APPENDIX D – 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 covered individuals is current; the DECs can provide information on whether NIH employees have filed financial disclosure.

[1]**Date Received by Ethics Office**:

[2]**Date of Memo:**

[3]**Date of IRB Meeting**:

[4]**Date Protocol Expires:**

☐ [5]New Protocol

☐ [6]Continuing Review

☐ [7]Amendment: check all that apply:

- ☐ Investigator Added
- ☐ Product Added or Changed
- ☐ Change in role—new covered investigator
- ☐ Change in status—new covered protocol

[8]**To:** _____

I.C. Deputy Ethics Counselor

[9]**From:**_____

Principal Investigator

CC:

[10]**Protocol #:**

[11]This protocol involves (check all pertinent boxes): (See Sop 21 for definition of a "covered research protocol")

- ☐ Investigational biologic, drug and/or device (IND/IDE)
- ☐ Studies of a technology/product developed outside NIH
- ☐ A research question that evaluates a commercially available drug or device
- ☐ Collaboration with a for-profit entity receiving data/specimens from NIH to develop a product

[12]**Title:**

[13]**Principal Investigator's I.C.:**

[14]**Responsible IRB:**

Name of study product(s) (drug, biologic or device):

[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** *who are covered individuals, identifying for each their affiliation (i.e., outside entity) and if an NIH Employee or Non-NIH Employee. Covered individuals are personnel who have independent decisional roles in conducting a specific covered research protocol. These individuals are influential in the design, direction, or conduct of a covered research protocol, or engaged in the analysis or*

interpretation of data. Individuals who participate only through isolated tasks that are incidental to the research (for example, scheduling patient tests), and those individuals who support research of many protocols through the performance of routine patient care tasks are not covered individuals. Covered Individuals include the principal investigator, personnel whose resume or CV is provided to a sponsor, personnel listed on a FDA 1572 Form, and personnel engaged in human subjects research, including but not limited to individuals who obtain informed consent or who make decisions about research eligibility. Others who have decisional responsibilities that meet the definition of a covered individual, e.g. as co-investigator, research nurse, associate investigators, or an individual who interprets or analyzes research data, are also covered individuals. The PI determines which individuals are "covered individuals" under this SOP. When protocols contain sub-studies that ask a research question about a product, it is possible that only those individuals involved in decisional roles in the sub-study are "covered individuals."

Enter Name, Affiliation, Employment Status and for NIH Employees enter Role on the study: (Enter one person per row)

Name:	**Affiliation:**	**Employment Status:**	**Role:**

Append a sheet with additional names and information if required.

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

22 ☐ If applicable, a "Conflict of Interest (COI) Certification for Non-Federal Employees" form has been submitted.

22 ☐ If applicable, a "Conflict of Interest (COI) Certification form for NIH Employees who do not file financial disclosure form 717-1 or 450" has been submitted

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

23 ☐ No 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):

24 ☐ No 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 ☐ 8/3/2015