

TEMPLATE OF NKTi CLINICAL TRIAL AGREEMENT

CLINICAL TRIAL AGREEMENT

THIS AGREEMENT is made by and between

<Name of Contracting Company>. <(Acronym)>, a corporation duly organized and existing under the laws of the Philippines, with address at **<Complete Business Address>**, (hereinafter referred to as SPONSOR);

- And -

NATIONAL KIDNEY AND TRANSPLANT INSTITUTE (NKTi), a Philippine tertiary hospital, holding office at East Avenue, Diliman, Quezon City, Philippines 1101 (hereinafter referred to as INSTITUTION);

- And -

<Name>, **<Department, and Complete Business Address of the Physician>** (hereinafter referred to as INVESTIGATOR)

regarding

<Protocol No: _____> (hereinafter Protocol)
<Title of the Research Study> (hereinafter Study)

WHEREAS, SPONSOR and **<Name of Clinical Research Organization>. <(Acronym)>** (hereinafter CRO if any) or an affiliate have agreed (under a separate written agreement) that CRO will act on behalf of SPONSOR as its authorized representative and agent; in all cases in this Agreement in which reference is made to CRO (whether in the context of an act to be taken by CRO, or the delivery of documents to CRO, or the delivery by CRO of amounts that are payable under Section 10, and all similar references), CRO is acting solely on behalf of and as agent for SPONSOR, and that CRO is not a party to this Agreement.

WHEREAS, Investigator is an active medical staff of this Institution;

WHEREAS, Institution and Investigator each desire to collaborate in the Study as described in this Agreement; and

WHEREAS, this Agreement explains the joint and several obligations of Institution and Investigator, and the obligations of SPONSOR.

1. CONDUCT OF THE STUDY

1.1 Institution agrees to allow Investigator and other Institution staff and agents ("Study Personnel") to conduct the Study. The Institution warrants that the Investigator is a member of the Medical Staff of the Institution. Investigator shall take all reasonable steps to inform all Study Personnel of all of their obligations under this Agreement and Investigator shall ensure that Study Personnel fully comply with same.

1.2 Investigator shall directly supervise the conduct of the Study by the Study Personnel at the Institution, to the full extent contemplated by the Protocol and by applicable law. Investigator hereby agree to (and warrant that Study Personnel will) conduct the Study

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in a diligent, efficient, and skilful manner, in strict compliance with the terms and conditions of this Agreement, the Protocol including any subsequent amendments thereto, any specific Study instructions from SPONSOR or CRO, applicable law, rules, regulations and guidelines of relevant health authorities, all policies of the Institution, and any other professional standards applicable to their professional industries and fields including, but not limited to applicable version(s) of the World Medical Association Declaration of Helsinki. The Investigator or any Study Personnel shall not commit any negligent acts or any willful misconduct in connection with the performance of the Study.

- 1.3 The parties will fulfill their respective obligations to the applicable Institutional Review Board (IRB) or Ethics Committee (EC) at the Institution.

SPONSOR or CRO shall obtain the written approval of the Institute's IRB/EC prior to commencement of the Study and will furnish Investigator with the IRB/EC's letter of approval.

If required by applicable law, SPONSOR or CRO shall make the necessary submissions or notifications to the regulatory authorities. The Study may not commence until the Investigator has been informed by CRO that such authorization has been granted.

- 1.4 Investigator shall, prior to a subject's participation in the Study, obtain the subject's written informed consent to participate in the Study. Investigator shall not make any written or oral promises, statements or other representations to Study subjects (whether or not formally documented in the informed consent forms) that SPONSOR or CRO will provide any form of compensation, reimbursement or payment, medical treatment and/or any other support or thing of value, except to the extent expressly provided within this Agreement or the Protocol. Investigator shall comply with applicable laws when obtaining Study subjects' consent to participate in the Study. Investigator shall be solely responsible for ensuring that such consents and authorizations are duly obtained. Investigator shall be responsible for any claim, loss, damages, suit, proceeding, cost or expense arising out of any failure to obtain any such consent or authorization.
- 1.5 Investigator shall enroll the number of duly qualified (according to the Protocol) patients for the Study and agrees that SPONSOR or CRO may unilaterally revise the number of subjects that Investigator shall enroll, and/or the timeframe for such enrollment, via Study instructions at any time.
- 1.6 In accordance with the Protocol and all applicable laws and regulations, Investigator shall maintain all necessary subject records of safety data and/or documents whether electronic, paper, or in any other form relating to the Study off site for five (5) years or as mandated by the study protocol, after the end or the premature termination of the Study. Investigator shall follow Protocol instructions for the reporting of any serious adverse event.
- 1.7 Investigator agrees that they are not presently under any agreement or obligation which conflicts with the duties and obligations owed to SPONSOR or CRO under this Agreement, and further agree not to undertake any such obligation or agreement during the course of the Study.
- 1.8 Investigator represents and warrants that neither they, nor any Study Personnel are officials, agents, or representatives of any government or political party or international organization where they may be in positions of authority to be able to improperly help CRO or SPONSOR obtain a business advantage. Investigator further

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represents and warrants that neither they nor any Study Personnel shall make any payment, either directly or indirectly, of any money or other consideration ("Payment"), to government or political party officials, officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing ("Officials") where such Payment would constitute violation of any law, including the U.S. Foreign Corrupt Practices Act. In no event shall any Study Personnel make any Payment either directly or indirectly to Officials if such Payment is for the purpose of influencing decisions or actions with respect to the subject matter of this Agreement or any other aspect of CRO's or SPONSOR's business. Institution shall report any violation of this warranty promptly to CRO and agree to respond to any CRO inquiries about any potential violations and make appropriate records available to CRO or SPONSOR upon request.

- 1.9 The Protocol, including any amendments thereto, constitute an integral part of this Agreement by reference. In case of any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence on matters of medicine, science and conduct of the Study; otherwise the terms of this Agreement shall prevail.
2. REPORTS, MONITORING, INSPECTIONS AND AUDIT
 - 2.1 Investigator shall, in a timely manner, submit to CRO complete and accurate written and electronic records, reports and data resulting from the performance of and/or relating to the Study (including, but not limited to applicable case report forms, other source documents and other essential documents).
 - 2.2 Investigator agrees to permit access and shall fully cooperate with representatives of SPONSOR, CRO, or their designee(s), at mutually convenient times according to a schedule set forth in Study instructions for monitoring visits, consultations and to allow direct inspection of all Study related records, and for any other purposes relating to the Study as deemed necessary by SPONSOR or CRO.
 - 2.3 Investigator shall fully cooperate with audits or inspections performed during or after completion of the Study, by SPONSOR or CRO. The Physician shall notify SPONSOR and CRO immediately of any inquiries, correspondence or communication from or to the governmental or regulatory authority in connection with the Study and will provide SPONSOR and CRO with copies of all communications and documents related thereto, simultaneously upon sending or receipt.
 - 2.4 Investigator shall fully cooperate with audits or inspections performed by SPONSOR or CRO during or after completion of the Study. Investigator shall allow SPONSOR, CRO and governmental or regulatory authorities access to resources used to perform tasks related to the Study, shall make all requested documents available to them and shall provide them with any further Information as may be requested.
 - 2.5 In the event the audit or regulatory inspection identifies a lack of compliance with this Agreement on the part of Investigator or any Study Personnel, SPONSOR or CRO may terminate this Agreement in accordance with Section 11.1.
 - 2.6 Investigator shall immediately notify CRO and Institution by telephone, email or fax if a governmental or regulatory authority, requests to carry out an inspection of Institution's facilities, or does so. Institution shall allow SPONSOR and CRO to be present during such inspection, and shall provide to SPONSOR and CRO copies of all materials, correspondence, statements, forms and records that Institution receives, obtains or generates pursuant to or in connection with any such inspection.

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3. CONFIDENTIAL INFORMATION

- 3.1 Investigator agrees, during the term of this Agreement and for a period of ten (10) years thereafter, to hold in strict confidence any confidential or proprietary information of SPONSOR which is provided to Institution and Investigator pursuant to this Agreement, or to any information Institution and Investigator may generate or derive in the course of performing the Study ("Confidential Information"), to use such Confidential Information only for the purpose of the Study, and not to transfer or disclose Confidential Information to any third party other than Study Personnel involved in the performance of the Study with "need to know" who also agree to be bound by the terms hereof.
- 3.2 Institution may disclose Confidential Information only to (a) Investigator and Study Personnel, or other employees or staff who require access thereto for the purposes of this Agreement provided, however, that prior to making any such disclosures Institution binds such Investigator and Study Personnel, employees or staff in writing to the same obligations as are contained herein to maintain Confidential Information in confidence and not to use such Confidential Information for any purpose other than in accordance with the terms of this Agreement, and (b) to the appropriate EC or IRB having jurisdiction over the performance of the Study at Institution.
- 3.3 Nothing contained herein will in any way restrict or impair any party's right to use, disclose, or otherwise deal with any Confidential Information which at the time of its receipt:
 - 3.3.1 Is generally available in the public domain or becomes available to the public through no act of the party receiving said Confidential Information; or
 - 3.3.2 Is independently known by the party receiving the Confidential Information, prior to receipt thereof, which said party can demonstrate by documented proof; or
 - 3.3.3 Is lawfully given to the receiving party by a third party who is not bound by any obligation to preserve it as confidential.
- 3.4 Investigator acknowledges that SPONSOR or its affiliated company, which may be located in another jurisdiction such as the United States or European Union, may be required to report to governmental agencies or disclose to the public the amount of the compensation hereof, including fees and/or other items of value provided, the nature of the Study hereof and other facts relating to this Agreement pursuant to applicable laws, regulations or codes, and Investigator hereby consents to such report or disclosure by SPONSOR or its affiliated company.

4. PUBLICITY

- 4.1 No party to this Agreement shall use the name of any other party hereto, or CRO's name, in connection with any advertising or promotion of any product or service without the prior written consent of such party or CRO, as appropriate. Each party agrees that it will not disclose the terms of this Agreement to any third party (except for the CRO) without the written permission of the other parties, except as required by applicable law.

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5. PUBLICATION

- 5.1 Investigator may publish the Study results only in accordance with this Section 5. Before submission for publication or presentation, Investigator shall allow SPONSOR not less than forty-five (45) days to review any manuscript and not less than thirty (30) days to review any poster presentation, abstract or any other written or oral material which describes or discloses the Study results. If SPONSOR so requests in writing, Investigator shall withhold any publication or presentation for an additional sixty (60) days to allow for the filing of a patent protection or the taking of any other measure to preserve SPONSOR's proprietary rights. If Investigator publishes the results of the Study, SPONSOR is hereby granted a perpetual, royalty-free license to make and distribute copies of such publications under any copyright rights or privileges of Investigator or the Institution.
- 5.2 SPONSOR reserves the right to remove all Confidential Information from any publications or presentations. In the event that SPONSOR deems that such removal would not sufficiently protect its intellectual property rights, then SPONSOR may require that Investigator does not publish such publication or presentation, and Investigator and Institution agree not to publish any such publication or presentation in any such case.
- 5.3 Investigator agrees that because the Study is part of a multi-center Study, any publication by the Investigator of the Study Results shall not be made before the first multi-center publication of participating sites.

6. INTELLECTUAL PROPERTY

- 6.1 Investigator agrees to promptly disclose, in writing, to SPONSOR any Inventions (as defined herein). Institution and Investigator agree that SPONSOR shall own all rights in and to any inventions, discoveries, improvements related to or derived from, either directly or indirectly, the Study which are conceived of or reduced to practice or developed by Investigator or Study Personnel as a result of the performance of the Study, whether patentable or not ("Inventions"). Investigator will cooperate with SPONSOR, including assisting SPONSOR in the execution of all necessary documents, at SPONSOR's expense, in obtaining proper patent protection in such Inventions in any country which SPONSOR desires to obtain patent protection.
- 6.2 All parties to this Agreement and CRO shall retain all right, title and interest in any pre-existing intellectual property that was owned or controlled by such party or CRO prior to or apart from the commencement of this Agreement.
- 6.3 Nothing in this Agreement shall be construed as granting Institution or Investigator any assignment or license under any patent, trademark, trade secret, or copyright of SPONSOR or CRO.

7. DATA USE, PROTECTION & PRIVACY

- 7.1 Investigator hereby represents and warrants that they consent, and they shall obtain all necessary consents in writing from (a) all subjects as per the informed consent form, and (b) the key members of Study Personnel participating in the Study for administrative / study management and any other purpose required by law, so that the Investigator, and such subjects and Study Personnel's personal data can be processed by (including transferred to) CRO, any of its affiliates, and SPONSOR or

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any of its affiliates and regulatory authorities in each case within or outside the country where such data originates.

- 7.2 Institution and Investigator agree that all data generated in the performance of the Study ("Study Data") are hereby the exclusive property of SPONSOR and hereby assigns any and all of its rights, title and interest, including intellectual property rights, in and to same. Study Data may be used by SPONSOR for any purpose without further obligation or liability to Institution or Investigator; provided, however, that such use is consistent with the applicable informed consent document and applicable laws. Study Data shall be transmitted to SPONSOR by magnetic media or other mutually agreed upon method. Subject medical records shall remain the property of the Institution; provided, however, any Study Data recorded therein shall be used and disclosed only as expressly permitted by this Agreement. Investigator shall, where duly authorized or required by applicable law, provide or make such subject's medical records and individual subject data available to SPONSOR (at mutually agreeable times, during normal business hours) and relevant governmental agencies.
- 7.3 Investigator shall use and disclose Study Data solely for the following purposes (i) to the extent required to conduct the Study; or (ii) in order to publish the Study results in accordance with Section 5. Investigator shall not use or disclose Study Data for any other purpose without SPONSOR's prior written consent. Any public disclosure (including publications) that contains or otherwise arises from the use of Study Data shall be subject to the terms of Section 5.

8. INDEMNIFICATION AND INSURANCE

- 8.1 SPONSOR shall indemnify, defend and hold harmless Investigator, Study Personnel and Institution, its medical affiliates, and its and their directors, trustees, officers (collectively, the "**Indemnitees**"), from and against any costs, losses, damages, including reasonable attorneys' fees, resulting from claims, legal proceedings or causes of actions by any third party(ies) (collectively, "**Claims**"), to the extent such Claims arise directly from SPONSOR's use of the Study Data and results or due to any breach by SPONSOR of any laws.
- 8.2 SPONSOR's obligations in Section 8.1 above will not apply, and SPONSOR will not be liable for any Claim, to the extent it is attributable to:
- 8.2.1 The failure of any Indemnitee to adhere to the terms of the Protocol or this Agreement, or to comply with applicable law; and/or
 - 8.2.2 Any negligent or wrongful act or omission, or willful malfeasance, of any Indemnitee.
- 8.3 Furthermore, Sponsor shall have no obligation to indemnify pursuant to the foregoing unless (i) Indemnitees promptly notify SPONSOR in writing of any Claims; (ii) Indemnitees cooperate fully in the handling thereof; and (iii) SPONSOR has sole control of the disposition of such Claim including choice of counsel, any investigation, trial, defense or settlement provided that no settlement shall include an admission of liability on the part of the Indemnitees without the Indemnitee's prior written consent where such consent shall not be unreasonably withheld.

9. DEBARMENT

- 9.1 Investigator or other staff members performing the Study have such current licenses and permits as may be required to perform clinical studies and that none of them is now

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nor in the past ever been debarred or excluded from any national healthcare programs nor are any of them currently under investigation by the U.S. Food and Drug Administration ("FDA") for debarment action or license debarred pursuant to the U.S. Generic Drug Enforcement Act of 1992 (21 U.S.C. 301 et seq) or other national equivalent, and the Institution shall notify SPONSOR and CRO immediately in accordance with the Notice Section herein upon any inquiry concerning or the commencement of any such proceeding concerning any person performing the Study.

10. PAYMENT TERMS AND CONDITIONS

- 10.1 In full consideration for the Services of Institution, Investigator and Study Personnel rendered in compliance with the Protocol, SPONSOR through CRO agrees to pay the fees and expenses set forth. Such fees and expenses will be paid solely to the Institution, except as otherwise expressly set forth for the Investigator. The parties agree that Payment Schedule is part of this Agreement clarifying the schedule of payments associated with this Agreement. Payments shall be made in accordance with the provisions set forth, with the last payment being made after Investigator complete all of their obligations under this Agreement and any Exhibits thereto.
- 10.2 Investigator shall comply with all obligations with respect to taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement including, without limitation, those that relate to any payments made hereunder to Institution, Investigator, Study Personnel or, as the case may be those that relate to any payments made by Institution or Investigator to Study Personnel.
- 10.3 The fees and expenses paid by SPONSOR shall be used solely to offset the costs to the Institution of conducting the Study and in no event shall such fees and expenses exceed the aggregate cost incurred by the Institution in conducting the Study. As such, Investigator shall provide SPONSOR or CRO a reconciliation of funding paid by SPONSOR upon completion of the Study. If the Investigator does not use all of the fees and expenses provided for the Study, the Investigator shall return all unused funds within thirty days of completion of the Study.
- 10.4 Investigator acknowledges and agrees that CRO is the payment agent for SPONSOR under this Agreement and that CRO shall neither have any payment obligations, nor be liable hereunder, in the event adequate funds are not made available by SPONSOR for payment hereunder.

11. TERMINATION

- 11.1 This Agreement will become effective upon the date it is fully executed by all parties and shall continue in effect for the full duration of the Study according to the Protocol unless sooner terminated in accordance with the provisions of this Section 11. SPONSOR (whether directly or acting through CRO) may terminate this Agreement immediately upon written notice to Institution and Investigator for any reasons, in which case, SPONSOR will pay fees earned for services performed through the termination date.
- 11.2 This Agreement may be terminated by Institution or Investigator, upon sixty (60) days' prior written notice, for a material breach of this Agreement by SPONSOR if the breach is not cured within thirty (30) days following receipt of such notification.
- 11.3 Termination of this Agreement by any party shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Agreement. Any provision of this Agreement that should survive expiration or termination of this

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Agreement in order to give proper effect to its intent, shall survive expiration or termination of this Agreement.

12. CONTRACTUAL

- 12.1 This Agreement constitutes the entire agreement and final understanding of the parties with respect to the subject matter hereof and supersedes and terminates all prior and/or contemporaneous understandings and/or discussions between the parties, whether written or verbal, express or implied, relating in any way to the subject matter hereof. This Agreement may not be altered, amended, modified or otherwise changed in any way except by a written agreement, signed by all parties.
- 12.2 Institution and Investigator understand and agree that this Agreement is being signed by CRO exclusively on behalf of and as an agent of SPONSOR and for SPONSOR's benefit and that CRO is not a party to this Agreement. Upon request, CRO on behalf of SPONSOR can provide a delegation of authority and/or power of attorney letter.
- 12.3 Failure to insist upon compliance with any of the terms and conditions of this Agreement shall not constitute a general waiver or relinquishment of any such terms or conditions, and the same shall remain at all times in full force and effect.
- 12.4 Investigator shall act as an independent contractor[s] of SPONSOR and shall not be construed for any purpose as the partner, agent, employee, servant, or representative of SPONSOR. SPONSOR shall not be responsible for any employee benefits, pensions, employer liability insurance, withholding, or employment-related taxes of the Physician. Investigator shall not enter into any contract or agreement with a third party that purports to obligate or bind SPONSOR. Investigator acknowledges that SPONSOR may perform its obligations hereunder either itself or through a third party.
- 12.5 The respective signatories of the parties to this Agreement represent and warrant that they have the authority and ability to enter into the terms, provisions and conditions of this Agreement on behalf of their respective parties.
- 12.6 All notices necessary or appropriate to be given pursuant to this Agreement shall be effective when delivered personally, facsimile, e-mail, or mailed by certified or registered mail, postage prepaid to the appropriate party or CRO in writing at the address or number below:

To SPONSOR: *<Name of the Sponsor>*
<Complete Business Address>

To CRO: *<Name of the Clinical Research Organization>*
<Complete Business Address>

To Investigator: *<Name of the Investigator>*
<Complete Business Address>

**To Institution: NATIONAL KIDNEY AND TRANSPLANT INSTITUTE
(NKTI), East Avenue, Diliman, Quezon City, Philippines
1101**

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- 12.7 The parties agree that this Agreement shall be governed by the laws of Philippines, without regard to the conflicts of law provisions thereof. In case a dispute is brought before a court of law, the courts of Quezon City will have sole jurisdiction over the litigation.
- 12.8 Investigator may not assign its rights or delegate its obligations under this Agreement without the prior written consent of SPONSOR, which shall not be unreasonable withheld. Any unauthorized attempted assignment by Investigator shall be null and void and of no force or effect. CRO shall have the power to assign this Agreement to SPONSOR without Institution or Investigator's consent.
- 12.9 If any term or condition of this Agreement, the deletion of which would not adversely affect the receipt of any material benefit by any party hereunder, shall be held illegal, invalid or unenforceable, the remaining terms and conditions of this Agreement shall not be affected thereby and such terms and conditions shall be valid and enforceable to the fullest extent permitted by law.

IN WITNESS WHEREOF, the parties hereto have set their hands in duplicate with the intention that this is a binding agreement as provided herein.

(1) <Name of Sponsor>
Represented by its authorized agent,
<Name of Clinical Research Organization>

Signature of Authorized Official

Typed or printed Name

Date

(2) National Kidney and Transplant Institute

Signature of Authorized Official

Typed or printed Name

Date

(3) <Name of Investigator>

Signature of Investigator

Typed or printed Name

Date

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DEFINITIONS:

“Affiliate” means in relation to either party to this Agreement, any company, partnership or other entity which directly or indirectly controls, is controlled by, or is under common control with such party. For purposes of this definition, “control” means the beneficial ownership of more than fifty (50) per cent of the issued voting shares or the legal power to direct or cause the direction of the general management of the company, partnership or other entity in question, and “controlled” shall be construed accordingly.

“Applicable Law” means any international, national, federal, state, provincial, commonwealth, or local government law, statute, rule, requirement, code, regulation, or ordinance that applies to any party or to a Study, the Services, or this Agreement, as well as the current good clinical practices guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Topic E6: Guidelines on Good Clinical Practice, and applicable version(s) of the World Medical Association Declaration of Helsinki, and, where applicable, rules governing good manufacturing practice and good laboratory practice, and rules governing the collection and processing of Personal Data and the collection and storage of human tissue samples and the performance of DNA testing.

“Completed Subject” means any Subject who has completed the prescribed course of treatment for a subject in the Study in accordance with the Protocol.

“Confidential Information” refers to any and all Information belonging to SPONSOR, CRO and/or their respective Affiliates including, but not limited to, Information that SPONSOR, CRO and/or their respective Affiliates consider to be trade secrets and / or the release of which could prejudice legal, commercial or other interests of SPONSOR, CRO and/or their respective Affiliates and which are (i) provided, disclosed or submitted to Institution or Investigator or (ii) which are otherwise obtained by Institution and Investigator.

“Data Security Breach” means: (a) the loss or misuse (by any means) of Personal Data; (b) the inadvertent, unauthorized, and/or unlawful Processing, disclosure, access, alteration, corruption, transfer, or sale or rental, destruction, or use of Personal Data; or (c) any other act or omission that compromises the security, confidentiality, or integrity of Personal Data.

“eCRFs/CRFs” (Electronic Case Report Forms or Case Report Forms) are paper or electronic questionnaires specifically used by Institution and Investigator pursuant to the Protocol for Subject data reporting. “Fully Cooperate” means to assist in completing a specified end or purpose.

“Information” refers to any and all oral, written (including all other tangible forms) and other information, material and assets of any nature, whether or not protected by Intellectual Property Rights or any applications for such rights, such as, but not limited to, data, data information, data and Reports on the Study and the Study Drug, (e)CRFs (whether completed or not), final Reports, all other clinical data, manufacturing data, the Protocol, the Investigator Brochure, laboratory records, information contained in submissions to regulatory authorities, unpublished data and Reports, any and all other Study documentation, technical information, findings, samples, interim results and results, Intellectual Property Rights and any other information and assets potentially subject to any kind of intellectual property rights, whether protectable or not, and any

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existing or future rights therein; Subjects' medical files and documents facilitating identification of the Study Subjects.

"Intellectual Property Rights" refers to existing and / or future patents, patent applications, trademarks, trade names, service marks, domain names, copyrights, moral rights, rights in and to databases (including rights to prevent the extraction or reutilization/reutilization of Information from a database), design rights, topography rights, know-how, trade secrets 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; furthermore rights of use, rights of exploitation, rights of utilization and licenses, whether royalty-free or otherwise.

"Investigational Product" refers to SPONSOR's investigational product(s) including the Study Drug and / or investigational device and to placebo, comparator drug / device or any other control material as defined in the Protocol.

"Investigator" is the individual named in item (3) in the introduction to this Agreement, and is the person responsible for the conduct of the Study at Institution. If a Study is conducted by a team of individuals at an Institution, Investigator is the responsible leader of the team and may be called the principal investigator.

"Liability Insurance" is insurance that provides coverage against liabilities for claims made by an entity or individual as a result of fault, negligence, malpractice or any other inappropriate action committed by Institution, Investigator and/or Study Personnel in their provision of professional services for the Study.

"Personal Data" means any information relating to an identified or identifiable natural person; an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.

"Process" means any operation or set of operations which is performed upon Personal Data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

"Reports" means any reports that are required by the applicable regulatory committee to close out the Study. "Resources" refers to any facilities and equipment that are utilized for the conduct of the Study.

"Services" means the services to be provided by the Institution, the Investigator and/or the Study Personnel under the terms of this Agreement.

"Study" means the scientific research as defined in the Protocol.

"Study Instructions" means any written document, other than the Protocol, issued by SPONSOR or CRO that specifically relates to and references the Study and which provides additional information and/or instructions on how the Institution and Investigator shall conduct the Study. Study Instructions may be transmitted from SPONSOR or CRO to Institution and/or Investigator by personal delivery, fax, e-mail, registered post, certified post or courier.

"Study Personnel" means any employees of Institution or Investigator, and/or contractors engaged by Institution or Investigator, who are involved in performing the Study, including Sub-

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Investigator(s), Study coordinator(s), and any other contractors, agents and employees of Institution or Investigator who assist Institution and Investigator with the Study.

“Study Results” refers to any and all Information and any other material and results directly or indirectly arising from or in connection with the Study, regardless of whether the Study was aimed at yielding the relevant Study Results or whether they are ancillary in connection with the Study.

“Sub-Investigator” is any individual member of the Study team designated and supervised by the Investigator at Institution to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).

“Subject” is a person participating in the Study and identified in the signed informed consent form.