

APPENDIX F: CONFLICT OF INTEREST (COI) CERTIFICATION FOR NON-FEDERAL EMPLOYEES

This form should be completed by the Principal Investigator and signed by covered individuals who are not federal employees.

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.”**

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| Name of Non-NIH Employee: | |
| Role on Study: | |
| NIH Institute: | |
| Home Institution/Employer: | |
| 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.

 (Signature)

 (Date)

If applicable, I certify that my home institution/employer has a Conflict of Interest Policy and that I am in compliance with the Conflict of Interest policy of my home institution. I understand and agree that I must promptly inform the PI of this protocol if I am no longer in compliance with the Conflict of Interest policy of my home institution.

 (Signature)

 (Date)