

CONFLICT OF INTEREST (COI) CERTIFICATION

PART 1: To be completed by the NIH Principal Investigator (PI) on a Covered Research Protocol¹

Step 1: **Fill in** the information requested in the chart below. Complete one form for each member of the NIH study team who is:

(1) is listed as an Investigator², or (2) will perform statistical analysis of the primary endpoint data obtained from human subjects research³, but:

- (a) is not employed by or otherwise affiliated with *any* federal agency; or
- (b) is employed by or otherwise affiliated with a federal agency other than NIH; or
- (c) is affiliated with NIH as a trainee, fellow, contractor (or other) and does NOT file an NIH financial disclosure report⁴.

Name:	
Role on Study:	
Employer (insert NIH for those in group (c) listed above):	
Name of NIH PI:	
NIH PI Institute/Center:	
Title of the NIH Protocol:	
IRB Number/Protocol ID:	

Step 2: **PROVIDE** form (after completing chart) to Study Team Member to complete PART 2.

Step 3: **COLLECT** signed form.

Step 4: **SUBMIT** this signed/completed form to the Institute/Center Ethics Office with the protocol clearance request in the electronic IRB system.

¹ Covered Research Protocols and sub-studies include: (1) studies of investigational drugs and devices; (2) studies with a research question about a commercially available drug or device; and (3) studies involving collaborations with a substantially affected organization (SAO) or other for-profit entities when the entity is receiving data or specimens from the NIH for the purpose of developing a product. Most interventional protocols will be Covered Research Protocols unless the intervention does not involve the criteria listed above (e.g., a behavioral intervention might not meet the criteria for a covered research protocol).

² For purposes of this form, "Investigator" means any individual listed on the IRB application as an Associate Investigator.

³ For individuals involved in statistical analysis, use of this form is limited to those whose role has the potential to bias the research results.

⁴ It is the NIH PI's responsibility to confer with study team members, supervisors, ethics officials and others to establish whether an NIH trainee, fellow, contractor, or other affiliate files a financial disclosure report with NIH. NIH employees, SGES, and others, including IPA appointees and detailees, who file financials disclosure reports should NOT be asked to sign this form.

Effective Date: 8/1/2022

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PART 2: To be completed by Study Team Member

Step 1: **READ** each of the following:

[Guide to Avoiding Financial and Non-Financial Conflicts or Perceived Conflicts of Interest in Human Subjects Research at the National Institutes of Health \(NIH\)](#)

[Policy 102 Investigator Conflicts of Interest and Government Royalties](#)

Step 2: **REVIEW** and **SIGN** the certification below (if appropriate).⁵

Step 3: **RETURN** signed document to the NIH PI identified in PART 1.

I certify that I have read the Guide to Avoiding Financial and Non-Financial Conflicts or Perceived Conflicts in Human Subjects Research at the National Institutes of Health (NIH) and that I will comply with Policy 102: Investigator Conflict of Interest and Government Royalties. I certify that I have no conflict of interest with the protocol identified in PART 1 of this form and that if I become aware of any potential conflict of interest while working on this protocol, I will immediately notify the NIH PI and the IRB. Additionally, if I am not a federal employee, I certify that I will comply with any applicable conflict of interest policies established by my home institution or employer.

(Print Name)

(Signature)

(Date)

⁵ If you have any concerns about whether to attest to the certification statements, please contact your supervisor and ethics official.