



CDISC Policy 001 Code of Ethics and Conflict of Interest Policy

Revision History

Date	Revision	Description	Author
1 June 2003	0.1	Original	Shirley Williams
22 October 2004	1.0	Approved	Board of Directors
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July 2016	3.0	Update	Marine Laurent
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August 2018	4.0	Update	Marine Laurent - VP Finance and HR
May 2019	4.1	Refinement	CDISC Board of Directors

CDISC Policy 001

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Statement of CDISC's Core Values

CDISC Vision

The CDISC Vision is to inform patient care and safety through higher quality medical research.

Values

We treat others the way we want to be treated

We create an environment that encourages big thinking, inclusion and doing the right thing

We acknowledge that CDISC is not an island, all we do is connected to the work of others

Mission

The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.

1 Purpose

This policy is designed to foster public confidence in the integrity of CDISC (the "Organization"), to describe the professional ethics and conduct expected of its Board, officers, committee members, staff, paid consultants, team leaders, team members and others who conduct activities on behalf of CDISC ("CDISC participants"), and to protect the Organization's interest when it is contemplating entering a transaction (defined below) that might benefit the private interest of a Director, officer, key employee (defined below) or other Interested Person (defined below).

2 Code of Ethics

CDISC requires Directors, officers, employees and other CDISC participants to observe high standards of business and personal ethics in the conduct of their duties and responsibilities. Employees and representatives of CDISC must practice honesty and integrity in fulfilling their responsibilities and comply with all applicable laws and regulations.

CDISC is an equal employment employer and is committed to providing an environment that is free of discrimination of all types and from abusive, offensive or harassing behavior. Any employee or CDISC participant who feels harassed or discriminated against should report the incident to his or her manager or to human resources.

2.1 Key Questions for Ethical Decision-Making

Several key questions can help identify situations that may be unethical, inappropriate or illegal. Ask yourself:

- Does what I am doing comply with the CDISC guiding principles, Code of Ethics and Conflict of Interest Policy?
- Have I been asked to misrepresent information or deviate from normal procedure?
- Would I feel comfortable describing my decision at a staff meeting?
- How would it look if it made the news?
- Would it be acceptable if others did it?
- Is this the right thing to do?

2.2 Participation in CDISC business and activities

- CDISC participants will comply with all applicable laws and regulations (including those applying to tax-exempt organizations), the CDISC Bylaws, all applicable policies and procedures adopted by the CDISC Board of Directors and CDISC Operations, and applicable trademark, intellectual property and copyright law.
- CDISC participants will contribute their knowledge and experience to further the development of CDISC standards and models, but will also respect confidentiality agreements where applicable.
- CDISC participants will promote, acknowledge and support proper and authorized use of the CDISC standards. Similarly, CDISC participants will not misrepresent use of the CDISC standards in products, services or organizations. They will not support or condone improper or unauthorized use of the CDISC standards and will report such uses to CDISC management.
- When participating in any CDISC business, CDISC participants will disclose to the CEO and/or the VP, Finance any potential conflict of interest that may compromise CDISC's mission or integrity. In particular, consultants employed by CDISC must fully disclose any other employment, contractual or governance relationships that may be related to the work or mission of CDISC.
- CDISC meetings should be free of marketing presentations, recruiting overtures and unauthorized non-CDISC promotional material.
- From time to time, CDISC selects vendors to provide goods and services. Such selection will be made in adherence with the CDISC Ethics and Procurement Policies, to ensure a fair and transparent process.

2.3 Procurement integrity

CDISC bids fairly and ethically on potential work and we ensure that all statements, communications, and representations to potential clients or customers are accurate and truthful. When contracts are awarded, CDISC must comply with all specifications, requirements, and clauses.

As a federal contractor, CDISC must abide by a set of rules developed to help contractors and federal employees avoid ethical misconduct or appearance of ethical misconduct. The principle of procurement integrity encompasses a range of legislation, regulations, and directives and was established to preserve the integrity of federal procurements.

CDISC's procurement and hiring process is fair and transparent.

2.4 Board Compensation

No Board of Directors member can receive compensation unless approved by the Board of Directors on an individual basis.

2.5 Corporate Recordkeeping

CDISC creates, retains and disposes of company records as part of the normal course of business in compliance with all CDISC policies and guidelines, as well as all regulatory and legal requirements.

All corporate records must be true, accurate and complete, and company data must be promptly and accurately entered in CDISC books in accordance with CDISC's and other applicable accounting principles.

CDISC employees and participants must not improperly influence, manipulate or mislead any audit, nor interfere with any auditor engaged to perform an internal independent audit of CDISC books, records, processes or internal controls.

2.6 Gifts

CDISC may make modest business gifts to stakeholders, in accordance with local customs and regulations. The purchase of any gift with a fair market value of US\$75 or more must be justified and pre-approved in writing by the VP that staff reports to, or the CEO.

CDISC staff may accept modest business gifts, gratuities or favors from stakeholders in societies where such gifts are customary and legal; however, the gift should be reported to VP Finance or CEO and any gift with a fair market value of US\$75 or more should be turned over to CDISC management.

In general, CDISC staff should use their best judgment when offering or accepting a gift, and avoid any appearance of favoritism to a specific vendor or potential vendor.

CDISC staff may host business meals in accordance with the CDISC Travel Policy. In the event a stakeholder wishes to host a CDISC staff member for a business meal, that meals should be pre-approved by the VP that staff member reports to, or the CEO.

Under no circumstances will CDISC participants bribe or attempt to bribe anyone. CDISC has a zero tolerance in regards to bribery.

2.7 Violation of the Ethics Policy

Any CDISC participant that the CEO determines has violated the Ethics Policy may be submitted to disciplinary action. Such action may include a verbal warning; a written warning; removal from a team or a specific activity; contractor's agreement termination; employee discharge; suspension without pay; suspension with pay; or other appropriate disciplinary action.

Furthermore, any CDISC employee, representative or participant who knowingly and deliberately violates the provisions of this policy may be open to civil suit by CDISC without the legal protection of CDISC.

2.8 Whistleblower and Non-Retaliation Policy Reporting Responsibility

This Whistleblower Policy is intended to encourage and enable employees and others to raise serious concerns internally so that CDISC can address and correct inappropriate conduct and actions. It is the responsibility of all Board members, officers, employees and volunteers to report concerns about violations of CDISC's code of ethics or suspected violations of law or regulations that govern CDISC's operations.

2.9 No Retaliation

It is contrary to the values of CDISC for anyone to retaliate against any Board member, officer, employee or volunteer who in good faith reports an ethics violation, or a suspected violation of law, such as a complaint of discrimination, or suspected fraud, or suspected violation of any regulation governing the operations of CDISC. An employee who retaliates against someone who has reported a violation in good faith is subject to discipline up to and including termination of employment.

2.10 Reporting Procedure

CDISC has an open door policy and suggests that employees and volunteers share their questions, concerns, suggestions or complaints with their supervisor. If a person is not comfortable speaking with their supervisor or they are not satisfied with their supervisor's response, they are encouraged to speak with the CEO or the Chair of the CDISC Governance Committee (if the concern is about the CEO). Supervisors and managers are required to report complaints or concerns about suspected ethical and legal violations in writing to the CEO, who has the responsibility to investigate all reported complaints. Employees with concerns or complaints may also submit their concerns in writing directly to their supervisor, the VP of HR or CEO.

The CEO is responsible for ensuring that all complaints about unethical or illegal conduct are investigated and resolved. The CEO will advise the Board of Directors of any complaints related to illegal, unethical, and/or significant violations of policy and their resolution.

In addition, the CEO shall immediately notify the Finance Oversight Committee of any concerns or complaint regarding corporate accounting practices, internal controls, compliance activities or auditing and work with the committee until the matter is resolved.

2.11 Acting in Good Faith

Anyone filing a written complaint concerning a violation or suspected violation must be acting in good faith and have reasonable grounds for believing the information disclosed indicates a violation. Any allegations that prove not to be substantiated and which prove to have been made maliciously or knowingly to be false will be viewed as a serious disciplinary offense.

2.12 Confidentiality

Violations or suspected violations may be submitted on a confidential basis by the complainant. Reports of violations or suspected violations will be kept confidential to the extent possible, consistent with the need to conduct an adequate investigation.

2.13 Handling of Reported Violations

The VP of HR or CEO will notify the person who submitted a complaint and acknowledge receipt of the reported violation or suspected violation. All reports will be promptly investigated and appropriate corrective action will be taken if warranted by the investigation.

As part of the investigation both the complainant and the individual about whom a complaint has been made will be interviewed separately by the CEO or his/her designee. The person about whom the complaint has been made will be generally made aware of the nature of the complaint so that he or she has a due process opportunity to respond before a final determination is made.

Depending on the severity of the complaint, the CEO may:

- direct the parties to engage in a conversation which may be moderated by a disinterested third party;
- appoint a disinterested third party (VP of HR or outside counsel) to investigate a complaint and to make recommendations about the severity of the complaint and potential actions to be taken.
- for allegations of illegal activities by a CDISC staff member, the CEO has authority to report the allegation to law enforcement and may elect to do so in lieu of an internal investigation.

Investigations will be handled in a timely manner and generally should be completed within 30 calendar days. They also must include an interview of the person being investigated. In addition, the results of the investigation (including the final report as appropriate) must be shared with the person being investigated, and they will be given a due process opportunity to respond to the allegation before a final determination is made on the complaint.

Based on the results of the conciliation or investigation, the CEO may decide to take any steps deemed appropriate, included any disciplinary action as detailed in the Ethics Policy.

Should the complaint be about the CEO, the matter will be handled as for any other staff member with the exception that the Chair of the Governance Committee will oversee the investigation process, following the due process steps detailed above.

3 Conflict of Interest Policy

CDISC must avoid any relationship or activity that might impair, or even appear to impair, our ability to make objective and fair decisions when performing our jobs. At times, we may be faced with situations where the business actions we take on behalf of CDISC may conflict with our own personal or family interests. CDISC participants owe a duty to CDISC to advance its legitimate interests when the opportunity to do so arises. They must never use CDISC property or information for personal gain or personally take for themselves any opportunity that is discovered through our position with CDISC.

3.1 Definitions

- The following are considered *interested persons* for the purposes of this policy if they have a direct or indirect *interest* (as defined below):
 - Each member of the Board of Directors, or any committee with Board-delegated powers, or other governing body.
 - The president, treasurer, clerk, or any person with the responsibilities of any of these positions (whether or not the person is an officer or Director of the Organization under the Organization's Bylaws).
 - Any *key employee*, meaning an employee who (a) has responsibilities or influence over the organization similar to that of officers, Directors, or trustees; **or** (b) manages a program that represents 10% or more of the activities, assets, income, or expenses of the organization; **or** (c) has or shares authority to control 10% or more of the organization's capital expenditures, operating budget, or compensation for employees.
 - Any other person who has the ability to exercise substantial influence over the Organization.
- *Interest* means any commitment, investment, relationship, obligation, or involvement, financial or otherwise, direct or indirect, through business, investment or family, that may influence a person's judgment, including an existing or contemplated compensation, ownership or investment arrangement with the Organization or with any entity or individual with which the Organization has or contemplates a transaction.
- A *Conflict of Interest* is present when, in the judgment of the Board of Directors, an Interested Person's Interest is such that it may reduce the likelihood that the Interested Person's responsibility to the Organization can be exercised in the best interests of the Organization. Conflicts of Interest include (but shall not be limited to) nepotism, financial investments, business relations, etc. An *Interest* is not necessarily a Conflict of Interest. An Interested Person may have a Conflict of Interest only if the Board decides that a Conflict of Interest exists.

- *Transaction* means any transaction, agreement, or arrangement between an Interested Person and the Organization, or between the Organization and any third party where an Interested Person has an Interest in the Transaction or any party to it. It does not include compensation arrangements between the Organization and a Director, officer, or other insider that are wholly addressed under the Organization's Compensation Policy.

3.2 Identifying a potential conflict of interest

Determining whether a conflict of interest exists is not always easy to do. Employees with a conflict of interest question should seek advice from management. Before engaging in any activity, transaction or relationship that might give rise to a conflict of interest, employees must seek review from their managers or the HR department.

Here are some ways in which conflicts of interest could arise:

- Being employed (you or a close family member) by, or acting as a consultant to, a competitor or potential competitor, supplier or contractor, regardless of the nature of the employment, while you are employed with CDISC.
- Hiring or supervising family members or closely related persons.
- Serving as a board member for an outside commercial company or organization.
- Owning or having a substantial interest in a competitor, supplier or contractor.
- Having a personal interest, financial interest or potential gain in any CDISC transaction.
- Placing company business with a firm owned or controlled by a CDISC employee or his or her family.
- Accepting gifts, discounts, favors or services from a customer/potential customer, competitor or supplier.

3.3 Procedures

3.3.1 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 CDISC leadership considering the proposed transaction or arrangement.

All conflicts of interest, whether resolved or not, must be disclosed to the CEO and the VP of Finance and HR.

3.3.2 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, CDISC leadership will determine whether a conflict of interest exists.

In the case of a Board member, he/she shall recuse themselves from the discussion while the determination of a conflict of interest is discussed and voted upon by The remaining Board or committee members.

3.3.3 Procedures for Addressing the Conflict of Interest

- Staff-level decision:
 - The interested person should recuse themselves from any decision making relative to the transaction or arrangement that results in the conflict of interest.
 - After exercising due diligence, CDISC leadership 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.
 - If a more advantageous transaction or arrangement is not reasonably attainable under circumstances that would not give rise to a conflict of interest, CDISC leadership will determine 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.

- Board-level decision:
 - 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 results in the conflict of interest.

 - 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.

 - 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.

 - 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.

3.4 Records of Proceedings

The minutes of the decision-making process shall contain:

- the names of the persons who disclosed or otherwise were found to have an interest in connection with an actual or possible conflict of interest, the nature of the interest, any action taken to determine whether a conflict of interest was present, and 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, the content of the discussion, including any alternatives to the proposed transaction, those who voted on it, and to what extent interested persons were excluded from the deliberations, any comparability data or other information obtained and relied upon by the decision makers and how the information was

obtained, and the result of the vote, including, if applicable, the terms of the transaction that was approved and the date it was approved.

3.5 Violations of the Conflict of Interest Policies

If CDISC leadership or the Board has reasonable cause to believe that a participant has failed to disclose actual or possible conflicts of interest, it shall inform the participant of the basis for such belief and afford the participant an opportunity to explain the alleged failure to disclose.

If, after hearing the response of the participant and making such further investigation as may be warranted in the circumstances, CDISC leadership and/or the Board determines that the participant has in fact failed to disclose an actual or possible conflict of interest, it shall take appropriate disciplinary and/or corrective action.

4 Annual Statements

Each interested person or other individual designated by the Board of Directors shall annually sign a statement on the form attached that:

- affirms that the person has received a copy of this Policy, has read and understood the Policy, and has agreed to comply with the Policy; and
- discloses the person's Interests and family relationships that could give rise to conflicts of interest.

5 Authorization

This document has been approved and is in effect on this date:

Name	CDISC Board of Directors
Date	10/08/2018



STATEMENT OF AGREEMENT

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

Signature

Date

Printed name

Disclosure of Financial Interests

We are required annually to file Form 990 with the Internal Revenue Service, and the form we file is available to the public. To complete Form 990 fully and accurately, we need each officer, Director and key employee to disclose the information requested in this disclosure form.

A “conflict of interest,” for purposes of Form 990, arises when a person in a position of authority over an organization, such as an officer, Director, or key employee, may benefit financially from a decision he or she could make in such capacity, including indirect benefits such as to family members or businesses with which the person is closely associated.

Please check ONE of the following boxes:

- I do not have any interests and relationships that could give rise to a conflict of interest, or my interests and relationships have not changed since my last disclosure of interests.
[Proceed to signature block below. Do not complete the tables.]

OR

- I hereby disclose or update my interests and relationships that could give rise to a conflict of interest: [Complete the table below. Use additional pages as needed.]

Family Relationships	Names of those presenting a potential conflict of interest
Include spouse/domestic partner, living ancestors, brothers and sisters, children, grandchildren, great grandchildren, and spouses/ domestic partners of brothers, sisters, children, grandchildren, and great grandchildren	

Type of interest	Description of interest that could lead to a conflict of interest
Transactions or arrangements with the Organization	
Transactions or affiliations with other nonprofit organizations	
Substantial business or investment holdings	
Transactions or affiliations with businesses not listed above	

I am not aware of any financial interest involving me or a family member that could present a conflict of interest that I have not disclosed either above or in a previous disclosure statement.

Signature

Date

Printed Name