

Instructions for confidential disclosure agreements

Dear,

May we please ask you to follow the below instructions for confidential disclosure agreements

1. Regarding the content

a. The CDA should be

a two-party agreement, including you as a sponsor and the investigator as a self-employed physician with a place of business at the institution

OR

a tri-partite agreement, including you as a sponsor, AZ Sint-Jan Brugge-Oostende AV (institution) and the investigator as a self-employed physician with a place of business at the institution

b. Please note that it is hospital policy to integrate the following paragraph regarding law and venue

“All issues, questions and disputes concerning the validity, interpretation, enforcement, performance or termination of this Agreement, and any non-contractual obligations arising out of or in connection with it, shall be governed by and construed in accordance with Belgian law, excluding its conflicts of law provisions.

The Parties shall attempt to settle all disputes arising out of or in connection with the present Agreement in an amicable way. Any dispute concerning the validity, interpretation, enforcement, performance or termination of this Agreement, and any non-contractual obligations arising out of or in connection with it, shall be submitted to the exclusive jurisdiction of the Courts of Brugge or the Brugge division of such Courts.”

2. All parties must sign the agreement.

- In case of the two-party agreement, the PI signs for his own responsibilities. CDA review through the clinical trial center is not obliged.
- In case of the tri-partite agreement, CTC review is obliged. Please submit your CDA for legal review to ctc@azsintjan.be.

Please take into account that the hospital always signs “wet-ink”. The sponsor may sign with a validated electronic signature (cfr. DocuSign; GCP/FDA part 11 compliant). Scanned signatures are not allowed.

We thank you in advance for your kind cooperation,

Kind regards

Clinical Trial Center