



SIDCER-FERCAP Survey Form 14: Quality of Continuing Review
Version 3.0, 30 April 2020

EC Name			
Survey Date		Group	

Defects	Protocol 1	Protocol 2	Protocol 3	Protocol 4	Protocol 5	Total
	Grade: 0 = No defect; 1 = With evidence of defect (Write 0 or 1)					
01. Inappropriate amendment review						
02. Inappropriate SAE review						
03. Inappropriate deviation/violation review						
04. Incomplete progress report review						
05. Incomplete final report review						
Total						

Definition of defects:

- 01. Inappropriate amendment review:** Inappropriate channel (expedited for minor amendment vs. full board for major amendment); incomplete review or inappropriate decision (does not check change in risk/benefit ratio); unsuitable reviewer (not familiar or does not check the conditions of original approval); non-compliance with SOP about review of amendments;
- 02. Inappropriate SAE review:** Inappropriate channel (expedited for offsite vs. full board for on-site); inappropriate decision (patient safety not addressed); unsuitable reviewer (not familiar about SAE review issues); non-compliance with SOP about SAEs;
- 03. Incomplete protocol deviation/violation review:** Inappropriate channel (expedited vs. full board); inappropriate decision/corrective action (does not address patient safety issues); unsuitable reviewer (not familiar with GCP requirements or conditions of the original EC approval); non-compliance with SOP about protocol deviation/ violation;
- 04. Incomplete progress report review:** No annual progress report after due date (no evidence of EC reminder); inappropriate channel (expedited for minimal risk protocols vs. full board for medium to high risk protocols); inappropriate decision (does not check patient safety issues or change in risk/benefit ratio); unsuitable reviewer (not familiar with type of protocol, does not cross check data in the report vs. reports in protocol files); non-compliance with SOP about continuing review/ progress report;
- 05. Incomplete final report review:** No final report in the files after study completion (no evidence of EC reminder); no evidence of review of the report; no approval notification sent to PI; non-compliance with SOP about final report.



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	Protocol Code/Number	Protocol Title (in English)	Defects in Review
Protocol 1			
Protocol 2			
Protocol 3			
Protocol 4			
Protocol 5			