Standard Clinical Trial Agreement

Preamble

WHEREAS this Standard Clinical Trial Agreement ("Agreement") was approved by the Danish Regions on May 1, 2012 as version 1;

WHEREAS this Agreement shall be used when entering into agreements between Sponsor (defined in Appendix A) and a public institution in Denmark, represented by the Principal Investigator (defined in Appendix A);

WHEREAS the purpose of this Agreement is to enable the Parties to enter into an agreement under standardised legal terms;

WHEREAS the main body of this Agreement may not be changed;

WHEREAS the Parties on a project by project basis agree on the specific work and payments to be executed under this agreement, and define these in details using Appendix A-J and signing the Agreement by using Appendix K;

WHEREAS Sponsor is the regulatory Sponsor of the clinical multi-centre study and wishes to enter into an agreement with Institution (defined in Appendix A);

WHEREAS Sponsor has requested Institution's employee, Principal Investigator, to conduct the Study (defined in Appendix A) on behalf of Institution involving the Study Product (defined in Appendix A) according to this Agreement and it's Appendices, the Protocol including subsequent Protocol amendments (defined in Appendix C); and

WHEREAS Principal Investigator is equipped and authorized to undertake the Study and Principal Investigator have agreed to perform the Study on the terms and conditions hereinafter set forth;

NOW THEREFORE in consideration of the premises and the mutual promises and covenants expressed herein, the Parties agree as follows:

1. Applicable Law and Regulations

1.1 The Parties shall comply with all applicable national and international laws, regulations and guidelines, especially those governing the conduct of clinical trials, dealings in medicinal products, responsibilities of clinical investigators, informed consents, protection and privacy of personal data and storage of data and records, including, without limitation, the ICH Guidelines and the European Guidelines on Good Clinical Practice (hereinafter referred to as "ICH-GCP"), Good Laboratory Practice, the revised versions of the Declaration of Helsinki Directive 95/46/EC and Directive 2001/20/EC of the European Parliament and of the Council, and professional industry association regulations.

1.2 The Parties agree that the collection, processing and disclosure of personal data and medical information related to the Study subject, and personal data related to Principal Investigator and any investigational staff (e.g., name, hospital or clinic address and phone number, curriculum vitae) is subject to compliance with applicable personal data protection and security laws and regulations. Institution/Principal Investigator shall not disclose to the Sponsor the identity of the subjects or information from which the identity of the subject can be deduced without prior written consent of the subject.

1.3 Institution/Principal Investigator agrees to inform the investigational staff that their personal data may be collected. In such case the Sponsor may transmit such personal data to other affiliates or group companies and their respective agents worldwide. Accordingly, personal data may be transmitted to countries outside the European Economic Area, such as the United States, which the EU has determined currently lack appropriate privacy laws providing an adequate level of privacy protection. Nonetheless, Sponsor will apply adequate privacy safeguards to protect such personal data. Personal data may also be disclosed as required by individual regulatory agencies or applicable law, such as to report serious adverse events.

1.4 The Institution confirms that neither it, and to the best of its knowledge nor any of its investigators, employees, agents or other personnel providing services for the Study pursuant to this Agreement, has ever been debarred, disqualified, or banned from conducting Investigations or is under investigation by the competent authority or any equivalent regulatory authority within the US for debarment, disqualification or any similar regulatory action.

2. Obligations of the Parties

2.1 Ethics Committee (EC) - Authorizations

2.1.1 Institution/Principal Investigator shall assist Sponsor in obtaining all necessary approvals from the Ethics Committee, hereunder but not limited to the Protocol and its amendments and informed consent form, and relevant regulatory authorities.

2.1.2 In the event that EC requires amendments in the Protocol or informed consent form, such amendments shall be agreed upon by both the Institution/Principal Investigator and Sponsor and be documented in writing.

2.2 Conduct of Study

2.2.1 The Parties shall conduct the Study in accordance with the Protocol and its amendments, the terms of this Agreement, and the terms and conditions of the approval of relevant authorities.

2.2.2 Institution/Principal Investigator shall adhere to separate manuals and specific procedures provided by Sponsor applicable for conducting the Study.

2.2.3 Institution/Principal Investigator shall be fully informed of the Protocol and the Study Product and attend, or ensure a delegate attends, all Investigators' meetings for the Study from time to time as reasonably required by Sponsor.

2.2.4 Institution/Principal Investigator shall ensure that all the Institution's employees and collaborators, who are involved in the Study fully, understand and adhere to the Protocol and the obligations of both the Institution and the Principal Investigator.

2.2.5 Sponsor shall provide all relevant clinical pharmacology and toxicology information and advice to Institution/Principal Investigator, which are required for the proper planning and conduct of the Study. Such information will include the Investigator's Brochure (IB) and information on Suspected Unexpected Serious Adverse Events (SUSARs) for unlicensed products or the Summary of Product Characteristics (SPC) for licensed products.

2.3 Data and Safety Reporting

2.3.1 Institution/Principal Investigator shall submit written reports, in accordance with all laws, regulations and guidelines including the Ethics Committee standards, to Sponsor and the EC regarding the Study being conducted at the Institution on request.

2.3.2 In case Electronic Data Capture ("EDC") is used for the Study: Institution/Principal Investigator will submit Study data using the electronic system provided by the Sponsor. Institution/Principal Investigator shall also comply with Sponsor's instructions for data entry into the system, which includes that investigational staff using the system understands that their electronic signatures are the legally binding equivalent of handwritten signatures, and they attest to the accuracy and completeness of the data entered.

2.3.3 Required Systems: Institution/Principal Investigator agrees to implement and use any electronic system that Sponsor may specify for use in the reporting and monitoring of the Study and Study findings at Sponsor's expense. Institution/Principal Investigator shall have all available data entered in the system agreed.

2.3.4 Institution/Principal Investigator agrees to report to Sponsor immediately but not later than twenty-four (24) hours after learning of any serious adverse events and other important medical events, as identified in the Protocol, affecting any Study subject in the Study. Institution/Principal Investigator further agrees to follow up such report with detailed, written reports in compliance with all applicable legal and regulatory requirements

2.4 Record Management

2.4.1 Institution/Principal Investigator will retain in a safe and secure location, one (1) copy of all printed and electronic data and reports resulting from the Study for the longer of (a) two (2) years after the last marketing authorization for the Study Product has been approved or Sponsor has discontinued research on the Study Product or (b) such longer period as required by regulatory requirements. Sponsor will provide instructions for the retention or destruction of documentation.

2.4.2 Institution may store Study documents at a mutually agreed third party site at Sponsor's expense. Such documents will only be accessed with the written consent of the Institution/Principal Investigator. In case of retrieval of the Study documents, stored on behalf of the Institution/Principal

Investigator, prior written authorization is required. If the Institution/Principal Investigator wants to move the Study documents to another location, the Sponsor must be notified in writing.

2.4.3 Institution/Principal Investigator shall keep all related correspondences by the Institution/Principal Investigator, the Institution's employees, Sponsor and any other person involved in the Study in accordance with Section 2.4.1.

2.4.4 Institution/Principal Investigator shall maintain accurate data collection and up-to-date records of all Study subjects;

2.4.5 Institution/Principal Investigator shall record and evaluate all Adverse Events experienced by the Study subjects in accordance with the Protocol.

2.5 Study Product

2.5.1 Sponsor shall provide free of charge, or as appropriate, reimburse Institution for materials that Sponsor is required to provide per the Protocol including Study Product necessary for the conduct of the Study.

2.5.2 Institution/Principal Investigator shall ensure that the Study Product are handled correctly and stored securely for the duration of the Study and any period thereafter as required by applicable law or this Agreement, whichever is later, in accordance with the Protocol.

2.5.3 Only those persons who are under the Principal Investigator's direct control and who will be using the Study Product shall have access to the Study Product.

2.5.4 Institution/Principal Investigator shall not use the Study Product for any purpose other than the conduct of the Study.

2.5.5 Upon termination or completion of the Study, all unused Study Product shall be returned to Sponsor at Sponsors expense or, at Sponsor's sole option and at Sponsor’s expense, destroyed.

2.6 Informed Consent

2.6.1 Institution/Principal Investigator undertakes to use the patient information sheet as approved by the Ethics Committee and to obtain written informed consent from each Study subject prior to inclusion or initiation of any Study specific procedures for screening according to the Protocol.

2.7 Study subject Enrolment

2.7.1 Institution/Principal Investigator shall make reasonable efforts to ensure that the recruitment target of eligible subjects in accordance with the Protocol is met timely and that data from all eligible Study subjects are available on or before the expiration of the Study.

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

2.8 Monitoring and Audit

2.8.1 Sponsor shall provide reasonable supervision, training and monitoring during the conduct of the Study.

2.8.2 Institution/Principal Investigator shall during the Study, on reasonable prior written notice and at an agreed upon time, permit authorized personnel of Sponsor or its representatives (including the CRO) to access the site during normal business hours in order to conduct monitoring and audits. Any review by Sponsor or its representative of source documents shall be performed with due regard for Study subject confidentiality.

2.9 Biological Samples

2.9.1 Institution/Principal Investigator shall use all samples derived from Study subjects enrolled in the Study, including blood, bone marrow, sera, platelets and other biological materials in accordance with the Protocol and the Study subject informed consent.

2.10 Equipment

2.10.1 Sponsor-Provided Required Equipment: The Parties acknowledge that certain equipment may be needed to properly conduct the Study. If Sponsor and Institution/Principal Investigator agree that Institution/Principal Investigator does not have sufficient access to some or all of that certain equipment, then such equipment shall be identified. The Sponsor or its representative will supply Institution/Principal Investigator with the Required Equipment free of charge or reimburse

Institution/Principal Investigator for the costs of such, subject to the terms of this Agreement. If the Sponsor shall supply Required Equipment to Institution/Principal Investigator, the Sponsor or its representative shall arrange for the delivery of such Required Equipment to the address specified by Institution/Principal Investigator. If Institution/Principal Investigator is to take ownership of Required Equipment, ownership and title of the Required Equipment shall transfer to Institution/Principal Investigator at the time of delivery. If Institution/Principal Investigator upon termination or expiration of Study shall return Required Equipment to Sponsor it shall be at Sponsors expense.

2.10.2 Sponsor-Lent Required Equipment. If a Protocol specifies that the Required Equipment will be lent to the Institution/Principal Investigator for the duration of a Study, Sponsor or its representative shall provide the Required Equipment. Such Required Equipment shall remain Sponsor's or its representative's property at all times and shall be identified as such and can only be used to perform Study. The Institution/Principal Investigator shall ensure that the Required Equipment is stored and used properly. Upon termination or expiration of Study, Institution/Principal Investigator shall, at Sponsors expense, return Sponsor-Lent Required Equipment to Sponsor.

3. Compensation

3.1 The budget and compensation to be paid for the Study is included in Appendix D. Payment shall be due and payable in accordance with the schedule and details set forth in Appendix D and E.

3.2 The parties acknowledge and agree that the compensation and support provided by Sponsor to Institution pursuant to this Agreement represents the fair market value for the Study conducted by Institution, has been negotiated in an arms-length transaction, and has not been determined in a manner that takes into account the volume or value of any referrals or other business otherwise generated between Sponsor and Institution. Nothing contained in this Agreement shall be construed in any manner as an obligation or inducement for the Institution to recommend that any person or entity purchase the Sponsor’s products or those of any entity affiliated with Sponsor.

3.3 Institution shall not bill any third party for any Study Product or other items or services furnished by Sponsor in connection with the Study, or any services provided to Study subjects in connection with the Study for which payment is made as part of the Study.

3.4 Changes to the Protocol: In the event of a change to the Study Protocol that results in an increased cost, or if any increase in the compensation due for the conduct of the Study is necessary or

appropriate, the Parties shall negotiate further remuneration and the, Sponsor shall provide written notice in the form of a budget increase letter.

4. Confidentiality

4.1 All information furnished by Sponsor ("Confidential Information") pursuant to this Agreement, to Institution/Principal Investigator, shall be treated by Institution/Principal Investigator as confidential for a period of five (5) years after termination of this Agreement. Institution/Principal Investigator 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 Study, 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 to return the Confidential Information and any copies of it or to confirm in writing that it has been destroyed. However, Institution/Principal Investigator may keep one copy for documentation purposes.

4.2 The foregoing Section 4.1 does not apply to any of the Confidential Information which Institution/Principal Investigator can show i) is already lawfully known to Institution/Principal Investigator at the date it was disclosed to it by Sponsor and is or becomes free of restriction on the disclosure or use in question, or ii) is or becomes generally known or freely available to the public (except by reason of any breach by Institution/Principal Investigator of its obligations hereunder), or iii) is disclosed to Institution/Principal Investigator, free of restriction on the disclosure or use in question, by a third party who was entitled to make such unrestricted disclosure, or iv) is independently developed by Institution/Principal Investigator, or v) is disclosed, retained or maintained by law or any regulatory or government authority.

5. Registry

5.1 Prior to the initiation of enrolment, Sponsor shall publicly register protocol summaries and Institution contact details from company sponsored trials of both investigational medicinal products and marketed medicinal products that meet at least one of the following criteria i) clinical trials that are adequately-designed and well-controlled, ii) clinical trials to test effectiveness, involving a medicinal product to treat a serious or life-threatening disease or condition, or iii) clinical trials intended to be published in the international peer-reviewed literature (http://www.icmje.org).

5.2 Protocol summaries being publicly registered will contain the World Health organization (WHO) minimal registration data set of 20 items adopted by International Committee of Medical Journal Editors. Registration will be to the United States National Library of Medicine web site designed for this purpose at (www.clinicaltrials.gov) . In addition equivalent official websites and Sponsor's websites may be used for registration purposes.

5.3 Any person accessing a clinical trial listing for a clinical trial on www.clinicaltrials.gov may elect to complete an online eligibility-screening questionnaire made available through Sponsor funding. For Study subjects screened as potentially eligible in Institution's geographical area, Institution/Principal Investigator will receive a report with the completed screen and the Study subject's contact information. Institution/Principal Investigator agrees to follow-up on the report and to document such follow-up in source records.

6. Publication

6.1 The Parties recognize that Danish law places an obligation on hospitals carrying out health and social care research to publish their work. The Parties agree that this Section 6 should be interpreted in light of such obligation.

6.2 Following completion of the entire Study at all sites, Sponsor shall use all reasonable endeavors to ensure the appropriate publication or other dissemination of the conclusions of the Study, and Institution/Principal Investigator for such Study shall not publish data/results derived from the individual institution site until the combined results from the entire Study has been published in a joint, multi-centre publication. If such a multi-centre publication is not submitted within twelve (12) months after conclusion, abandonment or termination of the Study at all sites, or after the Sponsor confirms there will be no multi-centre clinical trial publication, Institution/Principal Investigator may publish the data/results from the Institution individually in accordance with this Section.

6.3 If Institution/Principal Investigator wish to publish data/results from the Study, a copy of the manuscript must be provided to the Sponsor for review at least thirty (30) days prior to submission for publication, presentation or release. The Sponsor and Principal Investigator will arrange expedited reviews for abstracts, poster presentations or other materials. Within this 30 day period, the Sponsor shall review such proposed publication or presentation or release to determine whether it contains any Confidential Information of Sponsor (as defined in Section 4), or whether Sponsor desires to file patent applications on subject matter contained therein. Upon receiving any notification from Sponsor

requesting deletion of Confidential Information of Sponsor, or requesting a delay in publication to allow the filing of patent applications before publication or release, Principal Investigator shall take the requested action; provided however, that any delay in publication shall not exceed ninety (90) days from the date on which Sponsor received the draft manuscript for review.

7. Publicity

7.1 None of the Parties shall use the name of any other Party for marketing or promotional purposes without the prior written consent of the Party whose name is proposed to be used, nor shall either Party disclose the existence or substance of this Agreement except as required by law or otherwise provided for in this Agreement. Pursuant to the rules and regulations on public research made by the Danish Ministry of the Interior and Health, the public shall have access to information about private financing at research institutions. Consequently Sponsor accepts that the Study title, the name of the Parties and the amount of funding will be disclosed to the public. Furthermore, Institution being a Danish public body is encompassed by the Act of Publicity within the Public Administration.

8. Ownership of Data

8.1 All data/results generated by Institution/Principal Investigator in the direct course of conducting the Study ("Data") shall be the property of Sponsor, which may utilize the Data in any way it deems appropriate, subject to and in accordance with applicable privacy and security laws and regulations and the terms of this Agreement.

8.2 Institution/Principal Investigator retain right to use Data for further research, education and treatment purposes.

8.3 Notwithstanding the foregoing, Institution retains ownership of all raw clinical data, including biological materials (blood, bone marrow, sera, platelets and other biological materials) as contained in Institution's patient and medical records or other original source documentation.

9. Ownership of Inventions

9.1 Any inventions/improvements within the field of research, an resulting directly from the Study shall be owned by Sponsor ("Inventions"). Sponsor shall be entitled to file in its own name relevant patent applications or in other ways protect the Inventions, and the said Inventions will become and remain the property of Sponsor solely.

9.2 Institution/Principal Investigator shall promptly disclose and assign to Sponsor all Inventions generated by Institution/Principal Investigator pursuant to this Agreement.

10. Indemnification

10.1 Sponsor shall defend, indemnify and hold harmless Institution, its trustees, officers, agents and employees (including the Principal Investigator and co-investigators) from any and all losses, costs, expenses, liabilities, claims, actions and damages, based on a personal injury or death to a Study subject caused by the use of the Study Product during the course of the Study.

10.2 The above obligation of Sponsor, as stated in Section 10.1, shall not apply and Sponsor shall not be liable for any indemnification or expenses, for actions or claims arising from or caused by the wilful, reckless, or gross negligent acts or omissions, or professional malpractice of Institution or any of its trustees, officers, agents or employees, or arising from or caused by failures to comply with the Protocol, with Sponsor's written instructions related to the use of the Study Product, or with any applicable legal and regulatory requirements.

10.3 The obligation of the indemnifying Party hereunder shall apply only if the other Party provides prompt notification upon receipt of notice of any claim or suit, permits – if permitted by law - the indemnifying Party and its attorneys and personnel to handle and control the defence of such claims or suits, including pre-trial, trial or settlement, and the indemnified Party fully cooperates and assists in such defence. The indemnified Party further agrees that it will not settle or compromise any such claim or suit without the prior written consent of the indemnifying Party.

11. Liability and Insurance

11.1 Institution as a public Danish body is self-insured according to Danish law. Institution's assets are sufficient to cover any contemplated self-insured liability assumed by Institution under this Agreement. All Study subjects are covered by Danish mandatory law "Lov om klage- og erstatningsadgang inden for sundhedsvæsenet, kapitel 4 (lov nr. 547 af 24. juni 2005)" as amended from time to time. Institution shall not be liable for any indirect losses, consequential damages, operational losses, loss of profit or other consequential financial losses, including claims for damages from a third party.

11.2 Sponsor carries general liability and product liability insurance or is self-insured in an amount sufficient to support its obligations under this Agreement. Sponsor shall secure and maintain in full force and effect through-out the performance of the Study (and following termination of the Study to cover any claims arising from the Study) insurance coverage for i) product and study design liability and ii) general liability, each such insurance coverage in amounts appropriate to the conduct of Sponsor's business activities and in compliance with the applicable legal and regulatory requirements.

11.3 Upon request, Sponsor shall provide Institution with certificates of insurance evidencing the required insurance coverage.

13. Term and Termination

13.1 This Agreement shall be considered fully executed on the latest date that a Party executes the same, and will remain in effect until completion of the Study, close-out of Institution or completion of the obligations of the Parties under this Agreement or earlier termination in accordance with this Section 13 whichever occurs first.

13.2 This Agreement may be terminated by either Party at any time in the exercise of its sole discretion upon thirty (30) calendar days prior written notice to the other Party, if i) a material breach of this Agreement occurs, including failure to comply with the Protocol and applicable laws and regulations, ii) receipt of safety information makes it advisable to do so.

13.3 Notwithstanding the above, Sponsor may immediately terminate the Study if, within its sole judgment, such immediate termination is necessary based upon considerations of subject safety or upon receipt of data suggesting lack of sufficient efficacy. Upon receipt of notice of termination, Institution/Principal Investigator agrees to promptly terminate the conduct of the Study to the extent medically permissible for any individual who participates in the Study.

13.4 In the event of termination hereunder, other than as a result of a material breach by Institution/Principal Investigator, the total sums payable by Sponsor pursuant to this Agreement shall be equitably prorated for actual work performed to the date of termination including any reasonably non-cancellable costs and start-up costs, with any unexpended funds previously paid by Sponsor to Institution being refunded to Sponsor.

13.5 Institution/Principal Investigator shall immediately deliver to Sponsor or its designee all Data generated as a direct result of the Study and shall, at Sponsor's expense return to Sponsor or destroy upon instructions of the Sponsor, all unused Study Product, all documents, materials and equipment provided by Sponsor and all Sponsor Confidential Information, as defined in Section 4, at the earlier of the conclusion of the Study or termination of this Agreement. This provision does not apply to those documents that should be maintained and retained by Institution/Principal Investigator at Institution, as defined in the Protocol and as requested by applicable laws and regulations.

13.6 The rights and obligations of the Parties which by intent or meaning have validity beyond termination as set forth above, including, but not limited to, rights with respect to patent rights, ownership of Inventions, confidentiality, liability limitations, indemnification and insurance, and publication shall survive the termination or expiration of this Agreement.

14. Notices

14.1 Any notices given hereunder shall be sent by first class mail, by fax or personally delivered, with postage prepaid, to the people listed in Appendix F, if related to this Agreement.

14.2 Any notices given hereunder shall be sent by first class mail, by fax or personally delivered, with postage prepaid, to the people listed in Appendix G, if related to serious adverse events and medical events.

15. Miscellaneous

15.1 Sponsor shall have the right to assign this Agreement to an affiliate of Sponsor upon prior written notice to Institution. In all other instances, neither Party shall assign its rights or duties under this Agreement to another without prior written consent of the other Party. Subject to the foregoing, this Agreement shall bind and inure to the benefit of the respective Parties and their successors and assigns.

15.2 Institution is an independent contractor to Sponsor, and not a partner, agent, employee, representative, or joint-venture of Sponsor. Except as set forth in this Agreement, no Party, or its employees, agents, or subcontractors, has any right or authority to bind or act on behalf of another Party.

15.3 Principal Investigator confirms that there is no conflict of interest that will inhibit or affect the Principal Investigator's performance under this Agreement and confirm that their performance under this Agreement does not violate any other agreement with third parties. Principal Investigator will promptly inform Sponsor if any conflict of interest arises during the performance of this Agreement. For the avoidance of doubt, Institution and Principal Investigator are free to enter into any other agreement with any third parties as long as this does not prevent Institution and/or Principal Investigator from fulfilling their obligations according to this Agreement.

15.4 This Agreement may not be altered, amended or modified except by written document signed by the Parties.

15.5 If any of the provisions of this Agreement conflicts with any provision of the Protocol or any other relevant document, this Agreement shall take precedence.

15.6 If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect.

15.7 This Agreement constitutes the entire agreement of the Parties with respect to the subject matter hereof. It expressly supersedes any prior or contemporaneous oral or written representations or agreements. The Appendices form an integral part of the Agreement.

16. Law and Venue

16.1 In the event of any dispute arising between the Parties in relation to the terms of this Agreement, the Parties shall use their best endeavours to resolve the matter on an amicable basis. This Agreement shall be governed by and shall be construed in accordance with the laws of Denmark without regard to any conflicts of law's provisions. The Parties consent to the competent courts of Denmark for the resolution of all disputes or controversies between the Parties hereto that the Parties are unable to settle amicably.

17. Signatures

17.1. Both the Institution appointed signee(s) and Principal Investigator shall sign this Agreement to be legally binding.

17.2 This Agreement is executed in three counterparts, each of which shall constitute the original.

Appendix A – The Parties

[Insert name and address]
("Institution")

Dr XX will be responsible on behalf of Institution for the conduct of the Study
("Principal Investigator")

and

[Insert name and address]
("Sponsor")

Institution and Sponsor are hereinafter also individually referred to as a "Party" and collectively as the "Parties".

The Institution has entered into an agreement with Sponsor for the clinical trial research project entitled

[Insert title of Protocol]
("Protocol")

The Protocol agreed with the Sponsor is formally incorporated into this Agreement as Appendix C.

Appendix B – Sponsor Study details

(to be amended as required)

Study name:

Study Product:

Protocol name:

Protocol ID:

EUdraCT number:

Institution:

Estimated study start date:

Estimated last patient visit date:

Estimated end of trial:

Sponsor provided equipment:

Sponsor lent equipment:

Required systems:

Appendix C – Protocol copy

Appendix D – Work and payment details as agreed between Sponsor and Principal Investigator

(To be modified as needed)

Maximum enrolment fee per patient:

(Please note whether the amount(s) are inclusive or exclusive of VAT).

Other compensations:

(Please note whether the amount(s) are inclusive or exclusive of VAT).

Payment milestones:

Payment terms:

Other payment details:

Appendix E – Payment details

The payment details for transfer of payments, as advised by the Institution:

Account number: _____

Account or payment reference: _____

Appendix F – Notices in relation to the Agreement

Notices in relation to the Agreement shall be sent to the following:

Sponsor:

To:

Attention:

Facsimile:

To:

Attention:

Facsimile:

Principal Investigator:

To:

Attention:

Facsimile:

To:

Attention:

Facsimile:

Other:

To:

Attention:

Facsimile:

To:

Attention:

Facsimile:

Appendix G – Reporting of Serious Adverse Events and important medical events

Notices shall within 24 (twenty-four) hours be documented and reported to:

Sponsor:

To:

Attention:

Facsimile:

To:

Attention:

Facsimile:

Appendix H - Financial Disclosure

Principal Investigator agrees on the request of Sponsor to provide all information to Sponsor necessary to comply with any disclosure requirements mandated by any competent Health Authority (including, if applicable, the US FDA), including any information required to be disclosed in connection with any financial relationship between Sponsor and other affiliates or group companies and respective agents and the Principal Investigator and any co-investigator involved in the Study and between any other agent or employee of Principal Investigator and Sponsor. This disclosure requirement may require disclosure of information involving immediate family members of those involved in the Study.

Appendix I – Roles and duties of an appointed Clinical Research Organisation acting on behalf of Sponsor

Add documentation for CRO activities as Appendix H

Add documentation for Sponsor payment

Add documentation for Sponsor indemnification

Appendix J - National Coordinator Agreement

Whereas it is has been agreed between the Institution and Sponsor that Institution will be the co-ordinator in Denmark for the Study and will subcontract a number of institutions in Denmark. Sponsor agrees that each site involved in this Study shall, prior to beginning of the Study, enter into a sub-site agreement regarding its participation in the Study. The form of agreement to be used with such sub-sites shall be prepared by Institution using the Standard Sub-site Agreement for Clinical Trial (attached hereto) and shall be consistent with the terms of this National Coordinator Agreement. By signing the National Coordinator Agreement, Sponsor also accepts to be bound by any applicable terms of the Sub-site Agreements.

Appendix K– Signatures

I hereby sign this Agreement and verify that the Standard Clinical Trial Agreement Section 1 to 17 in its entirety has not been modified.

For Institution:	For Sponsor:
Date:	Date:
_____	_____
[Insert Name]	[Insert Name]
[Insert Title]	[Insert Title]
Date:	Date:
_____	_____
[Insert Name]	[Insert Name]
[Insert Title]	[Insert Title]

Principal Investigator:

I hereby acknowledge that I have read and agree with the terms of this Agreement, and that I will act and perform my duties in the study in accordance with the content of this Agreement and the details outlined in the Appendices.

Date:

_____

[Insert Name]

[Insert Title]