**Financial Disclosure Form by Clinical Investigators**

**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:

The principal investigator, sub-investigators and any member of the research team must declare their financial conflicts of interest in relation to the sponsor or any organization linked to the sponsor, as well as any changes in these conflicts of interest during the course of the medical experiment and up to one year after its completion.

This declaration concerns conflicts of interest specific to the person completing it as well as those of his/her spouse/legal cohabitant or dependent children. Similarly, any funding from the sponsor to an investigator or member of the research team and to the institution must be declared.

The Conflict of Interest Declaration form for investigators and research team members is included in Part 2 of this document.

As the principal investigator, you are required to complete this declaration form prior to the start of the study, as well as the Conflict of Interest Research Team form (029-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.

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.

This declaration form must also be completed and submitted to the Ethics Committee and the study sponsor whenever there is a change in the financial status initially declared, preferably within 30 days.

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.

**Financial Disclosure by Clinical Investigators**

**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 (role : ……….) | | |
| 4. Investigator/sub-investigator/Study team member Name:  Institution Name: | | |
| 5. Institution Address: | | |
| 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: | | |
|  | 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 : | |
|  | Significant payments of other sorts, excluding the costs of conducting the study or other clinical studies, that have a monetary value of more than €20,000. 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 : | |
|  | A proprietary or financial interest in the test product such as a patent, trademark, copyright or licensing agreement. If yes, please describe : | |
|  | 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 €40,000.  If yes, please describe : | |
| *Only for Principal Investigator*  I hereby certify that none of the financial interests or arrangements listed above exists for myself, my spouse/legal cohabitant, or my dependent children. | | |
| I declare that the information provided on this form is, to the best of my knowledge and belief, true, correct and complete. Furthermore, if my financial interests and arrangements, or those of my spouse/legal cohabitant and dependent children, change from the information provided above during the course of the study or within one year after the last patient has completed the study as specified in the protocol, I will notify Sponsor, Ethics Committee and Clinical trial center promptly.  I declare that I have read and understood the information provided on the “anti-corruption law” document which is attached to this form. | | |
| 9. Signature: | | 10. Date: |