

IMPAACT Clinical Investigators Disclosure of Financial Interests and Arrangements for US FDA

<p>Please complete all of the information below, including providing your signature where indicated. Once complete, retain in your site regulatory binders.</p>					
<p>1. Protocol Number: IMPAACT <INSERT STUDY NUMBER></p>					
<p>2. Protocol Title: <INSERT FULL STUDY NAME></p>					
<p>3. Site Name/Number: <INSERT SITE NAME/NUMBER></p>					
<p>4. Participating Pharmaceutical/Biotechnology Company(ies): <INSERT PHARMACEUTICAL COMPANY NAME(S)></p>					
<p>5. Principal Investigator/Subinvestigator name as listed on 1572 : <INSERT INVESTIGATOR NAME></p> <p style="text-align: center;"> <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Subinvestigator </p>					
<p>6. Investigator Contact Information: <INSERT INSTITUTION NAME, TELEPHONE NUMBER, E-MAIL ADDRESS></p>					
<p>7. For the participating pharmaceutical/biotechnology company(ies) listed in item 4, indicate by marking YES or NO if any of the financial interests or arrangements of concern to FDA (as described below) apply to you, your spouse, or dependent children. If you respond "yes" to any of the items, please provide the details of the interest or arrangement. Attachments to this document are permitted. The company(ies) also includes any affiliates, joint ventures, and subsidiaries.</p>					
<p>Any financial arrangement whereby the value of the compensation could be influenced by the outcome of the study? This includes compensation that is explicitly greater for a favorable clinical outcome, compensation in the form of an equity interest in the product provider(s)/developer(s), or compensation tied to sales of the product tested in the above study such as a royalty interest.</p> <p>If yes, please describe: _____</p>	<table style="width: 100%; border: none;"> <tr> <td style="border: none;">YES</td> <td style="border: none;">NO</td> </tr> <tr> <td style="border: none; text-align: center;"><input type="checkbox"/></td> <td style="border: none; text-align: center;"><input type="checkbox"/></td> </tr> </table>	YES	NO	<input type="checkbox"/>	<input type="checkbox"/>
YES	NO				
<input type="checkbox"/>	<input type="checkbox"/>				
<p>Any significant payments of other sorts from any participating pharmaceutical/biotechnology company? This could include, for example, payments made to the investigator or the institution to support activities that have a monetary value greater than \$25,000 (i.e., a grant to fund ongoing research compensation in the form of equipment, or retainers for ongoing consultation of honoraria).</p> <p>If yes, please describe: _____</p>	<table style="width: 100%; border: none;"> <tr> <td style="border: none;">YES</td> <td style="border: none;">NO</td> </tr> <tr> <td style="border: none; text-align: center;"><input type="checkbox"/></td> <td style="border: none; text-align: center;"><input type="checkbox"/></td> </tr> </table>	YES	NO	<input type="checkbox"/>	<input type="checkbox"/>
YES	NO				
<input type="checkbox"/>	<input type="checkbox"/>				
<p>Any proprietary interest in the product tested in the study such as a patent, trademark, copyright, or licensing agreement?</p> <p>If yes, please describe: _____</p>	<table style="width: 100%; border: none;"> <tr> <td style="border: none;">YES</td> <td style="border: none;">NO</td> </tr> <tr> <td style="border: none; text-align: center;"><input type="checkbox"/></td> <td style="border: none; text-align: center;"><input type="checkbox"/></td> </tr> </table>	YES	NO	<input type="checkbox"/>	<input type="checkbox"/>
YES	NO				
<input type="checkbox"/>	<input type="checkbox"/>				
<p>Any significant equity interest in any participating pharmaceutical/biotechnology company? This would include, for example, any ownership interest, stock options, or other financial interest whose value cannot be easily determined through reference to public prices, or an equity interest in a publicly traded company exceeding \$50,000.</p> <p>If yes, please describe: _____</p>	<table style="width: 100%; border: none;"> <tr> <td style="border: none;">YES</td> <td style="border: none;">NO</td> </tr> <tr> <td style="border: none; text-align: center;"><input type="checkbox"/></td> <td style="border: none; text-align: center;"><input type="checkbox"/></td> </tr> </table>	YES	NO	<input type="checkbox"/>	<input type="checkbox"/>
YES	NO				
<input type="checkbox"/>	<input type="checkbox"/>				
<p>Employee of the participating pharmaceutical/biotechnology company(ies) listed in item 4?</p> <p>If yes, please describe: _____</p>	<table style="width: 100%; border: none;"> <tr> <td style="border: none;">YES</td> <td style="border: none;">NO</td> </tr> <tr> <td style="border: none; text-align: center;"><input type="checkbox"/></td> <td style="border: none; text-align: center;"><input type="checkbox"/></td> </tr> </table>	YES	NO	<input type="checkbox"/>	<input type="checkbox"/>
YES	NO				
<input type="checkbox"/>	<input type="checkbox"/>				
<p>In accordance with 21 CFR § 54.1 to 54.6, I declare that the information provided on this form is, to the best of my knowledge and belief, true, correct, and complete. Furthermore, if my financial interests and arrangements, or those of my spouse and dependent children, change from the information provided above during the course of the study or within one year after the last patient has completed the study as specified in the protocol, I will complete a new financial disclosure form.</p>					
<p>8. Signature</p>	<p>9. Date:</p>				