

Clinical and Translational Science Institute
University of Rochester Medical Center
Policy on Conflict of Interest With Respect to Educational and Career
Development Programs

Scope:

This document describes the policy and process for managing conflicts of interest with respect to CTSI educational and career development programs (TL1, KL2 and certificate programs).

Rationale:

CTSI educational and career development programs share certain goals, several of which are highly relevant to this policy:

1. Encourage the best possible science;
2. Promote the pursuit of high-impact careers in science; and
3. Conduct fair and impartial reviews of submitted applications.

These goals are in conflict at times. For instance, through their ongoing relationships with University researchers, those chosen to serve as reviewers have tremendous insight into the nature of research that takes place at the institution and the strategic value that particular lines of research may bring to the institution or individual researchers. These relationships may create perceived conflicts of interest, but to prevent an individual from reviewing any application where such a relationship exists would weaken the review process. As another example, a faculty member on the CTSI Executive Team may serve as a mentor for an applicant to a CTSI educational program. Due to the close relationships among CTSI Executive Team members, if the application were successful it could create a perception of an unfair advantage. In these and other similar situations, the real or perceived conflict of interest must be managed.

Definitions:

Conflict of Interest: a situation in which a Reviewer has an interest in the outcome of an application review process or a situation in which an Applicant could be perceived as having a potential advantage. An interest generally arises when a relationship exists between a Reviewer and an Applicant. Examples of such relationships include the following: mentor-protégé relationships; a department chair that serves as a Reviewer for a program to which one of their department faculty has applied; and cases where a Reviewer is also an Applicant or Current Trainee in the particular educational or career development program.

Reasonable Person Standard: the standard to be applied to judge the acceptability of a conflict of interest management plan. A management plan will be judged acceptable if a reasonable person would conclude that the plan will lead to a fair and unbiased review of an application.

Reviewer: an individual that has been asked to review an application to a CTSI educational or career development program, or who reviews such applications as part of their role in the CTSI.

Applicant: an individual that is listed as an investigator, co-investigator or mentor in an application to a CTSI educational or career development program.

CTSI Educational or Career Development Program Director: a faculty member responsible for overseeing a CTSI educational or career development program.

CTSI Executive Team: a committee comprised of the PIs of the UL1, TL1, and KL2 components of the NIH-funded CTSA award, as well as individuals in key CTSI leadership roles.

CTSI Branch Director: an individual who provides strategic direction or operational leadership for a branch of the CTSI.

Responsibilities:

- **Reviewers:** must disclose any potential or actual Conflicts of Interest and create a management plan.
- **CTSI educational or career development program directors:** must review Conflict of Interest management plans according to the reasonable person standard.
- **CTSI Executive Team:** must review Conflict of Interest management plans submitted by CTSI educational or career development program directors.

Process:

1. At the time that review assignments are made, Reviewers will be asked to state whether they have a conflict of interest with regard to any assignment. Also, at any other time that a Reviewer becomes aware of a Conflict of Interest, he or she will disclose it to the director of the CTSI educational or career development program for which they are serving as a Reviewer.
2. At the time that a conflict of interest is identified, the Reviewer will propose a management plan. The management plan need not be elaborate, but must be designed so that a reasonable person would conclude that the review process will not be biased. In all cases, the management plan must be proportional to the Conflict of Interest, i.e., the more severe the Conflict, the more stringent should be the management plan. A template for a disclosure statement and management plan is attached as Appendix A.
3. The director of the CTSI educational or career development program at issue must review the Reviewer's management plan and agree that it meets the "reasonable person" standard described above.
4. At the start of the review meeting the CTSI education coordinator will identify the applications that have COI Disclosure and Management plans on file. The COI Disclosure and Management plans will then be disclosed at the time of review of the conflicted proposals. The CTSI education coordinator will also indicate when the conflicted reviewer or program director is to be excused during that discussion.
5. To avoid the perception of a potential advantage, a program or Branch director currently or previously serving as a primary mentor for an applicant must recuse themselves from all review-related duties. In a case where a program director or a CTSI branch director is a co-mentor but not primary mentor for the applicant, the program or branch director must create a management plan and submit it to the CTSI Executive Team for review and approval.

Precedents:

None established to date.

Applicable Date:

This policy went into effect on October 30, 2018.