# Republic of Ireland Model Clinical Trial Agreement

**The information set out below provides a checklist of information that needs to be included in the model Clinical Trial Agreement (mCTA) in preparation for execution by the Parties.**

**It is the Sponsor’s responsibility to provide the required information for review by the Clinical Organisation.**

### Footers

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

### Front page

Complete all of the required information.

### Contents page

If Appendices 4, 5 and/or 6 are not used, delete reference(s) in the Contents Page.

### Recitals

Add, remove and/or update recitals as applicable to the Clinical Trial (as a preamble to the Agreement, such changes do not constitute modification to the template Agreement). Recital D should be completed where a corporate Affiliate of the Sponsor is formally empowered by the Sponsor to sign the Agreement on behalf of the Sponsor thereby binding the Sponsor as Party to the Agreement (and should be removed where this is not the case).

Recital E should be deleted if the Sponsor is established in the EU.

### Main Body of the Agreement

**Clause 3.3.4** – Check that this Clause references the version of the Declaration of Helsinki applicable to this Clinical Trial and update where needed.

**Clause 3.3.5** – Delete if the Clinical Trial does not involve transplantation of human cells, tissue or organs.

**Clause 4.12** – Select ‘enrols’, ‘doses’ or ‘randomises’ as appropriate to the Clinical Trial and inset target number for the Clinical Organisation.

**Clauses 4.14.10** and **4.14.11** – Delete either or both clauses depending upon whether Material will be analysed locally, centrally or if no Material will be analysed. Where no Material will be analysed, delete the definition ‘Material’.

**Clause 4.15** – Delete if no equipment or resources are provided by the Sponsor.

**Clause 7.2.6** – The yellow highlighted text should be deleted; i) where the Sponsor does not intend to permit the use of Participant Identification Centres (PICs) in the Clinical Trial; ii) where the Sponsor does intend to permit the use of PICs in the Clinical Trial but, in accordance with GDPR Article 28(2), requires the Clinical Organisation to obtain specific written authorisation from or on behalf of the Sponsor prior to engaging a PIC. The yellow highlighted text should be retained where the Sponsor does intend to permit the use of PICs in the Clinical Trial and, in accordance with GDPR Article 28(2), authorises the Clinical Organisation to engage PICs under this general written authorisation.

**Clause 19** – Complete the full names, addresses (and e-mail addresses, as applicable) for contact persons for notices to the Parties.

### Signature page

It is best practice 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.

**State Claims Agency’s Clinical Trial Indemnity Form (CTIF)**

The current State Claims Agency’s Clinical Trial Indemnity Form must be signed by the Parties as a separate document at the time of signature of this Agreement and must be in place prior to commencement of the Clinical Trial.

### Appendix 1

Complete Appendix 1 showing the milestones/division of responsibilities between the Parties and target Site completion date.

### Appendix 2

The detailed financial arrangements with respect to the Clinical Trial should be appended as Appendix 2. Sponsors and Clinical Organisations should note the Guidance provided with respect to the matters for inclusion in Appendix 2. The optional suggested wording included in Appendix 2 may be used or replaced/amended with specifically agreed wording.

### Appendix 4

Appendix 4 (Material Transfer Provisions) should be omitted if not relevant to the specific Clinical Trial.

### Appendix 5

Complete details of any equipment and/or resources being supplied to the Clinical Organisation for the Clinical Trial. Clearly indicate whether liability will be determined in accordance with the main body of the Agreement. Where no equipment and/or resources is/are being provided, Appendix 5 should be omitted.

### Appendix 6

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

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

[INSERT FULL NAME OF THE CLINICAL TRIAL]

[INSERT SPONSOR’S PROTOCOL REFERENCE NUMBER]

# Clinical Trial Agreement

**Between**

[INSERT NAME OF HOSPITAL located at [insert address] a facility of the Health Service Executive having an administration address at Lime Tree Avenue, Millennium Park, Naas, Co Kildare (**“Clinical Organisation”)**

AND

[INSERT NAME OF SPONSOR, COMPANIES REGISTRATION NUMBER AND REGISTERED ADDRESS OF SPONSOR] **(the “Sponsor”)**

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

# Clinical Trial Agreement

**Clause**

1. Definitions
2. Principal Investigator and Personnel
3. Clinical Trial Governance
4. Obligations of the Parties and the Principal Investigator
5. Liabilities and Indemnities
6. Medical Records
7. Data Protection
8. Freedom of Information
9. Confidential Information
10. Publicity
11. Publications
12. Intellectual Property
13. Financial Arrangements
14. Term
15. Termination
16. Relationship of the Parties
17. Agreement and Modification
18. Force Majeure
19. Notices
20. Dispute Resolution
21. Miscellaneous

Appendix 1 Timelines and Responsibilities of the Parties

Appendix 2 Financial Arrangements

Appendix 3 Conditions Applicable to the Principal Investigator

Appendix 4 Material Transfer Provisions **– DELETE IF NOT USED**

Appendix 5 Equipment and Resources **– DELETE IF NOT USED**

Appendix 6 Formal Delegation of Authority to a Corporate Affiliate of the Sponsor to Contractually Bind Sponsor **– DELETE IF NOT USED**

**Whereas**

1. The Sponsor is a pharmaceutical company involved in the research, development, manufacture and sale of medicines for use in humans;
2. The Clinical Organisation is concerned with the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare;
3. The Sponsor wishes to contract with the Clinical Organisation to undertake a clinical trial;
4. The Sponsor of the Clinical trial is [INSERT FULL COMPANY NAME OF SPONSOR], and references throughout this Agreement to Sponsor shall be construed to include reference to [INSERT FULL COMPANY NAME OF SPONSOR’s AFFILIATE] as Affiliate empowered by the Sponsor to legally bind the Sponsor to this Agreement and to act on its behalf, in accordance with Appendix 6;
5. [The Sponsor, not being established in the EU, has appointed [insert details] with its registered office at [insert details] as its legal representative in the EU].

It is therefore, agreed that the following terms and conditions shall apply to the conduct of the Clinical Trial (as further defined below):

## Definitions

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

**Adequacy Decision**

means a decision adopted by the European Commission that a relevant third country, territory or one or more specified sectors within such third country or international organisation ensures an adequate level of data protection within the meaning of Article 45 of the GDPR;

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

**Agent**  
means any contracted third-party providing services to the Sponsor under a contract for services or otherwise;

**Agreement**  
means this agreement comprising its clauses, schedules and any appendices attached to it;

**Appropriate Safeguards**

means such legally enforceable mechanism(s) for transfers of Personal Data as may be permitted under the Data Protection Laws and Guidance, including but not limited to Art 46 GDPR;

**Auditor**  
means a person being a representative of the Sponsor, or Affiliate, who is authorised to carry out a systematic review and independent examination of Clinical Trial related activities and documents to determine whether the evaluated Clinical Trial related activities were conducted, and the data were recorded, analysed and accurately reported, according to the Protocol, ICH GCP, GMP, GVP and the applicable regulatory requirements;

**Clinical Trial**

means the investigation to be conducted at the Site in accordance with the Protocol;

**Clinical Trial Authorisation**

means the authorisation of the Clinical Trial in accordance with the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004, SI No 190 of 2004 or the EU Clinical Trials Regulation, as applicable;

**Clinical Trial Data**

shall include all forms and reports relating to the Clinical Trial including raw data, CRFs (or their equivalent) or electronic data records as well as any other documents or materials including X-ray, MRI, or other types of medical images, CG, EEG or other types of tracings or printouts or data summaries created for the purposes of the Clinical Trial and this Agreement and shall exclude Medical Records. The definition of Clinical Trial Data includes Clinical Trial Subject Personal Data processed for the conduct of the Clinical Trial.

**Clinical Trial Subject**

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

**Confidential Information**

means all confidential information (however recorded or preserved) disclosed by a Party and/or its Affiliate (as defined above) to the other Party in connection with the Clinical Trial which is information that would be regarded as confidential by a reasonable businessperson relating to the business, affairs, plans, intentions or market opportunities of the disclosing Party and/or its Affiliate, including (but not limited to):

* the operations, processes, product information, designs, trade secrets or Know-How of the disclosing party;
* any information developed by the Parties in the course of carrying out this Agreement;
* in the case of Sponsor Confidential Information, the Protocol, the Investigator Brochure(s) relating to the Clinical Trial and Appendix 2 to this Agreement (‘Financial Arrangements’);
* in the case of Clinical Organisation, the Clinical Trial Data of a Clinical Trial Subject.

**Controller**

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

**Data Protection Laws and Guidance**

means the General Data Protection Regulation (EU) 2016/679 (“**GDPR**”); the Data Protection Act 2018; S.I. No. 314 of 2018 - Data Protection Act 2018, (Section 36(2)) (Health Research) Regulations 2018; and S.I. No. 336/2011 - European Communities (Electronic Communications Networks and Services) (Privacy and Electronic Communications) Regulations 2011, as well as any legally enforceable HSE requirements, Codes of Practice or Guidance and including also Recommendations issued by the DPC and the European Data Protection Board, and any amendments and re-enactments thereof;

**DPIA**

means a data protection impact assessment of the envisaged processing operations on the protection of Personal Data in accordance with the Data Protection Laws and Guidance.

**DPC**

means the Data Protection Commission of Ireland, the authority under the Data Protection Laws in Ireland;

**Data Subject**

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

**EEA**  
means the European Economic Area comprising the countries of the European Union as well as Iceland, Liechtenstein and Norway;

**Effective Date**

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

**EU Clinical Trials Regulation**

means Regulation No 536/2014 of the European Parliament and of the Council of 16 April 2014 on Clinical Trials on Medicinal Products for Human Use, and repealing Directive 2001/20/EC,

**FOIA**  
means the Freedom of Information Act 2014;

**GMP**  
means any relevant European Union and appropriate national regulations on good manufacturing practices;

**GVP**  
means any relevant current European Union and appropriate national regulations on good pharmacovigilance practices;

**HPRA**  
means the Health Products Regulatory Authority;

**ICH-GCP**  
means the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) together with such other good clinical practice requirements as are specified in Directive 2001/20/EC of the European Parliament, the Council of 4 April 2001 relating to medicinal products for human use, the EU Clinical Trial Regulation (where applicable) and in guidance published by the European Commission pursuant to such Directive and Regulation;

**IND**  
means the Investigational New Drug application process by which the United States Food and Drug Administration exempts pharmaceutical companies from the federal statute that prohibits an unapproved drug from being shipped in interstate commerce;

**Inspector**  
means a person, acting on behalf of a Regulatory Authority, who conducts an official review of the documents, facilities, records and any other resources that are deemed by a Regulatory Authority to be related to a Clinical Trial and that may be located at the Site;

**Intellectual Property Rights**

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

**Investigational Drugs**

means the Investigational Medicinal Product (as defined below) together with control material (e.g., placebo, comparator drug, concomitant drug) as detailed in the Protocol;

**Investigational Medicinal Product or IMP**

means the Sponsor product that is being studied as detailed in the Protocol;

**IPHA Code of Practice**

means the most recent edition of the Code of Practice for the Pharmaceutical Industry, issued by Irish Pharmaceutical Healthcare Association from time to time;

**Joint Position**

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

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

**Medical Records**

means primary medical records kept by the Clinical Organisation in relation to a Clinical Trial Subject;

**Material [Delete if 4.14.10, 4.14.11 and Appendix 4 are not required]  
means any clinical biological sample, or portion thereof, derived from Clinical Trial Subjects, including information related to such material, analysed by the Clinical Organisation in accordance with the Protocol, or otherwise supplied under Appendix 4 to the Sponsor or its nominee;**

**Multi-Centre Trial**

means a Clinical Trial where at least one other institution is participating in the Clinical Trial;

**Personal Data**

means any and all information, data and material of any nature received or obtained by any Party in connection with this Agreement which is personal data as defined in the Data Protection Laws and Guidance and which relates to a Clinical Trial Subject (or potential Clinical Trial Subject) and/or their treatment or medical history;

**Personal Data Breach**

means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, Personal Data transmitted, stored or otherwise Processed;

**Personnel**  
means the Clinical Organisation’s employees or persons with a secondment agreement or on a contract of service or other formal agreement with the Clinical Organisation who undertake the conduct of the Clinical Trial at the Site(s) on behalf of the Clinical Organisation;

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

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

**Principal Investigator**

means the medical practitioner employed by the Clinical Organisation who will take primary responsibility for the conduct of the Clinical Trial at the Site on behalf of the Clinical Organisation;

**Protocol**  
means the full description of the Clinical Trial with the reference number set out on the front page of this Agreement, together with any amendments thereof made in accordance with clause 17.3, and incorporated into this Agreement by reference;

**Pseudonymised Data**

means individual-level data relating to a natural person (as opposed to aggregated data) who is made no longer identified or identifiable from 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;

**Research**  
means the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods;

**Regulatory Authority**

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

**Results**  
means the research findings produced in the Clinical Trial;

* **SAE**  
  means Serious Adverse Event and shall have the definition set out in EU Clinical Trials Regulation or the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004, SI No 190 of 2004, as applicable;

**Standard Contractual Clauses**

means standard sets of contractual terms dealing with the transfer of Personal Data outside the EEA, to third countries which do not have an Adequacy Decision, and which have been pre-approved by the European Commission or the DPC, as may be amended or replaced from time to time;

**State Claims Agency’s Clinical Trial Indemnity Form (CTIF)**

means the State Claims Agency’s current clinical trial indemnity form (CTIF);

**SUSAR**  
means Suspected Unexpected Serious Adverse Reaction and shall have the definition set out in the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004, SI No 190 of 2004 or the EU Clinical Trials Regulation, as applicable;

**Site**means the physical location(s) within the Clinical Organisation where the Clinical Trial will be conducted, under the primary responsibility of the Principal Investigator and as approved by the relevant Regulatory Authority and research ethics committee approval;

**Site File**

means the file maintained by the Principal Investigator containing the documentation specified in Section 8 of the ICH GCP (Edition CPMP/ICH/135/95);

**Site Trial Completion**

means the conclusion of all Protocol required activities for all enrolled Clinical Trial Subjects at the Site;

**Timelines**  
means the timelines set out in Appendix 1 for the completion of certain milestones;

**Trial Completion**

means the conclusion of all Protocol required activities for all enrolled Clinical Trial Subjects in all locations where the Sponsor (or any Affiliate of the Sponsor) is carrying out the Clinical Trial described in the Protocol on the IMP;

**Trial Monitor**

means one or more persons appointed by the Sponsor, or Affiliate, to monitor compliance of the Clinical Trial with ICH-GCP and to conduct source data verification.

* 1. Any reference to a statutory provision, code or guidance shall be deemed to include reference to any subsequent modification or re-enactment of it provided, however, that the provisions of the Declaration of Helsinki relating to post-trial supply of IMP (as further defined herein) shall be those that are explicitly indicated in this Agreement and all subsequent modifications to or re-enactments of the Declaration of Helsinki, whether set out in a modification or amendment or otherwise, shall not apply to this Agreement.
  2. The headings to clauses are inserted for convenience only and shall not affect the interpretation or construction of this Agreement.
  3. Where appropriate, words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders.
  4. A reference to this Agreement or to any other agreement or document referred to in this Agreement is a reference to this Agreement or such other agreement or document as amended, varied or novated (in each case other than in breach of the provisions of this Agreement) from time to time.

## Principal Investigator and Personnel

* 1. The Clinical Organisation represents that it is entitled to procure, and the Clinical Organisation will procure the services of the Principal Investigator, and Personnel to fulfil these functions and shall ensure the performance of the obligations of the Principal Investigator and other Personnel set out in Appendix 3 and elsewhere in this Agreement.
  2. The Clinical Organisation represents that the Principal Investigator holds the necessary registration and has the necessary expertise, time and resources to perform the Clinical Trial and will ensure that the Principal Investigator is made aware of and acknowledges the obligations applicable to the Principal Investigator set out in this Agreement, including but not limited to those set out in Appendix 3.
  3. Subject to all applicable laws and Clinical Organisation policy and procedure the Clinical Organisation shall notify the Sponsor if the Principal Investigator ceases to be employed by the Clinical Organisation, is erased from the register of medical practitioners (or equivalent Irish professional register where the Principal Investigator is not a medical doctor) or is otherwise sanctioned by an applicable regulatory or other governmental authority, or is otherwise unavailable to continue as Principal Investigator. The Clinical Organisation shall use all reasonable endeavours to find a replacement acceptable to both the Sponsor and the Clinical Organisation, subject to the Clinical Organisation’s overriding obligations in relation to Clinical Trial Subjects and individual patient care. If no mutually acceptable replacement can be found the Sponsor may terminate this Agreement pursuant to Clause 15.3.
  4. The Clinical Organisation shall procure, and shall ensure that the Principal Investigator procures, the performance of the obligations of the Personnel as set out in this Agreement.
  5. The Principal Investigator and/or Personnel shall attend any meetings regarding the Clinical Trial as reasonably requested by the Sponsor (“Investigator Meetings”). Such meetings to be conducted by the Sponsor to convey or exchange information with the Principal Investigator or other Personnel to support the effective conduct or close-out of the Clinical Trial. The Clinical Organisation agrees that no additional compensation shall be due hereunder for Principal Investigator’s or any other Personnel’s respective participation in Investigator Meetings. The Sponsor shall reimburse or pay for reasonable pre-approved expenses for attendance at the Investigator Meetings upon receipt of documentation. It is further agreed that any such expenses will be paid at the rate of fair market value (in line with the IPHA Code of Practice) and subject to the documentation evidencing the expenses being in sufficient detail for the Sponsor’s financial reporting purposes, provided that the required detail does not impose an unreasonable administrative burden upon the Clinical Organisation. Such expenses may be publicly reportable.
  6. The Clinical Organisation represents that it will support the Principal Investigator to make good faith diligent efforts to ensure the completion of all case report forms in a timely manner.
  7. The Clinical Organisation through the Principal Investigator may appoint such other persons as the Principal Investigator may deem appropriate as Personnel to assist in the conduct of the Clinical Trial. All Personnel will be adequately qualified, timely appointed and an updated list will be maintained. Principal Investigator shall be responsible for leading such team of Personnel. The Clinical Organisation and Principal Investigator are responsible for the services performed by the Personnel and undertake in particular to have the services executed by competent persons. In the event that the Clinical Organisation and/or Principal Investigator use the services of others to conduct the Clinical Trial pursuant to this Agreement, the Clinical Organisation and Principal Investigator shall be responsible for ensuring that all are appropriate, in compliance with the terms of this Agreement.

## Clinical Trial Governance

* 1. The Sponsor shall inform the Clinical Organisation and the Principal Investigator of the name and telephone number of the Trial Monitor and the name of the person who will be available as a point of contact. The Sponsor shall also provide the Principal Investigator with an emergency telephone number to enable SAE reporting at any time.
  2. To the extent applicable to each, the Parties shall comply with, and the Clinical Organisation shall ensure that the Principal Investigator and all Personnel comply with, all relevant and applicable laws, including but not limited to:
     1. Laws of the European Union if directly applicable or of direct effect;
     2. The European Convention of Human Rights Acts 2003 and 2014;
     3. The Data Protection Laws and Guidance;
     4. Statutory Instrument No. 158 of 2006 (Quality and Safety of Human Tissues and Cells) Regulations;
     5. The Control of Clinical Trials Act 1987;
     6. The Control of Clinical Trials and Drugs Act 1990;
     7. The European Union (Clinical Trials on Medicinal Products for Human Use) Regulations, (Principal) 2022, SI No 99 of 2022;
     8. European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004, SI 190 of 2004 or the EU Clinical Trials Regulation, as applicable;
     9. The Criminal Justice (Corruption Offences) Act 2018

as may be amended, replaced, repealed or modified from time to time.

* 1. The Parties shall comply with, and the Clinical Organisation shall ensure that the Principal Investigator and all Personnel comply with, all relevant guidance relating to medicines and clinical trials from time to time in force, including but not limited to:
     1. the ICH-GCP;
     2. GMP;
     3. GVP;
     4. the World Medical Association Declaration of Helsinki entitled, “Ethical Principles for Medical Research Involving Human Subjects (2013)”;
     5. [DELETE IF NOT APPLICABLE – the ethical principles set out in WHA63.22 (https://apps.who.int/gb/ebwha/pdf\_files/WHA63/A63\_R22-en.pdf) with regard to the Clinical Trial].

In addition, where the Clinical Trial is conducted as part of an IND, the Clinical Organisation will comply with any other reasonable relevant requirements notified by the Sponsor to the Clinical Organisation, at the cost of the Sponsor.

In addition, the Sponsor herby agrees to conduct the Clinical Trial in accordance with the HSE National Framework for Governance, Management and Support of Health Research (September 2021) and the HSE National Consent Policy, as may be amended from time to time.

* 1. The Clinical Organisation shall ensure that the Principal Investigator and Personnel undertake any such appropriate training as the Sponsor may consider necessary for the conduct of the Clinical Trial, including but not limited to the training and provision of information given during Investigator Meetings.
  2. **Location of the Clinical Trial**

The Clinical Trial will be conducted at the Site.

* 1. **Adverse Event Reporting**

Both Parties acknowledge the obligation to comply with the Protocol and/or applicable regulations governing the collection and reporting of adverse events of which they may become aware during the course of the Clinical Trial. Both Parties agree to fulfil and ensure that their Personnel and Agents respectively fulfil regulatory requirements with respect to the reporting of adverse events.

* + 1. **Adverse Event Reporting in Phase I Trials**

Notwithstanding the generality in Clause 3.6, the Parties further acknowledge and agree that with respect to Phase I trials:

1. It is the responsibility of the Sponsor to report all SUSARs relating to the Clinical Trial to the relevant Regulatory Authority within the timeframes set out in the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004, SI No 190 of 2004 or the EU Clinical Trial Regulations, as applicable and to report relevant follow-up information as required.
2. The Principal Investigator will provide the Sponsor with details of all SAEs irrespective of causality or whether the SAE is thought to be related to the Investigational Drugs and all other safety information as set out in the Protocol.
3. It is the responsibility of the Sponsor to submit safety reports to the relevant Regulatory Authorities as applicable and in accordance with both the Note for Guidance on Planning Pharmacovigilance Activities (ICH E2E) and the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004, SI No 190 of 2004 or the EU Clinical Trial Regulations, as applicable
4. If, during the course of the Clinical Trial, the Sponsor becomes aware of any information relating to the IMP which may impact the Clinical Trial, the Sponsor will notify the Clinical Organisation immediately or where immediate notification is not possible, within a maximum of three (3) business days of becoming aware of the information, and if requested to do so by the Clinical Organisation, will provide the Clinical Organisation with a report detailing the information.
5. The Sponsor must provide any ongoing safety and toxicology data updates to the Principal Investigator immediately, to ensure the safety of the Clinical Trial Subjects in this Phase I Clinical Trial.
   1. **Anti-Bribery and Corruption**
      1. Each Party warrants and represents that to the best of its knowledge, information and belief:
6. It has not committed any offence under the Criminal Justice (Corruption Offences) Act 2018 or any of the following acts (“Prohibited Acts”):
7. other than in accordance with applicable laws, valid agreements and the provisions of this Agreement, offered, given or agreed to give any officer or employee of 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
8. 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.
   * 1. If either Party has committed or commits any of the Prohibited Acts or has committed or commits any offence under the Criminal Justice (Corruption Offences) Act 2018 in relation to this Agreement, the other Party shall be entitled to terminate this Agreement in accordance with Clause 15, in addition to any other remedy available, taking into consideration the potential effects of termination on the health of Clinical Trial Subjects.

## Obligations of the Parties and the Principal Investigator

* 1. Each Party represents and warrants that it has the right and authority to enter into this Agreement and that it has the capability and capacity to fulfil its obligations under this Agreement.
  2. The Parties agree to adhere to the principles of medical confidentiality in relation to Clinical Trial Subjects involved in the Clinical Trial.
  3. The Sponsor shall be responsible for obtaining and maintaining Regulatory Authority approval, as well as research ethics committee favourable opinion and any other approvals needed for the conduct of the Clinical Trial.
  4. The Principal Investigator shall be responsible for:
     1. ensuring that the informed consent form, approved by the Sponsor and the relevant research ethics committee, is signed by or on behalf of each Clinical Trial Subject before the first Clinical Trial related procedure starts for that Clinical Trial Subject (or otherwise that the requirements of The European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, S.I. No. 314 of 2018 - Data Protection Act 2018, (Section 36(2)) (Health Research) Regulations 2018 and 2004, SI No 190 of 2004 and Statutory Instrument No. 158 of 2006 (Quality and Safety of Human Tissues and Cells) Regulations, SI 99 of 2022- European Union (Clinical Trials on Medicinal Products for Human Use) (Principal) Regulations 2022 and SI No. 158 of 2006 – European Communities (Quality and Safety of Human Tissue and Cells) Regulations, as may be amended, repealed or replaced from time to time are met in accordance with the Protocol;
     2. making any necessary disclosures of financial interests and arrangements, as defined and requested by the Sponsor, provided that such disclosures may be made prior to the commencement of work activities associated with the Clinical Trial as well as subsequent to Site Trial Completion, and that the Principal Investigator and Personnel shall update such disclosures as necessary to maintain their accuracy and completeness during the term of this Agreement and for any other period required by applicable law.
  5. The Sponsor shall submit the Clinical Trial for listing in a free, publicly-accessible clinical trial registry within twenty-one (21) days of initiation of the Clinical Trial by enrolment of the first Clinical Trial Subject. The Clinical Organisation agrees that such listing may include a summary of the Protocol, the name of the Clinical Organisation and the details of the Site(s) where the Clinical Trial is being conducted. Subject to Clause 7 of this Agreement, in the event that the Sponsor intends to publish the name of the Principal Investigator on a publicly-accessible clinical trial registry, the Sponsor shall be responsible for obtaining the written permission of the Principal Investigator for the use of the Principal Investigator’s name (and any other personal information) in such a publication.
  6. The Parties shall conduct the Clinical Trial in accordance with the terms of this Agreement (including the incorporated Protocol) and:
     1. any current marketing authorisation for the IMP and, as the case may be, the Clinical Trial Authorisation granted by the HPRA; and
     2. the terms and conditions of the favourable opinion of the research ethics committee.
  7. Until the Sponsor has obtained approval from the HPRA, the research ethics committee and any other necessary approvals, it shall not supply the Investigational Drugs to the Clinical Organisation. The Clinical Organisation shall ensure that neither administration of the IMP (nor any other Investigational Drug supplied by Sponsor for use in the Clinical Trial) to any Clinical Trial Subject nor any other clinical intervention mandated by the Protocol takes place in relation to any Clinical Trial Subject until the Sponsor has confirmed and provided all required approvals.
  8. In the event of any substantial amendments being made to the Protocol and approved by the HPRA and Ethics Committee, the amendments shall be signed by the Principal Investigator and shall be implemented by the Personnel as required by the Sponsor. The Sponsor shall initiate simultaneously the change control procedures set out in Clause 17.3 of this Agreement.
  9. The Sponsor shall make the Protocol available to the Principal Investigator and provide evidence of the approvals set out in Clause 4.6 and the Principal Investigator shall include such documents in the Site File. The Sponsor shall ensure that any and all safety and/or toxicology data relating to the IMP, which the Sponsor is aware of or which comes to the attention of the Sponsor from time to time, and which may, in the reasonable opinion of the Sponsor, be materially relevant to the conduct of the Clinical Trial, will also be provided to the Principal Investigator for inclusion in the Site File.
  10. The Clinical Organisation shall not, and will ensure that the Principal Investigator shall not, permit the Investigational Drugs supplied by or on behalf of the Sponsor for the purposes of the Clinical Trial to be used for any purpose other than the conduct of the Clinical Trial. Upon termination or expiry of this Agreement all unused Investigational Drugs supplied for the purposes of the Clinical Trial shall, at the Sponsor’s option, either be returned to the Sponsor or disposed of in accordance with the Protocol or the Sponsor’s reasonable written instructions.
  11. Subject to the Clinical Organisation’s and the Principal Investigator’s overriding obligations in relation to Clinical Trial Subjects and individual patient care, the Clinical Organisation shall ensure that neither it nor the Principal Investigator, shall during the term of this Agreement conduct any other Research that might hinder the Clinical Organisation’s or Principal Investigator’s ability to enrol and study the required cohort of Clinical Trial Subjects.
  12. The Clinical Organisation shall use its all-reasonable endeavours to ensure that the Principal Investigator enrols/doses/randomises a minimum of [INSERT NUMBER] Clinical Trial Subject(s), to participate in the Clinical Trial and the Parties shall conduct the Clinical Trial in accordance with the Timelines.
  13. In the event that the Clinical Trial is part of a Multi-Centre Trial, the Sponsor may amend the number of Clinical Trial Subjects to be enrolled pursuant to the Protocol as follows:
      1. If, in the reasonable opinion of the Sponsor, enrolment of the Clinical Trial Subjects at the Clinical Organisation is proceeding at a rate below that required to enable the Timelines to be met, and upon the Sponsor’s request to increase the enrolment rate, the Clinical Organisation is unable to comply, the Sponsor may by notice to the Clinical Organisation, require the Clinical Organisation to cease enrolment of Clinical Trial Subjects.
      2. If, with respect of the Clinical Trial, the global enrolment target has been reached, upon receipt of a notice, the Clinical Organisation shall ensure that the Principal Investigator shall immediately stop the enrolment of Clinical Trial Subjects and the terms and conditions of this Agreement shall not apply to individuals who at the time of receipt of such notice have not signed informed consent and have not been enrolled in the Clinical Trial. Payments shall be made according to the number of Clinical Trial Subjects enrolled up to the date of receipt of the notice.
      3. If enrolment of Clinical Trial Subjects is proceeding at a rate above that which is required to meet the Timelines, the Sponsor may, with the written agreement of the Clinical Organisation, increase the number of Clinical Trial Subjects to be enrolled at the Site and the payment to be made will be adjusted in accordance with Clause 17.2.
  14. **Access, Research Misconduct and Regulatory Authorities**
      1. The Clinical Organisation represents that neither it nor, to the best of its knowledge arrived at after reasonable due diligence, any of the Personnel, including the Principal Investigator, are restricted or prevented under any law from taking part in clinical research and the Clinical Organisation will not knowingly use in any capacity the services of any person who is so restricted or prevented under any such laws with respect to the services to be performed under this Agreement. During the term of this Agreement, the Clinical Organisation and the Principal Investigator will notify the Sponsor if the Clinical Organisation and/or the Principal Investigator, becomes aware of any restriction or prevention being applied to it, the Principal Investigator or any of the Personnel.
      2. The Clinical Organisation represents that it and, to the best of its knowledge arrived at after reasonable due diligence, the Principal Investigator or any of the Personnel, are not the subject of any past or pending government or regulatory investigation, inquiry, warning or enforcement action (collectively “Agency Action”) related to its conduct of research that has not previously been disclosed to the Sponsor. The Clinical Organisation will promptly notify the Sponsor if it becomes aware of any Agency Action regarding compliance with ethical, scientific or regulatory standards for the conduct of research, if the Agency Action relates to events or activities that occurred prior to or during the period in which the Clinical Trial is conducted.
      3. Each Party shall inform the other immediately upon becoming aware of any serious breach of the Protocol and/or the conditions and principles of ICH-GCP or any other rules, principle or guidance, relating to the Clinical Trial at the Site. The Sponsor shall inform the relevant Regulatory Authority of such serious breach in writing within seven (7) days of becoming aware of that breach. The Sponsor shall, at its discretion, inform other sites that a serious breach has occurred but shall not be under any obligation to do so unless a regulatory obligation is applicable or as instructed by a Regulatory Authority. For the purposes of this Clause 4.14, a “serious breach” is a breach that is likely to affect, to a significant degree:

1. the safety or physical or mental integrity of the Clinical Trial Subjects; or
2. the scientific value of the Clinical Trial.
   * 1. The Clinical Organisation shall permit the Trial Monitor and any Auditor or Inspector access to all relevant clinical data of the Clinical Trial Subjects for monitoring and source data verification, such access to be arranged at mutually convenient times and on reasonable notice. The monitoring may take such form as the Sponsor reasonably thinks appropriate, including the right to inspect any facility being used for the conduct of the Clinical Trial and to examine any procedures or records relating to the Clinical Trial, subject to compliance with Data Protection Laws and Guidance. The Sponsor will alert the Clinical Organisation, promptly in accordance with Clause 19.3, of significant issues (in the opinion of the Sponsor) relating to the conduct of the Clinical Trial.
     2. In the event that the Sponsor reasonably believes that there has been research misconduct in relation to the Clinical Trial, the Clinical Organisation shall, and shall ensure that the Principal Investigator shall, provide all reasonable assistance to any investigation undertaken by or on behalf of the Sponsor into any alleged research misconduct. The results of the investigation shall, subject to any obligations of confidentiality, be communicated to the Clinical Organisation. In the event that the Clinical Organisation reasonably believes that there has been research misconduct in relation to the Clinical Trial, the Sponsor shall provide all reasonable assistance to any investigation undertaken by or on behalf of the Clinical Organisation into any alleged research misconduct. The results of the investigation shall, subject to any obligations of confidentiality, be communicated to the Sponsor.
     3. The Clinical Organisation shall promptly inform the Sponsor of any intended or actual inspection, written enquiry and/or visit to the Site by any Regulatory Authority, in connection with the Clinical Trial, and forward to the Sponsor copies of any correspondence from any such Regulatory Authority relating to the Clinical Trial. The Clinical Organisation will use reasonable endeavours to procure that the Sponsor may have a representative present during any such visit or inspection and the opportunity to review and comment on the Clinical Organisation’s response to the visit or inspection by a Regulatory Authority in connection with the Clinical Trial. The Parties further acknowledge that inspections and written enquiries by Regulatory Authorities may also occur after the conclusion of the Clinical Trial and both Parties shall cooperate with any such inspection or written enquiry.
     4. The Clinical Organisation will permit the Sponsor to examine the conduct of the Clinical Trial and the Site upon reasonable advance notice during regular business hours to determine that the Clinical Trial is being conducted in accordance with the Protocol, ICH-GCP and the applicable regulatory requirements. The Parties agree that the Sponsor shall have the right to audit Clinical Trial records during, and subsequent to, the Clinical Trial.
     5. Upon Site Trial Completion (whether prematurely or otherwise), the Principal Investigator shall co-operate with the Sponsor in producing a report of the Clinical Trial detailing the methodology, Results and containing an analysis of the Results and drawing appropriate conclusions.
     6. The Clinical Organisation shall retain all Clinical Trial Data for a minimum period of twenty five (25) years after Trial Completion. Upon the expiry of the record retention period specified above the Clinical Organisation shall transfer such Clinical Trial Data to the Sponsor if requested by Sponsor and shall not destroy any Clinical Trial Data without Sponsor’s prior written approval, such approval not to be unreasonably withheld or delayed.
3. The Sponsor will reimburse the Clinical Organisation in full for the costs of archiving the Clinical Trial Data or, in agreement with the Clinical Organisation, will arrange for the archiving of the Clinical Trial Data on behalf of the Clinical Organisation. In the event that costs of archiving are to be incurred by the Clinical Organisation, it is agreed that all such costs will be reasonable and subject to prior written agreement with the Sponsor. Reimbursement will be paid to the Clinical Organisation in accordance with Appendix 2. In the event that the Clinical Trial Data are archived offsite by the Sponsor and the Clinical Organisation does not incur any costs, no amounts will be payable to the Clinical Organisation.
   * 1. [DELETE IF NOT APPLICABLE] Where the Clinical Organisation is responsible for analysis of Material during the course of the Clinical Trial it shall ensure that such analysis is conducted at a laboratory approved by the Sponsor or, in the case of point of care analysis, by methodology and using equipment that is acceptable to, or provided by, the Sponsor. The Clinical Organisation shall ensure that analysis of Material is undertaken in accordance with the Protocol and any other document agreed between the Sponsor and the Clinical Organisation (including the provisions of Appendix 4).
     2. [DELETE IF NOT APPLICABLE]Where the Sponsor undertakes the analysis of Material and/or has contracted with a third-party laboratory (“Central Laboratory”) to undertake the analysis of Material, the Sponsor shall comply, and shall ensure the Central Laboratory shall comply, with the terms of Appendix 4 herein that are expressed to be the responsibility of the Sponsor.
   1. [DELETE IF NOT APPLICABLE] Equipment and Resources  
      The Parties agree that the Sponsor shall arrange for the provision of the equipment and resources to the Clinical Organisation, pursuant to the terms set out in Appendix 5.

## Liabilities and Indemnities

* 1. In the event of any claim or proceeding in respect of personal injury (including death) made or brought against the Clinical Organisation by or on behalf of a Clinical Trial Subject or their dependants, the Sponsor shall indemnify the Clinical Organisation, its Personnel, agents, servants and employees in accordance with the terms of the State Claims Agency’s Clinical Trial Indemnity Form (“CTIF”). In the event of any conflict between this Agreement and the terms of the CTIF, the terms of the CTIF shall prevail.
  2. Nothing in this Clause 5 shall operate so as to restrict or exclude the liability of any Party in relation to death or personal injury caused by the negligence or wilful misconduct of that Party or its Personnel or Agents or employees, or to restrict or exclude any other liability of either Party that cannot be so restricted or excluded in law.
  3. In no circumstances shall either Party be liable to the other Party in contract or tort (including negligence or breach of statutory duty) or otherwise howsoever arising or whatever the cause thereof, for any loss of profit, business, reputation, contracts, revenues or anticipated savings or for any special, indirect or consequential damage of any nature, which arises directly or indirectly from any default on the part of any other Party.
  4. Subject to Clauses 5.2 and 5.5 the Clinical Organisation’s liability to the Sponsor arising out of or in connection with any breach of this Agreement or any act or omission of the Clinical Organisation in connection with the performance of the Clinical Trial shall in no event exceed the amount of fees payable by the Sponsor to the Clinical Organisation under this Agreement. In the case of equipment loaned to the Clinical Organisation for the purposes of the Clinical Trial, the Clinical Organisation’s liability for loss or damage to this equipment arising from its negligence shall exclude fair wear and tear and shall not exceed the value of the equipment.
  5. In respect of any wilful and/or deliberate breach by the Clinical Organisation, or any breach of Clauses 6, 9, 11 or 12 the Clinical Organisation’s liability to the Sponsor arising out of or in connection with the breach shall not exceed two times the value of the Agreement.
  6. The Sponsor shall take out appropriate insurance cover including but not limited to Employer’s Liability Insurance, Public Liability Insurance, Product Liability Insurance, Clinical Trials Insurance (to include No Fault Compensation) and Professional Indemnity Insurance. Insurance should be detailed in the certificate of insurance provided by the Sponsor to the Clinical Organisation. The Clinical Organisation is a delegated state authority under the NTMA Amendment Act and has the benefit of state indemnity cover. State Indemnity is provided under two schemes – the Clinical Indemnity Scheme (CIS) covers personal injury claims arising from the provision of, or the failure to provide professional medical services by the Clinical Organisation) and the General Indemnity Scheme (GIS) (covers personal injuries and property damages claims by staff, patient (arising from the provision of non medical services) visitors and contractors which were the result of a negligent act of omission on the part of the Clinical Organisation) State Indemnity is operated by the State Claims Agency on behalf of the Minister. It is enshrined in legislation and is unlimited in amount.
     1. The Sponsor shall produce to the Clinical Organisation on request, copies of insurance certificates, together with evidence that the policies to which they refer remain in full force and effect, or other evidence concerning the indemnity. Insurance shall be placed with an insurer authorised to transact business within the Republic of Ireland (or within the EU under the Freedom of Services Directive) and the Insurance territorial and jurisdictional limits shall include Ireland. The Clinical Organisation shall produce to the Sponsor on request evidence of its continued membership of the relevant State Claims Agency’s CIS and/or GIS. The terms of insurance, or of the relevant State Claims Agency’s negligence indemnity scheme(s), or the amount of cover, shall not relieve either Party of any liabilities under this Agreement.
  7. Nothing in this Agreement will operate to limit or exclude any liability for fraud.

## Medical Records

* 1. **Medical Records**: All right and title and interest in a Clinical Trial Subject’s Medical Records shall vest and remain vested in the Clinical Organisation.
  2. **Medical Confidentiality**: The Parties shall adhere to the principles of medical confidentiality in relation to Clinical Trial Subjects. The Medical Records and any other Personal Data of a Clinical Trial Subject shall not be disclosed to the Sponsor by the Clinical Organisation, save where necessary in any of the following circumstances:
     1. to the extent that the disclosure is required to satisfy the requirements of the Protocol;
     2. for the purpose of monitoring, auditing or adverse event reporting or investigation;
     3. for the purposes of investigation or defending any claim or proceeding brought by a Clinical Trial Subject in connection with the Clinical Trial; and
     4. for the purpose of allowing the Sponsor to follow-up with the Clinical Trial Subject after the conclusion of the Clinical Trial.

The Sponsor shall not disclose the identity of any Clinical Trial Subject to any third party save in accordance with Data Protection Laws and Guidance or as required by law, and the Clinical Organisation and the relevant Clinical Trial Subject shall be notified by Sponsor of such intended disclosure prior to such disclosure being made, unless the Sponsor is otherwise prohibited from doing so in accordance with law.

* 1. Clinical Trial Subject Consent:
     1. The explicit consent of each Clinical Trial Subject shall be obtained by the Clinical Organisation in accordance with applicable laws, the Protocol, HSE consent Policy, the Informed Consent Form (“ICF”) and the Patient Information Leaflet (“PIL”) provided by the Sponsor to the Clinical Organisation for provision to the Clinical Trial Subject, or to the Clinical Trial Subject directly, for their participation in, and the processing of their Personal Data for the purposes of, the Clinical Trial.
     2. The Sponsor shall obtain ethics committee approval for the PIL and ICF to be utilised for the purposes of 6.3.1.

## Data Protection

* 1. The Parties agree:
     1. To comply with all Data Protection Laws and Guidance in Processing the Personal Data of Clinical Trial Subjects. This Clause 7 is in addition to and does not replace, relieve or remove a Party’s obligations or rights under the Data Protection Laws and Guidance.
     2. When the Parties are acting as separate and independent Controllers, to promptly and without undue delay, notify and inform the other Party in the event of any Personal Data Breach that relates to Personal Data Processed for the purpose of the Clinical Trial.
     3. If the Parties are joint Controllers in connection with the processing of Personal Data for the purpose of the Clinical Trial, the Parties shall enter into an appropriate arrangement according to the GDPR Article 26.
  2. **Processing of Clinical Trial Subject Personal Data**
     1. For the purpose of the Data Protection Laws and Guidance, the Sponsor is the Controller and the Clinical Organisation is the Processor of Personal Data Processed for the purpose of the Clinical Trial. The Sponsor shall ensure that there is a lawful basis for the processing of Personal Data for the purpose of the Clinical Trial, in accordance with GDPR requirements.
     2. The Clinical Organisation’s Processing of Personal Data, as a Processor of the Sponsor, shall be governed by this Agreement, including the Protocol, which sets out the subject matter, duration, nature and purpose of the Processing, the type of Personal Data and the categories of Data Subjects, and obligations and rights of the Sponsor as Controller. It is the Sponsor’s obligation to ensure that Article 28(3) of the GDPR is complied with and Sponsor shall ensure that where required a DPIA will be completed, and the Sponsor shall ensure that the DPIA does not conflict with this Agreement.
     3. The Clinical Organisation is the Controller of Personal Data Processed for purposes other than the Clinical Trial, e.g., the provision of medical care.
     4. The Clinical Organisation, in its role as Processor of the Personal Data under clause 7.2.1, agrees to only Process Personal Data for and on behalf of the Sponsor in accordance with the documented instructions of the Sponsor, including with regard to transfers of personal data to a third country or an international organisation. If the Clinical Organisation is required by law to otherwise Process the Personal Data, the Clinical Organisation shall notify the Sponsor before undertaking the Processing, or as soon as possible thereafter, unless such notification is prohibited on important grounds of public interest in accordance with GDPR Article 28(3)(a).
     5. The Clinical Organisation agrees to comply with the obligations applicable to Processors described by Article 28 of the GDPR, as well as those additional obligations required by the Sponsor pursuant to this Agreement, including but not limited to the following:

1. implementing and maintaining appropriate technical and organisational security measures for Personal Data Processed in its systems, in keeping with its obligations as an HSE organisation, thereby providing guarantee to the Sponsor pursuant to GDPR Article 28(1);
2. ensuring that Personnel authorised to Process Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality (Article 28(3)(b));
3. taking all measures required by GDPR Article 32 in relation to the security of Processing (GDPR Article 28(3)(c));
4. subject to Clause 7.2.6 complying with the conditions described in GDPR Article 28(2) and (4) for engaging another Processor (GDPR Article 28(3)(d));
5. taking into account the nature of the Processing, assist the Sponsor, by implementing appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising Data Subjects’ rights (GDPR Article 28(3)(e));
6. assisting the Controller, to ensure compliance with the obligations pursuant to GDPR Articles 32 to 36, taking into account the nature of the Processing and the information available to the Clinical Organisation (GDPR Article 28(3)(f));
7. maintaining a record to demonstrate compliance with this Clause and Data Protection Laws and Guidance, including the records required pursuant to GDPR Article 30(2);
8. in the event of any Personal Data Breach by the Clinical Organisation as a Processor of the Sponsor, the Clinical Organisation shall: (i) promptly and without undue delay following discovery of such Personal Data Breach, send written notice of the incident via e-mail to [INSERT EMAIL ADDRESS OF SPONSOR’s DATA PROETECTION OFFICER]; (ii) not make any statements or notifications about the Personal Data Breach, as it relates to the Processing for the purpose of the Clinical Trial, to any individual affected by the incident, the public or any third party without having sought the Sponsor’s prior written approval; and (iii) immediately take steps to investigate and mitigate the Personal Data Breach and reasonably cooperate with the Sponsor.
   * 1. In furtherance of its obligations under Article 28 GDPR, the Clinical Organisation agrees that it will not engage another Processor for the purpose of the Clinical Trial without the prior written authorisation of the Sponsor (GDPR Article 28(2)), excepting where that other Processor is a Participant Identification Centre (PIC), in which case Clause 7.2.6 (a) shall apply;
9. In accordance with GDPR Article 28(2), the Clinical Organisation may appoint PICs, on the basis of an unmodified template data processing agreement agreed in advance with the Sponsor, by notifying the Sponsor that they intend to contract the PIC. The Sponsor will be considered to have authorised this sub-processing if it does not notify the Clinical Organisation to the contrary within five (5) business days.
   * 1. At the expiry or lapse of this Agreement, the Clinical Organisation shall, at the choice of the Sponsor, destroy or return all Clinical Trial Data to the Sponsor unless there is a legal requirement for retention and storage (GDPR Article 28(3)(g)), and/or where that Personal Data is held by the Clinical Organisation as Controller for its own purpose(s).
     2. The Clinical Organisation will:
10. ensure that its Personnel and the Principal Investigator, do not Process Personal Data except in accordance with the Protocol and this Agreement;
11. take all reasonable steps to ensure the reliability and integrity of the Principal Investigator and any of its Personnel who have access to the Personal Data and will ensure that the Principal Investigator and the Personnel:
12. are aware and comply with the Clinical Organisation’s duties under this Clause 7 (Data Protection);
13. are subject to mandatory training in their information governance responsibilities and have appropriate contracts, including sanctions, including for breach of confidence or misuse of Personal Data; and
14. are informed of the confidential nature of the Personal Data and understand their responsibilities for information governance, including their obligation to Process Personal Data securely and to only disseminate or disclose it for lawful and appropriate purposes.
    * 1. The Clinical Organisation agrees to:
15. Provide the Sponsor with evidence of its compliance with the obligations set out in this Agreement, and/or, at the Sponsor’s discretion and on reasonable notice, to allow the Sponsor, or a third party appointed by the Sponsor, to audit the Clinical Organisation’s compliance with the obligations described in this Agreement, Data Protection Laws and Guidance (including but not limited to Article 28 GDPR), subject to the Sponsor, or its appointed third party, complying with all relevant health and safety and security policies of the Clinical Organisation.
16. Obtain prior written agreement of the Sponsor to Process Personal Data outside of the EEA.
    * 1. In addition to the Clinical Organisation’s obligations under clause 7.2.9 (b) where the Clinical Organisation, acting as the Sponsor’s Processor, Processes Personal Data outside of the EEA, the Clinical Organisation warrants that it does so in compliance with the Data Protection Laws and Guidance.
      2. Any transfer of Personal Data outside of the European Economic Area (“Restricted Transfer”) shall be in accordance with Data Protection Laws and Guidance and in particular in accordance with Chapter 5 of the GDPR. The Parties agree that a Restricted Transfer shall only take place where there is either an Adequacy Decision or Appropriate Safeguards in place governing that Restricted Transfer. All relevant regulatory authority requirements in relation to Restricted Transfers, in particular the use of Standard Contractual Clauses or other Appropriate Safeguards and any related measures required to be taken in the context of any Restricted Transfer, shall be put in place including adopting additional measures, such as an transfer assessment to protect the Clinical Trial Subject.
    1. **Sharing of Personal Data and/or Clinical Trial Subject Pseudonymised Data**
       1. Neither Personal Data nor Pseudonymised Data of Clinical Trial Subjects shall be transferred by the Clinical Organisation to the Sponsor unless this is required directly or indirectly to satisfy the requirements of this Agreement, or for the purposes of monitoring and reporting of adverse events or in relation to a claim or proceeding brought by a Clinical Trial Subject in connection with the Clinical Trial or is otherwise required by applicable law.
       2. The Sponsor agrees not to pass Personal Data or Pseudonymised Data of Clinical Trial Subjects provided under this Agreement to a third party, unless that third party is bound by contractual obligations at least as stringent as in this Clause 7.
       3. The Sponsor agrees to use Personal Data and/or Pseudonymised Data of Clinical Trial Subjects for the purpose of the Clinical Trial and in all circumstances for no purpose which is incompatible with the Clinical Trial purpose. The Sponsor further agrees not to disclose the Personal Data or Pseudonymised Data of Clinical Trial Subjects to any person except as required or permitted by law or applicable guidance.
       4. The Sponsor agrees to comply with the obligations placed on it as a Controller pursuant to Data Protection Laws and Guidance, including but not limited to demonstrating compliance with the principles relating to Processing of Personal Data (Article 5 GDPR).
       5. The Sponsor agrees to ensure persons Processing Personal Data and/or Pseudonymised Data of Clinical Trial Subjects under this Agreement are equipped to do so respectfully and safely. In particular:
17. to ensure any such persons (excluding employees, honorary employees, students, researchers, consultants and sub-contractors of the Clinical Organisation) understand the responsibilities for information governance, including their obligation to Process Personal Data and/or Pseudonymised Data of Clinical Trial Subjects securely and to only disseminate or disclose for lawful and appropriate purposes;
18. to ensure any such persons (excluding employees, honorary employees, students, researchers, consultants and sub-contractors of the Clinical Organisation) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable Personal Data Breaches.
    * 1. The Sponsor agrees to use best endeavours proactively prevent Personal Data Breaches, and/or equivalent breaches relating to Pseudonymised Data of Clinical Trial Subjects, and to respond appropriately to incidents or near misses. In particular:
19. to ensure that Personal Data and/or Pseudonymised Data of Clinical Trial Subjects are only accessible to persons who need it for the purposes of the Clinical Trial and to remove access as soon as reasonably possible once it is no longer needed;
20. to ensure all access to Personal Data and/or Pseudonymised Data of Clinical Trial Subjects on IT systems Processed for Clinical Trial purposes can be attributed to individuals;
21. to review processes to identify and improve processes which have caused Personal Data Breaches or near misses, or which force persons Processing Personal Data and/or Pseudonymised Data of Clinical Trial Subjects to use workarounds which compromise data security;
22. to adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice;
23. to take action immediately following a Personal Data Breach or near miss.
    * 1. The Sponsor agrees to ensure Personal Data and/or Pseudonymised Data of Clinical Trial Subjects are Processed using secure and up-to-date technology. In particular:
24. to ensure no unsupported operating systems, software or internet browsers are used to support the Processing of Personal Data and/or Pseudonymised Data of Clinical Trial Subjects for the purposes of the Clinical Trial;
25. to put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework;
26. to ensure IT suppliers are held accountable via contracts for protecting Personal Data and/or Pseudonymised Data of Clinical Trial Subjects they Process and for meeting all relevant information governance requirements.

## Freedom of Information

* 1. The Sponsor acknowledges that the Clinical Organisation is subject to the FOIA and associated guidance and codes of practice.
  2. If the Clinical Organisation or its Personnel receive a request under the FOIA to disclose information that belongs to the Sponsor or its Affiliates, it will notify the Sponsor as soon as is reasonably practicable, and in any event, no later than five (5) working days after receiving the request. The Clinical Organisation will consult with the Sponsor in accordance with all applicable guidance.
  3. The Sponsor acknowledges that subject to Clause 7.3.1, the decision on whether any exemption applies to a request for disclosure of recorded information under the FOIA is a decision solely for the Clinical Organisation.
     1. The Sponsor shall cooperate with the Clinical Organisation and shall use its reasonable endeavours to respond within ten (10) working days of the Clinical Organisation’s reasonable request for assistance.
  4. Where the Clinical Organisation determines that it will disclose information, notwithstanding any objections from the Sponsor, it will notify the Sponsor in writing, giving at least two (2) working days’ notice of its intended disclosure.

## Confidential Information

* 1. The Clinical Organisation and the Sponsor shall ensure that only those of its officers, Agents, Personnel and employees (and in the case of the Sponsor, those of its Affiliates and (if applicable) other parties who may have contractual rights in the Results or to develop the IMP (for example, through a license, collaborative agreement, Co-Promotion Agreement, Co-Development Agreement etc. with Sponsor)) directly concerned with the carrying out of this Agreement, have access to relevant and necessary Confidential Information of the other Party. Each Party shall ensure that any party to whom disclosure of or access to such Confidential Information has been given by that Party shall comply with the provisions of this Agreement and the Party disclosing the Confidential Information shall be liable for any breach of the Agreement by the party they have disclosed Confidential Information to. Each Party undertakes to treat as strictly confidential and not to disclose to any third party any Confidential Information of the other Party, save where disclosure is required by a Regulatory Authority or by law (including any disclosure required to ensure compliance by the Clinical Organisation, with the FOIA in accordance with Clause 8 of this Agreement). The Party required to make the disclosure shall inform the other within a reasonable time prior to being required to make the disclosure (and, where appropriate in accordance with Clause 8) of the requirement to disclose and the information required to be disclosed. Each Party undertakes not to make use of any Confidential Information of the other Party other than in accordance with this Agreement, without the prior written consent of the other Party.
  2. The obligations of confidentiality set out in this Agreement, shall not apply to information that is:
     1. published or becomes generally available to the public other than as a result of a breach of this Agreement by the receiving Party;
     2. in the possession of the receiving Party prior to its receipt from the disclosing Party, as evidenced by contemporaneous written evidence, and is not subject to a duty of confidentiality;
     3. independently developed by the receiving Party, as evidenced by contemporaneous written evidence and is not subject to a duty of confidentiality;
     4. obtained by the receiving Party from a third party that is not subject to a duty of confidentiality.
  3. In the event of a Party visiting the establishment of the other Party, the visiting Party undertakes that any further Confidential Information that may come to the visiting Party’s knowledge as a result of any such visit, shall be treated as Confidential Information in accordance with this Clause 9.
  4. This Clause 9 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, this Clause 9 shall remain in force for a period of 10 years after the termination or expiry of this Agreement.

## Publicity

* 1. Subject to Clauses 4.5, 11.5 and 13.3, the Sponsor will not use the name of the Clinical Organisation or any Site in any publicity, advertising or news release without the prior written approval of an authorised representative of the Clinical Organisation, such approval not to be unreasonably withheld. Nothing in this Agreement will prohibit the Sponsor from publishing the identities and contact information of the Clinical Organisation and the Clinical Trial recruitment status at the Site for the purpose of registering the Clinical Trial in a publicly available clinical trials database, making information about the Clinical Trial available to potential Clinical Trial subjects, or otherwise as may be required under Clause 4.5.
  2. Save in compliance with applicable laws and Clinical Organisation policy and procedure, the Clinical Organisation will not, and will ensure that the Principal Investigator and the Personnel do not, use any information which is not publicly available in relation to the Sponsor, the Sponsor’s employees, nor the Clinical Trial, nor the IMP in any publicity, advertising or news release without the prior written approval of the Sponsor, such approval not to be unreasonably withheld. The provisions of this Clause 10.2 shall also apply to the Clinical Organisation’s use of the name, trademark, service mark, and/or logo of any third parties collaborating with the Sponsor on the Clinical Trial and/or the IMP (“Sponsor Collaborators”) provided that the Clinical Organisation has been notified of the identity of the Sponsor Collaborators.
  3. Neither the Clinical Organisation, nor the Principal Investigator, will issue any information or statement to the press or public including but not limited to advertisements for the enrolment of Clinical Trial Subjects without the prior written permission of the Sponsor, not to be unreasonably withheld, and the delivery of research ethics committee approval, where applicable.

## Publications

* 1. The Sponsor recognises that the Clinical Organisation and Principal Investigator have a responsibility to ensure that results of scientific interest arising from the Clinical Trial are appropriately published and disseminated.
     1. The Sponsor agrees that employees of the Clinical Organisation and the Principal Investigator shall be permitted to present at symposia, national and regional professional meetings and to publish in journals, theses or dissertations, or otherwise of their own choosing, the methods and Results of the Clinical Trial, subject to this Clause 11 and any publication policy described in the Protocol, provided any such policy is consistent with the Joint Position.
     2. If the Clinical Trial is a Multi-Centre Trial, any publication based on the results obtained at any one Site (or group of Sites) shall not be made before the first Multi-Centre publication.
     3. If a publication concerns the analyses of sub-sets of data from a Multi-Centre Trial, the publication must make reference to the relevant Multi-Centre Trial publication.
  2. Upon Site Trial Completion, and any prior publication by the Sponsor of Multi-Centre Trial data or when the Clinical Trial Data are adequate (in the Sponsor’s reasonable judgment), the Clinical Organisation and or the Principal Investigator may prepare the data derived from the Site(s) for publication. Such data will be submitted to the Sponsor for review and comment prior to publication.
     1. In order to ensure that the Sponsor will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to the Sponsor for review at least sixty (60) days (or the time specified in the Protocol if longer) prior to submission for publication, public dissemination, or review by a publication committee.
  3. The Clinical Organisation agrees and shall ensure that the Principal Investigator agrees that all reasonable comments made by the Sponsor in relation to a proposed publication by the Clinical Organisation and/or the Principal Investigator will be incorporated by the Clinical Organisation and/or the Principal Investigator into the publication.
  4. The Sponsor shall ensure that the Results of the Clinical Trial are published on a free, publicly-accessible clinical trial results database in accordance with the principles of the Joint Position within one (1) year after the IMP is first approved and made commercially available in any country or, if the Clinical Trial is a post-approval clinical trial, within one (1) year of Trial Completion. In respect of a clinical trial that is under review by peer reviewed journals that prohibit disclosure of Results pre-publication, the Results will be posted at the time of publication.
     1. The Clinical Organisation acknowledges that the Sponsor may present at symposia, national or regional professional meetings, publish in journals, theses or dissertations or otherwise of their own choosing, the methods and Results of the Clinical Trial and in particular, but without limiting the foregoing, post a summary of the Clinical Trial Results in an on-line clinical trials register(s) before or after publication by any other method.
  5. Subject to Clause 9 regarding Confidential Information, the Clinical Organisation will accurately describe and will ensure that the Principal Investigator will accurately describe the financial support of the Sponsor for the Clinical Trial in all publications and presentations.
  6. In the event that the Sponsor coordinates a Multi-Centre publication, the participation of the Principal Investigator or Personnel as named authors shall be determined in accordance with the Sponsor’s policy and generally accepted standards for authorship. If the Principal Investigator or other Personnel are to be named as authors of the Multi-Centre publication, such person shall have access to the Clinical Trial data from all sites involved in the Clinical Trial, as necessary to participate fully in the development of the Multi-Centre publication.
  7. During the period for review of a proposed publication referred to in Clause 11.2.1 above, the Sponsor shall be entitled to make a reasoned request to the Clinical Organisation that publication be delayed for a period of up to six (6) months from the date of first submission to the Sponsor in order to enable the Sponsor to take steps to protect its proprietary information and/or Intellectual Property Rights and Know-How and the Clinical Organisation shall not unreasonably withhold its consent to such request. The Clinical Organisation shall not unreasonably withhold or delay its consent to a request from the Sponsor for an exceptional additional delay if, in the reasonable opinion of the Sponsor, the Sponsor’s proprietary information and/or Intellectual Property Rights and Know-How might otherwise be compromised or lost.

## Intellectual Property

* 1. All Intellectual Property Rights and Know-How owned by or licensed to the Sponsor or Affiliate(s) prior to and after the date of this Agreement, other than any Intellectual Property Rights and Know-How arising from the Clinical Trial, are and shall remain the property of the Sponsor.
  2. All Intellectual Property Rights and Know-How owned by or licensed to the Clinical Organisation prior to and after the date of this Agreement, other than any Intellectual Property Rights and Know-How arising from the Clinical Trial, are and shall remain the property of the Clinical Organisation.
  3. All Intellectual Property Rights and Know-How arising from and relating to the Clinical Trial, the IMP (including but not limited to its formulation and use alone or in combination with other drugs), and/or the Protocol, but excluding any clinical procedure and improvements thereto that are clinical procedures of the Clinical Organisation, shall vest in the Sponsor in accordance with Clauses 12.4 and 12.5 of this Agreement.
  4. In accordance with Clause 12.3, the Clinical Organisation hereby assigns, and shall procure that its Personnel assign, its rights in relation to all Intellectual Property Rights and Know-How, falling within Clause 12.3, to the Sponsor or its nominee. At the request and expense of the Sponsor, the Clinical Organisation shall execute, and shall procure that its Personnel shall execute, all such documents and do all such other acts as the Sponsor may reasonably require in order to vest fully and effectively all such Intellectual Property Rights and Know-How in the Sponsor or its nominee.
  5. The Clinical Organisation shall and will ensure that the Principal Investigator promptly disclose to the Sponsor any Know-How generated pursuant to this Agreement and falling within Clause 12.3 and undertakes not to use or disclose such Know-How other than for the purposes of this Agreement.
  6. Nothing in this Clause 12 shall be construed so as to prevent or hinder the Clinical Organisation from using Know-How gained during the performance of the Clinical Trial in the furtherance of its normal activities, to the extent that such use does not result in the disclosure or misuse of Confidential Information or the infringement of any Intellectual Property Right or Know-How of the Sponsor.
  7. The Parties acknowledge and agree that in agreeing the arrangements for the Clinical Trial and preparing this Agreement, including the allocation of Intellectual Property Rights and Know-How between the Parties set out herein, due consideration has been given to Ireland’s National Intellectual Property Protocol (2019).

## Financial Arrangements

* 1. Arrangements relating to the financing of this Clinical Trial by the Sponsor are set out in Appendix 2. All payments will be made according to Appendix 2.
  2. In the event that any change to the Protocol results in amendment to the financial arrangements set out at Appendix 2, it is agreed that the Parties will amend Appendix 2 in accordance with Clause 17.2.
  3. The Parties agrees that the other Party may make public the financial support provided to the Clinical Organisation by the Sponsor for the conduct of the Clinical Trial as required by applicable laws and/or a Party’s policy and procedure in place from time to time and may identify the Clinical Organisation and/or Sponsor as part of this disclosure as required by applicable laws and/or a Party’s policy and procedure in place from time to time.
  4. The Sponsor will notify the Clinical Organisation of Site Trial Completion in order to trigger the generation of a final invoice in accordance with Appendix 2.
  5. The Sponsor shall promptly respond to any reasonable request for invoicing data received from the Clinical Organisation for the purposes of the final invoice for the specific Site(s), provided that the request is received within forty-five (45) days of the notification of Site Trial Completion.
  6. **Longstop Dates**

It is agreed that the Sponsor shall not be required to make payment for any amounts that the Clinical Organisation fails to notify the Sponsor of within sixty (60) days of the Sponsor providing the final invoicing information (if requested), in accordance with Clause 13.5, or sixty (60) days from Site Trial Completion if invoicing information is not requested (“**Longstop Dates**”). For the avoidance of doubt, it is not an obligation for the Sponsor to pay invoices dated after the Longstop Date.

* 1. The Sponsor will make payment to the Clinical Organisation of invoices within forty-five (45) days of the date of receipt of invoices (excluding disputed amounts, which will be resolved in good faith in a timely manner in accordance with Clause 20).
  2. Any delay in the payment of the payee invoices by the Sponsor will incur an interest charge on any undisputed amounts overdue of four (4) per cent per annum above the Bank of Ireland base rate prevailing on the date the payment is due.

## Term

* 1. This Agreement will commence on the Effective Date and shall remain in effect until Site Trial Completion or earlier termination in accordance with this Agreement.

## Termination

* 1. Either the Sponsor or the Clinical Organisation (the “**Terminating Party**”) may terminate this Agreement with immediate effect at any time if the other Party or the Principal Investigator (the “**Defaulting Party**”) is:
     1. in breach of any of the Defaulting Party’s obligations hereunder (including a failure without just cause to meet a timeline set out in this Agreement or the Protocol) and fails to remedy such breach where it is capable of remedy within twenty-eight (28) calendar days of a written notice from the Terminating Party specifying the breach and requiring its remedy;
     2. declared insolvent or has an examiner or receiver appointed over all or any part of its assets or ceases or threatens to cease to carry on its business.
  2. A Party may terminate this Agreement on notice to the other Party with immediate effect if it is reasonably of the opinion that the Clinical Trial should cease in the interests of the health of Clinical Trial Subjects involved in the Clinical Trial.
  3. The Sponsor may terminate this Agreement on notice to the Clinical Organisation if the Principal Investigator is no longer able (for whatever reason) to act as Principal Investigator and no replacement mutually acceptable to the Clinical Organisation and the Sponsor can be found.
  4. The Sponsor may terminate this Agreement immediately upon notice in writing to the Clinical Organisation for reasons not falling within Clauses 15.1, 15.2 or 15.3 above. In all such circumstances, the Sponsor shall confer with the Principal Investigator and use its best endeavours to minimise any inconvenience or harm to Clinical Trial Subjects caused by the premature termination of the Clinical Trial.
  5. In the event of early termination of this Agreement by the Sponsor, pursuant to Clauses 15.1, 15.2, 15.3 or 15.4 and subject to an obligation on the Clinical Organisation and the Principal Investigator to mitigate any loss, the Sponsor shall pay all costs incurred and falling due for payment up to the date of termination, and also all non-cancellable expenditure falling due for payment after the date of termination that arises from commitments reasonably and necessarily incurred by the Clinical Organisation for the performance of the Clinical Trial prior to the date of termination, and agreed with the Sponsor.
  6. In the event of early termination, if payment (whether for salaries or otherwise) has been made by the Sponsor to the Clinical Organisation in advance for work not completed, such monies shall be applied to termination related costs, agreed as per clause 15.5, and the Clinical Organisation shall issue a credit note and repay the remainder of the monies within forty-five (45) days of receipt of written notice from the Sponsor.
  7. At Site Trial Completion, the Clinical Organisation shall promptly deliver, and shall ensure that the Principal Investigator delivers, to the Sponsor all Confidential Information (which for the avoidance of doubt shall not include Medical Records) and any other unused materials provided to the Clinical Organisation and/or the Principal Investigator pursuant to this Agreement, excepting such Confidential Information and other information that forms the Investigator File, as per ICH-GCP 8.4, and other documents as agreed between Clinical Organisation and Sponsor or that are otherwise required by applicable legislation to be retained by the Clinical Organisation, which will be retained by the Clinical Organisation in accordance with 4.14.9.
  8. Termination of this Agreement will be without prejudice to the accrued rights and liabilities of the Parties under this Agreement.

## Relationship of the Parties

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

## Agreement and Modification

* 1. **Order of Precedence**

Should there be any inconsistency between the Protocol and the terms of this Agreement, or any other document incorporated herein, the terms of the Protocol shall prevail to the extent of any inconsistency except insofar as the inconsistency relates to Clauses 5, 6, 7, 8, 9, 11, 12 and 17 of this Agreement.

* 1. Any change in the terms of this Agreement shall be valid only if the change is made in writing, agreed and signed by the Parties.
  2. Any amendment to the Protocol (“**Protocol Amendment**”) shall be managed by means of the change control procedure set out in this Clause.
     1. For the purposes of this Agreement, a “change request” is a request by either Party to change the obligations of the Parties arising from a Protocol Amendment.
     2. Where the Sponsor originates a change request, the Clinical Organisation shall provide the Sponsor, within thirty-five (35) days of receiving the change request, details of the impact that the proposed Protocol Amendment will have upon the costs of carrying out the Clinical Trial and the other terms of this Agreement.
     3. A change request shall become a “change order” when the requirements of the change control procedure have been satisfied and any necessary change to this Agreement is signed by the authorised representatives of the Parties.
     4. An amended financial appendix shall be signed and appended to this Agreement according to Clause 13.2 above.
  3. This Agreement 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 Clinical Trial that is the subject of this Agreement.

## Force Majeure

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

## Notices

Any notice required to be given by either Party shall be in writing quoting the date of the Agreement and shall be delivered by hand or sent by registered post or by email to the contact persons listed below, as per the contact details listed below, or such other person as one Party may inform the other Party in writing from time to time, or such other address or email address as may be notified in writing by that Party from time to time for this purpose.

* + 1. A notice shall be treated as having been received:

1. if delivered by hand within normal business hours when so delivered, or if delivered by hand outside normal business hours, at the next start of normal business hours. For the avoidance of doubt, a notice shall be deemed to have been received when delivered to the address of the other Party, irrespective of whether any individual addressee has received the notice pursuant to an organisation’s internal postal arrangements; or
2. if sent by registered post on a normal business day, at 9.00am on the second business day subsequent to the day of posting or, if the notice was not posted on a business day, at 9.00am on the third business day subsequent to the day of posting. For the avoidance of doubt, a notice shall be deemed to have been received when delivered to the address of the other Party, irrespective of whether any individual addressee has received the notice pursuant to an organisation’s internal postal arrangements day, at 9.00am on the third business day subsequent to the day of posting; or
3. if sent by email, if sent within normal business hours when so sent or, if sent outside normal business hours at the next start of the normal business hours provided the sender has either received an electronic confirmation of delivery or has telephoned the recipient and confirmed with the recipient that the email has been received.
   1. Notices to the Sponsor shall be addressed to:  
      [INSERT CONTACT NAME & ADDRESS – INCLUDE EMAIL ADDRESS AS APPLICABLE]
   2. Notices to the Clinical Organisation shall be addressed to:

[INSERT CONTACT NAME & ADDRESS – INCLUDE EMAIL ADDRESS AS APPLICABLE]

|  |  |
| --- | --- |
| **HSE** | **OTHER PARTY** |
| Hospital Name:  Hospital Address:  Email:  Tel:  National Legal Contact:  Legal Contact: Ms Racheal Batten  General Counsel for Legal & Data Governance  Email: racheal.batten@hse.ie  Tel: +353 87 1437655 | Project Lead:  Email:  Tel:  Legal Contact:  Email:  Tel: |

## Dispute Resolution

* 1. In the event of a dispute arising under this Agreement, authorised representatives of the Parties will discuss and meet as appropriate (either in person or via remote means) to try to resolve the dispute within seven (7) days of being requested in writing by either Party to do so. If the dispute remains unresolved, it will then be referred to a senior manager from each of the Parties who will use all reasonable endeavours to resolve the dispute within a further fourteen (14) days.
  2. In the event of failure to resolve the dispute through the steps set out in Clause 20.1, the Parties agree to attempt to settle it by mediation. To initiate a mediation, either Party shall give notice in writing (“ADR Notice”) to the other Party requesting mediation in accordance with this clause 20.2. The Parties shall seek to agree the nomination of the mediator, but in the absence of agreement the mediator shall be nominated by the President for the time being of the Irish Medical Organisation. The person so appointed will act as an expert and not as an arbitrator. The mediation will start no later than twenty (20) days after the date of the ADR Notice. Save where otherwise agreed within mediation, the Parties shall share equally the costs of the independent third party. If the dispute is not resolved within thirty (30) days of the ADR Notice, either Party shall be entitled to submit to the exclusive jurisdiction of the Irish courts.
  3. Nothing in this Agreement shall prevent either Party from seeking an interim injunction in respect of a breach of this Agreement. For the avoidance of doubt, nothing in this Clause shall amount to an agreement that either of the Parties is entitled to an interim injunction or interdict as applicable.

## Miscellaneous

* 1. **Rights of Third Parties**

Nothing in this Agreement is intended to confer on any person who is not a party to this Agreement any right to enforce any term of this Agreement. Any right or remedy of a third party that existed or is available is not affected; in particular, without limitation, any right of any Clinical Trial Subject to claim compensation.

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

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

**Clause 1** Definitions

**Clause 3.2 to 3.7** Clinical Trial Governance

**Clause 4.14** Access, Research Misconduct and Regulatory Authorities

**Clause 5** Liabilities and Indemnities

**Clause 6** Medical Records

**Clause 7** Data Protection

**Clause 8** Freedom of Information

**Clause 9** Confidential Information

**Clause 10** Publicity

**Clause 11** Publications

**Clause 12** Intellectual Property

**Clause 15** Termination

**Clause 16** Relationship of the Parties

**Clause 17** Agreement and Modification

**Clause 18** Force Majeure

**Clause 19** Notices

**Clause 20** Dispute Resolution

**Clause 21** Miscellaneous

* 1. **Governing Law and Jurisdiction**

This Agreement is governed and construed in accordance with the laws of Ireland and the Irish courts shall have exclusive jurisdiction to hear any dispute relating to this Agreement.

* 1. **Counterparts and Signature**

This Agreement may be executed in any number of counterparts, each of which when executed shall constitute a duplicate original, but all the counterparts shall together constitute the one agreement. This Agreement may be executed through the use of an electronic signature. Transmission of the executed signature page of a counterpart of this Agreement by email (in PDF, JPEG or other agreed format) to the other Party shall take effect as delivery of an executed counterpart of this Agreement. If either method of delivery is adopted, without prejudice to the validity of the Agreement thus made, each Party shall provide the others with the original of such counterpart as soon as reasonably possible thereafter. No counterpart shall be effective until each Party has executed and delivered at least one counterpart.

|  |  |
| --- | --- |
| Signed for and on behalf of:  **[INSERT NAME OF SPONSOR ORGANISATION]**  Signature:  Title:  Date: | Signed for and on behalf of:  **[INSERT NAME OF CLINICAL ORGANISATION]**  Signature:  Title:  Date: |

# Appendix 1: Timelines and Responsibilities of the Parties

The milestones and division of responsibility set out below are provided as examples only. The milestones for each Clinical Trial are to be agreed between the Sponsor and the Clinical Organisation in accordance with the specific Clinical Trial arrangements that are applicable at each Site. Please remove this text once the document has been agreed for the Clinical Trial.

|  |  |  |  |
| --- | --- | --- | --- |
| **Milestone** | **Sponsor responsibility** | **Clinical Organisation responsibility** | **Target date for completion at Site** |
| Site Initiation visit | Yes | Yes | [ENTER DATE] |
| First Clinical Trial Subject enrolled | No | Yes | [ENTER DATE] |
| Last Clinical Trial Subject enrolled | No | Yes | [ENTER DATE] |
| All Case Report Form queries submitted | Yes | No | [ENTER DATE] |
| All Case Report Form queries completed | No | Yes | [ENTER DATE] |

# Appendix 2 – Financial Arrangements

**The Industry Costings Template should be used by the Sponsor to formulate the budget with respect to the Clinical Trial. When the template has been populated the agreed financial arrangements should form this Appendix.**

**Note**: This Appendix should only be used to specify financial matters and should not be used to include additional or different terms to those set out in the Agreement. The optional suggested wording below may be used or replaced/amended with specifically agreed wording.

**Please remove this text once the document has been agreed for the Clinical Trial.**

**Price and Payment Schedule**

Any costs or expenses not specified in the Clinical Trial Agreement or changes to the budget must be approved in advance in writing by the Sponsor. Without such approval, the Sponsor will not pay any additional costs, expenses or changes in budget.

All fees set out below are exclusive of VAT.

**Insert agreed Industry Costings Template**

For subjects who do not complete the study, payment will be made on a pro-rata basis according to the number of visits attended, depending upon the reason for withdrawal being satisfactorily documented.

The Sponsor agrees to reimburse all reasonable subject travel expenses. The Clinical Organisation will retain records of journeys made by subjects including receipts of travel if applicable.

Payment of the amounts due under this Agreement is subject to:

1. The Clinical Trial being completed in accordance with the Protocol
2. The Clinical Organisation providing to the Sponsor all requested documentation/receipts for expenses; and
3. The Principal Investigator complying with the terms of this Agreement.

Payment will be made when the data has been entered onto the EDC system and on submission of a valid invoice to the Sponsor by the Clinical Organisation.

All invoices relating to the Clinical Trial Agreement and subsequent amendments must quote the Purchase Order number XXXXXXXXXXXX. Invoices which do not display a valid Purchase Order number cannot be processed for payment and will be returned to the Clinical Organisation as disputed. The address stated on the invoice must be**: [INSERT ADDRESS]**

In order for invoices to be processed without delay, please ensure that invoices are emailed in an unzipped PDF format (1 invoice per email, quote PO number in subject line) to our Accounts Payable Department at **[INSERT ADDRESS]:**

**Payment will be made to:**

**Account Details:**

|  |  |
| --- | --- |
| Vendor Registered Name | Click or tap here to enter text. |
| Vendor Address | Click or tap here to enter text. |
| EIR Code | Click or tap here to enter text. |
| Phone | Click or tap here to enter text. |
| Fax | Click or tap here to enter text. |
| Email address | Click or tap here to enter text. |
| VAT Registration number | Click or tap here to enter text. |
| Bank Name | Click or tap here to enter text. |
| Bank Address | Click or tap here to enter text. |
| Account Number | Click or tap here to enter text. |
| IBAN Code | Click or tap here to enter text. |

# Appendix 3 – Conditions Applicable to the Principal Investigator

1. The Principal Investigator is free to participate in the Clinical Trial and there are no rights that may be exercised by, or obligations owed to, any third party that may prevent or restrict the performance by the Principal Investigator of the obligations set out in the Agreement.
2. The Principal Investigator is not the subject of any regulatory litigation or misconduct litigation or investigation. No data produced by the Principal Investigator in any other clinical trial has been rejected because of concerns as to its accuracy or because it was generated by fraudulent means.
3. The Principal Investigator has considered and is satisfied that facilities appropriate to the Clinical Trial are available at the Clinical Organisation and that in the performance of obligations under this Agreement, is satisfied that he/she will be supported by medical and other staff of sufficient number and experience to enable the Clinical Organisation to perform the Clinical Trial efficiently and in accordance with the obligations under this Agreement.
4. During the Clinical Trial, the Principal Investigator will not serve as principal investigator or sub-investigator in any clinical trial for another sponsor if such activity would adversely affect the ability of the Principal Investigator to perform his/her obligations under this Agreement.

# Appendix 4 – Material Transfer Provisions

Where the Protocol requires the Clinical Organisation to supply Material to the Sponsor this Appendix 4 shall apply.

**[DELETE THIS APPENDIXIF NOT APPLICABLE]**

1. In accordance with the Protocol, the Clinical Organisation shall send Material to the Sponsor or, in accordance with Section 7 below, to a third party nominated by the Sponsor.
2. The Clinical Organisation will arrange for the signed informed consent approved by the Principal Investigator, Sponsor and HRPA/Ethics Committee for the collection of Materials to be signed by the Clinical Trial Subject and shall collect and handle the Materials in accordance with such consent, applicable law (including, without limitation, Statutory Instrument No. 158 of 2006 (Quality and Safety of Human Tissues and Cells) Regulations) and as required by the Protocol.
3. Subject to Section 2 above, the Material is supplied without any warranty, expressed or implied, including as to its properties, merchantable quality, fitness for any particular purpose, or freedom from infection.
4. The Sponsor shall ensure, or procure through an agreement with the Sponsor’s nominee as stated in item 1 above, that:
   1. the Material is used in accordance with the consent of the Clinical Trial Subject and the approval of all Regulatory Authorities for the Clinical Trial and the Protocol;
   2. the Material is handled, used and stored in accordance with applicable law;
   3. the Material shall not be redistributed or released to any person other than in accordance with the Protocol or for the purpose of undertaking other research approved by an appropriate ethics committee and in accordance with the Clinical Trial Subject’s consent.
5. The Parties shall comply with all relevant laws, regulations and codes of practice governing the Clinical Trial and the use of human biological material.
6. The Clinical Organisation and the Sponsor shall each be responsible for keeping a record of the Material that has been transferred according to this Appendix 4.
7. To the extent permitted by law, the Clinical Organisation and its Personnel shall not be liable for any consequences of the supply to or the use by the Sponsor of the Material, or of the supply to or the use by any third party to whom the Sponsor subsequently provides the Material, or the Sponsor’s nominee as stated in Section 1 above, save to the extent that any liability that arises is a result of the negligence, wrongful acts or omissions or breach of statutory duty of the Clinical Organisation or its Personnel, or their failure to comply with the terms of this Agreement and the Sponsor shall indemnify and keep indemnified the Clinical Organisation in relation to any claims arising from or as a result of the supply to or use of the Materials by the Sponsor .
8. The Sponsor undertakes that, in the event that Material is provided to a third party in accordance with Section 1 above, it shall require that such third party shall undertake to handle any Material related to the Clinical Trial in accordance with all applicable statutory requirements and codes of practice and under terms no less onerous than those set out in this Appendix 4.
9. Unless otherwise agreed, any surplus Material that is not returned to the Clinical Organisation or retained for future research shall be destroyed in accordance with Statutory Instrument No. 158 of 2006 (Quality and Safety of Human Tissues and Cells) Regulations.

# Appendix 5 – Equipment and Resources

**[DELETE IF NOT APPLICABLE]**

1. Sponsor-Provided Equipment
   1. Sponsor will provide the CE-Marked equipment identified below (“Sponsor Equipment”) for use by the Clinical Organisation in the conduct or reporting of the Clinical Trial:

| **No.** | **Equipment** | **Estimated Original Value** | **Depreciation** |
| --- | --- | --- | --- |
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Where applicable, the Sponsor Equipment will be provided with current records of calibration and electrical safety testing.

1. Sponsor-Provided Resources
   1. Sponsor will provide the Sponsor owned or licensed proprietary resources identified below (“Sponsor Resources”) for use by the Clinical Organisation in the conduct or reporting of the Clinical Trial.
   2. Sponsor Resources Supplied: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Permitted Uses of Sponsor Equipment and Sponsor Resources
   1. The Clinical Organisation may use Sponsor Equipment and Sponsor Resources only for the purpose of this Clinical Trial.

[**Alternatively, specify permitted uses**. If use for non-Clinical Trial Subjects is permitted for Equipment, specify that (1) a charge will be assessed (deducted from Clinical Trial funding) based on estimated or actual usage or (2) the Clinical Organisation agrees that use of the Equipment for non-Clinical Trial Subjects will not be charged to the patient or third-party payer. Non-Clinical Trial use of Sponsor Resources is generally not permitted.]

1. Disposition of Sponsor Equipment and Sponsor Resources

**Alternative #1 – Return to Sponsor**

After completion of the Clinical Trial at the Site, or at an earlier time specified by Sponsor, the Sponsor will contact the Clinical Organisation to make arrangements for return of any [**Sponsor Equipment**] [and] [**Sponsor Resources**], at Sponsor’s expense, to the Sponsor or a location designated by Sponsor. The Clinical Organisation’s responsibilities under this Agreement for the [**Sponsor Equipment**] [and] [**Sponsor Resources**] will cease or transfer to the Sponsor at the time of removal from the Clinical Organisation.

**Alternative #2 – Return of Sponsor Resources to Sponsor and transfer of Sponsor Equipment to the Clinical Organisation with value included in funding.**

After completion of the Clinical Trial at the Site, or at an earlier time specified by Sponsor, the Sponsor will contact the Clinical Organisation to make arrangements for return of any [**Sponsor Equipment**] [and] [**Sponsor Resources**], at Sponsor’s expense, to the Sponsor or a location designated by Sponsor. The Clinical Organisation’s responsibilities under this Agreement for the [**Sponsor Equipment**] [and] [**Sponsor Resources**] will cease or transfer to the Sponsor at the time of removal from the Clinical Organisation.

The total compensation for Clinical Trial conduct allocated to the Clinical Organisation has been calculated to include the estimated depreciated value of Sponsor Equipment at the termination of this Agreement. The Sponsor will transfer title or arrange for transfer of title in Sponsor Equipment to the Clinical Organisation at the termination of this Agreement, provided that the Clinical Organisation (through the Principal Investigator) has enrolled the targeted number of Clinical Trial Subjects (or some other number of Clinical Trial Subjects agreeable to the Sponsor), has complied with the terms of the Agreement and has satisfactorily completed all Protocol requirements. The Sponsor will ensure that this transfer is documented in writing and the Parties hereby acknowledge and agree that the estimated depreciated value of Sponsor Equipment at termination of this Agreement is part of the total compensation payable for Clinical Trial conduct.

If any Sponsor Equipment is so transferred, it will be transferred ‘as is’ and Sponsor does not make any representation or provide any warranty of any kind concerning it.

**Alternative #3 – Return of Sponsor Resources to Sponsor and purchase of Sponsor Equipment by Clinical Organisation.**

After completion of the Clinical Trial at the Site, or at an earlier time specified by Sponsor, the Sponsor will contact the Clinical Organisation to make arrangements for return of any [**Sponsor Equipment**] [and] [**Sponsor Resources**], at Sponsor’s expense, to the Sponsor or a location designated by Sponsor. The Clinical Organisation’s responsibilities under this Agreement for the [**Sponsor Equipment**] [and] [**Sponsor Resources**] will cease or transfer to the Sponsor at the time of removal from the Clinical Organisation.

After completion of the Clinical Trial at the Site, Sponsor will make Sponsor Equipment available for purchase by the Clinical Organisation at its then depreciated value. If Clinical Trial conduct is completed significantly earlier or later than originally estimated, the depreciated value identified in the table above will be adjusted accordingly. The Sponsor will ensure that any transfer of ownership is documented in writing.

If any Sponsor Equipment is so transferred, it will be transferred ‘as is’ and Sponsor does not make any representation or provide any warranty of any kind concerning it.

1. Vendor-Provided Equipment or Resources
   1. **The Sponsor** will arrange for a vendor to provide the following equipment or proprietary materials (“Vendor Property”) for use in this Clinical Trial:

| **No.** | **Equipment** | **Estimated Original Value** | **Depreciation** |
| --- | --- | --- | --- |
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**Permitted Uses of Vendor Property**

The Clinical Organisation will use Vendor Property only for purposes of this Clinical Trial.

**[Alternatively, specify permitted uses.]**

1. Disposition of Vendor Property
   1. The Vendor will determine the disposition of Vendor Property after completion of the Clinical Trial at the Site.
2. Ownership, Responsibilities, and Liability
   1. **Ownership**: Sponsor Equipment and Sponsor Resources and Vendor Property are and remain for the duration of the Clinical Trial at the Clinical Organisation, the property of Sponsor, the Vendor or the licensor, as the case may be.
   2. **Liability**: Equipment and Resources Only.

**Alternative #1 – indemnity provided by this Appendix 5**

The Sponsor has no liability for damages of any sort, including personal injury or property damage resulting from the use of [**Sponsor Equipment**], [**Sponsor Resources**] [or] [**Vendor Property**] except to the extent that:

1. such damages were caused by the wilful misconduct, negligent acts or omissions of Sponsor or the Vendor; or
2. a personal injury to a Clinical Trial Subject is one covered by the State ClaimsAgency’s Clinical Trial Indemnity.

Sponsor shall be responsible for organising and ensuring payment for all costs associated with the routine maintenance of the [**Sponsor Equipment**], [**Sponsor Resources**] [and] [**Vendor Property**] and will replace the same at no cost to the Clinical Organisation in the event replacement of the foregoing is deemed required as a result of equipment failure or routine maintenance.

Subject to Clauses 5.4 of the Agreement, the Clinical Organisation shall be liable for any damage, loss or destruction of the [**Sponsor Equipment**], [**Sponsor Resources**] or [**Vendor Property**] and for any losses attributable to the [**Sponsor Equipment**], [**Sponsor Material**] [or] [**Vendor Property**] caused by the Clinical Organisation’s wilful misconduct, negligent acts or omissions. Under no circumstances shall the Clinical Organisation be liable for any damage caused as a result of using the equipment per instructions or due to normal wear and tear. To avoid doubt, the Clinical Organisation shall not insure the [**Sponsor Equipment**], [**Sponsor Material**] or [**Vendor Property**].

# Appendix 6 – Formal Delegation of Authority to a Corporate Affiliate to Contractually Bind Sponsor

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