



## Conduct of a Follow-up Site Visit

### SIDCER-FERCAP Survey SOP 07

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## Conduct of a Follow-up Site Visit

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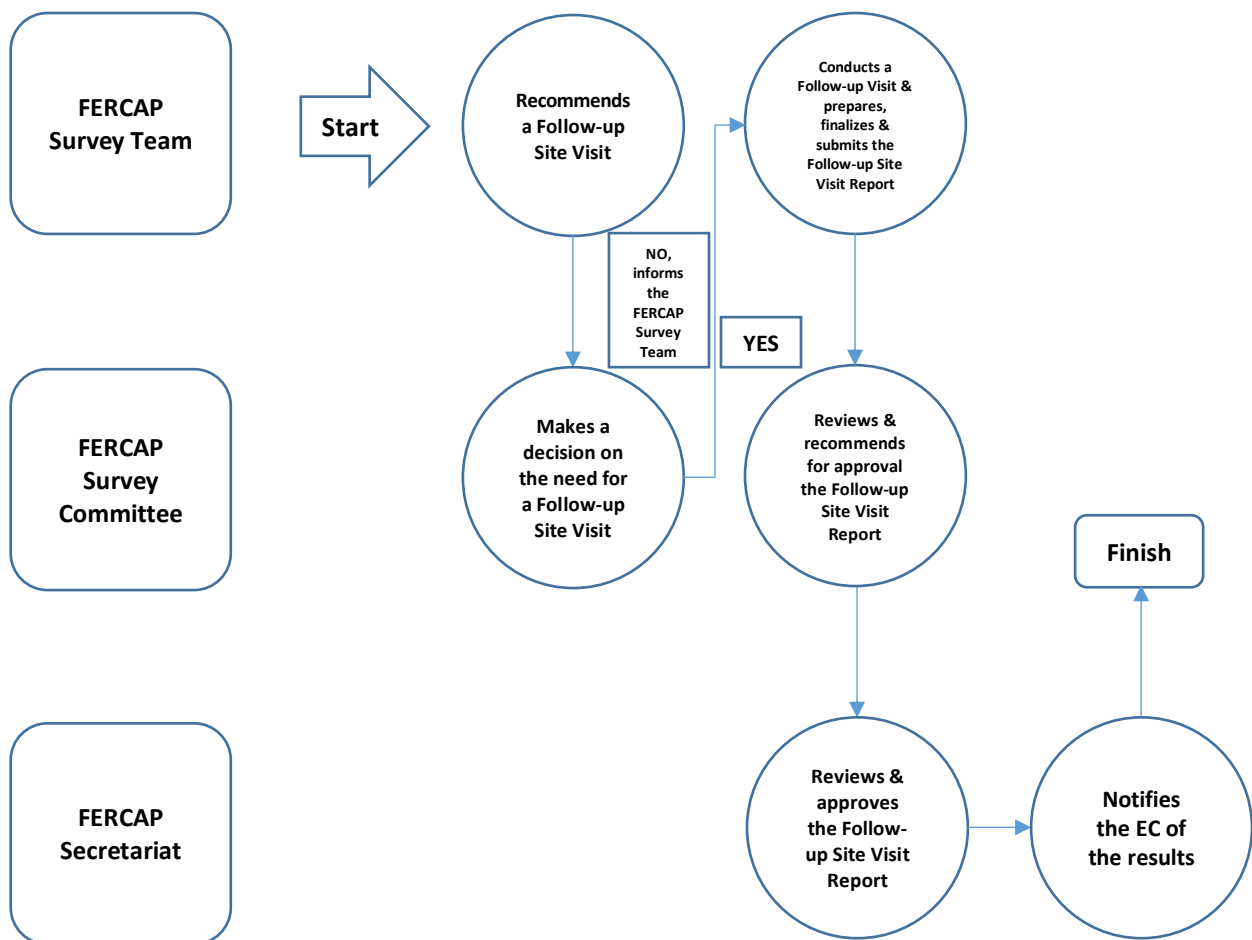
### 1. OBJECTIVE

The objective of this Standard Operating Procedure (SOP) is to describe the processes in recommending and conducting a Follow-up Site Visit.

### 2. SCOPE

This SOP covers the processes in recommending and conducting a Follow-up Site Visit.

### 3. RESPONSIBILITY AND WORKFLOW



## 4. DETAILED INSTRUCTIONS

### 4.1. Recommendation for a Follow-up Site Visit

- The FERCAP Survey Team indicates in the Final Survey Report the need for a Follow-up Visit.
- The FERCAP Survey Team recommends a Follow-up Site Visit (maybe before or after making a decision on EC recognition; in some cases, depending on the national requirements, Follow-up Site Visit is mandatory).

### 4.2. Decision-making on the Need for Follow-up Site Visit

- The follow-up site visit should be considered when there is evidence to suggest a significant deficiency in the completeness of review that poses research participants to risk.
- The FERCAP Survey Committee makes a decision on the need for Follow-up Site Visit and informs the FERCAP Survey Team.
- If the FERCAP Survey Committee does not agree with the need for Follow-up Site Visit, the FERCAP Survey Committee provides the FERCAP Survey Team with the reason and monitors the compliance of the EC through the Annual Progress Report.
- If the FERCAP Survey Committee confirms the need for Follow-up Site Visit, the FERCAP Survey Committee asks the FERCAP Local Coordinator to identify the suitable FERCAP Local Surveyor to conduct the Follow-up Site Visit.

### 4.3. Conduct of a Follow-up Site Visit

- The FERCAP Local Coordinator (as part of the FERCAP Survey Committee) identifies the suitable FERCAP Local Surveyor to conduct the Follow-up Site Visit.
- The FERCAP Local Surveyor coordinates with the EC, informs the EC if the Follow-up Site Visit includes Board Meeting Observation and Update Training for the EC, and conducts the Follow-up Site Visit.

### 4.4. Preparation of the Follow-up Site Visit Report

- The FERCAP Local Surveyor writes the Follow-up Site Visit Report.
- The FERCAP Local Surveyor submits the Follow-up Site Visit Report to the FERCAP Survey Committee within one week after the Follow-up Site Visit.

### 4.5. Recommendation for Approval of the Follow-up Site Visit Report

- The FERCAP Local Coordinator (as part of the FERCAP Survey Committee) reviews the Follow-up Site Visit Report for any local concerns and issues.
- The FERCAP Local Coordinator recommends for approval the Follow-up Site Visit Report and submits it to the FERCAP Secretariat within three days after receipt from the FERCAP Local Surveyor.

### 4.6. Approval of the Survey Report

- The FERCAP Coordinator or FERCAP Program Manager (as part of the FERCAP Secretariat) reviews the Follow-up Site Visit Report for clarity, consistency, and compliance.
- The FERCAP Coordinator or FERCAP Program Manager notifies the EC of the results at least two weeks after the Site Visit.

## 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 Coordinator	The coordinator of the activities of FERCAP.
FERCAP Lead Surveyor	An experienced FERCAP Surveyor who leads the FERCAP Survey Team and writes the Survey Report.
FERCAP Local Coordinator	A FERCAP Steering Committee Member representing a FERCAP area/country or a Representative of the national accreditation institution ( <i>e.g.</i> NECAST, PHREB) or a Representative of the area/country network of ECs ( <i>e.g.</i> FERCI, FERCSL, FERCIT, FIRREC, NERCIM, PHREN, TAIRB) who coordinates the EC surveys in a FERCAP area/country.
FERCAP Local Surveyor	A FERCAP Surveyor from the area/country of the EC being surveyed.
FERCAP Program Manager	Manager of the activities of FERCAP.
FERCAP Secretariat	Composed of the SIDCER Coordinator, FERCAP Coordinator, FERCAP Program Manager, and FERCAP Treasurer that serves as the coordinating and managing arm of FERCAP
FERCAP Survey Coordinator	An experienced FERCAP Surveyor who supervises the FERCAP Survey Team.
FERCAP Survey Committee	Composed of the SIDCER Coordinator, the FERCAP Coordinator or FERCAP Program Manager, and the FERCAP Local Coordinator that serves as the coordinating arm in a FERCAP area/country.
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).

## 6. DOCUMENT HISTORY

Version/Year	SOP Code	Revisions
1.0/2005	FERCAP SRP 05	Initial SIDCER-FERCAP Survey SOP.
2.0/2007	FERCAP SRP SOP005	Procedures and workflow were elaborated according to practice.
3.0/2010	SIDCER-FERCAP Survey SOP007	Coding was changed to SOP007. Procedures and workflow were elaborated according to practice.
4.0/2020	SIDCER-FERCAP Survey SOP 07	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 25 - Follow-up Site Visit

## 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