Survey and Evaluation Report

Draft/Final Report:
Month/Day/Year

This report contains the collective views of the FERCAP Surveyor Team and contains their findings and recommendations.

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Section 1: General Information

1.1. EC Name:
1.2. EC Address:
1.3. Contact Person(s) (Name/Position/E-mail):
1.4. Survey Team **Lead Surveyor** (Name/Institution/E-mail): **Foreign Surveyor** (Name/Institution/E-mail): **Local Surveyor** (Name/Institution/E-mail): **Survey Coordinator** (Name/Institution/E-mail):
1.5. Survey Trainees (Name/Institution/E-mail):
1.6. List of Persons Interviewed (Name/Position):
1.7. Survey Visit Date:
1.8. Survey Report Date:

Section 2: Executive Summary

This Survey Report contains findings and suggestions for Corrective Actions prepared during the survey and evaluation done by the FERCAP Survey Team based on the SIDCER Recognition requirements.

The overall survey objective was to assist the <u>Name of EC</u> to improve the quality of its ethical review practices through an assessment of its performance based on the SIDCER criteria for recognition.

The reference documents that were used for assessment were the following:
- Applicable laws, regulations, guidelines, and organizational policies for the EC
- WMA Declaration of Helsinki, 2013
- CIOMS guidelines for ethics review, 2002, 2009, 2016
- WHO standards and operational guidance for ethics review of health-related research with human participants, 2011
- WHO surveying and evaluating ethical review practices, 2002
- ICH-GCP (E-6), 1996, 2016
- SIDCER-FERCAP Survey TOR, 2020
- SIDCER-FERCAP Survey SOPs, 2007, 2010, 2020
- SIDCER-FERCAP Survey Forms, 2009, 2013, 2020

Main Findings:

Section 3: Objectives and Scope

The objectives of the survey are:

- To conduct an independent evaluation of the EC and to provide feedback on its practices and overall performance
  - ➢ To review existing written Standard Operating Procedures (SOPs) and adherence to these procedures
  - ➢ To observe compliance to international, national and local standards
- To make recommendations as appropriate to ensure best standards of quality and transparency in ethical review for the EC

The Survey Team conducted this survey and evaluation for and on behalf of FERCAP:

- EC office visit date:
- EC Members and Staff interview dates:
- EC full board observation date:
- EC document review:
  - ➢ Number of SOPs reviewed:
  - ➢ Number of Agenda reviewed:
  - ➢ Number of Minutes reviewed:
  - ➢ Number of Protocols reviewed:
  - ➢ Number of SAE Reports reviewed:

Section 4: Methodology

4.1. EC Self-Assessment Form

The Survey Team was furnished a copy of the accomplished/completed EC Self-Assessment Form for study and analysis. This was later compared with the observations of the Surveyors and the discrepancies were analyzed.

4.2. Document Review

The Survey Team identified the protocols for review. This list was forwarded to the EC Secretary and the Protocol Files were made available to the Survey Team.

The Survey Team prepared the lists of documents for review including the SOP Files, Membership and Staff Files, the selected Protocol Files, Meeting Agenda and Minutes, SAE Reports, and Communication Records that were made available for review by the Survey Team.

4.3. Interview of EC Members and Staff

The interviewees were identified and the interview schedules were set according to the availability and preferred time of the interviewees.

4.4. EC Full Board Meeting Observation

The EC Full Board Meeting was observed on Month/Day/Year. The Agenda and Protocol Files were provided to the Survey Team in preparation for observation of the meeting. The Local Surveyor(s) assisted the Foreign Surveyor(s) by translating the protocols to be reviewed during the meeting. The Survey Team reviewed the Agenda, Protocol Files, and the relevant SOPs for Full Board Meeting before the actual meeting. The number of new protocols discussed during the Full Board Meeting was number.

4.5. Visit of EC Office, Document Storage, and Archiving Facilities

The Survey Team visited the office of the EC located at address.

Section 5: Findings and Suggestions for Corrective Actions

This section describes the findings and recommendations of the FERCAP Survey Team.

5.1. Structure and Composition

5.1.1. Membership Requirements	
Good Practices	
Weaknesses	*Recommendations*

5.1.2. Administrative Requirements (Financial, Staff & Office Support)	
Good Practices	
Weaknesses	*Recommendations*

5.1.3. Membership Initial & Continuous Training	
Good Practices	
Weaknesses	*Recommendations*

5.1.4. Management of Conflicts of Interest (Policy & Practice)	
Good Practices	
Weaknesses	*Recommendations*

5.2. Adherence to Specific Policies

5.2.1. Availability of Guidelines & Regulations for EC Reference	
Good Practices	
Weaknesses	*Recommendations*

5.2.2. Adherence to National & International Guidelines	
Good Practices	
Weaknesses	*Recommendations*

5.2.3. Availability of SOPs (to the EC Members, Investigators & the Public)	
Good Practices	
Weaknesses	*Recommendations*

5.2.4. Areas & Functions Covered by the SOPs (Completeness & Consistency)	
Good Practices	
Weaknesses	*Recommendations*

5.2.5. Availability of Forms & Checklists (including the Use of SOP Forms & Checklists)	
Good Practices	
Weaknesses	*Recommendations*

5.2.6. Periodic Updating of SOPs (Frequency of Updates & SOP Versions)	
Good Practices	
Weaknesses	*Recommendations*

5.3. Completeness of the Review Process

5.3.1. Assignment of Appropriate Reviewers	
Good Practices	
Weaknesses	*Recommendations*

5.3.2. Availability of Comprehensive Reviewer Assessment Form	
Good Practices	
Weaknesses	*Recommendations*

5.3.3. Review Process (Expedited & Full Board)	
Good Practices	
Weaknesses	*Recommendations*

5.3.4. Elements of Review/Quality of Review (Science, Ethics & Informed Consent)	
Good Practices	
Weaknesses	*Recommendations*

5.3.5. Decision-making Process (Types of Decision, Approval Letter & Communication to PI)	
Good Practices	
Weaknesses	*Recommendations*

5.3.6. Completeness of Meeting Agenda (Details in the Meeting Agenda)	
Good Practices	
Weaknesses	*Recommendations*

5.4. After Approval Review Process

5.4.1. Meeting Minutes (Complete Sections to include Initial & Continuing Review, Discussion Points & Board Decision)	
Good Practices	
Weaknesses	*Recommendations*

5.4.2. Amendments	
Good Practices	
Weaknesses	***Recommendations***

5.4.3. Progress Reports (Progress of Review & Decision-Making)	
Good Practices	
Weaknesses	***Recommendations***

5.4.4. SAE Reports (Proper Classification of Onsite/Offsite SAE, SUSAR & Appropriate EC Action)	
Good Practices	
Weaknesses	***Recommendations***

5.4.5. Site Visits (EC Procedures & Reporting to the Board for EC Action)	
Good Practices	
Weaknesses	***Recommendations***

5.4.6. Protocol Deviations/Violations (EC Procedures and Action)	
Good Practices	
Weaknesses	***Recommendations***

5.4.7. Final Reports (EC Procedures and Action)	
Good Practices	
Weaknesses	***Recommendations***

5.5. Documentation and Archiving

5.5.1. EC Office (Adequate Space, Equipment, Confidentiality & Security Protection)	
Good Practices	
Weaknesses	*Recommendations*

5.5.2. Comprehensive Documentation (in the Protocol Files, Membership Files & Other Files)	
Good Practices	
Weaknesses	*Recommendations*

5.5.3. Orderly Filing System	
Good Practices	
Weaknesses	*Recommendations*

5.5.4. Separation of Active from Inactive Files (Protocol Files)	
Good Practices	
Weaknesses	*Recommendations*

5.5.5. Archiving	
Good Practices	
Weaknesses	*Recommendations*

5.5.6. Database for Tracking (Complete Details)	
Good Practices	
Weaknesses	*Recommendations*

Section 6: Conclusions and Recommendations

6.1. Over-all Assessment

The overall assessment is that the Name of EC is/is not a functional EC, whose members are description and staff are description. The EC has essentially description SOPs. Generally, the EC review process is description and their after review process is description. Overall, EC documentation and archiving is description.

The major strengths of the EC are description. The major weaknesses of the EC are description. The recommendations to address the major weaknesses are description.

6.2. Follow-up Action

The items identified for improvement should be properly addressed by following the recommendations of the Survey Team. The Name of EC should submit its Action Plan with documentary evidence to indicate its compliance with the recommendations. A Follow-up Site Visit is/is not required before/after Recognition. The EC should provide information on the full compliance with its Action Plan either through the submission of documentary evidence or through the conduct of Post-Recognition Follow-up Site Visit.

Section 7: Attachments

7.1. List of SOPs Reviewed

#	SOP Code/Number	SOP Title
01		
02		
03		

7.2. List of Protocols Reviewed

#	Protocol Code/Number	Protocol Title
01		
02		
03		

7.3. List of Meeting Minutes Reviewed

#	Meeting Minutes Code/Date
01	
02	
03	

7.4. List of SAE Reports Reviewed

#	Protocol Code/Number	Onsite	Offsite	SAE	SUSAR
01					
02					
03					

7.5. Closing Meeting Presentation

Closing meeting presentation prepared by the Survey Team was presented by the Local Surveyor to the Name of EC on Month/Day/Year.

7.6. Summary of Recommendations

Structure and Composition
01.
02.
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05.
Adherence to Specific Policies
06.
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Completeness of the Review Process
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After Approval Review Process
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Documentation and Archiving
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7.7. Quality of Ethical Review