

CLINICAL STUDY SITE AGREEMENT

Clinical Study: Global Research Initiative Patients screening on NASH (GRIP on NASH)

Protocol: v1.3, 08-06-2022

Sponsor (initiator): Julius Clinical

Target: 1000 subjects / 500 subjects

The undersigned,

- A. Julius Clinical, a registered trade name of Julius Clinical Research B.V., [REDACTED]
[REDACTED] duly represented by Eelco Brouwer, in his capacity as
Chief Financial Officer
(hereinafter referred to as "**Sponsor**")

and

- B. Hospital Universitario Virgen del Rocío, located [REDACTED]
[REDACTED] duly represented by Manuel Molina Muñoz, in his capacity of Managing Director
(hereinafter referred to as "**Study Site**")

and

- C. Fundación Pública Andaluza para la Gestión de la Investigación en Salud de Sevilla, located at
[REDACTED] José
Cañón Campos, in his capacity of Managing Director
(hereinafter referred to as "**Managing Body**")

in the presence of:

Study Site's employee, Manuel Romero Gómez
(hereinafter referred to as "**Site Investigator**")

[REDACTED]

WHEREAS,

- The Sponsor is an science driven contract research organization involved in the design, conduct and interpretation of clinical studies;
- the Study Site is involved in patient care, research and education;
- the Sponsor and in particular M. Castro Cabezas, MD, PhD and D. E. Grobbee, MD, PhD, FESC (hereinafter the “Principal Investigators”), researchers employed by Sponsor who have designed the Clinical Study identified hereof;
- the Study Site has facilities and personnel with the requisite skills, experience, and knowledge required to support the performance of the Clinical Study by the Site Investigator;
- the Sponsor wishes to engage the Study Site and Site Investigator to perform part of the Clinical Study and Site Investigator and Study Site, having reviewed the Protocol and relevant Clinical Study information, are willing to participate in the Clinical Study.

In consideration of the undertakings and commitments set forth herein, the Parties agree to enter into this Clinical Study Site Agreement.

1. DEFINITIONS

The following words and phrases have the following meanings:

- a. “**Affiliate**” means any business entity which controls, is controlled by, or is under the common control of, a Party. For the purposes of this definition, a business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity or to elect or appoint 50% or more of the members of the management of such business entity;
- b. “**Agreement**” means this agreement comprising its recitals, clauses, schedules and any annexes attached hereto, including the Protocol and including any written amendments to the Agreement agreed between the Parties;
- c. “**Auditor**” means a person who is authorised by Sponsor to carry out a systematic review and independent examination of clinical study related activities and documents to determine whether the evaluated Clinical Study related activities were conducted, and the data were recorded, analysed and accurately reported according to the Protocol, (if applicable) the standard operating procedures of Sponsor, ICH-GCP and the applicable regulatory requirements;
- d. “**Authorisation**” means the authorisation of the clinical study by a local Ethics Committee in accordance with local requirements (if applicable);
- e. “**Clinical Study**” means the investigation as defined in the cadre above, (also) to be conducted at the Study Site in accordance with the Protocol;
- f. “**Clinical Study Subject**” means a person enrolled to participate in the Clinical Study;
- g. “**Confidential Information**” means any and all information, data and material of any nature belonging or entrusted to a Party and/or its Affiliate(s), or which is a trade secret, which such Party (the “**Disclosing Party**”) may disclose in any form to the other Parties (each a “**Receiving**”

Party”) pursuant to this Agreement, the release of which is likely to prejudice the interests of the Disclosing Party;

- h. “**CRF**” means the case report form in a format prepared by Sponsor and documenting all tests and observations related to the Clinical Study and “**eCRF**” means a CRF in electronic form;
- i. “**Effective Date**” the date this Agreement comes into effect, being the date of the last Party’s signature to this Agreement;
- j. “**Ethics Committee**” means the accredited medical research ethics committee competent to review the Clinical Study in accordance with applicable Law, and to which the Protocol has been submitted for approval;
- k. “**GDPR**” means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation);
- l. “**ICF**” means the Informed Consent Form as approved by the Ethics Committee in which the Clinical Study Subject consents to his participation in the Clinical Study, including a consent, as defined in article 4 paragraph 11 of the GDPR, regarding the processing of the Clinical Study Subject’s Personal Data which shall meet the requirements relating thereto of the GDPR;
- m. “**ICH-GCP**” means the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95 together with such other good clinical practice requirements as are specified in Directives 2001/20/EC and 2005/28/EC of the European Parliament and the Council relating to medicinal products for human use and in guidance published by the European Commission pursuant to such Directives;
- n. “**Intellectual Property Rights**” means intellectual property rights including but not limited to patents, trade-marks, trade names, service marks, copyrights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them;
- o. “**Know How**” means all technical and other information which is not in the public domain (other than as a result of a breach of confidence), including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, manufacturing data and information contained in submissions to regulatory authorities, whether or not protected by Intellectual Property Rights;
- p. “**Law**” means any international, European Union and local law and regulations, as well as generally accepted international conventions applicable to the performance of the Clinical Study. Such Law including but not limited to:
 - the GDPR, and any applicable national implementing legislation,
 - ICH-GCP,
 - The Declaration of Helsinki,
 - and/or any successors of the above mentioned Laws.

- q. **"Party"** means the Sponsor or the Study Site or, *only if the Site Investigator is a separate Party to this Agreement*, the Site Investigator, and **"Parties"** shall mean the two or all of them jointly;
- r. **"Personal Data"** means personal data as defined in article 4(1) of the GDPR, i.e. any information relating to an identified or identifiable natural person, e.g. such information of a Clinical Study Subject;
- s. **"Protocol"** means the document as defined in the cadre at the beginning of this Agreement, detailing all aspects of the Clinical Study, and for which Authorisation has been obtained, a copy of which is attached as Annex 1 to this Agreement. The Protocol includes all amendments thereto for which Authorisation has been obtained;
- t. **"Research Staff"** means the person(s) who will undertake the conduct of the Clinical Study at the Study Site on behalf of the Site Investigator and under the supervision of the Site Investigator;
- u. **"Samples"** means any human biological materials, including but not limited to blood, body tissue, plasma and any other material containing human cells;
- v. **"Site Investigator"** means the person who will take primary responsibility for the conduct of the Clinical Study at the Study Site or any other person as may be agreed from time to time between the Parties as a replacement;
- w. **"Site Parties"** mean the Study Site and Site Investigator jointly;
- x. **"Target"** means the estimated number of Clinical Study Subjects to be included in the Clinical Study as referred to in the cadre above.

2. **OBLIGATIONS**

- 2.1. The Parties agree to perform the Clinical Study in accordance with the Protocol, this Agreement and applicable Law.
- 2.2. The Parties represent and warrant that they each have the authority to enter into this Agreement. In case the Site Investigator is not a Party to this Agreement, Study Site shall ensure the performance of the tasks assigned to the Site Investigator under this Agreement and by no means will the Site Investigator be held liable hereunder in person in the event that he/she is not a Party to this Agreement. The Study Site will ensure the availability of and/or access to any resources necessary to perform the Clinical Study at the Study Site, including departments, facilities and Research Staff and support personnel, and the Study Site certifies that the Site Investigator holds the necessary registration and has the necessary qualifications, expertise and time to perform the Clinical Study.
- 2.3. The Study Site shall notify the Sponsor if the Site Investigator ceases to be associated with the Study Site where the Clinical Study will be conducted or if he/she is otherwise unavailable to continue as Site Investigator, and Study Site shall use all reasonable endeavours to find a qualified successor acceptable to the Sponsor. Replacement of the Site Investigator is subject to authorisation by the Ethics Committee, if applicable. If subject to the foregoing no mutually acceptable replacement can be found, within reasonable time as not to hinder the safe continuation of the Clinical Study at the Study Site, and provided that the Sponsor will not unreasonably withhold its approval of the proposed replacement of Site Investigator, each Party may terminate this Agreement pursuant to clause 11.2.g below.

3. CLINICAL STUDY GOVERNANCE AND COMPLIANCE

- 3.1. The Sponsor shall be responsible for obtaining and maintaining Authorisation for the Clinical Study and (substantial) amendments to the Protocol.
- 3.2. In the event of any substantial amendments being made to the Protocol, the amendments shall be signed by the Site Investigator and shall be implemented after Authorisation and a favourable opinion of the Ethics Committee (if applicable). The Site Investigator shall not consent to any change in the Protocol requested by the Ethics Committee without the prior written consent of the Sponsor.
- 3.3. The Clinical Study shall be performed at the Study Site.
- 3.4. The Sponsor shall be responsible for submitting the Clinical Study for listing on a free, publicly accessible clinical study registry (if applicable).
- 3.5. The Site Investigator shall submit CRF/eCRFs to the Sponsor as outlined in the Protocol.
- 3.6. The Managing Body shall carry out the economic and administrative management of the Clinical Study at the Study Site, in accordance with the Collaboration Agreement signed between the Andalusian Health Service and the managing foundations of the research, development and innovation of the Andalusian Public Health System.
- 3.7. The Site Parties shall make and retain records regarding the Clinical Study as required by the Protocol, applicable Law, and in accordance with the Study Site's standard archiving procedures. Site Parties will retain such records for the minimum period of time required under applicable Law. If indicated by Sponsor that such is reasonably required for regulatory purposes, Site Parties shall retain the records for a longer period of time, and to the extent applicable, at Sponsor's expense.

4. LIABILITIES, INDEMNIFICATION AND INSURANCE

- 4.1. Each Party shall be liable towards the other Party, and shall indemnify and hold harmless the other Party and its employees, (the "Indemnitees") against all losses, damages, claims, demands, actions or proceedings (to include any settlements or ex gratia payments made with the consent of the Parties hereto and reasonable legal and expert costs and expenses) arising from its failure to comply with this Agreement or the Protocol, or from its gross negligence or intentional misconduct.
- 4.2. Parties shall keep each other reasonably informed of developments in relation to any such claim or proceeding. Parties will consult with each other on the nature of any defence to be advanced.
- 4.3. Parties will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding made or brought by or on behalf of Clinical Study Subjects (or their dependants).
- 4.4. Except in the event of intentional behaviour or gross negligence of a Party, in no event will a Party's liability towards the other Party include any indirect damages (indirect damages meaning: loss of profit, loss of revenue and loss of business opportunities).
- 4.5. Parties shall take out and/or maintain an insurance cover, or have a system of self-insurance in place, in amounts sufficient to cover their potential liability under this Agreement.

5. CLINICAL STUDY SUBJECT RECRUITMENT AND ENROLLMENT

- 5.1. The Site Parties shall use reasonable endeavours to recruit the Target of Clinical Study Subjects to the Clinical Study as indicated in the cadre above. Site Investigator shall make sure that the Clinical Study Subjects (and/or their legal representatives, if applicable) will, in accordance with applicable Law, be duly informed prior to their participation in the Clinical Study, in a language the Clinical Study Subjects (and/or their legal representatives, if applicable) can fully understand on all aspects of the Clinical Study which are deemed relevant in their decision to participate, and give informed consent. Site Investigator shall inform each Clinical Study Subject of the collection, the use and the transfer of Personal Data and the Clinical Study Subjects rights in respect of such processing as set forth in articles 13 and 14 GDPR.
- 5.2. If circumstances or events have occurred or will occur that will substantially delay or are likely to substantially delay the progress of recruitment or enrolment of the Clinical Study Subjects, the Site Investigator shall without undue delay inform the Sponsor in writing. In each such event Parties shall discuss the consequences of the delay and each Party shall undertake reasonable endeavours to agree on measures to handle the delay.
- 5.3. In the event that the Clinical Study is part of a multi-centre clinical study, the Site Investigator acknowledges and agrees that recruitment may be competitive and that Sponsor may stop further recruitment of Clinical Study Subjects at the Study Site when the recruitment target for all investigational sites for this Clinical Study has been met, even if the Study Site has not yet recruited the Target.

6. QUALITY ASSURANCE AND CONTROL

- 6.1. To the extent applicable, the Site Parties shall permit the Study Monitor, Auditor, the Ethics Committee and any official with a legal right to inspect and access all relevant documentation and source data for monitoring of the progress of the Clinical Study, the proper collection and recording of Clinical Study data, and altogether the good quality of the Clinical Study and compliance with applicable Law. Parties will make in good faith arrangements concerning the planning and follow-up of such audits or inspections.

7. CONFIDENTIALITY AND DATA PROTECTION

Confidential Information

- 7.1. The Receiving Party shall ensure that only those of its officers and employees concerned with the carrying out of this Agreement have access to the Confidential Information of the Disclosing Party. The Receiving Party shall take all practicable steps to ensure that such persons abide by the same obligations of confidentiality as apply to the Receiving Party under this Agreement. The Receiving Party undertakes to treat as strictly confidential and not to disclose to any third party any Confidential Information of the Disclosing Party, except where disclosure is required by a regulatory authority or by law, in which case the Receiving Party shall inform the Disclosing Party in writing of such requirement and the information to be disclosed. Notification will be within a reasonable time prior to being required to make the disclosure or if such time is not available,

immediately upon becoming known of the requirement to disclose, Confidential Information. The Receiving Party undertakes not to make use of any Confidential Information of the Disclosing Party, other than in accordance with this Agreement, without the prior written consent of the Disclosing Party. For purposes of this Agreement and subject to clause 10 (Publication and Authorship), the Clinical Study results generated by Site Parties as disclosed through the CRF shall be considered Confidential Information of Sponsor and the Sponsor shall be considered the Disclosing Party and Site Parties the Receiving Party and this clause 7 shall not provide Site Parties the rights granted hereunder to the Disclosing Party, where it relates to such Clinical Study results owned by Sponsor.

- 7.2. The obligations of confidentiality and non-use set out in clause 7.1 shall not apply to information which the Receiving Party can show by competent evidence:
- a. is or becomes part of the public domain by any other means than a wrongful act or breach of this Agreement by the Receiving Party;
 - b. was or becomes in the Receiving Parties' lawful possession prior to the disclosure without restriction on disclosure;
 - c. has been independently developed by the Receiving Party without the use of Confidential Information of the Disclosing Party;
 - d. has been obtained by the Receiving Party from a third party without breach of a confidentiality obligation; or
 - e. is published in accordance with clause 10 hereof.

Medical confidentiality, data protection and data controlling

- 7.3. The Study Site, Managing Body and Sponsor are considered each a controller for the processing of the Personal Data provided by the Study Site to Sponsor for the Clinical Study, if such Personal Data is processed and maintained by the Study Site for purposes of the Clinical Study and the Agreement. Parties will both handle all Personal Data in accordance with the terms of this Agreement, the GDPR and any other applicable laws or regulations covering the protection of Personal Data (collectively "Data Protection Law"). Each Party shall take the necessary measures to comply with the Data Protection Law and each Party shall maintain a record of processing activities under its responsibility.
- In the event law and interpretation by a relevant data protection authority or a court decision should prescribe or indicate another qualification of the roles of the parties in clinical trial agreements, the Parties hereto shall consult with each other and shall adapt the qualification of their roles and change arrangements as may be deemed appropriate.*
- 7.4. Each Party shall be responsible for its own processing of Personal Data in accordance with all Data Protection Law and with the ICFs obtained from Clinical Study Subjects and to the extent applicable, Personal Data consents obtained from the Site Investigator and Research Staff.
- 7.5. Both Sponsor, Study Site and Managing Body shall implement appropriate technical and organizational measures to meet the requirements of the GDPR.
- 7.6. If any Party becomes aware of a Personal Data breach in connection with this Clinical Study or the performance of this Agreement, that Party shall promptly notify the other

Party/-ies, and, the Party that is the controller of the relevant Personal Data shall also document the Personal Data breach and report the breach to the applicable regulatory authorities. In such case, Parties will fully cooperate with each other in order to fulfil the (statutory) notification obligations timely. A Personal Data breach refers to: a personal data breach as defined in article 4 paragraph 12 GDPR and further determined by articles 33 and 34 of the GDPR.

- 7.7. Each Party agrees to co-operate with any competent supervisory authority and to allow such supervisory authority to audit each Party's compliance with the GDPR.
- 7.8. The Parties agree to adhere to the principles of medical confidentiality in relation to Clinical Study Subjects.
- 7.9. Sponsor shall provide the ICF to Site Parties.
- 7.10. Sponsor acknowledges that Clinical Study Subjects – and/or their legal representatives on their behalf – may withdraw, in whole or in part, their initial informed consent. Site Investigator shall promptly notify Sponsor of any such withdrawal of the informed consent of a Clinical Study Subject, which may affect the use of such Clinical Study Subject's Personal Data under this Agreement. The Site Investigator will communicate with Sponsor on behalf of the Clinical Study Subject. However, the procedure followed upon such withdrawal of a Clinical Study Subject's consent will be according to the instructions, to the extent laid down in the Protocol and the ICF, and in accordance with the Applicable (Data Protection) Law.
- 7.11. Sponsor shall refrain from tracing and/or identifying any Clinical Study Subject, except where Sponsor is under a legal obligation to do so. In the event any Clinical Study Subject, for any other than aforementioned reason, becomes identifiable to Sponsor, Sponsor agrees to preserve, at all times, the confidentiality of information pertaining to such Clinical Study Subjects.

8. The signatories may contact the Data Protection Delegate at the following email address

[REDACTED]

They may exercise their rights of access, rectification, deletion of their personal data, or the limitation or opposition to their treatment, as well as the portability of their data, by requesting it in writing, with a copy of their personal ID, to the Andalusian Public Foundation for the Health

[REDACTED]

8.1.

Site Investigator's (and Research Staff's) personal information

- 8.2. Where applicable, Sponsor shall inform the Site Investigator, and to the extent applicable other Research Staff involved in the Clinical Study as well, of the collection, the use and the transfer of his/her/their Personal Data and his/her/their rights in respect of such processing as set forth in articles 13 and 14 GDPR. Site Parties agree to help Sponsor obtain any express consents, as may be necessary in accordance with applicable Data Protection Law from the Site Investigator, and to the extent applicable and necessary from other Research Staff involved in the Clinical Study as well, for any intended processing of his/her/their Personal Data by Sponsor.

[REDACTED]

9. INTELLECTUAL PROPERTY

- 9.1. All Intellectual Property Rights and Know How owned by or licensed to any of the Parties prior to and after the date of this Agreement, other than any Intellectual Property Rights and Know How arising from the Clinical Study, are and shall not be affected by this Agreement.
- 9.2. The Sponsor shall own the Intellectual Property Rights and Know How arising from and directly relating to the Clinical Study and the Protocol, but excluding (1) any clinical procedure and improvements thereto that are clinical procedures of the Site Investigator or of Study Site (2) any patient medical records and (3) copyrights on work published by the Site Investigator in accordance with clause 10 hereinafter, which copyrights shall either vest in the Study Site or, if made by the Site Investigator and other authors, in the Study Site and the other co-author(s) in accordance with applicable copyright laws or as mutually agreed between the Parties, or shall vest in the publisher of such work upon the transfer of copyrights by the author(s).
- 9.3. The Site Investigator will promptly inform the Sponsor of any invention or discovery arising from and directly relating to the Clinical Study, and Study Site hereby assigns rights in relation to all Intellectual Property Rights in relation to such invention or discovery, and will provide reasonable assistance to the Sponsor in filing or prosecuting Intellectual Property Rights, at the expense of the Sponsor.
- 9.4. Nothing in this clause 8 shall be construed so as to prevent or hinder the Site Parties from using the Know How generated during their conduct of the Clinical Study for their normal hospital, non-commercial research and education activities, to the extent such use does not result in the disclosure or misuse of Confidential Information or the infringement of any Intellectual Property Rights of the Sponsor.

10. PUBLICITY

- 10.1. The Sponsor will not use the logo or name of the Study Site, Site Investigator, nor of any member of the Research Staff, for promotional purposes, in any publicity, advertising or news release without the prior written approval on a case-by-case basis of the Study Site or Site Investigator, such approval not to be unreasonably withheld. The Study Site and Site Investigator will not, and will ensure that the Research Staff will not, use the name or logo of the Sponsor or of any of its employees for promotional purposes, in any publicity, advertising or news release without the prior written approval of the Sponsor on a case-by-case basis, such approval not to be unreasonably withheld.
- 10.2. The Site Parties will not issue and will ensure the Research Staff will not issue any information or statement to the press or public, including but not limited to advertisements for the enrolment of Clinical Study Subjects, without, where appropriate, the review and the issue of a favourable decision from the Ethics Committee and the prior written permission of the Sponsor.
- 10.3. In conformity with the obligation regarding “transparency” applicable to FISEVI by virtue of the Law 1/2014, 24 June on “Public Transparency in Andalucía”, the present contract will be published to allow citizens and the society in general to have access to

transparency of the activity, functioning and control measures of FISEVI. Being also the principles of personal data protection applicable, the publicity will proceed without indication of the personal data.

11. PUBLICATION AND AUTHORSHIP

Principles and multi-centre publication

- 11.1. The Sponsor, Study Site and the Site Investigator each acknowledge the importance of public disclosure/publication of information collected or generated as a result of or related to the Clinical Study, under the condition that public disclosure/publication takes place under the provisions of this clause 10.
- 11.2. Upon completion of the Clinical Study (whether prematurely or otherwise) the Site Investigator and Sponsor may co-operate in producing a report of the Clinical Study detailing the methodology, results and containing an analysis of the results and drawing appropriate conclusions.
- 11.3. As the Clinical Study is a multi-centre study, any publication based on the results obtained at the Study Site (or a group of sites) shall not be made before the first multi-centre publication or presentation, which shall be coordinated by Sponsor, unless otherwise agreed in writing, or as provided for in this clause 10. Notwithstanding the foregoing, if a multi-centre publication is not published within twelve (12) months after completion of the Clinical Study and lock of the Clinical Study database at all research sites that are part of the multi-centre Clinical Study or any earlier termination or abandonment of the Clinical Study, the Site Investigator and/or members of the Research Staff shall have the right to publish or present the methods and results of the Clinical Study in accordance with the provisions of this clause 10.

Publications by Site Investigator

- 11.4. Subject to clause 10.3 above, the Sponsor agrees that the Site Investigator and/or members of the Research Staff shall be permitted to present at symposia, national or regional professional meetings, and to publish in journals, theses or dissertations, or otherwise of its own choosing, methods and results of the Clinical Study, subject to the terms of this clause 10 and of any publication policy described in the Protocol, provided any such policy does not obstruct publication unreasonably.
- 11.5. Material for public dissemination will be submitted to the Sponsor for review at least thirty (30) days prior to submission for publication, public dissemination, or review by a publication committee. If Sponsor does not respond within this period, Site Parties are free to proceed with the intended publication or presentation without further delay.
- 11.6. The Site Investigator and/or Research Staff agree that all reasonable scientific comments made by the Sponsor in relation to a proposed publication or presentation shall be considered for incorporation into the publication or presentation.
- 11.7. During the period for review of a proposed publication referred to in clause 10.5 above, the Sponsor shall be entitled to
 - a. require the Site Investigator and/or Research Staff that publication be delayed for an additional period of sixty (60) days (following the thirty (30) day period referred

- to in clause 10.5 in order to enable the Sponsor to take steps to protect its proprietary information and/or Intellectual Property Rights and/or Know How ; and
- b. cause the Site Investigator and/or Research Staff to remove from the intended publication any Sponsor Confidential Information received by Site Investigator that does not constitute results of the Clinical Study.

Authorship and copyrights

- 11.8. Publications will be in accordance with international recognized scientific and ethical standards concerning publications and authorship, including the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, established by the International Committee of Medical Journal Editors. Copyrights concerning publications of the Clinical Study remain with the authors of the publication, regardless of any other provisions regarding intellectual property rights.

12. TERM AND TERMINATION

- 12.1. This Agreement commences on the Effective Date and shall continue in force until the earlier of:
 - a. completion of the Clinical Study, close-out of the Study Site and completion of the obligations of the Parties under this Agreement; or
 - b. early termination in accordance with clauses 11.2 or 11.3 of this Agreement;
- 11.2 Each Party may terminate this Agreement upon written notice to the other Parties with immediate effect in the following events only:
 - a. if the approval by the Ethics Committee is not granted or irrevocably revoked (if applicable);
 - b. if it can be reasonably assumed that the Clinical Study must be terminated in the interests of the health of the Clinical Study Subjects;
 - c. if it becomes apparent that continuation of the Clinical Study cannot serve a scientific purpose;
 - d. if the Sponsor and/or the Study Site become or are declared insolvent or a petition in bankruptcy has been filed against it or if one of them is dissolved;
 - e. if circumstances beyond a Party's control occur that render continuation of the Clinical Study unreasonable as outlined in clause 13;
 - f. if one of the Parties fails to comply with the obligations arising from the Agreement and, if capable of remedy, is not remedied within 30 days after receipt of written notice from the other Party specifying the non-compliance and requiring its remedy, unless the severity of the failure to comply does not reasonably justify the premature termination of the Clinical Study; or
 - g. if the Site Investigator is no longer able (for whatever reason) to act as investigator for this Clinical Study and no mutually acceptable replacement has been found in accordance with clause 2.3.
- 11.3 Without prejudice to Article 11.2 and in addition to the reasons for termination listed therein, Sponsor may terminate this Agreement in writing at any time for any reason upon a sixty (60) days written notice.

- 11.4 At close-out of the Study Site following termination or expiration of this Agreement the Site Investigator and the Study Site shall, upon first request, immediately return to the Sponsor or destroy with confirmation thereof all Confidential Information, Equipment and/or unused materials provided by Sponsor in accordance with Sponsor's instructions, except for copies to be retained in order to comply with Site Parties' archiving obligations or for evidential purposes.

13. FINANCIAL PROVISIONS

- 13.1. The Sponsor will provide reimbursement in support of the Study solely if and to the extent as set out in Annex 2.
Any payment shall occur within 45 days after receipt of an invoice from the Study Site, including, when applicable, the rate of VAT in effect on the date of the invoice.

14. FORCE MAJEURE

- 13.1 No Party shall be liable to the other Parties or shall be in default of its obligations hereunder if such default is the result of war, hostilities, terrorist activity, revolution, civil commotion, strike, and epidemic or pandemic or because of any other cause beyond the reasonable control of the Party affected. The Party affected by such circumstances shall promptly notify the other Parties in writing when such circumstances cause a delay or failure in performance and where they cease to do so.

15. MISCELLANEOUS

- 15.1. Site Parties shall have the right to assign, delegate, subcontract or transfer any of their rights, obligations or performance under this Agreement to an Affiliate only upon explicit prior written consent of Sponsor, which may be withheld or refused at Sponsor's discretion. Any approval by Sponsor of an assignment, transfer or encumbrance by Site Parties shall not release Site Parties of any of their obligations under this Agreement due up until such assignment. Subject to the foregoing, this Agreement shall bind and inure to the benefit of the respective Parties and their successors and assignees.
- 15.2. Site Parties may not sub-contract the performance of all or any of their obligations under this Agreement without the prior written consent of the Sponsor, such consent not to be unreasonably withheld or delayed. Any Party who so sub-contracts shall be responsible for the acts and omissions of its sub-contractors as though they were its own.
- 15.3. Nothing in this Agreement shall be construed as creating a joint venture, partnership or contract of employment between the Parties.
- 15.4. This Agreement, including any exhibits and schedules hereto, constitutes the entire agreement between the parties with respect to the subject matter hereof. This Agreement supersedes and cancels all previous agreements among the parties, written and oral in respect of the subject matter hereof.
- 15.5. Should there be any inconsistency between the Protocol and the terms of this Agreement, or any other document incorporated therein, the Protocol shall prevail in case such inconsistency concerns clinical matters and the Agreement shall prevail the inconsistency

concerns non-clinical matters. For the avoidance of doubt, Termination and Publication provisions of this Agreement shall always prevail above the Protocol.

- 15.6. The clauses 4 (Liabilities, Indemnification and Insurance); 6 (Quality Assurance and Control); 7.3-7.11 (Medical confidentiality, data protection and data controlling); 8 (Intellectual Property); 9 (Publicity); 10 (Publication and Authorship); 11 (Term and Termination); 12 (Financial Provisions); this clause 14.6 (Surviving Clauses); 14.7 (Governing Law); 15 (Human Samples) or other clauses contemplating performance after termination, shall survive termination or expiry of this Agreement. The provisions of clauses 7.1 and 7.2 (Confidential Information) shall remain in force for a period of five (5) years from the date of such termination or expiry.
- 15.7. This Agreement shall be exclusively governed by, and construed in all respects in accordance with the laws of The Netherlands without regard to any of its conflicts of laws rules. Any claims, controversies or disputes arising out of or in connection with this Agreement which cannot be settled amicably between the Parties, shall be subject to the exclusive jurisdiction of the competent court in The Netherlands.
- 15.8. Each person signing this Agreement represents and warrants that he or she is duly authorized and has legal capacity to execute and deliver this Agreement. Each Party represents and warrants to the other that the execution and delivery of the Agreement and the performance of such party's obligations hereunder have been duly authorized and that the Agreement is a valid and legal agreement binding on such party and enforceable in accordance with its terms.

16. HUMAN SAMPLES

- 15.1 As part of the Protocol, Samples derived from Clinical Study Subjects may be transferred to Sponsor or another organization indicated by Sponsor (hereinafter: "**Sponsor's Designee**"), however only if this is arranged for in the ICF.
- 15.2 Sponsor, and if applicable Sponsor's Designee, shall have the right to store, transfer and use the Samples only in accordance with the applicable Law (at least laws and regulations concerning the protection of privacy), the Protocol and ICF. Site Parties shall promptly notify Sponsor of any withdrawal of or changes in the informed consent of a Clinical Study Subject, which may affect the use of such Clinical Study Subject's Samples under this Agreement. In such event, Sponsor or Sponsor's Designee shall destroy, with written confirmation thereof, or return the affected Samples, where necessary and possible.
- 15.3 Upon termination or expiration of the Clinical Study, and at least at any time the Samples are no longer needed to be retained by Sponsor, or Sponsor's Designee, for purposes defined in the ICF, or as required per any applicable Law or regulation, the remainder of the Samples in Sponsor's or Sponsor's Designee's possession will be returned to the Site Parties, or retained by the Sponsor in accordance with clause 15.2 or destroyed by the Sponsor/Sponsor's Designee, as described in the Protocol and/or the ICF, with written confirmation thereof.

Annexes

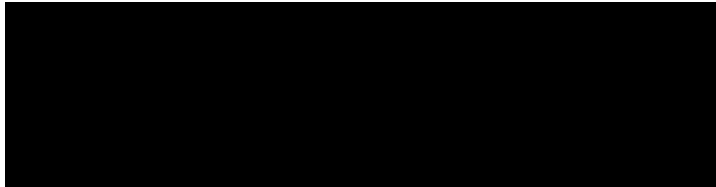
Annex 1: Protocol

Annex 2: Financial Provisions

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Signed on behalf of the **Sponsor**

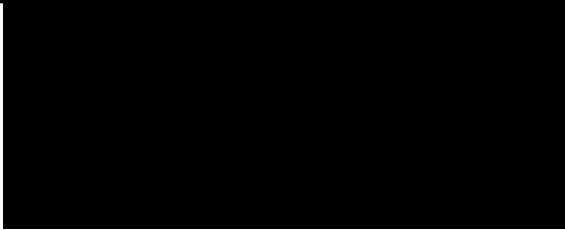


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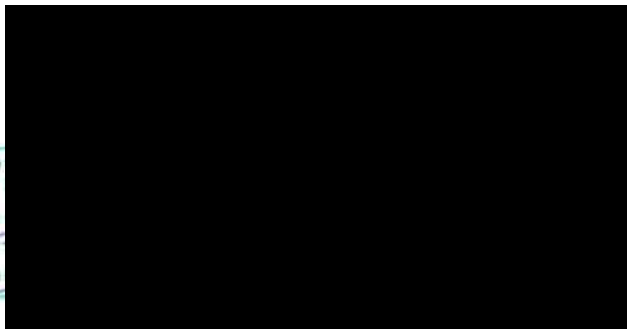
Name:

Title:

Date:



Signed on behalf of the **Study Site**



Signature:

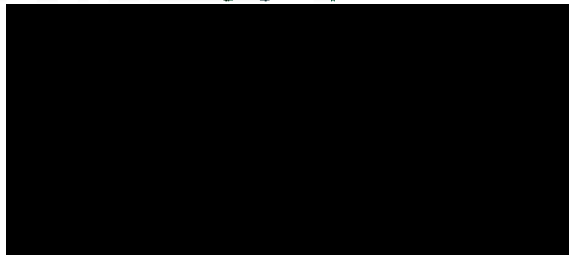
Name:

Title:

Date:



Signed on behalf of the **Managing Body**



Signature:

Name: José

Title: Manag

Date:

