

## Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Campbell EG, Weissman JS, Vogeli C, et al. Financial relationships between institutional review board members and industry. *N Engl J Med* 2006;355:2321-9.

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The Harvard Medical School  
Study of Academic-Industry Relationships  
Among IRB Members

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Funded by a grant from the  
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Conducted by faculty of  
the Harvard Medical School  
and the  
Center for Survey Research  
UMass Boston

Your responses are completely anonymous.

*ABOUT THIS SURVEY*

This survey is about your experience as an IRB member. The answers you provide will help us better understand how the academic-industry relationships of IRB members are disclosed and managed. We plan to widely disseminate the results of this survey in peer-reviewed journals. The results will help inform IRB policy and practice. The survey is designed to take about 20 minutes to complete.

Your responses are completely anonymous. Your institution will not be informed about your decision to participate in this study. *Neither your name nor any data that may identify you appear anywhere on the survey. The enclosed postage-paid postcard has an identifying number that is our only means of tracking your participation. Please mail it separately from the completed questionnaire.*

For each question, please fill in one box  or write in an answer, as requested.

If you have any questions about this survey, please call Matthew Jans at the Center for Survey Research, U Mass Boston 1-800-492-5845, or Christine Vogeli, PhD in the Department of Medicine, Harvard Medical School at the MGH Institute for Health Policy at 1-617-724-0984. This study has been reviewed and approved by the UMass Boston and MGH Institutional Review Boards.

When you are finished, please return this survey in the postage-paid envelope provided to the Center for Survey Research, and mail the enclosed postage-paid postcard separately.

Have you ever been a voting member of an IRB (full or alternate)?

YES If Yes, please go to question A1 on the next page

NO If NO, Please check this box and stop here. Please return the survey in the accompanying envelope to CSR. Please also mail the postcard separately to avoid unnecessary reminders from us.

**SECTION A:  
IRB ACTIVITIES**

**A1.** Are you currently a voting member of an IRB?

Yes

→ In what year did you begin serving on your current IRB?

\_\_\_\_\_ year

No

→ In what year did you stop being a voting member of an IRB?

\_\_\_\_\_ year

**A2.** Which best describes the setting for your most recent IRB service?

*(Check all that apply)*

- A medical school IRB
- Other university IRB
- A hospital IRB
- A commercial IRB
- Other (specify: \_\_\_\_\_)

**A3.** In your most recent year of IRB service, which category best describes your relationship to the institution for which your IRB reviewed clinical research proposals?

*(Please check only one)*

- <sub>1</sub> Affiliated member
- <sub>2</sub> Non-affiliated/community member
- <sub>3</sub> Other (specify: \_\_\_\_\_)

**A4.** Other than coverage for your expenses, in your most recent year of IRB service, did you receive any direct financial compensation for your IRB service?

- <sub>1</sub> Yes
- <sub>2</sub> No

**A5.** In your most recent year of IRB service, about how many times a month did your IRB meet?

\_\_\_\_\_ meeting(s) per month

**A6.** In your most recent year of IRB service, about what percentage of the scheduled meetings did you attend?

\_\_\_\_\_ % of meetings attended

**A7.** In your most recent year of IRB service, about how many **new protocols** received full board review in an average IRB meeting?

\_\_\_\_\_ average # of new protocols per IRB meeting

**A8.** In your most recent year of IRB service, did your IRB use a primary reviewing system, where certain individuals were assigned primary or “in-depth” review responsibilities for the group?

- <sub>1</sub> Yes
- <sub>2</sub> No **(If No, go to Section B)**

**A9.** In your most recent year of IRB service, how many protocols did you review as a primary reviewer?

\_\_\_\_\_ protocols in your most recent year

**SECTION B:  
IRB DISCLOSURE OF MEMBER  
RELATIONSHIPS WITH INDUSTRY**

**B1.** Does your IRB have a defined process for members to disclose to the IRB, financial and other relationships with industry?

- <sub>1</sub> Yes
- <sub>2</sub> No
- <sub>3</sub> Don't Know

**SECTION C:  
IDENTIFYING CONFLICTS OF INTEREST**

**B2.** In your most recent year as a member of an IRB, did any members of your IRB actually disclose (required or not) financial or other industry relationships related to their activity as IRB members?

- 1  Yes  
 2  No (If No, Go to Question B4)  
 3  Don't Know (If Don't Know, Go to B4)

**B3.** To whom did the IRB member(s) disclose their financial or other industry relationship(s)?

**Yes No**

- 1  2  a. The chair
- 1  2  b. The entire IRB
- 1  2  c. A group or individual separate from the IRB, but within the university or hospital it serves
- 1  2  d. An entity external to the IRB and the organization it serves
- 1  2  e. Someone else (specify: \_\_\_\_\_)

**B4.** Which of the following does your IRB do regarding members' financial and other industry relationships?

**Yes No**

- 1  2  a. IRB members are specifically asked about or are expected to complete a form documenting their financial and other industry relationships when joining the IRB.
- 1  2  b. Financial and other relationships are openly discussed in IRB meetings or other IRB forums.
- 1  2  c. Each IRB member is expected to self identify financial or other relevant relationships that could be considered problematic.
- 1  2  d. The IRB uses specific thresholds to determine if an IRB member's financial or other relationships are problematic.
- 1  2  e. The IRB follows specific written guidelines to determine the appropriate actions to take when IRB members' financial or other industry relationships are considered problematic.
- 1  2  f. The chair ensures that persons with financial or other relationships that can be problematic act appropriately.

**C1.** Does your IRB have a **written policy** that defines when an IRB member's financial or other industry relationship is a conflict of interest?

- 1  Yes (If Yes, go to Question C3)  
 2  No  
 3  Don't Know

**C2.** In the absence of a written policy, who decides whether an IRB member's relationship with industry is a conflict of interest?

*(Please check one)*

- 1  The IRB member  
 2  The Chair  
 3  The entire IRB  
 4  A group or individual separate from the IRB, but within the university or hospital it serves  
 5  An entity external to the IRB and the organization it serves  
 6  Other (specify: \_\_\_\_\_)

**C3.** Regardless of how your IRB currently operates, where do you think the oversight responsibility regarding IRB members' relationships with industry **should** reside?

*(Please check one)*

- 1  The IRB member  
 2  The Chair  
 3  The entire IRB  
 4  A group or individual separate from the IRB, but within the university or hospital it serves  
 5  An entity external to the IRB and the organization it serves  
 6  Other (specify: \_\_\_\_\_)

**SECTION D:  
MANAGING MEMBERS'  
CONFLICTS OF INTEREST**

**D1.** In practice during your most recent year of IRB service, were any IRB members actually identified as having an industry relationship that was a conflict of interest?

- 1  Yes  
 2  No (If No, go to Question D4)  
 3  Don't Know (If Don't Know, go to D4)

**D2.** In your most recent year of IRB service, when a member had a conflict of interest with industry, how often did the member...

	Never	Rarely	Usually	Always
a. leave the room when the protocol was under consideration?	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
b. partially participate in the discussion by only responding to specific questions?	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
c. fully participate in the general discussion?	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
d. vote on the protocol?	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

**D3.** In hindsight, over the last year, how confident are you that your IRB correctly managed conflicts of interest between IRB members and industry in **every** case?

- 1  Very Confident  
 2  Moderately Confident  
 3  Not Very Confident  
 4  Not at all Confident

**D4.** Has your IRB ever explored members' relationships with **competitors of companies sponsoring protocols** as potential sources of conflicts of interest?

- 1  Yes  
 2  No  
 3  Don't Know

**D5.** In your most recent year of IRB service how often have you ....

	Never	Rarely	Sometimes	Often
a. felt an IRB member's relationship with a company inappropriately affected his/her IRB-related decisions?	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
b. felt an IRB member's relationship with a principal investigator inappropriately affected his/her IRB-related decisions?	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
c. felt that a protocol was presented in a biased manner because of a member's relationship with a company?	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
d. felt that a member did not properly disclose a financial relationship?	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
e. believed your IRB failed to take appropriate action regarding a member's relationships with a company?	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
f. expressed concern about a member's relationship with industry to your IRB chair or other official?	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
g. felt pressure from your institution or department to approve a protocol that you felt was not ready for approval?	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

## SECTION E: POTENTIAL BENEFITS OF MEMBERS' INDUSTRY RELATIONSHIPS

**E1.** There is often a tension between the **benefits** that accrue to an IRB from having members with experience with industry sponsors, and the **potential conflicts of interest** they may bring to the table.

Compared to other IRB members, of what added benefit are the views of IRB members **with prior or ongoing experience working with industry** on the following?

	No Added Benefit	Small Benefit	Large Benefit
a. Conveying the scientific benefit of the drug/device/product in comparison to others currently on the market	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
b. Understanding industry standards for data management	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
c. Understanding the impact of industry regulations on study design	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
d. Understanding industry's use of multi-phase or multi-site trials	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
e. Understanding industry requirements for secrecy	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>

## SECTION F: PERSONAL EXPERIENCE

**F1.** In your most recent year of IRB service were you involved with industry in any of the following ways?

**Yes No**

- 1  2  **a.** Officer, executive, or paid employee of a company
- 1  2  **b.** Member of a board of directors of a company
- 1  2  **c.** Paid consultant for a company\
- 1  2  **d.** Member of a scientific advisory board of a company
- 1  2  **e.** Recipient of royalties (e.g. patent licenses, milestone payments, etc.) from a company
- 1  2  **f.** Member of the speakers bureau for a company

**F2.** In your most recent year of IRB service did you receive ...

**Yes No**

- 1  2  **a.** any funding for university/hospital research from an industry source?
- 1  2  **b.** any support for your students or post-doctoral fellows from an industry source?
- 1  2  **c.** equity in a company in exchange for professional services or intellectual property?
- 1  2  **d.** compensation from industry for participation in meetings, conferences or other activities?

**F3.** During your most recent year of IRB service, about how many protocols came before your IRB that were either sponsored by a company with which you personally had a relationship (see questions F1 and F2 above), or sponsored by a company that was in competition with a firm with which you had a personal relationship?

- 1  None (If None, go to Section G on Page 6)
- 2  1-2 protocols
- 3  3-5 protocols
- 4  6-10 protocols
- 5  More than 10 protocols

**F4.** For the protocols involving companies with which you had relationships of these kinds, how often did you...

	Never	Rarely	Usually	Always
a. disclose the relationship to the IRB or an IRB official?	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
b. leave the room when the protocol was under consideration?	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
c. partially participate in the discussion by only responding to specific questions?	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
d. fully participate in the general discussion?	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
e. vote on the protocol?	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

**F5.** In hindsight, how confident are you that you did the right thing in **every** case?

- <sub>1</sub> Very Confident
- <sub>2</sub> Moderately Confident
- <sub>3</sub> Not Very Confident
- <sub>4</sub> Not at all Confident

**SECTION G:  
OPINIONS ABOUT STUDY  
INVESTIGATORS AND STUDY SPONSORS**

*We are also interested in your beliefs about the role of IRBs in monitoring industry relationships between study investigators and the companies sponsoring their research.*

**G1.** How much of a problem, if any, do investigators' industry relationships pose for research integrity...

	No Problem at all	Small Problem	Moderate Problem	Big Problem	Don't Know
a. at your institution?	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
b. at other institutions in the US?	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>

**G2.** Which of the following **should be** the rule when reviewing new study protocols?

*(Please check only one)*

- <sub>1</sub> IRBs should not consider any investigator-industry relationships when reviewing new study protocols
- <sub>2</sub> IRBs should consider all investigator-industry relationships whether or not they are deemed to be conflicts of interest
- <sub>3</sub> IRBs should consider only those investigators' industry relationships that have been deemed to be conflicts of interest
- <sub>4</sub> Other (specify: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_) )

**G3.** In your most recent year of IRB service, how often did your IRB consider information about **investigator-industry relationships** when reviewing protocols?

- <sub>1</sub> Always (If Always, go to Section H)
- <sub>2</sub> Usually
- <sub>3</sub> Sometimes
- <sub>4</sub> Rarely
- <sub>5</sub> Never

**G4.** Why were investigators' industry relationships not **always** considered when reviewing protocols?

	Yes	No	
<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>		a. The issue didn't come up.
<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>		b. Financial disclosure information was not part of my IRB's responsibility.
<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>		c. It was difficult to obtain reliable information on investigators' financial interests from the institution.
<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>		d. Most members of my IRB did not have the requisite expertise to consider matters pertaining to conflicts of interest.

**SECTION H:  
OPINIONS ABOUT THE HANDLING OF  
RESEARCH PARTICIPANTS**

**H1.** About which of the following should study participants be informed prior to enrolling in a clinical study?

Yes No

<sub>1</sub>  <sub>2</sub> a. The sponsor of the research

<sub>1</sub>  <sub>2</sub> b. The industry relationships of the members of investigative team.

<sub>1</sub>  <sub>2</sub> c. The industry relationships of the institution at which the research is taking place

**H2.** In your most recent year of IRB service how often did your IRB require that study participants receive information on...

	<u>Always</u>	<u>Sometimes</u>	<u>Never</u>
a. the sponsor of the research?	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>
b. the industry relationships of the members of the investigative team?	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>
c. the industry relationships of the institution at which the research was taking place?	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>

**H3.** In your view, should sponsors of clinical trials have a responsibility to provide access to the tested treatment, assuming it is proven effective, to study participants once a trial is over?

- <sub>1</sub> Yes, for all trials  
 <sub>2</sub> Yes, for certain trials  
 <sub>3</sub> No

**SECTION I:  
BACKGROUND INFORMATION**

**I1.** Are you male or female?

- <sub>1</sub> Male  
 <sub>2</sub> Female

**I2.** Please indicate your race/ethnicity:

*(Check all that apply)*

- American Indian or Alaskan Native  
 Asian/Pacific Islander  
 Black  
 Hispanic  
 White  
 Other (specify: \_\_\_\_\_)

**I3.** At the start of your most recent year of IRB service, about how many years of experience did you have conducting research involving living humans as research subjects (clinical research)?  
 \_\_\_\_\_ years (if none, enter "0")

**I4.** At the start of your most recent year of IRB service, about how many years of experience did you have conducting research not involving living humans as research subjects (basic research)?  
 \_\_\_\_\_ years (if none, enter "0")

**I5.** At the start of your most recent year of IRB service, about how many years of experience did you have providing patient care?  
 \_\_\_\_\_ years (if none, enter "0")

**I6.** At the start of your most recent year of IRB service, approximately how many articles had you published in refereed journals over the previous 3 years?  
\_\_\_\_\_ articles (if none, enter "0")

**I7.** At the start of your most recent year of IRB service, which of the following graduate degrees had you earned?  
(Check all that apply)

- Master's Degree
- MD
- PhD
- Other Doctorate: \_\_\_\_\_

**I8.** What do you consider your primary professional field (e.g. Medicine, Nursing, Biochemistry, Law, etc.)? Please be as specific as possible.  
\_\_\_\_\_

**I9.** In your most recent year of IRB service, did you hold a faculty appointment?

- Yes
- No

**I10.** In your most recent year of IRB service, what was your academic rank

- None
- Instructor, Lecturer, etc
- Assistant professor
- Associate professor
- Professor
- Other (specify: \_\_\_\_\_)

**I11.** In your most recent year of IRB service, what was the total value of all goods and services you received from companies other than your primary employer related to your area of professional expertise?  
\$ \_\_\_\_\_

**I12.** In your most recent year of IRB service, what was your total income for all activities related to your area of professional expertise?  
\$ \_\_\_\_\_

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Thank you for participating.