SOP 105C.002

Conflicts of Interest - Institution

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1.0 PURPOSE

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

2.0 SCOPE

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

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.
5.0 PROCEDURE

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

The REB must be fair and impartial, immune from pressure by the sponsor, the parent institution and the Researchers whose research is submitted for review. In the interest of public trust and the integrity of the ethics review, the REB must act independently from its parent institution, and avoid or manage real or apparent COI. The institution must respect the autonomy of the REB 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 REB actions or decisions could be based on factors other than the rights, welfare, and safety of the research participants.

5.1 Disclosure of Conflict of Interest

5.1.1 All institutional employees must be familiar with the Conflict of Interest Policy and must complete a Disclosure of Conflict of Interest Form(s) (if applicable) at the time of hire and annually thereafter, or as per institutional policy;

5.1.2 Prior to engaging in any of the professional activities listed in the Conflict of Interest Policy, employees must seek the approval of the appropriate Institutional Official to ensure that no conflict exists in doing so;

5.1.3 REB members shall be apprised of the institutional structure with emphasis placed on the independent nature of the relationship between the REB and the institution. The actions of the REB members relating to their responsibilities to protect human research participants shall not be measured or evaluated in terms of institutional or financial goals;

5.1.4 REB meetings are closed to employees of the institution unless they are REB members, REB Office Personnel, permitted as observers, or invited by the REB to provide information, and only after signed confidentiality agreements are in place;

5.1.5 Institutional senior administrators shall not serve as REB members nor observe REB meetings when their presence may influence REB deliberations.
5.2 Management of Conflicts of Interest

5.2.1 The REB Chair or designee must be notified if an institutional COI relating to the REB is declared or discovered;

5.2.2 The REB Chair or designee must be notified immediately if any institutional employee attempts to, or appears to attempt to, influence the research ethics review process or to obtain preferential treatment;

5.2.3 The REB 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 REB 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 REB Office Personnel whose job status or compensation is impacted by research that is reviewed by the REB,
- If institutional staff members are involved, inform the appropriate responsible institutional management personnel to develop and implement a management plan for remediation;

5.2.5 If the REB Chair or designee is unable to satisfactorily manage the COI, or if there are unresolved concerns about any undue influence on the REB, the REB Chair or designee will bring this to the appropriate Institutional Officials for determination of the appropriate course of action;

5.2.6 In the event that the REB Chair or designee cannot bring the matter to the appropriate Institutional Officials because of an emergent situation or competing COI with the institution, the REB Chair or designee may escalate the issue to the board authority.

6.0 REFERENCES

See References.
## 7.0 REVISION HISTORY

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<th>SOP Code</th>
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<th>Summary of Changes</th>
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<tr>
<td>SOP105C.001</td>
<td>15-Sep-2014</td>
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