



SIDCER-FERCAP Survey Form 26: Action Plan
Version 3.0, 30 April 2020

Name of the EC received SIDCER-FERCAP Survey on Month/Day/Year. The following Corrective Action Plan has been discussed among the EC members and the staff, and approved by Name of EC Chair. Supportive documents are attached with this Corrective Action Plan. [NOTE: Surveyor Assessment will be filled-up by the FERCAP Surveyors.]

1. Structure and Composition

1.1. Membership Requirements			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

1.2. Administrative Requirements (Financial, Staff & Office Support)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

1.3. Membership Initial & Continuous Training			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

1.4. Management of Conflicts of Interest (Policy & Practice)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

2. Adherence to Specific Policies

2.1. Availability of Guidelines & Regulations for EC Reference			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

2.2. Adherence to National & International Guidelines			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

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2.3. Availability of SOPs (to the EC Members, Investigators & the Public)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

2.4. Areas & Functions Covered by the SOPs (Completeness & Consistency)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

2.5. Availability of Forms & Checklists (including the Use of SOP Forms & Checklists)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

2.6. Periodic Updating of SOPs (Frequency of Updates & SOP Versions)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

3. Completeness of the Review Process

3.1. Assignment of Appropriate Reviewers			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

3.2. Availability of Comprehensive Reviewer Assessment Form			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

3.3. Review Process (Expedited & Full Board)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

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3.4. Elements of Review/Quality of Review (Science, Ethics & Informed Consent)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

3.5. Decision-making Process (Types of Decision, Approval Letter & Communication to PI)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

3.6. Completeness of Meeting Agenda (Details in the Meeting Agenda)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

4. After Approval Review Process

4.1. Meeting Minutes (Complete Sections to include Initial & Continuing Review, Discussion Points & Board Decision)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

4.2. Amendments			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

4.3. Progress Reports (Progress of Review & Decision-Making)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

4.4. SAE Reports (Proper Classification of Onsite/Offsite SAE, SUSAR & Appropriate EC Action)			
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4.5. Site Visits (EC Procedures & Reporting to the Board for EC Action)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

4.6. Protocol Deviations/Violations (EC Procedures and Action)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

4.7. Final Reports (EC Procedures and Action)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

5. Documentation and Archiving

5.1. EC Office (Adequate Space, Equipment, Confidentiality & Security Protection)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

5.2. Comprehensive Documentation (in the Protocol Files, Membership Files & Other Files)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

5.3. Orderly Filing System			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

5.4. Separation of Active from Inactive Files (Protocol Files)			
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5.5. Archiving			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

5.6. Database for Tracking (Complete Details)			
<i>Recommendation</i>	<i>Corrective Action</i>	<i>Full Compliance Date</i>	<i>Surveyor Assessment</i>

This Action Plan was prepared by: _____

Date: _____