



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 |

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 responsible for following these documents. Only one version of each unique document should be effective 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 Operations 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 to produce and provide services for the internal operations of the CDISC organization and help staff understand how certain tasks are accomplished.
- **CDISC Senior Management:** The CEO and other C or VP level executives identified by the CEO as having primary responsibility for CDISC functional areas.

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

4 Procedural Details

- Policies
 - Policies should be followed by all who provide services for CDISC or perform work on behalf of CDISC, which includes the Board of Directors, employees, consultants, and member organization representatives. 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 to be signed and returned to the CDISC Clerk to ensure compliance with following the policy.
 - Each policy must have a number and an effective date,.
 - All CDISC Policies must be approved by the Board of Directors.
 - CDISC Policies are available publicly on the CDISC website. New and updated Policies are also communicated to all employees and Board members.
- CDISC Operating Procedures (COPs)
 - COPs are made available to all employees. CDISC hiring managers are responsible for making consultants and contractors aware of any necessary COPs that may apply to their work duties. COPs may also be distributed to other external contributors, such as team leaders/members. COPs are reviewed by CDISC Senior Management with needed input obtained from relevant, reliable sources.
 - Each COP is assigned a number and an effective date.
 - COPs are drafted by relevant CDISC staff and must be approved by the CEO, COO 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 must be approved by the CEO, COO and any VP in charge of the operations described in the CIP.
 - Each CIP is assigned a number and an effective date. Copies of new or updated CIPs are made available to all Operations employees and any relevant contractor, for instance through the CDISC Operations portal.

5 Authorization

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

| | |
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| Name | |
| Title | Board of Directors |
| Date | 03 November 2016 |