 1. Material Transfer
 | 1. Ensure appropriate and timely collection of Material and transfer to the Sponsor’s nominated laboratory(ies), all in accordance with the Protocol and in compliance with Schedule 4.
 |  | N/A |  |

# SCHEDULE 3

## STUDY SUPPORT ARRANGEMENTS

### Financial Arrangements

**Where no payments are to be made to the Trial Site under this Agreement tick this box** [ ]  **and delete the rest of this Section A.**

The overall, study-wide recruitment for this Study is competitive with a maximum figure of 525 Participants. Once this target has been reached, the Sponsor will notify the Trial Site. No additional per Participant payments will be made by the Sponsor to the Trial Site for patients consented after such notification becomes effective, in accordance with clause 13.3.

|  |  |  |
| --- | --- | --- |
|  | **Area of Cost**  | **Payment (£ Sterling)** |
|  | Per patient payment, payable on randomisation | £40 |
|  | Per patient payment, payable on return of primary outcome data at 12 week follow-up | £35 |
|  | Archiving of Investigator Site File | £500 |

* Payments by the Sponsor during the course of the Study are dependent on continued availability of funds from the Funder. In the event of a change to the availability of funds, the Trial Site will be notified and a decision would be made about the continuation of the Study at the Trial Site.
* The Sponsor reserves the right to amend/withhold final payments in cases where the Trial Site has not performed their duties according to the terms of the Protocol and/or this Agreement.
* The Trial Site is expected to keep accurate accounts of all costs incurred in the performance of the Agreement. Financial records, including substantiating documents, shall be retained by the Trial Site for a period of six (6) years from the date of submission of the final expenditure report, except that records pertaining to audits, appeals, litigation or settlement of claims arising out of performance of the Agreement shall be retained until such audits, appeals, litigation or claims have been disposed of.
* All costs incurred under the Agreement may be subject to audit by the Sponsor. The Trial Site shall allow the appropriate Sponsor representatives (including the Funder) access to records where necessary to support costs relating to this Agreement.
* Payment shall be made in Pounds Sterling according to this Schedule 3 on presentation of VAT (if applicable) invoices from the Trial Site.
* Details of requested payments, including Trial number (where applicable) and amounts requested, must be submitted with each invoice.
* At the end of the Study any outstanding amounts must be submitted by the Trial Site within the timeframe reasonably requested by the Sponsor, after which any outstanding invoices will not be paid.

If VAT is payable, then the Sponsor shall pay the VAT in addition to the payment of the agreed costs on presentation of a VAT invoice in which the VAT is stated as a separate item. Such invoices should quote the Trial Site’s VAT registration number. 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 quarterly in arrears based on actual costs incurred to the STARFISH trial team with the Birmingham Clinical Trials Unit at the University of Birmingham, using the email address below:

STARFISH@trials.bham.ac.uk

All invoices must state PO number as supplied by the Sponsor Payments by BACS

Transfer to: [Insert BANK NAME]

Sort code: [Insert SORT CODE]

Account: [Insert ACCOUNT NUMBER]

And send the relevant paperwork to [Insert ADDRESSEE FOR PAPERWORK] at the above address.

Invoices must be paid promptly within 30 days of receipt. No payment shall be made in the case where invoices are not presented in a complete, accurate and timely fashion and funding has been irrecoverably reclaimed by the Funder as a result of such delay or inadequacy.

### Supplies Arrangements

**Where no items are to be provided to, or procured for/by, the Trial Site under this Agreement tick this box** [ ]  **and delete the rest of this Section B.**

Any medicine, equipment, materials, consumables, software or other items being provided by the Sponsor or procured by the Trial Site for use in the Study shall be specified below.

**Note 1**: Parties should complete the table below. If the Trial Site is to procure any Items and is to be reimbursed by the Sponsor this should be specified in this Schedule. Similarly, if the Trial Site is to pay the Sponsor for any Items provided to the Trial Site 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 Trial Site only)** |
| --- | --- | --- | --- |
| Investigator Site File | 1 | Once, then additional supplies if required on request | Sponsor |
| Ear phonesWritten instructions provided. Ear phones can be kept by participant at the study end | As required for the number of participants recruited to the relevant substudy | As required for the number of participants recruited to the relevant substudy  | Sponsor |

# SCHEDULE 4

## MATERIAL TRANSFER PROVISIONS\*

## [NOT USED]

# SCHEDULE 5

## PRINCIPAL INVESTIGATOR DECLARATION

### As a Principal Investigator for the Study I declare that:

1. I acknowledge the Agreement, and the roles and responsibilities to be undertaken as Principal Investigator at the Trial Site.
2. I am free to participate in the Study and am not restricted by any third-party obligations which might prevent or restrict my performance of the obligations as Principal Investigator.
3. I have considered the facilities required for the Study, and am satisfied that the Trial Site can, and will continue to, make appropriate facilities available for the proper performance of the Study.
4. I shall conduct the Study at the Trial Site in accordance with the Protocol.
5. I consent to the Sponsor(s), and to any relevant third-party providing support, products and/or services to the Study, holding my name and other relevant details on an appropriate database for the purpose of communicating with me in relation to the Study.
6. I confirm that where I wish to delegate responsibilities to another member of the Study team, that individual will be appropriately qualified for the delegated role, will receive sufficient support and training to fulfil that role and all delegated duties will be detailed in a delegation log, or as required by the Sponsor.
7. I am not involved in any regulatory or misconduct litigation or investigation by any regulatory authority, and no data produced by me in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.
8. During the Study, I will not serve as an investigator or other significant participant in any study for another sponsor if such activity might adversely affect my ability to perform my obligations as Principal Investigator to the Study.
9. Neither I, nor any dependents, have entered into and will not enter into arrangements, financial or otherwise, with any third-party providing support, products and/or services to the Study that would present a conflict of interests.

**Name: Position:**

Signature: ………………………………………….. Date: …………………………………..