INSELSPITAL
UNIVERSITÄTSSPITAL BERN
HOPITAL UNIVERSITAIRE DE BERNE
BERN UNIVERSITY HOSPITAL

To whom it may concern:

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Minimum requirements for contracts of sponsored clinical trials at Inselspital Bern

The following regulations apply to clinical trial agreements (CTAs) for interventional clinical trials entered into by Inselspital Bern with an external Sponsor. **These conditions are mandatory and non-negotiable.**

1. Contractor / Preamble
   - The "Foundation Inselspital" (or: “Inselspital-Stiftung”, if German) has to be named as the formal contract partner for all sponsored clinical trials at the University Hospital / Inselspital Bern. The contract party to be named on the first page is **Foundation Inselspital,** (optional: **represented by <principal investigator>**), **<address of the clinic>, 3010 Bern (hereinafter "Insel”)**. The principal investigator must not be listed as a separate party.
   - The contract should be entered into directly with the Sponsor because of the legal and contractual duties and obligations assigned to the Sponsor (e.g. responsibility for study medication and/or study device). Where the contract partner is a CRO (Clinical Research Organisation), either of the following options are mandatory:
     - **CRO** and **Inselspital** sign the CTA. In addition, the Sponsor and Inselspital have to sign a separate agreement specifying the obligations of the Sponsor (Letter of Indemnification) wherein the Sponsor fully acknowledges and assumes all sponsor-specific obligations (e.g. liability, insurance, indemnification)
     - **CRO**, **Sponsor** and **Inselspital** sign a three-party CTA
     - **CRO** and **Inselspital** sign the CTA. CRO explicitly assumes all obligations of the Sponsor in addition to its own ones (including liability, insurance, indemnification)

     Power of attorney documents of the Sponsor authorizing the CRO will not be accepted as evidence for the assumption of obligations by the Sponsor. Signing of contracts by the CRO *"...on behalf of the Sponsor..."* is not possible.

2. Performance of Inselspital / protocol
   - The duties of the Inselspital and the principal investigator shall be briefly described and reference shall be made to the protocol (however, the protocol is usually not needed for review of the agreement).

3. Payments
   - The contract shall contain the approximate enrolment goals and the financial details. The agreement must contain a statement that either the Sponsor or the CRO shall have the obligation to pay the entire amount in due time for the performance of the clinical trial. The financial details may be directly integrated into the main agreement or attached by a separate annex thereto.
   - The contract must indicate the payment account at the Inselspital.
   - The principal investigator is responsible for the budget and payment terms.
   - In the event of an early termination of a CTA, Sponsor or CRO shall be liable for all reasonable costs incurred or obligated by the Inselspital at the time of such termination, subject to the total amount specified.

4. Indemnification / Insurance / Liability

   This part of the contract is of particular importance!

   - The Sponsor of a clinical trial will be held liable for all damages caused by Inselspital’s performance of the clinical trial.

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- Inselspital will request that Sponsor indemnifies and holds harmless Inselspital, except in case of gross negligence or willful misconduct or a material breach of the contract, the protocol or relevant statutory provisions.
- If Sponsor has its place of business outside Switzerland, according to Swiss law (Ordinance on Clinical Trials in Human Research KlinV § 2 [lit . c] , September 20 , 2013, SR 810 305) Sponsor has to designate an agent within Switzerland to whom, among other obligations, subjects shall be able to assert their claim.
- The contract further must include an obligation of Sponsor to maintain appropriate damage coverage for the study (e.g. through insurance).

5. Publication and Confidentiality
   - Inselspital reserves the right to publish the results of a clinical study, regardless of its outcome. Veto clauses such as *"...publication only with the written consent of the Sponsor..."* will not be accepted. However, the Sponsor will have the right to review and delay the publication (usually 30 days, extendable to 90 days in case of protection of intellectual property) to protect its intellectual property if necessary.
   - In the case of multicenter studies, Inselspital accepts that the first publication shall be a multicenter publication. In the event that the multicenter publication will not have been completed within one (1) year from the date of the completion or termination of the study, then Inselspital reserves the right to individually publish its results.

6. Privacy
   - Inselspital, the Sponsor and the CRO must comply with the data protection laws applicable in Switzerland.

7. Applicable laws
   - In the conduct of the study, Inselspital adheres exclusively to laws and regulations if and to the extent applicable in Switzerland.

8. Intellectual Property
   - In sponsored studies, inventions conceived in the direct performance of the study and pertaining to the indications contemplated by the protocol, are usually transferred to Sponsor.

9. General
   - If the protocol contains provisions concerning publications, protection of intellectual property, financial details etc., these provisions must also be included in the contract. In cases of doubt, the protocol must be submitted for contract review. The CTA has to set forth that in case of disputes between the CTA and the protocol, the CTA will prevail.
   - All CTAs must be governed by the laws of Switzerland, without giving effect to its conflict of law provisions. Exclusive place of jurisdiction must be Switzerland (usually Bern).

10. Signatures
    - All CTAs will be signed for the Inselspital by the Director Teaching and Research and a physician in accordance with the current list of “PAT-Vertragsärzte/-ärztinnen” (PAT = “privatärztliche Tätigkeit”). The principal investigator (if not identical with the “PAT-Vertragsarzt/-ärztin”) acknowledges the contract by co-signature.

Prof. Dr. med. Matthias Gugger

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