



CDISC Policy
Code of Conduct and Professional Ethics

Revision History

Date	Revision	Description	Author
1 June 2003	0.1	Original	Shirley Williams
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1 Introduction

1.1 Purpose

The purpose of this CDISC Policy is to describe the professional ethics and conduct expected by its Board, staff, paid consultants and others who conduct business on behalf of CDISC. This policy should be understood and acknowledged by all CDISC participants, including Board Members, staff, consultants and project contributors.

1.2 Background

CDISC is an open, multidisciplinary, non-profit organization that has established worldwide industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development. The mission of CDISC is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.

For more information on CDISC objectives and principles, please see the CDISC website at www.cdisc.org.

1.3 Authority

This document is approved by the CDISC Board of Directors and should be followed by all CDISC Operations staff, Board members, project leaders, project participants, and any person conducting work on behalf of CDISC.

1.4 References

The following information sources are referenced in this document:

- **CDISC Website:** www.cdisc.org

2 Professional Ethics Policies

- CDISC participants will promote, acknowledge and support proper and authorized use of the CDISC standards. Similarly, CDISC participants will not support or condone improper or unauthorized use of the CDISC standards and will report such uses to CDISC.
- CDISC participants will comply with the applicable laws and regulations applying to non-profit organizations, the CDISC bylaws, all policies and procedures adopted by the CDISC Board of Directors, and applicable trademark and copyright law.
- CDISC participants will contribute knowledge and experience to further the development of CDISC standards and models, but will also respect confidentiality agreements where applicable.
- Only CDISC business will be conducted during CDISC meetings. CDISC meetings should be free of marketing presentations, recruiting overtures and non-CDISC promotional material.

CDISC participants will not engage in non-CDISC marketing activities while representing CDISC at industry conferences or other standards meetings.

- CDISC participants will not misrepresent use of the CDISC standards in products, services or organizations.
- CDISC will not exhibit favoritism by endorsing the products or services of any particular organization.
- When conducting any CDISC business, CDISC participants will disclose any potential conflicts of interest that may compromise the CDISC mission.

3 Conflicts of Interest Policies

3.1 Definitions

3.1.1 Interested Person

Any director, principal officer, or key employee as designated by the board of directors that has a direct or indirect financial interest, as defined below, is an interested person. If a person is an interested person with respect to any entity in the pharmaceutical industry or any technology/service provider for that industry with which the Corporation interacts, he or she is an interested person with respect to all parent or subsidiary organizations of that entity.

3.1.2 Financial Interest

A person has a financial interest if the person has, directly or indirectly, through business, investment or family –

- a) an ownership or investment interest in any entity with which the Corporation has a transaction or arrangement, or
- b) a compensation arrangement with the Corporation or with any entity or individual with which the Corporation has a transaction or arrangement, or a potential ownership or investment interest in, or compensation arrangement with, any entity or individual with which the Corporation is negotiating a transaction or arrangement. Compensation includes direct and indirect remuneration as well as gifts or favors that are substantial in nature.

A financial interest is not necessarily a conflict of interest. A person who has a financial interest may have a conflict of interest only if the appropriate board or committee decides that a conflict of interest exists.

3.1.3 Procedures

3.1.3.1 Duty to Disclose

In connection with any actual or possible conflicts of interest that may be pertinent to any discussion or decision, an interested person must disclose the existence of his or her financial interest and must be given the opportunity to disclose all material facts to the

directors and members of committees with board delegated powers considering the proposed transaction or arrangement.

3.1.3.2 Determining Whether a Conflict of Interest Exists

After disclosure of the financial interest and all material facts, and after any discussion with the interested person, he/she shall leave the board or committee meeting while the determination of a conflict of interest is discussed and voted upon. The remaining board or committee members shall decide if a conflict of interest exists.

3.1.3.3 Procedures for Addressing the Conflict of Interest

1. An interested person may make a presentation at the board or committee meeting, but after such presentation, he/she shall leave the meeting during the discussion of, and the vote on, the transaction or arrangement that result in the conflict of interest.
2. The chairperson of the board or committee shall, if appropriate, appoint a disinterested person or committee to investigate alternatives to the proposed transaction or arrangement.
3. After exercising due diligence, the board or committee shall determine whether the Corporation can obtain a more advantageous transaction or arrangement with reasonable efforts from a person or entity that would not give rise to a conflict of interest.
4. If a more advantageous transaction or arrangement is not reasonably attainable under circumstances that would not give rise to a conflict of interest, the board or committee shall determine by a majority vote of the disinterested directors whether the transaction or arrangement is in the Corporation's best interest and for its own benefit and whether the transaction is fair and reasonable to the Corporation and shall make its decision as to whether to enter into the transaction or arrangement in conformity with such determination.

3.1.3.4 Violations of the Conflicts of Interest Policies

- If the board or committee has reasonable cause to believe that a member has failed to disclose actual or possible conflicts of interest, it shall inform the member of the basis for such belief and afford the member an opportunity to explain the alleged failure to disclose.
- If, after hearing the response of the member and making such further investigation as may be warranted in the circumstances, the board or committee determines that the member has in fact failed to disclose an actual or possible conflict of interest, it shall take appropriate disciplinary and/or corrective action.

3.1.3.5 Records of Proceedings

The minutes of the board and all committee with board- delegated powers shall contain -

- the names of the persons who disclosed or otherwise were found to have a financial interest in connection with an actual or possible conflict of interest, the nature of the financial interest, any action taken to determine whether a conflict of

interest was present, and the board's or committee's decision as to whether a conflict of interest in fact existed.

- the names of the persons who were present for discussions and votes relating to the transaction or arrangement, the content of the discussion, including any alternatives to the proposed transaction or arrangement, and a record of any votes taken in connection therewith.

3.1.3.6 Annual Statements

Each director, principal officer, key employee or other person(s) as designated by the board of directors shall annually sign a statement, which affirms that such person --

- has received a copy of the Code of Conduct and Professional Ethics policy,
- has read and understands the policy,
- has agreed to comply with the policy, and
- understands that the Corporation is a non-profit organization and that in order to maintain its federal tax exemption it must engage primarily in activities that accomplish one or more of its tax-exempt purposes.

4 Authorization

This document has been authorized by:

Name	CDISC Board of Directors
Date	6 June 2006



STATEMENT OF AGREEMENT

This is to certify that I, _____, have received a copy of the Clinical Data Interchange Standards Consortium's Code of Conduct and Professional Ethics Policy, I have read and understand the policy and I agree to comply with the policy.

Printed name

Signature

Date

Please sign and return to the CDISC Treasurer/Clerk