

**Ancillary Information Conflicts of Interest
Disclosure Form
Relating to PCORI-Funded Research Project**

All fields are required.

Contract Number: ME-1303-6016

1. Name of Recipient (Awardee Institution):

Daniel Scharfstein (Johns Hopkins University)

2. Name of PCORI-Funded Research Project:

Sensitivity Analysis Tools for Clinical Trials with Missing Data

3. Names and Institutions of Principal Investigator (PI) and Key Personnel:

Name:	Role:	Recipient (Awardee Institution):
Daniel Scharfstein	Principal Investigator	Johns Hopkins University

Key Personnel Name:	Institution:
Aidan McDermott	Johns Hopkins University
Chenguang Wang	Johns Hopkins University
Tianjing Li	Johns Hopkins University
Elizabeth Stuart	Johns Hopkins University

4. Does Recipient have a Conflicts of Interest Policy or Guidelines that meets the requirements of the federal financial conflicts of interest regulations of the US Public Health Service (<http://grants.nih.gov/grants/policy/coi/>) that it applies to PCORI-funded research?

YES

NO (See Question 5)

5. If you checked "No," Recipient must provide information describing how Recipient will ensure that the PCORI-Funded Research Project is not influenced by conflicts of interest.
-
-

6. Report the existence of any financial or personal interests or associations of Recipient, Principal Investigator, and Key Personnel related to the PCORI-Funded Research Project under this Contract that constitute a conflict of interest. Attach the management plan that addresses identified conflicts of interest.

Print "None" if Recipient, Principal Investigator, and Key Personnel have no financial or personal interests or associations that constitute a conflict of interest. (Attach additional documents, if needed).

Dr. Scharfstein regularly consults with industry. These consultations are reported to and reviewed by the Johns Hopkins University (JHU) Conflict of Interest (COI) Review Board. The JHU COI Review Board have not determined any of these consultations to be conflicts. Companies that Dr. Scharfstein has consulted with include: Ameritox, Janssen, Otsuka, Pfizer, Merck, Asubio, Bayer, Bausch & Lomb, Cephalon, Helsinn, Daiichi Sankyo, Ethicon, Novartis, Luitpold, Depuy, Actavis, InVivo, Glaxo, MelaSciences. He owns stocks in the following healthcare companies: Merck, Johnson and Johnson, AbbVie, Pfizer, Tonix, Sanofi, Abbott, Express Scripts, Medtronic, Mallinckrodt.

Dr. McDermott has consulted with Sapphire Consulting, Inc., a company owned by Dr. Scharfstein, on projects for Janssen and Otsuka.

Dr. Wang has consulted with Sapphire Consulting, Inc., a company owned by Dr. Scharfstein, on project for Helsinn.

Dr. Li has no direct and indirect links to industry.

Dr. Stuart's links to industry are documented at <http://www.pcori.org/people/elizabeth-stuart-phd-am>

.

7. Please list any direct or indirect links to industry (such as pharmaceutical, medical device, health insurance, and other healthcare-related companies) that Recipient has related to the PCORI-Funded Research Project.

Print "None" if there are no direct or indirect links to industry as described above. There is no need to include disclosures here that are reported under Question 6 above. (Attach additional documents, if needed).

-
8. If Recipient has any additional material information relating to disclosures or management of conflicts of interest, or other protections against bias pertinent to the PCORI-Funded Research Project, please describe it here. Print "None" if there is no additional material information as described above.

The undersigned certify that the above information is complete and true to the best of their knowledge and understand that this completed form, with these disclosures, will be made publicly available by PCORI in conjunction with the research findings relating to the Research Project. Both the Administrative Official and Principal Investigator must complete and sign one form.

Administrative Official:

Signed: _____
Print Name: Alexandra M. Albinak
Title: Associate Vice Provost
Date: 11-6-2017

Principal Investigator:

Signed: *Daniel Scharfstein*
Print Name: Daniel Scharfstein
Title: Professor of Biostatistics
Date: 11/3/17