

APPENDIX E: CONFLICT OF INTEREST (COI) CERTIFICATION FOR NIH EMPLOYEES WHO DO NOT FILE FINANCIAL DISCLOSURE FORMS 717 OR 450

This form should be completed by NIH employees who are covered individuals who do not file financial disclosure forms 450 or 717.

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.”

Name:	
Role on Study:	
NIH Institute:	
Name of PI:	
Title of Protocol:	

I certify that I have received and read the NIH ***Guide to Avoiding Financial and Non-Financial Conflicts or Perceived Conflicts of Interest in Human Subjects Research at NIH*** and that I will comply with the Policy. I certify I have no conflict of interest with this protocol. In the event I become aware of any potential conflict of interest, I will contact my ethics office.

(Signature)

(Date)