



## CDISC Policy 000 Policies, Procedures and Processes

### Revision History

Date	Version	Description	Author
16 Jan 2012		Original	Shirley Williams
14 Feb 2012	1.0	Approval	Board of Directors
June 2016	2.0	Update	Marine Laurent
03 November 2016	2.0	Approved	CDISC Board of Directors
June 2019	2.1	Review	COO
14 October 2019	2.1	Approved	CDISC Board of Directors
23 April 2024	3.0	Minor updates to include charters and reference to electronic tracking	CEO

# Policy 000

## Policies, Procedures, and Processes

### 1 Purpose

This Policy defines and explains the different types of policies and procedures the CDISC organization maintains and the different methods to create, approve and use them.

### 2 Policy

All CDISC policies, operating procedures, and internal procedures are controlled documents, which must be approved by the appropriate level of authority, versioned, and made available to those expected to abide by these documents. Only one version of each unique document is in effect at any point in time, and the electronic source file for each approved version must be retained in a centralized location for archival purposes.

Each CDISC policy, operating procedure, and internal procedure document must include the following sections: Purpose, Revision History describing all approved versions, Authorization. In addition, such documents should include a Definitions section for any newly introduced key terms, and details of the policy, procedure or instructions within the scope of the document.

### 3 Definitions

- **CDISC Policies:** a policy defines general guiding principles for the organization. It has broad application throughout the company and helps ensure compliance with applicable laws and regulations, promotes operational procedures and reduces institutional risks.
- **CDISC Operating Procedures (COPs):** COPs are procedures that apply primarily to operational work processes used by CDISC staff and/or CDISC teams and stakeholders to complete deliverables and perform CDISC administrative, technical and support tasks or related communications and interactions consistent with the CDISC mission, core principles and goals.
- **CDISC Internal Processes (CIPs):** CIPs are detailed work instructions intended for internal use by CDISC staff only. CIPs capture processes frequently used for the internal operations of the CDISC organization and help staff understand how certain tasks are accomplished.
- **CDISC Board Committee Charters (Charters):** Charters are high level guiding documents that describe the governing policies, membership, and scope of work for each of the defined CDISC Board committees.
- **CDISC Senior Management:** The CEO and other C or Vice President (VP) level executives identified by the CEO as having primary responsibility for CDISC functional areas.

- **CDISC Supervisor:** The person primarily responsible for managing a CDISC employee or contractor.

## 4 Procedural Details

- CDISC Policies
  - Policies apply to all who provide services for CDISC or perform work on behalf of CDISC, which may include the Board of Directors, employees, consultants, and volunteers. A policy may include a statement of agreement (SoA) that confirms that a person has read and understands the policy. In such cases, the SoA is electronically signed and returned to the CDISC Supervisor for storage in the CDISC repository to ensure compliance with following the policy.
  - Each policy must have a number and an effective date.
  - Each policy should be reviewed at least once every 3 years.
  - All CDISC Policies must be approved by the Board of Directors.
  - CDISC Policies are available publicly on the CDISC website after approval.
  - New and updated Policies are communicated to all employees and Board members.
- CDISC Operating Procedures (COPs)
  - COPs are made available and apply to all employees and stakeholders whose work fall under the scope of the COP. CDISC supervisors are responsible for making employees, consultants, contractors and any other relevant external contributors, such as volunteers, aware of any necessary COPs that may apply to their work duties.
  - Each COP is assigned a number and an effective date.
  - COPs are drafted by relevant CDISC staff and reviewed by CDISC Senior Management. They are approved by the CEO and any VP in charge of the operations described in the COP
  - COPs are available publicly. New and updated COPs are communicated to all employees and appropriate external parties and are posted on the CDISC website.
- CDISC Internal Processes (CIPs)
  - CIPs are drafted by relevant CDISC staff and reviewed by CDISC Senior Management. They are approved by the CEO or VP in charge of the operations described in the CIP as determined by Senior Management.
  - Each CIP is assigned a number and an effective date. Copies of new or updated CIPs are made available to all employees and any relevant contractor.

- CDISC Board Committee Charters (Charters):
  - Charters are drafted by the specific Board committee and reviewed and approved by the Board of Directors
  - Each charter is assigned a number and effective date.
  - Each charter should be reviewed and updated if applicable every 3 years.

## 5 Authorization

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

Name	
Title	Board of Directors
Date	23 April 2024