



SIDCER-FERCAP Survey Form 11: Full Board Meeting Observation
Version 4.0, 30 April 2020

EC Name	
Survey Date	
Group	

GENERAL INFORMATION		
Venue:	Date of meeting:	
Time started:	Time adjourned:	
Number of members present:	Number of members absent:	
Number of male members:	Number of female members:	
Was a non-affiliated member present? <input type="checkbox"/> YES / <input type="checkbox"/> NO		
Was a non-medical/non-scientific (lay) member present? <input type="checkbox"/> YES / <input type="checkbox"/> NO		
Was there an agenda? <input type="checkbox"/> YES / <input type="checkbox"/> NO		
Was the agenda approved? <input type="checkbox"/> YES / <input type="checkbox"/> NO		
Was the agenda followed? <input type="checkbox"/> YES / <input type="checkbox"/> NO		
If No , explain:		
Were previous meeting minutes presented and approved? <input type="checkbox"/> YES / <input type="checkbox"/> NO		
REVIEW OF INITIAL SUBMISSIONS		
Number of new protocols reviewed: (Use another form if there are more than 2 new protocols)		
PROTOCOL Code and Short Title	PROTOCOL 1:	PROTOCOL 2:
Was there Conflict of Interest among the EC members?	<input type="checkbox"/> YES / <input type="checkbox"/> NO If Yes , how was it addressed?	<input type="checkbox"/> YES / <input type="checkbox"/> NO If Yes , how was it addressed?
Was quorum maintained during the deliberations?	<input type="checkbox"/> YES / <input type="checkbox"/> NO If No , why not?	<input type="checkbox"/> YES / <input type="checkbox"/> NO If No , why not?
Were there primary reviewers?	<input type="checkbox"/> YES / <input type="checkbox"/> NO If No , who presented the protocol?	<input type="checkbox"/> YES / <input type="checkbox"/> NO If No , who presented the protocol?
Were the presentation and discussion of the protocol appropriate and comprehensive?	<input type="checkbox"/> YES / <input type="checkbox"/> NO If No , explain:	<input type="checkbox"/> YES / <input type="checkbox"/> NO If No , explain:
Were the findings and recommendations adequate?	<input type="checkbox"/> YES / <input type="checkbox"/> NO If No , explain:	<input type="checkbox"/> YES / <input type="checkbox"/> NO If No , explain:
Did the EC members raise relevant issues?	<input type="checkbox"/> YES / <input type="checkbox"/> NO	<input type="checkbox"/> YES / <input type="checkbox"/> NO
Describe how the members participated		

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Was the discussion dominated by a few members?	<input type="checkbox"/> YES / <input type="checkbox"/> NO	<input type="checkbox"/> YES / <input type="checkbox"/> NO
Was the review systematic and organized?	<input type="checkbox"/> YES / <input type="checkbox"/> NO	<input type="checkbox"/> YES / <input type="checkbox"/> NO
Did the Chair present the summary of the discussion points before the decision/voting?	<input type="checkbox"/> YES / <input type="checkbox"/> NO	<input type="checkbox"/> YES / <input type="checkbox"/> NO
Did the EC comply with their SOPs on the review of initial submissions?	<input type="checkbox"/> YES / <input type="checkbox"/> NO	<input type="checkbox"/> YES / <input type="checkbox"/> NO
REVIEW ELEMENTS		
Were issues on the following items/elements raised and discussed adequately? <i>(Please comment)</i>		
Adequate Scientific Review	PROTOCOL 1	PROTOCOL 2
Rationale		
Objective		
Study Design		
Study Population		
Inclusion/Exclusion/ Withdrawal Criteria		
Sample Size		
Study Procedures and Tools		
Use of Control or Placebo		

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Safety Monitoring		
Outcome Measurement		
Data Management and Analysis		
<i>Risk/Benefit Assessment</i>	PROTOCOL 1	PROTOCOL 2
Comprehensive Review of Risks		
Justification of Risks/Benefits		
<i>Vulnerability Assessment</i>	PROTOCOL 1	PROTOCOL 2
Recognize Vulnerability in Different Contexts		
Detect Inappropriate Use of Vulnerable Participants		
Recognize Lack of Measures to Protect Vulnerable Participants		
<i>Quality of Informed Consent Review</i>	PROTOCOL 1	PROTOCOL 2
Contents and Language of ICF		
Voluntary Participation		



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Medical Care				
Costs and Compensation				
Confidentiality				
Consent/Assent Forms				
Procedures in Obtaining Informed Consent				
REVIEW OF RESUBMITTED PROTOCOLS				
Number of resubmitted protocols reviewed:				
What issues were raised? Explain.				
Number of resubmitted protocols approved:				
What issues do you (as FERCAP Surveyor/Surveyor Trainee) think were missed in the deliberations?				
Protocol Code/Number	Issues Missed			
REVIEW OF PROTOCOL AMENDMENTS				
Number of protocol amendments reviewed:				
What issues were raised? Explain.				
Number of protocol amendments approved:				
What issues do you (as FERCAP Surveyor/Surveyor Trainee) think were missed in the deliberations?				
Protocol Code/Number	Issues Missed			



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REVIEW OF SERIOUS ADVERSE EVENTS (SAE) REPORTS	
Number of SAE reports reviewed:	
Onsite:	Offsite:
What issues were raised? Explain.	
What were the EC actions/decisions on the different SAEs?	
What issues do you (as FERCAP Surveyor/Surveyor Trainee) think were missed in the deliberations?	
Protocol Code/Number	Issues Missed
REVIEW OF PROTOCOL DEVIATIONS/VIOLATIONS	
Number of protocol deviations/violations reviewed:	
What issues were raised? Explain.	
What were the EC actions/decisions on the different protocol deviations/violations?	
What issues do you (as FERCAP Surveyor/Surveyor Trainee) think were missed in the deliberations?	
Protocol Code/Number	Issues Missed
REVIEW OF PROGRESS REPORTS	
Number of progress reports reviewed:	
What issues were raised? Explain.	
What were the EC actions/decisions on the different progress reports?	
What issues do you (as FERCAP Surveyor/Surveyor Trainee) think were missed in the deliberations?	
Protocol Code/Number	Issues Missed



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REVIEW OF FINAL REPORTS	
Number of final reports reviewed:	
What issues were raised? Explain.	
What were the EC actions/decisions on the different final reports?	
What issues do you (as FERCAP Surveyor/Surveyor Trainee) think were missed in the deliberations?	
Protocol Code/Number	Issues Missed
OTHER COMMENTS AND SUMMARY	
OTHER COMMENTS	
GOOD PRACTICES	
RECOMMENDATIONS	