



Pennsylvania Department of Education Institutional Review Board (PDE IRB) Application for PDE IRB Review

Attachment N: Conflict of Interest Reporting

Project Title:

Name of Principal Investigator (PI):

Research Staff Member (if other than the PI):

Research Staff Member's Institution:

Date Prepared:

In accordance with [42 Code of Federal Regulations Part 50](#) and [45 Code of Federal Regulations Part 94](#), investigators and any other research staff (including consultants and students) who have responsibilities related to the design, conduct, or reporting of research must report all significant financial interests and other conflicts of interest. All

potential conflicts of interest must be reported to the PDEIRB using Appendix N in the following circumstances:

1. at the time of initial submission of any Application for PDE IRB Review or Exempt Determination Request;
 2. at the time of submission of a Continuation Approval Request if there is a change regarding potential conflict of interest;
 3. within thirty (30) days of discovering or acquiring a new or updated potential conflict of interest; and
 4. at any time when adding new investigators or research staff to an existing PDE IRB - approved study.
 5. Appendix N is intended to provide the PDE IRB with information about the PI's and research staff members' potential conflicts of interest so that the PDE IRB may determine if the design, conduct, and reporting of research will be free from bias that may result from such conflicts. A separate Appendix N must be completed and submitted for each research staff member.
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Section 1: Determining Applicability of 42 CFR 50 and 45 CFR 94

Answer the following questions A and B.

- A. Is this project funded by or under application for funding by any U.S. Public Health Service (PHS) awarding component (e.g., NIH, CDC, FDA, ATSDR, AHRQ, HRSA, IHS, and SAMHSA)? *If you are unsure about your response, see your institutional official or grants/contract office before answering this question.*

Yes No

- B. Is the institution with which you are affiliated funded by or applying for funding by any PHS awarding component? *If you are unsure about your response, see the institutional official or grants/contract office before answering this question.*

Yes No

If you answered NO to both questions 1A and 1B, the requirements under 42 CFR 50 or 45 CFR 94 pertaining to significant financial interests may not apply to you as of the date that you prepared this Appendix N. Go to Section 3.

If you answered YES to either question 1A or 1B, go to Section 2.

Section 2: Requirements under 42 CFR 50 and 45 CFR 94

As you answered YES to either question 1A or 1B, the requirements under [42 CFR 50 or 45 CFR 94](#) may apply to you. You may be required to comply with your own institution's policy for completing related training, disclosing significant financial interests, and managing financial conflicts of interest. See your own institutional official for further information.

Section 3: Potential Conflicts of Interest

Investigators and all research staff (including consultants and students) who have responsibilities related to the design, conduct, or reporting of research must report all potential conflicts of interest. Answer questions 3A and 3B.

- A. Do you or a member of your immediate family (spouse or dependent children) have a potential financial interest in the research, its products, or the study sponsor? For purposes of this question, a financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Yes. In the space below or on a separate page, (1) identify the individual (you or a member of your immediate family) with the potential financial interest; (2) describe the nature or monetary value of the potential financial interest; and (3) explain how this potential conflict of interest will be managed. Then proceed to Question 3B.

No; go to question 3B.

- B. Do you or a member of your immediate family (spouse or dependent children) have a potential non-financial interest in the research, its products, or the study sponsor? For purposes of this question, a non-financial interest means any personal, professional, political, academic, ideological, or religious interest that may influence professional judgment. *For example, you are investigating outcomes of a school district program designed to improve student test scores. Your spouse is the superintendent at the school district. A reasonable person may question your role in analyzing, interpreting, or reporting study findings where the results might or may not benefit your spouse. Another common example of a possible non-financial interest may be when investigators or research staff recruit prospective subjects from among their students, employees, clients, patients, or other persons that they supervise or for whom they provide benefits or services.*

Yes. In the space below or on a separate page, (1) identify the individual (you or a member of your immediate family) with the potential non-financial interest; (2) describe the nature and value of the potential non-financial interest; and (3) explain how this potential conflict of interest will be managed. Then proceed to Section 4.

No, go to Section 4.

Section 4: Statement of Affirmation

By submitting this form, I affirm that all responses and statements provided on this Appendix N are accurate and complete.