**The Johns Hopkins University School of Medicine**

**Significant Financial Interest Statement for JHU SOM Subrecipients Conducting PHS-Funded Research**

|  |  |
| --- | --- |
| Grantor Name |  |
| Prime Grant Number |  |
| Study Title |  |
| Budget Period |  |
| JHU Principal Investigator |  |
| Subrecipient Name |  |
| Subrecipient Principal Investigator |  |

Under 42 C.F.R. Part 50, Subpart F, institutions carrying out PHS-funded research must maintain an up-to-date, written, enforced policy on financial conflict of interest. In addition, if an institution carries out such research through a subrecipient (*e.g.*, subcontractor or consortium member), the institution must take reasonable steps to ensure that any subrecipient investigator complies with the regulation. The institution must either require that subrecipient investigators comply with the institutional policy or the subrecipient must certify that its policy complies with the regulation.

**This form must be completed by all Subrecipients of PHS-funded research before any sub-agreements/subcontracts are finalized.** The form must be completed by the Subrecipient’s designated institutional official and returned to the Office of Research Administration Subawards Group with the submission of the Subaward paperwork to ORASUBCONTRACTS@jhmi.edu. (Note: Questions about this form should be directed to the Office of Policy Coordination by telephone at 410-516-4732 or by email at [policy@jhmi.edu](mailto:policy@jhmi.edu).)

**1) Does the subrecipient certify that it maintains an up-to-date, written, enforced policy on financial conflict of interest pursuant to 42 C.F.R. 50.604(a)? (Answer “yes” if the subrecipient has registered with the FDP Institutional Clearinghouse as an institution that is in compliance with these regulations.)**

Yes. Subrecipient agrees to submit a Subrecipient FCOI Report to JHU SOM for any investigator determined to have a financial conflict of interest with the Subrecipient’s work for JHU. (See separate form titled “Subrecipient FCOI Report.”) *(Proceed to signatures in Question #3. )*

No. *(Go to Question #2.)*

**2) Subrecipient certifies that it will abide by the JHU School of Medicine (SOM) Disclosure and Professional Commitment Policy (sections A, B(1), C and E) and the JHU Policy on Individual Financial Interests and Financial Conflicts of Interest in Research. In accordance with these policies, subrecipient certifies that it will report to JHU SOM any identified significant financial interests of subrecipient investigators that are directly related to the Subrecipient’s work for JHU. If the JHU SOM determines that a subrecipient investigator’s significant financial interest constitutes a financial conflict of interest, subrecipient will comply with JHU SOM’s management plan to ensure the conflict is managed.**

An investigator means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding, which may include, for example, collaborators or consultants. This definition includes all study team members on PHS-funded IRB applications. This definition is independent of whether one is appointed by or employed by the subrecipient institution.

*Investigators also include the following:*

* *Faculty members, if the subrecipient is an academic institution*
* *Any individual who receives any percent of effort under a PHS sub-award*
* *Graduate students at sub-recipient institutions who participate in PHS-supported research or*
* *Any individual who is responsible for the design, conduct, or reporting of PHS-supported research and exercises enough independence to influence the outcome of said research*

*The final determination regarding who is considered an investigator in PHS-supported research should be made by the PI of the project.*

A subrecipient investigator’s significant financial interest means any payment to the investigator and/or an investigator’s financial interest or fiduciary role that is *directly related to the subrecipient’s work for JHU*. This includes, but is not limited to, the following:

* Income for services (e.g., consulting fees or honoraria) that exceeds $5,000 per year
* Equity interests (e.g., stock, stock options or other ownership interests) with a fair market value greater than $5,000, but not including equity interests in mutual funds
* Intellectual property rights and interests (e.g. receipt of royalty payments), upon receipt of income related to such rights and interests
* Fiduciary role (e.g., Board of Directors member, officer, or manager)
* A significant financial interest **does not include** payments to the investigator by the sub-recipient institution, provided that the institution employs the investigator

None of the investigators or their spouses, domestic partners or dependent children has a significant financial interest that is directly related to the Subrecipient’s work for JHU.

One of more of the investigators, their spouses, domestic partners or dependent children, has a significant financial interest that is directly related to the Subrecipient’s work for JHU.

Name(s) and email(s) of investigator(s) who have a significant financial interest:

|  |  |  |
| --- | --- | --- |
| **First (Given) Name** | **Last (Family) Name** | **Email Address** |
|  |  |  |
|  |  |  |
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Subrecipient warrants that it will comply with requests from JHU SOM for additional information and that it will take all steps identified by JHU SOM as necessary in order for JHU SOM to determine if the significant financial interest(s) constitutes a financial conflict of interest(s) under the regulation. Further, subrecipient agrees that each investigator listed above will disclose his/her significant financial interest that is directly related to the Subrecipient’s work for JHU in accordance with the JHU SOM Disclosure and Professional Commitment Policy. (Questions regarding the disclosure process should be directed to the Office of Policy Coordination at 410-516-5560 or [policy@jhmi.edu](mailto:policy@jhmi.edu).)

**3) Subrecipient certifies that the statements on this document are true, as evidenced by the following signatures:**

Name of Subrecipient Signature Date

Designated Institutional Official

Name of Subrecipient Signature Date

Principal Investigator

Name of JHU Signature Date

Principal Investigator