1. PRELIMINARY NOTICE

The sponsor must accept the principal investigator for the conduct of the experiment prior to any contact negotiations.

2. CONTRACT REVIEW PROCESS

A commercial central desk is in charge of the initial submission of commercial studies and is the single access path to the Ethics Committee. As soon as the site has been selected, the requested documents described below and practical information must be provided by email to: guichetcommercial@saintluc.uclouvain.be. The commercial central desk transfers all the completed documents to the contracts, finances and reporting *(CoFi)* team.

To speed up the process of contract review we invite you to strictly respect the following steps described on our website: https://www.saintluc.be/en/commercial-studies

1) **FILL IN THE CONTRACT SET-UP QUESTIONNAIRE AVAILABLE ON OUR WEBSITE :** https://www.saintluc.be/en/commercial-studies
2) **SEND THE FOLLOWING DOCUMENTS BY EMAIL :** guichetcommercial@saintluc.uclouvain.be

- **The contract set-up questionnaire**
- **The GDPR – Initial Questionnaire**
- **The complete study protocol with a flow chart**. The investigator will define in regard of the flow chart what is to be considered as "standard of care" or not. This information must also be reported in the participant's information form *(CUSL internal procedure related to the Belgian Law dated 10 April 2014 art.46 as well as ICF templates from the FAHMP)*.
- **The patient information sheet and the informed consent form** *(FR or EN)*
- **The selected draft of the agreement** *(word version)*
- **A budget proposal** with detailed items *(per visit fee- overhead included, VAT excluded)* of the different topics *(data management, investigator fee, technical assessments, additional fees such as start-up etc)* to be covered. Any information transmitted in relation to the protocol must be paid for. The principal investigator budget proposed must not include the fees accounted for in the additional contracts. Please note that the holdback is refused.

3) **THE COMMERCIAL CENTRAL DESK TRANSFERS ALL THE COMPLETED DOCUMENTS TO THE CONTRACTS, FINANCES AND REPORTING TEAM *(COFI).***

Please take into account that the contract review time can be accelerated when an already validated template is proposed:

- **Either the commercial template validated by the Belgian academic hospitals and Pharma.be** *(available on our website)*
- **Either a master agreement already negotiated between your company and the Cliniques universitaires Saint-Luc**
- **Either a recent** *(<1 year)* **contract validated by the Cliniques universitaires Saint-Luc**

To decrease the reviewing time, the Sponsor/CRO is advised to take into account the regulatory and financial requirements detailed in this document and in the "Financial requirements" document and to propose an updated contract and/or budget in function of our needs.

Composition of the COFI team		
Mr S. Livolsi	san.livolsi@sainluc.uclouvain.be	+32 2 764 23 10
Mme M. Masson	marie.masson@saintluc.uclouvain.be	+32 2 764 15 74
Mme C. Patti	celine.patti@saintluc.uclouvain.be	+32 2 764 13 95
Mme P. Stevaux	pauline.stevaux@saintluc.uclouvain.be	+32 2 764 12 42

The contract signatures will be initialized after the Ethics Committee has approved the experiment. The sponsor is requested to provide us with the Leading Ethics Committee approval as soon as it is issued.

The electronic signature is preferred. In case of hard copy the contract must be signed at least by 3 parties: sponsor, principal investigator and *(on behalf of the institution)* Prof Jean-Louis Vanoverschelde, Medical Director.

3. Specific mandatory regulatory requirements for the Clinical Trial Agreements and references of the corresponding articles in the "Pharma.be" contract template: (AAHRPP elements in yellow must be taken into account)

The Cliniques universitaires Saint-Luc have been awarded full accreditation for its human research protection program by the Association for the Accreditation of Human Research Protection Programs *(AAHRPP),* an independent and non-profit organization. Considered the "gold seal" for human subject protection, AAHRPP accreditation signifies that an organization follows rigorous standards for ethics and quality. Therefore, the regulatory section of the agreements must fulfill the GCP and the local legislation declined in an AAHRPP approved wording.

TITLE	ELEMENT	TYPE OF SENTENCE OR REFERENT ARTICLE IN THE PHARMA.BE TEMPLATE
Parties	Sponsor or CRO and Cliniques universitaires Saint-Luc	Cliniques universitaires Saint-Luc ASBL**,** Avenue Hippocrate 10, 1200 Bruxelles, registered to the BCE with the n° 416.885.016, legally represented by the Medical Director
Term of the agreement	Subject of the trial	Article 2
	Effective date = date of the last signature	Article 5.1.1

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	Total number of patients to be included Number of patients locally expected	
Regulatory pre condition	Compliance with the protocol, Helsinki declaration, GCP, Belgian laws, GDPR, patient's rights, Belgian Sunshine Act, European directives or regulations and ethics committees. IND or IDE experiments are also regulated by the FDA regulation.	Article 1.2
Responsibilities	**Sponsor responsibilities** **AAHRPP Element I.8.D.:** Before initiating research, the Organization has a written agreement with the Sponsor about plans for disseminating findings from the research and the roles that Researchers and Sponsors will play in the publication or disclosure of results.	- *Sponsor will publicly register a protocol summary in **Clinicaltrials.gov.** (or equivalent)* Sponsor is responsible: - Of the study drug - Initial and continuing review by the Ethics Committee - Authorization by the Health authorities - Safety reporting during and after the study Article 3.2.4
	Investigator and center responsibilities	*The Principal Investigator has the experience and will respect the protocol* *The Principal Investigator agrees that he is primarily responsible for all aspects of the trial, and for the full conduct and the quality of all protocol related treatments given in his own institution.* *The Principal Investigator is responsible for the submission to his ethics committee (!! Will be adapted for the CTR trials).* *In the event that the Principal Investigator ceases to be involved in the Trial for whatever reason, the center agrees to notify SPONSOR immediately. Within thirty (30) days after such notification the SPONSOR and center shall agree a successor acceptable to both parties.* *It is the responsibility of center to ensure that all work performed by its*

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		employees, agents, contractors and/or the representatives is done in compliance with the protocol, *Institution/investigator shall not conduct any other trial which adversely affects their ability to perform their obligation* Articles 3.2 to 3.5
Recruitment-Communication	**AAHRPP Element I.8.D.:** Before initiating research, the Organization has a written agreement with the Sponsor about plans for disseminating findings from the research and the roles that Researchers and Sponsors will play in the publication or disclosure of results.	*The SPONSOR and the Ethics Committee must approve, in writing, the text of any communication soliciting patients for the study before placement, including but not limited to, newspapers and radio advertisements, direct mail pieces, internet advertisements or communications and newsletters. Such communications must comply with applicable laws and guidelines.* *Information published in Clinicaltrials.gov (or equivalent) can be publicly disclosed.* Article 3.5
	Participant's consent	*The Principal Investigator shall obtain from each subject legally signed written informed consent prior to the first trial specific procedure, in compliance with applicable regulations and guidelines and any modifications thereof.* Article 3.3.4
Study data	Data transmission	*Principal Investigator agree to provide Sponsor periodically and in a timely manner with all trial results and other data called for in the protocol on properly completed (written or electronic) case report forms.* Timing for data entry in eCRF: 5 working days; queries : 2 days; Data base lock/query : 24 hours Article 3.3.3
	Data property	The SPONSOR is owner of the study data (data collected in relation to the study).

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		The sponsor may utilize the data in any way it deems appropriate, subject to and in accordance with applicable privacyand security laws and regulations and the terms of this agreement. Article 6.2
Monitoring	**AAHRPP Element III.2.A :** The investigator permits monitoring and auditing by the sponsor and inspection by the appropriate regulatory authority.	Subject to the provisions of this agreement, ***SPONSOR's appointed monitors shall have the right to access and use the medical records*** during the term of this Agreement and thereafter. Article 3.4.5
	AAHRPP Element I.8.B: In studies where Sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the Organization has a written agreement with the Sponsor that the Sponsor promptly reports to the Organization findings that could affect the safety of participants or influence the conduct of the study.	Article 3.2.4 ***Valid for I8B, I8C and I8E*** *:During and for a period of [specify a period of time appropriate to the specific study, for example, at least two years after the completion of the study; or specify a triggering event, for example completion of data analysis], [the sponsor] shall promptly (or in a timely manner appropriate to the level of risk involved) report to the investigator any information that could directly affect the health or safety of past or current study subjects 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 organization] shall be free to communicate these findings to each study subject and the IRB.*
	AAHRPP Element I.8.C: When the Sponsor has the responsibility to conduct data and safety monitoring, the Organization has a written agreement with the Sponsor that addresses provisions for monitoring the data to ensure the safety of participants and for providing data and safety monitoring reports to the Organization. At a minimum, data and safety monitoring reports should be sent annually, so they can be considered by the IRB at the time of continuing review.	
Results notification	**AAHRPP Element I.8.E:** When participant safety could be directly affected by study results after the study has ended, the Organization has a written agreement with the Sponsor that the Researcher or Organization will be notified of the results in order to consider informing participants.	
Audit, inspection		***Audit:*** *announced audit: the claiming party informs the investigative center in a reasonable timeline compatible with the clinical activity of the investigator. The audit planned date can be discussed (e.g.*

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		in case of absence of the investigator) but the audit itself cannot be refused by the center. Article 8.3 ***Inspection :*** *2 possibilities:* - *the inspection is sudden and unexpected and is linked to a presumptive fraud or severe misconduct related to the medical research rules. Must be accepted as is.* - *the routine inspection is scheduled and will be announced by the inspector. The visit date is negotiable according to the investigator availabilities in a window determined by the inspector.* Article 8.1;8.2
Emergency medical treatment for patients experiencing SAE or AE	**AAHRPP Element I.8.A:** The Organization has a written agreement with the Sponsor that addresses medical care for research participants with a research-related injury, when appropriate	**INVESTIGATOR RESPONSIBILITY : MEDICAL CARE TO THE PARTICIPANTS :** *« The participating site and investigator will ensure adequate resources and staff for the study and will ensure medical care of the subjects. ».* **AND** **SPONSOR RESPONSIBILITY:** ***RESEARCH-RELATED INJURY.*** *[The sponsor] shall be responsible for payment of the actual and reasonable medical expenses incurred in diagnosing and treating any injury, illness, or adverse reaction of a study subject that results from the administration of the study drug [or device] in accordance with the protocol or the proper performance of any Protocol procedure.* Article 7.3 **AND** **NO-FAULT INSURANCE :** In accordance with the article 29 of the Belgian Law relating to experiments on

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		humans dated May 7, 2004, SPONSOR shall assume, even without fault, the responsibility of any damages incurred by a Study Patient and linked directly or indirectly to the participation to the Trial, and shall provide compensation therefore through its insurance. Article 7.1
Confidentiality	Both parties Sponsor's confidential information	Definition, exclusion, disclosure, authorisation for disclosure, accidental disclosure, property End of study, disclosure of confidential information generated by the study, collaborators Article 6.1
	Personal data confidential information Study participants, study staff	Article 3.1 and DPA 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. 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 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" 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

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		the data contained in its patients' medical records for the purposes of providing medical care to its patients and for academic research purposes. DATA BREACH MANAGEMENT BY BOTH PARTIES
Use of names, patent and intellectual property rights	**AAHRPP Element I.8.D**: Before initiating research, the Organization has a written agreement with the Sponsor about plans for disseminating findings from the research and the roles that Researchers and Sponsors will play in the publication or disclosure of results.	Article 6.4 **Use of names:** Neither Parties shall use the other's names or the names of the other's employees in any advertising or sales promotional material or in any other way without the prior written consent of the other." **Background IP:** Background IP are not covered by this agreement and no Party hereunder shall have any claims to or rights in such Background IP of the other Party. **Intellectual property:** Sponsor IP: shall remain the sole property of the sponsor. Transfer of the sponsor IP to the sponsor. **Patent:** Disclosure of sponsor's invention Patent's rights
Publication rights	**AAHRPP Element I.8.D:** Before initiating research, the Organization has a written agreement with the Sponsor about plans for disseminating findings from the research and the roles that Researchers and Sponsors will play in the publication or disclosure of results.	Article 6.3 **Institution/investigator:** Respect of the academic freedom to publish **Agreed with the sponsor:** - Investigator will not publish before the study report is sent to the authorities AND xx months after the end of the study - Any draft manuscript will be submitted to the sponsor - Financial acknowledgement - Respect of the ethical standards of ICMJE

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		- Multicenter study: the first publication will be a joint publication. In connection with any data generated from the services conducted under this agreement by the center, sponsor shall have the right to publish such data without approval from the center. Sponsor AND investigator point of view must OBLIGATORY be taken into account. Authorship depending of the investigator's participation in the study should be discussed. **In case of doubt, contact the CUSL legal department.**
Insurance	Both the institution and the sponsor will maintain a civil liability insurance.	*The investigator will maintain a medical professional liability and general liability insurance.* *Article 7.6*
	Sponsor has a no-fault insurance according to Belgian law	*In accordance with the Belgian Law relating to experiments on humans dated May 7, 2004, SPONSOR shall assume, even without fault, the responsibility of any damages incurred by a Study Patient and linked directly or indirectly to the participation to the Trial, and shall provide compensation therefore through its insurance.* *Article 7.1*
Liability		Articles 7.7; 7.2;7.4;7.5;7.8 Exclude liability for: gross negligence or wrongful acts or omissions **INDEMNIFICATION FOR DIRECT DAMAGES:** Indemnification of investigator by sponsor Indemnification of sponsor by investigator : (same sentence can apply for indemnification of investigator by

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		sponsor: each party shall indemnify defend and hold harmless the other) **Add a cap for the indemnification by the institution:** …. 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, the effective coverage under such insurance policy, and (b) for damages not covered under the civil liability insurance policy of the INSTITUTION an amount corresponding to the aggregated fees (excluding pass through costs) paid or/to be paid by the SPONSOR **INDEMNIFICATION FOR INDIRECT DAMAGES:** …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. **Information:** All Parties shall promptly inform each other of any claims or imminent claims relating to the conduct of the Study.
Termination		Articles 5.2 to 5.5 and 10.3
	Termination by the sponsor	SPONSOR may terminate this Agreement at any time for an **objectively justified reason** upon [*thirty (30)*] days prior written notice to the other Party.
	Termination by both parties	Suspension and restart conditions for the sponsor. Termination for force majeure, breaches, default, cause, fraud, negligence, gross misconduct, no investigator anymore, insolvency
	Termination for safety reasons	Either Party may terminate this Agreement upon written notice with

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		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
	Consequences of the termination or suspension for the investigator	Ensure patient safety and continuity of treatment if agreement is terminated
	Final Payments must be foreseen	
General provisions	Governing law	**MANDATORY: This Agreement shall be construed and interpreted in accordance with the laws of Belgium, excluding its conflicts of law provisions... The competent court shall be the courts of Brussels. (where the work is being performed).** Principle: Applicable Law are the law of the country where the study is conducted (execution place law). Article 10.8
	Resolving dispute	*In the event of a dispute between the PARTIES relating to the validity, interpretation or execution of the present agreement, which could not be resolved amicably, the PARTIES agree to attempt to resolve their dispute through the use of mediation in accordance with the mediation rules of BMediation. Mediation will begin no later than 15 days after the request for mediation notified by a PARTY to the other PARTY [IES] and the duration of mediation may not exceed 60 days, unless expressly agreed by the PARTIES. The mediation cost will be share equally between the PARTIES. In the event of failure of mediation, only the courts of Bruxelles will be competent.* Article 10.9
Terms of payment	**AAHRPP Element III.1.E:** Researchers and Research Staff must recruit participants in a fair and equitable manner.	In case of doubt related to the “fair and equitable” recruitment: ask the Ethics Committee for advice.

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		Payment arrangements in exchange for referrals of prospective participants ("finder's fees" or "referral fees") are allowable. Payment arrangements designed to accelerate recruitment that are tied to the rate or timing of enrolment ("bonus payments") are not allowed or are subject to previous Ethics Committee approval.
	Invoice and payment request: A payment request of the services rendered during the reference period will be agreed by both parties. An invoice based upon this document will be issued by us and sent to your attention. The contract must reflect this provision by the following wording (or re-phrase):	"*The sponsor will send every three months a payment request form to the center with a summary of all reported visits or services rendered during the reference period. Upon agreement with the payment request form, the center will draw up an invoice at the attention of the sponsor. The sponsor will pay within 30 days after receipt of the invoice. Amounts due under this agreement are net of all taxes. VAT if applicable will be charged on top of the fees mentioned in this agreement and according the VAT directive".* *If the payment request is provided by the center : "Such [PO – payment request] will be deemed to be approved if no objection has been raised by [the other party – the Sponsor – CRO – Company Name] within a period of fifteen (15) calendar days".*
	Following invoicing data is needed:	Corporate name VAT number Billing address Mailing address Contact name and e-mail
Signature page	Signed by Medical Director on behalf of Cliniques universitaires Saint-Luc AND by the principal investigator or the medico-technic department AND the sponsor or the CRO	Esignature is preferred. APPROVED by the sponsor/CRO and by the medical director. ACKNOWLEDGED by the investigator

4. ACCESS TO THE INSTITUTIONAL PROCEDURES FOR SPONSORS/CRO

A quality system is in place and covers all the process of a clinical research as well as the Ethics Committee performance. Applicable procedures are available to sponsors/CRO upon request to the clinical research quality manager. Only the French version of the documents related to the biomedical research quality system have been validated. An English translation is available upon request to the quality manager for clinical research

QAM Clinical Research at the CUSL	isabelle.beaufay@saintluc.uclouvain.be	+32 2 764 23 99
Ethics Committee	comite.ethique@saintluc.uclouvain.be	+32 2 764 55 14