



<b>SOP Title</b>	<b>Conflicts of Interest - Organization</b>
<b>Number.Version</b>	105C.003
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## Approvals

<b>Name and Title of Signatories</b>	<b>Signature</b>	<b>Date</b> mm/dd/yyyy
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### 1. PURPOSE

This standard operating procedure (SOP) describes potential Conflicts of Interest (COI) in the relationship between the organization establishing the Health Science Research Ethics Board (HSREB) and the HSREB itself, and the requirements and procedures for disclosure and for managing potential COI within this relationship.

### 2. GENERAL POLICY STATEMENT

The SOP pertains to HSREBs that review human participant research in compliance with applicable regulations and guidelines.

### 3. RESPONSIBILITY

All REB members and Office of Human Research Ethics (OHRE) staff are responsible for ensuring that the requirements of this SOP are met.

### 4. DEFINITIONS

See Glossary of Terms.

### 5. SPECIFIC POLICIES AND PROCEDURES.

Organizational policies should address the roles, responsibilities and process for identifying, eliminating, minimizing, or otherwise managing COI relevant to research, including disclosure to the HSREB. Management of COI includes, but is not limited to, prevention, evaluation, disclosure, and the application of appropriate remedies as defined by the organization.

The HSREB must be fair and impartial, immune from pressure by the sponsor, the parent organization, and the researchers whose research is submitted for review. In the interest of public trust and the integrity of the ethics review, the HSREB must act independently from its parent organization, and avoid or manage real or apparent COI. The organization must respect the autonomy of the HSREB and ensure that the REB has the appropriate financial and administrative independence to fulfill its primary duties.

The standard that should guide decisions about determining conflicting interests is whether an independent observer could reasonably question whether the HSREB actions or decisions could be based on factors other than the rights, welfare, or safety of the research participants.

## **5.1. Disclosure of Conflict of Interest**

- 5.1.1. All organizational employees must be familiar with the COI policy and must complete a Disclosure of COI Form(s) (if applicable) at the time of hire and annually thereafter, or as per organizational policy;
- 5.1.2. Prior to engaging in any of the professional activities listed in the COI Policy, employees must seek the approval of the appropriate Organizational Official to ensure that no conflict exists in doing so;
- 5.1.3. HSREB members shall be apprised of the organizational structure with emphasis placed on the independent nature of the relationship between the HSREB and the organization. The actions of the HSREB members relating to their responsibilities to protect human research participants shall not be measured or evaluated in terms of organizational or financial goals;
- 5.1.4. HSREB meetings are closed to employees of the organization unless they are HSREB members, OHRE staff, permitted as observers, or invited by the HSREB to provide information, and only after signed confidentiality agreements are in place;
- 5.1.5. Organizational senior administrators shall not serve as HSREB members nor observe HSREB meetings when their presence may influence HSREB deliberations.

## **5.2. Management of Conflicts of Interest**

- 5.2.1. The HSREB Chair or designee must be notified if an organizational COI relating to the REB is declared or discovered;
- 5.2.2. The HSREB Chair or designee must be notified immediately if any organizational employee attempts to, or appears to attempt to, influence the research ethics review process or to obtain preferential treatment;
- 5.2.3. The HSREB Chair or designee will review the available information to determine if a conflict exists, and to determine those aspects of the COI that might reasonably affect human participant protection;
- 5.2.4. The HSREB Chair or designee may require a management plan, which may include actions to eliminate or to mitigate the conflict. Required actions may include, but are not limited to:
  - Divestiture or termination of relevant economic interest,

- Recusal of OHRE staff whose job status or compensation is impacted by research that is reviewed by the HSREB,
  - If organizational staff members are involved, inform the appropriate responsible organizational management personnel to develop and implement a management plan for remediation;
- 5.2.5. If the HSREB Chair or designee is unable to satisfactorily manage the COI, or if there are unresolved concerns about any undue influence on the HSREB, the HSREB Chair or designee will bring this to the appropriate Organizational Officials for determination of the appropriate course of action;
- 5.2.6. In the event that the HSREB Chair or designee cannot bring the matter to the appropriate Organizational Officials because of an emergent situation or competing COI with the organization, the HSREB Chair or designee may escalate the issue to the Board of Governors.

## 6. REFERENCES

## 7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
105C.001	Original	09/25/2014
105C.002	Minor administrative revisions for clarity	05/10/2016
105C.003	Minor administrative updates	01/27/2022