

COI Screening for [Month Day, YYYY] [CIRB TYPE] CIRB Meeting

Attachment B09_Col_Scr_Mtgs

OMB# 0925-0753, Expiration Date: 07/31/2021

The purpose of the information collection is to conduct reviews of clinical trial studies. NCI guidelines mandate the participation of institutions in the CIRB for Network group studies. You are being requested to complete this instrument so that we can conduct activities involved with the operations of the NCI CIRB Initiative. Although your participation in Network group research and completion of the forms is voluntary, if you wish to participate in the CIRB, you must complete all questions on the form. The information you provide will be combined for all participants and reported as summaries. It will be kept private to the extent provided by law. 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 (0925-0753). Do not return the completed form to this address.

| 1. Initial Reviews | | You | Family Member | Supervisor/ Employee |
|---|--|--------------------------|--------------------------|--------------------------|
| <p>[Study ID], [Study Title] (Protocol Version Date MM/DD/YYYY)</p> <p>Study Chair: [Name]; [Institution]</p> <p>Agent / Drug / Enterprise [Agent] – [Manufacturer] ([Supplier])</p> | <p>Check the box next to the statement if the statement is true of you, an immediate family¹ 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.</p> <p>Have a primary role in the oversight, design or conduct of the project or has a role in the analysis or management of the data. This includes:</p> <ul style="list-style-type: none"> <input type="checkbox"/> serving on a governing body or other supervisory committee with group-wide oversight of the coordinating group that submitted the study, <input type="checkbox"/> serving on a Disease Committee, Working Group, or Data Monitoring Committee of the coordinating group that submitted the study for CIRB review, <input type="checkbox"/> serving as a Study Chair of a study under review with the CIRB <input type="checkbox"/> employed by the same institution as the Study Chair | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

¹ “Immediate Family” is defined by the CIRB SOPs as a spouse, significant other or dependent ch

| 1. Initial Reviews | | <i>You</i> | <i>Family Member</i> | <i>Supervisor/ Employee</i> |
|--------------------|---|--------------------------|--------------------------|-----------------------------|
| | 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 two years before the deliberations from any enterprise involved in the study under consideration, or any direct competitor | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | 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 derive benefit (financial benefit, career advancement or otherwise) based upon the outcome of 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"/> |

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| 2. Other Reviews | | You | Family Member | Supervisor/ Employee |
|---|--|--------------------------|--------------------------|--------------------------|
| <p>[Study ID], [Study Title] (Protocol Version Date MM/DD/YYYY)</p> <p>Study Chair: [Name]; [Institution]</p> <p>Agent / Drug / Enterprise [Agent] – [Manufacturer] ([Supplier])</p> | <p>Check the box next to the statement if the statement is true of you, an immediate family² 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.</p> | | | |
| | <p>Are a Signatory Institution Principal Investigator for this study AND have done any of the following:</p> <ul style="list-style-type: none"> <input type="checkbox"/> identified a prospective participant for the study (i.e. actively evaluating a patient for potential participation in the study) <input type="checkbox"/> enrolled a participant in the study, <input type="checkbox"/> performed or directed research interventions and interactions with the study participant (does not apply to other physicians who may be involved in the care of the patient, such as cross-over attendings, surgeons, or radiotherapists.) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | <p>Have a primary role in the oversight, design or conduct of the project or has a role in the analysis or management of the data. This includes:</p> <ul style="list-style-type: none"> <input type="checkbox"/> serving on a governing body or other supervisory committee with group-wide oversight of the coordinating group that submitted the study, <input type="checkbox"/> serving on a Disease Committee, Working Group, or Data Monitoring Committee of the coordinating group that submitted the study for CIRB review, <input type="checkbox"/> serving as a Study Chair of a study under review with the CIRB <input type="checkbox"/> employed by the same institution as the Study Chair | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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|-------------------------|---|--------------------------|--------------------------|-----------------------------|
| | 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 two years before the deliberations from any enterprise involved in the study under consideration, or any direct competitor | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | 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 derive benefit (financial benefit, career advancement or otherwise) based upon the outcome of 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"/> |