Template Clinical Trial Agreement

(Template agreement for industry initiated and sponsored Clinical Trials, with human subjects, conducted in the Netherlands by academic (NFU) and non-academic (STZ) hospitals, Prinses Máxima Centrum voor Kinderoncologie and NKI/AvL)

Scope of use:

This template clinical trial agreement is created in joint cooperation between the Nationale Federatie van Universitair Medische Centra (NFU), the vereniging Samenwerkende Topklinische opleidingsZiekenhuizen (STZ), Vereniging Innovatieve Geneesmiddelen (previously Nefarma), Stichting Het Nederlands Kanker Instituut - Antoni van Leeuwenhoek Ziekenhuis (NKI/AvL), Prinses Máxima Centrum voor Kinderoncologie (Máxima), the Associatie van Contract Research Organisaties in Nederland (ACRON), to facilitate conducting clinical trials in the Netherlands. The clauses on termination and publication meet the Revised Directive on the Assessment of the Clinical Trial Agreement of the CCMO (Centrale Commissie Mensgebonden Onderzoek) of 2011.
In case a Contract Research Organisation (CRO) is signing this agreement on behalf of the Sponsor or in its own name, please note that depending on the Power of Attorney / Delegation of Authority given by Sponsor to the CRO (see Annex 8) please fill out Annex 8. Please note that also a separate indemnity letter signed by Sponsor may be needed.

This template can only be modified as agreed upon between the Parties for accommodating the correct party structure, study-specific requirements, financial arrangements or any other terms and conditions which are relevant for the purpose of the collaboration. During the negotiations any modifications should be marked and explained. When parties have agreed on the necessary modifications, the amendments will be incorporated into an annex of amendment. The template itself will not be adjusted. Mark-up version are only used in the negotiations.

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Clinical Trial Agreement

Clinical Trial: [*insert title*]

Protocol: [*insert EUDRACT number or Dutch Registration NL-number, date and version number*]

Study Drug: [*insert name*]

Effective date of agreement: [*date*]

The undersigned,

OPTION 1 ***if the Sponsor is signing on its own behalf, use this text:***

[*insert name of the Sponsor*], whose registered office is at [*insert address*], lawfully represented by [*insert name(s) and function(s)*], whose registered office is at [*insert address*] (hereinafter referred to as "**Sponsor**")]

OPTION 2 ***if the Sponsor is represented by its CRO in compliance with Annex 8, use this text*:**

[*insert name of the Sponsor*] whose registered office is at [*insert address*], lawfully represented by its CRO, whose registered office is at [*insert address of CRO*], in accordance with the power of attorney as set forth in **Annex 8** by [*insert name(s) and function(s)*], (hereinafter referred to as the "**Sponsor**")]

and

[*insert name of institution*], whose address is at [*insert address*], lawfully represented by [*insert name(s) and function(s)*]
(hereinafter referred to as "**Institution**")

[N.B. In case the "medisch specialistisch bedrijf" will cosign the agreement, the following text can be used for the Institution:]

"[*Name of the hospital*], located at [*address*], , lawfully represented by [*name and function*] (hereinafter referred to as "[*name of hospital*]"; and
[*name of medisch specialistisch bedrijf*], located at [*address*], , lawfully represented by [*name and function*] (hereinafter referred to as "[*name of MSB*]";
(hereinafter [*name of hospital*] and [*name of MSB*] jointly referred to as "Institution")"

[If the Principal Investigator is not an employee of the Institution and acts as a Party:]

and

[INVESTIGATOR], [*insert name of physician …», …[function], [tax/office address and chamber of commerce registration number, if applicable*]
(hereinafter referred to as "**Principal Investigator**")]

[Or if the Principal Investigator is an employee of the Institution and not a Party:]

in the presence of Institution's employee, [INVESTIGATOR] [*insert investigator's title, name and department of the Institution where the investigator is employed*], the supervisor under whose responsibility the conduct of the Clinical Trial will be carried out (hereinafter referred to as "**the Principal Investigator**")

WHEREAS, the Sponsor is a pharmaceutical company involved in research, development, registration, manufacture and/or sale of medicines for use in humans;

WHEREAS, the Sponsor has designed the Clinical Trial identified hereof, to evaluate Sponsor's drug [*insert study drug(s)*] ("**Study Drug**") in accordance with the Protocol; and

[**ONLY INSERT IF APPLICABLE**] WHEREAS, the Sponsor contracted the CRO to perform one or more of a Sponsor's clinical trial-related duties and functions as summarized in the Power of Attorney / Delegation of Authority attached herein as **Annex 8** [and to enter into this Agreement on the Sponsor's behalf];

WHEREAS, the Principal Investigator and the Institution are involved in the diagnosis, treatment and prevention of disease and/or clinical research for the improvement of healthcare;

WHEREAS, the Institution has facilities and personnel with the requisite skills, experience, and knowledge required to support the performance of the Clinical Trial by the Principal Investigator; and

WHEREAS, the Principal Investigator, having reviewed the Protocol for the Clinical Trial, the investigator brochure and having been supplied with sufficient information by the Sponsor regarding the Investigational Medicinal Product in order to evaluate and determine his/hers interest in participating in the Clinical Trial, wishes to participate in the Clinical Trial and the Principal Investigator assures that he/she has sufficient authority, competence and experience in conducting clinical trials.

WHEREAS, clauses in this Agreement include the Dutch translation of specific terms Parties consider that those terms have the meaning of the Dutch terms in the Dutch legal system and context.
In consideration of the undertakings and commitments set forth herein, the Parties agree to enter into this Agreement.

1. DEFINITIONS

The following words and phrases have the following meanings:

- "**Affiliate**" means any business entity which controls, is controlled by, or is under the common control of either party. 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 or to elect or appoint 50% or more of the members of the management of such business entity;
- "**Agent**" shall include, but shall not be limited to, any person providing services to a Party under a contract for services or otherwise, to include without limitation any pharmacist, clinical chemist, nurse or other health professional.
- "**Agreement**" means this agreement comprising its recitals, clauses, schedules and any appendices attached to it, including the Protocol and including any amendments to the Agreement agreed between the Parties;
- "**Auditor**" means a person 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, the Standard Operating Procedures of the Sponsor, ICH GCP and the applicable regulatory requirements;
- "**Clinical Trial**" means the investigation to be conducted at the Trial Site in accordance with the Protocol;
- "**Clinical Trial Authorisation**" means the authorization of a Clinical Trial authorised in accordance with the Law;
- "**Clinical Trial Data**" means all data and information arising from the Clinical Trial which may include Personal Data of a Clinical Trial Subject except for a Clinical Trial Subject's medical records;
- "**Clinical Trial Subject**" means an individual who participates in the Clinical Trial, who signed the ICF and will participate or is participating either as recipient of an Investigational Medicinal Product or as a control;
- "**Competent Authority**" means any relevant governmental authority, regulatory authority, ethics committee or other body responsible under Applicable Law for the approval, assessment, supervision, and oversight of clinical trials, including any required notifications or submissions via CTIS; In the Netherlands, this includes, where applicable, the Dutch Committee for Human Research (CCMO), an accredited Medical Research Ethics Committee (METC) and any other authority or body exercising such functions under Applicable Law;

- "**Confidential Information**" means information provided by a Party (the Disclosing Party) to the other Party (the Receiving Party) or to any other of such Receiving Party's employees or Agents, and means all information (including, without limitation, study protocols, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of the Disclosing Party or the Disclosing Party's Affiliates that are provided in connection with this Agreement or the Clinical Trial. The Sponsor's Confidential Information shall also include information relating to the Study Drug, Clinical Trial Data, results, or reports created by the Institution, Principal Investigator, or Research Staff in direct connection with the Clinical Trial (except for a Clinical Trial Subject's medical records); and cumulative Clinical Trial Data, results, and reports from all sites conducting the Clinical Trial;
- **"Controller"** means controller as defined in the GDPR;
- "**CRF**" means the case report form in a format prepared by the Sponsor and documenting the administration of the Investigational Medicinal Product to Clinical Trial Subjects as well as all tests and observations related to the Clinical Trial;
- "**eCRF**" means a CRF in electronic form;
- "**CRO**" means Contract Research Organisation which is the organisation which can be contracted by a sponsor. The tasks and obligations that might be executed by the CRO on behalf of the Sponsor are defined a delegation of authority and/or a power of attorney / limited agency agreement, as applicable, which will be included as **Annex 8**;
- "**Data Subject**" means data subject as defined in the GDPR;
- "**Effective Date**" the date this Agreement comes into effect, being the date set forth in this Agreement in the cadre on page 4 of this Agreement;
- "**ICF**" means the informed consent form as approved by the Competent Authority, in which the Clinical Trial Subject consents to his/her participation in the Clinical Trial;
- "**ICH-GCP**" means the ICH E6(R3) guideline for good clinical practice (GCP);
- "**Independent Committee**" means a committee such as a Data and Safety Monitoring Board (DSMB), which is a group of individuals with pertinent expertise that have oversight of and reviews on a regular basis accumulating data from one or more ongoing clinical trials and that advise the Sponsor regarding the continuing safety of Clinical Trial Subjects and those to be recruited to the Clinical Trial, as well as the continuing validity and scientific merit of the Clinical Trial;
- "**Intellectual Property Rights**" means patents, trademarks, trade names, service marks, domain names, copyrights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the 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 Medicinal Product**" means the Study Drug and its comparator or placebo (if applicable) as further detailed in the Protocol;

- "**Know How**" means all technical and other information which is not in the public domain (other than as a result of a breach of confidence), including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, the Investigational Medicinal Product, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, Clinical Trial 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;
- "**Law**" means any applicable international, European Union and Dutch law and regulations, as well as generally accepted international conventions applicable to the performance of the Clinical Trial. Such Law including, but not limited to:
    - Directive 2005/28/EC and Regulation 536/2014/EU of the European Parliament and the Council relating to medicinal products for human use and in guidance published by the European Commission pursuant to such Directives and any implementation in the Institution's national Law,
    - ICH E6(R3) guideline for good clinical practice (GCP),
    - Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation or GDPR), and any applicable national implementing legislation.
    - the Dutch Medical Research Involving Human Subjects Act (Wet Medisch-wetenschappelijk Onderzoek met Mensen or WMO),
    - the Dutch Medical Treatment Agreements Act (Wet op de geneeskundige behandelingsovereenkomst or Wgbo),
    - the Directives on "the assessment of Clinical Trial Agreements (2011)" and on "External Review (2012)" issued by the CCMO,
    - the principles of the Dutch Code of Conduct for Health Research (COREON, 2022), and
    - the Declaration of Helsinki, the most recent version.

    References to EU Council Directives and Dutch Law include any amendments or replacements of such Law.
- "**Party**" means the Sponsor, the Institution or, only if the Principal Investigator is a separate party to this Agreement, the Principal Investigator, and "Parties" shall mean all of them. CRO shall not be included in the definition of Parties and to the extent necessary specific CRO obligations are indicated throughout;
- "**Personal Data**" means personal data as defined in the GDPR;
- **"Personal Data Breach"** means a personal data breach as defined the GDPR;
- "**Principal Investigator**" means an investigator who is the responsible leader of a team of investigators who conduct a clinical trial at the Trial Site or any other person as may be agreed between the Parties as a replacement;
- **"Processor"** means processor as defined in the GDPR;

- "**Protocol**" means the document that describes the objectives, design, methodology, statistical considerations and organisation of the Clinical Trial, signed by the Principal Investigator, as defined in the cadre on page 4 of this Agreement, a copy of which is at **Annex 1** to this Agreement. The Protocol includes all amendments thereto for which Clinical Trial Authorisation has been obtained;
- "**Research Staff**" means the persons who will undertake the conduct of the Clinical Trial at the Trial Site on behalf of the Institution and/or the Principal Investigator and under the supervision of the Principal Investigator;
- "**Samples**" means any human biological materials, including but not limited to blood, body tissue, plasma and any other material containing human cells;
- "**Site Parties**" shall refer to the Principal Investigator and the Institution jointly, regardless whether the Principal Investigator acts as a Party to the Agreement;
- "**Sponsor**" means the Party which takes responsibility for the initiation, for the management and for setting up the financing of the clinical trial as set out in Article 2.1.(14) CTR;
- **"Study Drug"** means the Sponsor's medicinal product being tested in the Clinical Trial, as referred to in the cadre on page 4 of this Agreement;
- "**Target**" means the estimated number of Clinical Trial Subjects to be included in the Clinical Trial as referred to in clause 5.2;
- "**Timelines**" means the dates set out in **Annex 2** hereto as may be amended by agreement between the Parties and "Timeline" shall mean any one of such dates;
- "**Trial Monitor**" means one or more persons appointed by the Sponsor to monitor compliance of the Clinical Trial with GCP and the Protocol and to conduct source data verification;
- "**Trial Site**" means the premises at the Institution where the Clinical Trial will be conducted.

2. OBLIGATIONS

2.1 The Parties shall perform the Clinical Trial in accordance with the terms and conditions of this Agreement.

2.2 The Parties represent and warrant that they each have the authority to enter into this Agreement. In case the Principal Investigator is not a party to this Agreement, the Institution shall ensure the performance of the responsibilities assigned to the Principal Investigator under this Agreement and by no means shall the Principal Investigator be liable hereunder in person. The Institution will ensure the availability of and/or access to any resources necessary to perform the Clinical Trial at the Trial Site, including departments, facilities and Research Staff and support personnel, and the Institution certifies that Principal Investigator holds the necessary registration and has the necessary qualifications, expertise and time to perform the Clinical Trial.

2.3 The Institution shall notify the Sponsor if the Principal Investigator ceases to be associated with the Institution where the Clinical Trial will be conducted or if he/she is otherwise unavailable to continue as Principal Investigator, and the Institution (or Principal Investigator, if he/she is a Party to this Agreement) shall use all reasonable endeavours to find a qualified successor acceptable to the Sponsor, subject to the Principal Investigator's overriding obligations in relation to Clinical Trial Subjects and individual patient care.

2.4 The Institution shall procure the performance of the obligations of the Research Staff as set out in this Agreement.

2.5 The Institution, and if the Principal Investigator is a Party, the Principal Investigator, will guarantee the availability of sufficient and adequately trained and experienced Research Staff. This will include the participation of the Principal Investigator and Research Staff in any training provided by the Sponsor reasonably required for the sound conduct of the Clinical Trial.

2.6 The Institution ensures that subject to the Principal Investigator's overriding obligations in relation to Clinical Trial Subjects and individual patient care, the Principal Investigator shall not, and the Institution shall ensure that the Research Staff shall not, during the term of this Agreement conduct any other trial which will jeopardize the Principal Investigator's ability to recruit, enrol and study the required cohort of Clinical Trial Subjects.

2.7 Terms and conditions on any equipment provided by the Sponsor, shall be described in **Annex 5**.

2.8 The Site Parties acknowledge that the Sponsor and their respective Affiliates and/or subsidiaries need to adhere to the provisions of (i) the Bribery Act 2010 of the United Kingdom ("**Bribery Act**"); (ii) the Foreign Corrupt Practices Act 1977 of the United States of America ("**FCPA**") and (iii) any other applicable anti-corruption legislation (together the ***Applicable Anti-Corruption Legislation***). A summary of the key principles underlying the Bribery Act and the FCPA is set out in **Annex 6**. The Institution and the Principal Investigator shall not permit nor induce employees, agents, consultants nor other representatives, whether directly or indirectly, to engage in any activity that is prohibited by the Applicable Anti-Corruption Legislation including bribery, kickbacks, payoffs or other corrupt business practices, as outlined in the summary in **Annex 6**. Sponsor shall be responsible for keeping the summary up to date in case of any changes to the Bribery Act and the FCPA affecting the Clinical Trial.

3. CLINIAL TRIAL GOVERNANCE AND COMPLIANCE

3.1 The Sponsor shall obtain and maintain Clinical Trial Authorisation for the Clinical Trial and substantial amendments to the Protocol. The Sponsor may require, by written notice the Principal Investigator to apply for the Clinical Trial Authorisation for the Sponsor, in which case the Principal Investigator shall keep the Sponsor fully apprised of the progress of Competent Authority submissions and shall upon request provide the Sponsor with all correspondence relating to such submissions.

3.2 The Principal Investigator shall not consent to any change in the Protocol requested by the Competent Authority without the prior written consent of the Sponsor.

3.3 In the event of any substantial amendments being made to the Protocol, the amendments shall be signed by the Principal Investigator and shall be implemented by the Research Staff as required by the Sponsor after approval of the amendments by the Competent Authority .

3.4 The Clinical Trial shall be performed at the Trial Site. The Principal Investigator shall obtain authorisation from the representatives of the Trial Site to perform the Clinical Trial at the Trial Site, which shall include but not be limited to the engagement of sub-investigators, to the extent applicable the pharmacist of the Institution (unless a separate Pharmacy Agreement is made as set out in clause 7.1), clinical chemists, and the Research Staff required to perform the Clinical Trial as set out in this Agreement.

3.5 The Sponsor shall use the Clinical Trials Information System (CTIS) to apply to run a clinical trial.

3.6 The Parties shall conduct the Clinical Trial in accordance with:

a. the Agreement;
b. the Protocol;
c. the terms and conditions of the Clinical Trial Authorisation granted by the Competent Authority; and
d. the Law.

3.7 The Site Parties shall make and retain records regarding the Clinical Trial as required by the Protocol, the Law, and in accordance with the Institution's standard archiving procedures. The Institution will retain such records for a minimum of time as required by the Law. If indicated by the Sponsor that such is reasonably required for regulatory purposes, Institution shall retain the records for a longer period of time at the Sponsor's expense.

3.8 The Site Parties shall notify the Sponsor of any adverse events in a manner and time frame in accordance with the Protocol and the Law, (in particular Clause 41 and 42 CTR), and will cooperate with the Sponsor in connection with any reports or filings related to such adverse event.

4. LIABILITIES, INDEMNIFICATION AND INSURANCE

4.1 Subject to the limitations set out hereinafter, Sponsor shall indemnify (in Dutch "*schadeloosstellen*") and hold harmless (in Dutch "*vrijwaren*") Institution, its employees, Agents, the Principal Investigator and the Research Staff (the "**Indemnitees**") against all claims, demands, actions or proceedings (to include any settlements or ex gratia payments made with the consent of the Parties hereto and reasonable legal and expert costs and expenses) made or brought:

a. by or on behalf of any Clinical Trial Subject in connection with personal injury or death – including also costs for medical treatment in relation to such injury or death – arising out of the administration or use of the Investigational Medicinal Product during or as a result of the Clinical Trial, or of any clinical intervention or procedure provided for or required by the Protocol, to which the Clinical Trial Subject would not have been exposed but for its participation in the Clinical Trial.
In addition, Sponsor shall reimburse Institution for reasonable and necessary medical costs and expenses incurred for the Clinical Trial Subject who has suffered personal injury as described above if not already compensated otherwise.

b. by or on behalf of any Clinical Trial Subject or by a data protection authority for a Personal Data breach, as defined in the Law, which is attributable to Sponsor, its Affiliates or Agents.

4.2 Sponsor's indemnification and defence of the Indemnitees shall not apply to any claim or proceeding pursuant to clause 4.1, and Sponsor shall not be liable

a. to the extent that said personal injury (including death) is caused by any of the Indemnitees' failure to comply with this Agreement including Sponsor's written instructions related to the use of the Investigational Medicinal Product); or

b. to the extent that said personal injury (including death) is caused by gross negligence, willful recklessness or willful conduct or willful misconduct (in Dutch: *bewuste roekeloosheid, of opzettelijk handelen of nalaten*) of any of the Indemnitees; or

c. if any of the Indemnitees shall have made any admission in respect of such claim or proceeding or taken any action relating to such claim or proceeding prejudicial to the defence of it, without the written consent of Sponsor. This condition shall not be treated as breached by any statement required to be made by any of the Indemnitees where such a statement is required by Law or in connection with the operation of Institution's internal complaint procedures, accident reporting procedures or disciplinary procedures, provided that the aforementioned statement of Indemnitee does not contain an admission of guilt or acknowledgment of liability on behalf of Sponsor.

4.3 Sponsor shall keep Site Parties reasonably informed of the progress of any such claim or proceeding.

4.4 The Parties will each use their reasonable endeavours to inform each other promptly of any circumstances reasonably thought likely to give rise to any claim or proceeding resulting from the Clinical Trial of which it is directly aware. Parties shall keep each other reasonably informed of developments in relation to any such claim or proceeding. The Parties will use reasonable efforts to consult with each other on the nature of any defence to be advanced.

4.5 Institution, Principal Investigator and Sponsor will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding made or brought by or on behalf of Clinical Trial Subjects (or their dependants).

4.6 Nothing in this clause 4 shall operate so as to restrict or exclude the liability of any Party vis-à-vis the Clinical Trial Subjects in relation to their death or personal injury caused by the negligence of that Party or their servants or employees or to restrict or exclude any other liability of a Party which cannot be so restricted or excluded by Law.

4.7 In no circumstances shall any Party be liable to the other in contract or otherwise howsoever arising or whatever the cause thereof, for any indirect or consequential damages of any nature, such as but not limited to any loss of profit, business, goodwill, reputation, contracts, revenues or anticipated savings which arise directly or indirectly from any default on the part of Sponsor, Institution or the Principal Investigator, except and to the extent such damages

a. shall be covered under and paid out of any insurance policy of the liable party, or
b. are caused by gross negligence, willful recklessness or willful conduct or willful misconduct (in Dutch *bewuste roekeloosheid, of opzettelijk handelen of nalaten*) of any of the Indemnitees and cannot be so restricted or excluded by Law.

4.8 The liability of the Site Parties for a claim or proceeding of Sponsor under this Agreement shall be limited to an amount of three (3) times the total contract sum which is payable out under this Agreement, or the amount covered and paid out under the insurance policy taken out in accordance with clause 4.11 below, whichever is the highest, unless such limitation is excluded by the Law.

4.9 The limitation of the liability pursuant to clause 4.8 does not apply to the extent such claim or proceeding is made for damages caused by: gross negligence, willful recklessness or willful conduct or willful misconduct (in Dutch: *bewuste roekeloosheid, of opzettelijk handelen of nalaten*) of any of the Site Parties.

4.10 Sponsor will take out or maintain:

a. insurance cover in respect of its potential liability for damages to Clinical Trial Subjects resulting from the Clinical Trial in accordance with the requirements set out in the (Dutch) Medical Research Involving Human Subjects Act and the Decree on Obligatory Insurance for Medical Studies involving Human Subjects unless this requirement has been waived by the Competent Authority; and

b. further appropriate insurance cover that it reasonably deems necessary in respect of its other potential liability under this Agreement. Sponsor shall produce to Institution, on request, copies of such insurance certificates. Except for the limitations stated in clause 4.7 above, the terms of any insurance or the amount of cover shall not relieve Sponsor of any liabilities under this Agreement.

4.11 Institution as it reasonably deems necessary, will take out and maintain an adequate insurance to cover (potential) liability of Institution, the Research Staff, the Principal Investigator and any other employees and Agents involved with the conduct of the Clinical Trial pursuant to this Agreement. Institution shall produce to Sponsor, on request, copies of insurance certificates, together with evidence that the policies to which they refer remain in full force and effect during the term of this Agreement and any period thereafter as may be required by mandatory law. Except for the limitations stated in clause 4.7 and 4.8 above, the terms of any insurance or the amount of cover shall not relieve Institution or the Principal Investigator of any liabilities under this Agreement. Where the Institution cannot cover Agents under its insurance, it shall verify that such Agents have sufficient insurance and inform the Sponsor of such insurance upon request.

5. CLINICAL TRIAL SUBJECT RECRUITMENT AND ENROLMENT

5.1 The Institution shall make sure that the Clinical Trial Subjects (and/or their legal representatives) will, in accordance with the Law, be duly informed and that each give his or her informed consent prior to his participation in the Clinical Trial.

Prior to usage of Clinical Trial recruitment materials to recruit Clinical Trial Subjects by the Institution, the Institution needs written approval from the Sponsor. Clinical Trial recruitment materials are all materials used in recruitment of potential Clinical Trial Subjects (including ICF) regardless of the medium.

5.2 The Institution, through its Principal Investigator, shall use reasonable endeavours to recruit the Target of Clinical Trial Subjects within the Timelines. The Target and Timelines in this clause are specified in **Annex 2**. As soon as the Principal Investigator expects to reach the Target, the Principal Investigator shall notify the Sponsor.

5.3 If circumstances will or are likely to substantially delay the recruitment and/or enrolment of the Clinical Trial Subjects, the Principal Investigator shall without undue delay inform the Sponsor in writing. In each such event the Parties shall discuss the consequences of the delay and each Party shall undertake reasonable endeavours to agree on measures to minimise the delay.

5.4 In the event that the Clinical Trial is part of a multi-centre clinical trial, the Sponsor may amend the number of Clinical Trial Subjects to be recruited pursuant to the Target as per clause 5.2 subject to this clause 5.4.

a. The Sponsor may require further recruitment of Clinical Trial Subjects at the Trial Site to cease if:
    i. in the reasonable opinion of the Sponsor recruitment of Clinical Trial Subjects at the Trial Site will not or will not likely meet the Target within the Timelines; or
    ii. if the global recruitment target for the Clinical Trial has been reached through other clinical trial centres.
b. The Principal Investigator will be informed by Sponsor promptly if the global recruitment target for the Clinical Trial has been reached through other trial sites.
c. Upon receipt of a notice subject to clause 5.4, the Principal Investigator shall immediately stop the recruitment and inclusion of Clinical Trial Subjects.
d. The terms and conditions of this Agreement regarding the Clinical Trial Subjects shall also apply to individuals who, at the time of receipt of such notice, have signed the ICF. Payments shall only be made according to the number of Clinical Trial Subjects recruited and included up to the date of receipt of the notice. The Sponsor will not take any responsibility or have a duty to make any payment for the Clinical Trial Subjects recruited after the date of receipt of such notice.
e. If recruitment of Clinical Trial Subjects is proceeding at a rate above the one required to meet the relevant Timelines the Sponsor may with the written consent of the Principal Investigator increase the number and amend the number of Clinical Trial Subjects to be recruited and enrolled at the Trial Site.

6. QUALITY ASSURANCE AND CONTROL

6.1 The Site Parties shall comply with all procedures defined in the Protocol, in order to ensure that all data generated at the Trial Site are reliable and have been processed correctly (including the randomisation lists, and the blind character of the Clinical Trial as the case may be). The Site Parties shall ensure that the content of the CRFs or e-CRFs accurately reflect source documents. The Principal Investigator and any member of the Research Staff will be trained by the Sponsor with respect to the use of eCRFs.

6.2 The Site Parties will permit the Sponsor via its Trial Monitor to examine the conduct of the Clinical Trial and the Trial Site upon reasonable prior notice and in the company of a Site Party's representative, during regular business hours at mutually agreed times, and at the Sponsor's sole expense to determine that the Clinical Trial is being conducted in accordance with the Protocol, this Agreement and the Law, provided that Trial Monitor will comply with all internal policies and regulations of the Trial Site to the extent these are sufficiently communicated to the Trial Monitor. Upon request from the Sponsor, the Site Parties may permit remote electronic access to Clinical Trial records when implemented at the Trial Site and permitted under the Law. Site Parties will not withhold the aforementioned permission on unreasonable grounds.

6.3 The Site Parties shall permit the Trial Monitor and any Auditor access to the Trial Site and all relevant clinical data of Clinical Trial Subjects and relevant source documents for monitoring of the progress of the Clinical Trial, the proper collection and recording of Clinical Trial Data, the welfare of the Clinical Trial Subjects, and altogether the good quality of the Clinical Trial and its compliance with the Law and explicitly agreed standard operating procedures regarding monitoring as that will then be attached to this agreement as an annex.

For the avoidance of any doubt, the Sponsor shall be responsible for the confidential handling of all Personal Data of Clinical Trial Subjects and other patients which the Trial Monitor and any Auditor comes across with during its monitoring or auditing activities. Before the start of the monitoring visits, the Sponsor shall provide the Institution with adequate information to identify the appointed Trial Monitor and the Institution shall arrange authorisation for the on-site monitoring. Sponsor warrants that such Trial Monitor has signed a confidentiality statement regarding the above.

6.4 The Site Parties shall promptly inform the Sponsor of any intended or actual inspection, written enquiry and/or visit to the Trial 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 Site Parties shall allow the Sponsor and/or its Agents to be present during any such visit as permitted by Law. The Institution will, if legally permissible, promptly forward to the Sponsor copies of any inspection findings that Institution receives in relation to the Clinical Trial. Whenever feasible and permitted by Law, the Site Parties will also provide the Sponsor with an opportunity to prospectively review and comment on any responses to regulatory authority GxP inspections regarding the Clinical Trial.

6.5 The Site Parties shall permit authorised representatives of the Competent Authority, to have access to, copy and verify information relating to the Clinical Trial, and inspect the Trial Site as required by and in accordance with the Law.

The Sponsor acknowledges and agrees that the Institution executive management (or a local review board appointed by such management) will have the right to audit the performance of the Clinical Trial at the Trial Site.

The Parties acknowledge that the Clinical Trial and the Trial Site is subject to inspection by regulatory authorities worldwide and that such inspections may occur after the completion of the Clinical Trial.

6.6 In the event that the Sponsor reasonably believes that there has been any research misconduct in relation to the Clinical Trial at the Study Site, the Site Parties shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Sponsor. The results of which the Party on whose behalf the investigation was undertaken shall, subject to any obligations of confidentiality, be communicated to the Principal Investigator.

In the event that the Principal Investigator reasonably believes there has been any research misconduct in relation to the Clinical Trial at the Study Site or at the Sponsor, the Sponsor shall provide all reasonable assistance to any investigation undertaken by or on behalf of the Principal Investigator, the results of which shall, subject to any obligations of confidentiality, be communicated to the Sponsor.

6.7 The Site Parties shall take appropriate measures and cause the Research Staff to take appropriate measures and corrective actions without delay as the Sponsor may reasonably require in order to solve any problems found and reported by the Trial Monitors and any of the aforesaid Auditors, or representatives of the Competent Authority or other regulatory authority.

6.8 The Parties agree that

a. the Sponsor will not compensate the Principal Investigator nor any member of the Research Staff for the assistance or guidance of representatives of the Competent Authority or other regulatory authority and
b. the assistance or guidance of Trial Monitors or by the Sponsor appointed Auditors by the Principal Investigator and the Research Staff shall be deemed included in the remuneration paid pursuant to clause 14 unless expressly agreed otherwise in writing.

7. INVESTIGATIONAL MEDICINAL PRODUCTS

7.1 The Parties acknowledge and agree that the Institution's pharmacy, or such other pharmacy as appointed by the Parties, will be responsible for certain tasks in relation to the handling of the Investigational Medicinal Product. Any agreements between the pharmacy and any Party need to be in writing and must be in accordance with the Institution's internal policies. Any such agreements will be attached to this Agreement as **Annex 4**.

7.2 Subject to the Agreement as set forth in clause 7.1, the Sponsor will provide the Principal Investigator and the pharmacy with all necessary information on the Investigational Medicinal Product(s), quality and handling instructions thereof and sufficient quantities needed to conduct the Clinical Trial free of charge.

7.3 The Site Parties shall not use or permit the Research Staff or any third party to use the Investigational Medicinal Product for any purpose other than the conduct of the Clinical Trial. Upon termination or expiration of this Agreement all unused Investigational Medicinal Product shall, at the Sponsor's option, either be returned to the Sponsor or disposed of in accordance with the Protocol or the Sponsor's written instructions.

8. DATA PROTECTION

8.1 Each Party will process Personal Data in accordance with the GDPR and any other applicable laws or regulations covering the protection of Personal Data (collectively "Data Protection Law") and taking into account the description of the data that is Personal Data processed under the Agreement as set out in **Annex 9.**

8.2 Each Party shall notify the other Party(/ies) immediately if this Party reasonably suspects that processing of Personal Data or any instruction pertaining to this Agreement constitutes a violation of Data Protection Law.

8.3 Within reasonable boundaries Parties shall fully cooperate to provide each other assistance, including taking measures reasonably necessary to comply with Data Protection Law.

Right of access, rectification, erasure, restriction and objection

8.4 The Institution shall – (also) on behalf of the Sponsor – provide the Clinical Trial Subject with information regarding its rights referred to in articles 13 and 14 of the GDPR to the Clinical Trial Subject, for example through the ICF.

8.5 In the event a Party receives a complaint, notice, request or communication that directly or indirectly affects the processing of the Personal Data regarding the execution of this Agreement or on a Party's compliance with Data Protection Law related to the conduct of the Clinical Trial (including without limitation a request from a Data Subject to exercise its rights under Data Protection Law), the Parties shall:

a. without undue delay inform the other Party(/ies) of any such complaint, notice, request or communication received;
b. provide reasonable assistance to the other Party(/ies) in the handling of any such complaint, notice, request or communication;
c. fulfill their obligations arising from this clause 8.5 as far as allowed under the Data Protection Law and while maintaining the confidentiality of the Personal Data of de the Data Subject as far as possible.

8.6 For reasons of uniformity between participating institutions, and to ensure the Clinical Trial is not jeopardized, the Sponsor and the Institution will decide together upon the action to be taken pursuant to the exercise of the Data Subject right as referred to in clause 8.5 all to the extent necessary for compliance with Data Protection Law.

8.7 Each Party shall promptly notify the other Party(/ies) of any withdrawal of or changes in the consent of a Data Subject. The procedure followed upon a withdrawal of a Data Subject's consent will be according to the instructions in the Protocol and the ICF and in accordance with the Law.

Security of processing

8.8 Both the Sponsor and the Institution shall implement appropriate technical and organisational measures to meet the requirements of Data Protection Law in their respective premises, systems or processing activities under their respective control, including appropriate technical and organisational measures to protect the Personal Data against accidental or unlawful destruction or accidental loss, alteration, unauthorized disclosure or access, which provide a level of security appropriate to the risk represented by the processing and the nature of the data to be protected. At the very least, the measures shall include the following:

a. measures designed to guarantee that only authorised employees can access the Personal Data for the purposes outlined;
b. measures involving only granting employees access to the Personal Data through individual named accounts, with the use of said accounts being adequately logged and with the accounts concerned only granting their users access to those Personal Data whose access is necessary for the Party concerned;
c. measures designed to protect the Personal Data from unintentional or unlawful destruction, unintentional loss or changes and unauthorised or unlawful retention, processing, access or disclosure;
d. measures designed to identify weaknesses with regard to the processing of the Personal Data;
e. measures designed to guarantee that the Personal Data are available when due; and
f. measures designed to guarantee that the Personal Data are separated in a sensible manner from the Personal Data each Party processes on its own behalf or on third parties' behalf.

8.9 The Parties acknowledge that security requirements change from time to time and that effective security requires frequent assessments and regular updating of outdated security measures. Therefore, the Parties shall periodically evaluate their own measures implemented by virtue of clause 8.8 of this Agreement, and, where necessary, shall update said measures so as to ensure that the obligations arising from clause 8.8 of this Agreement continue to be fulfilled.

8.10 Each Party shall keep records within the meaning of article 30 of the GDPR of the processing activities performed by that Party pursuant to this Agreement.

Personal Data Breach obligations

8.11 If a Party becomes aware of a Personal Data Breach pertaining to this Agreement, that Party shall within 24 hours after the discovery of such breach notify the other Party(/ies). In such case each Party will cooperate with the other Party to the extent reasonable in fulfilling the (statutory) notification obligations of either Party in a timely manner. Each Party will ensure that it provides the other party with clear contact details of who to inform in regard to this this clause 8.11, for example by including the details in the Protocol or as an addition to **Annex 7**.

8.12 Without prejudice to the other obligations arising from this clause 8, the affected Party shall be required to implement any measures it can be reasonably expected to implement so as to undo the damage caused by a Personal Data Breach as referred to in clause 8.11 as soon as possible or minimise further consequences to the maximum extent possible. The affected Party shall consult the other Party(/ies) without delay so as to make further arrangements regarding the foregoing.

8.13 Each Party shall be responsible for its respective notification and related costs and remedies related to a Personal Data Breach, unless otherwise specified in this Agreement.

Confidentiality of Personal Data

8.14 Each Party shall adhere to the principles of medical confidentiality in relation to the Clinical Trial Subjects.

8.15 Each Party will safeguard that their employees who have access to the Personal Data maintain the confidentiality of Personal Data and only process the Personal Data in compliance with this Agreement.

8.16 The Institution ensures that Personal Data related to Clinical Trial Subjects, when supplied to the Sponsor, will be pseudonymized to replace any information that directly identifies a Clinical Trial Subject with a subject identification code. Site Parties will not provide the Sponsor with the key or code that enables Clinical Trial Subjects to be re-identified.

8.17 Subject to arrangements set out in this Agreement and the ICF, the Personal Data shall not be disclosed to or processed by the Sponsor save where this is permitted by Data Protection Law and necessary to satisfy the requirements of the Protocol or other uses permitted by the ICF or in relation to a claim or proceeding brought by a Clinical Trial Subject in connection with the Clinical Trial.

8.18 The Sponsor shall refrain from tracing and/or identifying any Clinical Trial Subject, except where the Sponsor is under a legal obligation to do so in which case the Principal Investigator will conduct the re-identification. In the event any Clinical Trial Subject, for reasons other than the aforementioned reason, becomes identifiable to the Sponsor, the Sponsor agrees to preserve, at all times, the confidentiality of information pertaining to such Clinical Trial Subjects.

Processors

8.19 Each Party shall safeguard that reasonable measures are put in place in order to assess if the processing of the Personal Data by a Processor engaged by either Party not being the other Party is in compliance with the data processor agreement entered into with such Processor.

Personal Data transfer outside EEA

8.20 To the extent Personal Data is transferred outside the European Economic Area under this Agreement (EEA), Parties are responsible for ensuring that such transfer is carried out in accordance with the requirements under GDPR, in particular Chapter V GDPR. **Unless otherwise provided for by GDPR** (for example by an adequacy ruling or derogation under Article 49 GDPR), the DECISION (EU) 2021/914 EU Standard Contractual Clauses (SCC) could be applicable and can act as an appropriate safeguard for transfer of Personal Data to a country outside the EEA under the GDPR and will then be attached to this Agreement in an annex. **If** an agreement with the SCC needs to be concluded between Institution and an entity in a country outside the EEA in order to perform task in accordance with this Agreement, the Sponsor will arrange that the entity in the country outside the EEA will enter into such an agreement with Institution.

Sponsor based outside EU

8.21 When based outside the EU, the Sponsor will appoint a representative in the EU in order to fulfil its duties under the GDPR.

Retention, destruction, return and migration period

8.22 Each Party shall store the Personal Data obtained in the context of this Agreement as long as required by the Law or for longer periods insofar as the Personal Data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) of the GDPR, subject to implementation of the appropriate technical and organisational measures in order to safeguard the rights and freedoms of the Data Subject.

Data protection impact assessment

8.23 The Parties shall reasonably cooperate and assist each other with respect to any data protection impact assessments and/or prior consultations with a government authorities that may be required by the Law in respect of processing of the Personal Data carried out under this Agreement.

Principal Investigator and Research Staff's Personal Data

8.24 Prior to and during the course of the Clinical Trial, the Sponsor may request the Institution to provide Personal Data from Research Staff. The Sponsor is responsible for collecting consent from the Research Staff and the Principal Investigator if consent is required for the processing of their Personal Data in connection to the Clinical Trial. The Institution shall provide reasonable assistance to the Sponsor in this regard.

8.25 The Institution agrees to provide the Research Staff and the Principal Investigator with the Sponsor's notice aimed at providing, in accordance with Data Protection Law, the mandatory information regarding the processing of their Personal Data.

9. CONFIDENTIAL INFORMATION

9.1 The Receiving Party shall ensure that only those of its officers, employees (and those of its Affiliates and members of the Research Staff) and Agents directly concerned with the carrying out of this Agreement have access to the Confidential Information of the Disclosing Party. The Receiving Party shall take all appropriate steps to ensure that such persons abide by the same obligations of confidentiality as applicable to the Receiving Party under this Agreement.

9.2 The Receiving Party undertakes to treat as strictly confidential and not to disclose to any third party any Confidential Information of the Disclosing Party, except where disclosure is lawfully required by a government authority or by the Law, in which case the Receiving Party shall, to the extent allowed by the Law, inform the Disclosing Party of such requirement and the information to be disclosed and Receiving Party shall take reasonable steps to limit the scope of such disclosure. Notification will be within a reasonable time prior to being required to make the disclosure or if such time is not available, immediately upon becoming aware of the requirement to disclose Confidential Information.

9.3 The Receiving Party undertakes not to make use of any Confidential Information of the Disclosing Party, other than in accordance with this Agreement, without the prior written consent of the Disclosing Party.

9.4 The obligations of confidentiality and non-use set out in clauses 9.1, 9.2 and 9.3 of this Agreement shall not apply to information which as evidenced by written records:

a. is or becomes part of the public domain by any other means than a wrongful act or breach of this Agreement by the Receiving Party;
b. was or becomes in the Receiving Parties' lawful possession prior to the disclosure without restriction on disclosure;
c. has been independently developed by the Receiving Party without the use of Confidential Information of the Disclosing Party;
d. has been obtained by the Receiving Party from a third party who is not subject to a duty of confidentiality; or
e. is published in accordance with clause 12 hereof.

10. INTELLECTUAL PROPERTY

10.1 All Intellectual Property Rights and Know How owned by or licensed to any of the Parties prior to and after the Effective Date of this Agreement other than any Intellectual Property Rights and Know How arising from and directly related to the Clinical Trial are and shall not be affected by this Agreement.

10.2 The Sponsor shall own the Intellectual Property Rights and Know How arising from and directly related to the Clinical Trial (including but not limited to Intellectual Property Rights and Know How related to the reporting, review or analysis of the Clinical Trial by the Institution or the Principal Investigator), the Protocol, Confidential Information of the Sponsor and/or the Investigational Medicinal Product (directly related to the Clinical Trial and/or Protocol, including but not limited to its formulation and use alone or in combination with other products), only excluding:

a. any clinical procedure and improvements thereto that are clinical procedures of the Institution and/or the Principal Investigator; and
b. copyrights on work published by the Principal Investigator in accordance with clause 12 hereinafter, which copyrights shall either vest in the Institution or, if made by the Principal Investigator and other authors, in the Institution and the other co-author(s) in accordance with applicable copyright laws or as mutually agreed between the Parties, or shall vest in the publisher of such work upon the transfer of copyrights by the author(s). For the avoidance of doubt, unless the publisher requires exclusive rights with regards to such copyrights protected work, Institution hereby grants Sponsor a non-exclusive, irrevocable, fully paid-up, royalty-free, worldwide license to distribute copies of each publication made in accordance with clause 12 and to prepare derivative works of any such publication, all in accordance with clause 12.12. The Institution will inform the Sponsor if the publisher requires exclusive rights with regards to such copyrights protected work as aforementioned.

10.3 The Site Parties hereby assign all their rights in relation to all Intellectual Property Rights and Know How, falling within clause 10.2 of this Agreement to the Sponsor and shall procure that Agents and/or the Research Staff shall assign and transfer, without additional consideration, all assignable rights and title in relation to all Intellectual Property Rights and Know How, falling within clause 10.2 of this Agreement to the Sponsor. At the request and expense of the Sponsor the Site Parties shall procure that their Agents and/or the Research Staff will provide reasonable assistance to the Sponsor in filing or prosecuting such Intellectual Property Rights and Know How.

10.4 Institution or the Principal Investigator may use Know How gained during the performance of the Clinical Trial in the furtherance of its normal activities meaning its internal hospital and/or non-commercial research and/or educational activities such research or educational activities whether or not in collaboration with other non-commercial institutions provided that such use is in compliance with the Law and does not result in the disclosure or misuse of Confidential Information or the infringement of any Intellectual Property Rights or Know How of the Sponsor, or results in breach of any other term of this Agreement.

10.5 Institution and or Principal Investigator will not prevent or hinder the Sponsor from using clinical procedures generated in the Clinical Trial that are necessary for the use of Sponsor's Intellectual Property Rights and Know How to the extent such use does not result in the disclosure or misuse of Confidential Information or the infringement of any Intellectual Property Rights of the Site Parties.

10.6 In case a third party brings a claim or initiate proceedings against the Site Parties claiming that use of Sponsor's Intellectual Property Rights to conduct the Clinical Trial in accordance with the terms of this Agreement amounts to infringement of that third party's Intellectual Property Rights, Sponsor shall indemnify ('schadeloosstellen') the Site Parties against such claims or proceedings, provided the Site Parties shall have notified Sponsor promptly in writing of such claim or proceeding and shall, upon Sponsor's request and at Sponsor's costs, have permitted Sponsor to have full care and control over the claim or proceeding using legal representation of its own choosing.

Excluded from this indemnification are claims or proceedings to the extent arising from (1) failure by the Institution, the Principal Investigator and/or the Research Staff to comply with the Protocol or the terms of this Agreement, or (2) gross negligence, willful recklessness or willful conduct or willful misconduct (in Dutch: *bewuste roekeloosheid, of opzettelijk handelen of nalaten*) by the Institution, the Principal Investigator and/or the Research Staff.

11. PUBLICITY

11.1 The Sponsor will not use the logo or name of the Site Parties, nor of any member of the Research Staff, in any publicity, advertising or news release without the prior written approval of the Site Parties, such approval not to be unreasonably withheld.

11.2 The Principal Investigator and the Institution will each not use the name or logo of the Sponsor, its affiliates' or Agents', nor of the Sponsor's, its affiliates' or Agents' employees, nor of the Clinical Trial, nor of the Investigational Medicinal Product, in any publicity, advertising or news release without the prior written approval of the Sponsor, such approval not to be unreasonably withheld.

11.3 The Site Parties will not issue and will ensure the Research Staff will not issue any information or statement to the press or public, including but not limited to advertisements for the enrolment of Clinical Trial Subjects, without, where appropriate, the review and the delivery of a favourable opinion from the Competent Authority and the prior written permission of the Sponsor.

11.4 Unless required by Law or provided elsewhere in this Agreement, the Parties shall not disclose terms of this Agreement without the prior written approval of the other Party.

12. PUBLICATION AND AUTHORSHIP

Principles

12.1 The Sponsor, the Institution and the Principal Investigator each acknowledge the importance of public disclosure/publication of Clinical Trial results, under the condition that public disclosure/publication takes place under the provisions of this clause 12.

12.2 Upon completion of the Clinical Trial (whether prematurely or otherwise) the Principal Investigator and the Sponsor may co-operate in producing a report of the Clinical Trial detailing the methodology, results and containing an analysis of the results and drawing appropriate conclusions.

Publication by Sponsor

12.3 The Site Parties each acknowledge that the Sponsor may present at symposia, national or regional professional meetings, and publish in journals, theses or dissertations, or otherwise of its own choosing, methods and results of the Clinical Trial and in particular, but without limiting the foregoing, post a summary of Clinical Trial results in online clinical trials register(s) before or after publication by any other method.

12.4 Sponsor shall coordinate a multi-centre publication. When the Clinical Trial is at an advanced stage, the Sponsor shall consider whether the Principal Investigator shall be involved in the publication in accordance with clause 12.5. If the Principal Investigator wants to be involved and wants to review and provide input (hereafter: "Review"), the Sponsor and the Principal Investigator will implement a process to ensure that this Review will be as efficient and effective as possible and that any publication can be published within a reasonable timeline.

12.5 The participation of the Principal Investigator or other representatives of the Institution as a named author shall be determined in accordance with generally accepted academic standards for authorship as outlined in this clause 12 and especially clause 12.12. If the Principal Investigator or other representative of the Institution is a named author of the multi-centre publication, such person shall have access to the Clinical Trial Data from all Clinical Trial sites as necessary to participate fully in the development of the multi-centre publication.

Publication by Principal Investigator

12.6 Site Parties shall be permitted to present at symposia, national or regional professional meetings, and to publish in journals, theses or dissertations, or otherwise of its own choosing, methods and results of the Clinical Trial, subject to this clause 12 and any publication policy described in the Protocol, provided any such policy does not obstruct publication unreasonably. The Principal Investigator shall appropriately disclose Sponsor's role in the Clinical Trial in any such publication or presentation.

12.7 If the Clinical Trial is a multi-centre Clinical Trial, neither the Principal Investigator nor the Institution has the right to publish or present the results of the Clinical Trial obtained at the Trial Site (or group of sites) before the first multi-centre publication or presentation by the Sponsor unless otherwise agreed in writing. If a publication concerns the analyses of sub-sets of data from a multi-centre Clinical Trial the publication shall refer to the relevant multi-centre publication(s).

12.8 If the Clinical Trial is a single site Clinical Trial, neither the Principal Investigator nor the Institution has the right to publish or present the results of the Clinical Trial before the Sponsor publishes the results.

12.9 Notwithstanding the foregoing, if a multi-centre publication or a publication about a single site Clinical Trial is not published within twelve (12) months after completion of the Clinical Trial and lock of the Clinical Trial database at all research sites that are part of the (multi-centre) Clinical Trial or any earlier termination or abandonment of the Clinical Trial, or if the Sponsor informs the Principal Investigator in writing that such (multi-centre) publication will not take place, or if publication has been agreed otherwise in writing between the Parties, the Principal Investigator shall have the right to publish or present the methods and results of the Clinical Trial in accordance with the provisions of this clause 12. The foregoing provided however, that any such publication will take into account the rights and interests of all investigators involved in the multi-centre Clinical Trial and authorship will be determined in accordance with clause 12.12.

12.10 Material for public dissemination will be submitted to the Sponsor for review at least thirty (30) days prior to submission for publication, public dissemination, or review by a publication committee. If the Sponsor does not respond within this period, the Principal Investigator is free to proceed with the intended publication or presentation without further delay. The Sponsor may share such proposed public dissemination with its Affiliates and Agents.

12.11 During the thirty (30) days period for review of a proposed publication referred to in clause 12.10 above, the Sponsor shall be entitled to:

a. comment on the scientific content of the proposed publication. The Principal Investigator agrees that all reasonable comments made by the Sponsor in relation to a proposed publication or presentation will be incorporated into the publication or presentation. Reasonable comments for the purposes of this clause 12.11 shall mean such comments and suggestions that, with a view to the scientific interest or the treatment of patients, will clarify or improve the proposed publication or presentation of the results of the Clinical Trial or the conclusions drawn from such results, and such other comments that aim to avoid that such publication or presentation will misrepresent the results;

b. make a reasoned request to the Principal Investigator that publication be delayed for an additional period of sixty (60) days (following the 30 day period referred to in clause 12.10) in order to enable the Sponsor to take steps to protect its proprietary information and/or Intellectual Property Rights and Know How, and the Principal Investigator shall not unreasonably withhold his or her consent to such a request; and

c. require the Principal Investigator to remove from the projected publication any Sponsor Confidential Information that are not results of the Clinical Trial. The Institution shall not unreasonably withhold or delay its consent to the reasoned request from the Sponsor.

Authorship and Copyrights

12.12 Publications will be in accordance with international recognized scientific and ethical standards concerning publications and authorship, including the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, established by the International Committee of Medical Journal Editors. Copyrights concerning Publications of the Clinical Trial remain with the authors of the Publication, regardless of any other provisions regarding intellectual property rights.

13. TERM AND TERMINATION

13.1 This Agreement commences on the Effective Date and shall be effective until:

a. completion of the final Clinical Trial report and the final payment under this Agreement; or

b. early termination in accordance with clauses 13.2 or 4;

13.2 Each Party may terminate this Agreement upon written notice to the other Party(/ies) with immediate effect in the following events only:

a. the approval by the Competent Authority in charge of the Clinical Trial is not granted or irrevocably revoked;

b. it can be reasonably concluded that the Clinical Trial must be terminated in the interests of the health of the Clinical Trial Subjects;

c. it becomes apparent, following confirmation of the Competent Authority or the Independent Committee, that continuation of the Clinical Trial cannot serve a scientific purpose, and this is notified to the Competent Authority;

d. the Sponsor and/or the Institution and/or, in case the Principal Investigator is a Party to this Agreement, the Principal Investigator becomes or are declared insolvent or a petition in bankruptcy has been filed against it or if one of them is dissolved;

e. if the Principal Investigator is no longer able (for whatever reason) to act as the Principal Investigator and no mutually acceptable replacement has been found within a reasonable period of time, in accordance with clause 2.3, provided that the Sponsor will not unreasonably withhold its approval of the proposed replacement of the Principal Investigator;

f. one of the Parties fails to comply with the obligations arising from this Agreement and if remedy of such non-compliance is not permanently impossible, is not able to remedy within thirty (30) days after receipt of written notice from the other Party specifying the non-compliance and requiring its remedy, unless failure to comply is not in reasonable proportion to the premature termination of the Clinical Trial;

g. circumstances beyond a Party's control occur that render continuation of the Clinical Trial unreasonable as outlined in clause 17.

13.3 In all circumstances causing the termination of this Agreement, the Sponsor shall confer with the Principal Investigator and use their best endeavours to minimise any inconvenience or harm to Clinical Trial Subjects. In case of termination of this Agreement, the Parties will in good faith make necessary arrangements concerning transition of the treatment of the enrolled Clinical Trial Subjects to post-study care in accordance with the Protocol and discuss, if and which continued treatment is in the medical best interest of the Clinical Trial Subjects.

13.4 Up until a Clinical Trial Subject has signed the ICF, the Sponsor may terminate this Agreement upon written notice to the Principal Investigator and the Institution, with immediate effect, in the following events:

a. for lack of recruitment at the Trial Site in case the Clinical Trial is conducted at one Site only; or

b. in case of a multicenter trial, if termination at the Trial Site does not affect performance of the Protocol.

13.5 After receipt of the written notice of termination of this Agreement, the Site Parties will not recruit and/or enrol additional Clinical Trial subjects. The Parties will cooperate with the Sponsor in the orderly discontinuation of the Clinical Trial, including, without limitation:

a. discontinuing Investigational Medicinal Product as soon as medically appropriate;

b. allowing the Sponsor access to records and facilities as required for Clinical Trial close-out procedures at mutually agreed times; and

c. requiring the Principal Investigator to complete any actions required by the role of the Principal Investigator.

13.6 In case of early termination of this Agreement, the financial provisions of clauses 14.3 and 14.4 shall apply.

13.7 At close-out of the Trial Site following termination or expiration of this Agreement the Parties shall upon request immediately deliver, or destroy with confirmation thereof, if requested, to the other Party all Confidential Information, except for copies to be retained in order to comply with the Institution's archiving obligations or for evidential purposes. Furthermore, the Site Parties shall immediately deliver to the Sponsor any equipment provided to them pursuant to the terms and conditions of **Annex 5**.

13.8 Termination of this Agreement will be without prejudice to the accrued rights and liabilities of the Parties under this Agreement.

14. FINANCIAL PROVISIONS

14.1 The Sponsor will provide funding in support of the Clinical Trial, as set out in **Annex 3**. All payments shall occur on the conditions as set out in this **Annex 3**. The Parties agree that no payments are being provided for the purpose of inducing anyone to purchase or prescribe any drugs, devices or products and that the compensation being paid hereunder is fair market value for the services being provided. In addition, Site Parties shall comply with clause 2.8 and shall not:

a. bill any Clinical Trial Subject, insurer, or governmental agency for any items, visits, services or expenses provided or paid for by, or on behalf of, the Sponsor; or

b. provide any money or item of value to any government official or representative to improperly influence government actions.

14.2 In the event that amendments to the Protocol require changes to the Clinical Trial financing arrangements, an amended financial schedule will be agreed upon and signed by the Parties which will replace the existing **Annex 3**.

14.3 If this Agreement is terminated for one of the reasons in clauses 13.2 or 13.4, except for material breach by the Institution and/or the Principal Investigator under clause 13.2f, and subject to an obligation on the Institution and the Principal Investigator to mitigate any loss, the Sponsor shall pay:

a. all fees and expenditures payable to the Principal Investigator and/or the Institution up to the date of termination in accordance with **Annex 3**; and

b. all expenditure payable after the date of termination which arises from uncancellable commitments reasonably and necessarily incurred by the Principal Investigator and/or the Institution for the performance of the Clinical Trial prior to the date of termination, in accordance with **Annex 3**.

In the case of termination for material breach by the Institution and/or the Principal Investigator under clause 13.2f, and subject to an obligation on the Institution and the Principal Investigator to mitigate any loss, the Sponsor shall pay all fees and expenditures payable of properly performed services up to the date of the material breach by the Institution and/or the Principal Investigator in accordance with **Annex 3**.

In case of termination for fraud, bribery or corruption, the Sponsor will not provide any further payment under this Agreement, regardless of any activities that Principal Investigator or Institution has entered into before termination.

14.4 In the event of early termination, if payment has been made by the Sponsor to the Institution or the Principal Investigator in advance for work not completed in accordance with clause 13.2f, the Institution and/or the Principal Investigator shall issue a credit note and repay the remainder of the monies within 45 days of receipt of written notice from the Sponsor.

15. MISCONDUCT AND DEBARMENT

15.1 The Institution and/or the Principal Investigator represent and warrant that neither the Principal Investigator nor, to their best knowledge, any collaborator of the Principal Investigator involved in conducting the Clinical Trial nor any member of the Research Staff, has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct including without limitation United States Code of Federal Regulations ("U.S.C." or "CFR") title 21 section §335a and section §312.70.

15.2 The Institution and/or the Principal Investigator shall immediately notify the Sponsor should the Principal Investigator or any collaborators or any member of the Research Staff involved in conducting the Clinical Trial, be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Agreement and during the twelve months following the expiration or termination of this Agreement.

15.3 The Institution certifies that neither it nor the Principal Investigator is the subject of any past or pending governmental or regulatory investigation, inquiry, warning, or enforcement action (collectively, " GoR-Action ") related to its conduct of clinical research that has not been disclosed to the Sponsor. The Principal Investigator or the Institution will notify the Sponsor promptly if it or the Principal Investigator receives notice of or becomes the subject of any GoR-Action regarding compliance with ethical, scientific, or regulatory standards for the conduct of clinical research if the GoR-Action relates to events or activities that occurred prior to or during the period in which the Clinical Trial was conducted.

16. DISCLOSURE OF FINANCIAL INTEREST

16.1 The Principal Investigator shall ensure that he/she, collaborators and any member of the Research Staff involved in the Clinical Trial at Principal Investigator's Clinical Trial Site provide the Sponsor with financial disclosure information required under the U.S. Food and Drug Administration financial disclosure requirements set forth in 21 CFR Part 54 and any other applicable laws or regulations relating to investigator financial disclosure, upon the Sponsor's request and on such forms as the Sponsor may supply or approve. It shall be Sponsor's responsibility to identify and communicate the financial disclosures it requires to the Principal Investigator, collaborators and any member of the Research staff.

16.2 During the term of this Agreement and for one (1) year following termination or completion of the Clinical Trial, the Principal Investigator shall promptly notify the Sponsor of any material change in the information disclosed on a previous form.

16.3 The Parties may disclose the financial terms of this Agreement as required by applicable transparency, reporting, or disclosure laws or regulations, including but not limited to the U.S. Physician Payments Sunshine Act (Open Payments) and similar laws in other jurisdictions. Sponsor may disclose payments made under this Agreement to regulatory authorities, government agencies, and public databases as required by such laws.

17. FORCE MAJEURE

17.1 No Party shall be liable to the other Party(/ies) or shall be in default of its obligations hereunder if such default is the result of war, hostilities, terrorist activity, revolution, civil commotion, strike, fire, flood, pandemic and epidemic or because of any other cause beyond the reasonable control of the Party affected. The Party affected by such circumstances shall promptly notify the other Party(/ies) in writing when such circumstances cause a delay or failure in performance and where they cease to do so. However, such non-performance or delay is excused under this provision only for the duration of the qualifying event.

18. GOVERNING LAW AND DISPUTE RESOLUTION

18.1 This Agreement shall be exclusively governed by, and construed in all respects in accordance with, the laws of The Netherlands without regard to its conflict of laws rules. Any claims, controversies or disputes arising out of or in connection with this Agreement which cannot be settled amicably between the Parties, shall be subject to the exclusive jurisdiction of the competent court in the Netherlands.

19. HUMAN SAMPLES

19.1 As part of the Protocol, Samples may be transferred to the Sponsor or another organisation indicated by the Sponsor only if this is covered under the ICF.

19.2 The Sponsor, and the other organisation referred to in clause 19.1, shall have the right to store, transfer and use the Samples only in accordance with the Law, the Protocol and ICF (as approved by the Competent Authority). The Principal Investigator shall promptly notify the Sponsor of any withdrawal of or changes in the informed consent of a Clinical Trial Subject, which may affect the use of such Clinical Trial Subject's Samples under this Agreement. In such event, the Sponsor shall destroy or return the affected Samples if necessary.

19.3 Upon termination or expiration of the Clinical Trial, and at least at any time the Samples are no longer needed to be retained by the Sponsor for any pending registration purpose related to the Study Drug in relation to the Protocol or as defined in the ICF, or as required per any Law or regulation the remainder of the Samples in the Sponsor's or any of its designee's possession will be returned to the Site Parties, retained by the Sponsor in accordance with clause 19.2 or destroyed by the Sponsor, as described in the Protocol and/or the ICF.

19.4 For the avoidance of doubt, the control (in Dutch: zeggenschap) of the Samples remains at all times at the Clinical Trial Subjects they are derived from, the Institution and/or Site Parties agree that any Samples collected as part of the Clinical Trial that are transferred to Sponsor or a Sponsor's Agent, or held by Institution for Sponsor, will be under the custodianship of Sponsor. If (part of) Samples are retained by Site Parties, Site Parties will comply with all applicable Law.

20. MISCELLANEOUS

20.1 The Sponsor shall have the right to assign this Agreement or delegate any or all of its duties to an Affiliate or an Agent upon prior written notification to the Institution. The Sponsor may also assign this Agreement to a successor (including the survivor company of any consolidation or merger) or assignee of all or substantially all of its business upon prior written notification.

The Institution shall have the right to assign this Agreement to an Affiliate upon prior written approval from the Sponsor which approval shall not be withheld unreasonably. Any approval by a Party of an assignment, transfer or encumbrance by the other Party shall not release the assigning Party of any of its obligations under this Agreement due up until such assignment. Subject to the foregoing, this Agreement shall bind and inure to the benefit of the respective Parties and their successors and assignees.

20.2 The Institution and/or the Principal Investigator may not sub-contract the performance of all or any of their obligations under this Agreement without the prior written consent of the Sponsor, such consent not to be unreasonably withheld or delayed. Any Party who so sub-contracts shall be responsible for the acts and omissions of its sub-contractors as though they were its own.

20.3 Nothing shall be construed as creating a joint venture, partnership or contract of employment between the Parties.

20.4 Any agreement to amend, vary or modify the terms of this Agreement in any manner shall be valid only if effected in writing and signed by duly authorised representatives of each of the Parties hereto.

20.5 Should there be any inconsistency between the Protocol and the terms of this Agreement, or any other document incorporated therein, the Protocol shall prevail in case such inconsistency concerns clinical matters and this Agreement shall prevail if the inconsistency concerns non-clinical matters. For the avoidance of doubt, Termination and Publication provisions of this Agreement shall always prevail above the Protocol.

20.6 Unless otherwise agreed, formal notices to the respective Party(/ies) required by this Agreement shall be given, made or served if in writing and delivered personally or sent by registered mail or by facsimile with receipts confirmed to the contact details as set out in **Annex 7**. Other communication between the Parties may also be effected by other means such as e-mail with acknowledgement of receipt, which fulfils the conditions of written form. Change of the contact details has to be notified to the other Party(/ies), but shall not require amendment of this Agreement.

20.7 The clauses 1 (Definitions); 3.7 and 3.8 (Clinical Trial Governance and Compliance); 4 (Liabilities, Indemnification and Insurance); 6 (Quality Assurance and Control); 7.3 (Use of Investigational Medicinal Product); 8 (Data Protection); 10 (Intellectual Property); 11 (Publicity); 12 (Publication and authorship); 13.5-13.8 (Term and Termination); 14.3 and 14.4 (Financial Provisions); 15.2 (Misconduct and Debarment); 16.2 (Disclosure of Financial Interest); 17 (Force Majeure); 18 (Governing Law and Dispute Resolution); 19 (Human Samples) and this clause 20.7 (Surviving clauses) or other clauses (including but not limited to those in Annexes) contemplating performance after termination, shall survive termination or expiry of this Agreement. Clause 9 (Confidentiality) shall remain in force for a period of [*five (5)*] / [*ten (10)*] years as from the date of termination or expiration of this Agreement.

21. PARTIES & CONDITIONAL CONSENT INSTITUTION

21.1 Each person signing this Agreement represents and warrants that he or she is duly authorised and has legal capacity to execute and deliver this Agreement. Each Party represents and warrants to the other Party that the execution and delivery of this Agreement and the performance of such Party's obligations hereunder have been duly authorised and that the Agreement is a valid and legal agreement binding on such Party and enforceable in accordance with its terms.

21.2 This Agreement is signed and entered into under the condition that recruitment and/or inclusion of Clinical Trial Subjects will not start until the Competent Authority has approved the Protocol as submitted to the Competent Authority.

21.3 In case the Competent Authority makes its approval subject to modification(s) of the Protocol that requires amendment(s) of the Verklaring Geschiktheid Onderzoeksinstelling (“VGO”) [Declaration Feasibility Site] and/or this Agreement and Parties cannot reach an agreement on those amendment(s) in good faith within reasonable timelines, either Party may terminate this Agreement in accordance with and in addition to clause 13.

ANNEXES

Annex 1: Protocol
Annex 2: Timelines
Annex 3: Financial arrangements
Annex 4: Pharmacy agreement
Annex 5: Equipment
Annex 6: Bribery and Corruption Statement
Annex 7: Contact details
Annex 8: Power of Attorney / Delegation of Authority to CRO
Annex 9 Description of the personal data, methods of transfer and storage, allowed processors

[The remainder of this page is intentionally left blank; for signatures, see next page]

Signed on behalf of the **Sponsor***

Signature: ……
Name: ……
Title: ……

Date: ……

*If the Sponsor is represented by a CRO and the CRO will sign on behalf of the Sponsor a copy of the power of attorney/power of delegation will be attached to this Agreement as Annex 8

Signed on behalf of the **Institution**

Signature: ……
Name: ……
Title: ……

Date: ……

[If the Principal Investigator is NOT a contracting party, insert: The undersigned Principal Investigator hereby declares that he/she has read the above Agreement between the Parties and that he/she acknowledges the provisions of this Agreement relative to his/her role, responsibilities and duties concerning the Clinical Trial:]

Signed by the **Principal Investigator**

Signature: ……
Name: ……
Title: ……

Date: ……

Signed on behalf of the **Contract Research Organisation***

Signature: ……
Name: ……
Title: ……

Date: ……

[If the CRO needs to be included in the Agreement to be able to fulfil financial obligations towards the institution and/or the Principle Investigator following this Agreement]*

Signed on behalf of the **Medisch specialistisch bedrijf**: ***[insert the name of medisch specialistisch bedrijf]****

Signature: ……
Name: ……
Title: ……

Date: ……

[In case the "medisch specialistisch bedrijf" will cosign this Agreement.]*

ANNEX 1 - PROTOCOL

(by reference only)

ANNEX 2 - TIMELINES

ANNEX 3 - FINANCIAL ARRANGEMENTS

ANNEX 4 - PHARMACY AGREEMENT

ANNEX 5 - EQUIPMENT

ANNEX 6 - BRIBERY AND CORRUPTION

Anti-corruption laws and international conventions, including the U.K. Bribery Act, U.S. Foreign Corrupt Practices Act (or FCPA), and various other local laws prohibit the payment of bribes to certain persons, including government officials ("Anti-Corruption Laws"). These laws prohibit international businesses, among most Sponsors and its parent company, from making payments or promising to make payments, directly or indirectly, to certain persons, including public officials for the purpose of receiving favorable treatment, to obtain or retain business or to direct business to any person. Prohibited payments are not limited to cash; they include payments of anything of value or provision of favors or any other advantages that result in improper influence.

In addition, some Anti-Corruption Laws, including in the U.K. Bribery Act, also prohibit giving or offering any advantage (which need not be financial in nature) to persons operating in the public or private sectors as a quid pro quo for the recipient improperly performing a function they are expected to perform in good faith, impartially or in accordance with any other expectation arising as a result of the recipient being in a position of trust.

Furthermore, the expectations to be taken into account when determining whether a function has been properly performed may be those of the country whose Anti-Corruption Laws apply rather than the country in which any potentially unlawful conduct occurred. Accordingly, Sponsor's distributors, agents and service providers have to comply with the highest standards of ethics and professional conduct.

Sponsor may find itself liable under these Anti-Corruption Laws for prohibited payments made, or practices carried out, on Sponsor's behalf, including due to the actions of its distributors, agents and service providers. It may also find itself liable for having failed to prevent unlawful conduct carried out by others with the intention of obtaining or retaining business, directing business to any person, or securing an improper advantage in the conduct of business, for Sponsor.

A. The Site Parties must at all times act with integrity and honesty and comply with the highest ethical standards.

B. The Site Parties must not make, give, or offer any payment, gift or other benefit or advantage to any person for the purposes of:
   i. securing any improper advantage; or
   ii. inducing the recipient or another person to do or omit to do any act in violation of their duties or responsibilities (or for the purposes of rewarding such conduct).

C. This restriction applies at all times and in all contexts. For the avoidance of any doubt, it applies both to dealings with "public officials" and to dealings with employees and agents of commercial enterprises.

D. Nevertheless, particular care must be exercised with dealings with public officials. The Site Parties must not make, give or offer any payment, gift or other benefit or advantage for the purposes of influencing any act or decision of a public official (or inducing such official to use their influence with another person, entity or government instrumentality or to affect or influence any act or decision of such other person, entity or government instrumentality).

E. The term "***Public Official***" includes any person acting on behalf of any government department, agency or instrumentality or any state-owned or controlled enterprise. By way of example, this includes health care professionals employed by a state- or local municipality-run hospital or clinic, and representatives of public international organisations.

F. The Site Parties must not make, give or offer any payment, gift or other benefit or advantage to any person whilst knowing or suspecting that all or a portion of such money, gift, benefit or advantage will be used, whether directly or indirectly, in breach of (B) or (C) above.

G. The Site Parties shall make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Site Parties, in accordance with Dutch law.

H. The Site Parties shall devise and maintain a system of internal accounting controls in accordance with Dutch law, sufficient to provide reasonable assurances that:

i. transactions are executed in accordance with management's general or specific authorisation;

ii. transactions are recorded as necessary
   (I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and
   (II) to maintain accountability for assets;

iii. access to assets is permitted only in accordance with management's general or specific authorisation; and

iv. the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

ANNEX 7 - CONTACT DETAILS

Recipients of Notice in accordance with clause 20.6 of this Agreement:

If to the **Sponsor***
*if a CRO represents the Sponsor the contact details of the CRO could be included below
For scientific matters:
Name:
Address:
Tel.:
Mail:

For legal matters:
Name:
Address:
Tel.:
Mail:

For financial matters:
Name:
Address:
Tel.:
Mail:

If to the **Institution** / the **Principal Investigator**
For scientific matters:
Name:
Address:
Tel.:
Mail:

For legal matters:
Name:
Address:
Tel.:
Mail:

For financial matters:
Name:
Address:
Tel.:
Mail:

ANNEX 8 - POWER OF ATTORNEY / DELEGATION OF AUTHORITY TO THE CRO

ANNEX 9 - DESCRIPTION OF THE PERSONAL DATA, METHODS OF TRANSFER AND STORAGE, ALLOWED PROCESSORS

This Annex needs to be read and considered in conjugation with clause 8 of the Agreement.

Data subjects

Describe the categories of Data Subjects of who personal data will be processed. For example:

- *Staff of institution involved in the study at site*
- *Principal Investigator*
- *Clinical Trial Subject*

…

Purpose of the data processing

Describe the purpose of the data processing. For example:

- *Conducting a clinical trial. Staff will be documented in the ISF and TMF and investigator name and resume is part of submission package to EC*
- *Study data and if applicable study samples will be collected and sent to sponsor after pseudonymization to be added to the study database and sample collection. All in accordance with the respective ICF that was signed*

…

Data protection roles under the GDPR

Under the GDPR the actual processing activities are decisive in the GDPR-role (i.e., controller, joint-controller or processor) of a natural or legal person. Therefore, the Agreement does not include a standard clause on who is controller, joint-controller, or processor in regard to the full Agreement. To the extent such roles are clear in regard to a specific clinical trial the roles may be outlined below for example as followed.

	Sponsor	Institution
Role of parties relating to Clinical Trial Data		
Role of parties relating to medical records and Personal Data used for the treatment of the patient and thereto related		
Role of parties relating to the Personal Data of Research Staff		

Categories of personal data

Specify the categories of personal data of Clinical Trial Subjects and Research Staff (and potentially others) that will be processed in the course of and in follow-up of the Clinical trial

For example:

- *Personal data: names, resume, date of birth, address etc.*

- *Special categories of personal data:*
    - *data concerning health*
    - *genetic data*
    - *data revealing racial or ethnic origin*
    - *biometric data for the purpose of uniquely identifying a natural person*
    - *data concerning a natural person's sex life or sexual orientation)*
    - *political opinions*
    - *religious or philosophical beliefs*
    - *trade union membership*

NB: All health information qualifies as special category of personal data.

…

Method of transfer of personal data from Institution to Sponsor

Describe the method of data transfer. For example:

- *encrypted sending via Surffile sender*
- *Encrypted via a secured USB stick.*
- *Amazon*
- *database entry like Castor, etc.*

If there is any doubt about the method, please consult with the Clinical Research Unit (CRU)

For example.
Study data: Validated e-CRF (refer to protocol/datamanagement plan) with encrypted transfer. ISO 27001 compliant.
Study documents: secured email

…

Method of data storage and security measures (e.g. method of encoding)

For the participating centers describe:

- *Which center provides the coding (only pseudonymised data can be sent to the participating center and vice versa).*
- *Where the key to the code is kept.*
- *Where the encrypted data is stored (data safe or a place reserved for research on the department's research-disk) and describe who has access to this encrypted data.*
- *Where the unencrypted data is stored (prefer to keep as few unencrypted lists as possible) and who has access to these data.*
- *Retention period of the data.*

For example:

- *All patient data and samples will be pseudonymized with a study code prior to transfer. The key to the code is kept at Institution.*
- *Location of data servers: […]*

Retention period of study data is 25 years.

…

Authorised (sub)processors

List the authorised processors. This means, for example: any external parties that provide analyses or offer an online service in which the data is stored (e.g. Castor).
Note that the processor in this case is not one of the cooperating parties.

….