SIDCER-FERCAP Survey Form 13: Quality of Initial Review
Version 4.0, 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. Non-compliance with SOP						
02. Failure to assess PI competence and COI						
03. Incomplete assessment forms						
04. Unsuitable reviewer						
05. Failure to assess inappropriate study design						
06. Inappropriate risk/benefit assessment						
07. Failure to assess vulnerability of participants						
08. Incomplete and inappropriate informed consent review						
a. Contents and language of ICF						
b. Voluntary participation						
c. Medical care						
d. Costs and compensation						
e. Confidentiality						
f. Consent/Assent forms						
g. Procedures in obtaining informed consent						
Total						

Definition of defects:

01. Non-compliance with SOPs: Review did not adhere to the EC's SOPs on the type of review, timeliness, etc.;

02. Failure to assess PI competence and COI: Primary investigator(s) qualifications (including GCP training whenever necessary) and conflict of interest were not adequately reviewed by the EC;

03. Incomplete assessment form: Assessment form is not comprehensive and/or was not correctly and fully accomplished;
04. Unsuitable reviewer: Reviewer did not have the necessary expertise suitable for reviewing the specific protocol and/or did not take responsibilities seriously (*e.g.*, absence during the Board Meeting, late or non-submission of assessment forms, etc.);
05. Failure to assess inappropriate study design: EC failed to detect and discuss inappropriate research design, comparator/placebo, inclusion and exclusion/withdrawal criteria, sample size, primary endpoint(s), etc.;
06. Inappropriate risk/benefit assessment: EC failed to assess and comment on risks, benefits, and the balance in risk/benefit ratio;
07. Failure to assess vulnerability of participants: EC failed to: a) detect the inappropriate use of vulnerable participants given that the protocol can be done in other non-vulnerable groups; b) recognize vulnerability of participants in different contexts; and c) recognize the lack of measures to protect vulnerable participants;
08. Incomplete and inappropriate informed consent review: EC failed to review any of the following items (any defect in the following items will only count as 1): confidentiality, medical care, contents and language of ICF, voluntary participation, consent/assent forms, costs and compensation, and procedures in obtaining informed consent.

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