

**Disclosure of Financial Conflict of Interest**

**Principal Investigator Certification**

All investigators with responsibility for research design, conduct and reporting activities must engage in training on institution-specific policies and federal regulations regarding financial conflicts of interest. Investigators also must disclose to their institution all significant financial interests that would reasonably appear to be related to their Institutional Responsibilities and to their research activities. See [table](http://www.institute2000.org/wp-content/uploads/2013/11/Changes-to-the-1995-Regulations.pdf) to identify what constitutes significant financial interests.

Principal Investigators in the Institute for Family Health use the Principal Investigator Certification form to declare the names of Investigators involved in their project, to affirm that the training has been accomplished and related documents submitted, to affirm that conflict of interest disclosures have been submitted for each Investigator, and to provide basic status information to the Institutional Review Board (IRB).

**Submit completed form to:**

Saskia Shuman: sshuman@institute2000.org or

Nandini Shroff: nshroff@institute2000.org

All five sections of this certification must be completed by the Principal Investigator at the time of application for human subject research to the IRB or at other times as indicated in Institutional policy referenced below.

**1**. **Principal Investigator and Project Identification**

Principal Investigator’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title of Proposal/Project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**2**. **Support/Sponsor Status (Check One)**

A. Is there any funding for this project from any non-IFH source?

[ ]  Yes [ ]  No

If yes, indicate sponsor name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

B. Is the sponsor providing any medication or device at no cost to IFH?

[ ]  Yes [ ]  No [ ]  Not Applicable

C. Will IFH provide the sponsor with study data?

[ ]  Yes [ ]  No [ ]  Not Applicable

D. Are all study-related (non-routine) costs covered by the sponsor?

[ ]  Yes [ ]  No [ ]  Not Applicable

E. Is the sponsor using wire transfer, mailing payment to IFH, or using another method?

[ ]  Yes [ ]  No [ ]  Not Applicable

**3**. **Are there other investigators? (Check either A or B)**

**[ ]** A. No other individuals associated with this project bear responsibility for the design, conduct or reporting of the proposed or on-going research; OR

[ ]  B. In addition to the Principal Investigator, the following individuals (attach additional page if needed) may be responsible for design, conduct or reporting activities. I have confirmed completion of on-line NIH Conflict of Interest training for each Investigator. I have obtained confirmation from the IRB or from each Investigator that s/he has submitted a Disclosure of Significant Financial Interests statement to the IRB administrators via email within the past twelve months, and the Investigator indicates that s/he does not have undisclosed new interests.

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| --- | --- | --- |
| **All Investigators Including Principal Investigator (Name & Role)** | **Training**  | **Disclosure**  |
|  | [ ]  NIH FCOI Online Tutorial | Disclosure for Significant Financial Interests Form[ ]  Attached[ ]  Previously Submitted Date: \_\_\_\_\_\_\_\_\_\_ |
|  | [ ]  NIH FCOI Online Tutorial | Disclosure for Significant Financial Interests Form[ ]  Attached[ ]  Previously Submitted Date: \_\_\_\_\_\_\_\_\_\_ |
|  | [ ]  NIH FCOI Online Tutorial | Disclosure for Significant Financial Interests Form[ ]  Attached[ ]  Previously Submitted Date: \_\_\_\_\_\_\_\_\_\_ |

4. Does any Significant Financial Interest (SFI)—as defined by the regulations—disclosed by you or by any Investigator listed above represent a real or potential conflict of interest with this submission?

[ ]  Yes [ ]  No

If yes, please provide details:

5. **Principal Investigator Certification**

Enter your name in the space below and check yes to complete certification.

Do you certify that you and all Investigators associated with the proposed project have complied with Federal and Institutional requirements for conflict of interest training, and for disclosure of significant financial interests as defined in the referenced policy?

[ ]  Yes [ ]  No

Principal Investigator’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*References: Institutional Review Board Policies and Procedures*