CLEARANCE OF NIH INVESTIGATOR PERSONAL FINANCIAL HOLDINGS BY IC ETHICS OFFICE (PFH)

Instructions: Email the completed document to the IC DEC for your Institute and include the protocol précis for ALL protocols. To facilitate this process, ensure that the list of investigators is current and complete by comparing this with the protocol face sheet and PQS (<http://pqs.cc.nih.gov/>).

1**Date Received by Ethics Office:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 2**Date of Memo** |  |  |  | 5New Protocol |
| 3**Date of IRB Meeting:** |  |  |  | 6Continuing Review |
| 4**Date Protocol Expires:** |  |  |  | 7Amendment: check all that apply  Investigator Added  Product Added or Changed |

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| 8**To:** |  |

I.C. Deputy Ethics Counselor

|  |  |
| --- | --- |
| 9**From:** |  |

Principal Investigator

|  |  |
| --- | --- |
| cc: |  |

|  |  |
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| 10**Protocol #:** |  |
| 11**Research Type:** | Screening  Training  Nat. History – Dx Progression/Physiology  Nat. History–Sample/Data Collection/Analysis:  Recruiting  Not Recruiting  Pharmacokinetics/Dynamics  Clinical Trial: Phase:  0  1  1-2  2  3  4 |
| 12**Title:** |  |
| 13**Principal Investigator’s I.C.:** |  |
| 14**Responsible IRB:** |  |

|  |
| --- |
| 15**: Does this study include any commercial interests?: 🞏 Yes 🞏 No**  **Does this study involve any technology transfer? 🞏 Yes 🞏 No**  **Does this study involve any products made by a commercial interest? 🞏 Yes 🞏 No**  16**Manufacturer of study product(s) (drug, biologic or device):**  17**IND/IDE# (if applicable):**  18**IND/IDE Sponsor (if applicable):**  19**Do you know of competitors for study drug, biologic or device manufacturer(s) for purposes related to this protocol? If yes, please list :**  20**: Objective of the study *(one sentence summary)***: |

21 **List individuals serving on the protocol as an:** Adjunct PI,Accountable Investigator, Medical Advisory Investigator, Lead Associate Investigator, Associate Investigator and/or Research Contact, identifying for each their affiliation (i.e., outside entity) and if an NIH Employee or Non-NIH Employee.

Name, Affiliation, Employment Status (NIH Employee/Non-NIH Employee)

**The information below is for IRB information only and shall not be included on the protocol consent form.**

22No conflicts identified for NIH employees, or conflicts have been resolved through divestiture or waiver.

23No conflicts exist however one or more NIH employees have a *de minimis* holding in the manufacturer of the product(s) used in the study. Name of manufacturer(s):

24No conflicts exist however one or more NIH employees have an over the *de minimis* holding in the manufacturer of the product(s) used in the study and has been cleared to participate by waiver. Name of manufacturer(s):

Deputy Ethics Counselor for IC of P.I. Date Signed Date Returned to P.I.

Ethics Office Use Only: DER  9/10