

**INSTITUTIONAL OVERSIGHT OF INDIVIDUAL FINANCIAL INTERESTS IN HUMAN  
SUBJECTS RESEARCH:  
ASSESSING POLICIES AND PRACTICES**

Introduction and Explanatory Notes

This study aims to describe the current status of university or academic medical center (as applicable) policies, procedures, and practices relating to the identification, management, and oversight of individual conflicts of interest in human subject research.

*Note 1: Institutions may have a variety of policies that relate to research, including those that govern financial conflicts of interest, review of human subjects research, publications, intellectual property, extramural activity, and grants and contracts administration. References in the questionnaire to the your institution's Conflicts of Interest "Policy" indicate the applicable Conflicts of Interest **policy or policies** governing the disclosure, evaluation, and management of individual financial conflicts of interest at your institution.*

*Note 2: At the end of this questionnaire, an assessment is sought of the overall impact on your institution of the AAMC recommendations regarding individual financial conflicts of interest. We ask that you consult with the senior research official at your institution in formulating your response.*

*Note 3: Abbreviations used: **COI**: Conflict of Interest; **HSR**: Human Subjects Research; **IRB**: Institutional Review Board; **SFI**: Significant Financial Interest.*

*Note 4: Please return to survey by June 15 to Susan Ehringhaus by email at [sehringhaus@aamc.org](mailto:sehringhaus@aamc.org), by fax at (202) 828-1125.*

### Recent Policy Changes

1. Have changes been made in university or academic medical center (as applicable) policies and procedures relating to **individual** financial conflicts of interest (COI) in human subjects research (HSR) since December 2001?
- Yes  No

Briefly describe the purpose of the changes.

### Characteristics of COI Policy

2. Whether or not changes to your COI policy have been made since December 2001, which of the following does your policy contain (check all that apply)?
- Special reference to HSR in policy standards.
- A rebuttable presumption or similar standard against participation in HSR by a researcher with a significant financial interest (SFI).
- A prohibition on payments from any source for particular research results.
- Reference to special obligations owed to students and other trainees.
- Sanctions for violations of the policy.
3. Does the policy cover all HSR, and not just HSR that is federally funded?
- Yes  No
4. For a researcher with a SFI, is there a different standard of review for a HSR proposal than for a proposal that does not involve human subjects?
- Yes  No

Explain your answer.

5. Does your policy permit a researcher with SFI to conduct HSR when compelling circumstances are judged to exist?  
 Yes  No
6. Does the policy contain a definition of compelling circumstances or similarly high standard?  
 Yes  No
7. To whom is the COI policy applicable (check all that apply)?  
 All faculty engaged in HSR.  
 All nonfaculty research staff that are engaged in HSR.  
 Administrative officials.  
 Others.

8. How is your policy publicized to the covered community?

Specify

### **Significant Financial Interest**

9. Does your policy contain a definition of SFI or similar concept?  
 Yes  No
- A. What is your institution's threshold for disclosure of an individual financial interest (check the one that applies)?  
 PHS (\$10,000).  
 FDA (\$25,000).  
 Other.

- B.** Which of the following does SFI include (check all that apply)?
- Equity in non-publicly traded companies, regardless of percentage share of equity.
  - Equity in non-publicly traded companies, regardless of estimations as to valuation.
  - Royalty income from your institution, above a certain threshold.
  - Royalty income from your institution, regardless of amount.
  - Non-royalty payments not directly related to reasonable costs of research.

### Standing Committee on COI

**10.** With regard to your process for disclosure and management of COIs in HSR:

**A.** Is there a standing committee on COI?

Yes  No

(If “No”, skip to question **11**.)

**B.** To whom does this standing committee report?

Specify

**C.** Does this standing committee have final decision authority on management of COIs in HSR?

Yes  No

If not, where does the final decision authority rest?

Specify

**D.** Must this standing committee evaluate SFIs in HSR prior to final IRB review?

Yes  No

**E.** Which of the following responsibilities does this standing committee have (check all that apply)?

- Review of individual COI disclosures.  
 Documentation of its decisions or recommendations.  
 Communication to IRBs and institutional officials about its findings and recommendations.

**F.** Does this standing committee include representation from outside the institution?

- Yes  No

**G.** Are there appeal rights from this standing committee's determinations?

- Yes  No

**H.** Is review by this standing committee required of proposed licensing agreements that would create SFIs for individuals?

- Yes  No

**I.** If not, is there other review of such potential SFIs?

Specify

### **Reporting of COIs**

**11.** Is annual reporting of COIs required for covered employees?

- Yes  No

If not, with what frequency is reporting required?

Specify

12. Is updated reporting required whenever there are relevant changes?  
 Yes  No
13. Are covered individuals required to report their relevant SFIs prior to undertaking HSR?  
 Yes  No
14. Is special training available for covered individuals about the requirements of the COI policy and process?  
 Yes  No

If yes, specify the type of training offered (e.g., on-line, seminars, etc.).

15. Is COI information (either in individual or aggregate format) periodically reported by the standing committee or, in the absence of a standing committee, a designated COI official with responsibility for administration of the COI process (COI official), to a senior institutional official for review?  
 Yes  No

If yes, how frequently? Specify.

16. May covered individuals submit required COI reports online?  
 Yes  No

### **Linkages to IRBs**

17. Is the standing committee or the COI official required to notify institutional IRBs of its determinations regarding SFIs in HSR?  
 Yes  No

**18.** With which of the following must researchers file their current COI information (check all that apply)?

- Standing COI committee or designated COI official.
- IRB.
- Department Chair or Director.
- Dean.
- Vice President/Vice Chancellor for Research.
- Other.

Specify.

**19.** Who makes the final decision on questions as to whether or not a covered individual with a relevant SFI will be permitted to engage in human subjects research?

- IRB.
- COI committee.
- Administrative official. Specify
- Other.

Specify.

### **Management of COIs**

**20.** In connection with the management of permitted COIs in HSR, check all of the following that are either suggested or required by the policy:

- Reduction of SFI.
- Elimination of SFI.
- Monitoring of research project.
- Disclosure of SFI to human subjects in consent form.
- Regular audits of informed consent and subject enrollment process.
- Involvement of patient representative, ombudsman, or the like during subject recruitment.
- Involvement of patient representative, ombudsman, or the like during subject consenting and enrollment.
- Use of either internal or external data safety monitoring boards.

### Monitoring of COIs

21. When research is permitted to go forward with the participation of a researcher with a SFI, is the research monitored in order to manage the COI?  
 Yes  No

If “Yes”, how frequently (annually, semiannually, monthly, other) is monitoring generally required of a given research project?

Specify.

22. To the extent monitoring of research is employed as a tool for managing COI in HSR, who conducts the monitoring (check all that apply)?

- Standing COI committee.
- Standing monitoring committee.
- Ad hoc monitoring committee.
- Individual appointed to monitor the research project.

23. To the extent monitoring is employed as a tool for managing COI in HSR, are written reports of monitoring efforts required?

Yes  No

If yes, to whom are the reports sent? Specify.

24. When a researcher with a SFI is permitted to proceed with HSR, is disclosure required of the researcher’s SFI (check all that apply)?

- To sponsors or funders of the research.
- To editors of journals, etc., to which papers or reports of research are submitted.
- In oral presentations of research results.
- For multicenter trials, to investigators, to sponsors and to other IRBs participating in the trial.
- To subjects in informed consent forms.

Other. 

Specify.
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### Institutional Impact

25. Following consultation with the senior research official at your institution, how would you assess the impact on your institution of the AAMC recommendations regarding individual financial conflicts of interest (check the one that applies)?

- Substantial.  
 Moderate.  
 Slight.  
 None.

Please provide a brief explanation of your answer.
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If you answered “Substantial” or “Moderate”, please provide an indication of your institution’s plans for addressing the impact of the recommendations.

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26. If you have found any of the AAMC Task Force’s recommendations on individual conflicts of interest unworkable or otherwise unfeasible, please specify those that have been problematic for your institution and provide any suggestions you have for improvement.

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