DRAFT AGREEMENT FOR CLINICAL TRIALS

**Study Protocol n°** [INSERT NUMBER]

**Center:** [INSERT NUMBER]

|  |  |
| --- | --- |
| BETWEEN | **Cliniques Universitaires de Bruxelles - Hospital Erasme**, Located at 808 Route de Lennik, 1070 Brussels, Belgium, represented by, entity part of l’Université Libre de Bruxelles - registered under number 0407.626.464 -, located at Avenue Franklin Roosevelt 50 1050 Brusselsduly represented by Prof. Jean-Paul Van Vooren, Directeur Generalhereinafter referred to as the “**INSTITUTION**”, |
| AND | [INSERT NAME][INSERT ADDRESS]duly represented by [INSERT NAME],hereinafter referred to as “**SPONSOR**”, |

AND […]

The INSTITUTION, […] and the SPONSOR are hereinafter individually referred to as “**Party**” and collectively referred to as the “**Parties**”.

# RECITALS

**WHEREAS**, the SPONSOR wishes to perform a clinical study with [**INSERT STUDY DRUG NAME**];

**WHEREAS**, the SPONSOR wishes to retain the Institution and [**INSERT NAME**]**,** hereinafter referred to as the “Investigator” (as defined in Article 1.7), and the Institution and Investigator wish to be retained by the SPONSOR to perform the clinical study as set forth herein, using funds provided by the SPONSOR ;

**WHEREAS**, the Investigator is experienced in the evaluation and treatment of [**INSERT DISEASE / DRUG NAME**] and is willing to conduct the above mentioned clinical study according to the Protocol and the principles of Good Clinical Practices;

**NOW, THEREFORE, in consideration of the premises and of the following mutual promises, covenants and conditions and any sums to be paid, the Parties hereto agree as follows:**

**OPERATIVE PROVISIONS**

1. **DEFINITIONS**
	1. “**Agreement**” means the present agreement for the Study (as defined below in Article 1.12) and its schedules;
	2. “**Applicable Laws**” means the current version of the World Medical Association’s Declaration of Helsinki, applicable international, European, national and local laws, rules and regulations relating to clinical trials, medical devices and the use of human bodily material for research purposes; the guidelines and guidance documents specifying Good Clinical Practice (“GCP”); all applicable rules and legislation in relation data protection and the processing of personal data (including the General Data Protection Regulation 2016/679 (“GDPR”), the Belgian law of 30 July 2018 on the protection of individuals with regard to the processing of personal data and or other applicable Belgian or European regulation in relation to the processing of personal data), patient’s rights, and the Belgian Sunshine Act implemented by the Royal Decree of 14 June 2017;
	3. “**Case report form**” or “**CRF**”means and includes any document - printed, optical, electronic or others - designed to record all Protocol information required to be reported to the SPONSOR for each patient participating in the Study (“Study Participant” as defined below in Article 1.16). The CRF shall be reported electronically between the Parties. The Parties agree that CRF’s data reported electronically shall have the same probative force as scriptural data or signature;
	4. “Pseudonymised Clinical Trial Personal Data” means any Personal Data (as defined below in Article 1.8) that is collected, pseudonymised and provided by the INSTITUTION to the SPONSOR for the sole purpose of the Study as described in Annex 1;
	5. “Human Bodily Material” means in accordance with the law of 19 December 2008 regarding the procurement and use of human bodily material destined for human medical applications or for scientific research purposes, every biological bodily material, including human tissues and cells, as well as substances extracted therefrom, whatever the degree to which they have been processed;
	6. “**Intellectual Property Rights**” means any and all patent rights (including but not limited to divisionals, extensions, improvement patents, supplementary protection certificates), know-how, trademarks, copyrights (including moral rights), trade and business names, domain names, rights in and to databases (including the right to prevent the extraction or reutilisation of information from a database), design rights, topography rights and any other rights or forms of protection of a similar nature or having equivalent or similar effect, whether or not registered and including all applications for registration of any of foregoing;
	7. “INVESTIGATOR” means the principal investigator, i.e.
* the physician, or
* any other person exercising a profession referred to in all Applicable Laws as defined under Article 1.2 and who is qualified for conducting a study, responsible for the conduct and supervision of the Study, for the integrity, health and welfare of the eligible Study Participants (as defined below in Article 1.16) during the Study and the clinical follow-up of these Study Participants, for the distribution of the Study Drug to the Study Participants and for the reporting of the Study Participants data;
	1. “Personal Data” means any information relating to an identified or identifiable natural person (“Data Subject”) as defined in Applicable Laws, including without limitation Pseudonymized Clinical Trial Personal Data (as defined above in Article 1.4);
	2. “Protocol” means the document entitled [INSERT NAME] dated [INSERT DATE] and bearing the number [INSERT NUMBER], that describes the objective(s), design, methodology, statistical considerations and organisation of the Study, including – but not limited to - the clinical trial plan that defines the clinical tests to be performed on and/or with the Study Drug*, and that is attached hereto as SCHEDULE B*. The term “Protocol” refers to the Protocol successive versions of the Protocol and the Protocol amendments;

Substantial amendments to the Protocol shall only be binding if they have been agreed to in writing by the SPONSOR, the INVESTIGATOR and the responsible ethics committee, and have been attached to the Protocol in the form of a Protocol amendment;

For the purpose of this provision, the term “substantial” shall mean modifications which are likely to have an impact on the safety of the Study Participants or to change the interpretation of the scientific documents in support of the conduct of the Study or which are otherwise significant;

* 1. “SPONSOR” means the individual, company, institution or organisation or, where appropriate, its legal representative, which takes the responsibility for the initiation, management and/or financing of the Study;
	2. “SPONSOR’s Invention(s)” means, for the purposes of this Agreement, any and all inventions, improvements or discoveries (whether or not patentable), innovations, know-how, suggestions, ideas, and reports developed, generated or conceived by the INSTITUTION and/or the INVESTIGATOR from conducting the Study and arising from the use of the Study Drug or other Confidential Information of the SPONSOR;
	3. “Study” means the clinical trial conducted or to be conducted in accordance with the Protocol to test the Study Drug;
	4. “Study Data” means all data, databases, documents, reports and other information resulting from, collected or developed in the performance of the Study;
	5. “Study Drug” designates the investigational product named [INSERT STUDY DRUG NAME] and described in the Protocol;
	6. “Study Equipment” means the specific equipment necessary and provided by the SPONSOR to conduct the Study as described in the Protocol;
	7. “Study Participant” means the individual who participates in the Study at INSTITUTION;
	8. “Study Report” means the clinical trial summary report based on the Study Data and drafted by the SPONSOR which should be notified to the competent authorities in accordance with section 4.3 of the Communication of the Commission nr. 2010/C 82/01, entitled “*Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (CT-1)*”;
	9. “Subcontractor” means any party who has been contracted by a Party or the INVESTIGATOR to perform part of the Study or provide goods and services in support thereof.
1. **SUBJECT MATTER**

The purpose of this Agreement is to define the terms of cooperation between the INSTITUTION, the INVESTIGATORand the SPONSOR.

Within the scope of such cooperation, the INVESTIGATOR, who has been entrusted by
the INSTITUTION to conduct the Study, shall test the Study Drug according to the Protocol.

1. **RESPONSIBILITIES OF THE PARTIES AND THE INVESTIGATOR**
	1. PROCESSING OF PERSONAL DATA

The Parties shall handle all Personal Data in accordance with the GDPR and with any other applicable data protection laws in relation to the processing of Personal Data.

1. **Study Participants Personal Data**
	1. **Role and qualification of the Parties**

SPONSOR is subject to the rights and obligations as “data controller” set forth under the GDPR in relation to the processing of personal data for the purpose of conducting the Study in accordance with the Protocol. In that respect SPONSOR shall be considered as data controller of all Personal Data processed for Study purposes.

INSTITUTION is subject to the rights and obligations as “data processor” set forth under the GDPR in relation to the processing of personal data for the purpose of conducting the Study in accordance with the Protocol. [Pursuant to Article 28.3 GDPR SPONSOR and INSTITUTION have concluded a data processing agreement attached in SCHEDULE F.]

INSTITUTION is also subject to the rights and obligations as a separate “data controller” set forth under the GDPR in relation to the processing of personal data of its patients for purposes other than conducting the Study. In particular, INSTITUTION remains data controller of the data contained in its patients’ medical records for the purposes of providing medical care to its patients and for academic research purposes.

* 1. **Cooperation**

Both Sponsor and Institution shall implement appropriate technical and organizational measures to meet the requirements of the GDPR.

If either Party becomes aware of a personal data breach, that Party shall promptly notify the other Party/ies without undue delay and, where feasible, within 72 hours. In such a case Parties will fully cooperate with each other to remedy the personal data breach, fulfil the notification obligations timely and cure the damages. A personal data breach refers to a personal data breach as meant in articles 33 and 34 of the GDPR.

In order to protect the identity of the Study Participants vis-à-vis the SPONSOR, the SPONSOR and the INSTITUTION agree that, as between them, the data protection officer of the INSTITUTION (as identified in SCHEDULE F) will act as an intermediary to manage and resolve requests from a Study Participant, as the case may be, to access, modify, transfer, block, or delete of her/his personal data, and that he/she will contact the data protection officer of the SPONSOR (as identified in SCHEDULE F) in such case.

INSTITUTION acknowledges that in order to maintain the integrity of Study results, the ability to amend, modify, or delete Personal Data may be limited by SPONSOR, in accordance with Applicable Laws.

3.1.2. Study staff

Prior to and during the course of the Study, the SPONSOR may request to process personal data of Study staff of INSTITUTION, including from INSTITUTION’s investigators, sub-investigators, other Institution staff or personnel involved in the conduct of the Study.

The SPONSOR as data controller for the processing of such Study staff’s personal data for Study purposes is responsible for supplying such INSTITUTION’s Study staff with the necessary information regarding the collection of their personal data pursuant to GDPR.

The INSTITUTION through the INVESTIGATOR will assist the SPONSOR in providing such information to the INSTITUTION’s Study staff upon request from the SPONSOR.

The supplied information should address, where applicable, the transfer of personal data to countries outside the European Economic Area, including without limitation the United States, possibly not providing an adequate level of data protection, in which case the supplied information should also address the steps taken by the SPONSOR to ensure that the personal data remains secure.

The purposes for which the personal data of INSTITUTION’s Study staff are processed by the SPONSOR shall be detailed in the supplied information and may include:

* + 1. the conduct and interpretation of the Study;
		2. review by governmental or regulatory agencies, the SPONSOR, and its affiliates;
		3. satisfying legal or regulatory requirements;
		4. publication on www.clinicaltrials.gov and other websites and databases that serve a comparable purpose;
		5. upon request of individual patients and doctors provision of information regarding the Study to individual patients and doctors who may be interested in participating in the clinical study at Institution;
		6. storage in SPONSOR’s databases for use in selecting sites in future clinical studies.

The supplied information should also include the right to access, modify, rectify or remove their personal data from such processes as well as the retention period of the data by the SPONSOR.

* 1. SPONSOR
1. [OPTIONAL CLAUSE]

*The SPONSOR hereby mandates/delegates* in accordance with the Belgian Civil Code *to [****INSERT NAME CRO, ADDRESS****] the performance of the monitoring and verification of the data obtained within the scope of the Study*. *The SPONSOR is entitled to delegate/mandate, in accordance with the Belgian Civil Code, the performance of these tasks to any other person(s) of its choice during the course of the Study. The SPONSOR remains liable for the performance of the tasks by the CRO. The SPONSOR shall duly inform the INSTITUTION and the INVESTIGATOR of any such change accordingly. Any change of CRO during the course of the Study shall be notified in writing by the SPONSOR to the INSTITUTION and the INVESTIGATOR. As an exception to Article 10.2, such notification can be given by ordinary mail, electronic mail or telefax.*

1. For the purposes of this Agreement, the SPONSOR is responsible for the manufacturing, labelling, import and/or supply of the Study Drug and shall obtain or shall ensure that the third party entrusted with any of these four tasks obtains from the authorities the necessary authorisation pertaining thereto. The SPONSOR assumes product liability to the extent applicable, and in accordance with the applicable legislation. The SPONSOR will provide the Study Drug free of charge.
2. The SPONSOR shall ensure that
	* + - * for the initial and continuing review, positive opinions of the appropriate ethics committee are obtained by the INVESTIGATOR, and
				* all necessary authorizations of the relevant health or regulatory authorities are obtained,

prior to the commencement of the Study.

1. The SPONSOR shall notify to and seek approval of the competent authorities and the INVESTIGATOR must notify to and seek positive opinion of the ethics committee for any substantial amendment of the Protocol. The SPONSOR shall ensure that relevant parties shall be notified of the end or suspension of the Study. The SPONSOR will be responsible for ensuring that all safety reporting to the relevant health authorities and ethics committees is performed according to Applicable Laws. After analysis of Study Data from all sites is complete, the SPONSOR will provide INVESTIGATOR with a summary of the overall Study results. If the Study results could affect the safety of Study Participants, the SPONSOR, in consultation with the ethics committee, will cooperate with the INVESTIGATOR to ensure that those results are appropriately communicated to the Study Participants during a [2 (two) year] period following the closure of the Study. During and for a period of [specify a period of time appropriate to the specific study, for example, at least 2 (two) years after the completion of the study; or specify a triggering event, for example completion of data analysis], the SPONSOR shall ensure to report promptly (or in a timely manner appropriate to the level of risk involved) to the INVESTIGATOR any information that could directly affect the health or safety of past or current Study Participants or influence the conduct of the Study, including but not limited to the Study results and information in site monitoring reports and data safety monitoring committee reports as required by the Protocol. In each case, the INVESTIGATOR and the INSTITUTION shall be free to communicate these findings to each Study Participants and the responsible ethics committee.

The SPONSOR will publicly register a Protocol summary in a public website (e.g. Clinicaltrials.gov.) and the published information can be publicly disclosed as per Article 6.1.2.e.

In order to ensure the same quality and safety standards in patient care for clinical research as commonly applied by the INSTITUTION in its regular activities, also in accordance with Joint Commission International standards, the SPONSOR shall comply with the following obligations:  (a) the SPONSOR will use trained and qualified employees or contractors to manage and coordinate the Study; (b) the SPONSOR will ensure that multi-center Study reporting is reliable and valid,  statistically accurate, ethical, and unbiased. The same requirements are applicable if multi-center Study Data and multi-center Study results are provided to the INSTITUTION; (c) the SPONSOR will not grant incentives, other than standard compensations and reimbursement of costs, to Study Participants or to the INSTITUTION’s staff that would compromise the integrity of the research; (d) the SPONSOR is responsible for monitoring and evaluating the quality, safety, and ethics of the Study and will respect the INSTITUTION’s policies and processes when performing such monitoring and evaluation activities; (e) the SPONSOR will protect the privacy and confidentiality of the Study Participants in accordance with all Applicable Laws, as mentioned in this Agreement.

1. *[OPTIONAL CLAUSE]*

*The SPONSOR will put any Study Equipment to be used for the execution of the Study at the disposal of the INSTITUTION and the INVESTIGATOR (as further detailed in Schedule C).*

* 1. INVESTIGATOR
1. The Study will be conducted by the INVESTIGATOR and performed at [**INSERT NAME AND ADDRESS**].
2. The INVESTIGATOR will have the experience and capability to efficiently and expeditiously perform the Study in a professional and competent manner, and in strict adherence to the Protocol.
3. The INVESTIGATOR is responsible for the verification and completion of all the data on CRFs and the clarification of any data queries that may have arisen in this process.
4. The INVESTIGATOR shall be responsible to obtain prior written informed consent from any Study Participant, in compliance with the Applicable Laws.

The INVESTIGATOR is responsible for the explanation to each Study Participant of the nature of the Study, its purpose, the procedures, the expected duration as well as the potential benefits and risks. Each Study Participant must be informed that participation in the Study is voluntary and that the Study Participant can withdraw from the Study at any time without stating any reason.

* 1. INSTITUTION
1. The Parties acknowledge and agree that the relationship of SPONSOR to INSTITUTION is that of independent entity and not as agents, employee, or franchisee.
2. The INSTITUTION shall ensure and control that the INVESTIGATOR fulfils all the tasks described in the Protocol and complies with all requirements under this Agreement.
3. The Institution represents and warrants that it has the experience, capability and resources including, but not limited to, sufficient personnel and equipment, to efficiently and expeditiously perform the Study in a professional and competent manner, and in strict adherence to the Protocol, and the Institution further represents and warrants that it will utilize all reasonable efforts at all times to devote the necessary personnel and equipment to perform the Study hereunder in such a manner.
4. In the event the Investigator becomes unable to perform the duties required by this Agreement, the Institution shall give as soon as practically possible written notice of such fact to the SPONSOR. In the event a mutually acceptable replacement is not available, this Agreement may be terminated by either Party in accordance with Article 5.2.2 herein.
5. The INSTITUTION shall provide the SPONSOR [*and/or its delegate*] with all infrastructures, equipment, personnel and resources required to enable the SPONSOR to monitor the Study during any visit by the SPONSOR to the site where the Study is being performed.

To that effect the INSTITUTION shall notably ensure that the SPONSOR [and/or its delegate] has access to the relevant Study Data, subject to SPONSOR’s compliance with the INSTITUTION procedures.

* 1. INSTITUTION AND INVESTIGATOR
1. The INSTITUTION and the INVESTIGATOR are responsible for recruitment of Study Participants. The INSTITUTION and the INVESTIGATOR agree to use all reasonable efforts to enrol eligible Study Participants during the agreed enrolment period. If it becomes apparent that the recruitment rate is lower than required or expected, the INSTITUTION and the INVESTIGATOR shall inform the SPONSOR accordingly and allow him to make alternative arrangements or terminate this Agreement pursuant to Article 5.2.1.
2. The INSTITUTION and the INVESTIGATOR undertake that they are under no obligation or restriction which would in any way interfere or be inconsistent with or present a conflict of interest with the obligations undertaken herein. In particular, the INSTITUTION and the INVESTIGATOR undertake that they comply with any applicable anti-corruption law and that this Agreement or the conduct of this Study shall not result into any conflict of interest.
3. The INSTITUTION and the INVESTIGATOR undertake that until the term of this Agreement they shall not conduct any other trial which adversely affects the INSTITUTION’s and/or the INVESTIGATOR’s ability to perform its obligation under this Agreement.
4. The INSTITUTION and the INVESTIGATOR undertake to archive all the Study Data and Study files for a period of at least twenty (20) years[[1]](#footnote-2) and medical records during at least thirty (30) years, in full compliance with any Applicable Laws.
5. The INSTITUTION and the INVESTIGATOR may not use any information other than publicly available information regarding the Study in any publicity and advertising without SPONSOR’s prior written consent and ethics committee approval.
6. **PAYMENT OF FEES**
	1. Subject to the terms and conditions hereof, in consideration of the services to be provided by the INSTITUTION and the INVESTIGATOR under the terms of this Agreement, the SPONSOR shall pay to the INSTITUTION a fee, as detailed in the Study budget attached in SCHEDULE A of this Agreement.
	2. Payment of any amount due by the SPONSOR to the INSTITUTION shall be in accordance with SCHEDULE A upon receipt of an invoice request of the INSTITUTION issued in accordance to SCHEDULE D.
7. **TERM, TERMINATION AND SUSPENSION**
	1. TERM
8. This Agreement is a limited term agreement which will be coming into force at the date of the last signature by the Parties of this Agreement (‘**Effective Date**’), it being understood that the actual Study cannot start without having obtained the necessary legally required approvals.
9. Unless earlier terminated in accordance with the provisions of this Agreement, this Agreement shall continue until complete performance of the Study, i.e. when the last enrolled Study Participant has finished the treatment described in the Protocol and all CRFs, the Study Report and any other pertinent Study-related documents have been received by and completed to the reasonable satisfaction of the SPONSOR. The SPONSOR shall confirm in writing when the Study has been completed.
10. The Study is anticipated to be completed on [**INSERT DATE**]. The Institution and the Investigator shall use their best efforts to complete the Study, including the delivery to the SPONSOR of all documents referenced in the Protocol, by this date.
11. If at any time the Institution and/or the Investigator have reason to believe that the Study will not be initiated or completed in accordance with the present Agreement or the schedule agreed upon by the Parties in the Protocol, the Institution and/or the Investigator shall notify the SPONSOR in writing of the reason(s) and length of additional time required to commence or complete work, and the sponsor may at his own discretions either:
* agree with the Institution and the Investigator to extend the periods or deadlines agreed upon in this Agreement or in the Protocol for a limited term; or
* terminate this Agreement, upon written notice in accordance with Article 5.2.3.
	1. TERMINATION

Notwithstanding Article 5.1 this Agreement may be terminated early as follows.

* + 1. Termination for default

Either Party may terminate this Agreement upon written notice if the other Party materially breaches any provision of this Agreement, which breach continues and is not remedied within [*thirty (30)*] calendar days after the date of receipt of such notice.

* + 1. Termination for cause

 Either Party may terminate this Agreement:

* upon [thirty (30)] days prior written notice to the other Party, if the INVESTIGATOR leaves the INSTITUTION or becomes permanently unavailable and Parties fail to agree upon a replacement INVESTIGATOR; or
* upon written notice with immediate effect to the other Party if either Party or the ethics committee determines that termination of the Study is necessary for the safety of the Study Participants;
* upon written notice with immediate effect to the other Party if the other Party becomes insolvent, or if proceedings are instituted against it for reorganization or other relief under any bankruptcy law, or if any substantial part of its assets come under the jurisdiction of a receiver or trustee in an insolvency proceeding authorized by law.
	+ 1. Termination upon written notice

SPONSOR may terminate this Agreement at any time for an objectively justified reason upon [*thirty (30)*] days prior written notice to the other Party.

* + 1. Termination for fraud, gross misconduct or negligence

Either Party may immediately terminate this Agreement at any time in case of fraud, gross misconduct or negligence of the other Party, or in case of breach by the other Party of any applicable anti-corruption laws.

* 1. SUSPENSION OF THE STUDY
		1. Notwithstanding Article 5.1, in the event the conditions for a favorable opinion of the ethics committee or authorization from the Minister in relation to the conduct of the Study are no longer met, or when doubts arise about the safety or scientific validity of the Study, the SPONSOR may immediately and at any time suspend this Agreement and the conduct of the Study for a maximum period of [*twelve (12)*] months. The SPONSOR shall notify the INSTITUTION and the INVESTIGATOR in writing of any such suspension.
		2. Before the end of the [*twelve (12)*] months period, the SPONSOR may notify in writing the INSTITUTION and the INVESTIGATOR of the restart of the Study. In such case, the INSTITUTION and the INVESTIGATOR undertake to restart forthwith the services stated in this Agreement in accordance with the SPONSOR’s instructions. Should the SPONSOR not have notified the INSTITUTION and the INVESTIGATOR of the restart of the Study within the [*twelve (12)*] month period, the Agreement may be terminated by either of the Parties in accordance with Article 5.2.1 of this Agreement.
		3. Any further decision taken by the SPONSOR with regard to the restart of further actions regarding the Study will be communicated by the SPONSOR in due time and in accordance with all applicable laws and regulations.
	2. TERMINATION OR SUSPENSION – PRACTICAL CONSEQUENCES AND OBLIGATIONS FOR THE PARTIES AND THE INVESTIGATOR
		1. Upon any termination or suspension of this Agreement or the Study, the INSTITUTION and the INVESTIGATOR will comply with the provisions of the Protocol pertaining notably to the practical consequences of such termination or suspension.
		2. Immediately upon receipt of a notice of termination or suspension, the Investigator and the INSTITUTION shall stop enrolling Study Participants into the Study, shall cease conducting procedures on Study Participants already enrolled in the Study as directed by the SPONSOR, to the extent medically and ethically permissible, and shall refrain from incurring additional costs and expenses to the extent possible.
		3. In the event the Study is terminated or suspended for other reasons than Study Participant safety or public health motivations, but also in case of completion of the Study, the SPONSOR and the INVESTIGATOR shall discuss the on-going treatment needs of Study Participants and will, if appropriate given the circumstances of the Study termination, agree on a plan for discontinuing treatment of Study Drug to ensure enrolled Study Participants have adequate continuum of care during the reasonable period necessary to organise and provide an alternative treatment to ensure the Study Participant’s safety.
		4. In the event this Agreement or the Study is terminated, the INSTITUTION and the INVESTIGATOR shall stop the Study as expeditiously as possible and in accordance with Article 5.4.3 and all applicable national and local laws, regulations and guidelines. The INSTITUTION and the INVESTIGATOR undertake not to start any work not already engaged.
	3. TERMINATION OR SUSPENSION – AMOUNTS PAYABLE
		1. In the event of termination or suspension of this Agreement by the SPONSOR, except in case of termination under Articles 5.2.1 or 5.2.4, the SPONSOR shall pay to the INSTITUTION an amount corresponding to all reasonable non-cancellable commitments incurred by the INSTITUTION for this Study and to the work actually performed by the INVESTIGATOR until the date of termination or suspension, provided that such work has not been started after receipt of the SPONSOR's notification of its decision to terminate or suspend this Agreement, less any amounts which have been paid by the SPONSOR in advance for the work. In any case, the amount payable shall not exceed the total maximum fee calculated according to SCHEDULE A.
		2. No further compensation or indemnity of any kind whatsoever shall be due to the INSTITUTION and/or the INVESTIGATOR in relation with such termination or suspension.
		3. Amounts owed to the INSTITUTION by the SPONSOR pursuant to Article 5.5.1 of this Agreement shall be paid (i) within [*INSERT NUMBER*: XXX] days after date of termination or suspension, or (ii) upon the SPONSOR's receipt of all of the data, whichever occurs last, provided that the INSTITUTION has sent to the SPONSOR an invoice. The INSTITUTION shall refund to the SPONSOR any overpayment within [*INSERT NUMBER*: XXX] days of the date of termination or suspension.
1. **CONFIDENTIALITY, LEGAL PROTECTION AND PUBLICATION OF INVESTIGATION RESULTS, INTELLECTUAL PROPERTY**
	1. CONFIDENTIALITY
		1. For the purposes of this Agreement, the following is and shall be considered throughout and during a period [*xx years – needs to be between five (5) and ten (10) years (depending on the type of study)*] after the term or termination of this Agreement as confidential information (hereinafter referred to as “**CONFIDENTIAL INFORMATION**”), whether marked as “confidential” or not,
* all information received by the SPONSOR from the INSTITUTION and/or INVESTIGATOR, including but not limited to proprietary information, trade secret, unpublished data, know-how (hereafter “INSTITUTION’s CONFIDENTIAL INFORMATION”);
* all information received by the INSTITUTION and/or the INVESTIGATOR from the SPONSOR, including but not limited to proprietary information, trade secret, unpublished data, know-how (hereafter “SPONSOR’s CONFIDENTIAL INFORMATION”);
* all data, databases, documents, reports and other information developed with respect to the SPONSOR or in the performance of or as a result of the Study by the SPONSOR, the INSTITUTION or the INVESTIGATOR or their respective employees, agents, Subcontractors or participants.

CONFIDENTIAL INFORMATION notably includes but is not limited to, (i) this Agreement, (ii) the CRF, (iii) the Protocol, (iv) the Investigator's Brochure (“IB”), (v) [OPTIONAL: *INSERT list of documents*].

* + 1. CONFIDENTIAL INFORMATION does not include information that:
1. at the time of disclosure thereof is or thereafter becomes part of the public domain through no breach, fault or omission of the receiving Party or of their respective employees, agents, Subcontractors or participants;
2. at the time of disclosure thereof by the disclosing Party, is already in the receiving Party's lawful possession as evidenced by the receiving Party's competent written records and not subject to prior confidentiality obligations;
3. the receiving Party receives from a third party who has the right to disclose the same and who did not obtain such information in violation of the disclosing Party’s rights;
4. is independently developed by the receiving Party without the use of CONFIDENTIAL INFORMATION as evidenced by the receiving Party's written records and is not subject to confidentiality obligations;
5. the receiving Party is required to disclose by applicable law, by a court or by a governmental authority, provided that the receiving Party (i) promptly notifies the disclosing Party of such requirement prior to disclosure –to the extent reasonably legally and permissible possible- in order to allow them the opportunity to oppose the requirement or seek an appropriate protective order; (ii) discloses only that CONFIDENTIAL INFORMATION required to comply with the legal requirement and (iii) continues to maintain the confidentiality of this CONFIDENTIAL INFORMATION with respect to all other third parties.

The burden of proving the applicability of any of these exceptions resides with the receiving Party.

* + 1. The receiving Party shall hold such CONFIDENTIAL INFORMATION of the disclosing Party in strict confidence and shall only disclose such CONFIDENTIAL INFORMATION on a need-to-know basis to their agents, employees, Subcontractors or participants who are directly involved in the conduct or monitoring of the Study.

The receiving Party shall further use the CONFIDENTIAL INFORMATION of the disclosing Party only for the purpose of fulfilling their respective obligations under this Agreement.

* + 1. The receiving Party shall not disclose to any third party any of the CONFIDENTIAL INFORMATION without specific prior, express written authorisation from the disclosing Party with respect to such disclosure, except for publication in accordance with Article 6.3 of this Agreement.
		2. The receiving Party shall notify the disclosing Party immediately upon discovery of any unauthorized disclosure or use of the CONFIDENTIAL INFORMATION and will collaborate with the disclosing Party in every reasonable way to assist the disclosing Party regaining the possession of the CONFIDENTIAL INFORMATION and prevent its further unauthorized use or disclosure.
		3. The CONFIDENTIAL INFORMATION is and shall remain the exclusive property of the disclosing Party. The disclosure of CONFIDENTIAL INFORMATION does not grant any expressed or implied rights or license to the receiving Party to any Intellectual Property Rights possessed by the disclosing Party.
		4. Except for essential documents of the trial master file and the copies of SPONSOR’s CONFIDENTIAL INFORMATION that the INSTITUTION and/or the INVESTIGATOR are required to keep for regulatory purposes or by law, the INSTITUTION and the INVESTIGATOR shall at the end of the Study and within thirty (30) days following the written request of the SPONSOR destroy or return to the SPONSOR all SPONSOR’s CONFIDENTIAL INFORMATION, including without limitation all copies and translations thereof. If requested by the SPONSOR, such destruction shall be promptly confirmed in writing by the INSTITUTION or the INVESTIGATOR.

At the end of the Study, all CONFIDENTIAL INFORMATION related to Study Participants other than Study Data, whether in documentary, permanent or machine-readable form, including any copies of all or any part there of shall be returned to the disclosing Party, save that each Party may retain one copy of such CONFIDENTIAL INFORMATION solely for record-keeping purposes pursuant to applicable laws or regulations.

* + 1. The INSTITUTION and the INVESTIGATOR understand and agree that the CONFIDENTIAL INFORMATION generated in the performance of or as a result of the Study can be used in connection with the development of the Study Drug and may therefore be disclosed by the SPONSOR as required to notably other clinical investigators, regulatory or health authorities or governmental agencies in compliance with the Applicable Laws.
		2. The obligations of the INSTITUTION and the INVESTIGATOR under this Article 6.1, shall apply to the INSTITUTION’s and the INVESTIGATOR’s agents, employees, representatives, Subcontractors or participants involved in the services to be performed by the INSTITUTION and/or the INVESTIGATOR under this Agreement. The INSTITUTION and the INVESTIGATOR agree to have agreements or undertakings in place ensuring compliance with this Article 6.1. The INSTITUTION and the INVESTIGATOR shall ensure that their agents, employees, representatives, Subcontractors or participants involved in the services under this Agreement shall be informed of, bound and obligated by similar provisions of confidentiality as are the INSTITUTION and the INVESTIGATOR under Article 6.1.
	1. OWNERSHIP AND USE OF DATA

The Study Data shall be the sole property of the SPONSOR and shall be subject to the SPONSOR's exclusive use, commercial or otherwise, including use in publications, communications or in submissions to any regulatory authority or other governmental agency.

Subject to the confidentiality provisions of this Agreement, the SPONSOR hereby grants to the INSTITUTION and/or the INVESTIGATOR a non-exclusive, non-transferable and non-assignable right to use the Study Data solely for non-commercial research purposes, educational purposes and, subject to Article 6.3, for publication purposes.

* 1. PUBLICATION OF PAPERS UTILISING STUDY DATA AND COMMUNICATIONS
		1. The SPONSOR supports the exercise of academic freedom and recognises the INSTITUTION’s and the INVESTIGATOR’s interest in making publications and presentations relating to the Study in scientific journals, at symposia, professional meetings or otherwise. It shall therefore permit such publications and presentations, provided however that the INSTITUTION and the INVESTIGATOR comply with the requirements set forth in the present Article 6.3.
		2. The INSTITUTION and the INVESTIGATOR undertake and agree that they will not publish, communicate or otherwise disclose in whatever manner or through any vehicle any information derived from the Study or the Study Data (i) for the whole duration of the Study, (ii) before the Study Report is notified to the competent authorities and (iii) for a period of eighteen (18) months after the end of the Study.

This provision applies to mono-centre as well as to multi-centre trials.

* + 1. Any and all written or oral publication and/or communication or any other type of disclosure relating to the Study and/or to the Study Data (hereinafter referred to as “PUBLICATION”) shall have to be submitted in writing to the SPONSOR for review and comments before it is submitted or otherwise disclosed.

A manuscript of any project of PUBLICATION shall be submitted to the SPONSOR at least forty-five (45) working days for a written publication and twenty (20) working days for an abstract, an oral communication or any other type of disclosure before the forecasted date of submission to the editor or to the organiser of a scientific meeting or of said other type of disclosure.

The SPONSOR shall have the right to make comments on the content of the manuscript within thirty (30) working days for a written publication and fourteen (14) working days for an abstract, an oral communication or any other type of disclosure, after the receipt of the manuscript (the “Review Period”).

The INSTITUTION and the INVESTIGATOR agree and undertake to take all SPONSOR’s comments into due consideration and to incorporate them in the project of PUBLICATION, provided that those comments do not jeopardize the scientific integrity of the PUBLICATION.

The INSTITUTION and/or the INVESTIGATOR shall, on request of the SPONSOR, remove any SPONSOR’s CONFIDENTIAL INFORMATION or SPONSOR’s Intellectual Property before the disclosure, except for Study related information necessary to the appropriate scientific presentation or understanding of Study results.

Should the INSTITUTION or the INVESTIGATOR fail to erase previously undisclosed SPONSOR’s CONFIDENTIAL INFORMATION or SPONSOR’s Intellectual Property, the SPONSOR shall be entitled to refuse and impede the disclosure of the PUBLICATION.

In order to enable the SPONSOR to take steps necessary to protect its Intellectual Property Rights, the INSTITUTION and/or the INVESTIGATOR shall postpone the PUBLICATION with ninety (90) days upon the SPONSOR’s written request, provided the INSTITUTION and/or the INVESTIGATOR received the SPONSOR’s request before expiry of the review timelines. The ninety (90) days period starts upon expiry of the Review Period.

The SPONSOR shall be entitled to make a reasoned request to the INSTITUTION and the INVESTIGATOR that the PUBLICATION be delayed for an additional period of sixty (60) days (upon expiry of the ninety (90) days period referred to in the previous paragraph) in order to enable the SPONSOR to take steps to protect its proprietary information and/or Intellectual Property Rights and knowhow, and the INVESTIGATOR shall not unreasonable withhold its consent to such a request.

If SPONSOR did not respond within the delays granted to him in this Article 6.3.3, the INSTITUTION and the INVESTIGATOR may proceed with the PUBLICATION.

* + 1. The INSTITUTION and/or the INVESTIGATOR shall, where applicable, acknowledge the SPONSOR’s sponsorship and financial support of the Study in any PUBLICATION.
		2. Both Parties and the INVESTIGATOR shall comply with recognized ethical standards concerning publications and authorship, including the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, http://www.icmje.org/index.html#authorship, established by the International Committee of Medical Journal Editors.
		3. If the Study is part of a multi-centre study, the INSTITUTION and the INVESTIGATOR agree, that the first PUBLICATION shall be a joint publication based on the analysis of the consolidated data from all participating centers, as described in the Protocol by the SPONSOR’s statisticians, and not by the INVESTIGATOR(S) or the INSTITUTION (hereinafter referred to as the “**JOINT PUBLICATION**”).

Subject to the conditions under Articles 6.3.2, 6.3.3, 6.3.4 and 6.3.5, the INSTITUTION and the INVESTIGATOR participating in a multi-centre study are allowed to present or publish data gathered from one centre or a small group of centres, after the JOINT PUBLICATION, or after the period of eighteen (18) months starting from the date of the completion of the Study whichever occurs first.

Any authorised publication relating to a sub-set of data originating from one centre or a small group of centres shall explicitly make reference to the relevant primary JOINT PUBLICATION(s), if any.

* 1. INTELLECTUAL PROPERTY RIGHTS
		1. It is recognized and understood that all Intellectual Property Rights existing as of the Effective Date (“**Background IP**”) and know how owned or controlled by a Party are that Party’s separate property and are not affected by this Agreement, and no Party hereunder shall have any claims to or rights in such Background IP of the other Party.

The INSTITUTION acknowledges and agrees that the Study Drug is and remains the property of the SPONSOR, and that all Intellectual Property Rights on the Study Drug are Background IP owned by the SPONSOR. Except for and limited to, the use specified in the Protocol, the SPONSOR grants the INSTITUTION no express or implied Intellectual Property Rights or other rights in the Study Drug or in any methods of making or using the Study Drug.

* + 1. Under this Agreement each Party shall have the right to use the other Party’s Background IP solely and to the extent necessary for the performance of the Study and only for the duration of the Study under this Agreement. This usage right of the other Party’s Background IP does not grant to either Party any option, grant, or license to commercialize, or otherwise use the other Party’s Background IP.
		2. Intellectual Property Rights that are developed, generated or conceived in the performance of the Study and that relate to SPONSOR’s Inventions (“**SPONSOR IP**”) shall be and at all times remain the sole property of the SPONSOR without any further compensation payable to the INSTITUTION and/or the INVESTIGATOR. The INSTITUTION and/or the INVESTIGATOR shall have no right therein, except the rights as provided in Articles 6.2 and 6.3.
		3. Intellectual Property Rights that are developed, generated or conceived in the performance of the Study and that do not relate to SPONSOR’s Inventions (“**Non**-**SPONSOR IP**”) shall be subject to a separate agreement between the INSTITUTION and the SPONSOR.
		4. As far as permitted by Applicable Laws, the INSTITUTION and/or the INVESTIGATOR hereby assign its/his/her rights to the SPONSOR in relation to any Sponsor IP free from any obligation or consideration beyond that provided in this Agreement. The INSTITUTION and/or the INVESTIGATOR shall, at the request and expense of the SPONSOR, execute any documents or acts as the SPONSOR may reasonably require in order to fully and effectively transfer all such SPONSOR IP to the SPONSOR.

The INSTITUTION and the INVESTIGATOR hereby declare:

* That, to their knowledge, the INSTITUTION and the INVESTIGATOR are entitled to assign any such Intellectual Property Rights;
* or that they will cause their agents, employees or representatives to promptly execute all documents and take all such other actions necessary to obtain the benefit of said SPONSOR’s IP and the right to assign them.

Where applicable, the INSTITUTION and the INVESTIGATOR shall be solely responsible for all payments due to their respective agents, employees or representatives [in accordance with the Higher Education Codex / the regulations of the Institution] for any transferred Intellectual Property Rights.

* + 1. SPONSOR’s Invention(s) as defined in Article 1.11 , of the Agreement shall be promptly disclosed in full written details to the SPONSOR and shall be transferred and therefore be the sole property of the SPONSOR.

The SPONSOR shall, at its own and sole discretion and responsibility, be entitled to apply for patent rights in respect of any SPONSOR’s Invention. The SPONSOR shall be responsible for the application, grant and maintenance of such patent rights.

Upon the SPONSOR's request, the INSTITUTION and/or the INVESTIGATOR shall reasonably assist the SPONSOR in connection with the application and prosecution for patent rights throughout the world for any SPONSOR’s Invention. It shall in particular execute such documents and take such reasonable actions as the SPONSORdeems necessary or appropriate toenable the SPONSOR to obtain patent rights or other proprietary protection in the SPONSOR's name concerning any of the foregoing. The INSTITUTION and/or the INVESTIGATOR shall be reimbursed for the time devoted to such activities and for the expenses incurred as a result of this assistance.

* + 1. The INSTITUTION and the INVESTIGATOR shall not file for or maintain patent rights in respect of any SPONSOR’s invention and shall also cause their respective employees, Subcontractors, participants and agents to refrain from filing or maintaining any such patent rights. In case any patent application is filed or patent is obtained in breach of this Article, all rights to such patent application or patent shall vest in the SPONSOR and the INSTITUTION and/or the INVESTIGATOR shall promptly assign such patent application or patent to the SPONSOR.

In particular, the INSTITUTION and the INVESTIGATOR agree and undertake, and shall cause their respective employees, sub-investigators and agents to agree and undertake, not to oppose or file cancellation actions against any patent (application) of the SPONSOR relating to any SPONSOR’s Invention.

1. **INSURANCE AND INDEMNIFICATION**
	1. In accordance with Applicable Laws, the SPONSOR shall assume, even without fault, the responsibility of any damage incurred by a Study Participant or, in the case of death, his rightful claimants, that arises either in direct or indirect connection with the experiments and shall provide compensation therefore. The SPONSOR shall enter into an insurance contract in accordance with Applicable Laws.
	2. Each Party, shall indemnify and hold harmless the other, its agents and employees (collectively the “Other Party’s Indemnitees”) from any and all duly evidenced liabilities, claims, actions, or suits to the extent caused by its ***negligence or wrongful acts or omissions***; or the negligence or wrongful acts or omissions of its agents or employees pertaining to the activities to be carried out pursuant to the obligations under this Agreement. Each Party shall promptly notify the other in writing of any such complaint, claim or injury relating to any loss subject to this indemnification.
	3. Without prejudice to SPONSOR’s no-fault liability towards Study Participant, the SPONSOR recognizes the need for the INVESTIGATOR to provide, at SPONSOR’s expense reasonable and necessary care for Study Participants involved in the Study with any adverse reaction in direct or indirect connection with the Study. In case of gross negligence or willful misconduct of the INVESTIGATOR and/or INSTITUTION, the SPONSOR may seek recourse against the INVESTIGATOR and/or the INSTITUTION.
	4. Except in case of gross negligence or wilful misconduct, [including breach of SPONSOR IP under 6.4.3., […] ], or where such limitation would be prohibited by mandatory provisions of law, the INSTITUTION’s total liability and indemnification obligation under this Agreement to the SPONSOR [and CRO jointly] under any and all circumstances for direct damages jointly shall under any and all circumstances not exceed (a) for damages covered under the civil liability insurance policy of the INSTITUTION in accordance with article 7.6, the effective coverage under such insurance policy, and (b) for damages not covered under the civil liability insurance policy of the INSTITUTION (i) per occurrence an amount corresponding to the aggregated fees (excluding pass through costs) paid or/to be paid by the SPONSOR (and/or CRO) to the INSTITUTION for the Study under this Agreement; and/or (ii) in aggregate, an amount corresponding to [XX times] the aggregated fees paid/or to be paid by the SPONSOR (and/or CRO) to the INSTITUTION for the Study under this Agreement ***[or such other fixed amount as may be agreed upon by the Parties upon a case by case basis]***.

In any case abovementioned the INSTITUTION’s total liability and indemnification obligation under this Agreement to the SPONSOR [and CRO jointly] shall terminate upon the 10th (tenth) anniversary ***[or such other time as may be agreed upon by the Parties upon a case by case basis]*** of the end date of the Study at the INSTITUTION in accordance with the Protocol.

* 1. Notwithstanding anything to the contrary herein, [and except in case of gross negligence and/or wilful misconduct, breach of SPONSOR IP under Article 6.4.3, [...]], or where such limitation would be prohibited by mandatory provisions of law, in no event shall either Party be liable as between the Parties to the other for any indirect or consequential damages (including lost profits) not covered under the civil liability insurance policy arising out of the subject matter or performance of this Agreement.
	2. The INSTITUTION declares that it has a mandatory civil liability insurance policy in accordance with Applicable Laws which notably covers the INSTITUTION, its employees and the INVESTIGATOR (if not an employee) and undertakes to maintain such insurance policy throughout the term of this Agreement and provides upon request of the SPONSOR any updated insurance certificate.

The SPONSOR declares and warrants that it has a civil liability insurance policy which notably covers the SPONSOR and its employees and undertakes to maintain such insurance policy throughout the term of this Agreement and provides upon request of the INSTITUTION any updated insurance certificate.

* 1. Neither Party shall indemnify and hold harmless the Other Party’s Indemnitees from liabilities arising out of gross negligence or wrongful acts or omissions of such Other Party’s Indemnitees.
	2. All Parties shall promptly inform each other of any claims or imminent claims relating to the conduct of the Study. No admission or settlements shall be made without the prior written approval of the other Party. If one of the Parties admits liability, it shall be given full conduct and control of any defense proceedings and negotiations concerning claims against the liable party. For the avoidance of doubt, each Party shall be entitled to seek own counsel for any claims against itself or its employees.
	3. Notwithstanding the provisions set out in Article 7.4, nothing in this Article 7 shall operate so as to restrict or exclude the liability of any Party vis-à-vis the Study Participants in relation to their death or personal injury caused by the negligence of that Party or its agents or employees or to restrict or exclude any other liability of a Party which cannot be so restricted or excluded in law.
1. **INSPECTION AND AUDIT**
	1. Upon request by any authorised officer or employee of any relevant regulatory agency, or other government authority, the INSTITUTION and the INVESTIGATOR are entitled and obliged to permit such officers or employees, at reasonable times, to have access to and inspect and verify any data records and reports in the INSTITUTION's and/or the INVESTIGATOR's possession, custody or control relating to the Study and shall submit such data records or reports to the said regulatory agency upon its request.
	2. In the case of a GCP inspection, the presence of the SPONSOR is required unless otherwise stated by the SPONSOR.

Unless prohibited by law or court order, the INSTITUTION and the INVESTIGATOR shall immediately inform the SPONSOR of any such inspection so as to allow the SPONSOR to be present to the inspection if he elects to be present, to allow the SPONSOR to prospectively review and comment on INSTITUTION’s responses, and send to the SPONSOR a copy of any such inspection report .

* 1. The SPONSOR shall be entitled at any time to audit or have audited (i) the INSTITUTION's fulfilment of its obligations hereunder (such as, but not limited to invoiced costs and expenses), and/or (ii) the performance of the Study by the INVESTIGATOR. The SPONSOR shall inform the INSTITUTION within a reasonable timeline compatible with the clinical activity of the INVESTIGATOR.
1. ***Optional section : ANTI BRIBERY AND ANTI CORRUPTION***

The INSTITUTION and the INVESTIGATOR acknowledge that the SPONSOR and/or CRO and its Affiliates need to adhere to the provisions of (i) the Bribery Act 2010 of the United Kingdom (“Bribery Act”); (ii) the Foreign Corrupt Practices Act 1977 of the United States of America (“FCPA”) and (iii) any other applicable anti-corruption legislation (together the Applicable Anti-Corruption Legislation).

***Optional [ summary of the key principles underlying the Bribery Act and the FCPA is set out in SCHEDULE E].*** *The INSTITUTION and the INVESTIGATOR shall not and shall not permit or induce employees, agents, consultants or other representatives, whether directly or indirectly, to engage in any activity that is prohibited by the Applicable Anti-Corruption Legislation including bribery, kickbacks, payoffs or other corrupt business practices, Optional [as outlined in the summary in SCHEDULE E]. Any violation of this Section constitutes a material breach of this Agreement. In addition to any other sanction provided by law and/or this Agreement, the SPONSOR may terminate this Agreement for cause and with immediate effect, if the obligations under this section are violated.*

1. **MISCELLANEOUS**
	1. DISCLOSURE OF TRANSFER OF VALUES

The INSTITUTION and the INVESTIGATOR acknowledge that the SPONSOR and its Affiliates need to adhere to the financial disclosure obligation on an aggregated basis in accordance with the Applicable Laws.

* 1. NOTIFICATION

All notices required by this Agreement will be given in writing to the other Party, and by means of registered letter in case of notices regarding term, termination and suspension (Article 5). All notices will be given by one Party to the other at its address stated on the first page of this Agreement unless a change thereof previously has been given to the Party giving the notice.

For the notices addressed to the SPONSOR, a copy shall be sent to [INSERT ADDRESS].

For the notices addressed to the INSTITUTION [INSERT ADDRESS], a copy shall be sent to INVESTIGATOR [INSERT ADDRESS].

* 1. FORCE MAJEURE

Neither Party shall be held liable for non-fulfilment or delayed performance of this Agreement or of part thereof due directly or indirectly to any cause outside the reasonable control of either Party, and which the affected Party was reasonably unable to foresee at the time of the coming into force of this Agreement, provided that notice of its inability to perform and the causes thereof shall be given immediately by the affected Party to the other. If such inability to perform shall continue for a period of three (3) months, the other Party shall have the right to terminate this Agreement by written notice to the affected Party at any time thereafter.

* 1. MODIFICATION AND WAIVER

No modification of this Agreement shall be deemed effective unless in writing and signed by each of the Parties hereto, and no waiver of any right set forth herein shall be deemed effective unless in writing and signed by the Party against whom enforcement of the waiver is sought.

* 1. ENTIRE AGREEMENT AND OBLIGATIONS TOWARDS THIRD PARTIES

This Agreement, together with its appendices (SCHEDULES [*INSERT LETTERS SCHEDULES: X, X, … and X*]) represents the entire agreement between the Parties in relation to the subject matter of this Agreement, and supersedes, replaces and extinguishes all prior negotiations, representations, undertakings, arrangements, draft agreements, agreements, including confidentiality agreements, written or oral, in relation to such subject matter.

Consequently, upon entry into force of this Agreement on the Effective Date of the Agreement as defined in Article 5.1.1, all confidentiality obligations provided and/or performed pursuant to any prior confidentiality agreement shall be deemed to constitute confidentiality obligations that have been performed or are to be performed, respectively, under Article 6 of this Agreement.

The INSTITUTION and the INVESTIGATOR warrant and represent that proceeding and performing hereunder is not inconsistent with contractual or other legal obligations they have and shall not be inconsistent with any contractual or other legal obligations they may hereafter have.

* 1. DESCRIPTIVE HEADINGS

The descriptive headings of the Articles of this Agreement are inserted for convenience only and shall not control or affect the meaning or construction of
any provision hereof.

* 1. TAXES

It is the INSTITUTION's personal responsibility to declare all revenues derived from the Agreement to the appropriate tax authorities*.*

VAT will be regulated in accordance with the provisions foreseen in the European Directives of 2008/8/EC and 2006/112/EC and applicable Belgian law. The regulations valid at the time of invoicing will be applicable.

In case services provided under this Agreement should be subject to VAT, the INSTITUTION shall be entitled to charge VAT at the legal rate in addition to the fees stated in this Agreement, provided the VAT is stated separately on the invoice made out to SPONSOR.

* 1. GOVERNING LAW

This Agreement and all terms used therein shall be construed and interpreted in accordance with the laws of Belgium, excluding its conflicts of law provisions.

* 1. SETTLEMENT OF DISPUTES

In the event of any disputes, controversies or claims arising from or in connection with this Agreement or the breach thereof, the Parties shall try to settle this issue amicably between themselves. Should the Parties so fail within sixty (60) days from the first notice of such dispute, controversy or claim, same shall be finally settled by the courts in Belgium having exclusive jurisdiction.

* 1. SUB-CONTRACTING - ASSIGNMENT

Neither Party may assign this Agreement or its obligations hereunder, nor may contract with third parties to perform any of its obligations hereunder, without the other Party's prior written consent which shall not be unreasonably withheld or delayed. However, SPONSOR shall have the right, upon prior written notice to INSTITUTION, to assign this Agreement to any of its affiliates , to a contract research organization in connection with the transfer of SPONSOR’s obligations or in connection with a merger or other corporate reorganization, or otherwise in connection with a transfer of all of SPONSOR's assets that bear on the Study Drug

* 1. SURVIVAL

Notwithstanding termination for any reasons under this Agreement, the rights and obligations under Articles 6 and 7 shall remain in full force and effect to the extent admitted by Applicable laws.

* 1. SEVERABILITY

If any of the provisions of or a portion of any provision of this Agreement is held to be unenforceable or invalid by a court of competent jurisdiction, the validity and enforceability of the enforceable portion of any such provision and/or the remaining provisions shall not be affected thereby.

* 1. COUNTERPARTS

The Agreement is executed in [*INSERT NUMBER AT LEAST EQUAL TO NUMBER OF PARTIES*: XX] original copies and each Party acknowledges having received an original.

* 1. PREVAILING TERMS

In case of any discrepancy between the terms of this Agreement and the terms of the Protocol, the terms of this Agreement shall prevail save that the Protocol shall prevail for the scientific conduct of the Study and the treatment of the Study Participants.

**Signatures on the following page**

**IN WITNESS WHEREOF, the undersigned by their duly authorised representatives have executed this Agreement on the date of last signature.**

|  |  |
| --- | --- |
| On behalf of the **INSTITUTION**Name: Prof. Jean-Paul Van VoorenTitle: Directeur GeneralDate:  | On behalf of the **INSTITUTION**Name: Prof. Jean-Michel HougardyTitle: CMODate: |

|  |  |
| --- | --- |
| Read and acknowledged by:The **INVESTIGATOR**Name:Title :Date: |  |

|  |  |
| --- | --- |
| On behalf of the **SPONSOR**Name:Title :Date: |  |

1.

**BUDGET - PAYMENT SCHEDULE**

***- intended for guidance only -***

[*TO BE COMPLETED BY THE PARTIES*]

As consideration for performance under the terms of this Agreement, the SPONSOR shall provide financial support for the Study in accordance with the budget set forth in this SCHEDULE A (the “Budget”).

Unless the SPONSOR requests that additional participants be enrolled in the Study, the total aggregate amount to be paid under this Agreement shall be estimated at **€ [AMOUNT]** (the “Study Cost”). The Study Cost assumes that:

* **[ANTICIPATED NUMBER OF PARTICIPANTS]** participants have completed all Protocol specified treatments. (Note: There will be no amendment to the Agreement if the number of participants at the Centre has been reached and will be increased before the total international number of participants has been reached. If the Centre has reached the above required number of participants and the Study is still open for recruitment, the new target will be discussed with the Principal INVESTIGATOR. The SPONSOR will inform the Principal INVESTIGATOR in writing that the recruitment is still open and with the new target number of participants. If no reaction is received within 5 (five) days, the SPONSOR will consider the Centre as continuing with the recruitment.);
* The maximum number of optional Protocol procedures listed in the Budget have been performed;
* The estimated number of screen failures/ unscheduled visits listed in the Budget has been reached;
* Other additional costs set forth in the Budget have been expended;
* The Study Cost does not include any Value Added Tax; and
* The Study Cost also includes the listed items in the below table and shall include the Overhead.

**1 - BUDGET**

|  |  |
| --- | --- |
| **Number of Participants:** | **[NUMBER OF PARTICIPANTS]** |
|   |
| **Description** | **Frequency/details** | **Per Unit** | **Total for all participants** |
| Per participant fee |  |  |  |
| Additional Assessments |  |  |  |
| Screen Failures  |  |  |  |
| Unscheduled visits |  |  |  |
| Subject Travel reimbursement |  |  |
| Pharmacy Cost |  |  |  |
| Start-up fee |  |  |  |
| Archiving fee |  |  |  |
| Audit fee |  |  |  |
| **TOTAL STUDY COST** |  |  |

1. **Per Participant Fee**

**Table 1**

|  |  |  |  |
| --- | --- | --- | --- |
| **Visit Description** | 1. *INVESTIGATOR fee*
 | 1. *Study nurse fee*
 | 1. *Total Visit Cost*
 |
| Screening Visit |  |  |  |
| Baseline Visit |  |  |  |
| Week x Visit |  |  |  |
| **Total Per Subject Fee** |  |  |  |

1. **Additional Assessments**

Additional Assessments will be reimbursed in accordance with the table 2 below, as required.

**Table 2**

|  |  |  |  |
| --- | --- | --- | --- |
| **Additional Assessments****(payable on invoice)** | **Detail** | **Per Procedure** | **Total per Participant** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| ***TOTAL Per Participant*** |

1. **Screen Failures**

Estimated **[NUMBER]** screen failures per site will be provided for, if necessary, at the rate of the screening visit and all performed procedures.

Screen failure payments will reflect the screening visits actually completed in accordance with the table 1 above. All screen failure payments are subject to monitor verification.

1. **Unscheduled visits**

Estimated **[NUMBER]** unscheduled visits per site will be provided for at a rate of €**[AMOUNT]** per each unscheduled visit.

1. **Participant Travel Costs**

Participant Travel shall be provided at a rate of **[AMOUNT]** € per visit

1. **Pharmacy costs**

**Table 4**

|  |  |  |
| --- | --- | --- |
| **Pharmacy procedures** | **Detail** | **Per Procedure** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

1. **Start Up Fee**

An administrative start-up fee of € **[AMOUNT]** shall be paid upon execution of this Agreement by all Parties, confirmation of EC approval, and completion of site initiation visit. The start-up fee will be considered non-refundable to cover Study start-up Costs.

1. **Archiving Fee**

An archiving fee of €**[AMOUNT]**/ box / 25 years will be paid upon final payment with a maximum of **[NUMBER]** boxes, with an estimated total cost of € **[AMOUNT]**. Only the actual amount of boxes that will be used for this study will be paid upon invoice. The SPONSOR may request for a longer storage period, in which case the amount shall be adapted accordingly.

1. **Audit Fee**

An Audit fee of € **[AMOUNT]** / hour, estimated but not limited to **[NUMBER]** hours will be paid, if applicable.

1. **[TO BE COMPLETED DEPENDING ON THE PROTOCOL (cf. Human Bodily Material)]**

**2 – PAYMENT TERMS**

Payments will be made as follows:

1. Payments will be made, upon invoice, *[every 6 months]* for visits and procedures which have been completed as set forth in the Budget above.

Payment shall only be due if the INSTITUTION and/or the INVESTIGATOR has satisfied his obligations under this Agreement.

Payment of the fees shall be made within thirty (30) days following receipt of the corresponding invoice submitted by the INSTITUTION to the SPONSOR/CRO.

1. To facilitate invoicing by the INSTITUTION, the SPONSOR/CRO will provide a request for invoice prior to each payment in accordance with the payment terms set forth in in this SCHEDULE A, to the INSTITUTION, Clinical Trial Center (finance department). This request will mention the study reference xxxxx and contain payment details in attachment.
2. The INSTITUTION as well as the INVESTIGATOR shall be notified in case the request for invoice relates to the final payment. The details of this final payment and of all previous payments that have been made during the study to the INSTITUTION will be provided to the INSTITUTION and the INVESTIGATOR.
3. As to the taxes, Section 10.7 of the Agreement shall apply.
4.

**STUDY PROTOCOL**

*[The latest version of the Protocol as approved by the relevant ethics committee is incorporated herein by reference]*

1.

**STUDY EQUIPMENT**

*[TO BE INSERTED IF APPLICABLE]*

Under this Agreement the SPONSOR will supply the INSTITUTION, for use in the Study, on............................(delivery date) following device […] (include description of the device, brand, type, serial number) (“EQUIPMENT”) on a loan-for-use or free lease base for the entire duration of the Study;

The INSTITUTION shall examine the Equipment upon its delivery and shall verify if satisfactory to the INSTITUTION’s needs. The Equipment is a medical device for which the SPONSOR expressly confirms that the device complies with the terms and conditions laid down under applicable law. The current value of the device is………..EUR (exclusive of VAT). This is without prejudice to Institution’s liability with respect to the Equipment being limited to duly evidenced wilful misconduct and/or gross negligence of Institution.

The INSTITUTION shall use the Equipment exclusively in the performance of the Protocol and shall not assign or sub-lease for any reason the Equipment to third parties, nor to use the Equipment as a warranty of whatsoever nature, nor to transfer it outside its facilities located at...............without prior consent of the SPONSOR;  Institution shall use the device with appropriate skill and care during the entire duration of the Study. If damage is caused through a defect in the Equipment, the SPONSOR shall be responsible for compensating the damage. The SPONSOR shall assume product liability of the Equipment and shall take out appropriate insurance to cover such product liability.

The SPONSOR shall be responsible to provide guidance and demonstration of the Equipment and accessories. The SPONSOR shall be responsible for commissioning the device. No purchase obligation on the part of Institution may be derived on the basis of this use of Equipment. The INSTITUTION acknowledges and represents that the Equipment is the exclusive property of the SPONSOR, which has full and valid title on it.

The SPONSOR shall be responsible for the overall ordinary and/or specialized maintenance and calibration, if applicable, of the Equipment. The SPONSOR shall pay all costs and expenses in connection with the use of the Equipment.

Upon termination of this Agreement, theSPONSOR undertakes to collect the Equipment at the INSTITUTION. INSTITUTION undertakes the SPONSOR that the Equipment (upon collection by Sponsor) shall be in the same conditions in which the Equipment is as of the delivery date, save for the ordinary wear and tear caused by the intended use.

**INVOICE REQUEST**

*[TO BE COMPLETED BY THE PARTIES]*

 **[Optional SCHEDULE E]**

**BRIBERY AND CORRUPTION**

1. The Parties must at all times act with integrity and honesty and comply with the highest ethical standards.
2. The Parties must not make, give, or offer any payment, gift or other benefit or advantage to any person for the purposes of:
	* 1. securing any improper advantage; or
		2. inducing the recipient or another person to do or omit to do any act in violation of their duties or responsibilities (or for the purposes of rewarding such conduct).
3. This restriction applies at all times and in all contexts. For the avoidance of any doubt, it applies both to dealings with "public officials" and to dealings with employees and agents of commercial enterprises.
4. Nevertheless, particular care must be exercised with dealings with public officials. The Parties must not make, give or offer any payment, gift or other benefit or advantage for the purposes of influencing any act or decision of a public official (or inducing such official to use their influence with another person, entity or government instrumentality or to affect or influence any act or decision of such other person, entity or government instrumentality).
5. The term "***Public Official***" includes any person acting on behalf of any government department, agency or instrumentality or any state-owned or controlled enterprise. By way of example, this includes health care professionals employed by a state- or local municipality-run hospital or clinic, and representatives of public international organizations.
6. The Parties must not make, give or offer any payment, gift or other benefit or advantage to any person whilst knowing or suspecting that all or a portion of such money, gift, benefit or advantage will be used, whether directly or indirectly, in breach of (B) or (C), (D) above.
7. The INVESTIGATOR and the INSTITUTION agree that the SPONSOR’s payment to theINVESTIGATOR and the INSTITUTION in connection with the services to be provided under this Agreement is not intended to influence any decision theINVESTIGATOR and the INSTITUTION may make regarding the prescription of SPONSOR medicines or to otherwise influence any pending or future SPONSOR business.

The Investigator and the Institution shall also ensure that each investigator and sub-investigator at the Institution’s Study Site (s) provides the Sponsor with the appropriate financial information for compliance with all applicable laws and regulations and the Sponsor policy, and the Investigator and the Institution understand and shall ensure that each investigator and sub-investigator understands that laws, regulations and the Sponsor policy may require certain financial information to be submitted to regulatory authorities.

1. The Parties shall make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Parties, in accordance with country’s law.
2. The Parties shall devise and maintain a system of internal accounting controls in accordance with country’s law, sufficient to provide reasonable assurances that:
	* 1. transactions are executed in accordance with management’s general or specific authorization;
		2. transactions are recorded as necessary
	1. to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and
	2. to maintain accountability for assets;
		1. access to assets is permitted only in accordance with management’s general or specific authorization; and
		2. the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

**SCHEDULE F**

**DATA PROCESSING AGREEMENT**

This data processing agreement, including any annexes hereto, (together the "Data Processing Agreement") is an integrated part of the Agreement.

All defined terms within the Agreement shall have the same meaning when used in this Data Processing Agreement, unless explicitly defined otherwise in this Data Processing Agreement.

# Scope of the data processing Agreement

* 1. The Institution acts as a data processor as defined under article 4, 8) of the GDPR (“Data Processor”) for the Sponsor who acts as data controller as defined under article 4, 7) of the GDPR (“Data Controller”), when the Institution processes Personal Data for the Sponsor as set out in Annex 1.

# Processing of Personal Data

* 1. **Instructions**: The Data Processor is instructed to process the Personal Data for the term of this Data Processing Agreement and only for the purposes of providing the data processing tasks set out in Annex 1. The Data Processor may not process or use Personal Data for any purpose other than a Data Subject’s medical records or other than provided in the Agreement or instructions, including with regard to transfers of personal data to a third country or an international organization, unless the Data Processor is required to do so according to Union or Member State law. In that case, the Data Processor shall inform the Data Controller in writing of that legal requirement before processing, unless that law prohibits such information on important grounds of public interest.
	2. Data Processor shall at all times maintain a record of processing of Personal Data in accordance with Applicable Law and if the Data Processor considers an instruction from the Data Controller to be in violation of the Applicable Law, the Data Processor shall promptly inform the Data Controller in writing about this.

# The Data Processor's obligations

* 1. The Data Processor must ensure that persons authorized to process the Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality. The Data Processor shall take full responsibility in the event there is a breach of said confidentiality obligation.
	2. The Data Processor shall implement appropriate technical and organizational measures to prevent that the Personal Data processed is:

accidentally or unlawfully destroyed, lost or altered,

disclosed or made available without authorization, or

otherwise processed in violation of Applicable Law.

* 1. The Data Processor must also comply with the special data security requirements of Annex 1.
	2. The appropriate technical and organizational security measures must be determined with due regard for:

the current state of the art,

the cost of their implementation, and

the nature, scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons.

* 1. The Data Processor shall upon request provide the Data Controller with sufficient information to enable the Data Controller to ensure that the Data Processor's obligations under this Data Processing Agreement are complied with, including ensuring that the appropriate technical and organizational security measures have been implemented.
	2. The relationship of the Parties and the nature of the Study outlined in the Agreement are such that the Data Controller has no access to the identity of the Study Participants. Therefore, the Data Controller needs to rely on the Data Processor in order to be able , by means of appropriate technical and organizational measures, to fulfil the obligation imposed to the Data Controller under Applicable Laws. Data Processor shall therefore respond to requests from Data Subjects in accordance with Article b of the Agreement pursuant to Applicable Laws (such as, the right of access, the right to rectification, the right to erasure, the right to restrict the processing, the right to data portability and the right to object).
	3. The Data Controller is entitled to appoint at its own cost an independent expert, who shall have access to the Data Processor's data processing facilities and receive the necessary information for the sole purpose of auditing whether the Data Processor has complied with its obligations The Data Processor may reasonably and in a justified manner object to the appointment of this proposed expert. The expert shall upon the Data Processor's request sign a non-disclosure agreement provided by the Data Processor, and treat all information obtained or received from the Data Processor confidentially, and may only pass on, the findings as described under clause 3.9(ii) below to the Data Controller.
	4. The Data Processor must give authorities who by Union or Member State law have a right to enter the Data Controller's or the Data Controller's processors’ facilities, or representatives of the authorities, access to the Data Processor's physical facilities against proper proof of identity and mandate, during normal business hours and upon reasonable prior written notice.
	5. The Data Processor must without undue delay, and where feasible within 72 hours, notify the Data Controller in writing about:

any request for disclosure of Personal Data processed under the Agreement by authorities, unless expressly prohibited under Union or Member State law,

any finding of (a) breach of security that results in accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, Personal Data transmitted, stored or otherwise processed by the Data Processor under the Agreement (“Data Breach”), or (b) other failure to comply with the Data Processor's obligations under Clause 3, or

any request for access to the Personal Data (with the exception of medical records of the Study Participants for which the Data Processor is considered Data Controller) received directly from the Data Subjects or from third parties.

* 1. Such a notification from the Data Processor to the Data Controller with regard to a breach of security as meant in Clause 3.9(ii)(a) will contain at least the following information:

The nature of the Personal Data Breach, stating the categories and (by approximation) the number of Data Subjects concerned, and stating the categories and (by approximation) the number of the personal data registers affected (datasets);

The likely consequences of the Personal Data Breach;

A proposal for measures to be taken to address the Personal Data Breach, including (where appropriate) measures to mitigate any possible adverse effects of such breach.

The Data Processor shall document (and shall keep such documentation available for the Data Controller) any Personal Data Breaches, including the facts related to the Personal Data Breach, its effects and the corrective measures taken. After consulting with the Data Controller, the Data Processor shall take any measures needed to limit the (possible) adverse effects of Personal Data Breaches (unless such consultation cannot be awaited due to the nature of the Personal Data Breach).

* 1. The Data Processor must promptly and reasonably execute all actions required to handle (a) responses to any breach of security as described in 3.9(ii) above and (b) any requests from Data Subjects under Chapter III of the GDPR, including requests for access, rectification, restriction of processing or erasure. The Data Processor must also reasonably implement the appropriate technical and organizational measures to enable the Data Controller to fulfil the Data Controller's obligation to respond to such requests. Any reasonable documented costs and expenses pre-approved in writing by the Data Controller related to the above will be reimbursed by the Data Controller to the extent such costs and expenses are not related to any requirements according to Applicable Law imposed on the Data Processor or due to any breach of this Schedule F or the Agreement by Data Processor.
	2. The Data Processor must reasonably assist the Data Controller with meeting the other obligations that may be incumbent on the Data Controller according to Union or Member State law where the assistance of the Data Processor is implied, and where the assistance of the Data Processor is necessary for the Data Controller to comply with its obligations. This includes, but is not limited to, at the request to provide the Data Controller with all necessary information about an incident under Clause 3.9(ii), and all necessary information for an impact assessment in accordance with Article 35 and Article 36 of the GDPR. Any reasonable documented costs and expenses pre-approved in writing by the Data Controller related to the above will be reimbursed by the Data Controller to the extent such expenses are not related to any requirements according to Applicable Law imposed on the Data Processor or due to breach of this Schedule F or the Agreement by Data Processor.

# SubProcessors

* 1. The Data Processor may only engage a subprocessor, with prior specific or general written consent from the Data Controller. At the time of this Data Processing Agreement, the Data Processor uses the subprocessor listed in Annex 2. The Data Processor undertakes to inform the Data Controller of any intended changes concerning the addition or replacement of a subprocessor by providing a reasonable prior written notice to the Data Controller. The Data Controller may reasonably and in a justified manner object to the use of a subprocessor. The Data Processor must inform the Data Controller in writing of the discontinued use of a subprocessor.
	2. Prior to the engagement of a subprocessor, the Data Processor shall conclude a written agreement with the subprocessor, in which at least the same data protection obligations as set out in this Data Processing Agreement shall be imposed on the subprocessor, including obligations to implement appropriate technical and organizational measures and to ensure that the transfer of Personal Data is done in such a manner that the processing will meet the requirements of the Applicable Law.
	3. The Data Controller has the right to receive a copy of the relevant provisions of Data Processor's agreement with the subprocessor related to data protection obligations. The Data Processor shall remain fully liable to the Data Controller for the performance of the subprocessor obligations under this Data Processing Agreement. The fact that the Data Controller has given consent to the Data Processor's use of a subprocessor is without prejudice for the Data Processor's duty to comply with this Data Processing Agreement.

# Confidentiality

* 1. The Data Processor shall keep Personal Data confidential.
	2. The Data Processor shall not disclose the Personal Data to third parties or take copies of Personal Data unless strictly necessary for the performance of the Data Processor's obligations towards the Data Controller according to this Data Processing Agreement, and on condition that whoever Personal Data is disclosed to is under the responsibility of a professional subject to the obligation of professional secrecy under Union or Member State law or rules established by national competent bodies or by another person also subject to an obligation of secrecy under Union or Member State law or rules established by national competent bodies.
	3. The Data Processor shall ensure that all employees and any persons that it involves in the conduct of the Study comply with this Data Processing Agreement.
	4. The Data Processor shall limit the access to Personal Data to all employees and any persons that it involves in the conduct of the Study for whom access to said data is necessary to fulfil the Data Processor's obligations towards the Data Controller.
	5. The obligations of the Data Processor under Clause 5 shall continue until such time as provided by Applicable Law and regardless of whether the cooperation of the parties has been terminated.

# Term and termination of the Data Processing Agreement

* 1. Regardless of the expiry or termination, for whatever reason, of the Agreement, this Data Processing Agreement remains in force and applicable as long as the Data Processor processes the Personal Data for the Data Controller under the Agreement.
	2. In case of termination of the Agreement, the Data Processor must provide the necessary transition services to the Data Controller. The Data Processor is obliged to reasonably assist Data Controller at Data Controller’s expense.

Data Processor shall have appropriate procedures in place for the archiving of the Personal Data after the end of the Study in accordance with Applicable Law and at the end of the legally mandated archiving period ensure the destruction of the Personal Data and promptly inform Data Controller of this same.

* 1. If the Data Processor is required based on Union or Member State law to retain all or part of the Personal Data for a longer period than is possible based on the period mentioned in the Data Processing Agreement, the Data Processor shall immediately communicate this to the Data Controller, stating the basis, term and scope of such obligation. Once compliance with the obligation is no longer impeded by Union or Member State law, the Data Processor shall as yet erase the data in accordance with the provisions in the Data Processing Agreement.

**Annexes:**

Annex 1: Instructions

Annex 2: Subprocessors

Annex 3 : EU Commission’s Standard Contractual Clauses for the transfer of Personal Data to third countries

**Annex 1 – Instructions**

This Annex 1 constitutes the Data Controller's instruction to the Data Processor in connection with the Data Processor's Personal Data processing for the Data Controller, and is an integrated part of the Data Processing Agreement.

Contact details of the Data Controller (including its Data Protection Officer, if applicable):

Contact details of the Data Processor (including its Data Protection Officer, if applicable):

***The processing of Personal Data***

a) Purpose and nature of the processing operations

* Performance of Clinical Study services under the Agreement and for the purpose of mandatory safety monitoring– as specifically described in the Protocol.
* Completion of data in the CRF system
* [to be completed on a case-by-case basis]

I. Transfer of Personal Data to a third country: YES/NO

II. If YES to I., transfer outside the EU: YES/NO

III. If YES to II., please complete Annex 3.

b) Categories of Data Subjects

I. Former, current or future persons and/or patients who voluntarily enrolled in the Study, and/or their relatives, and/or

II. […]

c) Categories of Personal Data

Re b) I: Date of birth and/or age, initials, personal identification number assigned to Data Subjects participating in the Study, description of characteristics of physical features of the body, medical condition, medical images and scans (such as X-ray and study results), drugs and other treatments administered during the Study

Re b) II: […].

d) Special categories of Personal Data

Re b) I: Health information including past medical history, medical condition and its development during the Study, medical test information (such as blood samples results from scans and biopsies) generated during the Study, treatment administered in the course of the Study, data revealing racial or ethnic origin, genetic data and/or social security number

e) [Insert address, city and country of all locations where the processing will be performed.]

f) Specific security requirements

The following requirements reflect the minimum data processing requirements expected of the Data Processor. It is a condition that other agreed documents, legislation or industry standards laying down requirements of the processing of Personal Data in connection with Study/ /mandatory safety monitoring are complied with as well.

1. The Personal Data may only be used for the Study and/or mandatory safety monitoring.

2. The collection, registration and other processing of Personal Data must be legally authorized under Applicable Law, or applicable policies issued of the supervisory authorities.

3. Any person who takes part in the processing of Personal Data must be familiar with these requirements.

4. Premises used for the storage and other processing of Personal Data must be arranged in such a way as to prevent unauthorized access.

5. Appropriate security measures must be implemented to protect data against accidental or unlawful destruction, loss or impairment. Furthermore, it must be ensured that no incorrect or misleading Personal Data is processed. Incorrect or misleading data, or data processed in contravention of the above Applicable Law, policy of the supervisory authority or these requirements, shall be rectified or erased.

6. Personal Data may not be stored in a way that makes it possible to identify the Data Subjects for longer than is necessary for the achievement of the Study and/or mandatory safety monitoring.

7. The publication of results from clinical studies must take place in such a way that it is impossible to identify individual persons.

8. It is a condition that other legislation laying down requirements of the processing of Personal Data in connection with Study and/or mandatory safety monitoring is complied with.

**Electronic data**

9. Identification data must be encrypted or replaced by a code number or similar. Alternatively, all data stored can be encrypted. Encryption keys, code keys, etc. must be stored securely and separately from the Personal Data. This also applies to Personal Data that is stored on portable devices such as laptop PCs, tablets, etc.

10. Data may only be accessed by using a unique user name and a confidential password. The password must be renewed at least once a year and when otherwise necessary in order to ensure the secure processing of the data.

11. On the transfer of Personal Data via the internet or other external networks, the necessary security measures must be taken to ensure that the Personal Data does not come to the knowledge of any unauthorized persons. This includes that encryption is required if sensitive Personal Data is transferred via the internet (or other open networks), and security of authenticity (identities of transmitter and recipient) and integrity (the authenticity of the transmitted Personal Data) must be appropriately ensured by the use of suitable security measures. On using internal networks, it must be ensured that no unauthorized persons can gain access to the data.

12. Removable storage media, safety copies of Personal Data, etc. must be stored securely and under lock and key, so that unauthorized access is prevented.

**Manual ("paper") data**

13. Manual material, including print-outs, error and control lists, etc. with Personal Data, must be stored securely under lock and key, and in such a way as to prevent unauthorized access.

**Biobank and biological material**

14. Samples with biological material and biological material in biobanks must be stored securely under lock and key so as to prevent unauthorized access, and in such a way as to ensure that the material is not lost, impaired, or accidentally or illegally destroyed.

15. Biological material collected for the purpose of the Study and marked with a civil registration number or name must be stored subject to special safety requirements.

16. Internal guidelines must be laid down within the Data Processor’s organization regarding the project for the storage of biological material.

**Information to be given to the Study Participant /** **Data Subject**

17. Where the Personal Data is obtained from the Study Participant/ Data Subject (via interviews, questionnaires, clinical or para-clinical examination, treatment, observation, etc.), more detailed information concerning the clinical Study/testing/safety monitoring shall be distributed/forwarded to the Data Subject in accordance with Article 13 of the GDPR. The Study Participant must, via the privacy notice or via the informed consent form (as applicable) as drafted by the Data Controller and as approved by the relevant ethics committee and /or relevant authorities, be informed of the name of the Data Controller and of the name of the Data Processor with clear indication that the Data Processor shall act as the first point of contact with the Study Participant in connection to the processing of the Personal Data and/or with the exercise of rights granted to Data Subjects under the GDPR, the purpose of the trial/testing/safety monitoring, the fact that it is voluntary to participate in the trial/testing, the identity of any recipients of Personal Data, and the purpose of the disclosure of Personal Data, as well as any further information which is necessary for the Study Participant / Data Subject to be able to safeguard his/her interests. The Data Subject has been informed about the right of access to the Personal data that is processed concerning the person in question.

**Disclosure**

18. Disclosure/issue of Personal Data to other parties may take place to the extent that this is legally authorized under Applicable Law.

**On the conclusion of the project**

19. At the latest on the conclusion of the Study/testing/safety monitoring the Personal Data (including biological material) shall be erased, made anonymous, or destroyed, unless Union or Member State law requires continued storage of the Personal Data. In accordance with Belgian Law as defined in the Agreement the Data Processor shall be allowed to store the medical records for at least 30 years. It must not subsequently be possible to identify individuals participating in the clinical Study/testing/safety monitoring. The deletion of Personal Data must be properly documented.

20. Alternatively, the Personal Data may be transferred for further storage in archives according to the Data Controller’s instructions. Any costs related to such transfer and further storage of Personal Data shall be borne by the Data Controller.

21. Erasure of Personal Data from electronic media shall take place in such a manner that it is impossible to recover the Personal Data and such erasure must be properly documented.

Annex 2 – Subprocessors

The Data Controller agrees that the Data Processor – subject to compliance with Clause 4 of the Data Processing Agreement – engages the parties listed below as subprocessors.

[Either 1) insert name, Data Controller reg. no., address, country of the relevant subcontractors and a description of the written agreement between the subcontractor and Data Processor for the processing of Personal Data under the Agreement or 2) mark as ‘None’]

Annex 3 - EU Commission's Standard Contractual Clauses for the transfer of Personal Data to third countries

[insert if applicable: The latest version of the EU Commission's Standard Contractual Clauses for the transfer of Personal Data to third countries are incorporated herein by reference]

**SCHEDULE G**

**USE OF HUMAN BODILY MATERIAL**

[to be discussed on a case-by-case basis the need to insert reference to the obligations under the law -in particular Royal Decree on Biobanks- and clarify that minimal data sets linked to the Human Bodily Material is personal data governed by Schedule F]

1. When the EU clinical trials regulation 536/2014 will be applicable, a period of twenty-five (25) years after the end of the study will be required. [↑](#footnote-ref-2)