

Please read before filling out this form:

FDA regulations require the clinical investigator to provide sufficient and accurate financial information to the sponsor to allow the sponsor to submit complete and accurate certification or disclosure statements under 21 CFR 54.4 (b). However, FDA regulations do not prescribe a particular method for collecting financial information from *investigators*.

This document is for Investigator use only and should only be used to track financial disclosures in order to provide documentation to the Sponsor. This form should not be submitted to an IND/IDE.

Please note that an investigator or subinvestigator for the purpose of financial disclosure is defined as individuals who are directly involved in the treatment or evaluation of research subjects, and also includes the financial interests of the **spouse and each dependent child** of that investigator or subinvestigator.

For the purpose of financial disclosure, the “Sponsor” refers to a party supporting a particular study at the time it was carried out. For example, if one entity designed and conducted the clinical study, a second entity provided funding, and a third entity provided the test product, there would be three sponsors of the clinical study. **Fill out a separate financial disclosure form for each entity that could be considered a sponsor for this study.**

For questions, refer to the FDA Guidance: *Financial Disclosure by Clinical Investigators* or contact the Office of Regulatory Affairs and Quality at ORAQ@duke.edu.

Financial Disclosure Form for Investigators

Please complete (print/type) all of the information below and retain a copy of this form for your records.	
1. Protocol Number:	2. Investigational Product:
3. Study Name:	
4. Sponsor of the clinical study:	
5. Principal Investigator (PI) <input type="checkbox"/> or Subinvestigator <input type="checkbox"/>	
6a. Your Name:	
6b. If you are a Subinvestigator, please provide the PI's name:	
7. Business address: 	
8. Affiliated Institution Name (if applicable):	
Indicate by marking YES or NO if any of the financial interests or arrangements (as described below) apply. For each YES , you must provide detailed information disclosing the nature of the financial arrangements in the space provided below. Please note that the threshold amounts described below are cumulative for the investigator, his/her spouse, and dependent children.	
9. YES <input type="checkbox"/>	NO <input type="checkbox"/>
I am a full-time or part-time employee of the Sponsor of this clinical study.	
10. YES <input type="checkbox"/>	NO <input type="checkbox"/>
I have entered into a financial arrangement with the Sponsor of this clinical study, whereby the outcome of the clinical study could affect my compensation, such as a bonus, royalty, or other financial incentive (<i>i.e.</i> , compensation that could be higher for a favorable outcome than for an unfavorable outcome).	
11. YES <input type="checkbox"/>	NO <input type="checkbox"/>
I have received significant payments of other sorts having total value in excess of \$25,000 from the Sponsor, other than payments for conducting this clinical study or other clinical studies. Examples of such significant payments include, but are not limited to, grants or funding for ongoing research, compensation in the form of equipment, retainers for ongoing consultation, and honoraria that are (A) paid directly to me or to the institution with which I am affiliated, and (B) paid in support of my activities (<i>i.e.</i> , payment paid directly or indirectly to me by the Sponsor).	
12. YES <input type="checkbox"/>	NO <input type="checkbox"/>
I have a proprietary or financial interest (<i>e.g.</i> , patent, trademark, copyright, licensing agreement) in the product tested in this clinical study.	
13. YES <input type="checkbox"/>	NO <input type="checkbox"/>
I have an equity interest (<i>e.g.</i> ownership interest, stock options) in the Sponsor, whose value cannot be readily determined through reference to public prices, or equity interest in a publicly held company that exceeds \$50,000, for this clinical study.	
14. For each YES above, you must provide detailed information disclosing the nature of the financial arrangement (if additional space is needed, please attach to this document): 	
Please Indicate Number of Attached Pages:	
With respect to the clinical study for the investigational product referenced above that I am conducting for the Sponsor, I hereby certify to the truth and accuracy of the statements above with the understanding that I am certifying not only for myself as a clinical investigator, <u>but also for my spouse and for each of my dependent children</u> . This certification shall apply throughout the entire term of the clinical study agreement and for one year following completion of the clinical study. If there is any change in the accuracy of the foregoing statements during such time period, I hereby agree that I will promptly notify the Sponsor in writing of such change.	
15. Signature:	16. Date:

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