

ZOL GUIDELINES FOR STUDY CONTRACTS

In an attempt to avoid double work and long timelines, we want to inform you that all study contracts must take into account the following guidelines and include the following boilerplates, please verify in advance if your study contract meets these requirements and modify in advance in order to comply with these requirements.

1. HOSPITAL/INSTITUTION IDENTIFICATION

ZIEKENHUIS OOST-LIMBURG AUTONOME VERZORGINGSINSTELLING, association of public law subject to the provisions of part 3, title 4, chapter 3 of the Decree on Local Governance, with registered office at Schiepse Bos 6, B-3600 Genk, Belgium and registered with the Crossroads Bank for Enterprises under number 0256.543.917, with VAT number BE0256.543.917, Legal Entities Register business court of Antwerp, division Tongeren, lawfully represented by Mr. Tom Arts, chairman, Mr. Erwin Bormans, general director, and Dr. Griet Vander Velpen, medical director.

2. PRINCIPAL INVESTIGATOR IDENTIFICATION

In ZOL, the physicians are independent, are solely responsible for their own obligations and therefore should be party to the agreement. In ZOL, the physicians very often have submit their professional activities in a company in which case the company should be party to the agreement.

Some medical specialities set up a common company for the executing of studies. In such case, both the physician or his/her company and the common company should be party to the agreement and are jointly indicated as PRINCIPAL INVESTIGATOR.

Please note that in this study contract, the PRINCIPAL INVESTIGATOR can be indicated as natural person, legal entity or association

... to be completed by the PI / study team member

3. INDEPENDENCE OF PRINCIPAL INVESTIGATOR

Solely the PRINCIPAL INVESTIGATOR (and not ZOL) is responsible (i) for the conduct and supervision of the study, (ii) for health and welfare of eligible patients, (iii) for the enrollment of study patients, (iv) to obtain the necessary written consents, (v) for the medical follow up and to report adverse effects and (vi) the completion of all study data.

The following clause should mandatory be included in the agreement:

The PRINCIPAL INVESTIGATOR is an independent Medical physician and not an employee of INSTITUTION and entered into this agreement in the capacity of independent contractor. Therefore, INSTITUTION cannot be held liable for any act, faults or omissions caused by the PRINCIPAL INVESTIGATOR nor can the PRINCIPAL INVESTIGATOR be held liable for any act, faults or omissions caused by INSTITUTION. PRINCIPAL INVESTIGATOR nor INSTITUTION may incur any liability on each other's behalf nor bind the other Party to any obligations without the prior written consent of the other Party.

4. SCOPE OF BELGIAN LAW OF MAY 7, 2004 CONCERNING EXPERIMENTS ON THE HUMAN PERSON

The Belgian law of May 7, 2004 concerning experiments on the human person is a mandatory law. The law is only not applicable on non-interventional retrospective studies in which the past is studied on the basis of information that is already available at the start of the study. Only involved are retrospective studies in which the patient is contacted in the context of the study and the data are collected on the hand of either the patient's medical records, or surveys of the therapeutic team or third party on medical data of patients or on the hand of other administrative sources in the rare circuits.

As soon as the patient is specially contacted in the context of an investigation, even if it is retrospective, then the search is interventional and the law is applicable.

In case the law is applicable, please add the following mandatory clauses on liability and insurance:

In accordance with the Belgian Law relating to experiments on the human person dated 07 May 2004, the SPONSOR shall assume, even without fault, the responsibility of any damage incurred by a Study Patient or, in the case of death, his rightful claimants sustained that arises either in direct or indirect connection with the experiments and shall provide compensation therefore. The SPONSOR shall enter into an insurance contract in accordance with article 29 of the Belgian Law relating to experiments on the human person dated 07 May 2004.

5. CONFIDENTIALITY CLAUSE

The confidential clause should be reciprocal. Confidential is:

- all information received by the SPONSOR from the INSTITUTION or PRINCIPAL INVESTIGATOR, including but not limited to proprietary information, trade secret, unpublished data, know-how;
- all information received by the INSTITUTION and/or PRINCIPAL INVESTIGATOR from the SPONSOR, including but not limited to proprietary information, trade secret, unpublished data, know-how;
- all data, databases, documents, reports and other information developed with respect to the SPONSOR or in the performance of or as a result of the Study by the SPONSOR, the INSTITUTION or PRINCIPAL INVESTIGATOR or their respective employees, agents, subcontractors or participants.

6. INTELLECTUAL PROPERTY

All Intellectual Property Rights owned by or licensed to the INSTITUTION and/or PRINCIPAL INVESTIGATOR prior to and after the date of this Agreement other than any Intellectual Property Rights arising from or relating to the Study shall be and remain the property of the INSTITUTION and/or PRINCIPAL INVESTIGATOR.

7. PROTOCOL

In case of a conflict between this agreement and the protocol, the protocol takes precedence in matters of medicine, science and conduct of the study. This agreement takes precedence in any other conflict (such as but not limited to the relationship between INSTITUTION and PRINCIPAL INVESTIGATOR and their respective duties.

8. APPLICABLE LAW AND DISPUTE SETTLEMENT

The agreement shall be construed and interpreted in accordance with the laws of Belgium, without taken into account its conflict-of-law rules.

In the event of any disputes, controversies or claims arising from or in connection with this Agreement or the breach thereof, the Parties shall try to settle this issue amicably between themselves. Should the Parties so fail within sixty (60) days from the first notice of such dispute, controversy or claim, same shall be finally settled by the courts of the judicial district Antwerp, division Tongeren.