**Part 1: Financial Disclosure Commitment**

Name of the investigator:

Name of the registrant (if other than principal investigator):

Name of the Sponsor:

Commercial company responsible for the funding of the study or any of its elements (if not the sponsor):

Study title:

Protocol number / Acronym:

This document is used to report the financial conflicts of interest, in relation to the sponsor or any organization linked to the sponsor, of the principal investigator as well as the co-investigators and any member of the research team. It will also be used to report any modification concerning them during the course of the medical experiment and up to one year after its end. This declaration concerns the conflicts of interest of the person completing it as well as those of his/her spouse/legal cohabitant or dependent children.

As the principal investigator, you are required to complete this declaration form prior to the start of the study (initial submission), as well as the Conflict of Interest Research Team form (AARHPP-FORM-037) certifying that no conflict of interest exists with respect to the co-investigator(s) or research team member(s), their spouse or legal cohabitant(s), or dependent children.

This declaration form must also be completed when there is a change in the initially declared financial status of the principal investigator or any other member of the research team. It should be sent to the sponsor and the CEHF, preferably within 30 days. If the CEHF is not involved (CTR/MDR/IVDR[[1]](#footnote-1)), the document will be sent to the Medical Direction of CUSL via the CTC "Contracts-Finance" referent.

Once a year, you must reassess the absence of conflicts of interest for yourself and your research team and inform the sponsor as well as either the CEHF or the Medical Direction (via the CTC "Contracts-Finance" referent) if a conflict of interest must be declared.

It is also your duty to inform all co-investigators and research team members of their obligation to complete this declaration in the event of a potential or actual financial conflict of interest. This information will also be given to any co-investigators and research team members added during the course of the study.

Any funding from the sponsor to an investigator or member of the research team and to the institution must also be declared.

Blank declaration forms can be printed and copied for investigators, co-investigators and research team members. Additional copies are also available through the PaCo document management software.

**Part 2: Financial Disclosure by the principal investigator, sub-investigator or research team member**

Please complete all of the information below and retain a copy of this form for your records.

If you are not the principal investigator, **complete this document only if you have a financial disclosure to declare**.

|  |  |  |
| --- | --- | --- |
| 1. Study name: | | |
| 2. Protocol number: | | |
| 3.  Investigator  Sub-investigators  Other study team member (specify role) : | | |
| 4. Investigator/sub-investigator/Study team member Name:  Institution Name: CLINIQUES UNIVERSITAIRES SAINT-LUC | | |
| 5. Institution Address: Av Hippocrate 10 - 1200 Brussels | | |
| 6. Telephone: | | 7. Fax: |
| 8. Indicate by marking YES or NO if any of the financial interests of arrangements with the Sponsor and/or its affiliates (described below) apply to you, your spouse/legal cohabitant, or dependent children: | | |
| Yes  No | Financial arrangements whereby the value of the compensation could be influenced by the outcome of the study. This could include, for example, compensation that is explicitly greater for a favourable outcome or compensation to the investigator in the form of any equity interest in the Sponsor or in the form of compensation tied to sales of the product, such as royalty interest.  If yes, please describe : | |
| Yes  No | Significant payments of other sorts, excluding the costs of conducting the study or other clinical studies, that have a monetary value of more than 25,000€ ($25 000). This could include, for example, payments made to the investigator or Institution to support activities of the investigator (included grant to fund ongoing research, compensation in form of equipment, retainers for ongoing consultation or honoraria).  If yes, please describe : | |
| Yes  No | A proprietary or financial interest in the test product such as a patent, trademark, copyright or licensing agreement. If yes, please describe : | |
| Yes  No | A significant equity interest owned by you, your spouse/legal cohabitant or dependent children in Sponsor of the study and/or its affiliates. This would include, for example, any ownership interests, stock options, or other financial interest whose value cannot be easily determined through reference to public prices, or an equity interest in a publicly traded sponsor company that exceeds 50 000€ ($50 000).  If yes, please describe : | |
| *Only for Principal Investigator*  I hereby certify that none of the financial interests or arrangements listed above exists for my spouse/legal cohabitant, my dependent children, or myself. | | |
| I declare that the information provided in this document is true, correct and complete to the best of my knowledge. I will inform the sponsor, the Ethics Committee or the Medical Direction of CUSL and the Clinical Trial Center as soon as possible of any change in my financial situation, as well as that of my spouse/legal guardian or dependent children during the trial and up to one year after the end of the trial.  I declare that I have read and understood the information provided on the “Anti-corruption laws” document (AAHRPP-DSQ-058) attached to this form. | | |
| 9. Signature: | | 10. Date: |

1. CTR : Clinical Trial Regulation : clinical drug trial under European regulation 536/2014

   MDR : Medical Device Regulation : clinical investigation with medical device under European regulation 2017/745

   IVDR : In Vitro Diagnostic Regulation : performance study with in vitro diagnostic device under European regulation 2017/746 [↑](#footnote-ref-1)