

Attachment_B08_Col_Scr_Wksht

OMB #0925-0753 Expiration Date: 06/30/2020

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.

NCI CIRB

MEMBER CONFLICT OF INTEREST SCREENING WORKSHEET

MEMBER NAME:

DATE COMPLETED:

The CIRBs follow standard operating procedures (SOPs) to ensure compliance with federal regulations and guidance. These SOPs include a Conflict of Interest Policy for CIRB members.

Identification and management of CIRB Member conflicts of interest is essential to maintaining the integrity of the NCI CIRB's reviews. This form is meant to help members and the CIRB Operations Office identify a member's actual or perceived conflicts of interest per CIRB SOPs. Please complete this worksheet and return it with your completed application and CV/Resume or Bio via email at cirbmembership@emmes.com

1. CIRB Standard Operations Procedures (SOPs) prohibit employees of the NCI from serving on the NCI CIRB [SOP 4.2.4].

Are you an employee of the NCI?

No.
Yes.

2. The CIRB SOPs prohibit employees of the NCI from serving on the NCI CIRB, but in some cases, individuals who are not employed by NCI but who have a working relationship with NCI in another

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capacity (e.g. a contractor or consultant, or serving on an NCI Disease-Specific Steering Committee) may be perceived as having a conflict of interest.

Do you have any such relationship with NCI?

No.

Yes. If yes, describe the relationship in the space below.

3. Individuals who have a primary role (e.g. member of a network group disease committee or a study chair) in the oversight, design or conduct of a study (or a particular subset of studies) under review by the CIRB are considered to be conflicted for those studies and may be too frequently conflicted to serve on the CIRB.

A conflict also exists if an immediate family member (i.e. spouse, significant other, dependent child) or an individual in a direct supervisory or reporting relationship to the member has such a role (e.g., a boss or employee). [SOP 4.11.3.1]

Do you, an immediate family member, or an individual in a direct supervisory or reporting relationship to you have a **primary role in the oversight, design or conduct** of a study (or a particular subset of studies) under review by the CIRB?

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CIRB Candidate (You)	Immediate family member (i.e. spouse, significant other, dependent child)	Individual in a direct supervisory or reporting relationship to the CIRB Candidate (i.e. your boss or your employee)
No.	No.	No.
Yes. Indicate which	Yes. Indicate which	Yes. Indicate which
study/studies:	study/studies:	study/studies:

4. Individuals who have a role in the analysis or management of data for a study or for a particular subset of studies under review by the CIRB are considered to be conflicted for those studies and may be too frequently conflicted to serve on the CIRB.

A conflict also exists if an immediate family member (i.e. spouse, significant other, dependent child) or an individual in a direct supervisory or reporting relationship to the member has such a role (i.e., a boss or employee). [SOP 4.11.3.1]

Do you, an immediate family member, or an individual in a direct supervisory or reporting relationship to you have a **role in the analysis or management of data** for a study or for a particular subset of studies under review by the CIRB?



CIRB Candidate (You)	Immediate family member (i.e. spouse, significant other, dependent child)	Individual in a direct supervisory or reporting relationship to the CIRB Candidate (i.e. your boss or your employee)
No. Yes. Indicate which study/studies:	No. Yes. Indicate which study/studies:	No. Yes. Indicate which study/studies:

5. Individuals who serve on a governing body or any significant supervisory committee of the coordinating group that submits studies for CIRB review, such as a Disease Committee, the Board of Directors, or a Data Monitoring Committee of the coordinating group are considered to be conflicted for those considered to be conflicted for those studies and may be too frequently conflicted to serve on the CIRB.

A conflict also exists if an immediate family member (i.e. spouse, significant other, dependent child) or an individual in a direct supervisory or reporting relationship to the member has such a role (i.e. a boss or employee). [SOP 4.11.3.1.1]

Do you, an immediate family member, or an individual in a direct supervisory or reporting relationship to you, serve on a governing body or any significant supervisory committee of the coordinating group that submits studies for review by the CIRB?		
CIRB Candidate (You) No. Yes. Indicate which coordinating group(s):	Immediate family member (i.e. spouse, significant other, dependent child) No. Yes. Indicate which coordinating group(s):	Individual in a direct supervisory or reporting relationship to the CIRB Candidate (i.e. your boss or your employee) No. Yes. Indicate which coordinating group(s):

6. Individuals who serve as Study Chairs of currently active studies (open to accrual) or who are employed by the same institution as Study Chairs may be considered to be conflicted for those studies and may be too frequently conflicted to serve on the CIRB.



A conflict also exists if an immediate family member (i.e. spouse, significant other, dependent child) or an individual in a direct supervisory or reporting relationship to the member has such a role (i.e. a boss or employee). [SOP 4.11.3.1.2 and SOP 4.11.3.2]

a. Do you, an immediate family member, or an individual in a direct supervisory or reporting		
relationship to you, serve as a Study Chair of a currently active study?		
	Immediate family member (i.e. spouse, significant other,	Individual in a direct supervisory or reporting relationship to the CIRB Candidate
CIRB Candidate (You)	dependent child)	(i.e. your boss or your employee)
No. Yes. Indicate which study/studies:	No. Yes. Indicate which study/studies:	No. Yes. Indicate which study/studies:



b. To the best of your knowledge, are you, an immediate family member, or an individual in a direct supervisory or reporting relationship to you, **employed by the same institution as the Study Chair of a currently active study**?

of a currently active study?		
		Individual in a direct supervisory or
	Immediate family member	reporting relationship to the CIRB
	(i.e. spouse, significant other,	Candidate
CIRB Candidate (You)	dependent child)	(i.e. your boss or your employee)
No.	No.	No.
Yes. Indicate which	Yes. Indicate which	Yes. Indicate which
study/studies:	study/studies:	study/studies:

7. Please list institutions with which you, an immediate family member, or an individual in a direct supervisory or reporting relationship to you, have an affiliation (as a consultant, contractor, or employee). [SOP 4.11.3.2]

CIRB Candidate (You)	Immediate family member (i.e. spouse, significant other, dependent child)	Individual in a direct supervisory or reporting relationship to the CIRB Candidate (i.e. your boss or your employee)
	If applicable.	If different from your own.
1.	1.	1.
2.	2.	2.
3.	3.	3.



8. Individuals who have a significant financial interest in any oncology-related agents/devices/enterprises may be considered to be conflicted for studies involving those agents/devices/enterprises (or agents/devices/enterprises developed by direct competitors) and may be too frequently conflicted to serve on the CIRB.

A conflict also exists if an immediate family member (i.e. spouse, significant other, dependent child) or an individual in a direct supervisory or reporting relationship to the member has such a role (i.e. a boss or employee). [SOP 4.11.3.3, 4.11.3.3.1, 4.11.3.3.2, 4.11.3.3.3]

a. Do you, an immediate family member, or an individual in a direct supervisory or reporting relationship to you, have a financial interest of \$5,000 or more in any oncology-related		
agents/devices/enterprises?		
		Individual in a direct supervisory or
	Immediate family member	reporting relationship to the CIRB
	(i.e. spouse, significant other,	Candidate
CIRB Candidate (You)	dependent child)	(i.e. your boss or your employee)
No.	No.	No.
Yes. Indicate which	Yes. Indicate which	Yes. Indicate which
agents/devices/enterprises:	agents/devices/enterprises:	agents/devices/enterprises:

b. Have you, or an immediate family member received any compensation from any oncology-related enterprise within the last two years?		
	Immediate family member	
CIRB Candidate (You)	(i.e. spouse, significant other, dependent child)	
 ☐ No. ☐ Yes. Indicate which agents/devices/enterprises: 	 No. Yes. Indicate which agents/devices/enterprises: 	