FÖRSÄTTSBLAD
Clinical Trial Agreement, Medicinal products (kliniska läkemedelsprövningar)

- Denna avtalsmall kan användas vid kliniska läkemedelsprövningar där såväl VGR är sponsor som när någon annan organisation är sponsor och deltagande site är ett sjukhus inom VGR (prövningsställe).

- Avtalsmallen har som utgångspunkt ingen geografisk begränsning utan kan användas för samarbeten mellan alla länder. Dock kommer det finnas behov för fler anpassningar i avtalet ju mer olika samarbetslandet hanterar kliniska läkemedelsprövningar.

- Under parter ska det för VGR stå både Västra Götalandsregionen och vilken förvaltning som ingår avtalet.

- Gula markeringar ska fyllas i med information.

- Ord och meningar som anges inom klamrar utan gul markering är sådana som eventuellt ska tas bort, beroende på omständigheterna i den aktuella prövningen. Även andra delar av avtalet kan behöva anpassas till omständigheterna i den aktuella prövningen.

- Röda texter är hjälptexter och raderas innan avtalsutkast delas med motparten. Likaså tas detta försättsblad bort innan delning med motpart.

CLINICAL TRIAL AGREEMENT

Medicinal product

THIS CLINICAL TRIAL AGREEMENT (this "**Agreement**") is entered into between:

(1) **[Name of institution] (**reg. no. [insert reg. no.]), a [insert legal form of entity such as "company/region(hospital)/university"] organised under the laws of [Sweden], through [insert department], with its offices at [insert address], [Sweden] ("**Institution**")

(2) **[Name of sponsor] (**reg. no. [insert reg. no.]), a [insert legal form of entity such as "company/region(hospital)/university"] organised under the laws of [Sweden], having its principal place of business at [insert address], [Sweden] ("**Sponsor**");

The above parties are hereinafter also referred to each as a "**Party**" and jointly as the "**Parties**".

Trial Acronym	
Trial Title	
Investigational Medicinal Product (IMP)	
CTIS number	
Anticipated completion of the Trial	Qx 20xx
Estimated number of Trial subjects to be included at Institution	

BACKGROUND:

(A) Whereas Sponsor is the regulatory sponsor of the above-mentioned trial (the "Trial") and wishes to have the Trial performed at Institution, under the direction of [insert name of Principal

Investigator] ("Principal Investigator"), an employee of Institution, who is willing to perform the Trial under the terms of this Agreement.

(B) Whereas Institution has the skills, knowledge, expertise and resources to conduct the Trial.

(C) Now therefore the Parties have agreed as follows.

(D) For the sake of clarity, all obligations applicable to Principal Investigator according to this Agreement will apply to him/her as an employee of the Institution and under the guidelines of Good Clinical Practice ("GCP"). Accordingly, Principal Investigator will not be jointly liable for Institution's responsibilities under this Agreement. Institution shall procure and ensure the performance of the obligations of Principal Investigator and Trial site staff as set out in this Agreement and all applicable laws and regulations, including GCP.

1. DEFINITIONS

1.1 **In this Agreement, the following definitions are used:**

"**Applicable Laws**" shall mean all applicable laws, regulations, ethical principles and guidelines, especially those governing the performance of the Trial including (A) the Helsinki Declaration; (B) all relevant International Conference on Harmonisation Good Clinical Practice guidelines and standards (ICH-GCP); (C) Regulation (EU) 536/2014 of the European Parliament and of the council of 16 April 2014 on clinical trials on medicinal products for human use (CTR), and repealing Directive 2001/20/EC (D); all data protection and data privacy laws and regulations including the GDPR; and (E) all anti-bribery and anti-corruption laws and regulations.

"Biological Materials" shall mean any human biological materials, including but not limited to blood, body tissue, plasma and any other material containing human cells.

"**GDPR**" shall mean 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, and repealing Directive 95/46/EC

(General Data Protection Regulation).

"**Intellectual Property**" means any inventions, patents for inventions, certificates of inventions, utility models, chip protection, design patents, registered designs or other design rights, topography rights, trademarks, service marks, trade secrets, right(s) in unpatented know-how, right of confidence and the like as well as applications therefore, and copyrights and any other intellectual or industrial property of any nature whatsoever in any part of the world.

"**Materials**" means any equipment, materials, documents, data, software and information supplied by or on behalf of, or purchased at the expense of, the Sponsor, in connection with a Trail as described and set out in the Protocol and/or, this Agreement. Materials defined as medical devices shall be CE marked.

1.2 In this Agreement, save where the context otherwise requires, words in the singular shall include the plural, and vice versa.

2. AUTHORISATIONS

2.1 The Sponsor shall be responsible for obtaining and maintaining required approvals for the conduct of the Clinical Trial. Institution shall assist Sponsor in obtaining all necessary approvals from relevant regulatory authorities.

2.2 In the event that relevant regulatory authorities require amendments in the Protocol or informed consent form, such amendments shall be agreed upon by both the Institution and Sponsor and be documented in writing.

3. CONDUCT OF THE TRIAL

3.1 Principal Investigator will be responsible for the performance of the Trial on behalf of Institution. All obligations to the Principal Investigator, as well as to other Institution personnel, will apply to them as representatives of Institution and Institution will be solely liable under this Agreement. The Institution shall ensure that its personnel and the Principal Investigator shall be appropriately qualified by training and expertise to conduct the Trial.

3.2 The Parties shall conduct the Trial in accordance with the Protocol and its amendments, as amended from time to time, and shall comply with all Applicable Laws, the terms and conditions of the approval of relevant regulatory authorities and the terms of this Agreement.

3.3 Institution and Principal Investigator shall be fully informed of the Protocol and the IMP. Sponsor shall provide all relevant clinical pharmacology and toxicology information and advice to Institution, which are required for the proper planning and conduct of the Trial. Such information will include the Investigator's Brochure (IB) and information on Suspected Unexpected Serious Adverse Events (SUSARs) or the Summary of Product Characteristics (SmPC) for licensed products. Principal Investigator shall attend, or ensure a delegate attend, all Investigators' meetings for the Trial from time to time as reasonably required by Sponsor.

4. DATA AND SAFETY REPORTING

4.1 Institution shall report to Sponsor adverse events as directed in the Protocol and as required by Applicable Laws. Institution shall cooperate with Sponsor in its efforts to follow-up on any adverse events. Sponsor will promptly report to Institution any findings that could affect the safety of Trial Subjects, influence the conduct of the Trial, or that Sponsor determines could alter the approvals from the relevant regulatory authority.

4.2 Institution shall report serious adverse events to Sponsor without undue delay, but not later than within 24 hours from obtaining knowledge of the events unless, for certain serious events, the Protocol provides that no immediate reporting is required. Where relevant, the Institution shall send a follow-up report to Sponsor if required to Sponsor´s assessment and reporting of the event.

4.3 Institution shall record and document all adverse events, unless the Protocol provides differently. Sponsor shall keep detailed records of all adverse events reported to it by Institution.

4.4 If Institution becomes aware of a serious adverse event with a suspected causal relationship to the IMP that occurs after the end of the Trial in a Trial Subject, the Institution shall, without undue delay, report the serious adverse event to Sponsor.

4.5 Sponsor shall be responsible for reporting any Suspected Unexpected Serious Adverse Reactions (SUSAR) to the relevant regulatory authority and investigators in accordance with regulatory requirements. Sponsor shall also be responsible for the preparation of the annual safety report and for the sending of the report to the relevant regulatory authority.

4.6 Principle Investigator is responsible for reporting any suspected serious breaches to Sponsor in accordance with protocol and regulatory requirements. Principle Investigator is also responsible for reporting any unexpected events, that may affect the benefit-risk balance of the Trial, to Sponsor in accordance with the Protocol and regulatory requirements. Sponsor shall be responsible for reporting the information to relevant regulatory authority in accordance with regulatory requirements.

5. RECORD KEEPING

5.1 Institution will archive its Trial documentation (the "**Investigator Site File**") for at least 25 years after the end of the Trial or longer period if required by applicable laws. The content of the Investigator Site File shall be archived in a way that ensures that it is readily available and accessible, upon request, to the relevant regulatory authorities. The media used to archive the content of the Investigator Site File shall be such that the content remains complete and legible throughout the period referred to above. Any alteration to the content of the Investigator Site File shall be traceable.

6. INVESTIGATIONAL MEDICINAL PRODUCT (IMP)

6.1 Sponsor will at no cost provide the IMP to Institution, suitably packaged and labelled and in sufficient quantity to conduct the Trial.

6.2 Institution shall not use IMP for any other purpose than the Trial and in compliance with Applicable Laws and in the manner outlined in the Protocol.

6.3 The IMP will remain the sole property of Sponsor. After termination of the Trial, Institution shall handle the IMP according to Sponsor instructions and at Sponsor's expense.

7. MATERIALS

7.1 Sponsor will provide Institution with the Materials required for the conduct of the Trial and free of charge. The Sponsor shall retain all rights, title and interest in and to the Materials unless otherwise agreed by the Sponsor in writing. Sponsor is responsible for maintaining service/maintenance agreements for the Materials and is liable for all taxes and insurance relating to the Materials.

7.2 The Materials may only be used by Institution, the Principal Investigator and the Trial site staff to the extent required for the conduct of the Trial. Institution shall be responsible for keeping any Materials in good repair and in such condition as they were on the date of delivery (fair wear and tear excepted). The Materials shall be kept and operated in a suitable environment and used only for the purpose for which they are intended, by trained staff, in accordance with any instructions provided by the Sponsor.

7.3 At Trial closure or at the Sponsor's earlier request, Institution shall promptly return all Materials to the Sponsor, at Sponsor's expense, unless the Parties agree that Institution shall acquire the Materials for their fair market value. The foregoing sentence shall not prevent Sponsor from donating Materials to Institution, e.g. in the form of consumables that have a low or no market value.

8. BIOLOGICAL MATERIALS

8.1 Institution shall ensure that any collection, handling, transportation, and retention of any Biological Materials is carried out in accordance with the Protocol, the informed consents of Trial subjects, and Applicable Laws. Institution shall further ensure that the security, integrity, quality and identity of the Biological Materials are maintained at all times.

8.2 The Biological Materials may be used by Sponsor, central lab, or other contracted party only for purposes of the Trial and as allowed by the Trial subjects' informed consent form, permit from the relevant regulatory authority and permit from relevant biobank.

8.3 All rights to the Biological Materials will remain to the Sponsor and within the biobank's control. After the Trial is completed, the Biological Materials will be retained or destroyed in

accordance with the Protocol, the biobank agreement (if any), the informed consents of Trial subjects and permit from the relevant regulatory authority.

9. TRIAL SUBJECT ENROLMENT

9.1 Institution shall make reasonable efforts to ensure that the recruitment target of eligible Trial subjects in accordance with the Protocol is met timely.

9.2 If the Trial is part of a multi-centre trial, Institution may enrol Trial subjects in mutual competition with other participating sites. Sponsor reserves the right to end the Trial subject enrolment under this Agreement when the desired number of Trial subjects for all sites has been reached. Further, Institution agrees that continued screening or randomisation of subjects must not take place after Trial subject enrolment has been ended by Sponsor and notice hereof has been given to Institution by Sponsor.

10. INFORMED CONSENT

10.1 Institution undertakes to use the Trial subject information sheet as approved by the relevant regulatory authority to obtain written informed consent from each Trial subject prior to inclusion of any Trial specific procedures for screening according to the Protocol.

11. MONITORING, AUDITS AND INSPECTIONS

11.1 Institution shall during the Trial, on reasonable prior written notice and at an agreed upon time, permit authorised personnel of Sponsor to access the Institution during normal business hours to conduct monitoring and audits. Institution and Principal Investigator shall permit Sponsor and its representatives access to medical records and other source documents relating to the Trial subjects participating in the Trial for such purposes. [Sponsor is aware that the Swedish Patient Data Act (*in Swedish: patientdatalagen (2008:355)*) prevents direct access to patient record system for monitoring or auditing Trials for Sponsor. Patient records will therefore be provided to the monitor in paper or in other permitted forms.]

11.2 Institution shall promptly inform Sponsor of any intended or actual inspection, written enquiry and/or visit to Institution by any regulatory authority in connection with the Trial and shall

forward to Sponsor copies of any correspondence from any such regulatory authority relating to the Trial. Institution and Principal Investigator shall make themselves available and shall reasonably cooperate with any regulatory authority with respect to inspections performed according to Applicable Laws. Unless prohibited by law, Institution will permit Sponsor, or its representative, to be present during such a regulatory authority inspection.

12. COMPENSATION

12.1 The budget and compensation to be paid by the Sponsor for the Trial is included in **Appendix 1** ("**Payment Schedule**"). Payment shall be due and payable in accordance with the schedule and details set forth in Appendix 1.

12.2 In the event of a change to the Trial Protocol that results in an increased cost, or if any increase in the compensation due for the conduct of the Trial is necessary or appropriate, the Parties shall negotiate further remuneration.

[Stycket nedan är aktuellt när Sponsorn är ett läkemedelsföretag. Radera den här röda texten innan avtalsutkast skickas till motparten.]

12.3 [Nothing contained in this Agreement shall be construed in any manner as an obligation or inducement for the Institution to recommend any person or entity to purchase the Sponsor's products or those of any entity affiliated with Sponsor.]

13. PUBLICATION

13.1 Sponsor recognizes Institution's interest in making publications and presentations relating to the Trial in journals, at meetings or otherwise and shall therefore permit such publications and presentations, provided however that Institution shall provide to Sponsor any proposed presentation at least fifteen (15) days prior to being disclosed and any proposed publication at least thirty (30) days prior to submission for publication. Within this period, Sponsor shall review such proposed presentation or publication to determine whether it contains any Confidential Information of Sponsor or whether Sponsor desires to file patent applications on subject matter contained therein.

13.2 If the Trial is a multi-centre trial, the first publication of data shall be based on consolidated data from all sites analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Trial and by Sponsor. Before the first publication, the proposed publication shall be discussed together with Sponsor and the Principal Investigators.

14. PUBLICITY

14.1 None of the Parties shall use the name of the other Party for marketing or promotional purposes without the prior written consent of the Party whose name is proposed to be used.

15. CONFIDENTIALITY

15.1 All information furnished to Institution by Sponsor pursuant to this Agreement ("**Confidential Information**") shall by treated by Institution as confidential for a period of five (5) years after termination of this Agreement. Institution shall (i) hold the Confidential Information in confidence and not disclose or permit it to be made available to any third party, without Sponsor's prior written consent, (ii) only use the Confidential Information for the Trial, (iii) take any reasonable steps to the effect that each person employed at the Institution to whom disclosure of the Confidential Information is made will be under the same confidentiality obligations as applies for Institution under this Agreement, and (iv) upon written demand from Sponsor either at Sponsor's expense return the Confidential Information and any copies of it or to confirm in writing that it has been destroyed. However, one (1) copy of Confidential Information may be retained by Institution in a secured location, solely to allow Institution to ensure its continued compliance with this Agreement or as required by law and for no other purpose.

15.2 Such information as described under (a) – (d) below is not considered as Confidential Information:

a) information which is, or subsequently becomes publicly available (other than as a result of a breach of this Agreement);

b) information which at the time of disclosure hereunder, was already known to and in the possession of Institution and which has not been acquired directly or indirectly from Sponsor;

c) information which Institution may obtain after the date of this Agreement from a person lawfully in possession of and having the right to disclose the same; and

d) information which is independently developed or generated by Institution without any recourse or reference to the Confidential Information disclosed to it.

15.3 This Agreement shall not prevent disclosure of Confidential Information which a Party is legally obliged to disclose by compulsory law, court order or by order of another authority of competent jurisdiction.

16. TRIAL DATA, RESULTS AND INTELLECTUAL PROPERTY

16.1 Nothing in this Agreement shall affect either Party's rights to its pre-existing Intellectual Property owned or controlled at the Effective Date ("**Background IP**") nor imply grant of any license to such Background IP unless expressly set forth herein.

16.2 All data, results and intellectual property generated by Institution or Principal Investigator in the direct course of conducting the Trial shall belong to Sponsor ("**Sponsor IP**").

16.3 Institution may use Sponsor IP for further non-commercial research, education and patient treatment as it deems reasonable and appropriate.

16.4 Institution retains ownership of all clinical data as contained in Institution's patient and medical records or other original source documentation.

17. INDEMNIFICATION

17.1 Sponsor agrees to indemnify and hold harmless Institution from and against any liability, costs or losses that may arise as a result of claims based on a personal injury or death to a Trial subject caused or claimed to be caused by the use of the IMP [or Material] during the course of the Trial or any other Protocol procedures performed pursuant to this Agreement.

17.2 Each Party agrees to indemnify and hold harmless each other from and against any liability, costs or losses that may arise as a result of their respective failure to adhere to the terms of this Agreement, or any applicable law or regulation, or that arise from their respective negligence or wilful misconduct.

18. LIMITATION OF LIABILITY

18.1 Neither Party shall be liable to the other Party for lost profits, or for any special, indirect, incidental, consequential or punitive damages, arising out of this Agreement. A Party's aggregate liability towards the other Party shall be limited to once the contract value.

19. INSURANCE

19.1 Each Party shall ensure that adequate provision is made by way of insurance arrangements sufficient to meet their obligations and liabilities under this Agreement and the Applicable Laws, in particular, towards the Trial Subjects for personal injury arising as a result of participation in the Trial. Proof of insurances and their coverage shall be provided to the other Party upon request.

19.2 Trial subjects in Sweden are covered under the Swedish patient insurance (*in Swedish: patientförsäkringen*) in accordance with the Swedish Patient Injury Act (*in Swedish: patientskadelagen SFS 1996:799*).

20. DATA PRIVACY

20.1 In respect of the processing of personal data related to the performance of the Trial and for the purpose of this Agreement, each Party shall be data controller as defined in the GDPR. The Parties further acknowledges that Institution will serve as independent controller for the Trial subjects' personal data to the extent such Trial subject personal data is processed by Institution or Principal Investigator in the treatment of Trial subjects as patients of Institution or Principal Investigator.

20.2 Sponsor and Institution ensure that they each have proper legal basis for the processing of personal data in compliance with GDPR.

20.3 Personal data of Trial subjects, when transferred to Sponsor, will be pseudonymized to replace any information that directly identifies a Trial subject with a subject identification code. Neither Institution nor Principal Investigator will provide Sponsor with the key or code that enables Trial subjects to be re-identified. The personal data shall at all times be transferred to Sponsor by appropriate technical and organisational measures to ensure a level of security appropriate to the risk of the transfer. Both Institution and Sponsor shall maintain appropriate technical and organisational security measures to protect the personal data they process in relation to the Trial and this Agreement. Sponsor shall safeguard the personal data from unauthorised access, use and theft.

20.4 Where the Parties' processing of the personal data will be carried out by a processor on behalf of Sponsor, Sponsor shall ensure that the processor will implement appropriate technical and organisational measures in such a manner that the processing will meet the requirements of data protection laws.

20.5 Sponsor shall only use the personal data of Trial subjects for the purposes of the Trial and within the limits set by the Protocol, Ethical or other regulatory permits, any biobank agreement, informed consent from Trial subjects and Applicable Laws. Sponsor shall not otherwise use or disclose the data unless required to do so by Applicable laws.

20.6 Sponsor shall ensure that confidentiality, to the full extent permitted by Applicable law, applies to the personal data and that access to the personal data is strictly limited to authorized users. Sponsor shall ensure that all authorised users (i) are informed of the confidential nature of the personal data, (ii) have received appropriate training of their responsibilities, and (iii) have executed written confidentiality agreements or are under an appropriate statutory obligation of confidentiality. Sponsor shall ensure that such confidentiality obligations survive the termination of their personnel arrangement.

[Använd stycket nedan om Sponsorn finns inom EU/EES men dess moderbolag finns utanför EU/EES eller om vi vet att Sponsorn som en del av studien ska föra över

personuppgifter till ett land utanför EU/EES. Radera den här röda texten innan avtalsutkast skickas till motparten.]

20.7 [Sponsor shall ensure that any transfer of the personal data, in whole or in part, including to any recipient located in a country outside the EU/EEA, is performed in accordance with data protection laws (including but not limited to Chapter V of the GDPR). Any transfer by Sponsor to such party shall be made solely for the purpose of this Trial and otherwise as required by Applicable laws.]

[Använd stycket nedan om Sponsorn finns utanför EU/EES och varken har hemvist i ett land som finns med på EU kommissionens lista över länder med adekvat skyddsnivå (se IMYs hemsida) eller tillämpar s.k. Binding Corporate Rules (BCR). Radera den här röda texten innan avtalsutkast skickas till motparten.]

20.8 [Institution and Sponsor are hereby entering into Standard Contractual Clauses (SCC) for the transfer of personal data from Institution (Data Exporter) to Sponsor (Data Importer) as set forth under **Appendix 2** attached hereto and incorporated herein by reference. As used herein, "**Standard Contractual Clauses**" means the European Union Standard Contractual Clauses (MODULE I: Transfer Controller to Controller) adopted by Commission Implementing Decision (EU) 2021/914 of 4 June 2021.]

21. TERM AND TERMINATION

21.1 This Agreement shall become effective on the last date of signature of this Agreement by the Parties ("**Effective Date**") and shall remain in effect until completion of the Trial (which means the conclusion of all Protocol required activities for all enrolled Trial subjects) and close-out of Institution or earlier termination in accordance with this Agreement.

21.2 Sponsor may terminate this Agreement at any time in exercise of its sole discretion upon giving thirty (30) days advanced written notice to Institution.

21.3 Institution may terminate this Agreement with immediate effect upon written notice to Sponsor if Sponsor commits a material breach under this Agreement and – after receipt of a written notice specifying the breach – fail to remedy the breach within thirty (30) days from the date of the said notice.

21.4 Either Party may terminate this Agreement with immediate effect by notice in writing to the other Party (i) if the other Party becomes insolvent or bankrupt or subject to reorganisation, reconstruction or liquidation makes any arrangement with its creditors, has an administrator, receiver or manager appointed, or ceases or threatens to cease to carry on its business; (ii) if the regulatory permissions and approvals previously granted to perform the Trial are withdrawn; or (iii) if the Principal Investigator becomes unavailable to continue his/her supervision of the Trial for any reason and a replacement to both Parties is not found; (iv) if either Party, in its sole discretion, determines that any of the Trial results support termination of the Trial for the safety or welfare of Trial subjects.

21.5 Upon termination or expiration of this Agreement, Sponsor shall be obligated to pay Institution for those items set forth in the Trial budget that have been incurred prior to the date of termination, and any non-cancellable expenses incurred by Institution pursuant to this Agreement and the Trial budget prior to such termination. Institution shall promptly refund to Sponsor any advanced payments for work not yet performed made by Sponsor under the Payment Schedule. In no event shall Sponsor be required to pay for Trial activities not performed.

22. NOTICES

22.1 All notices and other communications required or permitted under this Agreement shall be deemed to have been received by a Party when:

(a) delivered by certified or registered mail with postage prepaid, on the third (3rd) business day after the date it is so mailed;

(b) delivered by hand and receipted for by the Party to whom said notice or other communication shall have been directed, on the day of delivery; or

(c) sent by e-mail, the receipt of which has been confirmed by the receiving Party, on the day of receipt.

22.2 All notices and communications required or permitted under this Agreement shall be addressed as set out below or to such other addresses as may be given by written notice in accordance with this Clause**.**

(a) If to Institution, to:

[insert name of Institution]
Attn. [insert name of contact person]
[insert address]

[insert e-mail address]

(b) If to Sponsor, to:

[insert name of Sponsor]
Attn. [insert contact person of Sponsor]
[insert address]

[insert e-mail address]

23. MISCELLANEOUS

23.1 **Entire Agreement**. Each of the Parties to this Agreement confirms that this Agreement represents the entire understanding and constitutes the whole agreement between the Parties in relation to its subject matter and supersedes all prior agreements, covenants, arrangements, communications, representations or warranties, whether oral or written, by any officer, agent, employee or representative of either of the Parties.

23.2 **Amendments**. This Agreement may only be amended, changed or modified by an instrument in writing duly executed by the Parties.

23.3 **Counterparts**. This Agreement (and any Appendix) may be executed in two or more counterparts, each of which shall be deemed an original and all of which shall together be deemed to constitute one and the same agreement. The Parties agree that execution of this Agreement by industry standard electronic signature software and/or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures, and that in any proceedings arising under or relating to this Agreement, each Party hereby waives any right to raise any defence or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.

23.4 **Survival**. Any rights or obligations set forth herein which by their nature are intended to extend beyond the term of this Agreement shall survive the expiration or termination or the Agreement.

23.5 **No Waiver**. In no event shall any delay, failure or omission of a Party in enforcing, exercising or pursuing any right, claim or remedy under this Agreement be deemed as a waiver thereof, unless such right, claim or remedy has been expressly waived in writing.

23.6 **Assignment**. This Agreement shall not be assignable by either of the Parties without the prior written consent of the other Party which shall not be unreasonably withheld.

23.7 **Severability and Replacement**. If any provision of this Agreement or the application of it shall be declared or deemed void, invalid or unenforceable in whole or in part for any reason, the remaining provisions of this Agreement shall continue in full force and effect. The Parties shall seek to amend such void, invalid or unenforceable provisions and thereby this Agreement in order to give effect to, so far as is possible, the spirit of this Agreement and to achieve the purposes intended by the Parties.

23.8 **Mandatory National Law**. Nothing in this Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating.

23.9 **Inconsistency**. In the event of any inconsistency between this Agreement or any other document incorporated therein, including the Protocol, the terms of the Protocol shall prevail with respect to the conduct of the Trial and the treatment of Trial subjects in connection therewith; in all other respects, the terms of this Agreement shall prevail.

24. GOVERNING LAW AND DISPUTE RESOLUTION

24.1 This Agreement shall be governed by and construed in accordance with the laws of Sweden without regard to any conflict of law provisions. Any dispute, controversy or claim arising out of or in connection with this Agreement shall be settled by a Swedish court of general jurisdiction as the court of first instance.

This agreement is executed by the authorised representatives of the Parties of the dates indicated below.

Each Party agrees that this Agreement may be electronically signed, and that electronic signatures appearing on this Agreement are the same as handwritten signatures for the purposes of validity, enforceability and admissibility.

Authorised representatives of [Insert name of Institution]

_____

Place and date

_____

Signature

_____

Name printed and title

The undersigned Principal Investigator hereby declares that he/she has read the Agreement:

_____

Place and date

_____

Signature

_____

Name printed and title

Authorised representatives of [Insert name of Sponsor]

_____

Place and date

_____

Signature

_____

Name printed and title

Appendix 1

PAYMENT SCHEDULE

Appendix 2

STANDARD CONTRACTUAL CLAUSES