



Target ALS Conflict of Interest Policy and Procedures

POLICY

Target ALS was founded to foster collaboration between academic and for-profit laboratories with the goal of stimulating successful drug development programs. With the involvement of multiple institutions and multiple laboratories whose scientific and other interests may overlap, Target ALS participants may be expected to have conflicts of interest (COI) of several types and at different levels of organization. As a matter of scientific and fiduciary responsibility to our donors and to ALS patients and their families, it is important that Target ALS identify and manage any COI that may arise. The aim of our policy is to insure that board members, employees, investigators, and reviewers act impartially and confidentially where appropriate, and in a manner consistent with the aims of Target ALS. Columbia University, which administers Target ALS, has a COI policy, which Target ALS employees and board members must follow. The institutions with which Target ALS investigators and reviewers are associated also have COI policies to which their faculty must adhere. The COI policy of Target ALS is meant to complement and not to replace the COI policies of these institutions.

What constitutes a COI?

Conflicts of interest can be of two types, those affecting business decisions and those affecting scientific activities. The first are financial and personal; the second also involve issues of institutional or third party affiliation and overlapping scientific interests.

An apparent, potential or actual conflict of interest may arise if a board member, employee or reviewer or an immediate family member (spouse; child; sibling; spouse or child of a sibling):

- 1) Has an apparent, potential or actual financial or other interest that could cause an independent observer to question whether a decision on a grant, contract or other award made by Target ALS had been influenced by personal, business or familial financial gain.

Examples:

A member of the IRC or the director may influence the grant review process to benefit her/his company or university.

An employee may hire or contract with a company in which she/he or a family member may have a financial interest.

- 2) Has a scientific or professional conflict of interest that could directly and significantly affect a decision on a grant or contract or other award made by Target ALS or that results in a violation of confidentiality

Examples:

A member of the IRC or the director may influence the grant review process to benefit her/his own scientific program or that of a collaborator or former student.

A Board member, IRC member, director or employee may convey confidential or proprietary information from an application to other scientists, giving them an unfair competitive advantage.

Based on these criteria, all Board members, IRC members, the executive director and employees must agree to abide by this policy by identifying at the appropriate time any conflicts of interest they may have. Those with potential financial conflicts of interest must identify on an annual basis any biomedical companies in which they have a financial interest, i.e. any company with which they have a relationship as a consultant, board member or an employee or in which they holds directly more than \$10,000 in stock or any amount of stock in a non-publically traded company.

PROCEDURES:

Members of Target ALS Board:

Members of the Target ALS board must sign a statement that they agree to abide by the Target ALS COI Policy and identify, on an annual basis, any financial interests they may have in biomedical companies. In addition, they must sign an annual statement that they have not participated in any decisions in which they have a financial or scientific COI and that they have abided by the COI policy on confidentiality.

Director:

The Target ALS director will not be eligible for direct funding from Target ALS for her/his own laboratory, unless the director is at an academic or non-profit research institution. The director will not participate in initial review or ranking of research proposals, but will receive on a confidential basis, rankings, anonymous comments and the texts of the proposals from the IRC. If the director wishes to make any changes in the recommendations for funding made by the IRC, based either on the comments of the reviewers or for strategic reasons, consistent with the goals of Target ALS, a written recommendation will be made to the IRC that gives the rationale for the changes. The director will annually report to the COI committee on all changes that were proposed, along with their rationale. The director (or executive director) will also report on any contract decisions made with respect to any of the core facilities.

To avoid any bias in the RFA proposals, the director will circulate a draft of each proposed RFA for comment and suggestions to members of the board and to the IRC.

Executive Director:

The executive director is responsible for pharma/biotech outreach efforts. She/he will make an annual statement of any financial interests that she/he or family members may have and will recuse herself/himself from any activities with respect to this company.

Employees:

Employees (including the Executive Director) must sign a statement that they agree to abide by the Target ALS COI Policy. They must make an annual statement of any financial interests in biomedical companies and also sign an annual statement that they have not participated in any decisions in which they have a Conflict of Interest and that they have abided by the COI policy on confidentiality.

Members of the IRC:

IRC members themselves are not eligible for Target ALS funding. Before grant review, members of the IRC will be asked to identify any professional or financial COI that they have, based on the title of the grant applications and the primary investigators and institutional affiliations involved. Based on NIH guidelines, a conflict would include: a grant proposal from the same institution; a proposal from someone who is or has been a collaborator within the last five years; a proposal on a research theme that overlaps with the reviewer's research interests, non-profit or commercial)); a proposal from a company in which the reviewer or his/her family has a financial interest. Reviewers must identify at that time any COI and recuse themselves from reading, reviewing or discussing the proposal. The same procedures will be followed for reviews with respect to acceptance of projects of In Vivo Target Validation core, which are handled by a sub-group of IRC members.

The Chair of the IRC will make an annual report on the review process to the COI committee, including any COI conflicts that have arisen during the year.

Investigators:

The award letter for investigators should contain a statement that acceptance of the award constitutes an agreement by the investigator to abide by the principles of Target ALS with respect to confidentiality, i.e. that any unpublished work that is described in a Target ALS meeting must be regarded as confidential. Investigators of research projects supported by Target ALS also are expected to abide by the COI policies of their institutions and of the NIH with respect to research.

COI COMMITTEE:

The COI Committee, which reports to the Board, is charged with formulating the COI policy and procedures for Target ALS and for overseeing their implementation. The Chair of the COI Committee is appointed by the Board Chair from among Board members. The COI Committee will make an annual report to the Board concerning COI issues.

Identification and management of COI issues is vital to the success of Target ALS. If anyone associated with Target ALS has concerns about COI conflicts or about the COI policies and procedures of Target ALS, they are requested to direct them to the COI Committee, which will investigate them and recommend remedies, if appropriate.

The COI Committee welcomes any questions or suggestions for modification of the policy.