

**Jaeb Center for Health Research (JCHR)  
Site Investigator Conflict of Interests Disclosure Form**

General Information	
<b>Name of the Institution:</b>	
<b>Site Investigator Name:</b>	
<b>Title of Clinical Protocol:</b>	
<b>Protocol Short Name:</b> (e.g., ABC123)	
<b>Financially Interested Companies (FICs) with respect to this Study:</b> <i>(Any entity that provides funding or support for the research project or whose financial interests would reasonably appear to have the potential to be directly or indirectly affected by the outcome or conduct of <b>this research</b> (referred to collectively as <b>FICs</b>). May also include a competitor company.</i>	Pre-populate with a list of most likely FICs given the nature of this study (e.g., sponsor, manufacturer of device(s) or drug(s) used in study): <ul style="list-style-type: none"> <li>•</li> </ul>
Is this research supported (i.e., funded) by the <b>Public Health Service (PHS)</b> ?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Is this research regulated by the <b>Food and Drug Administration (FDA)</b> , i.e. research conducted under an IND or IDE?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Disclosure Information	
<b>Information collected at study time-point:</b>	<input type="checkbox"/> Initial Disclosure <input type="checkbox"/> Annual Update/Continuing Review <input type="checkbox"/> Changes to financial interest since last disclosure (through 1 year post-completion of study as applicable)
<b>Please complete below by marking "YES" or "NO" regarding the financial interests or arrangements that <u>are present currently, or were present during the past 12 months as it relates to you, your spouse or your dependent children.</u></b>	
1. Any financial interest (FI) from a financially interested company (see above) <b>valued at <math>\geq</math> \$5,000</b> (note: payments to your Institution on your behalf are not considered a Significant Financial Interest (SFI) unless otherwise specified): <ol style="list-style-type: none"> <li>a. The monetary value includes but is not limited to any <b>payment for services</b> (e.g., salary, consulting fees, honoraria, paid authorship, and advisory boards), <b>equity interest</b> including any stock, stock option, or <b>other ownership interest</b>, as determined through reference to public prices or other reasonable measures of fair market value, or</li> <li>b. <b>Intellectual property rights and interests</b> (e.g., patents, trademarks, licensing, copyrights), upon receipt of income related to such rights and interests that are FIs as defined.</li> </ol> <p><b>An SFI does not include:</b></p> <ol style="list-style-type: none"> <li>a. Salary, royalties, or other remuneration paid to you by your employing institution, including intellectual property rights assigned to the institution and agreements to share in royalties related to such rights.</li> <li>b. Equipment, research costs, consulting fees, or other remuneration paid by a for-profit or not-for-profit entity to the Institution on your behalf (unless you have any type of equity interest in the institution).</li> <li>c. Income from investment vehicles, such as mutual funds and retirement accounts, as long as you do not directly control the investment decisions made in those vehicles.</li> <li>d. Income from seminars, lectures, or teaching engagements sponsored by; or from service on an advisory committee/review panels for:               <ul style="list-style-type: none"> <li>o a Federal, state, or local government agency,</li> </ul> </li> </ol>	<input type="checkbox"/> YES <input type="checkbox"/> NO

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<ul style="list-style-type: none"> <li>○ an Institution of higher education as defined at 20 U.S.C. 1001(a),</li> <li>○ an academic teaching hospital,</li> <li>○ a medical center or a research institute that is affiliated with an Institution of higher education</li> </ul>													
<p>2. Is this <b>a change in a significant financial interest</b> (meets Criteria #1 above) that is now in a new category level? If yes, select new category level as follows:</p> <table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> \$10,000-\$19,999</td> <td><input type="checkbox"/> \$20,000-\$24,999</td> <td><input type="checkbox"/> \$25,000-\$34,999</td> </tr> <tr> <td><input type="checkbox"/> \$35,000-\$49,999</td> <td><input type="checkbox"/> \$50,000-\$69,999</td> <td><input type="checkbox"/> \$70,000-\$89,999</td> </tr> <tr> <td><input type="checkbox"/> \$90,000-\$99,999</td> <td colspan="2"><input type="checkbox"/> amounts above \$100,000 by increments of \$50,000</td> </tr> </table>	<input type="checkbox"/> \$10,000-\$19,999	<input type="checkbox"/> \$20,000-\$24,999	<input type="checkbox"/> \$25,000-\$34,999	<input type="checkbox"/> \$35,000-\$49,999	<input type="checkbox"/> \$50,000-\$69,999	<input type="checkbox"/> \$70,000-\$89,999	<input type="checkbox"/> \$90,000-\$99,999	<input type="checkbox"/> amounts above \$100,000 by increments of \$50,000		<input type="checkbox"/> YES  <input type="checkbox"/> NO			
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<input type="checkbox"/> \$35,000-\$49,999	<input type="checkbox"/> \$50,000-\$69,999	<input type="checkbox"/> \$70,000-\$89,999											
<input type="checkbox"/> \$90,000-\$99,999	<input type="checkbox"/> amounts above \$100,000 by increments of \$50,000												
<p>3. Any <b>reimbursed travel</b> paid to you or <b>sponsored travel</b> (i.e., that which is paid on your behalf, and not reimbursed to you, so that the exact monetary value may not be readily available), from a financially interested company, if the aggregate amount paid to or on your behalf is <b>\$5,000 or more within a 12-month period</b>. This is irrespective of whether the travel occurred as part of employment or as an outside activity (Note: payment of travel funds to the institution on your behalf does not require disclosure). Reporting of the <b>name of the payer and the purpose, destination, and duration of travel</b> for each trip during the 12-month period is required.</p> <p><i>Entities excluded from the reporting requirement: federal, state, or local government agencies, institutions of higher education as defined at 20 U.S.C. 1001(a), academic teaching hospitals, medical centers, and research institutes affiliated with an institution of higher education. NOTE: The Jaeb Center is an affiliate of the University of South Florida so therefore is an excluded entity.</i></p>	<input type="checkbox"/> YES  <input type="checkbox"/> NO												
<p>For each "YES" response to the items above, please indicate the following:</p> <p><b>Value Category</b></p> <table style="width: 100%; border: none;"> <tr> <td>A = \$5,000-\$9,999</td> <td>B = \$10,000-\$19,999</td> <td>C = \$20,000-\$24,999</td> <td>D = \$25,000-\$34,999</td> </tr> <tr> <td>E = \$35,000-\$49,999</td> <td>F = \$50,000-\$69,999</td> <td>G = \$70,000-\$89,999</td> <td>H = \$90,000-\$99,999</td> </tr> <tr> <td>I = \$100,000-\$149,999</td> <td>J = \$150,000-\$199,999</td> <td>K = \$200,000-or more</td> <td></td> </tr> </table> <p>L = Value cannot readily be determined</p> <p><b>Name of FIC</b> (see definition above)</p> <p><b>Recipient</b> (self, spouse, child, institution)</p> <p><b>Nature of Relationship</b> (e.g., consulting, travel, employment, etc.)</p> <ul style="list-style-type: none"> <li>• <b>For travel, this must include the purpose, destination and duration of the travel!</b></li> </ul>		A = \$5,000-\$9,999	B = \$10,000-\$19,999	C = \$20,000-\$24,999	D = \$25,000-\$34,999	E = \$35,000-\$49,999	F = \$50,000-\$69,999	G = \$70,000-\$89,999	H = \$90,000-\$99,999	I = \$100,000-\$149,999	J = \$150,000-\$199,999	K = \$200,000-or more	
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I = \$100,000-\$149,999	J = \$150,000-\$199,999	K = \$200,000-or more											
<p><b>Example: Value Category: E; Name of FIC: Drug Co. ; Recipient: Self ; Nature of Arrangement: Consulting</b></p>													
<p>1: Value Category: ; Name of FIC: ; Recipient: ; Nature of Arrangement:</p> <p>2: Value Category: ; Name of FIC: ; Recipient: ; Nature of Arrangement:</p> <p>3: Value Category: ; Name of FIC: ; Recipient: ; Nature of Arrangement:</p> <p>4: Value Category: ; Name of FIC: ; Recipient: ; Nature of Arrangement:</p> <p>5: Value Category: ; Name of FIC: ; Recipient: ; Nature of Arrangement:</p> <p>6: Value Category: ; Name of FIC: ; Recipient: ; Nature of Arrangement:</p> <p>7: Value Category: ; Name of FIC: ; Recipient: ; Nature of Arrangement:</p> <p>8: Value Category: ; Name of FIC: ; Recipient: ; Nature of Arrangement:</p> <p>9: Value Category: ; Name of FIC: ; Recipient: ; Nature of Arrangement:</p> <p>10: Value Category: ; Name of FIC: ; Recipient: ; Nature of Arrangement:</p>													

**By signing this form:**

1. I certify that the information provided on this form is, to the best of my knowledge and belief, true, complete and correct.

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2. I certify that I have been trained on conflicts of interest and will follow my (or JCHR's) policies and federal regulation on conflict of interest (21 CFR 50, 54, 56; 42 CFR 50 Subpart F; and 45 CFR 46, as applicable).
3. I certify that to the extent I have provided any information about me, my spouse and any of my dependent children, I have appropriate permission to provide the financial information on their behalf to JCHR.
4. I agree to promptly **update the above information if my legal name or financial interests and arrangements, or those of my spouse and dependent children, changes from the information provided above during the clinical study or within one (1) year after its completion.**
5. I agree to work with JCHR on a Conflict of Interest Management Plan to mitigate conflicts associated with this study.
6. I will provide this form (*all pages*) to JCHR as required.

***The signature and date below must either be a valid digital signature, or a handwritten signature and handwritten date.***

Investigator's Signature / Date:	
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JCHR ONLY	
Has the form been completed in its entirety?	<input type="checkbox"/> Yes <input type="checkbox"/> No: they cannot be reviewed until completed – provide comments:
Has the form been signed within the last 3 months?	<input type="checkbox"/> Yes <input type="checkbox"/> No: do not accept until provided – add comments:
a. Were any SFIs identified?	<input type="checkbox"/> No <input type="checkbox"/> Yes: please complete (b)
b. Please identify which reported rows are applicable.	which rows (1-10): _____
<b>Is this research <u>only</u> regulated by the FDA (but not PHS)?</b>	<input type="checkbox"/> <b>No: not regulated research, or does have PHS funding, please complete (c)</b> <input type="checkbox"/> <b>Yes: Skip to (f) – (i) below</b>
c. For any disclosures identified in (b) above, do you believe any could directly and significantly impact the design, conduct, or reporting of research?	<input type="checkbox"/> No <input type="checkbox"/> Yes, which rows (1-10): _____ Please complete (d), and A Management Plan is Required!
d. If any items are listed in (c), is this research funded by PHS?	<input type="checkbox"/> No <input type="checkbox"/> Yes, this form and the Management Plan will be provided to the Director of Grants Administration for reporting to PHS.
e. <b>Is the research <u>also</u> regulated by the FDA?</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes: <b>please complete (f) – (i) below</b>
FDA Studies Only!	
f. Are any disclosures from an FIC of the covered study, whereby the value of the compensation could be influenced by the outcome of the study (e.g., recruitment bonus, other bonus for favourable outcomes)?	<input type="checkbox"/> No <input type="checkbox"/> Yes: A Management Plan is required if not already developed
g. Are there any significant payments of other sorts from an FIC with a monetary value of more than \$25,000.00 (other than the cost for conducting the study) during the conduct of the study and for one (1) year after the completion of the study (e.g., ongoing open grant, retainer for ongoing consultation, equipment or honoraria)?	<input type="checkbox"/> No <input type="checkbox"/> Yes: A Management Plan is required if not already developed
h. Are there any proprietary interests in the product tested in the covered study (including, but not limited to, patents, trademarks, copyrights or licensing agreements in the product under investigation)?	<input type="checkbox"/> No <input type="checkbox"/> Yes: A Management Plan is required if not already developed
i. Are there any significant equity interests, including ownership interest, stock options, or other financial interests with a value not readily determinable; or any equity interests in a publically traded corporation that exceeds or will exceed \$50,000.00 during the	<input type="checkbox"/> No <input type="checkbox"/> Yes: A Management Plan is required if not already developed

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course of a study and for one (1) year following the completion of the study, received from an FIC of this study?	
<b>Conflict of Interest Management by JCHR</b>	
Has the Management Plan been developed with the Director of the HRPP?	<input type="checkbox"/> N/A – not a JCHR IRB Investigator <input type="checkbox"/> Yes <input type="checkbox"/> No, explain: _____
Has the Management Plan been shared with the Site Investigator?	<input type="checkbox"/> Yes <input type="checkbox"/> No
When will the Management Plan be brought before the convened Full IRB Board?	<input type="checkbox"/> N/A – not a JCHR IRB Investigator Date: ____ / ____ / ____
Do you believe all conflicts have been managed?	<input type="checkbox"/> Yes <input type="checkbox"/> No, explain: _____
When was the Director of Grants Administration notified?	<input type="checkbox"/> N/A – not PHS funded research <input type="checkbox"/> Date: ____ / ____ / ____
Name & Title of Person Evaluating these Disclosures on behalf of JCHR:	Signature/Date: