Guidelines for the Clinical Trial Agreement (CTA)

It is essential for our hospital to draw up contracts in a clear and effective manner. These guidelines are intended to provide a structured framework for drafting contracts. By adhering to these guidelines, we aim to ensure transparency, accuracy and legal compliance in all our contractual commitments, while simultaneously striving for constructive collaboration and achieving optimal outcomes for our patients and stakeholders.

1. **The Legal part**

- Multiparty Agreement:

The physicians at our hospital are self-employed medical doctors and not employees of the Institution. Neither the (Co-)Investigator(s) nor the 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. The agreement should explicitly state its multiparty nature, outlining the obligations of each party.

- Clarification of roles:

It is crucial to make a clear distinction between the roles of the Investigator, the Co-Investigator(s) and the Institution.

In concrete, the parties to the Agreement are described as follows:

Clinical trial agreement

between
Jan Yperman Ziekenhuis vzw, Briekestraat 12, 8900 Ieper, Belgium
Duly represented by Frederik Chanterie, CEO, by Maarten Crappé, CFO and by Dr. Hans Feys, CMO (VAT number: BE0462.915.078)
hereinafter referred to as the "INSTITUTION"

and

Dr. [to complete], [Title], representative of [association or legal entity], with legal office located at [Briekestraat 12 if applicable], 8900 Ieper, Belgium

hereinafter referred to as the "PRINCIPAL INVESTIGATOR"

and *If (a) supporting service(s) cooperate(s)*

Dr. [to complete], [Title], representative of [association or legal entity] with legal office located at [Briekestraat 12 if applicable], 8900 Ieper, Belgium

hereinafter referred to as the "Co-INVESTIGATOR"

and

Sponsor and/or CRO, or Academic Center, with their full address

The INSTITUTION, the PRINCIPAL INVESTIGATOR and the CO-INVESTIGATOR(s) are hereinafter collectively referred to as the "JYZ Parties".

The INSTITUTION, THE PRINCIPAL INVESTIGATOR and the CO-INVESTIGATOR(s) and the SPONSOR are hereinafter individually referred to as "Party" and collectively referred to as the "Parties".

2. The Financial part

Please find our requirements regarding financial negotiations listed below:

- The Principal Investigator, all cooperating Co-Investigators and the Institution are each described in a separate appendix.
- Each appendix describes the activity(ies) the party carries out for the clinical trial, with the corresponding compensation(s).
- If applicable, a clear distinction is made between activities that are part of standard care and those that are carried out specifically for the clinical trial.
- All amounts stated in the contract are exclusive of VAT. This will be added during invoicing.
- A minimum overhead rate of 15% must be applied to the budgets to which it applies.
- The invoicing address of the sponsor/CRO with their VAT number (except for USA).
- Delivery address, preferably an email address, if different from the invoicing address.
- The bank details of the Principal Investigator, all supporting services and the Institution. Ask our overview with the bank details of the participating parties of the clinical trial.

Invoices are issued separately by the Investigator, the supporting services and the Institution for their services provided under the clinical trial agreement. The institution issues invoices for the pharmacy and the Institution itself.

3. Contact person

Within the framework of these guidelines, our study nurses remain the point of contact for any questions or requests for information regarding the practical conduct of the clinical trial.

We extend our sincere gratitude for complying with our guidelines. Your commitment to following these guidelines is greatly appreciated and contributes significantly to our collective efforts in maintaining standards of excellence.

Thank you for your cooperation and dedication.

Sincerely

Clinical Trial Department

Florence Havegheer
Study nurse and main point of contact for CTA and budget negotiations

Jan Yperman Ziekenhuis
Route 98
Out of office on Wednesday
+ 32 57 35 72 97