



## COI Screening For Month, Day, Year Meeting

OMB #0925-xxxx

Expiry Date: xx/xx/xxxx

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### NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0625\*). Do not return the completed form to this address.

### 1. Initial Reviews

<p><b>Study ID, Study Title</b> (Protocol Version Date MM/DD/YY)</p> <p><b>Study Chair:</b> Name; Institution</p> <p><b>Agent / Drug / Enterprise</b> Agent – Manufacturer (Supplier)</p>	<p><b>Check the box next to the statement if the statement is true of you, an immediate family<sup>1</sup> member or a person in a direct supervisory or reporting relationship with you. A checked box indicates you are conflicted for review of the study. Report the conflict to the CIRB Operations Office in advance of the CIRB Meeting.</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 70%;"></th> <th style="width: 10%; text-align: center;">You</th> <th style="width: 10%; text-align: center;">Family Member</th> <th style="width: 10%; text-align: center;">Supervisor/ Employee</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">           Have a role in the oversight, design or conduct of the project or has a role in the analysis or management of the data (this includes:  <input type="checkbox"/> sitting on a governing body or significant supervisory committee of the Coordinating Group,  <input type="checkbox"/> serving as a Study Chair for any study of the Coordinating Group, or  <input type="checkbox"/> working at the same institution as the Study Chair         </td> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> </tr> <tr> <td style="padding: 5px;">           Have a financial interest of \$5000 or more in any agent/device/enterprise involved in the study, or any direct competitor (does not apply if the investment is not under your direct control, i.e. investment via a mutual fund)         </td> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> </tr> <tr> <td style="padding: 5px;">           Have received any compensation within the last two years from any enterprise involved in the study, or any direct competitor         </td> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> <td style="text-align: center; vertical-align: middle;"><input type="checkbox"/></td> </tr> </tbody> </table>		You	Family Member	Supervisor/ Employee	Have a role in the oversight, design or conduct of the project or has a role in the analysis or management of the data (this includes: <input type="checkbox"/> sitting on a governing body or significant supervisory committee of the Coordinating Group, <input type="checkbox"/> serving as a Study Chair for any study of the Coordinating Group, or <input type="checkbox"/> working at the same institution as the Study Chair	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Have a financial interest of \$5000 or more in any agent/device/enterprise involved in the study, or any direct competitor (does not apply if the investment is not under your direct control, i.e. investment via a mutual fund)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Have received any compensation within the last two years from any enterprise involved in the study, or any direct competitor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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<sup>1</sup> “Immediate Family” is defined by the CIRB SOPs as a spouse, significant other or dependent child.

**Pre-Meeting Conflict of Interest Worksheet**  
For Month, Day, Year

	Have a proprietary interest in the research such as a licensing agreement, copyright, patent, or trademark	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Have the potential to gain academic or career advancement based upon participation in the study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Have an interest (financial or non-financial) that the CIRB or the CIRB member believes conflicts with or biases his/her ability to objectively review the study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**2. Other Reviews**

<p><b>Study ID, Study Title</b> (Protocol Version Date MM/DD/YY)</p> <p><b>Study Chair:</b> Name; Institution</p> <p><b>Agent / Drug / Enterprise</b> Agent – Manufacturer (Supplier)</p>	<p><b>Check the box next to the statement if the statement is true of you, an immediate family member or a person in a direct supervisory or reporting relationship with you. A checked box indicates you are conflicted for review of the study. Report the conflict to the CIRB Operations Office in advance of the CIRB Meeting.</b></p>			
	<p>Are a Coordinating Group investigator for this study AND have done any of the following:</p> <p><input type="checkbox"/> enrolled a participant,</p> <p><input type="checkbox"/> identified a prospective participant (i.e. actively evaluating a patient for potential participation in the study)</p> <p><input type="checkbox"/> performed any directed research-related interventions and interactions with a participant on this study (this does not apply to cross-over attending)</p>	<p><b>You</b></p>    <input type="checkbox"/>	<p><b>Family Member</b></p>    <input type="checkbox"/>	<p><b>Supervisor/ Employee</b></p>    <input type="checkbox"/>
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