



Conflicts of Interests: Procedures for Coordinating Investigations

Policy

- Children's Hospital and Harvard Medical School (HMS) have various targeted policies that address conflicts of interest. To ensure that disclosures under those policies are addressed in a coordinated manner, conflicts of interest that affect research under all such policies shall be resolved by the collective efforts of the Vice President of Research Administration, the Office of General Counsel, and, where applicable, the Committee on Clinical Investigation (CCI), according to the terms of those policies.

Purpose

To describe the process by which conflicts of interest that affect research will be investigated and addressed.

Procedures

Conflicts disclosed to the CCI

The Principal Investigator (PI) submits the CCI Application Disclosure Form to the CCI along with the protocol application.

The Director of Clinical Research Compliance reviews the disclosure form, and includes it in any protocol materials forwarded to the CCI.

At the same time, the Director of Clinical Research Compliance forwards to the General Counsel any disclosure form that includes a positive response concerning any financial interest or relationship. General Counsel determines if any additional information is needed to apply Children's Hospital and HMS conflict standards. General Counsel may recommend that the CCI take immediate action based only on the written disclosure, pending further inquiry (e.g., seeking independent clinical assessment of a protocol where a conflicted investigator is the sole source of information regarding the protocol's description of risks and benefits). Based on the determination of what further inquiry is required, on any questions and requests for additional information from primary reviewers or that result from the CCI review of a protocol, and on the assessment of the Director of Clinical Research Compliance, General Counsel will follow-up with a PI for further information, or recommend that CCI staff do so. (For example, straightforward requests for information, such as confirmation of unrelatedness of unpaid consulting to research, may be made by e-mail from CCI staff. More complex situations may involve a meeting that includes General Counsel, the Director of Clinical Research Compliance, the CCI Chair, and the PI.)

After information has been obtained, General Counsel determines whether a conflict exists under any HMS policy and, if so, addresses resolution of the conflict first under such policies, and reports the resolution to the Director of Clinical Research Compliance. The Director of Clinical Research Compliance in turn reports to the IRB at a convened meeting, identifying any potential issues not resolved by the application of HMS or other policies.

The CCI reviews this information and may take extra steps to assure the protection of human subjects in accordance with CCI policy.

The resolution is documented in the CCI protocol file, together with a copy of the disclosure and resolution, and CCI approval or revision.

Conflicts disclosed in connection with applications for Public Health Service (PHS) and National Science Foundation (NSF) Grants

The PI submits the PHS/NSF Conflict of Interest Form to the Office of Sponsored Programs.

Any form that indicates a significant financial interest is forwarded by the Office of Sponsored Programs to the Vice President of Research Administration and General Counsel.

The Vice President of Research Administration and General Counsel determine the information needed from the PI and who will secure the information. If the information indicates a conflict that affects a clinical trial, the Vice President of Research Administration forwards a copy, or a summary of the pertinent information, to the Director of Clinical Research Compliance.

After information is obtained, the Vice President of Research Administration and the General Counsel determine whether a conflict exists and, if so, how to address it.

A written record is created of the nature of the disclosure, the information obtained, the resolution, and the conclusion.

A written record is reviewed with the Office of Sponsored Programs and the PI.

A copy of the disclosure and the resolution is maintained in the grant file by the Vice President of Research Administration and the Office of Sponsored Programs.

Where conflict affects a clinical trial, the Vice President of Research Administration or General Counsel discusses the resolution with the Director of Clinical Research Compliance who, with the CCI, addresses any remaining issues under the **Conflicts of Interest: Clinical Research**.

Resolution of managed conflicts is reported by the Vice President of Research Administration as required by applicable laws and regulations.

Conflicts disclosed under Harvard Medical School Policy

HMS sends forms that contain potential conflicts to the Vice President of Research Administration or General Counsel.

The Vice President of Research Administration and General Counsel review forms that indicate potential conflicts to determine the information needed and who will speak with the faculty member. If information indicates a conflict that affects a clinical trial, the Vice President of Research Administration forwards a copy, or a summary of the pertinent information, to the Director of Clinical Research Compliance.

After information has been obtained, the Vice President of Research Administration and General Counsel convene a COI committee comprised of predominantly of select faculty to provide review, input and approval of the resolution of each COI .

A written response to HMS is prepared by the Vice President of Research Administration and General Counsel, and is sent to HMS, with a copy retained by the Vice President of Research Administration.

Where conflict affects a clinical trial, the Vice President of Research Administration or General Counsel discusses the resolution with the Director of Clinical Research Compliance, who with the CCI, addresses any remaining issues under the **Conflicts of Interest: Clinical Research**.

Related Content

None Identified

Document Attributes

Title	Conflicts of Interests: Procedures for Coordinating Investigations		
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