

## SOP-M-001: TC IRB Standard Operation Procedures (SOP) on Conflict of Interests of IRB Members and Consultants

### Purpose

This procedure outlines the steps to identify and manage potential conflicts of interest (COI) for IRB members and consultants during the review of research studies. It ensures that personal or financial interests do not influence the impartiality of decision-making in IRB deliberations or voting.

### Scope

The procedure applies to all IRB members and consultants involved in the review of submissions, whether through individual reviews or during panel deliberations.

### Process Overview

The process begins when an IRB member or consultant is assigned to review a submission. It concludes when the IRB member or consultant has either confirmed they have no conflict of interest or has notified the IRB of a conflict, prompting reassignment.

### Policy

IRB members and consultants must avoid participating in the review, deliberation, or voting on submissions where they have a conflicting interest. This includes situations where the member:

- Is an investigator, co-investigator, or is otherwise directly associated with the study under review.
- Has a personal or financial relationship with the investigator or the study that may affect impartiality.

If a conflict of interest is identified, the IRB member or consultant must recuse themselves from all related deliberations and voting.

### Responsibilities

- **IRB Members and Consultants:** Identify potential conflicts of interest and report them in a timely manner. They must also ensure that they do not participate in the review of any submission where a conflict exists.
- **IRB Office Staff:** Reassign the review to another qualified member if a conflict is reported.

### Procedure

1. **Conflict Identification:**
  - Before beginning any review, IRB members and consultants must assess whether they have a personal or financial interest in the study or a relationship with the investigator that could present a conflict.
2. **Notification:**
  - If a conflict of interest is identified before or during the review, the IRB member or consultant must immediately notify IRB Office staff. The submission will then be reassigned.
3. **Recusal in Meetings:**
  - In a convened IRB meeting, if a conflict of interest exists, the IRB member must announce the conflict to the other panel members and recuse themselves from the discussion and voting on the submission.

- If the IRB requests that the conflicted member provides information during the meeting, the member may temporarily rejoin the discussion but must leave again for the final deliberation and vote.
4. **Documentation:**
- The conflict of interest and recusal should be documented in the meeting minutes, ensuring transparency in the review process.

**Materials**

- [TC Conflict of Interest and Commitment Policy](#)
- [TC Academic and Research Conflict of Interest and Commitment Policy](#)

**References**

- [21 CFR §56.107\(e\)](#)
- [45 CFR §46.107\(d\)](#)