**Attachment for Consortium Agreement for Clinical Trial Agreements with Trial Site**

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| This model Clinical Trial Agreement is provided as draft without assuming any warranty or responsibility. The use of the text in total or in part takes place on the users own risk and does not release users from legal examination to cover their interests and protect their rights. |

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| [Change Records]  |  |  |  | | --- | --- | --- | | Version | Date | Changes | | Version 1 | August 2020 |  | |  |  |  | |  |  |  |  REMARKS This model for clinical trial agreements with trial sites is created as attachment to the DESCA model Consortium Agreement for projects which will be governed by a [“Multi-beneficiary General Grant Agreement”](http://ec.europa.eu/research/participants/data/ref/h2020/mga/gga/h2020-mga-gga-multi_en.pdf) (MGA) under Horizon 2020, i.e. notably “Research and Innovation Actions” and “Innovation Actions”. A use for other types of projects will likely require adaptations.  This trial agreement is meant for projects where one beneficiary acts as sponsor of a clinical trial and another beneficiary participates in this clinical trial as study site. A different clinical trial agreement should be used when the trial site is not participating as beneficiary in the Horizon 2020 project, but is included as Third Party.  The core text contains different options in some clauses, especially for the inclusion of a CRO. Any optional parts of the text are marked grey.  This template was created in cooperation with the staff unit Strategic Research Funding & International Cooperation (Christiane Hennecke, M.A.) and the legal department (Dr. Christoph Gerst) at the Universitätsmedizin Göttingen (UMG), the EU liaison offices and legal departments at the Charité - Universitätsmedizin Berlin and Medizinische Hochschule Hannover in cooperation with the Legal Experts Group of the National Working Group (Bundesarbeitskreis) of EU Funding Advisors at German Universities and Colleges. |

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| **Clinical Trial Agreement – Trial Site** |
| (**“Agreement”)** |
| By and Between  **[insert beneficiary who acts as sponsor of the study]**, established in [**insert place of establishment**], represented for the purposes of signing this Agreement by [**insert responsible person**], hereinafter referred to as “**Sponsor**” [**Option in case Sponsor is not EU member:** or “**EU representative**” ]  and |
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| [**insert beneficiary who participates as clinical trial site**]  hereinafter referred to as “**Institution**” or “**Trial Site**”,  Responsible Department at the Trial Site :  [**insert responsible department at clinical trial site**] |
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| Responsible Investigator at the Trial Site:  [insert name of principal investigator]  hereinafter referred to as “**Investigator**” |
| singly referred to as “**Party**” and jointly referred to as “**Parties**”.  **OPTION: Only to be added for 2-party-contract while PI will not become separate contractual party**.  The Trial Site appoints its employee, [**insert name of principal investigator**] as principal investigator (“**Investigator”**). The Investigator does not become a Party to this agreement. Wherever, in this agreement, reference is made to obligations which are incumbent on the Investigator such obligations are intended to be obligations on the Institution who shall fulfil such obligations by imposing the same on the Investigator. |
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| **WHEREAS**, **[insert beneficiary who acts as sponsor of the study]** is Sponsor according to the EC Grant Agreement number [**insert GA number**], awarded for the action entitled “[**insert title and acronym**]”. The objective of this action is to [**insert purpose of study and duration as indicated in Annex I to the GA**]. |
| **WHEREAS**, the Investigator is an employee of the Institution and wishes to participate as a clinical investigator in the conduct of a trial at the Institution to form part of the study (**“Trial”**). |
| **OPTION for inclusion of CRO:**  **WHEREAS**, Sponsor has transferred, in compliance with the provisions of the Grant Agreement, some of its duties to [**insert CRO**], as specified in separate Services Agreements.  **WHEREAS**, this Agreement is governed by the provisions of the Grant Agreement (and its annexes) (“**Grant Agreement”**) and the related Consortium Agreement. |
| **IT IS THEREFORE AGREED AS FOLLOWS:** |
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| **1. Subject matter of this Agreement** |
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| Sponsor entrusts the Institution to conduct the Trial in accordance with the provisions as stipulated in the study protocol governing the Trial (as may be amended from time to time and confirmed in writing by Sponsor)(**“Protocol”**).The provisions as stipulated in the Protocol, the respective schedules and the information documents, including the informed consent of subjects participating in the Trial (“**Subject(s)”**), shall be binding on the Parties and thus constitute an integral part of this Agreement. This shall apply accordingly to any amendments of the Protocol and the resulting new versions of the Protocol. In the event of discrepancies between the Protocol compared to this Agreement, the contractual directions of the Agreement prevail, unless it is either expressly specified otherwise in this Agreement or it is a medical issue. |

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| **2. Obligations of the Sponsor** |
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| In its conduct of this Trial Sponsor shall assume the following tasks as the sponsor of the Trial: |
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| (a) preparing the Subject template information documents and informed consent forms for all participating Subjects; the Institution shall use exclusively the templates provided free of charge by the Sponsor for any necessary information of the patients and the corresponding consent. The responsibility for the content of these templates and their lawfulness lies with the Sponsor. |
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| (b) **OPTION for clinical trials with medicinal products:** obtaining a EUDRACT number; |
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| (c) obtaining the approval of the competent authorities (e.g. ethics committee, competent health authorities) to perform the Trial (**“Competent Authorities”**), as well as notifying other authorities, if applicable; |
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| (d) provision of the required Products [**please define according to type of Trial**] at no charge for the Institution (see Section. 5);  (e) quality management of the Trial, e.g. monitoring and auditing of the Institution;  (f) insofar it is required by law, provide a trial subject insurance. |
| **OPTION for inclusion of CRO:** Those tasks (a) to (d) have been transferred to [insert CRO], as specified in separate Services Agreements, in compliance with the provisions of the Grant Agreement, the Protocol, ICH-GCP Guidelines and applicable laws. |
| **3. Obligations of Institution/Investigator (3-party-contract)** |
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| The Institution**/Investigator (3-party-contract)** |
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| (a) assigns the Investigator as principal investigator of the Trial; **(2-party-contract)** |
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| (b) complies in connection with the performance of the Trial with all applicable legal and regulatory provisions in particular, without being limited to it, the applicable drug law provisions, and the Good Clinical Practice Standards (GCP) in the current version as well as the Declaration of Helsinki (in the version Fortaleza 2013) and all legal requirements relating to the processing of personal data including all national laws implementing the General Data Protection Regulation (EU) 2016/679 (GDPR) of the European Parliament and of the Council of 27 April 2016; |
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| (c) acknowledges that Sponsor and its affiliates need to adhere to the provisions of any applicable anti-corruption legislation (together the **“Applicable Anti-Corruption Legislation”**). The Institution shall not and shall not permit or induce employees, agents, consultants or other representatives to, whether directly or indirectly, engage in any activity that is prohibited by the Applicable Anti-Corruption Legislation including bribery, kickbacks, payoffs or other corrupt business practices. |
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| (d) complies with all applicable SOPs (meaning its own SOPs as long as Sponsor has not ordered otherwise),  guidelines and standards and further instructions of Sponsor and to inform Sponsor in writing about any deviations there from without undue delay; |
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| (e) only commences and continues and not permit the Investigator to commence and continue with the Trial only after approval by Sponsor, which depends on (i) all necessary notifications have been made and (ii) all necessary documentation and information have been delivered to Institution by Sponsor free of charge and (iii) he has obtained the Competent Authority’s approval, Ethics Committee’s positive vote, and any other necessary approval by any other applicable authority; |
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| (f) carefully prepares and maintains, apart from medical files, patient files in which all Trial relevant data are recorded and stores all such recordings as well as all data and documents collected and prepared in the course of the Trial in accordance with the applicable legal requirements, and in any event, at least for a period of [**define period**] after the termination of the Trial. Patient files will be deleted or destroyed at the end of retention period **optional:** unless Sponsor has notified Institution up front of a prolongation and Institution receives remuneration for additional archiving; |
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| (g) causes the Investigator to comply with all adverse event reporting requirements under the applicable laws and regulations, this Agreement and the Protocol and to cause the Investigator to immediately give written notice to Sponsor´s drug safety group of any and all serious adverse events associated with the use of the product whether or not the events are considered by the Investigator to be related to the product; |
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| (h) provides for the necessary equipment and human resources necessary for the conduct of the Trial; |
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| (i) educates all personnel who is involved in the conduct of the Trial about the details of the Trial in accordance with the Protocol and any changes therein and to document this instruction exercise; |
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| (j) allows Sponsor’s monitors to check source date during normal business hours and upon mutually agreed dates and to cooperate with the monitors and to adhere to their instructions; |
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| (k) cooperates and supports audits and inspections personally and to permit in this context Sponsor or auditors assigned by Sponsor access to the site and all locations used for the performance of the Trial during usual business hours upon mutually agreed dates and to make available all Trial relevant documents for review and duplication, if necessary; in case a Party receives knowledge that an authority intends to conduct an inspection in respect of the Trial, this Party shall inform the other Party thereof without undue delay; |
| (l) if stipulated in the Protocol, conducts the necessary follow-up visits in respect of Subjects included in the Trial even after the termination of this Agreement and to prepare the necessary documentation and to forward this documentation to Sponsor; |
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| (m) only uses and stores the data collected during the Trial for the purposes of this Trial or permitted use by this Agreement and to refrain from disclosing the data to any third parties; |
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| (n) adheres to the deadlines set out in the Protocol. |
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| **4. Recruitment[[1]](#footnote-1)** |
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| Recruitment at the different sites participating in the Trial is directly linked and based wholly on those numbers of evaluable Subjects that have been recruited to the Trial and consent to continue their participation into the Trial.  Institution shall use reasonable endeavours to recruit or cause the Investigator to use reasonable endeavours to recruit the target number of Subjects in accordance with the timelines, all as specified in the Protocol.  The recruitment and inclusion of Subjects by the Investigator above and beyond the target or threshold(s), or any adjustment of the target or threshold(s), shall be subject to prior written approval of Sponsor. As soon as the Investigator expects to reach a target or threshold, he/she shall notify Sponsor.  If circumstances or events have occurred or will occur that will substantially delay or that are likely to substantially delay the progress of recruitment or enrolment of the Subjects, Institution shall without any undue delay inform the Sponsor in writing. In each such event the Parties shall discuss the consequences of the delay and each Party shall undertake reasonable endeavours to agree on measures to overcome the delay or to agree such other arrangements that the Parties and the Investigator consider appropriate for the further implementation of the Trial.  Sponsor may amend the number of Subjects to be recruited pursuant to Protocol above subject to the following, and always based on timely and adequate exchange of information:   1. If in the reasonable opinion of Sponsor recruitment of Subjects at Institution will not meet or will not likely meet the target within the timelines or is proceeding at a rate below that required to enable the relevant timeline to be met, Sponsor may request Institution to increase the number and rate of Subjects to be recruited and enrolled at the Trial Site. If Institution is unable to do so, Sponsor may (i) by notice to Institution require recruitment at the Trial Site to cease, or (ii) with the agreement of Institution decrease the number of Subjects to be recruited at Institution subject to clinical trial authorization; or 2. If recruitment of Subjects is proceeding at a rate above that required to meet the relevant timelines, Sponsor may, with the agreement of Institution, increase the number and the rate of Subjects to be recruited and enrolled at the Trial Site; or 3. If the overall recruitment target for all clinical centers that are part of the multi-centre clinical trial of Sponsor and its Affiliated Entities has been reached, Sponsor may by notice to Institution require recruitment at the Trial Site to cease. Affiliated Entity means any legal entity as defined in Article 2.1(2) Rules for Participation Regulation No 1290/2013 and Article 14 of the Grant Agreement that is under the direct or indirect control of a participant, or under the same direct or indirect control as the participant, or directly or indirectly controlling a participant.   The Investigator shall upon receipt of a notice to cease the recruitment immediately stop further recruitment and inclusion of Subjects. |
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| **5. Supply of Material** |
| **OPTION without CRO:**  As provided by the Grant Agreement Sponsor shall provide the Institution, at no charge, with such quantities of the Product and other equipment (Investigator Site File, Trial documents, e.g. Informed Consent Form (ICF)) as may be required for the Trial (**“Material*”***). |
| **OPTION for inclusion of CRO:**  As provided by the Grant Agreement and the Services Agreement between Sponsor and [insert CRO], [insert CRO] shall provide the Institution, at no charge, with such quantities of the Product and other equipment (Investigator Site File, Trial documents, e.g. Informed Consent Form (ICF)) as may be required for the Trial (**“Material”**).  The Institution shall use the Material only pursuant to and in accordance with the Protocol. The Institution shall not use, and shall not permit an Investigator to use, the Material for any other purpose without the prior written consent of Sponsor. The Institution shall treat, handle, use and maintain, as applicable, the Material with the degree of care used for its own property and in accordance with the instructions of the Sponsor or its agents at any time. At the conclusion or termination of the Trial, the Institution shall account for all quantities used of the Material and, unless otherwise agreed in writing by the Parties, shall at [**insert Sponsor OR Institution as appropriate**] expense return or otherwise dispose of all remaining Material in accordance with the instructions of Sponsor or its agents. |
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| **6. Additional Obligations of the Investigator** |
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| The Investigator undertakes |
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| (a) to conduct the Trial as principal investigator and to fully comply with the Protocol and any further instructions as may be given by [**insert Sponsor OR CRO OR decision board as appropriate OPTION:** following procedures described by the Grant Agreement **[insert page of Grant Agreement**]] and endorsed during the kick-off meeting, and immediately give written notice of any deviations from the Protocol to Sponsor; |
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| (b) to read, understand, and sign any forms deemed necessary by Sponsor in order to conduct the Trial and return them to Sponsor; |
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| (c) not to commence the Trial and continue to conduct the Trial unless and until all required filings have been made and all documents have been deposited and the assenting ethics vote or the ethics votes, respectively, as well as all relevant permits under the applicable laws and regulationshave been obtained, this also applies to and especially for inclusion of further physicians as investigators in the Trial, which not known to the Sponsor before; |
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| (d) prior to the potential Subject’s involvement in the Trial, to thoroughly counsel any Subject regarding the character, relevance and consequences of the Trial and to inform him/her on the purpose and scope of the collection and use of personal data, particularly of health data, and according to the ICF provided by Sponsor to obtain the legally required written informed consent of the Subject regarding the participation in the Trial and the disclosure, transfer and processing of the data collected in accordance with the Protocol, taking the applicable data protection provisionsinto account; |
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| (e) without undue delay to entirely complete the electronic case report forms (“e**CRF*”***) provided by [**insert Sponsor OR CRO as appropriate**] for each Subject to be used in the Trial in accordance with the requirements as specified in the Protocol, and correct any errors possibly made as soon as such errors are discovered; |
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| (f) to pseudonymise any personal data prior to any transfer of the Subjects data of the Trial; |
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| (g) to give written notice to [**insert Sponsor OR CRO as appropriate**] and data safety monitoring board (DSMB) of any occurrence of serious adverse events (SAEs) according to the terms of the Protocol as soon as they get known without undue delay; |
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| (h) to open emergency envelopes in the event of double-blind studies in cases of emergency only, to document and notify Sponsor of the date and reason for the emergency situation; |
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| (i) to duly keep the Investigator Site File (**“ISF”**) and, in particular, to continuously file all relevant Trial-related original documents in the ISF; |
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| (j) not to recruit any more Subjects for the Trial after Sponsor has given notice that the total number of Subjects stipulated in the Protocol has already been enrolled in the Trial; |
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| (k) to comply with the time limits set in the Protocol; |
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| (l) to make himself/herself or his/her representative available for meetings and queries in respect of Trial data, and to cooperate with the monitors entrusted with the conduct of the Trial by Sponsor and to observe the instructions given by them; |
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| (m) to cooperate in the event of audits or official inspections and support the carrying out of such audits or official inspections; |
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| (n) to provide Sponsor with an up-to-date signed scientific curriculum vitae (CV); |
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| (o) if requested by the Sponsor to make a written declaration revealing whether or not the Investigator has any possible economic or other interests in connection with the conduct of the Trial and the Trial substances and – if so – what his interests are. |
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| (p) if requested by the Sponsor, to complete and sign further forms which are necessary for the conduct, evaluation and use of the Trial. |
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| **7. Trial team** |
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| (a) Investigator **(2-party-contract)**  (b) **Sub-investigator**. Sub-investigators are identified in the Grant Agreement and within the Study Team list at Institution and who have been notified to the EC and/or other applicable authorities. If required, the Institution is permitted to nominate with the consent of Sponsor one or more physicians as sub-investigators who support the Investigator in the conduct of the Trial. The participation of sub-investigators in the Trial has to be documented by the Institution in writing. The sub-investigators work under the direct supervision of the Investigator. The sub-investigators shall be obliged by the Institution to [**insert Sponsor OR CRO as appropriate**] with a signed CV and further records to document the qualification of the sub-investigators for the clinical trial and to adhere to all investigator obligations set out in this Agreement. |
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| (c) Study Personnel, meaning persons acting on the Trial under direct supervision of the Investigator and which are not Sub-investigator. |
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| **8. Payments to the Institution** |
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| Provisions applicable to payments to Institution are those provided by the Grant Agreement and further specified in the Consortium Agreement. |
| **9. Confidentiality** |
| Confidentiality is governed by Article 36 of the Grant Agreement (Confidentiality) and Article 10 of the Consortium Agreement (Non-disclosure of information). |
| **10. Publications** |
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| Publications are governed by Article 29 of the Grant Agreement (Dissemination of Results) and Article 8 of the Consortium Agreement (Dissemination). |
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| (a) Data protection  **Option A:**  (1) The responsibility:   * According to Article 4 (7) GDPR, within its area of responsibility each Party holds responsibility for the processing of personal data of the employees of the other Party that it has obtained during the course of this Trial or the execution of this Agreement. * According to Article 4 (7) GDPR, Sponsor is responsible for the database and the data contained in the CRF of the Trial as well as for the auditing of all data (including those of the Subjects) by monitors and auditors. * With regard to the data collected during the course of the Trial by Institution on behalf of Sponsor and entered into the CRF (“**Trial Data**”) as specified in the Protocol, Institution acts as a data processor pursuant to Article 4 (8) GDPR.   (2) As a data processor, Institution must comply with the requirements laid down in Article 28 GDPR, in particular:   * Trial Data will only be processed on the basis of this Agreement or on documented instructions from Sponsor. * Institution ensures that persons authorized to process the data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality. * Institution shall take all measures, particularly technical and organizational measures, to comply with the requirements of Article 32 GDPR. * In the event that Institution enters into any agreement whereby some of the processing activities are delegated to a third party, Institution shall ensure, in accordance with Article 28 GDPR, that such a third party provides sufficient guarantees to implement appropriate technical and organizational measures to ensure the protection of the rights of the Subjects. * Institution shall assist the Sponsor with appropriate technical and organizational measures to comply with its obligation to respond to requests for the exercise of rights of the Subject referred to in Chapter III of the GDPR. * Institution will assist the Sponsor in complying with the obligations set out in Articles 32 to 36 of the GDPR, taking into account the nature, context and purposes of processing and on the basis of the information at its disposal. * In contrast to Article 28 III (2)(g) GDPR, the regulations for the termination and archiving of this agreement apply, which are based on the primary legal and regulatory requirements for clinical trials and patient records. * Institution will make available all information necessary to demonstrate compliance with relevant GDPR obligations, including by allowing for and contributing to audits, including inspections, conducted by Sponsor or another auditor mandated by Sponsor, in accordance with Section 5 of this Agreement. Institution informs Sponsor immediately if an instruction violates the GDPR or other data protection provisions of the Union or other applicable data protection law. |
| **Option B:** Trail Site is joint controller with Sponsor  See extra Annex |

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| **11. Work Results and Invention Rights** |
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| Work Results and Invention Rights are governed by Chapter 4. Section 3 of the Grant Agreement (Rights and Obligations related to Background and Results – articles 23a to 31) and Sections 8 and 9 of the Consortium Agreement. |
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| **12. Term of contract and Termination** |
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| 1. **Term of contract.** This Agreement enters into force subject to the approval of the Trial by the Competent Authorities and shall continue until the due completion of the Trial unless terminated earlier by the written agreement of the Parties (email not sufficient) or under the other provisions of this Section 12. 2. **Termination.** Termination of this Agreement shall be governed by Chapter 6. Section 3 of the Grant Agreement (Suspension and Termination). Additionally, Sponsor is entitled to exclude the Trial Site from the Trial if Institution has received from Sponsor all Material, necessary to perform the Trial and it has not recruited any Subject within a reasonable period of time as mutually agreed by Parties in the Protocol or in other written documents. Upon Sponsor’s decision to exclude the Trial Site, the exclusion becomes effective within 3 (three) month prior written notice. The Sponsor t shall notify Institution without delay. |
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| **13. Subcontractors** |
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| Except for subcontracting expressly provided for by the Grant Agreement, the Institution and the Investigator may not assign, delegate or subcontract any of their rights or obligations under this Agreement or any part thereof to third parties without the prior written consent of Sponsor. |
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| **14. Liability - in addition to the liability within the Consortium Agreement the following clauses apply solely for the services within the Trial** |
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| (a) The Institution undertakes to carry out the Trial with care, observing approved and recognized scientific standards.  No warranty is made by the Institution that the prospective output, data or results obtained from the Trial can be commercially exploited.  (b) The Parties are each liable for wilful misconduct and gross negligence. The aforementioned limitations to the liability do not apply with respect to damages arising from injury of life, body, or health. The limitations further do not apply if damaging Party breaches fundamental duties of the Agreement. Additionally, the Parties shall not be responsible for any lost profit, indirect and/or consequential damages.  (c) Sponsor agrees to defend, indemnify and hold harmless Investigator and Institution, its trustees, officers, agents and employees (collectively, the “**Institutional Indemnitees**”) from any and all liabilities, claims, actions, suits, or proceedings for any injury arising out of or from the administration or use of the Products furnished by Sponsor pursuant to the Protocol or otherwise related to the conduct of the Studies, provided, however, that:  - The Studies are conducted in accordance with the Agreement and all written instructions delivered by Sponsor concerning the administration or use of the Products;  - The Institutional Indemnitees have complied with all regulations; and  - Sponsor shall not indemnify, defend and hold harmless the Institutional Indemnitees from liabilities arising out of gross negligence or wilful misconduct of any of the Institutional Indemnitees. |
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| **15. Miscellaneous** |
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| (a) **Assignment.** Except if otherwise provided for by the provisions of the Grant Agreement and particular agreements duly identified at the date of signature of this Agreement (**OPTION**: such as the Services Agreements between Sponsor and [**insert CRO**]),the obligations under this Agreement are designated personally to the Investigator for the Trial, and neither this Agreement nor any right or obligation hereunder may be assigned by the Sponsor or the Investigator to any third party. |
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| (b) **Legal position of the parties.** This Agreement shall not create any relationship of employment between Sponsor and the Investigator or staff or an agency or partnership, respectively, between Sponsor and the Institution and shall not give either party any authority to bind the respective other party. Neither Sponsor nor the Institution may use the other party's name in connection with any notification or other publication without the respective other party's consent. |
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| 1. **Applicable Law.**The Trial at the Institution shall be performed in accordance with the national law and regulations applicable to the Institution.     In the event of any dispute arising between the parties in relation to the terms of this Agreement, the parties shall use their best endeavours to resolve the matter on an amicable basis.  In the event the parties are unable to resolve any dispute in accordance with the provisions of this Agreement, any action brought by either party to this Agreement shall be heard by the appropriate court of competent jurisdiction sitting in [insert city, country of Trial Site]. |
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| (d) The invalidity or unenforceability of any provision of this Agreement shall in no way affect enforcement of any other provision of this Agreement. **OPTION German Site and German Sponsor:** (aa) In case the discarded stipulation was some general terms and conditions which breach §§305 ff. BGB, the void stipulation shall be replaced by the law. In the event a loophole remains, the hypothetical will of the Parties applies. (bb) In case of an otherwise discarded stipulation (especially if it was an individually agreed term), the void stipulation shall be replaced by a stipulation which best represents the will of the Parties; this also applies in case of any gab in the contractual regulations. The Parties then will negotiate in good faith such stipulation. **OPTION: German Site/Sponsor and international Site/Sponsor:** In case the discarded stipulation, the void stipulation shall be replaced by a stipulation which best represents the will of the Parties; this also applies in case of any gab in the contractual regulations. The Parties then will negotiate in good faith such stipulation. |
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| (e) **Amendments.** Any amendment or change or waiver of this Agreement shall be made in writing. |
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| (f) **Entire Agreement.** This Agreement (incl. all its negotiations notes) and any schedule, Protocol and documents referred to in this Agreement (such as the Grant Agreement and the Consortium Agreement), shall constitute the entire agreement between the Parties in relation to the conduct of the Trial. |
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| (g) **Waiver.** A waiver by either Party of any term or condition of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for any similar instance in the future or any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement are cumulative and none of them shall be a limitation of any other remedy, right, obligation or agreement. |
| (h) In case of inconsistency between provisions of this Agreement and provisions of the Grant Agreement, the provisions of the Grant Agreement shall prevail. In addition, the provisions of the Grant Agreement complete the provisions of this Agreement.  (i) **Notices.**  Any notice given in connection with this Agreement shall, unless otherwise provided herein, be in writing and shall be sent to the address given in this Agreement or to such other address as may have notified to the other party in writing. |
| **IN WITNESS WHEREOF**, Sponsor, the Institution and the Investigator have signed this Agreement (in the case of Sponsor and the Institution) through their duly authorised representatives. |
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| By:  Name:  Title: |
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| **Institution** [or in case of CRO: **CRO on behalf of the Sponsor**] |
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| By:  Name:  Title: |
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| [***to be signed by the administration of the Institution***] |
| Phone:  Fax: |
| Read and understood: (**in case of 2-party-contract**) |
| **Investigator**  By:  Name:  Title: |

**Annex**

**Joint Controllership pursuant to Article 26 GDPR**

1. Both the Sponsor and the Institution (Trial Site) are obliged to abide by all applicable data protection regulations, in particular the General Data Protection Regulation (GDPR), the Federal Data Protection Act (BDSG), as well as the respective federal state data protection laws and, if necessary, the law governing ecclesial data protection (KDG) and/or the Data Protection Act of the Protestant Church in Germany (DSG-EKD) in the scope of the joint project, and will secure this by the implementation of adequate technical and organizational measures in order to guarantee a reasonable level of data protection pursuant to Articles 24, 32 GDPR, and assure that the rights of the data subjects can be exercised within the statutory time limits.
2. The Sponsor and the Institution (Trial Site) agree that both Parties are joint controllers in the sense of Article 4 (7) GDPR in conjunction with Article 26 GDPR. The purpose of joint processing is the execution of the clinical research project, which is designed as a multicentric trial in the sense of Article 4 paragraph 23 of the German Medicinal Products Act (AMG) and described in detail in the contract. The Sponsor bears the overall responsibility for the clinical medicinal product trial in the sense of Article 4 paragraph 24 of the German Medicinal Products Act (AMG), in which the Institution (Trial Site) is involved as a further Institution (Trial Site) and conducts the Trial with the Subjects according to the latest valid version of the Protocol.
3. In the scope of the joint project, the data of the participating patients, inclusive of special categories of personal data, as well as data from employees of the Parties, shall be processed by both Parties to an extent which is necessary for the common purpose. The specific type of the Subjects’ data to be processed results in particular from the Protocol in its latest valid version, which is also part of the main contract.
4. **Responsibilities**

Pursuant to Article 4 (7) GDPR, each Party is responsible in its own field of competence for handling the personal data of employees of the respectively other Party, of which it gains knowledge in the scope of the Trial or fulfilment of this contract.

The Institution (Trial Site) is solely responsible for the processing of all data generated in the scope of treatment, in particular in the patient's file. It is also responsible for the factually faultless entry and, where applicable, necessary correction of personal data in the eCRFs.

The Sponsor is solely responsible for the technical and organizational measures relating to the eCRF and for processing in the scope of monitoring and audit activities. This also includes the responsibility for a transmission mode in conformity with the requirements of Article 32 GDPR. Besides, the Sponsor is responsible for the data processing in the eCRF as well as subsequent data processing.

1. The Sponsor is obliged to provide the Institution (Trial Site) with the necessary documents containing the information to be provided pursuant to Articles 13, 14 GDPR to the study participants as well as an informed consent which is compliant with data protection laws. The Sponsor is responsible for the content of the submitted documents. The Institution (Trial Site) is obliged to forward them to the study participants and lawfully obtain and store their informed consents. Reciprocal control obligations do not exist; each Party may rely on the lawful fulfilment of the obligations of the respective other Party.
2. The Institution (Trial Site) functions as a primary point of contact for the protection of the rights of data subjects pursuant to Articles 15 – 21 GDPR. The Institution (Trial Site) shall immediately inform the Sponsor about all protections of rights of data subjects as well as their specific realization, so that the Sponsor will be able to implement the corresponding requests in his database, where possible, provided that the request is not opposed by any other legal regulation, in particular the Medicinal Products Act (AMG). Where possible, communication between the Parties shall be performed in pseudonymized form based on study-specific identification numbers.
3. In the event that one of the Parties commissions a processor in the sense of Article 28 GDPR with the performance of certain tasks in connection with study, the respective Party shall assure that the processor fulfills the requirements of Article 28 GDPR. Any actions and processing activities of contractors of any one Party shall be ascribed solely to this Party.
4. The Sponsor and the Institution (Trial Site) are both obliged pursuant to Article 30 GDPR to keep a record of the processing activities, which complies with the respective requirements of the respective processing site. Where necessary, they shall support each other in creating such records.
5. In the event that a reportable violation of the protection of personal data should occur at the Institution (Trial Site) in the sense of Articles 33, 34 GDPR and be related to the data collected in the scope of this study, the Institution (Trial Site) shall be obliged to report the violation to the Sponsor within a period of 24 hours. Should the report be made later, the reasons for its delay must be provided. The report must contain the information required by Article 33 paragraph 3 GDPR; if and to the extent that the information cannot be provided at the same time, it must be made available successively without undue further delay. The Institution (Trial Site) is also obliged to immediately report any violation of personal data protection to its respectively competent federal state data protection authority and/or ecclesial supervisory data protection board within the legal time limits pursuant to the provisions of Article 33 GDPR and/or the respective regulations of the KDG and/or DSG-EKD. The Sponsor in his capacity as the overall responsible Party of the clinical drug trial in the sense of Article 4 paragraph 24 of the Medicinal Products Act (AMG) shall then report to his competent data protection authority. The Institution (Trial Site) shall examine whether a notification of the data subjects is necessary pursuant to Article 34 GDPR and, where necessary, immediately implemented send a copy of it to the Sponsor for his information.

In the event that a reportable violation of the protection of personal data should occur at the site of the Sponsor in the sense of Articles 33, 34 GDPR, relating to the personal data collected in the scope of this study, the Sponsor shall carry out the necessary measures pursuant to Articles 33, 34 GDPR and inform the test centers involved in the study and those affected by the reportable violation. If notification of a data subject pursuant to Article 34 GDPR should be necessary, but cannot be put into effect by the Sponsor himself, e.g. because he possesses only pseudonymized data of the data subjects, notification shall proceed by the respective Institution (Trial Site).

Here, where possible, communication between the Parties shall also be performed in pseudonymized form on the basis of study-specific identification numbers.

1. Each Party shall appoint a data protection officer, provided it is obliged to do so pursuant to Article 37 GDPR. Pursuant to paragraph 6, the primarily responsible data protection officer in this regard is the data protection officer of the Institution (Trial Site). If the Institution (Trial Site) is not obliged to designate a data protection officer pursuant to Article 37 GDPR, a qualified staff member shall assume the corresponding obligations resulting from this agreement. However, where necessary in the individual case, both Parties shall inform each other without delay when they have been contacted by a data subject in the scope of the study, and render support to each other in exercising the data subject rights.
2. The Sponsor shall ensure that significant contents of this agreement (Article 26 paragraph 2 sentence 2 GDPR) are made available to the data subjects in the scope of the patient information.
3. In their external relationship to third parties, liability of the parties to data subjects results from Article 82 GDPR. This agreement in itself does not substantiate any claims of data subjects or any other third parties.

In their internal relationship, each Party is liable to the respective other Party for damages to an extent in which damages have resulted from the processing it has been responsible for. This also applies to penalties provided that they have been imposed because of a circumstance lying in the responsibility of the respective Party. If a Party bears sole responsibility for an incurred damage (or a penalty), this Party shall take over the defense and indemnify the respective other Party against all claims or other damages of third Parties, or liabilities to third Parties, which may result from the breach of duty of this Party under this agreement and/or any other applicable data protection regulation.

1. This agreement shall survive the expiration of the main contract regulating the execution of a clinical research project until the contractual processing of personal data has been terminated. Giving separate notice to this agreement is not permitted, whereas the right to terminate this agreement for good cause remains unaffected. If the Institution (Trial Site) has been granted a right for use of data obtained in the scope of this research project for an indefinite period of time for the purpose of its own research and teaching activities, the Institution (Trial Site) shall be the sole controller in the sense of Article 4 (7) GDPR for all processing activities conducted in the scope of this granted privilege.

*(A tabular overview relating to the responsibility in the area of data protection is shown on the next page*)

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| **Task: Data Protection** | **Responsibility** | |
|  | Sponsor | Institution (Trial Site) |
| Art. 26 paragraph 1 Agreement in a transparent form defining who shall fulfil what kind of obligations pursuant to this regulation. | X | X |
| Determination of the purpose and means of data protection. | X | X |
| Determination of the type of personal data. | X | X |
| Art. 26 paragraph 1 Optional: Statement of contact office for data subjects. | X | X |
| Art. 27 Written appointment of a representative in der EU, in the event that a controller is not a resident of the European Union. | X | Not applicable |
| Provision of informed consents of the patients. | X |  |
| Lawful archiving of the informed consent of the patients. |  | X |
| Obtaining the informed consent of the patient. |  | X |
| Registration of personal data in the patient's file. |  | X |
| Provision of the observation protocol/ protocol as the basis for processing personal data. | X |  |
| Registration of pseudonymized personal data in the database based on the observation protocol / protocol |  | X |
| Guarantee of pseudonymization |  | X |
| Guarantee of processing of the pseudonymized data for a specific purpose. | X |  |
| Art. 13 (Art. 26 paragraph 2) Information to be provided when collecting personal data relating to the data subject. | (X) | X |
| Art. 14 Information to be provided where personal data have not been obtained from the data subject. | (X) | X |
| Art. 15 Processing of patients' inquiries |  | X |
| Art. 16 Processing of patients' requests for correction. |  | X |
| Art. 17 or 18 Processing of erasure applications of patients or restriction of processing and Art. 19 Notification obligation regarding erasure. | (X) | X |
| Art. 20 Management of data reclaims (data portability) on behalf of the patients. | (X) | X |
| Art. 21 Processing objections raised by patients. | (X) | X |
| Art. 24 paragraph 1 in conjunction with Art. 32 Determination of the technical/organizational measures after risk assessment and, where applicable, data protection impact assessment (Art. 35) and consultation of a supervisory authority / transfer of necessary information (Art. 36 (3)). | X | X |
| Art. 24 paragraph 1 Documentation of the selection of technical /organizational measures (as proof). | X | X |
| Art. 24 paragraph 1 review and updating of the measures. | X | X |
| Art. 28 Recruitment of processors and/or subcontractors and their inspection. | X | X |
| Art. 30 Keeping a record of processing activities. | X | X |
| Art. 33, 34 Proceedings in the event of reportable data mishaps. | X | X |
| Art. 37 Appointment of a data protection officer. | X | X |
| Art. 82 Liability. | X | X |
| **[if necessary]** Safeguarding the preconditions for the transfer of personal data into third party countries outside the EU (Art. 44 ss.) | X |  |

1. adopted from [CLINICAL TRIAL AGREEMENT (Template agreement for industry initiated and sponsored Clinical Trials, with human subjects, conducted by non-academic (STZ) hospitals and NKI/AvL in The Netherlands - Template Clinical Trial Agreement version July 2015](https://www.google.de/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwiVi8-Wy7vrAhUlwuYKHTJtCfwQFjAKegQIBBAB&url=https%3A%2F%2Fwww.stz.nl%2Fdownload%2F7a4445f2e0990207d5eb5cfb13d66c1a1875.pdf&usg=AOvVaw2PPlazZG7TNlzwnlKIn2kC) [↑](#footnote-ref-1)