CDISC 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 creating, approving and using 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.
  - A CDISC Policy is established by the Board of Directors. A Board of Directors Committee or CDISC Executive Operations may propose a CDISC Policy. CDISC Policies are available openly.
- 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. COPs are available openly.
- 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. CIPs are available only to CDISC staff.

- **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**
  - 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.
  - The Board of Directors approves all policies. Each policy must have a number and an effective date, be posted on the CDISC website, and be distributed to all Directors and staff.

- **CDISC Operating Procedures (COPs)**
  - COPs are provided 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.
  - COPs are approved by two members of Senior Management, including the CEO, and assigned a number and an effective date. 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 CDISC staff and delivered to all of Senior Management for input and review prior to approval.
  - CIPs are approved by two Senior Management team, including the CEO, and assigned number and an effective data. Copies of new or updated CIPs are made available to all Operations staff (including any contractors working as operations staff) and are posted on the CDISC Operations Portal (not on the open website).
5 Authorization

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Rebecca Kush</th>
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<tbody>
<tr>
<td>Title</td>
<td>President on behalf of Board of Directors</td>
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<tr>
<td>Date</td>
<td>14 Feb 2012</td>
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