

EAST TENNESSEE CHILDREN'S HOSPITAL



INSTITUTIONAL REVIEW BOARD

FINANCIAL CONFLICT OF INTEREST DISCLOSURE QUESTIONNAIRE (PART I)

Name of individual completing disclosure

Principal Investigator

Protocol Title/Sponsor

Instructions: The PI and each of the Key Personnel (those assigned to work on the project at the investigative site) are required to fill out and sign a Financial Conflict of Interest Disclosure Questionnaire for Research.

Definitions:

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Related Party means spouse, domestic partner, & dependent children, siblings, parents or equivalents by marriage, or other individuals residing in the household.

Senior/Key Personnel means the Project Director/Principal Investigator and any other person identified as senior/key personnel involved in the study.

Important: A *YES answer to any of the items in #1 - #5 below requires completion of PART II of this form. Please provide an answer for both items (a & b) of each question.

1. Within the **last** 12 months, have you, or to the best of your knowledge, has any related party performed any work (not directly related to the costs of conducting research) for:
 - (a) The sponsor? No Yes*
 - (b) Any commercial entity that would appear to be affected by the conduct or outcome of the research project? No Yes*
2. Within the **last** 12 months, have you, or to the best of your knowledge, has any related party received compensation (not directly related to the costs of conducting research), financial interest, or gifts of any kind from:
 - (a) The sponsor? No Yes*
 - (b) Any commercial entity that would appear to be affected by the conduct or outcome of the research project? No Yes*
3. Within the **next** 12 months, do you, or to the best of your knowledge, does any related party anticipate performing any work and/or receiving any compensation (not directly related to the costs of conducting research), financial interest, or gifts from:
 - (a) The sponsor? No Yes*
 - (b) Any commercial entity that would appear to be affected by the conduct or outcome of the research project? No Yes*
4. Do you, or to the best of your knowledge, does any related party own stock, stock options, or other forms of ownership in:
 - (a) The sponsor? No Yes*
 - (b) Any commercial entity that would appear to be affected by the conduct or outcome of the research project? No Yes*
5. Do you, or to the best of your knowledge, do any of your related parties have any intellectual property rights (e.g., named as an inventor in an issue patent or patent application, license fees, current or future royalties from patents and copy rights)? No Yes*
6. Would you like to voluntarily disclose anything else? No Yes

If yes, please describe here:

Any update to this form must be promptly reported to the IRB; otherwise, this form will be required to be reported annually.

Attestation:

I certify that I have read and received educational information on the ETCH IRB policy regarding Financial Conflict of Interest in Research. I hereby attest that with respect to the above clinical research project application that the above information is accurate and complete.

Printed Name

Signature

Date

