**Agreement**

between

AO Foundation

AO Network Clinical Research

AO Spine

Clavadelerstrasse 8

7270 Davos Platz

(Switzerland)

(hereinafter referred to as "AO Foundation")

and

please insert legal entity of contractor

please insert street

please insert city

please insert country

*(hereinafter referred to as "Contractor")*

regarding project

please insert project name

Either AO Foundation or Contractor may be referred to hereinafter as a “Party” or collectively as “Parties”.

# WITNESSETH:

**Whereas AO Foundation,** a foundation established under the laws of Switzerland, is focused on improving the quality of medical service through education, research, documentation, and communication;

**Whereas Contractor** is please insert legal entity of Contractor incorporated in please insert country with registered office in please insert city and has presented Project No. please insert project number as a Full Proposal with the title "please insert project title" to AO Foundation on please insert date;

**Whereas Project No**. please insert project number has been accepted by AO Foundation after a peer-review process, and a final decision by letter dated please insert date.

**Whereas** AO Foundation is willing to financially support this Project but not as a sponsor in the sense of the ICH-GCP Guideline and Contractor is willing to assume the duties as described below.

Therefore, and in consideration of the mutual covenants contained herein, the Parties hereto agree as follows:

# Article 1 – Definitions

For the purposes of this Agreement, the following terms shall have the meaning as set forth below:

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| --- | --- |
| **Contracto**r | means the legal entity which has concluded this Agreement with AO Foundation and which is the sole party contracting with AO Foundation responsible for the carrying out of the Project |
| **Principal Investigator** | means the person named by Contractor who shall be responsible for the performance of the Project as described in the Full Proposal |
| **Full Proposal** | means the description of the Project, which has been submitted by Contractor, and is attached to this Agreement as Annex I |
| **Confidential Information** | means all information, data, documents and other related information, received by either Party from the other Party under this Agreement |
| **Intellectual Property** | means any patents, patent applications, copyrights, trademarks, service marks, trade names, trade secrets, know-how, or other intellectual property rights recognized in any country or jurisdiction in the world, including, without limitation, any and all art, method, process, procedure, invention, idea, design, concept, technique, discovery, improvement or moral right, regardless of patentability; it is not required, but possible, that Intellectual Property is linked directly to the Project or a result of the Project |
| **Intellectual Property Protection** | means the registration, application, filing, prosecution or maintenance of a patent, copyright, trademark or other protective measure for Intellectual Property |
| **Knowledge** | means the results, including accompanying documentation, generated or arising in the performance of the Project, and all intellectual property rights relating to such results and documentation, including but not limited to copyrights, patents, designs and models, plant varieties, additional certificates, or other similar forms of protection and any related rights to patentable and non-patentable inventions; Knowledge is linked directly to the Project and comes out of the Project |
| **Project** | means Project No. please insert project number with the title "please insert project title", and all work relating thereto, as described in detail in the Full Proposal and as accepted by AO Foundation after a peer-review process and a final decision by letter dated please insert date |
| **Project Duration**  | means the period of performance of the Project, starting please insert start date provided the contract is signed and legally valid until the defined start date and continuing for 12 (twelve) months from that date  |
| **Project Completion** | means the receipt and written approval of Contractor’s final report pursuant to Article 4.2.2 by AO Foundation  |
| **Subcontractor** | means a third party as referred to in Article 5.1 of this Agreement entering into an agreement with Contractor  |

# Article 2 – Subject of Agreement

2.1 This Agreement governs the carrying out of the Project by Contractor and the financial support granted therefor by AO Foundation. The Project does not include patients or healthy volunteers.

2.2 AO Foundation hereby names Niccole Germscheid, to be responsible for all administrative, scientific and technical questions addressed by Contractor. AO Foundation shall not take over any responsibility for carrying out the Project.

2.3 Contractor hereby names name to be inserted by Contractor as Principal Investigator of the insert name of project as described in the Full Proposal.

# Article 3 – Obligations of AO Foundation

3.1. AO Foundation shall finance the Project for please insert number (please write number) months with a maximum amount of CHF please insert number (please write number) Swiss Francs; incl. all costs, expenses and taxes, as far as applicable. An extension of the Project and/or further financial support is possible in exceptional cases, but only subject to a prior written agreement between the Parties.

3.2 The amount referred to in Article 3.1 shall be transferred to an account of Contractor and not to the account of an individual. AO Foundation shall pay the amount[s] in accordance with the following schedule:

* CHF please insert number (please write number) (Swiss Francs) are due after signature of this Agreement by both Parties and the written confirmation of Contractor that the Project has started;
* CHF please insert number (please write number) (Swiss Francs) are due after AO Foundation’s approval of the '6-month Report' pursuant to Article 4.2.1.
* CHF please insert number (please write number) (Swiss Francs) is the guarantee retention. The guarantee retention period shall be thirty (30) days from the date of the approval of the final report. In the absence of any claims by AO Foundation against Contractor with respect to this Agreement, the guarantee retention shall be paid to Contractor within sixty (60) days after expiration of the guarantee retention period.

3.3 AO Foundation shall make all payments due pursuant to Article 3.2 within thirty (30) days. Contractor shall provide the corresponding bank account information for transfers. Contractor shall be exclusively responsible for any and all taxes which may be incurred as a result of this Agreement and/or the Project.

# Article 4 – Obligations of Contractor

4.1 Carrying out of the Project

4.1.1 Contractor shall:

(a) carry out the Project with suitable qualified, trained and competent investigators and employees only, and in accordance with all applicable laws and regulations, and all provisions as set forth in this Agreement;

(b) carry out the Project within the time frame and as set forth in the Full Proposal;

(c) provide all necessary facilities therefore;

(d) nominate in due time a sufficiently qualified new Principal Investigator in the event that the Principal Investigator nominated according to Article 2.3 of this Agreement leaves/leave Contractor by leaving the Project with the Contractor.

4.1.2 Contractor shall ensure that all payments made to Contractor pursuant to Article 3 above shall be used exclusively for carrying out the Project. Upon request by AO Foundation, Contractor shall provide details on the use of AO Foundation’s financial support and the Project account.

4.1.3 AO Foundation is entitled to request free of charge an update and/or amendment of the Project after receipt of a yearly or final report if AO Foundation is of the opinion that such update and/or amendment is appropriate and/or justified for scientific or business reasons.

4.1.4 AO Foundation and Contractor shall discuss any substantial material update and/or amendment of the Project with AO Foundation. Such update and/or amendment shall be possible only by prior written agreement between AO Foundation and Contractor.

4.1.5 In case of clinical investigations, Contractor shall use its best efforts and professional expertise to carry out the Project in accordance with the Full Proposal and in compliance with the current ICH-Good Clinical Practices Guideline ("ICH-GCP") and all applicable legal and regulatory requirements referring to clinical investigations. Contractor shall in particular, but not limited

4.1.5.1 assume all obligations of a sponsor pursuant to the ICH-GCP, designate the necessary number of competent investigators and make sure that all obligations of an investigator pursuant to the ICH-GCP are assumed by these persons;

4.1.5.2 be responsible for submission and obtaining approval of the Protocol, Informed Consent and Study advertisements, if any, from the appropriate IRB/IEC at each site prior to commencement of the Project;

4.1.5.2 be responsible for the notification to the competent national health authority;

4.1.5.3 be responsible for the notification of adverse events to the competent IRB/IEC and national health authorities;

4.1.5.4 be liable for harm caused to a trial subject within the framework of the Project and take out an insurance policy for full and complete compensation for injuries suffered by a trial subject in the course of the Project;

4.1.5.5 agree that AO Foundation shall in no event be liable for injuries suffered by a trial subject in the course of the Project.

4.2 Reporting

4.2.1 Contractor shall provide AO Foundation with a report and a cost statement within thirty (30) days at 6 months and 12 months from beginning of the Project. The periodic reports shall contain detailed information about the progress of work, resources employed, detailed financial statement, departures from the work schedule, and results, as required by the Full Proposal.

4.2.2 Contractor shall provide AO Foundation with a complete and detailed final report on the Project and a detailed final cost statement within thirty (30) days after completion of the Project for AO Foundation’s review and approval. Upon written request by AO Foundation, Contractor shall make any scientifically reasonable modification within thirty (30) days after receipt of such request.

4.2.3 The reports and the cost statements shall be submitted electronically to AO Foundation by the Principal Investigator.

4.2.4 Contractor shall be fully responsible that the study subjects’ rights for data privacy are respected when drafting the reports.

4.2.5 All reports shall be in English.

4.3 Communication of data for evaluation purposes

4.3.1 Without prejudice to Article 6, Contractor shall provide, at the request of AO Foundation or its authorized representatives, any data necessary for the ongoing review of the Project. Such request may be made throughout the term of this Agreement and up to three (3) years after the Project Completion. The data collected shall be used for statistical purposes.

4.3.2 Contractor shall retain and not destroy all media containing information on the Project, including, without limitation, books, paper- and electronic files, logs, films, videos, photographs, plans, etc. for a period of ten (10) years. This period starts with the Project Completion or the early termination of the Project.

4.3.3 Without prejudice to Article 6 and the provisions regarding protection and use of Knowledge, as set forth in Article 7, Contractor shall inform AO Foundation without delay of Knowledge which may contribute to the preparation of another research project or to commercial exploitations.

# Article 5 – Subcontractors

5.1. Contractor is entitled upon prior written consent of AO Foundation to delegate all or part of its obligations under this Agreement to any third party (each, a 'Subcontractor'), but only after the Subcontractor has agreed in writing to be subject to and to comply with all obligations, terms and conditions stipulated in Articles 5 to 9 of this Agreement. Nevertheless, the Contractor will remain fully liable with regard to the project.

# Article 6 – Data Protection and Confidentiality

6.1. This Agreement shall be governed by the applicable data protection laws, in particular the Federal Act on Data Protection and, where applicable, the Regulation 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the Processing of Personal Data and on the free movement of such data and repealing Directive 95/46/EC (GDPR).

6.2 Contractor must send all data of study participants to AO Foundation only in anonymized form. Anonymized data includes also data that has been pseudonymized but is deemed to be anonymized for AO Foundation, as AO Foundation does not hold any key to decrypt the data. Hence, Contractor may only transfer or make accessible to AO Foundation data that is anonymous data for AO Foundation in connection with study participants in the sense of the applicable data protection laws.

6.3. Contractor herewith confirms, if Contractor sends data of study participants to AO Foundation in pseudonymized (key-coded) form, to keep save and secret any key needed for decryption and not to disclose it to AO Foundation or its employees and officers but in emergency situations (e.g., immediate risk to the health of the person concerned). Under such conditions, pseudonymized (key-coded) study data is deemed to be anonymized for AO Foundation, as AO Foundation does not hold any key to decrypt the data.

6.4. All information, data, documents and other related information, received by either Party from the other Party under this Agreement (“Confidential Information”) is and shall be considered throughout, and for three (3) years after, the term or termination of this Agreement, as confidential, except for information which:

6.4.1 at the time of disclosure thereof is or becomes part of the public domain through no breach or fault of one of the Parties or its employees, agents, or Subcontractors;

6.4.2 at the time of disclosure thereof by one of the Parties is the other Party's lawful possession as evidenced by the concerned Party's competent written records;

6.4.3 the Party receives from a third party which has the right to disclose same and which did not obtain such information in violation of the other Party's rights;

6.4.4 is required by law or by the competent authorities within fulfilment of their responsibilities;

6.4.5 has been discovered or developed by the concerned Party independently of the present Agreement;

6.4.6 will be used for a potential future collaboration or will be subject to a license for AO Foundation pursuant to Article 7.3.1;

6.4.7 will be used for the purpose of scientific communications and publications or the disclosure of AO Foundation’s financial support of the Project, but only to the extent needed for such purpose and not exempted by Article 8.2.

6.5. Each Party shall hold Confidential Information in strict confidence and shall disclose Confidential Information to its employees, agents, or Subcontractors only on a need-to-know basis. Each Party shall ensure and shall be responsible that such employees, agents, or Subcontractors shall be bound and obligated by provisions of confidentiality identical to the Party’s own hereunder.

6.6. Contractor agrees and acknowledges that nothing in this Article shall operate so as to adversely affect AO Foundation’s rights to use all Knowledge as provided for under Article 6 of this Agreement and AO Foundation remains free to use and disclose same at its sole discretion.

6.7. The terms of this Agreement are Confidential Information, except for the fact of AO Foundation’s financial support.

# Article 7 – Intellectual Property Rights

7.1. Ownership

7.1.1 Any Intellectual Property developed by Contractor independently of this Agreement, and/or reduced to practice by Contractor prior to the date of this Agreement, shall be owned exclusively by Contractor.

7.1.2 Any Intellectual Property owned by AO Foundation and/or reduced to practice by AO Foundation prior to the date of this Agreement shall be owned exclusively by AO Foundation.

7.1.3 Any Knowledge discovered, developed and/or reduced to practice by Contractor under this Agreement, shall be owned by Contractor. Any potential transfer to AO Foundation shall be subject to a separate agreement between the Parties and AO Foundation shall be entitled to such transfer without any additional costs.

7.2. IP Filings

7.2.1 Contractor may, at its discretion, file an application for, and take steps to obtain and maintain Intellectual Property Protection in any country related to any Knowledge discovered or developed by Contractor in connection with the Project.

7.3. Licensing

7.3.1 AO Foundation License. AO Foundation shall be entitled to a permanent, non-exclusive, non-transferable, royalty-free license to use and make derivative works of all Knowledge, including, but not limited to the results, as soon as such Knowledge and results are known. AO Foundation shall be entitled to use such license for AO Foundation’s internal operations, further research use, internal and external teaching purposes, commercial exploitations, communications and publications, but the last ones only under the reservation of Article 8 of this Agreement. Contractor shall grant, within due time, AO Foundation all rights that are necessary for such use.

7.3.2 Commercial Exploitation. In case Contractor intends to commercially exploit the Knowledge or products embodying part or all of the Knowledge, prior to such exploitation, the Parties shall negotiate a profit-sharing agreement, including also AO Foundation’s royalties.

7.4. Use of Name and Disclosure of AO Foundation’s financial support

7.4.1 The Parties shall neither publish, disseminate nor otherwise use a reference to this Agreement, the Project or its relationship to the other Party nor use the other Party’s name or a name similar to that, except with the prior written consent of AO Foundation and as set forth in Article 7.4.2. Any reference to AO Foundation in a scientific publication shall be governed by the terms of Article 8.

7.4.2 Each Party is entitled to disclose AO Foundation’s financial support, but without giving any details of this Agreement and/or the Project, or only with the prior written consent of the other Party.

7.4.3 Neither Party may use the name, mark or symbol of the other Party or its employees in any commercial manner, including advertising or promotional sales literature, without the prior written consent of the other Party.

# Article 8 – Publications

 8.1. Contractor shall ensure that publications or other disclosures do not include personal data of Trial Subjects.

8.2. Contractor shall indicate AO Foundation’s financial support in an appropriate manner ('Project No please write number was supported by AO Foundation, AO Spine. AO Spine is a clinical division of the AO Foundation – an independent medically-guided not-for-profit organization based in Davos, Switzerland) in any oral presentation, publication, paper and/or further communication.

8.3. AO Foundation shall be entitled to submit an own publication if Contractor has failed to submit its publication within six (6) months after Project Completion. Contractor shall provide AO Foundation the necessary Knowledge and results upon its request within due time.

# Article 9 – Term and termination

9.1. This Agreement shall enter into force starting upon execution of the Agreement provided the contract is signed and legally valid until the defined start date and shall end automatically upon Project Completion.

9.2. Either Party may terminate this Agreement by written notice, if the other Party breaches this Agreement in any material manner and has failed to remedy such default within thirty (30) days after written notice thereof by the terminating Party.

9.3. AO Foundation may terminate this Agreement by written notice in the cases set forth hereinafter provided that Contractor has failed to remedy such situations within thirty (30) days after written notice thereof by AO Foundation:

9.3.1 if the potential to use the results of the Project diminishes in AO Foundation’s judgment to a considerable extent;

9.3.2 if Contractor has not performed his contractual obligations fully and/or in a timely manner;

9.3.3 if Principal Investigator leave/s Contractor by taking the Project with them/him;

9.3.4 if Principal Investigator leave/s Contractor by leaving the Project with the Contractor and Contractor fails to nominate a new Principal Investigator with appropriate qualification within due time or if the new Principal Investigator is/are not acceptable for AO Foundation for any reason;

9.3.5 if in AO Foundation's judgment a change of control over Contractor or a change of the individual investigator(s) assigned to the Project is likely to adversely affect the Project or the interests of AO Foundation. Contractor shall give prior written notice of any change of control to AO Foundation; in the absence of such notice AO Foundation is entitled to terminate this Agreement irrespective of the effects of the change of control on the Projects or the interests of AO Foundation. For the purposes of this Agreement the term "change of control" means:

9.3.5.1 The sale or other transfer to a person or legal entity (including affiliates) of a controlling interest in the ownership of the business that includes a majority of all tangible and intangible assets of Contractor. "Controlling interest" shall mean an effective majority, directly or indirectly, of either the voting rights or value of the shares (or other evidence of ownership) and shall include direct and indirect ownership.

9.3.5.2 The sale or other transfer to a person or legal entity (including affiliates) of all or substantially all of the tangible and intangible assets.

9.4. In the event of a termination of this Agreement pursuant Article 9.2 or 9.3, the obligations of AO Foundation under Article 3 shall cease with immediate effect, and any sums paid by AO Foundation but not used by Contractor up to such date shall be returned to AO Foundation. AO Foundation shall be entitled to request appropriate compensation in the event that no results nor Knowledge has resulted from the so far performed Project. In addition, Contractor shall immediately deliver to AO Foundation all reports pursuant to Article 4.2 – finalized and/or in draft form only – and other documentation, if any, related to the Project.

9.5. The provisions of Article 6 to 9 shall survive the termination of this Agreement for a period of three years.

# Article 10 – Liability and Indemnity

10.1. Contractor shall indemnify, defend and hold AO Foundation harmless against any and all liabilities, claims (including without limitation threatened claims), damages, losses, costs and expenses, including attorneys’ fees and expenses, experts’ fees and expenses and arbitrators' and the arbitration organization's fees and expenses (collectively, "Claims"), incurred by AO Foundation, resulting

* from negligence, bad faith, wilful misconduct or failure to perform obligations as set forth in this Agreement, on the part of Contractor.

10.2. Contractor shall not be liable to indemnify AO Foundation to the extent that Claims arise out of bad faith or wilful misconduct by AO Foundation’s execution of its obligations under this Agreement.

10.3. AO Foundation shall in no event be liable to indemnify and hold Contractor harmless against any claims asserted against Contractor resulting from the carrying out of the Project by Contractor.

# Article 11 – General Terms

11.1. Notwithstanding Article 5, Contractor shall not be entitled to assign or otherwise transfer its rights and obligations under this Agreement in whole or in part to any third party without the prior written consent of AO Foundation.

11.2. This Agreement together with its Annex sets forth the entire agreement between the Parties and supersedes all previous agreements regarding the subject matter hereof. This Agreement may be amended only in writing.

11.3. If any provision of this Agreement should be found to be invalid or unenforceable, the invalidity or unenforceability of such provision shall not affect the other provisions of this Agreement, and all provisions not affected shall remain in full force and effect. The Parties agree to attempt to replace the invalid or unenforceable provision taking into account the sense and the objectives of this Agreement.

11.4. The Parties are acting as independent parties hereunder and not as employees nor agents or Subcontractors of the other Party.

11.5. Neither Party shall be liable for delay or failure to perform hereunder due to Force Majeure, provided such Party promptly gives the other Party written notice claiming Force Majeure and uses its best efforts to eliminate the effect of such Force Majeure. Force Majeure means any unforeseeable and insurmountable event beyond the reasonable control of the Party affected thereby. If the period of delay or failure extends for more than three (3) months, either Party shall have the right to terminate this Agreement upon written notice at any time after expiration of said three (3) month period.

11.6. This Agreement shall exclusively be governed by, and construed in accordance with, the substantive laws of Switzerland.

11.7. Exclusive place of jurisdiction shall be Zurich, Switzerland..

11.8. All notices (“Notices”) to the Parties pursuant to this Agreement, other than regular business correspondence, shall be sent in writing by registered letter (return receipt requested) or international courier to the addresses of the Parties as indicated below or to another address indicated in writing by the Party in question. The 'Date of Notice' shall be the date of delivery indicated on the registered mail receipt.

**To AO Foundation**

AO Foundation

Niccole Germscheid

Research Manager AO Spine

Clavadelerstrasse 8

7270 Davos Platz

In case of legal and intellectual property aspects with copy to:

AO Foundation

Heiner Lehmann, General Counsel

Clavadelerstrasse 8

CH-7270 Davos Platz

**To Contractor**

insert name of PI

insert address

insert address

In Witness Whereof, the Parties hereto have caused this Agreement to be executed in duplicate by their duly authorized representatives.

|  |  |
| --- | --- |
| **AO Foundation** |  |
| Place and Date | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Claas AlbersExecutive Director AO FoundationInnovation Translation | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |
| Niccole GermscheidHead of Network Clinical ResearchResearch Manager AO Spine | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Contractor** |  |
| Place and Date | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| name and function of authorized representative | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| name and function of authorized representative | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| acknowledged byplease insert namePrincipal Investigator | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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**Annex I:** Description of the Project (Full Proposal)