



**SIDCER-FCAP Survey Form 12: Protocol File Review**  
Version 4.0, 30 April 2020

<b>EC Name</b>	
<b>Survey Date</b>	
<b>Group</b>	

General Information			
<b>Protocol Code/Number:</b>			
<b>Protocol Title (in English):</b>			
<b>Type of the study:</b> <input type="checkbox"/> Sponsored <input type="checkbox"/> Researcher Initiated			
<b>Study Design:</b> <input type="checkbox"/> Intervention <input type="checkbox"/> Observation			
Initial Submission Management			
<b>Documents in the Protocol File</b>	<b>Yes</b>	<b>No</b>	Any defect, grade "1" in SIDCER-FCAP Form 13 # 01
Protocol	<input type="checkbox"/>	<input type="checkbox"/>	Version indicated: <input type="checkbox"/> Yes #: _____ Date: _____ <input type="checkbox"/> No
Informed Consent Form	<input type="checkbox"/>	<input type="checkbox"/>	Version indicated: <input type="checkbox"/> Yes #: _____ Date: _____ <input type="checkbox"/> No
Others (e.g., Investigator's Brochure Protocol Summary, Communications, Technical Review, FDA Registration, etc.)	<input type="checkbox"/>	<input type="checkbox"/>	List the other documents found:
<b>Investigator(s) Competence and COI</b>	<b>Yes</b>	<b>No</b>	Any defect, grade "1" in SIDCER-FCAP Form 13 # 02
Investigator(s) CV	<input type="checkbox"/>	<input type="checkbox"/>	Signed and dated? <input type="checkbox"/> Yes <input type="checkbox"/> No
Appropriate Expertise	<input type="checkbox"/>	<input type="checkbox"/>	Expertise:
Certificate of Applicable Trainings	<input type="checkbox"/>	<input type="checkbox"/>	If <b>Yes</b> , what kind? <input type="checkbox"/> Basic Research Ethics <input type="checkbox"/> GCP
COI Declaration	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Initial Review Process			
<b>Documents in the Protocol File</b>	<b>Yes</b>	<b>No</b>	Date application received:
<b>Initial Review:</b> <input type="checkbox"/> Expedited <input type="checkbox"/> Full Board (FB)			Comply with SOP? <input type="checkbox"/> Yes <input type="checkbox"/> No If <b>No</b> , grade "1" in SIDCER-FCAP Form 13 # 01
<b>Protocol Assessment Form</b>	<input type="checkbox"/>	<input type="checkbox"/>	Complete: <input type="checkbox"/> Yes <input type="checkbox"/> No If <b>No</b> , grade "1" in SIDCER-FCAP Form 13 # 03
<b>Suitable Reviewer</b>	<b>Yes</b>	<b>No</b>	Any defect, grade "1" in SIDCER-FCAP Form 13 # 04
Suitable Expertise	<input type="checkbox"/>	<input type="checkbox"/>	Expertise:
Late or Non-Submission of Assessment Form	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Present and Participated at FB	<input type="checkbox"/>	<input type="checkbox"/>	Comments:

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<b>Adequate Scientific Review</b>	<b>Yes</b>	<b>No</b>	Any defect, grade "1" in SIDCER-FCAP Form 13 # 05
Rationale	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Objective	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Study Design	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Study Population	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Inclusion/Exclusion/Withdrawal Criteria	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Sample Size	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Study Procedures and Tools	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Use of Control or Placebo	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Safety Monitoring	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Outcome Measurement	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Data Management and Analysis	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
<b>Risk/Benefit Assessment</b>	<b>Yes</b>	<b>No</b>	Any defect, grade "1" in SIDCER-FCAP Form 13 # 06
Comprehensive Review of Risks	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Justification of Risks/Benefits	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
<b>Vulnerability Assessment</b>	<b>Yes</b>	<b>No</b>	Any defect, grade "1" in SIDCER-FCAP Form 13 # 07
Recognize Vulnerability in Different Contexts	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Detect Inappropriate Use of Vulnerable Participants	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Recognize Lack of Measures to Protect Vulnerable Participants	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
<b>ICF Assessment Form</b>	<input type="checkbox"/>	<input type="checkbox"/>	Complete: <input type="checkbox"/> Yes <input type="checkbox"/> No If <b>No</b> , grade "1" in SIDCER-FCAP Form 13 # 03
<b>Quality of Informed Consent Review</b>	<b>Yes</b>	<b>No</b>	Any defect, grade "1" in SIDCER-FCAP Form 13 # 08
Contents and Language of ICF	<input type="checkbox"/>	<input type="checkbox"/>	If <b>No</b> , grade "1" in SIDCER-FCAP Form 13 # 08 a
Voluntary Participation	<input type="checkbox"/>	<input type="checkbox"/>	If <b>No</b> , grade "1" in SIDCER-FCAP Form 13 # 08 b
Medical Care	<input type="checkbox"/>	<input type="checkbox"/>	If <b>No</b> , grade "1" in SIDCER-FCAP Form 13 # 08 c
Costs and Compensation	<input type="checkbox"/>	<input type="checkbox"/>	If <b>No</b> , grade "1" in SIDCER-FCAP Form 13 # 08 d
Confidentiality	<input type="checkbox"/>	<input type="checkbox"/>	If <b>No</b> , grade "1" in SIDCER-FCAP Form 13 # 08 e



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Consent/Assent Forms	<input type="checkbox"/>	<input type="checkbox"/>	If <b>No</b> , grade "1" in SIDCER-FERCAP Form 13 # 08 f
Procedures in Obtaining Informed Consent	<input type="checkbox"/>	<input type="checkbox"/>	If <b>No</b> , grade "1" in SIDCER-FERCAP Form 13 # 08 g
<b>Compliance with SOP</b>	<b>Yes</b>	<b>No</b>	Any defect, grade "1" in SIDCER-FERCAP Form 13 # 01
Documented in Meeting Minutes	<input type="checkbox"/>	<input type="checkbox"/>	Meeting date:
Appropriate Decision	<input type="checkbox"/>	<input type="checkbox"/>	Decision notification date:
Certificate/Letter of Approval	<input type="checkbox"/>	<input type="checkbox"/>	Date:
<b>Resubmission (Required by EC):</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable If <b>Not Applicable</b> , skip this section	<b>Yes</b>	<b>No</b>	Any defect, grade "1" in SIDCER-FERCAP Form 13 # 01
EC Specified Timeline for PI Response	<input type="checkbox"/>	<input type="checkbox"/>	If <b>Yes</b> , date(s) resubmission received:
EC Recommendations Followed	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Evidence of Review	<input type="checkbox"/>	<input type="checkbox"/>	If <b>Yes</b> , <input type="checkbox"/> Expedited <input type="checkbox"/> FB
Appropriate Type of Review	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Appropriate Decision	<input type="checkbox"/>	<input type="checkbox"/>	Decision notification date(s):
Letter of Approval	<input type="checkbox"/>	<input type="checkbox"/>	Date:
<b>Continuing Review Process</b>			
<b>Amendment:</b> <input type="checkbox"/> Yes #:____ <input type="checkbox"/> No <input type="checkbox"/> Not Applicable If <b>Not Applicable</b> , skip this section	<b>Yes</b>	<b>No</b>	Any defect, grade "1" in SIDCER-FERCAP Form 14 # 01
Evidence of Review	<input type="checkbox"/>	<input type="checkbox"/>	If <b>Yes</b> , <input type="checkbox"/> Expedited <input type="checkbox"/> FB
Appropriate Type of Review	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Amendment Discussed at FB	<input type="checkbox"/>	<input type="checkbox"/>	Meeting date(s):
Appropriate Decision	<input type="checkbox"/>	<input type="checkbox"/>	Decision notification date(s):
<b>SAE:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No If <b>Yes</b> , <input type="checkbox"/> Onsite #:____ <input type="checkbox"/> Offsite #:____	<b>Yes</b>	<b>No</b>	Any defect, grade "1" in SIDCER-FERCAP Form 14 # 02
Evidence of Review	<input type="checkbox"/>	<input type="checkbox"/>	If <b>Yes</b> , <input type="checkbox"/> Expedited <input type="checkbox"/> FB
Appropriate Type of Review	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
SAE Report Assessment Form	<input type="checkbox"/>	<input type="checkbox"/>	Complete: <input type="checkbox"/> Yes <input type="checkbox"/> No
Onsite SAE Discussed at FB	<input type="checkbox"/>	<input type="checkbox"/>	Meeting date(s):
Appropriate Decision	<input type="checkbox"/>	<input type="checkbox"/>	Decision notification date(s):



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<b>Protocol Deviation/Violation</b> <b>Report:</b> <input type="checkbox"/> Yes #: ____ <input type="checkbox"/> No If <b>No</b> , skip this section	<b>Yes</b>	<b>No</b>	Any defect, grade “1” in SIDCER-FERCAP Form 14 # 03
Evidence of Review	<input type="checkbox"/>	<input type="checkbox"/>	If <b>Yes</b> , <input type="checkbox"/> Expedited <input type="checkbox"/> FB
Appropriate Type of Review	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Deviation/Violation Discussed at FB	<input type="checkbox"/>	<input type="checkbox"/>	Meeting date(s):
Appropriate Decision	<input type="checkbox"/>	<input type="checkbox"/>	Decision notification date(s):
<b>Progress Report:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable If <b>Not Applicable</b> , skip this section	<b>Yes</b>	<b>No</b>	Any defect, grade “1” in SIDCER-FERCAP Form 14 # 04
Evidence of Review	<input type="checkbox"/>	<input type="checkbox"/>	If <b>Yes</b> , <input type="checkbox"/> Expedited <input type="checkbox"/> FB
Appropriate Type of Review	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Progress Report Discussed at FB	<input type="checkbox"/>	<input type="checkbox"/>	Meeting date (s):
Appropriate Decision	<input type="checkbox"/>	<input type="checkbox"/>	Decision notification date(s):
<b>Final Report:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable If <b>Not Applicable</b> , skip this section	<b>Yes</b>	<b>No</b>	Any defect, grade “1” in SIDCER-FERCAP Form 14 # 05
Evidence of Review	<input type="checkbox"/>	<input type="checkbox"/>	If <b>Yes</b> , <input type="checkbox"/> Expedited <input type="checkbox"/> FB
Appropriate Type of Review	<input type="checkbox"/>	<input type="checkbox"/>	Comments:
Final Report Discussed at FB	<input type="checkbox"/>	<input type="checkbox"/>	Meeting date:
Appropriate Decision	<input type="checkbox"/>	<input type="checkbox"/>	Decision notification date:
<b>Summary of Surveyor Findings:</b>  Use Form 13 to assess the weaknesses of initial review.  Use Form 14 to assess the weaknesses of continuing review.			