



Conduct of a Site Visit

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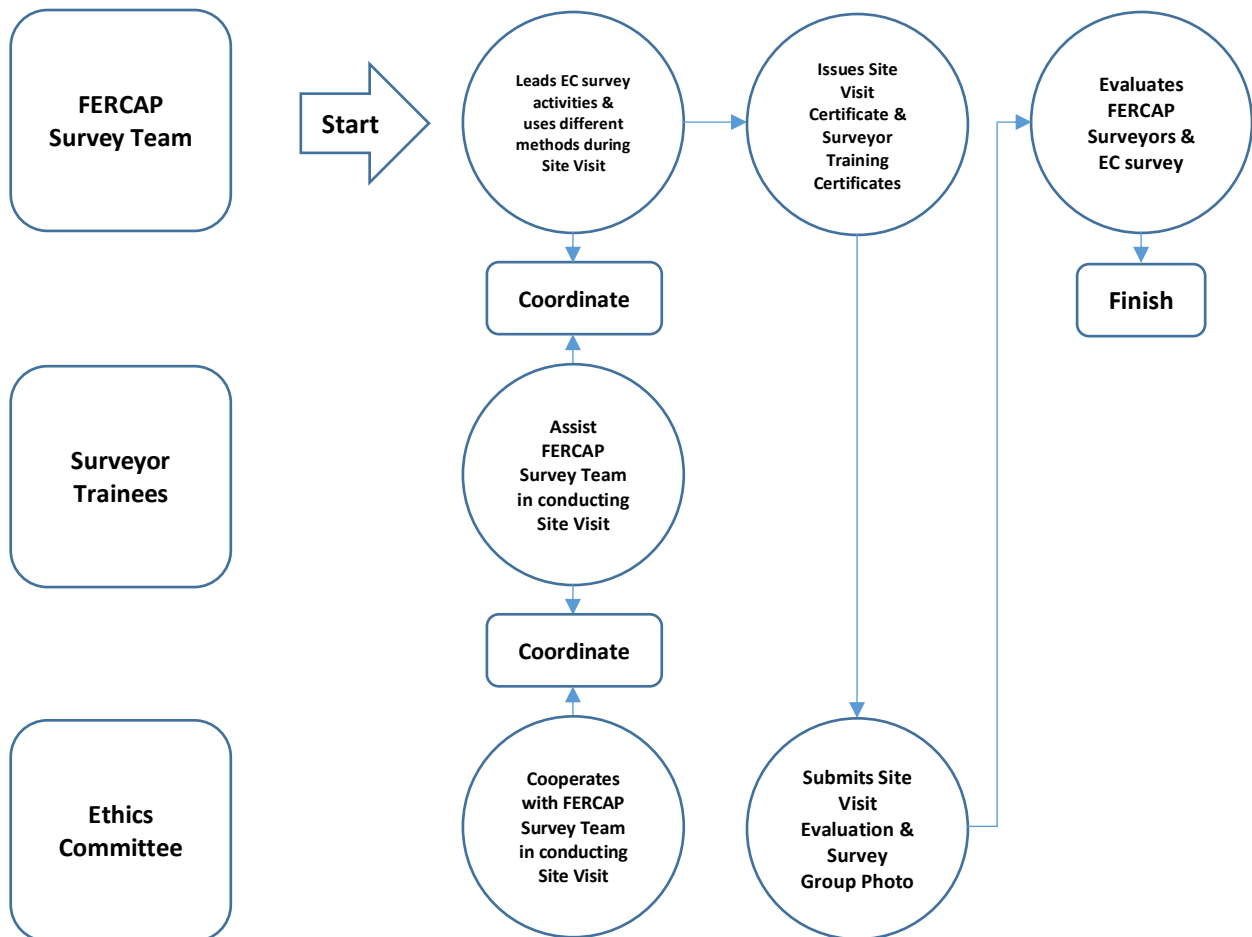
1. OBJECTIVE

The objective of this Standard Operating Procedure (SOP) is to describe the activities and different methods during the Site Visit.

2. SCOPE

This SOP covers the activities and different methods during the Site Visit.

3. RESPONSIBILITY AND WORKFLOW



4. DETAILED INSTRUCTIONS

4.1. Conduct of the EC Survey Activities

The FERCAP Survey Team leads the EC survey activities and uses the different EC survey methods during the Site Visit in coordination with the Surveyor Trainees and the EC. The Surveyor Trainees assist the FERCAP Survey Team in conducting the Site Visit. The EC cooperates with the FERCAP Survey Team in conducting the Site Visit.

4.1.1. Conduct of the Opening Meeting

The Opening Meeting is held on the first day of the Site Visit with EC Members and Staff in attendance. The purpose of the Opening Meeting is to formally explain the objectives and methods of the EC survey and for the FERCAP Survey Team to get an overview about the EC operations.

Guided by the EC Presentation Template (SIDCER-FERCAP Survey Template 01), the EC Chairperson or an appointed EC Representative provides the background information about the history, structure, operations, and procedures of the EC.

- Using the SIDCER-FERCAP Survey Template 02 - PPT Opening Meeting Survey Plan, the FERCAP Lead Surveyor presents the following:
- Purpose and scope of the Site Visit
- Composition of the FERCAP Survey Team and Surveyor Trainees
- SIDCER-FERCAP Survey Methods based on the 5 SIDCER-FERCAP Standards:
 - a) Structure and composition
 - b) Adherence to specific policies
 - c) Completeness of the review process
 - d) After approval review process
 - e) Documentation and archiving
- Reference documents that will be used as basis for the EC survey
- Documents that will be reviewed
- Selection of interviewees
- Schedule for the Closing Meeting

The FERCAP Survey Team and Surveyor Trainees submit signed and dated Confidentiality and COI Agreements to the EC.

4.1.2. Tour of the EC Office and Facilities

The FERCAP Survey Team and Surveyor Trainees tour the EC Office and Facilities to determine documentation and archiving procedures. The FERCAP Survey Team and Surveyor Trainees document the review (use SIDCER-FERCAP Survey form 08).

4.1.3. Review of the EC Legal and Regulatory Framework and EC TOR

The FERCAP Survey Team and Surveyor Trainees assess the compliance with applicable national/local laws, regulations, and procedures under which the EC

is established and the national and international ethical principles and guidelines under which the EC operates. The FERCAP Survey Team and Surveyor Trainees check the availability of copies of national and international ethical principles and guidelines in the EC Office and Facilities and determine how they are referenced by the EC. The FERCAP Survey Team and Surveyor Trainees evaluate the EC TOR. The FERCAP Survey Team and Surveyor Trainees document the review (use SIDCER-FERCAP Survey form 08).

4.1.4. Review of EC Membership Files

The FERCAP Survey Team and Surveyor Trainees assess the EC Membership Files.

- Review the appointment procedures for the EC Chair, EC Members, EC Secretary, and EC Staff to determine its transparency and avoidance of conflicts of interest.
- Review the TOR of the EC Chair, EC Members, and EC Secretary to ensure continuity, development and maintenance of expertise, and regular input of fresh ideas.
- Check EC Membership Files to determine:
 - a) Adequate number of EC Members
 - b) Relevant expertise and qualifications of EC Members
 - c) Adequate number of EC Medical Members
 - d) Inclusion of EC Non-Scientific Members
 - e) inclusion of EC Non-Affiliated Members
 - f) Adequate gender representation
 - g) Adequate age representation
- Review the job description of the EC Staff to ensure continuity, outlined duty, and clear workload.
- Check the EC Staff Files to determine
 - a) Adequate number to cover the EC workload
 - b) Qualifications of EC Staff
- Review the Training Records of the EC Chair, EC Members, and EC Secretary:
 - a) Basic Research Ethics/Human Participant Protection
 - b) Good Clinical Practice
 - c) SOP
- Review the Training Records of the EC Staff:
 - a) EC Office Management
 - b) SOP
- Review the EC Independent Consultants Files:
 - a) Appointment/contract
 - b) CV
- Check that Confidentiality and COI Agreements of the EC Chair, EC Members, EC Secretary, EC Staff, and EC Independent Consultants
- The FERCAP Survey Team and Surveyor Trainees document the review (use SIDCER-FERCAP Survey Form 09)

The FERCAP Survey Team and Surveyor Trainees document the review.

4.1.5. Review of EC SOPs and EC Forms

The FERCAP Survey Team and Surveyor Trainees assess recent and previous EC SOPs and EC Forms to determine that

- All EC SOPs and EC Forms are complete (all areas and functions of the EC are covered by the SOPs)
- All EC SOPs and EC Forms are consistent
- All EC SOPs and EC Forms are compliant with national and international ethical principles and guidelines
- There is continuous review and revision of the EC SOPs and EC Forms

The FERCAP Survey Team and Surveyor Trainees document the review (use SIDCER-FERCAP Survey Form 10)

4.1.6. Review of EC Protocol Files

The FERCAP Survey Team and Surveyor Trainees assess at least 15 Protocol Files reviewed by the EC in the last three years as applicable:

- Use SIDCER-FERCAP Survey Form 12 to
 - a) Review application/submission documents made to the EC
 - b) Review complete documentation of Protocols submitted and approved with all the copies and communications
 - c) Check the review of resubmitted protocols
 - d) Review the contents of approved Protocols together with the Primary Reviewers' comments
 - e) Review the adherence to the EC comments before final approval
 - f) Review communication procedures
- Use SIDCER-FERCAP Survey Form 13 to Assess the quality of initial review performed by Primary Reviewers
- Use SIDCER-FERCAP Survey Form 14 to Assess the quality of continuing review
 - a) The review of amendments
 - b) The review of protocol deviations, violations, and non-compliance
 - c) The review of Progress Reports and Final Reports (a representative samples)
- Use SIDCER-FERCAP Survey Form 17 to assess the review of a representative sample of SAE Reports to determine if:
 - a) SAEs are reported on time to the EC
 - b) SAEs are adequately reviewed and reported to the Full Board Meeting
 - c) SAEs are adequately followed-up and documented
- Assess the review of Site Visit Reports

The FERCAP Survey Team and Surveyor Trainees document the review

4.1.7. Review of EC Meeting Agenda, EC Meeting Minutes, and EC Communications

- The FERCAP Survey Team and Surveyor Trainees assess a representative sample of EC Meeting Agendas, EC Meeting Minutes, and EC Communications. The FERCAP Survey Team and Surveyor Trainees document the review (use SIDCER-FERCAP Survey Form 16)

4.1.8. Interview of EC Representatives

The FERCAP Survey Team and Surveyor Trainees interview the EC Chair, some EC Members (Medical, Lay, and SAE Reviewer), EC Secretary, and EC Staff about their appointment, training, responsibilities, and practices to determine who does what, how things are being done, their compliance to their written EC SOPs, and their workload. The FERCAP Survey Team and Surveyor Trainees document the review (use SIDCER-FERCAP Survey Form 15)

4.1.9. Observe EC Full Board Meeting

The FERCAP Survey Team and Surveyor Trainees observe the Full Board Meeting to:

- Determine their adherence to their written EC SOPs, requirements, and regulations
- Determine their review procedures (complete and covers all elements of review)
- Observe how COI are managed by the EC
- Observe their decision-making procedures
- Determine if the provisions and conditions for expedited EC review and decision are followed
- Determine if there are follow-up review procedures.

The FERCAP Survey Team and Surveyor Trainees document the review (use SIDCER-FERCAP Survey Form 11).

4.1.10. Hold Daily Summary Meeting

The FERCAP Survey Team and Surveyor Trainees hold daily (Closed-Door) Summary Meetings to:

- Discuss and document all findings and observations for each day, the coverage and adherence to the Survey Plan
- Analyze the findings, identify missing information, and make a plan for the following day to follow-up on the missing information
- Discuss any possible changes in the scope of the Site Visit or the Survey Plan

4.1.11. Prepare for closing meeting

- The lead surveyor prepares pareto chart using SIDCER-FERCAP Survey Template 04 and 05 to assess the frequency of defects of the Initial and continuing Review, respectively.
- The lead surveyor prepares draft closing meeting presentation using SIDCER-FERCAP Survey Template 03) based on the daily summary meetings and reports of each group.
- The lead surveyor presents the draft presentation and finalize the findings and recommendations based on the survey team consensus.

4.1.1.2. Conduct of the Closing Meeting

The lead surveyor or local surveyor presents the final findings and recommendation to the EC.

The objectives of the Closing Meeting with the EC Representatives are to:

- Thank the EC for their assistance and contribution during the Site Visit
- Present the Survey Findings based on the 5 SIDCER-FERCAP Standards
- Discuss the Survey Findings with the EC
- Explain the next procedures and the timeline for succeeding activities
 - a) Site Visit Certificate
 - b) Survey Report
 - c) Follow-up Site Visit
 - d) Communications between FERCAP and the EC
- Address all EC questions and concerns

4.2. Issuance of the Site Visit Certificate and Surveyor Training Certificates

4.2.1. The FERCAP Survey Coordinator issues the Site Visit Certificate to the EC (use SIDCER-FERCAP Survey Template 06)

4.2.2. The FERCAP Survey Coordinator issues the Surveyor Training Certificate to the FERCAP Surveyors and Surveyor Trainees (use SIDCER-FERCAP Survey Template 07).

4.3. Site Visit Evaluation and Survey Group Photo

4.3.1. The FERCAP Survey Coordinator provides EC with SIDCER-FERCAP Survey Form 22 and request the EC to evaluate the EC survey and submits its feedback to the FERCAP Survey Committee within three days after the Site Visit.

4.3.2. The EC also submits a Survey Group Photo within three days after the Site Visit as part of the documentation of the EC survey.

4.4. Surveyor Evaluation and Survey Deviation, Non-Compliance and Violation Form

4.4.1. The FERCAP Survey Coordinator evaluates the FERCAP Surveyors using SIDCER-FERCAP Survey Form 21 and submit its feedback to the FERCAP Survey Committee within three days after the Site Visit.

4.4.2. The FERCAP Survey Coordinator, as confirmed by the other FERCAP Survey Team Members, submit the Survey Non-Compliance Form (SIDCER-FERCAP Survey Form 23) within three days after the Site Visit if there are deviations and violations of the SIDCER-FERCAP Survey Terms of Reference (TOR) and SIDCER-FERCAP Survey Standard Operating Procedures (SOPs)

5. GLOSSARY

EC	An ethics committee. It is also known as ethical review board (ERB), ethical review committee (ERC), human research ethics committee (HREC), institutional review board (IRB), and research ethics committee (REC). It is a group of individuals who undertakes the ethical review of research protocols involving human participants using agreed ethical principles and guidelines.
FERCAP	The Forum for Ethical Review Committees in Asia and the Western Pacific. It is an organization of ECs within the Asia-Pacific region. It is regional forum under the umbrella of SIDCER.
FERCAP Lead Surveyor	An experienced FERCAP Surveyor who leads the FERCAP Survey Team and writes the Survey Report.
FERCAP Local Surveyor	A FERCAP Surveyor from the area/country of the EC being surveyed.
FERCAP Survey Coordinator	An experienced FERCAP Surveyor who supervises the FERCAP Survey Team.
FERCAP Survey Team	Composed of a FERCAP Survey Coordinator, a FERCAP Lead Surveyor, and two other FERCAP Surveyors tasked to conduct the EC survey.
SIDCER	The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER). It is a global network of EC fora composed of FERCAP and the Pan-African Bioethics Initiative (PABIN).
Surveyor Trainee	A potential FERCAP Surveyor undergoing training.

6. DOCUMENT HISTORY

Version/Year	SOP Code	Revisions
1.0/2005	FERCAP SOP SRP 03	Initial SIDCER-FERCAP Survey SOP.
2.0/2007	FERCAP SRP SOP003	Procedures and workflow were elaborated according to practice.
3.0/2010	SIDCER-FERCAP Survey SOP005	Coding was changed to SOP005. Procedures and workflow were elaborated according to practice.
4.0/2020	SIDCER-FERCAP Survey SOP 05	Format was changed. Procedures and workflow were revised. Responsibility (in the workflow) and references were added. Annex codes were revised.

7. ANNEXES

- SIDCER-FERCAP Survey Form 08 - Office Visit
- SIDCER-FERCAP Survey Form 09 - Membership File Review

- SIDCER-FERCAP Survey Form 10- SOP Review
- SIDCER-FERCAP Survey Form 11 - Full Board Meeting Observation
- SIDCER-FERCAP Survey Form 12 - Protocol File Review
- SIDCER-FERCAP Survey Form 13 - Quality of Initial Review
- SIDCER-FERCAP Survey Form 14 - Quality of Continuing Review
- SIDCER-FERCAP Survey Form 15- Interview
- SIDCER-FERCAP Survey Form 16 - Meeting Minutes
- SIDCER-FERCAP Survey Form 17 - SAE Review
- SIDCER-FERCAP Survey Form 22 - Survey Evaluation by EC
- SIDCER-FERCAP Survey Form 21 - Surveyor Evaluation by Survey Coordinator
- SIDCER-FERCAP Survey Form 23 - Survey Non-Compliance
- SIDCER-FERCAP Survey Template 01 – PPT Opening Meeting EC Presentation
- SIDCER-FERCAP Survey Template 02 - PPT Opening Meeting Survey Plan
- SIDCER-FERCAP Survey Template 03 - PPT Closing Meeting Presentation
- SIDCER-FERCAP Survey Template 04 - Quality of Initial Review (Pareto)
- SIDCER-FERCAP Survey Template 05 - Quality of Continuing Review (Pareto)
- SIDCER-FERCAP Survey Template 06- Site Visit Certificate
- SIDCER-FERCAP Survey Template 07- Surveyor Training Certificate

8. REFERENCES

- FERCAP Terms of Reference, 2000, 2004
- WHO Surveying and Evaluating Ethical Review Practices, 2002
- SIDCER-FERCAP Survey Standard Operating Procedures, 2005, 2007, 2010
- SIDCER-FERCAP Survey Forms, 2009, 2013