

# BayCare Health System Institutional Review Board

## Research Conflict of Interest Annual Financial Disclosure Form

*A form must be completed and signed by each investigator(s), sub investigator and all key study personnel (including, but not limited to, coordinators, pharmacists whenever necessary to do so)*

<b>Study Title:</b>	
<b>Study ID if applicable</b>	
<b>Protocol#</b> <b>* Study Sponsor</b>	
<input type="checkbox"/> <b>Principal Investigator(s)</b> <input type="checkbox"/> <b>Co-Investigator</b> <input type="checkbox"/> <b>Key Research Personnel</b>	<b>Name</b> <b>Address</b>  <b>Phone</b> <b>Email</b>
<p><b>"You"</b> refers to the investigator, key research personnel or immediate family member.</p> <p><b>"Investigator"</b> means any listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of research subjects.</p> <p><b>"Key Research Personnel"</b> means any other person regardless of title or position, who is responsible for the design, conduct, or reporting of research to be done within the BayCare Health System.</p> <p><b>"Immediate Family Member"</b> means spouse, domestic partner, or minor child.</p> <p><b>"Significant Financial Interest"</b> means:</p> <ol style="list-style-type: none"><li>1. Income in excess of * \$5,000 from a publicly traded entity (a company whose stock is available for purchase by the general public) during the past 12 months.</li><li>2. Stock values in excess of \$5,000 at the time of disclosure in a publicly traded entity.</li><li>3. A combination of the above two items (stock and income) that exceeds \$5,000.</li><li>4. Any amount of equity (stock, stock options, or other ownership interest) in a non-publicly traded entity (such as a start-up company).</li><li>5. Compensation that exceeds \$5,000 from a non-publicly traded entity in the past 12 months.</li><li>6. Income related to intellectual property rights paid by any source other than the investigators current institution.</li><li>7. Any reimbursed or sponsored travel paid by an entity, including non-profit organizations, <b>but excluding</b> travel sponsored by or reimbursed by a government agency, a U.S. institution of higher education or a research institute affiliated with such, a medical center, or an academic teaching hospital. The specific details that must be disclosed are the name of the entity sponsoring the travel and purpose, destination, and duration of the travel during the past 12 months.</li><li>8. Any other interests required under the BCHS IRB policy.</li></ol>	

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Indicate, by answering the following questions, any financial arrangements with the sponsor of the study for which you are seeking approval. Please be aware that you are answering the questions for you and your immediate family members and/or significant other

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1. Will there be, or has there been, compensation made to you of which the value could exceed \$5,000.00?

Yes  No

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2. Do you have a proprietary interest in the tested product, including but not limited to, a patent, trademark, copyright or licensing agreement?

Yes  No

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3. Do you have an equity interest in the study sponsor (i.e. any ownership interest, stock options or other financial interest whose value cannot be readily determined) through reference, public prices or resources?

Yes  No

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4. Do you have an equity interest in the sponsor, or any of its affiliates, of a publicly held company that exceeds \$5,000 in value? The requirement applies to interests held during the time the clinical investigator is carrying out the study and for one (1) year following completion of the study.

Yes  No

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5. Have you or the institution where the research will be conducted received significant payments from the sponsor, with a cumulative monetary value of \$5,000 or more? This includes compensation in the form of equipment, or retainers for ongoing consultation or honorariums. *This excludes the costs of conducting this, or other, clinical study for this sponsor.* This requirement applies during the study and for one (1) year following completion of the study.

Yes  No

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6. Do you have a significant financial interest to be disclosed as outlined in the significant financial conflict of interest definition found above?

Yes  No

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**\*If you answered YES to any of the questions above, please explain each answer on page 3 of this form**

I certify by my signature that the information provided above is accurate. I acknowledge I must promptly update this statement and notify the BCHS IRB Office at 727 467-4577 if any relevant changes occur in the course of this investigation. I agree to update this form annually, whenever there is a change in my financial interests, and then one year following study closure.

\_\_\_\_\_  
Printed Name of Signee

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

If you answered "Yes" to any question on page 2 of this form, please provide a detailed explanation.

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5. (please differentiate between speaking engagements, consulting fees, board work, product development)

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