This template should be adapted to reflect the specific requirements of the research project.

The text in red and the swissethics logo must be removed before the clinical study agreement is executed.

CLINICAL STUDY AGREEMENT

THIS Agreement is made this ….. day of ……, 201. ,between (University Hospital) …….. (Site"), and (Company Name), (Company's address) ("Sponsor"), to conduct a clinical study ("Study")……..I and Sponsor agree as follows:

1. PROTOCOL

1.1 Site agrees to use its good faith efforts to conduct the Study as an independent contractor, in accordance with site policy, applicable laws and regulations and the Protocol/Project (#) , "(Study title) " ("Protocol"). The Study will be supervised by (name of Principal Investigator) ("Principal Investigator") at Site with assistance from associates and colleagues as required.

1.2 Sponsor agrees to engage the services of Site to conduct the Study and further agrees to provide at no cost to Site the (drug, materials, or equipment) ("Study Material") for the conduct of the Study.

2. AWARD

In consideration for performance of the Study by Site, Sponsor shall pay Site a total amount of CHF …… (plus applicable VAT) for Study expenses for the clinical study of approximately ……(number)….. patients and other related costs to the following Site account:

Address: ……

Bank: ……

Account Number.: ……

Subaccount: ……

Swift: ……

IBAN: CH……

VAT Number: ……

This total amount, shown by approximate category of expense in Exhibit A, is payable in ….(number)…. installments of CHF ……. each by Sponsor to Site. The first installment is an initiation fee and is payable within thirty (30) days of the date set forth above, and subsequent installments are payable on a quarterly basis upon receipt by Sponsor of interim case reports for: (a) one- third (1/3) of the final patient enrollment; (b) two-thirds (2/3) of the

final patient enrollment; and (c) the remaining patient enrollment and Study close out, or as otherwise agreed upon by both parties and as set forth in Exhibit A.

SPONSOR will reimburse the fees for the ethics committee in the amount of CHF ….

In addition, SPONSOR shall reimburse Site for all costs arising out of inspections and audits by the officials of competent authorities, including but not limited to American regulatory authorities.

3. TERM

3.1 This Agreement shall continue in force until the earlier of completion of the Study as mutually agreed upon by the parties , or (number) (#) month(s) from the date set forth above; provided, however that either party may terminate the Agreement by giving sixty (60) days advance written notice to the other.

3.2 Upon early termination of this Agreement, Sponsor shall be liable for all reasonable costs incurred or obligated by Site at the time of such termination, subject to the total amount specified in Article 2. Sponsor shall pay Site for such costs within thirty (30) days of receipt of an invoice for same.

3.3 Upon termination of this Agreement and upon request by Sponsor, Site shall return unused Study Material to Sponsor.

3.4 Expiration or termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination. Upon expiration or termination of this Agreement, the obligations which by their nature are intended to survive expiration or termination of the Agreement, shall survive.

4. INDEMNIFICATION

4.1 Sponsor shall indemnify and hold harmless Site, its regents, officers, agents, employees and all Study personnel from any liability or loss resulting from judgments or claims against them arising out of the activities to be carried out pursuant to the obligations of this Agreement, including but not limited to the use by Sponsor of the results of the Study; provided, however, that Sponsor shall not hold Site harmless from liability resulting from wilful misconduct or gross negligence of Site, its agents, or employees.

4.2 Not in any limitation of the foregoing provisions, Sponsor will reimburse the costs of extra unanticipated tests, treatments, and hospitalizations of patients required as a result of adverse events which have resulted from the Study Material dispensed or administered properly and in accordance with the Protocol.

4.3 Sponsor shall secure and maintain in full force and effect through the performance of the Study (and following termination of the Study to cover any claims arising from the Study) insurance coverage or in some other matter (……) for general liability in amounts appropriate to the conduct of Sponsor's business activities and the scope of the Study.

4.4 If Sponsor has its place of business outside Switzerland, Sponsor has to designate an agent within Switzerland (Art. 2 c KlinV) to whom subjects shall be able to assert their claim.

5. PUBLICATION AND CONFIDENTIALITY

5.1 If the Study has been designed as a single-center Study, Site shall have the right, consistent with academic standards, to publish or present the results of its work performed pursuant to the Study, provided that any proposed publication or presentation (collectively, "Proposed Publication") is first reviewed by Sponsor in accordance with Section 5.4.

5.2 If the Study has been designed as a multicenter Study, Site acknowledges that, due to the limited patient population in its treatment group, the data generated from its individual participation in the Study and evaluation of its individual results, may not be sufficient from which to draw any meaningful scientific conclusions. For these reasons, except as provided below, Site agrees not to individually publish or present the results it obtains from Site's participation in the multicenter Study. Site may, however, upon written notice to Sponsor participate in a joint, multicenter publication of the Study results with other third party principal investigators and/or institutions, provided that the Proposed Publication is first reviewed by Sponsor in accordance with Section 5.4. In the event that the multicenter publication has not been completed within one (1) year from the date of the completion or termination of the Study, then notwithstanding the foregoing, Site may individually publish a Proposed Publication regarding its individual results from the Study, provided that the Proposed Publication is first reviewed by Sponsor in accordance with Section 5.4.

5.3 Each party shall hold in confidence for three (3) years after the termination of this Agreement any confidential information identified as confidential and obtained from the other party during the course of this Study ("Confidential Information"). Nothing herein, however, shall prevent Site from using any information generated hereunder for ordinary research and educational purposes of a university. Confidential Information may be disclosed to the extent required by law and for purposes of subject care.

5.4 Sponsor shall complete its review within sixty (60) days after receipt of any Proposed Publication (individual or multicenter) from Site. If Sponsor believes that any Proposed Publication contains any information relating to patentable items, the disclosure of such Proposed Publication to any third party shall be delayed for up to ninety (90) days to permit the filing of a patent application. Should Sponsor request such a delay, then upon the written request of Site, Sponsor shall use its best efforts consistent with reasonable business and scientific practice to do all things which it believes would expedite the filing of such patent application. However, if at the end of such ninety (90) day period, despite the use of diligent efforts on the part of Sponsor, additional time is necessary or required in order to complete the filing of a patent application, Sponsor may request, and Site shall not unreasonably refuse, an extension of the period of time within which to file the patent application not to exceed an additional ninety (90) days. If Sponsor believes that any Proposed Publication contains any Confidential Information of Sponsor, Sponsor shall so notify Site, and Site shall delete such Confidential Information, but the parties will use their best efforts to provide scientifically meaningful equivalent information for such deleted Confidential Information.

5.5 The parties agree that Site's use and disclosure of patient health and medical information is subject to compliance with applicable state and federal data privacy laws. The parties, therefore, agree to take all reasonable steps to protect the confidentiality of any patient health and medical information that they have access to and to comply with applicable laws.

5.6 Sponsor agrees i) not to distribute any patient material transferred by Site to Sponsor in the course of the Study to any third party without prior written consent from Site, ii) to use the material solely for investigating safety and efficacy of the Study Drug as foreseen in the Protocol and not for other investigations, iii) to use the material in accordance with patient consent and all applicable data privacy laws and iv) to return any remaining material to Site immediately after these investigations have been performed. Sponsor will secure that if a patient withdraws his or her consent to participate in the Study any patient material of such patient which is in Sponsor's possession is immediately destroyed and not longer used in the Study.

6. INTELLECTUAL PROPERTY

6.1 All rights to any invention conceived and reduced to practice in the direct performance of the Study and pertaining to the indications contemplated by the Protocol, shall belong to Sponsor. Site agrees to assign to Sponsor, at the request of Sponsor, the sole and exclusive ownership thereto.

6.2 All rights to inventions and discoveries arising from research conducted under this Agreement, other than as provided for above ("Other Inventions"), shall belong to Site and shall be disposed of in accordance with site policies. To the extent that Sponsor pays all costs associated with filing, prosecution, issuance and maintenance of patents related thereto, Sponsor is hereby granted the right to negotiate an exclusive, world-wide, royalty-bearing license to any Other Inventions conceived and reduced to practice during the course of the Study or conceived during the Study and reduced to practice within six (6) months thereafter. Such license shall contain reasonable terms and royalties and shall require diligent pursuit by Sponsor of the commercial development of such Other Inventions.

6.3 Site shall promptly disclose to Sponsor on a confidential basis any invention arising under this Agreement, and Sponsor shall advise Site in writing within ninety (90) days after disclosure to Sponsor whether it wishes to secure a commercial license to any Other Invention. If Sponsor elects not to secure such a license, rights to such Other Invention shall be disposed of in accordance with site policies, with no further obligation to Sponsor.

7. GENERAL

7.1 This Agreement, including the attached Exhibit A, constitutes the entire and only Agreement between the parties relating to the Study, and all prior negotiations, representations, agreements, and understandings are superseded hereby. No agreements altering or supplementing the terms may be made except by a written document signed by the duly authorized representatives of the parties.

7.2 Any conflicts between the Protocol and this Agreement are controlled by this Agreement.

7.3 This Agreement shall be governed by, and construed in accordance with, the laws of Switzerland, without giving effect to its conflict of law provisions. Exclusive place of jurisdiction shall be …….. (Switzerland).

SITE

Date: _____ Date: _____

By _____ By _____
Prof.

I have read this Agreement and understand the obligations hereunder.

By _____
(Principal Investigator)

SPONSOR

Date: _____

By _____
Title:

By _____
Title:

Exhibit A: Budget