CHS IRB 100 Form D



Legal Services Department Institutional Review Board Phone: (716) 821-4477 Fax: (716) 821-4465

INSTITUTIONAL REVIEW BOARD CONFLICT OF INTEREST DECLARATION FOR RESEARCH INVESTIGATORS

A conflict of interest exists when a research investigator has professional or financial interests that compromise or appear to compromise the investigator's independent professional judgment in any aspect of the conduct of a clinical trial. Investigator financial conflicts may arise from financial interests in the sponsor or test article. They may also arise from a compensation structure using milestone payments and/or incentives that reward investigators for rapid and/or high-volume enrollment of subjects. Professional conflicts could exist when an investigator attempts to recruit subjects from his/her own patients or employees.

Research Investigators are responsible for making known any potential or perceived conflict of interest concerning protocols reviewed by the IRB. Effective ways of management include disclosure in the consent document, third-party monitoring of the consent process, use of a data safety monitoring board, and/or divestiture of the financial interest that creates a conflict and preventing the conflicting investigator from participating in the research.

This document must be completed, signed and submitted by each principal investigator, co-principal investigator, investigator and collaborator who plans to devote 5% or more effort to the proposed project. The information will only be used to review the proposed research project to which it applies. This completed and signed document must accompany the proposal to which it applies or the proposal will not be considered for further review.

Name:

Title of Research Proposal:

Role (Check One): [] Principal Investigator

[] Co-Principal Investigator

[] Investigator

[] Collaborator

Percent Effort on Research Protocol:

Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner receive salary or other compensation (to include consulting fees, honoraria, gifts, and/or in kind compensation) from a business or other source related to the research proposal that in aggregate has in the prior year exceeded \$10,000 and/or is expected to exceed \$10,000 in the next 12 months?

[] Yes [] No

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If yes, explain source, value, and reason for compensation:

Do you or your spouse, minor child, general partner, or an organization at which you are an officer, director, and trustee or general partner own any patents, provisional or otherwise, that are related to the research project proposal?

[] Yes

[] No

If yes, please provide additional information below. (Patent Number/Date etc...)

Have any active or pending license agreements been issued? (If yes, attach a copy of each license) []Yes [] No

If yes, describe the period covered by each license and the projected royalty per year.

Do you or your spouse, minor child, general partner, or an organization at which you are an officer, director, trustee or general partner own or have any equity interests by way of stock ownership or stock options in a non-publicity-traded or publicly traded company that may or may not own a patent that is related to the research project proposal and is valued at more than \$10,000 (or value is projected to exceed \$10,000 in the next 12 months)??

> [] Yes [] No

If yes, what is the value of the stock/stock options? ____

Does this value represent more than a 5% ownership of the company? [] Yes

[] No

Please describe any of your duties that involve management of research project or contracts other than those on which you are a principal investigator, co- principal investigator or investigator. This includes oversight, approval, advertising, recommending, or initiating actions on research related projects.

I certify that to the best of my knowledge and belief, all of the information on this disclosure is true, correct, complete and made in good faith. I understand that false and fraudulent information on this disclosure may be grounds for not accepting the research proposal and may be punishable by fine or imprisonment (U.S. Code, Title 18, section 1001).

(Signature of Investigator)

(Signature of Investigator's Supervisor)

(Signature of CHS IRB Chairman)

Certification of Review by Catholic Health System Institutional Review Board		
[] (Check is appropriate) Review by IRB is not applicable to this protocol.		
(Signature of IRB Chairman)	(Date Signed)	
	applicable protocol have been reviewed for compliance with 1 for a determination of the existence of a financial conflict of	
A financial conflict of interest: [] has protocol.	[] has not been identified for this investigator on this research	
Any additional recommendations are addressed by letter from the IRB Chair to the investigator.		
(Signature of CHS IRB Chairman)	(Date Signed)	

(Date Signed)

(Date Signed)

(Date Signed)