*[Please note: This document contains text in red/italic and brackets, where text is either optional, or text is to be inserted to adjust to the clinical investigation in question.]*

**Standard Clinical Investigation Agreement**

*Agreement on the conduct of a clinical Investigation of medical devices in Denmark*

***Investigation ID***

*Investigation Title*

*Version 1.0*

# The Parties

**Institution/Site**

*[Site details]*

(The ”Institution/Site”)

represented by:

*[Investigator name]*

(The ”*[Coordinating or Principal]* Investigator”)

and

**Sponsor**

*[Sponsor details]*

Hereinafter together referred to as the Parties.

Dr. xx (“Investigator”) will be responsible for the conduct of the Investigation on behalf of Institution/Site. It is understood that Investigator is not a party to this Agreement but is bound by his/her employment to the Institution/Site to abide by the terms herein.

Site is defined as the facility (e.g. hospital, clinic, institution etc.), where the Investigation is carried out. Sponsor shall be informed in writing promptly after the institution or Site where the clinical investigation is carried out,(”Investigation site”) has learned that an Investigator is not able to or unwilling to perform his/her obligations according to this Agreement.

Coordinating investigator is defined as Investigator who is appointed by the sponsor to coordinate work in a multicentre clinical investigation,

The Principal Investigator (PI) is the health professional who is responsible and accountable for conducting the complete clinical investigation. The PI assumes full responsibility for the treatment and evaluation of human Subjects, and for the integrity of the research data and results. Furthermore, PI is responsible for conducting the investigation at site, has access to and control over the clinical investigation data from the site, and has the right to publish site results of the investigation.

# General requirements

The Parties have agreed to conduct a clinical investigation [insert investigation ID] (hereinafter referred to as the Investigation) investigating *[insert product name].*

The Parties are obliged to conduct the Investigation in conformity with the Clinical Investigation Plan (CIP) and the following law, standards and international guidelines as amended from time to time *[check and insert if new versions are published]*:

* World Medical Association Declaration of Helsinki, 1964, last amended at the 64th WMA General Assembly, Fortaleza, Brazil, October 2013.
* Medical Device Directive (MDD) 93/42/EEC as amended by Directive 2007/47/EC, Article 15, Annex X.
* DS/EN ISO 14155:2011 (Clinical investigation of medical devices for human subjects – Good clinical practice)
* Danish data protection law
* *[Insert any other applicable laws, rules or regulations pertaining to the investigation].*

The Parties have thus entered the agreement below (hereinafter referred to as the Agreement).

# Coming into force and duration of the Agreement

The Investigation will commence when all Parties have duly signed this Agreement, and when approvals from the regional Health Research Ethics Committee (REC; http://www.cvk.sum.dk/CVK/Home/English.aspx)and the Danish Health and Medicines Authority have been obtained and will remain in effect until completion of the Investigation, close-out of institution/site or completion of the Investigation or earlier termination in accordance with Section 11 of this Agreement, whichever occurs first. The Investigation is completed once the Coordinating Investigator [or ‘Principal investigator from each investigation site if no coordinating investigator is appointed], *[*and the Sponsor have signed either the final document describing the design, execution, statistical analysis and results of a clinical investigation (“Clinical Investigation Report”) which is prepared by Sponsor according to the Clinical Investigation Plan or the related affidavit

.

# Obligations of the Institution/SITE and the *[COORDINATING or PRINCIPAL]* Investigator

## [*If this Agreement (or Investigation) relates to Class I products only, then this bullet can be deleted*]: *It is the responsibility of the [Coordinating or Principal] Investigator to ensure that all Health Care Professionals (doctors, dentists, nurses and pharmacists) listed on the Investigation Site Delegation Log as site personnel has registered his/her collaboration with Sponsor with the Danish Health and Medicines Authority prior to initiating collaboration with Sponsor in accordance with “Bekendtgørelse om sundhedspersoners tilknytning til bl.a medicovirksomheder”. Information booklet regarding the Danish Transparency Rules is enclosed as Appendix A to the Agreement.*

## The Investigators, including the [Coordinating or Principal] Investigator and individual member of the investigation site team designated and supervised by the principal investigator at an investigation site to perform critical clinical-investigation-related procedures or to make important clinical-investigation-related decisions, undertakes to comply with the signed document that state(s) the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical investigation [investigation ID] (“Clinical Investigation Plan” or “CIP”) including any amendment hereto which the Parties agree upon and have approved in writing, as well as any separate manuals and specific procedures provided by Sponsor applicable for conducting the study. Should it turn out in the course of the Investigation that the CIP or any manuals/procedures belonging to it cannot be complied with; the *[Coordinating or Principal]* Investigator must report this to the Sponsor without undue delay.

## The Institution/Siteand the *[Coordinating or Principal]* Investigator undertakes to use the Subject information sheet as approved by the REC and to obtain written informed consent from each Subject prior to initiation of any investigation specific procedures according to the CIP. "Subject" is defined as an individual who participates in a clinical investigation. A subject can be either a healthy volunteer or a patient.

## The Institution/Site and the *[Coordinating or Principal]* Investigator will co-operate with Sponsor representatives, to ensure proper investigation conduct and follow-up.

## Each Investigator cannot fully or partly assign his/her obligations under this Agreement to any third party without the Sponsor’s written acceptance. In such case the Investigator is not able to or unwilling to perform his/her obligations according to this Agreement; the Institution/Site can appoint a substitute, in which case Sponsor shall be informed promptly in writing.

## “Sponsor has the right to approve the appointed substitute, and if a suitable replacement cannot, after reasonable efforts by the Institution/Site, be found that is acceptable to Sponsor, Sponsor and/or Institution/Site is entitled to terminate this Agreement within 14 calendar days after the written notification regarding the appointing of the substitute.

## The Institution/Site and the *[Coordinating or Principal]* Investigator declares to make the required facilities, manpower and expertise available for the Investigation and to use reasonable efforts to timely enrol the number of Subjects as described in this Agreement.

## The *[Coordinating or Principal]* Investigator declares that he/she has received sufficient information about *[insert product name]* by means of the Investigator’s Brochure, defined as compilation of the current clinical and non-clinical information on the investigational medical device(s), relevant to the clinical investigation, or the Instruction for Use to ensure that the Investigation is reasonable and safe as defined by the CIP.

## The Institution/Site and *[Coordinating or Principal]* Investigator shall ensure that the Products, defined as a medical device which is any instrument, apparatus, implement, machine, appliance, implant, software, material, or other similar or related article, which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means (“Product”) are handled and stored correctly (according to the Instructions for Use provided by Sponsor) and securely (to ensure the product is only used for Subjects enrolled into the Investigation with informed consent) for the duration of the investigation/Product shelf life and any period thereafter as required by applicable law or this Agreement, whichever is later, in accordance with the CIP. If additional initiatives to standard practice for Investigational products are necessary for a secure storage, these initiatives are to be paid solely by Sponsor.

## The Institution/Site and *[Coordinating or Principal]* Investigator shall not use the Products for any purpose other than the conduct of the clinical investigation.

## The Institution/Site and the *[Coordinating or Principal]* Investigator shall ensure that all the Institution’s employees and collaborators who are involved in the Investigation, understand and adhere to the CIP and the obligations of both the Institution and the Coordinating/Principal Investigator.

## The Institution/Site and *[Coordinating or Principal]* Investigator shall maintain accurate data collection and up-to-date records of all Subjects to ensure that data from all eligible Subjects are available for Sponsor in a timely manner according to the Subjects treatment.

## The Institution/Site and *[Coordinating or Principal]* Investigator shall record and evaluate all inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance including malfunctions, use errors, and inadequate labelling (“Device Deficiencies”) and any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in Subjects, users or other persons, experienced in relation to the treatment of a Subject in accordance with the CIP, whether or not related to the investigational medical device (“Adverse Events”). Adverse Events include events related to the investigational medical device or the comparator or the procedures involved; for users or other persons, this definition is restricted to events related to investigational medical devices.

## After the completion of the Investigation, the Institution/Site or *[Coordinating or Principal]* Investigator must return all unused products and technical equipment made available by Sponsor at Sponsor’s own reasonable cost and risk. Alternatively the Institution/Site must arrange for documented destruction of unused products at Sponsor’s own reasonable cost (*if applicable)*.

## If Sponsor makes any required equipment to be used for enrolled Subjects, it is the responsibility of the Institution/Site and *[Coordinating or Principal]* Investigator to ensure that the equipment is used for the Investigation.

## Furthermore, the Institution/Site and *[Coordinating or Principal]* is responsibleto inform Sponsor as soon as possible in case of any malfunctions etc. so that Sponsor can make the necessary arrangements for repair or replacement.

## The *[Coordinating or Principal]* Investigator shall report Adverse Events that may arise during the Investigation to Sponsor, who is responsible for forwarding these to the Danish Health and Medicines Authority. In the event of Adverse Events, Sponsor shall pay for the costs of emergency care or additional diagnostic procedures associated here with, where such Adverse Events have arisen in the course of Investigation as performed in strict adherence to the CIP.

## The Institution/Site is entitled to terminate this Agreement if unforeseen Adverse Events arise, being of such a nature that the safety of the Subjects is compromised. In such a case, Sponsor shall pay the expenses as described in section8.

## In case of premature termination by the Institution/Site, the *[Coordinating or Principal]* Investigator will promptly inform the Sponsor and use reasonable efforts to complete on-going activities related to the Investigation

## After completion of the Investigation, the Coordinating Investigator (*in case of multicentre clinical investigations*) or the Principal Investigator (*in case of single centre clinical investigations*) must sign the Clinical Investigation Report, confirming consistency of its contents and conclusions.

## In case of a multicentre investigation, defined as clinical investigation that is conducted according to a single CIP and takes place at two or more investigation sites (“Multicentre Investigation”), all Principal Investigators shall have the opportunity to review and comment on the Clinical Investigation Report. If the *[Coordinating or Principal]* Investigator does not sign the Clinical Investigation Report or the related affidavit, a justification for the absence shall be provided.

## The Institution/Site and the *[Coordinating or Principal]* Investigator declares that Sponsor is entitled to perform Monitoring, defined as act of overseeing the progress of a clinical investigation and to ensure that it is conducted, recorded, and reported in accordance with the CIP, written procedures, International Standards and guidelines, and the applicable regulatory requirements, of the progress of the Investigation according to agreed procedures. Furthermore, the Parties agree that monitoring shall take place during business hours and at mutually agreeable time.

## The Institution/Site and the *[Coordinating or Principal]* Investigator agrees to follow the harmonized standard DS/EN ISO 14155:2011 “*Clinical investigation of medical devices for human subjects – Good clinical practice”* regarding control of all investigation documents with respect to the identification, storage, protection, retrieval, retention time and disposition of records.

## The Institution/Site may store investigation documents at a mutually agreed third party site at Sponsor’s expense. Such documents will only be accessed by Sponsor with the written consent of the Institution/Coordinating/Principal Investigator.

## In case of retrieval of the investigation documents, stored on behalf of the Institution and the *[Coordinating or Principal]* Investigator, prior written authorization is required. If the Institution/Site and the *[Coordinating or Principal]* Investigator wants to move the investigation documents to another location, the Sponsor must be notified in writing.

# Obligations of the Sponsor

## The Sponsor shall prepare documents and facilitate submission in order to obtain approval of the Investigation and any amendment hereto, from the relevant Research Ethics Committee and/or authorities on behalf of the *[Coordinating or Principal]* Investigator.

## The Sponsor will supply the *[Coordinating or Principal]* Investigator with all relevant products, materials and required information on *[insert test and comparator product name]* necessary for conducting the Investigation. The Sponsor is responsible for updating the documentation as necessary.

## The Sponsor shall communicate all relevant information brought to Sponsor’s knowledge during the Investigation to the *[Coordinating and/or Principal]* Investigator and other investigators participating in this Investigation.

## Sponsor shall provide reasonable supervision, training and monitoring during the conduct of the Investigation in accordance with the CIP and this Agreement.

## The Sponsor is entitled to terminate this Agreement if unforeseen Adverse Events arise, being of such a nature that the safety of the Subjects is compromised or upon receipt of data suggesting lack of sufficient efficacy.

## In case the Sponsor prematurely terminates the Agreement, the Sponsor will pay the costs as described in section8. Furthermore, The Danish Health and Medicines Authority must be notified by the Sponsor.

## At the termination of the Investigation it is the responsibility of the Sponsor to notify the Research Ethics Committee and The Danish Health and Medicines Authority on behalf of the *[Coordinating or Principal]* Investigator. A copy of the notice of deregistration must be sent to the *[Coordinating or Principal]* investigator .

# Product liability and insurance

The Institution/Site 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 Subjects are covered by Danish mandatory law “Lov om klage- og erstatningsadgang indenfor sundhedsvæsenet, kapitel 4 (lov nr. 547 af 24. juni 2005)” as amended from time to time. The Institution/Site 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.

Sponsor agrees to abide by the guidelines in relation to compensation for injuries suffered by Subject included in the Investigation in accordance with the applicable legislation and provisions of Denmark (Bekendtgørelse af lov om produktansvar (lov nr. 61 af 20 marts 2007) and Lov om klage- og erstatningsadgang indenfor sundhedsvæsenet (lov nr. 547 af 24. juni 2005)). Sponsor carries general liability and product liability insurance. Sponsor shall secure and maintain in full force and effect throughout the performance of the investigation (and following termination of the investigation to cover any claims arising from the investigation) insurance coverage for i) product and investigational 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.

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

# Time schedule and number of Subjects

This Investigation site is expected to enrol *[insert number of Subject]* Subjects. All Subject must be completed according to the CIP incl. amendments.

The Institution/Site agrees to recruit the first Subject within *[insert number of weeks]* weeks of study initiation meeting. Otherwise the Sponsor has the right to terminate this Agreement with the Institution/Site.

*[Refer to (preliminary) timelines enclosed as Appendix B]*

The Sponsor has the right to include more Subjects from the other sites or to include new sites in order to attain a sufficient number of Subjects to the Investigation within the given time frame. The Sponsor has the right to terminate the cooperation with any Institution/Site in this Investigation if the Site cannot enrol the agreed number of Subjects within the agreed timeframe.

The Sponsor has the right to terminate the Investigation when the overall target number of Subjects has been attained. This may mean that an Investigation site may not be able to include the planned number of Subjects.

The Parties of this agreement agree that failure to comply with this provision 7 is not to be regarded to as breach of this Agreement.

# Financial conditions

The budget and compensation to be paid is included in Appendix C.

The Institution/Site is responsible for sending invoices to Sponsor. The invoice shall specify the work performed and in accordance with the schedule and details set forth in Appendix C. The invoice is due and payable *[insert terms]* to:

*[insert address]*

* *[Sponsor agrees to pay the Investigation site [amount] DKK in start-up fee to cover time and expenses related to initiating the Investigation at the Institution/Investigation site. No other payment will be made in advance unless this has been agreed in writing.*
* *Sponsor agrees to pay the Investigation site [amount] DKK for [document authorship etc...]*
* *Sponsor will pay the Investigation site per visit performed for each Subject when required documentation has been completed, and the visit data has been monitored, transferred to Sponsor, and no data queries are outstanding.*
* *Subjects with missing visits and documentation or not fulfilling the inclusion/exclusion criteria of the CIP, will not be reimbursed unless there is a reasonable explanation (e.g. Subject unplanned travel, illness etc. which must be documented in the patient record).*
* *Subjects that are screened, but not included are not reimbursed.*
* *Subject or investigator transport will be covered by the Sponsor on a basis of [amount] DKK pr km. or as pass through costs.*
* *The Sponsor will pay the Investigation site by instalments per [insert: month, three-month period, X number of Subjects recruited or other] and after receipt of an invoice according to the agreed payment.*
* *The Sponsor will reimburse reasonable additional pass through costs.*
* *The Sponsor will pay the fee for study approval by the Research Ethics Committee, Danish Health and Medicines Authority as well as other relevant authorities, directly upon receipt of invoice.]*
* *−* The Sponsor will pay, in the event of early termination, for all services required by the CIP that have been performed up to the effective date of termination and any reasonable non-cancellable costs.

*[Alternatively refer to enclosed budget]*

The Parties declare that the agreed payment is in reasonable proportion to the services provided and have agreed no other financial compensation from the Sponsor other than the payments referred to in this Agreement.

If any increase in compensation due for the conduct of the study is necessary or appropriate, the Parties shall negotiate further remuneration, and the Sponsor shall provide a written notice in the form of a budget increase letter. This includes an increase in the amount of Subjects to be enrolled, and if amendments are made to the CIP which result in increased cost for the Institution/Site.

# Registration and Publication

Sponsor is responsible for registration of the Investigation on [www.clinicaltrials.gov](http://www.clinicaltrials.gov). In addition equivalent official websites and Sponsor’s websites may be used for registration purposes.

All rights (including copyrights, patent rights, rights in inventions, designs and other kinds of intellectual property and know-how) attached to information, results and output such as reports, drawings, publications, computer software, etc. obtained by the Parties individually or in co-operation during and in direct connection with execution of this Investigation are the property of the Sponsor without separate compensation therefore.

However the above-mentioned provision must not imply any restriction on the rights of the Institution and the *[Coordinating or Principal]* Investigator’s own results

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

If Institution/ Investigator wish to publish data/results from the Investigation, 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 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 10), 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, 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.

Please refer to *[Appendix D or the CIP]* for agreement on Publication Policy regarding multicenter publications.

# Secrecy

10.1 All information furnished by Sponsor (“Confidential Information”) pursuant to this Agreement, to Institution/ Investigator, shall be treated by Institution/ Investigator as confidential for a period of five (5) years after termination of this Agreement. Institution/ 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 Investigation, iii) take any reasonable steps to the effect that each person employed at the Institution/Site to whom disclosure of the Confidential Information is made will be under the same confidentiality obligations as applies for Institution/Site 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/ Investigator may keep one copy for documentation purposes.

10.2 The foregoing Section 10.1 does not apply to any of the Confidential Information which Institution/ Investigator can show i) is already lawfully known to Institution/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/Investigator of its obligations hereunder), or iii) is disclosed to Institution/ 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/ Investigator, or v) is disclosed, retained or maintained by law or any regulatory or government authority.

10.3 The Parties agree that the collection, processing and disclosure of personal data and medical information related to the Subject, and personal data related to Investigator and any investigational staff (e.g., name, personal security number, hospital or clinic address and phone number, curriculum vitae) is subject to compliance with applicable personal data protection and security laws and regulations.

Institution/ 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.

# OWNERSHIP OF DATA

11.1 All data/results generated by Institution/ Investigator in the direct course of conducting the Investigation (“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.

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

11.3 Notwithstanding the foregoing, the Institution/Site 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.

# Ownership of Inventions

12.1 Any inventions/improvements within the field of research, and resulting directly from the Investigation 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.

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

# Termination

Both Parties may terminate this Agreement in writing with thirty (30) calendar days notice.

## Termination in case of material breach

In case of material breach of this Agreement by a Party, the non-breaching Party will give the breaching Party a reasonable period of time, considering the nature of the breach to remedy such breach. If the breach is not remedied within the reasonable period stated, the party who has not caused the breach may immediately hereafter terminate the Agreement by means of a written statement to the party who has caused the breach. Force majeure shall not be considered material breach. In case of suspension of the work with the Investigation for more than 14 (fourteen) days owing to force majeure the other party is, however, entitled to terminate the Agreement forthwith with no claim for compensation.

## Termination in case of Force Majeure

1. In the event of one of the Parties being prevented or delayed in fulfilling an obligation attaching to same due to circumstances arising after the signing of the Agreement, and which are beyond the reasonable control, and without the fault or negligence, of the Party affected thereby,
2. was not foreseeable by such Party at the time this Agreement was entered into, and
3. could not have been prevented by such Party taking reasonable step, the said Party’s control, the obligation concerned shall be suspended for the duration of the said circumstances, although by no more than *[insert number of days]* calendar days, after which period the Agreement may be terminated immediately by written notice to the breaching Party.

## Notwithstanding the above, Sponsor may immediately terminate the Investigation 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 Investigation to the extent medically permissible for any individual who participates in the Investigation.

# Inconsistencies between the Agreement and the Clinical Investigation Plan

If a provision of this Agreement conflicts with a provision of the CIP, the CIP takes precedence on matters of medicine, science, and conduct of the Investigation. This Agreement takes precedence in any other conflicts.

# INVALIDITY AND SEVERANCE

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

**16. CONFLICT OF INTEREST**

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

# 17 Applicable law AND JURISDICTION

The competent courts of [*Insert the name of the city court]* must settle any dispute arising out of or in connection with the performance of this Agreement in accordance with Danish law.

# 18 Amendment to the Agreement

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

# 19 Signatures

By signing this Agreement the Parties declare that they will both loyally comply with the wording of this Agreement.

This Agreement has been issued in two originals.

|  |  |  |
| --- | --- | --- |
| **Institution:** |  | **Sponsor:** |
| *[address]* |  | *[address]* |
| *[name]*  *[title]* |  | *[name]*  *[title]* |
|  |  |  |
| *Date* |  | *Date* |

|  |  |
| --- | --- |
| 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 Investigation in accordance with the content of this Agreement and the details outlined in the Appendices.  ***[Coordinating or Principal]* Investigator:** | |
| *[Address]* | |
| *[name]*  *[title]* |  |
| *Date* | |
|  | |
|  |  |

**Appendices *[if applicable]***

*[List all appendices referred to in this Agreement (Timelines, Budget, Publication Policy)]*

**Appendix A:** Information booklet regarding the Danish Transparency Rules

**Appendix B:** Preliminary timelines

**Appendix C:** Budget

**Appendix D:** Publication Policy

**Appendix A: Information booklet regarding the Danish Transparency Rules**

**Appendix B: Preliminary Timelines**

The following preliminary timelines are mutually agreed for the major *[insert study ID]* study milestones:

**Study period:**

* First Patient In: *[insert date, week, season as appropriate]*
* Last Patient In: *[insert date, week, season as appropriate]*
* Last Patient Out: *[insert date, week, season as appropriate]*

**Study follow-up:**

* All queries solved: *[insert date, week, season as appropriate]*

**Appendix C: Budget**

*[this is an example – adjust to specific study and include relevant amounts and currency]*

**Start-up fee EUR**

The start-up fee covers but is not necessarily limited to:

Site selection and training meeting (estimated 3 hours)

Initiation meeting (estimated 3 hours)

Product receipt (estimated ½ hour)

Recruitment by going through patient files/phone calls (estimated 1½ hours)

**Study Conduct:**

Visit 1 EUR

(Informed consent and in/exclusion criteria, inclusion visit, approx. 1h)

Visit 2

(Randomization visit, approx. 1h) EUR

Telephone call 1 EUR

(approx. 15min)

Visit 3 EUR

(Interim visit test period 1, approx. ½h)

Visit 4

(cross-over visit, approx. 1h) EUR

Telephone call 2 EUR

(approx. 15min)

Visit 5 EUR

(Interim visit test period 2, approx. ½h)

Visit 6

(termination visit, approx. 1 h) EUR

Administrative work and preparation time per Subject including query resolution EUR (approx. 2h)

**Total per Subject** **EUR**

(6 visits, 2 telephone calls and administrative work)

**Appendix D: *[insert name of company]* Publication Policy**

*[This is an example – adjust as appropriate]*

**1 Scope**

*[Sponsor]* is committed to provide transparent, open and ethical publication. This policy for Medical Publications covers publications originated or sponsored by *[Sponsor]*.

**2 Commitment to Data Disclosure**

Our commitment is met by:

* documenting all clinical and non-interventional investigations on a publicly accessible website e.g. [www.clinicaltrials.gov](http://www.clinicaltrials.gov/). A summary of results will be publicly available within 12 months after completion of the investigation.

**3 Access to Data**

To protect intellectual property rights collaboration between *[Sponsor]* and a third party will be subject to a formal agreement that will address ownership and access to data.

Investigators who are authors of a *[Sponsor]*-sponsored publication will be provided with the documents needed to take responsibility for the content of publications derived from clinical investigations.

*[Sponsor]* will follow specific journal requirements regarding access to data for a submitted manuscript considered for publication.

**4 Publication of Data**

Please refer to Section 9 (Registration and publication) in the Agreement for single-site publications.

**5 Publications from [Company] Sponsored Investigations**

*[Sponsor]* follows the guidelines by the International Committee of Medical Journal Editors (ICMJE) and its *Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals* (<http://www.icmje.org/urm_main.html>).

Importantly, these guidelines require recognition in the manuscript that the research was conducted in accordance with the *Ethical Principles for Medical Research Involving Human Subjects* (<http://www.wma.net/en/30publications/10policies/b3/>), otherwise known as the Declaration of Helsinki.

**6 Authorship**

Authorship for all publications should comply with the criteria defined by the ICMJE. These state that: "Each author should have participated sufficiently in the work to take public responsibility for the content."

Authorship credit should be based on:

1. substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data
2. drafting the article or revising it critically for important scientific content
3. final approval of the manuscript to be submitted for publication

Authors should meet all 3 conditions. *[Sponsor]* believes that participation solely in the collection of data or drafting the manuscript does not justify authorship. These conditions apply equally to external investigators and to *[Sponsor]* employees.

In case of a multicentre investigation, a *[Sponsor]* publication committee will identify the potential author(s) of the manuscript. Author(s) should meet the criteria for authorship defined above. Other contributors should be listed in the acknowledgments as appropriate.

**7 Use of Scientific Writers**

*[Sponsor]* may provide scientific writers (company employees, external consultants or communication agencies) to assist in manuscript preparation or presentations. Any such collaboration must follow ethically acceptable practice:

* the author(s) must approve the overall content and direction of the article before it is written
* the author(s) must critically review the manuscript and approve the final version before submission to a journal and retain full responsibility for the content of the manuscript
* the contribution of the writer must be acknowledged in the publication in line with their level of contribution

For the avoidance of doubt, it is at the Institution or the Investigators own discretion to decide on whether or not to use the option of assisting scientific writers.

**8 Conflicts of Interest**

To ensure transparency all authors must disclose any financial or personal relationships that might bias their contribution.

**9 Privacy**

*[Sponsor]* respects the privacy of the relationship between Subjects and healthcare professionals and is committed to ensure Subject confidentiality in accordance with Article 10 (secrecy) of this Agreement.

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