



SIDCER-FCAP Survey Form 10: SOP Review
Version 4.0, 30 April 2020

EC Name			
Survey Date		Group	

SOP No.	CONTENT	COMPLETENESS: (in terms of contents & sections)		COMMENTS
		YES	NO	
	Cover and Table of Contents	<input type="checkbox"/>	<input type="checkbox"/>	
	Overview/History/Statement of Principles	<input type="checkbox"/>	<input type="checkbox"/>	
	Writing and Revising SOPs	<input type="checkbox"/>	<input type="checkbox"/>	
	Preparing Guidelines	<input type="checkbox"/>	<input type="checkbox"/>	
	EC Structure and Composition	<input type="checkbox"/>	<input type="checkbox"/>	
	Selection and Appointment of Members	<input type="checkbox"/>	<input type="checkbox"/>	
	Diverse Membership	<input type="checkbox"/>	<input type="checkbox"/>	
	Independent Consultants	<input type="checkbox"/>	<input type="checkbox"/>	
	Staff Support	<input type="checkbox"/>	<input type="checkbox"/>	
	Training of Members and Staff	<input type="checkbox"/>	<input type="checkbox"/>	
	Confidentiality and COI Agreements	<input type="checkbox"/>	<input type="checkbox"/>	
	Management of Protocol Submissions	<input type="checkbox"/>	<input type="checkbox"/>	
	Initial Review Submissions	<input type="checkbox"/>	<input type="checkbox"/>	
	Resubmissions	<input type="checkbox"/>	<input type="checkbox"/>	
	Post-Approval Submissions	<input type="checkbox"/>	<input type="checkbox"/>	
	Initial Review Procedures	<input type="checkbox"/>	<input type="checkbox"/>	
	Exemption from Review	<input type="checkbox"/>	<input type="checkbox"/>	
	Expedited Review	<input type="checkbox"/>	<input type="checkbox"/>	
	Full Board Review	<input type="checkbox"/>	<input type="checkbox"/>	
	Other Types of Review (e.g. Review of Medical Device)	<input type="checkbox"/>	<input type="checkbox"/>	
	Resubmission Review Procedures	<input type="checkbox"/>	<input type="checkbox"/>	



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	Post-Approval Review Procedures	<input type="checkbox"/>	<input type="checkbox"/>	
	Protocol Amendments	<input type="checkbox"/>	<input type="checkbox"/>	
	SAE Reports	<input type="checkbox"/>	<input type="checkbox"/>	
	Protocol Deviation/Violation Reports	<input type="checkbox"/>	<input type="checkbox"/>	
	Management of Queries/Complaints	<input type="checkbox"/>	<input type="checkbox"/>	
	Site Visits	<input type="checkbox"/>	<input type="checkbox"/>	
	Progress Reports	<input type="checkbox"/>	<input type="checkbox"/>	
	Study Termination Reports	<input type="checkbox"/>	<input type="checkbox"/>	
	Final Reports	<input type="checkbox"/>	<input type="checkbox"/>	
	Meeting Procedures	<input type="checkbox"/>	<input type="checkbox"/>	
	Meeting Preparations	<input type="checkbox"/>	<input type="checkbox"/>	
	Meeting Agenda	<input type="checkbox"/>	<input type="checkbox"/>	
	Quorum Requirements	<input type="checkbox"/>	<input type="checkbox"/>	
	Conduct of Regular Meetings	<input type="checkbox"/>	<input type="checkbox"/>	
	Conduct of Emergency/Special Meetings	<input type="checkbox"/>	<input type="checkbox"/>	
	Documentation of EC Actions	<input type="checkbox"/>	<input type="checkbox"/>	
	Meeting Minutes	<input type="checkbox"/>	<input type="checkbox"/>	
	Communicating Decisions	<input type="checkbox"/>	<input type="checkbox"/>	
	Management and Archiving of Files	<input type="checkbox"/>	<input type="checkbox"/>	
	Managing Incoming/Outgoing Documents	<input type="checkbox"/>	<input type="checkbox"/>	
	Managing Active Files (Administrative and Study Files)	<input type="checkbox"/>	<input type="checkbox"/>	
	Archiving of Terminated, Inactive, and Completed Files	<input type="checkbox"/>	<input type="checkbox"/>	
	Managing Access to Confidential Files	<input type="checkbox"/>	<input type="checkbox"/>	
	Audit and Inspection	<input type="checkbox"/>	<input type="checkbox"/>	
	Other SOPs	<input type="checkbox"/>	<input type="checkbox"/>	
	Forms and Checklists	<input type="checkbox"/>	<input type="checkbox"/>	
	Glossary	<input type="checkbox"/>	<input type="checkbox"/>	
	References	<input type="checkbox"/>	<input type="checkbox"/>	



SIDCER-FERCAP Form 14: SOP Review
Version No. 4.0, 28 January 2020

CONSISTENCY: Please specify if there are inconsistency issues (among the SOPs, between the SOPs and Forms, and within each SOP).

COMPLIANCE: Please specify if there are non-compliance issues (with international and national ethical guidelines and regulations and institutional policies).

INSTRUCTIONS for FERCAP SURVEYORS:

[01] Review the latest and updated version of SOPs to suggest points for improvement.

[02] For SIDCER Standard 2, comment on SOPs as a stand-alone document to check compliance with international and national ethical guidelines and regulations and institutional policies.