



## CDISC Operating Procedure CDISC-COP-000 COP Development

### Revision History

<b>Date</b>	<b>Revision</b>	<b>Description</b>	<b>Author</b>
1 June 2003	0.1	Original	Shirley Williams
1 Jan 2006	2.0	Revisions required to align with current CDISC organization and procedures	CDISC Operations

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# CDISC Operating Procedure CDISC-COP-000

## COP Development

### 1 Introduction

#### 1.1 Purpose

The purpose of this CDISC Operating Procedure is to describe the procedure used to develop CDISC Operating Procedure.

#### 1.2 Background

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](http://www.cdisc.org).

#### 1.3 Authority

This document is approved by the CDISC President and should be followed by all CDISC Operations staff, team/project leaders, CDISC consultants and representatives, including volunteers participating in teams/projects or in user networks.

#### 1.4 References

The following information sources are referenced in this document:

- **CDISC Website:** [www.cdisc.org](http://www.cdisc.org)

### 2 Creation of a CDISC Operating Procedure

The following steps will be taken to determine whether a CDISC Operating Procedure is needed, then to prepare, discuss, approve and adopt such procedures:

- CDISC Operating Procedures apply to the operating aspects of the CDISC staff and community. They are distinguished from Board Charters and Board Policies, which are established and approved by the Board of Directors.
- Any CDISC Project Leader, Operations Staff or CDISC volunteer or member can initiate a CDISC Operating Procedure. If one feels that a COP is needed, they should let either the President or Director of Finance/Operations know of the issue that warrants a COP.
- The Operations Staff of CDISC will determine whether the suggestion is appropriate and necessary.
- The COP can be drafted by anyone who comprehends the issue and applicable procedure(s).
- If a COP has technical aspects or other specific aspects requiring additional reviews, then CDISC Operations will ensure that the appropriate advisor(s) review and edit the COP.

- The CDISC President will have final approval of the COP, after which it will be considered in effect and placed on the CDISC website as a reference.

### 3 Authorization

This document has been authorized by:

Date	Representation	Name
1 Jan 2006	CDISC President	Rebecca Kush