



# SIDCER-FERCAP SURVEY TERMS OF REFERENCE & STANDARD OPERATING PROCEDURES





# **SIDCER-FERCAP SURVEY TERMS OF REFERENCE & STANDARD OPERATING PROCEDURES**



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**STRATEGIC INITIATIVE IN DEVELOPING CAPACITY IN ETHICAL REVIEW  
FORUM FOR ETHICAL REVIEW COMMITTEES IN ASIA AND THE WESTERN PACIFIC**

## **SIDCER-FERCAP SURVEY TERMS OF REFERENCE & STANDARD OPERATING PROCEDURES**

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**Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP)**

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	<b>SIDCER-FERCAP Survey TOR &amp; SOPs</b>	SIDCER-FERCAP Survey TOR & SOPs Version 4.0  Effective Date: 30 April 2020
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The *Forum for Ethical Review Committees in Asia and the Western Pacific* (FERCAP) was established in Bangkok, Thailand on January 12, 2000. It was a project initiated by the *World Health Organization* (WHO) *Special Training and Research Programme in Tropical Diseases* (TDR) to develop capacity building in ethical review. It is a regional forum under the *Strategic Initiative in Developing Capacity in Ethical Review* (SIDCER). It is supported by the SIDCER-FERCAP Foundation.

Since 2005, FERCAP has been implementing the SIDCER Recognition Program in the Asia-Pacific region. The primary objective of the SIDCER Recognition Program is to conduct independent external evaluations of ethics committees (ECs) in the region based on five criteria or standards: 1) Structure and composition, 2) Adherence to specific policies, 3) Completeness of the review process, 4) After approval review process, and 5) Documentation and archiving.


To achieve this objective, FERCAP developed the SIDCER-FERCAP Survey Terms of Reference (TOR), SIDCER-FERCAP Survey Standard Operating Procedures (SOPs), SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates. The first version of the SIDCER-FERCAP Survey TOR and SIDCER-FERCAP Survey SOPs was prepared by Lisa Hamadian and Haitao Lui, reviewed and revised by Cristina Torres, and approved by Juntra Karbwang Laothavorn in 2007. The first version of the SIDCER-FERCAP Survey Forms and SIDCER-FERCAP Survey Templates was prepared by Arthur Navarro, revised by Torres, and approved by Karbwang Laothavorn in 2009. The SIDCER-FERCAP Survey SOPs were revised by Navarro, reviewed by Torres, and approved by Karbwang Laothavorn in 2010 and 2019. The SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates were revised by Navarro, reviewed by Torres, and approved by Karbwang Laothavorn in 2013.


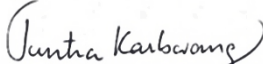
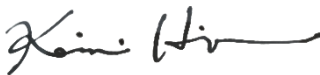
This year, FERCAP updated the SIDCER-FERCAP Survey TOR (version 04), SIDCER-FERCAP Survey SOPs (version 04), SIDCER-FERCAP Survey Forms (version 03), and SIDCER-FERCAP Survey Templates (version 03). The updated SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates were prepared by Navarro, reviewed by Karbwang Laothavorn, and approved by Kenji Hirayama. Prior to approval, these SIDCER-FERCAP Survey Documents undergone consultations with FERCAP Local Coordinators and FERCAP Surveyors.


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The updated SIDCER-FERCAP Survey TOR and SIDCER-FERCAP Survey SOPs are included in this publication while the updated SIDCER-FERCAP Survey Forms and SIDCER-FERCAP Survey Templates will be made available electronically to ECs and FERCAP Surveyors during SIDCER-FERCAP surveys.

With the publication of these SIDCER-FERCAP Survey Documents, FERCAP hopes to provide ECs and FERCAP Surveyors with the necessary updated materials to ensure quality SIDCER-FERCAP surveys.


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<b>Version</b>	04
<b>Prepared by</b>	 <b>Arthur Navarro</b> (FERCAP Program Manager)
<b>Reviewed by</b>	 <b>Juntra Karbwang Laothavorn</b> (SIDCER Coordinator)
<b>Approved by</b>	 <b>Kenji Hirayama</b> (FERCAP Chairperson)
<b>Approval date</b>	30 April 2020

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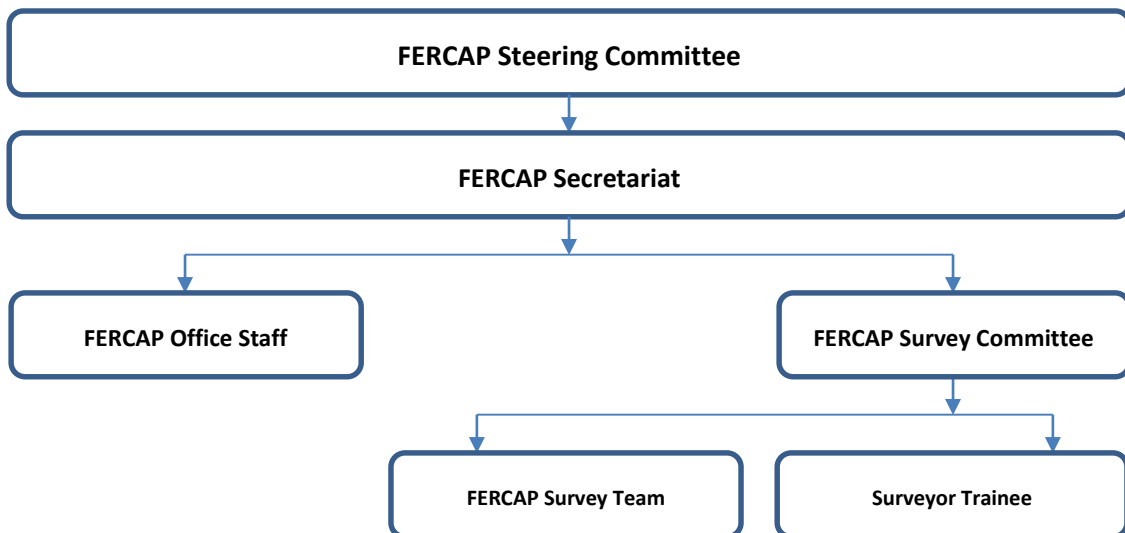
## 1. OBJECTIVE


The objective of this Terms of Reference (TOR) is to describe the organizational structure of the SIDCER-FERCAP survey and identify the responsibilities of the FERCAP Steering Committee, FERCAP Secretariat, FERCAP Office Staff, FERCAP Survey Committee, FERCAP Survey Team, and Surveyor Trainee in the conduct of ethics committee (EC) surveys for the SIDCER Recognition Program.

## 2. SCOPE

This TOR covers the organizational structure of the SIDCER-FERCAP survey and the responsibilities of the people involved in the conduct of EC surveys for the SIDCER Recognition Program.

## 3. ORGANOGRAM



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## 4. DETAILED INFORMATION


### 4.1. FERCAP Steering Committee

#### 4.1.1. Composition of the FERCAP Steering Committee

- 4.1.1.1. The FERCAP Steering Committee is composed of Representatives of FERCAP areas/countries with SIDCER-FERCAP recognized ECs, the SIDCER-FERCAP Foundation President, and the SIDCER Chairperson.
- 4.1.1.2. The Representative of a FERCAP area/country is nominated by FERCAP Steering Committee and decided upon during the FERCAP Steering Committee Meeting. The duration of the term of the Representative is five years. The FERCAP Chairperson certifies the appointment of the Representative of a FERCAP area/country to the FERCAP Steering Committee every year.
- 4.1.1.3. The SIDCER-FERCAP Foundation President is selected by the foundation. The SIDCER-FERCAP Foundation provides administrative, financial, and secretariat support to SIDCER-FERCAP. The duration of the term of the Representative is determined by the foundation. The FERCAP Chairperson certifies the appointment of the SIDCER-FERCAP Foundation President to the FERCAP Steering Committee every year.
- 4.1.1.4. The SIDCER Chairperson is selected according to the policies and procedures of SIDCER. The SIDCER Chairperson sits in the FERCAP Steering Committee in recognition of her/his vast knowledge about FERCAP and SIDCER. The duration of the term of the SIDCER Coordinator is determined by SIDCER. The FERCAP Chairperson certifies the appointment of the SIDCER Chairperson to the FERCAP Steering Committee every year.

#### 4.1.2. Officers of the FERCAP Steering Committee


- 4.1.2.1. FERCAP Steering Committee Members elect among themselves the FERCAP Chairperson and FERCAP Vice-Chairperson. The Chairperson and Vice-Chairperson are elected for a period of five years. The SIDCER Chairperson certifies the appointment of the FERCAP Chairperson and FERCAP Vice-Chairperson to the FERCAP Steering Committee every year.
- 4.1.2.2. The FERCAP Chairperson presides over the FERCAP Steering Committee Meeting and FERCAP General Assembly and signs all high-level legal documents (*e.g.* FERCAP Steering Committee and FERCAP Secretariat appointment certifications; memoranda of understanding) that bind FERCAP. The FERCAP Steering Committee Meeting and FERCAP General Assembly are conducted at least once a year.

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- 4.1.2.3. The FERCAP Vice-Chairperson assists the FERCAP Chairperson and performs the responsibilities of the FERCAP Chairperson in the latter's absence and in case of conflict of interest (COI).
- 4.1.2.4. In the absence of the FERCAP Chairperson and FERCAP Vice-Chairperson, the most senior FERCAP Steering Committee Member in attendance performs their responsibilities.
- 4.1.3. Responsibilities of the FERCAP Steering Committee in SIDCER-FERCAP surveys
  - 4.1.3.1. The FERCAP Steering Committee provides the general framework and policy direction for the conduct of EC surveys. The FERCAP Steering Committee also promotes the SIDCER Recognition Program among health research stakeholders. The FERCAP Steering Committee Meeting is held at least once every year. The agenda for the FERCAP Steering Committee Meeting is determined by the FERCAP Secretariat. Quorum for the FERCAP Steering Committee Meeting is at least five FERCAP Steering Committee Members.
  - 4.1.3.2. Based on the recommendations of the SIDCER-FERCAP Foundation, the FERCAP Steering Committee appoints the FERCAP Coordinator, FERCAP Program Manager, and FERCAP Treasurer.
  - 4.1.3.3. Based on the recommendations of the FERCAP Secretariat, the FERCAP Steering Committee approves the appropriate actions related to the general framework and policy direction for the conduct of EC surveys.
  - 4.1.3.4. Based on the recommendations of the FERCAP Secretariat, the FERCAP Steering Committee approves the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey Standard Operating Procedures (SOPs), SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates.
  - 4.1.3.5. Based on the recommendations of the FERCAP Secretariat, the FERCAP Steering Committee approves the ECs and FERCAP Surveyors for recognition during the FERCAP General Assembly.

## **4.2. FERCAP Secretariat**

- 4.2.1. Composition of the FERCAP Secretariat
  - 4.2.1.1. The FERCAP Secretariat is composed of the SIDCER Coordinator, FERCAP Coordinator, FERCAP Program Manager, and FERCAP Treasurer.
  - 4.2.1.2. The SIDCER Coordinator is selected according to the policies and procedures of SIDCER. The duration of the term of the SIDCER Coordinator is determined by SIDCER. The FERCAP Chairperson certifies the appointment of the SIDCER Coordinator to the FERCAP Secretariat every year.

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- 4.2.1.3. The FERCAP Coordinator, FERCAP Program Manager, and FERCAP Treasurer are appointed by the FERCAP Steering Committee upon the recommendations of the SIDCER-FERCAP Foundation. The SIDCER-FERCAP Foundation provides administrative, financial, and secretariat support to SIDCER-FERCAP. The FERCAP Coordinator, FERCAP Program Manager, and FERCAP Treasurer is supervised by the foundation. The duration of the term of the FERCAP Coordinator, FERCAP Program Manager, and FERCAP Treasurer is determined by the foundation. The FERCAP Chairperson certifies the appointment of the FERCAP Coordinator, FERCAP Program Manager, and FERCAP Treasurer to the FERCAP Secretariat every year.
- 4.2.2. Office of the FERCAP Secretariat
- 4.2.2.1. The FERCAP Secretariat holds office in one of the FERCAP areas/countries with SIDCER-FERCAP recognized ECs (*e.g.* Thailand).
- 4.2.2.2. The FERCAP Secretariat Office has adequate space, equipment, and personnel to perform activities related to the conduct of EC surveys.
- 4.2.3. Responsibilities of the FERCAP Secretariat in SIDCER-FERCAP surveys
- 4.2.3.1. The responsibilities of the FERCAP Secretariat are:
- Manage the FERCAP Secretariat Office
  - Raise and manage funds for the FERCAP Secretariat Office and the conduct of EC surveys
  - Supervise the FERCAP Office Staff composed of the FERCAP Finance Officer and FERCAP Administrative Officer
  - Perform day-to-day administrative activities related to the conduct of EC surveys
  - Conduct FERCAP Secretariat Meeting at least three times a year
  - Communicate and coordinate with SIDCER-FERCAP survey stakeholders (*e.g.* regulators, national accreditation institutions, country networks of ECs, ECs, Surveyors, Survey Trainees)
  - Prepare and review the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates to be approved by the FERCAP Steering Committee
  - Conduct the EC surveys
  - Coordinate the FERCAP Survey Committees
  - Appoint the FERCAP Survey Team
  - Coordinate and conduct FERCAP Surveyor Trainings at least once a year
  - Review and approve Survey Reports, Action Plans, Action Plan Assessments, and Annual Progress Reports

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- Recommend ECs and FERCAP Surveyors for recognition upon consultation with the FERCAP Survey Committees and FERCAP Survey Teams
- Prepare, present, and document the EC survey-related content of the FERCAP Annual Report and FERCAP Annual Financial Report during the FERCAP Steering Committee Meeting and FERCAP General Assembly
- Document the EC surveys
- Collate the major issues related to the conduct of EC surveys and recommend and/or implement appropriate actions to address these major issues
- Develop, finance, and manage the EC survey electronic database
- Prepare and finance the EC survey-related content of the FERCAP newsletter, FERCAP social media account, and FERCAP website
- Coordinate the external audit of the SIDCER Recognition Program
- Perform other survey-related duties assigned by the SIDCER-FERCAP Foundation

4.2.3.2. The responsibilities of the SIDCER Coordinator are:

- Preside over the FERCAP Secretariat Meeting
- Supervise the FERCAP Coordinator, FERCAP Program Manager, and FERCAP Treasurer
- Review the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates
- Serve as a FERCAP Survey Coordinator in EC surveys at least five times a year
- Coordinate FERCAP Surveyor Trainings
- Develop the EC survey electronic database
- Coordinate the external audit of the SIDCER Recognition Program
- Perform other survey-related duties assigned by the SIDCER-FERCAP Foundation

4.2.3.3. The responsibilities of the FERCAP Coordinator are:


- Communicate and coordinate with SIDCER-FERCAP survey stakeholders in Island Southeast Asia (*e.g.* Philippines, Indonesia, Malaysia), East Asia (*e.g.* China, South Korea, Taiwan, Japan), and the Western Pacific
- Coordinate the FERCAP Survey Committees and EC surveys in Island Southeast Asia, East Asia, and the Western Pacific
- Appoint the FERCAP Survey Team in Island Southeast Asia, East Asia, and the Western Pacific

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- Serve as a FERCAP Survey Coordinator or FERCAP Surveyor in EC surveys at least five times a year
- Conduct FERCAP Surveyor Trainings
- Review and approve Survey Reports, Action Plans, Action Plan Assessments, and Annual Progress Reports in Island Southeast Asia, East Asia, and the Western Pacific
- Recommend ECs and FERCAP Surveyors for recognition
- Prepare and/or present the EC survey-related content of the FERCAP Annual Report during the FERCAP Steering Committee Meeting and FERCAP General Assembly
- Perform other survey-related duties assigned by the SIDCER-FERCAP Foundation

4.2.3.4. The responsibilities of the FERCAP Program Manager are:

- Perform day-to-day administrative activities related to the conduct of EC surveys
- Participate in the FERCAP Secretariat Meeting
- Prepare the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates
- Communicate and coordinate with SIDCER-FERCAP survey stakeholders in Mainland Southeast Asia (*e.g.* Thailand, Myanmar), South Asia (*e.g.* India, Sri Lanka, Bhutan, Nepal), North Asia (*e.g.* Kazakhstan), and West Asia
- Coordinate the FERCAP Survey Committees and EC surveys in Mainland Southeast Asia, South Asia, North Asia, and West Asia
- Appoint the FERCAP Survey Team in Mainland Southeast Asia, South Asia, North Asia, and West Asia
- Serve as a FERCAP Survey Coordinator or FERCAP Surveyor in EC surveys at least five times a year
- Conduct FERCAP Surveyor Trainings
- Review and approve Survey Reports, Action Plans, Action Plan Assessments, and Annual Progress Reports in Mainland Southeast Asia, South Asia, North Asia, and West Asia
- Recommend ECs and FERCAP Surveyors for recognition
- Prepare, present, and document the EC survey-related content of the FERCAP Annual Report and FERCAP Annual Financial Report during the FERCAP Steering Committee Meeting and FERCAP General Assembly
- Document the EC surveys

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- Collate the major issues related to the conduct of EC surveys and recommend and/or implement appropriate actions to address these major issues
- Manage the EC survey electronic database
- Prepare the EC survey-related content of the FERCAP newsletter, FERCAP social media account, and FERCAP website
- Perform other survey-related duties assigned by the SIDCER-FERCAP Foundation

4.2.3.5. The responsibilities of the FERCAP Treasurer are:

- Manage the FERCAP Secretariat Office
- Raise and manage funds for the FERCAP Secretariat Office and the conduct of EC surveys
- Supervise the FERCAP Office Staff
- Participate in the FERCAP Secretariat Meeting
- Prepare and/or present the EC survey-related content of the FERCAP Annual Financial Report during the FERCAP General Assembly
- Finance the EC survey electronic database
- Finance the EC survey-related content of the FERCAP newsletter, FERCAP social media account, and FERCAP website
- Perform other survey-related duties assigned by the SIDCER-FERCAP Foundation

### 4.3. FERCAP Office Staff

4.3.1. Composition of the FERCAP Office Staff


4.3.1.1. The FERCAP Office Staff is composed of the FERCAP Finance Officer and FERCAP Administrative Officer.

4.3.1.2. The FERCAP Finance Officer and FERCAP Administrative Officer are selected by the FERCAP Treasurer. The duration of the term of the FERCAP Finance Officer and FERCAP Administrative Officer is determined by the FERCAP Treasurer. The FERCAP Treasurer certifies the appointment of the FERCAP Finance Officer and FERCAP Administrative Officer as FERCAP Office Staff every year.

4.3.2. Responsibilities of the FERCAP Office Staff in SIDCER-FERCAP surveys


4.3.2.1. The responsibilities of the FERCAP Office Staff are:

- Assist the FERCAP Treasurer in managing the FERCAP Secretariat Office
- Assist the FERCAP Treasurer in managing funds for the FERCAP Secretariat Office and the conduct of EC surveys

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- Assist the SIDCER Coordinator in the conducting FERCAP Secretariat Meeting
  - Assist the FERCAP Coordinator and FERCAP Program Manager in communicating with SIDCER-FERCAP survey stakeholders
  - Assist the FERCAP Treasurer in preparing the EC survey-related content of the FERCAP Annual Financial Report
  - Assist the FERCAP Program Manager in performing day-to-day administrative activities related to the conduct of EC surveys
  - Assist the SIDCER Coordinator, FERCAP Treasurer, and FERCAP Program Manager in developing, financing, and managing the EC survey electronic database
  - Assist the FERCAP Program Manager and FERCAP Treasurer in preparing and financing the EC survey-related content of the FERCAP newsletter, FERCAP social media account, and FERCAP website
- 4.3.2.2. The responsibilities of the FERCAP Finance Officer are:
- Assist the FERCAP Treasurer in managing the FERCAP Secretariat Office
  - Assist the FERCAP Treasurer in managing funds for the FERCAP Secretariat Office and the conduct of EC surveys
  - Assist the FERCAP Treasurer in preparing the EC survey-related content of the FERCAP Annual Financial Report
  - Assist the FERCAP Treasurer in financing the EC survey electronic database
  - Assist the FERCAP Treasurer in financing the EC survey-related content of the FERCAP newsletter, FERCAP social media account, and FERCAP website
- 4.3.2.1. The responsibilities of the FERCAP Administrative Officer are:
- Assist the SIDCER Coordinator in the conducting FERCAP Secretariat Meeting
  - Assist the FERCAP Coordinator and FERCAP Program Manager in communicating with SIDCER-FERCAP survey stakeholders
  - Assist the FERCAP Program Manager in performing day-to-day administrative activities related to the conduct of EC surveys
  - Assist the SIDCER Coordinator and FERCAP Program Manager in developing and managing the EC survey electronic database
  - Assist the FERCAP Program Manager in preparing the EC survey-related content of the FERCAP newsletter, FERCAP social media account, and FERCAP website



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#### 4.4. FERCAP Survey Committee

##### 4.4.1. Composition of a FERCAP Survey Committee

4.4.1.1. A FERCAP Survey Committee is composed of the SIDCER Coordinator, the FERCAP Coordinator or FERCAP Program Manager, and the FERCAP Local Coordinator.

4.4.1.2. A FERCAP Local Coordinator is appointed by the FERCAP Secretariat. A FERCAP Local Coordinator is a FERCAP Steering Committee Member representing a FERCAP area/country or a Representative of the national accreditation institution (*e.g.* NECAST, PHREB) or a Representative of the area/country network of ECs (*e.g.* FERCI, FERCSL, FERCIT, FIRREC, NERCIM, PHREN, TAIRB). In the absence of a FERCAP Local Coordinator, the FERCAP Coordinator or FERCAP Program Manager performs the responsibilities of the FERCAP Local Coordinator. The FERCAP Coordinator or FERCAP Program Manager certifies the appointment of a FERCAP Local Coordinator to a FERCAP Survey Committee every year.


##### 4.4.2. Responsibilities of a FERCAP Survey Committee in SIDCER-FERCAP surveys

4.4.2.1. The responsibilities of a FERCAP Survey Committee are:

- Communicate with the ECs in the FERCAP area/country
- Nominate the FERCAP Survey Team
- Coordinate the preparation of the FERCAP Surveyor Training in the FERCAP area/country
- Coordinate the preparation of activities (*e.g.* Site Visit, Follow-up Site Visit) and documents (*e.g.* FERCAP Survey Forms) related to the conduct of EC surveys in the FERCAP area/country
- Review and recommend for approval the Survey Reports, Action Plans, Action Plan Assessments, and Annual Progress Reports in the FERCAP area/country
- Recommend ECs and FERCAP Surveyors for recognition in the FERCAP area/country
- Document the EC surveys in the FERCAP area/country
- Identify the major issues related to the conduct of EC surveys in the FERCAP area/country and recommend and/or implement appropriate actions to address these major issues
- Maintain an EC survey electronic database in the FERCAP area/country (*e.g.* EC contact information, EC survey schedule, FERCAP Local Surveyor list)

4.4.2.2. The responsibilities of a FERCAP Local Coordinator are:

- Serve as the point person for communication with the ECs in the FERCAP area/country

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- Nominate the FERCAP Local Surveyors and select the Surveyor Trainees for each EC being surveyed in the FERCAP area/country
- Serve as a FERCAP Survey Coordinator or FERCAP Surveyor in EC surveys in the FERCAP area/country at least once a year
- Serve as the point person for the preparation of the FERCAP Surveyor Training in the FERCAP area/country
- Serve as the point person for the preparation of activities and documents related to the conduct of EC surveys in the FERCAP area/country
- Serve as the local adviser/consultant in the review of Survey Reports, Action Plans, Action Plan Assessments, and Annual Progress Reports in the FERCAP area/country
- Serve as the local endorser of ECs for recognition in the FERCAP area/country
- Document the EC surveys in the FERCAP area/country
- Identify the major issues related to the conduct of EC surveys in the FERCAP area/country and recommend and/or implement appropriate actions to address these major issues
- Maintain an EC survey electronic database in the FERCAP area/country

#### **4.5. FERCAP Survey Team**


##### **4.5.1. Composition of the FERCAP Survey Team**

4.5.1.1. A FERCAP Survey Team is composed of a FERCAP Survey Coordinator, a FERCAP Lead Surveyor, and two other FERCAP Surveyors. A least one of the FERCAP Survey Team Members is a FERCAP Foreign Surveyor or FERCAP International Surveyor. In some cases, depending on the national requirements, the FERCAP Survey Team have three or five Members provided at least one is a FERCAP Foreign Surveyor. All FERCAP Survey Team Members have the following qualifications:

- Appropriate designation as EC Member, EC Staff, Investigator or any professional with related competencies (*e.g.* GCP Auditor, Clinical Trial Monitor, etc.)
- Necessary academic qualifications (M.D. or non-M.D. with some post-graduate education)
- Familiarity with EC practices
- Has no affiliation/attachment with the EC being surveyed
- Trained in the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates

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- Participated in at least two FERCAP Surveyor Trainings and Site Visits as a Surveyor Trainee
  - Participated in at least one update FERCAP Surveyor Training every two years
  - Good Quality Evaluation (average rating of 3) the last two years
- 4.5.1.2. A FERCAP Survey Coordinator is appointed by the FERCAP Coordinator or FERCAP Program Manager. A FERCAP Survey Coordinator is an experienced FERCAP Surveyor who supervises the FERCAP Survey Team. Additional qualifications for a FERCAP Survey Coordinator are:
- Familiarity with international ethical principles and guidelines
  - Familiarity with the types of protocols being reviewed by the EC being surveyed
  - Served in at least three FERCAP Surveyor Trainings and Site Visits as a FERCAP Lead Surveyor
- 4.5.1.3. A FERCAP Lead Surveyor is appointed by the FERCAP Coordinator or FERCAP Program Manager. A FERCAP Lead Surveyor is an experienced FERCAP Surveyor who leads the FERCAP Survey Team and writes the Survey Report. Additional qualifications for a FERCAP Lead Surveyor are:
- Familiarity with international ethical principles and guidelines
  - Familiarity with the types of protocols being reviewed by the EC being surveyed
  - Served in at least two FERCAP Surveyor Trainings and Site Visits as a FERCAP Surveyor
- 4.5.1.2. A FERCAP Foreign Surveyor or FERCAP International Surveyor is appointed by the FERCAP Coordinator or FERCAP Program Manager. A FERCAP Foreign Surveyor or FERCAP International Surveyor is an experienced FERCAP Surveyor who is not from the area/country of the EC being surveyed. Additional qualifications for a FERCAP Foreign Surveyor or FERCAP International Surveyor are:
- Familiarity with international ethical principles and guidelines
  - Served in at least two FERCAP Surveyor Trainings and Site Visits as a FERCAP Local Surveyor
- 4.5.1.2. A FERCAP Local Surveyor is appointed by the FERCAP Coordinator or FERCAP Program Manager based on the recommendations of the FERCAP Local Coordinator. A FERCAP Local Surveyor is a FERCAP Surveyor from the area/country of the EC being surveyed. Additional qualifications for a FERCAP Local Surveyor are:
- Familiarity with the local/national laws, regulations, and procedures
  - Can speak and read the local/national language

	<b>SIDCER-FERCAP Survey TOR</b>	SIDCER-FERCAP Survey TOR Version 4.0  Effective Date: 30 April 2020
	<b>Structure and Composition</b>	Page 12


#### 4.5.2. Responsibilities of a FERCAP Survey Team in a SIDCER-FERCAP survey

##### 4.5.2.1. The responsibilities of FERCAP Survey Team Members are:


- Submit an individually signed and dated curriculum vitae (CV)
- Submit an individually signed and dated Confidentiality and COI Agreements
- Prepare for the FERCAP Surveyor Training and Site Visit
- Attend the entirety of and conduct the FERCAP Surveyor Training
- Attend the entirety of and conduct the Site Visit
- Identify the strengths and weaknesses of the EC during the Site Visit
- Provide recommendations for the improvement of the EC during the Site Visit
- Provide evidence to support various Survey Findings during the Site Visit
- Document the Survey Findings during the Site Visit
- Prepare, review, provide inputs to, finalize, and submit the Survey Report
- Review and provide inputs to the Action Plan submitted by the EC
- Prepare, consolidate inputs to, finalize, and submit the Action Plan Assessment
- Conduct a Follow-up Site Visit whenever necessary
- Document the Follow-up Site Visit Findings
- Prepare, finalize, and submit the Follow-up Site Visit Report
- Decide on whether to endorse the EC for recognition

##### 4.5.2.2. The responsibilities of a FERCAP Survey Coordinator are:

- Provide advice and guidance to the FERCAP Survey Team about international ethical principles and guidelines
- Provide advice and guidance to the FERCAP Survey Team about the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates
- Supervise the FERCAP Survey Team and oversee the FERCAP Surveyor Training and Site Visit to ensure its adherence to the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates
- Prepare and present a lecture during the FERCAP Surveyor Training
- Lead the discussion on the quality of review of the EC during the Site Visit
- Lead the Debriefing Session of the Surveyor Trainees
- Evaluate the FERCAP Surveyors

	<b>SIDCER-FERCAP Survey TOR</b>	SIDCER-FERCAP Survey TOR Version 4.0  Effective Date: 30 April 2020
	<b>Structure and Composition</b>	Page 13

- Review and provide inputs to the Survey Report written by the FERCAP Lead Surveyor
- 4.5.2.3. The responsibilities of a FERCAP Lead Surveyor are:
- Lead the Site Visit
  - Divide the FERCAP Survey Team into groups with specific assignments (in some cases, depending on the national requirements, this is the responsibility of the FERCAP Survey Coordinator)
  - Ensure that the Surveyor Trainees in each group can perform the tasks assigned to each group
  - Manage the time allocated for the different activities during the Site Visit
  - Prepare and present the Survey Plan during the Opening Meeting
  - Prepare and present the Survey Findings during the Closing Meeting (in some cases, depending on the national requirements, this is the responsibility of the FERCAP Local Surveyor)
  - Evaluate the Surveyor Trainees
  - Prepare, finalize, and submit the Survey Report to the FERCAP Secretariat
  - Prepare, consolidate inputs to, finalize, and submit the Action Plan Assessment to the FERCAP Secretariat
- 4.5.2.4. The responsibilities of the other FERCAP Surveyors are:
- Assist the FERCAP Lead Surveyor during the Site Visit
  - Perform the tasks assigned by the FERCAP Lead Surveyor
  - Orient the Surveyor Trainees on how to fill-up the Survey Forms especially how to review the review of protocols (by reviewing one protocol together)
  - Evaluate the Surveyor Trainees
  - Review and provide inputs to the Survey Report written by the FERCAP Lead Surveyor
- 4.5.2.5. The responsibilities of a FERCAP Local Surveyors are:
- Serve as local resource person about the local/national laws, regulations, and procedures
  - Serve as interpreter and/or translator of the local/national language
  - Present the Survey Findings during the Closing Meeting (in cases when the EC requests that the presentation be done in the local/national language)
  - Conduct a Follow-up Site Visit whenever necessary
  - Document the Follow-up Site Visit Findings

	<b>SIDCER-FERCAP Survey TOR</b>	SIDCER-FERCAP Survey TOR Version 4.0  Effective Date: 30 April 2020
	<b>Structure and Composition</b>	Page 14

- Prepare, finalize, and submit the Follow-up Site Visit Report

#### 4.6. Survey Trainee

##### 4.6.1. Qualifications of a Survey Trainee

4.6.1.1. A Surveyor Trainee is a potential FERCAP Surveyor. All Surveyor Trainees have the following qualifications:

- Appropriate designation as EC Member, EC Staff, Investigator or any professional with related competencies (*e.g.* GCP Auditor, Clinical Trial Monitor, etc.)
- Necessary academic qualifications (M.D. or non-M.D. with some post-graduate education)
- Familiarity with EC practices
- Has no affiliation/attachment with the EC being surveyed
- Trained in the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates

4.6.1.2. A Surveyor Trainee who cannot attend the entirety of the FERCAP Surveyor Training and Site Visit is considered to be a Survey Observer.


##### 4.6.2. Responsibilities of a Surveyor Trainee in a SIDCER-FERCAP survey

The responsibilities a Surveyor Trainee are:

- Submit an individually signed and dated CV
- Submit an individually signed and dated Confidentiality and COI Agreements
- Prepare for the FERCAP Surveyor Training and Site Visit
- Attend the entirety of and participate in the FERCAP Surveyor Training
- Attend the entirety of and participate in the Site Visit
- Assist the FERCAP Survey Team in identifying the strengths and weaknesses of the EC during the Site Visit
- Assist the FERCAP Survey Team in providing recommendations for the improvement of the EC during the Site Visit
- Assist the FERCAP Survey Team in providing evidence to support various Survey Findings during the Site Visit
- Assist the FERCAP Survey Team in documenting the Survey Findings during the Site Visit

## 5. DOCUMENT HISTORY


Version/Year	SOP Code	Revisions
1.0/2007	FERCAP SOP 01	Initial SIDCER-FERCAP Survey TOR.

	<b>SIDCER-FERCAP Survey TOR</b>	SIDCER-FERCAP Survey TOR Version 4.0  Effective Date: 30 April 2020  Page 15
	<b>Structure and Composition</b>	

2.0/2009	SIDCER-FERCAP Form 004	Major changes were made. The responsibilities of the FERCAP Survey Coordinator, FERCAP Foreign Surveyors, FERCAP Local Surveyors, and Surveyor Trainees were added.
3.0/2013	SIDCER-FERCAP Survey Form 004	Format was changed. Texts were edited for clarity.
4.0/2020	SIDCER-FERCAP Survey TOR	Major changes were made. Instead of a SOP or form, the TOR was made into a stand-alone document with eight sections. Previously, only the FERCAP Survey Team and Surveyor Trainees were described. This version describes the organizational structure of the SIDCER-FERCAP survey and identifies the responsibilities of the FERCAP Steering Committee, FERCAP Secretariat, FERCAP Office Staff, FERCAP Survey Committee, FERCAP Survey Team, and Surveyor Trainee in the conduct of EC surveys for the SIDCER Recognition Program.

## 6. ANNEXES

- SIDCER-FERCAP Survey Form 03 - Surveyor CV
- SIDCER-FERCAP Survey Form 04 - Surveyor Confidentiality and COI Agreements
- SIDCER-FERCAP Survey Form 05 - Appointment Certification
- SIDCER-FERCAP Survey Form 21 - Surveyor Evaluation by Survey Coordinator
- SIDCER-FERCAP Survey Form 22 - Survey Evaluation by EC
- SIDCER-FERCAP Survey Form 23 - Survey Non-Compliance
- SIDCER-FERCAP Survey Form 28 - Annual Surveyor Evaluation

	<b>SIDCER-FERCAP Survey SOP 01</b>	SIDCER-FERCAP Survey SOP 01 Version 3.0  Effective Date: 30 April 2020
	<b>Application for Survey</b>	Page 16

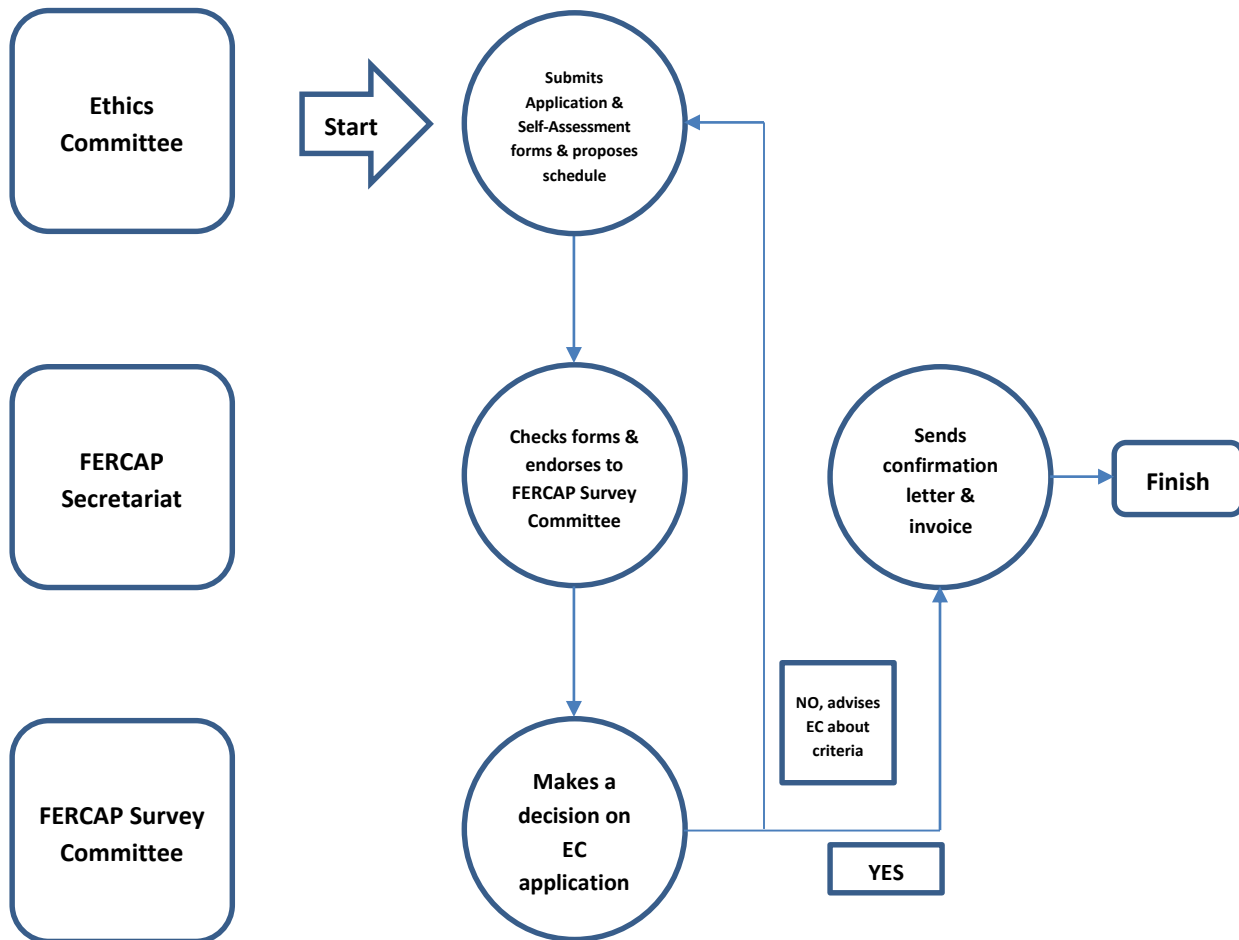
## 1. OBJECTIVE

The objective of this Standard Operating Procedure (SOP) is to describe the processes and ensure transparency of ethics committee (EC) survey application for the SIDCER Recognition Program.


## 2. SCOPE

This SOP covers the criteria and processes of EC survey application, including submission of application, endorsement of the application, and decision-making related to the application.

## 3. RESPONSIBILITY AND WORKFLOW





	<b>SIDCER-FERCAP Survey SOP 01</b>	SIDCER-FERCAP Survey SOP 01 Version 3.0  Effective Date: 30 April 2020
	<b>Application for Survey</b>	Page 17

## 4. DETAILED INSTRUCTIONS

### 4.1. Criteria for Application

The criteria for application are the following:

- The EC has been in operation for at least one year.
- The EC has reviewed at least 30 protocols.
- The EC has SOPs that have been implemented for at least six months prior to making an application for a survey.

### 4.2. Submission of Application


- The EC completes the EC Application Form (SIDCER-FERCAP Survey Form 01) and fills up the EC Self-Assessment Form (SIDCER-FERCAP Survey Form 02).
- The EC proposes a survey schedule.
- The EC submits the EC Application Form and EC Self-Assessment Form and the proposed survey schedule to the FERCAP Secretariat for checking and endorsement. In some cases, depending on the national requirements, the EC submits to the FERCAP Local Coordinator and the FERCAP Local Coordinator is the one to forward to the FERCAP Secretariat and FERCAP Survey Committee.

### 4.3. Checking and Endorsement of Application

- The FERCAP Secretariat checks the EC survey application for completeness of information.
- The FERCAP Secretariat endorses the EC survey application to the FERCAP Survey Committee within three days.

### 4.4. Decision on the Application

- The FERCAP Survey Committee makes a decision on the application within 15 days. If the application is not accepted, the FERCAP Survey Committee provides the reason and advises the EC on how to advance the application. If the application is accepted, the FERCAP Secretariat sends notification to the EC.
- The FERCAP Secretariat sends a Confirmation Letter (contains list of documents to submit, financial requirements, and survey date) (SIDCER-FERCAP Survey Template 08) and Survey Fee Invoice (SIDCER-FERCAP Survey Template 09) to the EC within 30 days of receipt of the application. In some cases, depending on the national requirements, the Confirmation Letter and/or Survey Fee Invoice is/are sent by the FERCAP Local Coordinator.


	<b>SIDCER-FERCAP Survey SOP 01</b>	SIDCER-FERCAP Survey SOP 01 Version 3.0  Effective Date: 30 April 2020  Page 18
	<b>Application for Survey</b>	

## 5. DOCUMENT HISTORY

Version/Year	SOP Code	Revisions
1.0/2010	SIDCER-FERCAP Survey SOP001	Initial SIDCER-FERCAP Survey SOP.
2.0/2019	SIDCER-FERCAP Survey SOP 01	Procedures and workflow were elaborated according to practice. FERCAP Survey Committee was added. Responsibility (in the workflow) and references were added.
3.0/2020	SIDCER-FERCAP Survey SOP 01	Format was changed. Texts were edited for clarity. Annex codes were revised and forms were added.

## 6. ANNEXES

- SIDCER-FERCAP Survey Form 01 - Application for Survey
- SIDCER-FERCAP Survey Form 02 - Self-Assessment
- SIDCER-FERCAP Survey Template 08 - Confirmation Letter
- SIDCER-FERCAP Survey Template 09 - Invoice

	<b>SIDCER-FERCAP Survey SOP 02</b>	SIDCER-FERCAP Survey SOP 02 Version 5.0  Effective Date: 30 April 2020
	<b>Formation of Survey Team</b>	Page 19

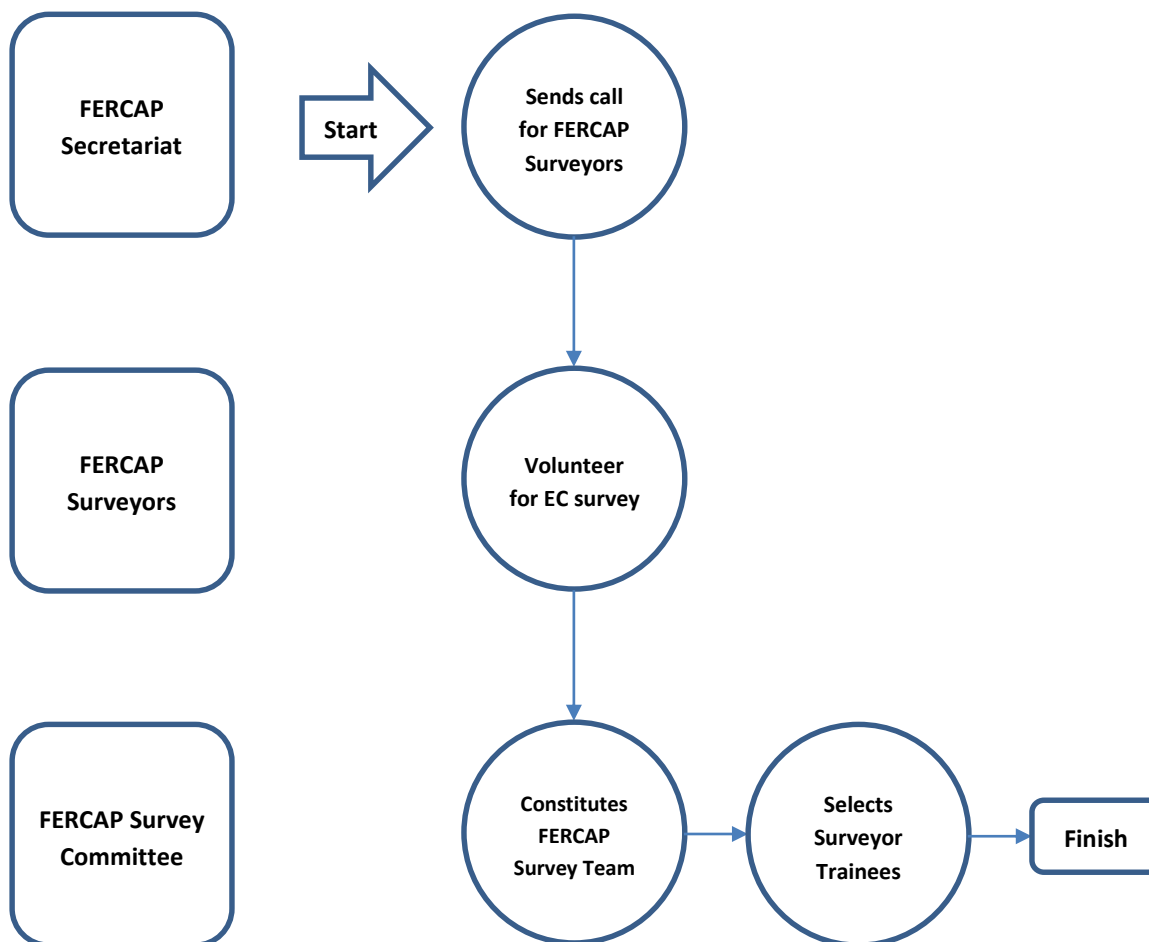
## 1. OBJECTIVE


The objective of this Standard Operating Procedure (SOP) is to describe the processes of selecting FERCAP Surveyors, forming a FERCAP Survey Team, and selecting Surveyor Trainees for the SIDCER Recognition Program.

## 2. SCOPE

This SOP covers the criteria and processes of selecting FERCAP Surveyors, forming a FERCAP Survey Team, and selecting Surveyor Trainees.

## 3. RESPONSIBILITY AND WORKFLOW



	<b>SIDCER-FERCAP Survey SOP 02</b>	SIDCER-FERCAP Survey SOP 02 Version 5.0  Effective Date: 30 April 2020
	<b>Formation of Survey Team</b>	Page 20

## 4. DETAILED INSTRUCTIONS

### 4.1. Call for FERCAP Surveyors

- The FERCAP Secretariat checks the FERCAP Surveyors List for potential FERCAP Surveyors for the EC survey.
- The FERCAP Secretariat sends a call for FERCAP Surveyors based on the FERCAP Surveyors List within three days after sending the confirmation letter and survey fee invoice to the EC.

### 4.2. Volunteering for an EC survey

- FERCAP Surveyors volunteer for an EC survey based on the FERCAP Working Survey Schedule.
- FERCAP Surveyors submit curriculum vitae (CV) (SIDCER-FERCAP Survey Form 03) and Confidentiality and Conflict of Interest (COI) Agreements (SIDCER-FERCAP Survey Form 04).

### 4.3. Formation of a FERCAP Survey Team


- The FERCAP Survey Committee discusses the selection of FERCAP Survey Team Members.
- The FERCAP Local Coordinator nominates the FERCAP Local Surveyors.
- The FERCAP Coordinator or FERCAP Program Manager appoints the FERCAP Survey Team Members (composed of a FERCAP Survey Coordinator, a FERCAP Lead Surveyor, and two other FERCAP Surveyors) based on the SIDCER-FERCAP Terms of Reference (TOR) and their expertise and proximity (SIDCER-FERCAP Survey Form 05).

### 4.4. Selection of Surveyor Trainees

- The FERCAP Local Coordinator sends a call for Surveyor Trainees.
- Surveyor Trainees volunteer for an EC survey based on the FERCAP Working Survey Schedule.
- The FERCAP Local Coordinator selects the Surveyor Trainees.

## 5. DOCUMENT HISTORY


Version/Year	SOP Code	Revisions
1.0/2005	FERCAP SOP SRP 01	Initial SIDCER-FERCAP Survey SOP.

	<b>SIDCER-FERCAP Survey SOP 02</b>	SIDCER-FERCAP Survey SOP 02 Version 5.0  Effective Date: 30 April 2020  Page 21
	<b>Formation of Survey Team</b>	

2.0/2007	FERCAP SRP SOP001	Functions and qualifications were elaborated according to practice.
3.0/2010	SIDCER-FERCAP Survey SOP002	Coding was changed to SOP002. Functions and qualifications were elaborated according to practice particularly pertaining to the Survey Coordinator.
4.0/2019	SIDCER-FERCAP Survey SOP 02	Procedures and workflow were elaborated according to practice. FERCAP Survey Committee was added. Responsibility (in the workflow) and references were added.
5.0/2020	SIDCER-FERCAP Survey SOP 02	Format was changed. Procedures and workflow were revised. Terms of Reference for FERCAP Survey Team Members were deleted since it is now a stand-alone document. Annex codes were revised and a form was added.

## 6. ANNEXES

- SIDCER-FERCAP Survey Form 03 - Surveyor CV
- SIDCER-FERCAP Survey Form 04 - Surveyor Confidentiality and COI Agreements
- SIDCER-FERCAP Survey Form 05 - Appointment Certification

	<b>SIDCER-FERCAP Survey SOP 03</b>	SIDCER-FERCAP Survey SOP 03 Version 5.0  Effective Date: 30 April 2020
	<b>Preparation for Survey</b>	Page 22

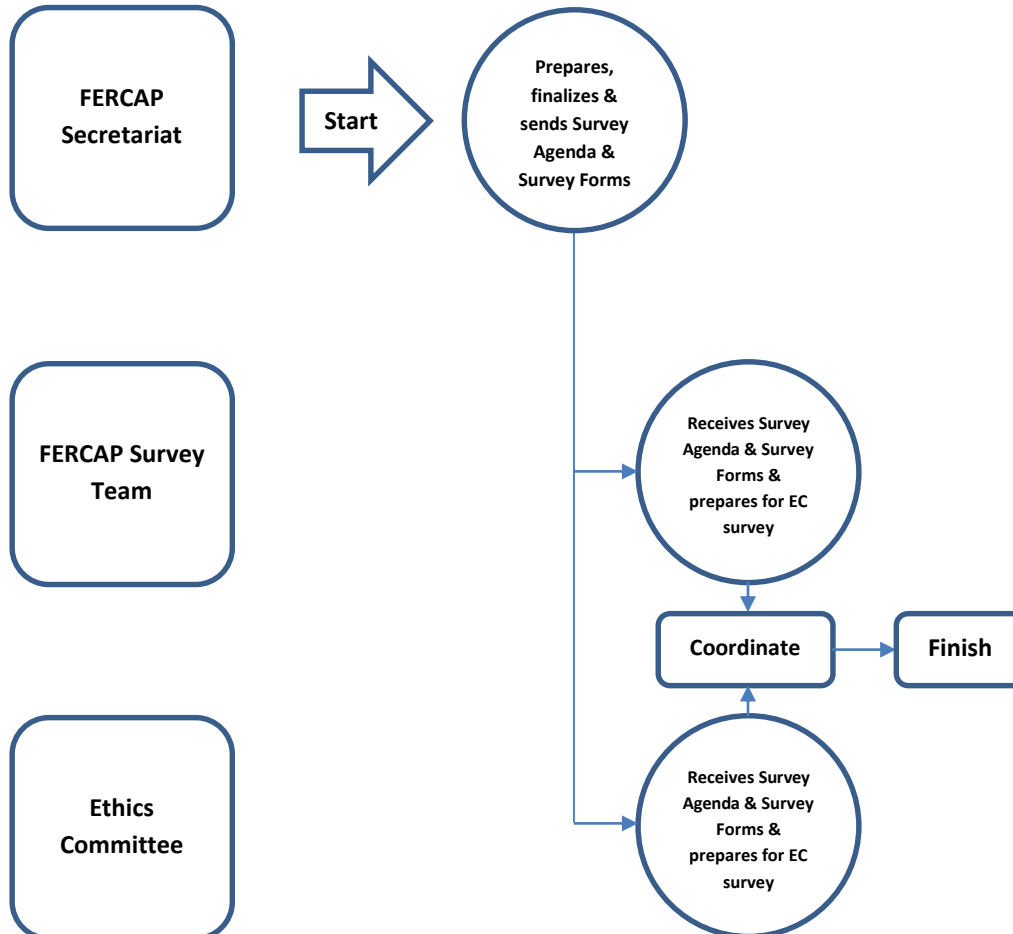
## 1. OBJECTIVE

The objective of this Standard Operating Procedure (SOP) is to describe the preparation processes for the FERCAP Surveyor Training and Site Visit.

## 2. SCOPE

This SOP covers the preparation processes for the FERCAP Surveyor Training and Site Visit.

## 3. RESPONSIBILITY AND WORKFLOW



	<b>SIDCER-FERCAP Survey SOP 03</b>	SIDCER-FERCAP Survey SOP 03 Version 5.0  Effective Date: 30 April 2020
	<b>Preparation for Survey</b>	Page 23

## 4. DETAILED INSTRUCTIONS

### 4.1. Preparation and Finalization of the Survey Agenda

- The FERCAP Coordinator or FERCAP Program Manager (as part of the FERCAP Secretariat) prepares and finalizes the Survey Agenda (SIDCER-FERCAP Survey Form 06). Speakers are identified from the EC and the FERCAP Survey Team.
- The FERCAP Coordinator or FERCAP Program Manager sends the Survey Agenda to the EC and the Survey Team at least 30 days before the survey.

### 4.2. Preparation for the FERCAP Surveyor Training and Site Visit

- The EC and the FERCAP Survey Team receive the Survey Agenda and coordinate regarding the arrangements for invitation letter (SIDCER-FERCAP Survey Template 10), travel, and accommodations. The EC sends invitation letter to the FERCAP Survey Team Members and covers their transportation and hotel. Upon request, the FERCAP Secretariat may also send invitation letter (SIDCER-FERCAP Survey Template 11) to the FERCAP Survey Team Members.
- The FERCAP Secretariat sends the Survey Forms (SIDCER-FERCAP Survey Forms 08-20) and Survey Templates (SIDCER-FERCAP Survey Templates 01-07) to the EC and the FERCAP Survey Team at least 15 days before the survey.
- The EC and the FERCAP Survey Team receive the Survey Forms and prepare for the FERCAP Surveyor Training and Site Visit using the Survey Team Assignments Form (SIDCER-FERCAP Survey Form 07), Opening Meeting EC Presentation Template (SIDCER-FERCAP Survey Template 01), and Opening Meeting Survey Plan Presentation Template (SIDCER-FERCAP Survey Template 02).
- The EC prepares for the FERCAP Surveyor Training and Site Visit by submitting the documents listed in the Confirmation Letter, paying the Survey Fee, and arranging the different EC survey activities and documents.
- The FERCAP Lead Surveyor (as part of the FERCAP Survey Team) prepares for the Surveyor Training and Site Visit by making a working draft of the Survey Team Assignments Form and Opening Meeting Survey Plan Presentation Template (in some cases, depending on the national requirements, this is the responsibility of the FERCAP Survey Coordinator).

	<b>SIDCER-FERCAP Survey SOP 03</b>	SIDCER-FERCAP Survey SOP 03 Version 5.0  Effective Date: 30 April 2020  Page 24
	<b>Preparation for Survey</b>	


## 5. DOCUMENT HISTORY

Version/Year	SOP Code	Revisions
1.0/2005	FERCAP SOP SRP 02	Initial SIDCER-FERCAP Survey SOP.
2.0/2007	FERCAP SRP SOP002	Procedures and workflow were elaborated according to practice.
3.0/2010	SIDCER-FERCAP Survey SOP003	Coding was changed to SOP003. Procedures and workflow were elaborated according to practice.
4.0/2019	SIDCER-FERCAP Survey SOP 03	Procedures and workflow were elaborated according to practice. Responsibility (in the workflow) and references were added.
5.0/2020	SIDCER-FERCAP Survey SOP 03	Format was changed. Procedures and workflow were revised. Annex codes were revised and a form was added.


## 6. ANNEXES

- SIDCER-FERCAP Survey Form 06 - Survey Agenda
- SIDCER-FERCAP Survey Form 07 - Survey Team Assignments
- 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 Report Review
- SIDCER-FERCAP Survey Form 18 - Surveyor Trainee Group Work
- SIDCER-FERCAP Survey Form 19 - Surveyor Trainee Reviewer
- SIDCER-FERCAP Survey Form 20 - Surveyor Training Evaluation
- SIDCER-FERCAP Survey Template 01 - Opening Meeting EC Presentation
- SIDCER-FERCAP Survey Template 02 - Opening Meeting Survey Plan Presentation
- SIDCER-FERCAP Survey Template 03 - Closing Meeting Survey Findings 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 - Survey Site Visit Certificate



	<b>SIDCER-FERCAP Survey SOP 03</b>	SIDCER-FERCAP Survey SOP 03 Version 5.0  Effective Date: 30 April 2020
	<b>Preparation for Survey</b>	Page 25

- SIDCER-FERCAP Survey Template 07 - Surveyor Training Certificate
- SIDCER-FERCAP Survey Template 10 - Surveyor Invitation from EC
- SIDCER-FERCAP Survey Template 11 - Surveyor Invitation from FERCAP

	<b>SIDCER-FERCAP Survey SOP 04</b>	SIDCER-FERCAP Survey SOP 04 Version 5.0  Effective Date: 30 April 2020
	<b>Conduct of Surveyor Training</b>	Page 26

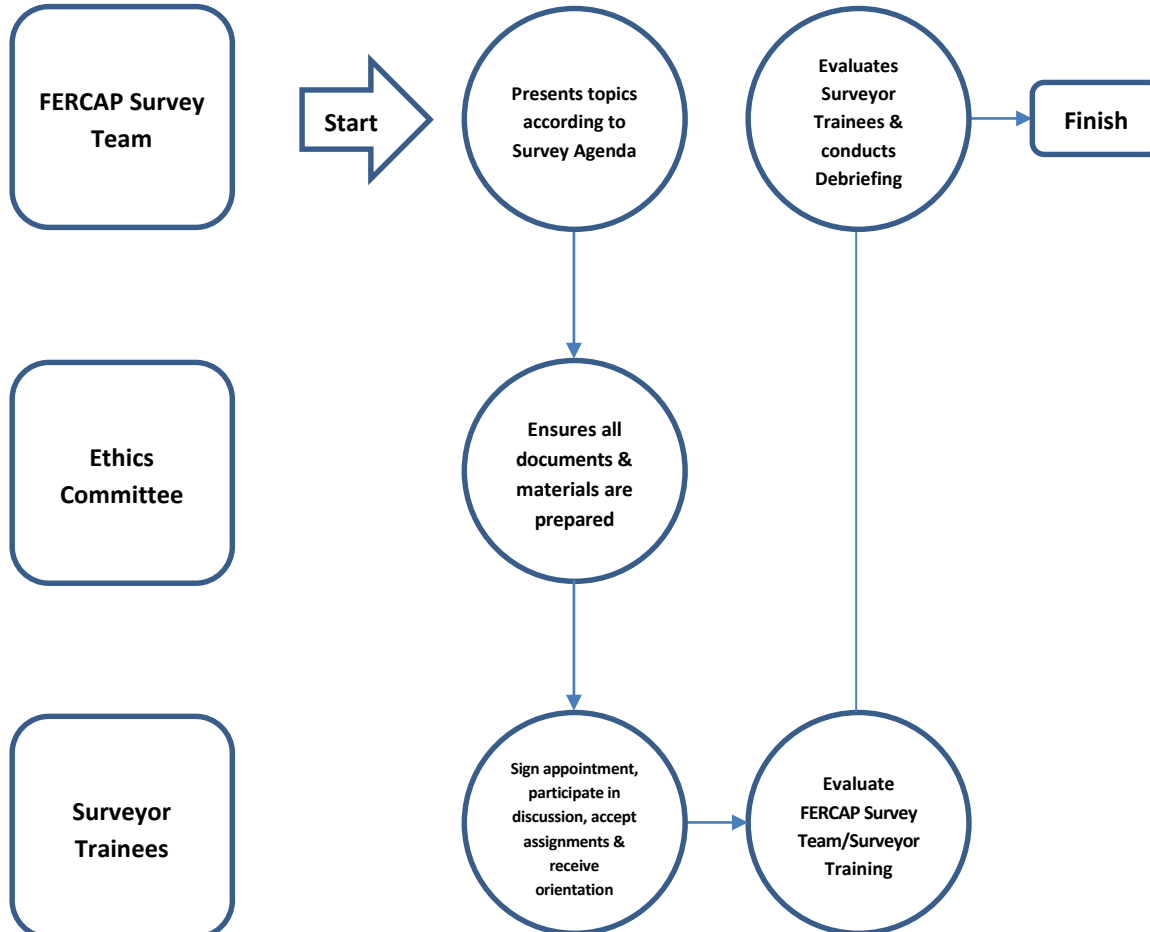
### 1. OBJECTIVE


The objective of this Standard Operating Procedure (SOP) is to describe the contents and conduct of the FERCAP Survey Team/Surveyor Training.

### 2. SCOPE

This SOP covers the contents and conduct of the FERCAP Surveyor Training.

### 3. RESPONSIBILITY AND WORKFLOW



	<b>SIDCER-FERCAP Survey SOP 04</b>	SIDCER-FERCAP Survey SOP 04 Version 5.0  Effective Date: 30 April 2020
	<b>Conduct of Surveyor Training</b>	Page 27

## 4. DETAILED INSTRUCTIONS

### 4.1. Contents of the Survey Agenda


The Survey Agenda (SIDCER-FERCAP Survey Form 06) follows the SIDCER-FERCAP Surveyor Training Curriculum which contains the following topics:

- Local Environment and Practical Challenges to Ethical Review
  - a) Current challenges to quality ethical review in the area/country
  - b) National/local laws, regulations, and procedures
- Framework for Evaluating Ethical Review Practices
  - a) International ethical principles and guidelines
  - b) Purpose of surveying and evaluating ethical review
  - c) Quality of ethical review
- Procedures in Surveying Ethics Committees (ECs)
  - a) Overview of the SIDCER-FERCAP Survey Terms of Reference (TOR) and SIDCER-FERCAP Survey Standard Operating Procedures (SOPs)
  - b) Roles of the FERCAP Survey Team and Surveyor Trainees
  - c) Overview of the SIDCER-FERCAP Survey Methods and SIDCER-FERCAP Survey Forms: Office Visit, Membership Files Review, SOP Review, Protocol Review, SAE Review, Meeting Minutes Review, Board Meeting Observation, and Interview (SIDCER-FERCAP Survey Forms 08-17)
  - d) Formation of Survey Groups: SIDCER-FERCAP Survey Team Assignments (SIDCER-FERCAP Survey Form 07)
- Site Visit

These topics may be modified according to the training needs of the EC.

### 4.2. Conduct of the FERCAP Surveyor Training

- The FERCAP Survey Team presents the topics according to the Survey Agenda. Generally, the FERCAP Local Surveyor presents on the Local Environment and Practical Challenges to Ethical Review but if the FERCAP Local Surveyor is unable to do it, the FERCAP Local Coordinator or an EC Representative presents on this topic. Generally, the FERCAP Survey Coordinator, who oversees the FERCAP Surveyor Training, presents on the Framework for Evaluating Ethical Review Practices while the FERCAP Lead Surveyor presents on the Procedures in Surveying ECs but the other Surveyors may also present on these topics.
- The EC ensures all documents and materials related to the FERCAP Surveyor Training and Site Visit are prepared.
- The Surveyor Trainees sign the appointment certification (SIDCER-FERCAP Survey Form 05), participate in the discussion, accept assignments as finalized in the Survey Team Assignments Form (SIDCER-FERCAP Survey Form 07), and receive orientation

	<b>SIDCER-FERCAP Survey SOP 04</b>	SIDCER-FERCAP Survey SOP 04 Version 5.0  Effective Date: 30 April 2020
	<b>Conduct of Surveyor Training</b>	Page 28

on how to fill-up SIDCER-FERCAP Survey Forms (SIDCER-FERCAP Survey Forms 08-17).

#### 4.3. Evaluation of the FERCAP Surveyor Training


- The FERCAP Survey Team evaluates the Surveyor Trainees using the Surveyor Trainee Group Work Evaluation Form (SIDCER-FERCAP Survey Form 18) and/or Surveyor Trainee Reviewer (SIDCER-FERCAP Survey Form 19). The FERCAP Survey Coordinator conducts a Debriefing Session with the Surveyor Trainees to discuss the Surveyor Trainee Reviewer as well as their assessment of and learnings from the FERCAP Surveyor Training.
- The Surveyor Trainees evaluate the FERCAP Surveyor Training using the Surveyor Training Evaluation Form (SIDCER-FERCAP Survey Form 20).

## 5. 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 SOP004	Coding was changed to SOP004. Procedures and workflow were elaborated according to practice.
4.0/2019	SIDCER-FERCAP Survey SOP 04	Procedures and workflow were elaborated according to practice. Responsibility (in the workflow) and references were added.
5.0/2020	SIDCER-FERCAP Survey SOP 04	Format was changed. Procedures and workflow were revised. Annex codes were revised.

## 7. ANNEXES

- SIDCER-FERCAP Survey Form 06 - Survey Agenda
- SIDCER-FERCAP Survey Form 07 - Survey Team Assignments
- 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

	<b>SIDCER-FERCAP Survey SOP 04</b>	SIDCER-FERCAP Survey SOP 04 Version 5.0  Effective Date: 30 April 2020
	<b>Conduct of Surveyor Training</b>	Page 29

- SIDCER-FERCAP Survey Form 15 - Interview
- SIDCER-FERCAP Survey Form 16 - Meeting Minutes
- SIDCER-FERCAP Survey Form 17 - SAE Report Review
- SIDCER-FERCAP Survey Form 18 - Surveyor Trainee Group Work
- SIDCER-FERCAP Survey Form 19 - Surveyor Trainee Reviewer
- SIDCER-FERCAP Survey Form 20 - Surveyor Training Evaluation

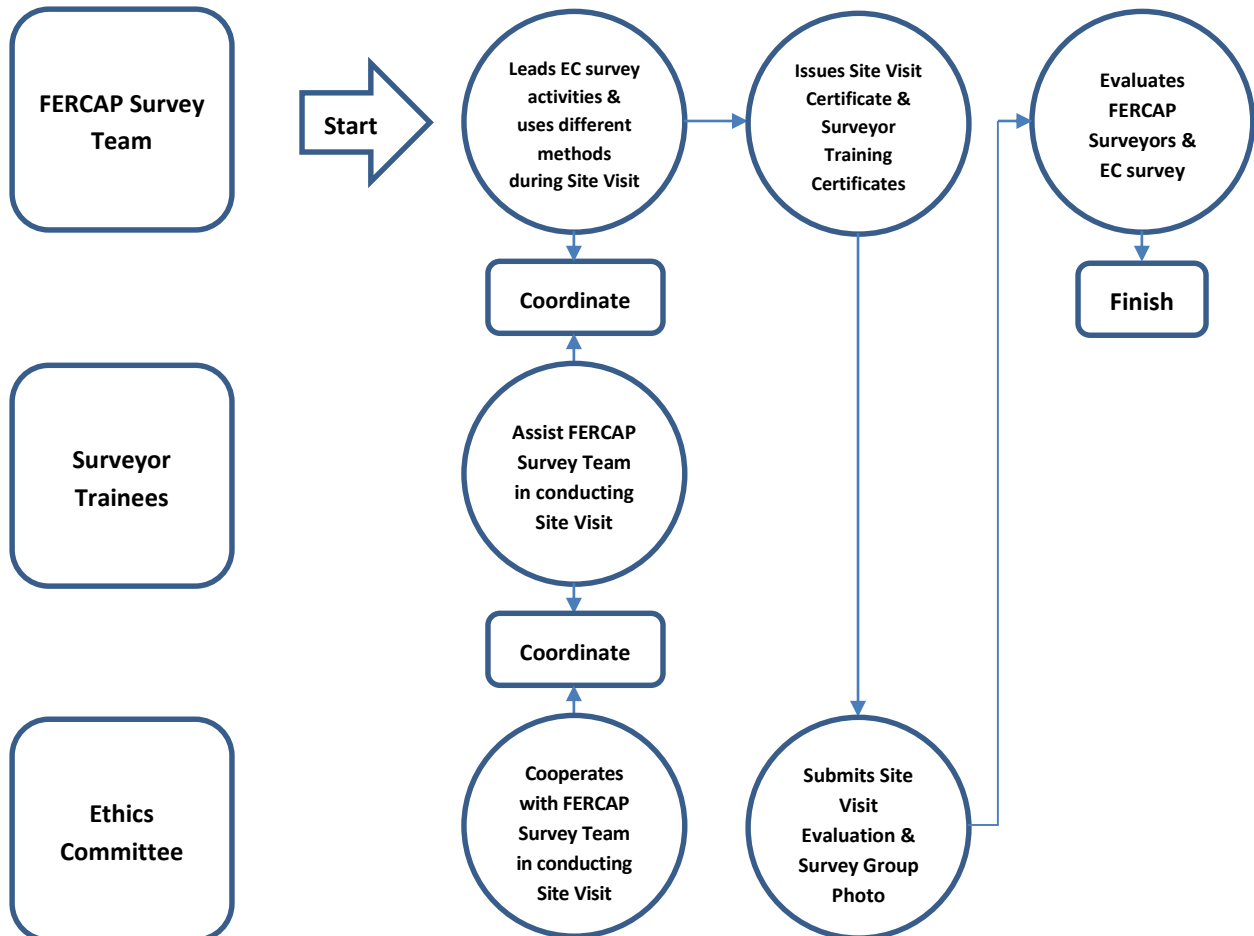
### 1. OBJECTIVE


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



	<b>SIDCER-FERCAP Survey SOP 05</b>	SIDCER-FERCAP Survey SOP 05 Version 4.0  Effective Date: 30 April 2020
	<b>Conduct of Site Visit</b>	Page 31

## 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 Opening Meeting 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 Opening Meeting Survey Plan Presentation Template (SIDCER-FERCAP Survey Template 02), 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.

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#### 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 (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 (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



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- 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 (SIDCER-FERCAP Survey Form 09).

#### 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 (SIDCER-FERCAP Survey Form 10).

#### 4.1.6. 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

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

#### 4.1.7. 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:

- Review application/submission documents made to the EC
- Review complete documentation of Protocols submitted and approved with all the copies and communications
- Review the contents of approved Protocols together with the Primary Reviewers' comments
- Assess the review performed by Primary Reviewers
- Review the adherence to the EC comments before final approval
- Review communication procedures
- Check the review of resubmitted protocols
- Assess the review of amendments
- Assess the review of protocol deviations, violations, and non-compliance
- 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
- Assess the review a representative sample of Progress Reports and Final Reports

The FERCAP Survey Team and Surveyor Trainees document the review (SIDCER-FERCAP Survey Forms 12-14, 17).

#### 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 (SIDCER-FERCAP Survey Form 15).

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#### 4.1.9. 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 (SIDCER-FERCAP Survey Form 16).

#### 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
- Based on consensus, list the findings and recommendations in the Closing Meeting Survey Findings Presentation Template (SIDCER-FERCAP Survey Template 03)

#### 4.1.11. Prepare for Closing Meeting


To prepare for the Closing Meeting, the FERCAP Lead Surveyor:

- Drafts the Closing Meeting Survey Findings Presentation (SIDCER-FERCAP Survey Template 03) based on the completed Survey Forms (SIDCER-FERCAP Survey Forms 08-17) of each group and the daily Summary Meetings
- Prepares the Quality of Review Pareto Charts (SIDCER-FERCAP Survey Templates 04-05) to assess the frequency of defects or areas for improvement in initial review and continuing review

#### 4.1.12. Conduct of the Closing Meeting

During the Closing Meeting with the EC Representatives, the FERCAP Lead Surveyor:

- Thanks the EC for their assistance and contribution during the Site Visit
- Presents the Survey Findings based on the 5 SIDCER-FERCAP Standards (in some cases, depending on the national requirements, this is the responsibility of the FERCAP Local Surveyor) (SIDCER-FERCAP Survey Template 03)
- 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

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- 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 (SIDCER-FERCAP Survey Template 06) to the EC.
- 4.2.2. The FERCAP Survey Coordinator issues the Surveyor Training Certificate (SIDCER-FERCAP Survey Template 07) to the FERCAP Surveyors and Surveyor Trainees.

#### **4.3. Submission of Site Visit Evaluation and Survey Group Photo**


- 4.3.1. The EC evaluates the EC survey and submits its feedback to the FERCAP Survey Committee using the Site Visit Evaluation Form (SIDCER-FERCAP Survey Form 22) 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. Submission of Surveyor Evaluation and Survey Deviation, Non-Compliance and Violation Form**

- 4.4.1. The FERCAP Survey Coordinator evaluates the FERCAP Surveyors and submit its feedback to the FERCAP Survey Committee using the Surveyor Evaluation Form (SIDCER-FERCAP Survey Form 21) 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), SIDCER-FERCAP Survey Standard Operating Procedures (SOPs), SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates.

### **5. DOCUMENT HISTORY**


<b>Version/Year</b>	<b>SOP Code</b>	<b>Revisions</b>
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.

	<b>SIDCER-FERCAP Survey SOP 05</b>	SIDCER-FERCAP Survey SOP 05 Version 4.0  Effective Date: 30 April 2020  Page 37
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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.
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## 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 Report Review
- SIDCER-FERCAP Survey Form 21 - Surveyor Evaluation by Survey Coordinator
- SIDCER-FERCAP Survey Form 22 - Survey Evaluation by EC
- SIDCER-FERCAP Survey Form 23 - Survey Non-Compliance
- SIDCER-FERCAP Survey Template 01 - Opening Meeting EC Presentation
- SIDCER-FERCAP Survey Template 02 - Opening Meeting Survey Plan Presentation
- SIDCER-FERCAP Survey Template 03 - Closing Meeting Survey Findings 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 - Survey Site Visit Certificate
- SIDCER-FERCAP Survey Template 07 - Surveyor Training Certificate

	<b>SIDCER-FERCAP Survey SOP o6</b>	SIDCER-FERCAP Survey SOP o6 Version 4.0 Effective Date: 30 April 2020
	<b>Writing of Survey Report</b>	Page 38

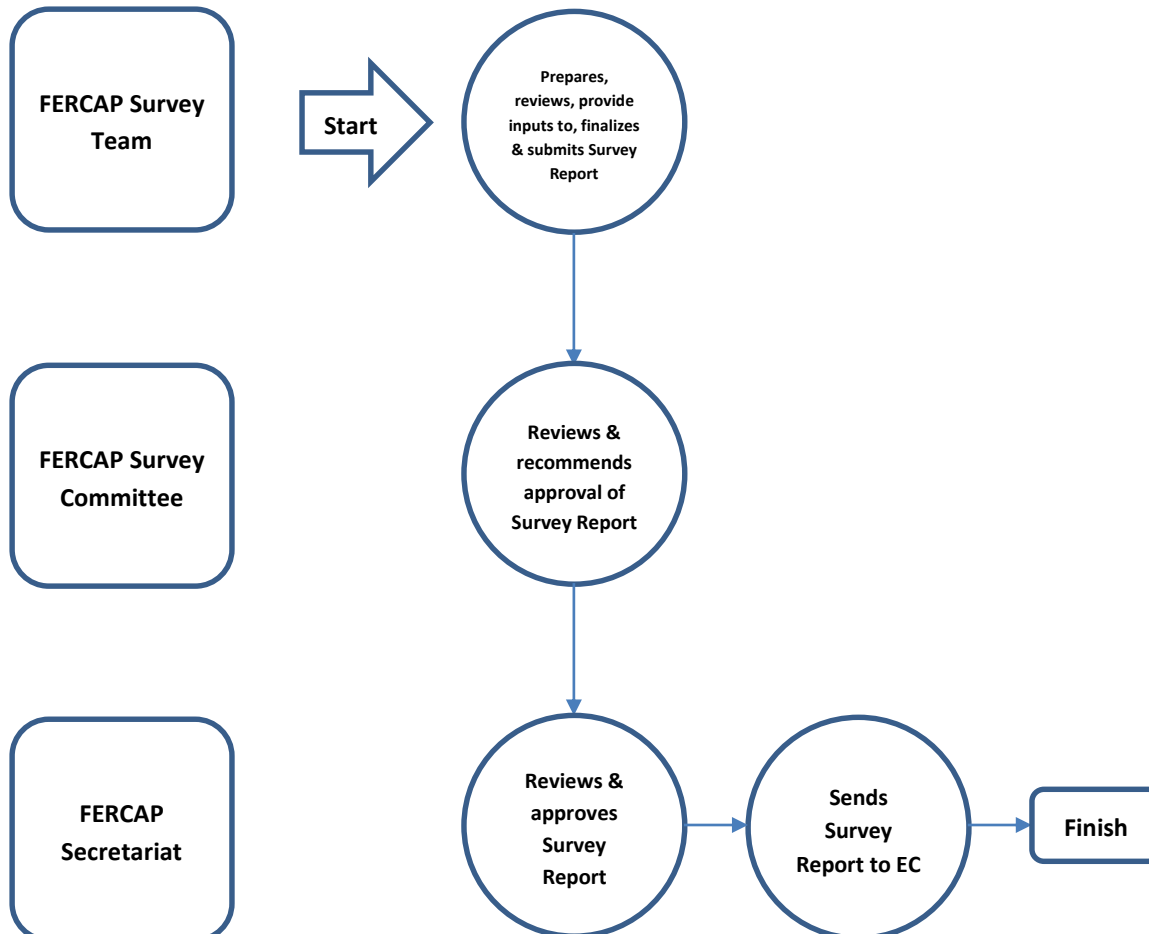
## 1. OBJECTIVE


The objective of this Standard Operating Procedure (SOP) is to describe the processes in preparing, finalizing, and approving the Survey Report.

## 2. SCOPE

This SOP covers the processes in preparing, finalizing, and approving the Survey Report.

## 3. RESPONSIBILITY AND WORKFLOW



	<b>SIDCER-FERCAP Survey SOP o6</b>	SIDCER-FERCAP Survey SOP o6 Version 4.0  Effective Date: 30 April 2020
	<b>Writing of Survey Report</b>	Page 39

## 4. DETAILED INSTRUCTIONS

### 4.1. Preparation of the Survey Report


- The FERCAP Lead Surveyor (as part of the FERCAP Survey Team) collates all relevant information from the Site Visit.
- The FERCAP Lead Surveyor submits the Closing Meeting Survey Findings Presentation (SIDCER-FERCAP Survey Template 03), Surveyor Training Evaluation Form (SIDCER-FERCAP Survey Form 20), Surveyor Trainee Reviewer (SIDCER-FERCAP Survey Form 19), and Surveyor Trainee Group Work Evaluation Form (SIDCER-FERCAP Survey Form 18) within three days after the Site Visit.
- The FERCAP Lead Surveyor writes the Draft Survey Report (SIDCER-FERCAP Survey Form 24) and circulates it to the other FERCAP Survey Team Members within two weeks after the Site Visit.
- The other FERCAP Survey Team reviews and provides inputs to the Draft Survey Report and the FERCAP Lead Surveyor corrects and finalizes the Survey Report for approval by the FERCAP Survey Team.
- The FERCAP Survey Team approves the Final Survey Report and the FERCAP Lead Surveyor submits the Final Survey Report to the FERCAP Survey Committee within three weeks after the Site Visit.

### 4.2. Recommendation for Approval of the Survey Report

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

### 4.3 Approval of the Survey Report

- The FERCAP Coordinator or FERCAP Program Manager (as part of the FERCAP Secretariat) reviews the Final Report for clarity, consistency, and compliance.
- The FERCAP Coordinator or FERCAP Program Manager approves the Final Survey Report and sends to the EC at least one month after the Site Visit.

	<b>SIDCER-FERCAP Survey SOP o6</b>	SIDCER-FERCAP Survey SOP 06 Version 4.0  Effective Date: 30 April 2020  Page 40
	<b>Writing of Survey Report</b>	


## 5. DOCUMENT HISTORY

Version/Year	SOP Code	Revisions
1.0/2005	FERCAP SOP SRP 04	Initial SIDCER-FERCAP Survey SOP.
2.0/2007	FERCAP SRP SOP004	Procedures and workflow were elaborated according to practice.
3.0/2010	SIDCER-FERCAP Survey SOP006	Coding was changed to SOP006. Procedures and workflow were elaborated according to practice.
4.0/2020	SIDCER-FERCAP Survey SOP 06	Format was changed. Procedures and workflow were revised. Responsibility (in the workflow) and references were added. Annex codes were revised.

## 6. ANNEXES

- SIDCER-FERCAP Survey Form 18 - Surveyor Trainee Group Work
- SIDCER-FERCAP Survey Form 19 - Surveyor Trainee Reviewer
- SIDCER-FERCAP Survey Form 20 - Surveyor Training Evaluation
- SIDCER-FERCAP Survey Form 24 - Survey Report
- SIDCER-FERCAP Survey Template 03 - Closing Meeting Survey Findings Presentation



	<b>SIDCER-FERCAP Survey SOP 07</b>	SIDCER-FERCAP Survey SOP 07 Version 4.0  Effective Date: 30 April 2020
	<b>Conduct of Follow-up Site Visit</b>	Page 41

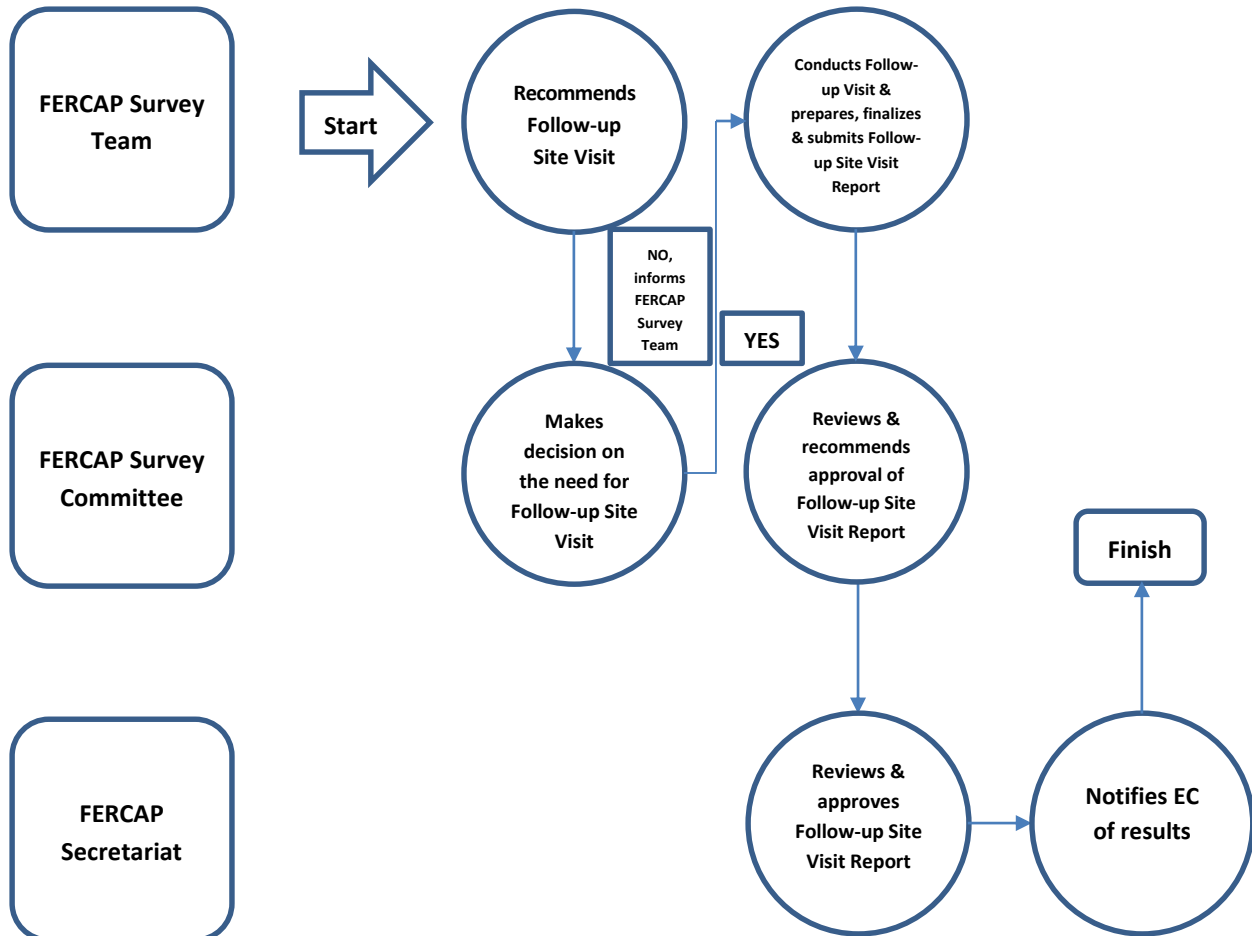
## 1. OBJECTIVE


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



	<b>SIDCER-FERCAP Survey SOP 07</b>	SIDCER-FERCAP Survey SOP 07 Version 4.0  Effective Date: 30 April 2020
	<b>Conduct of Follow-up Site Visit</b>	Page 42

## 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 FERCAP Survey Committee evaluates if there is evidence that suggests significant deficiencies in the completeness of the review process that put research participants at risk.
- Based on the evidence, 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 (SIDCER-FERCAP Survey Form 25).
- 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.

	<b>SIDCER-FERCAP Survey SOP 07</b>	SIDCER-FERCAP Survey SOP 07 Version 4.0  Effective Date: 30 April 2020
	<b>Conduct of Follow-up Site Visit</b>	Page 43

- 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. DOCUMENT HISTORY

Version/Year	SOP Code	Revisions
1.0/2005	FERCAP SOP 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.

### 6. ANNEX

- SIDCER-FERCAP Survey Form 25 - Follow-up Site Visit

	<b>SIDCER-FERCAP Survey SOP o8</b>	SIDCER-FERCAP Survey SOP o8 Version 4.0 Effective Date: 30 April 2020
	<b>Decision-Making on Recognition</b>	Page 44

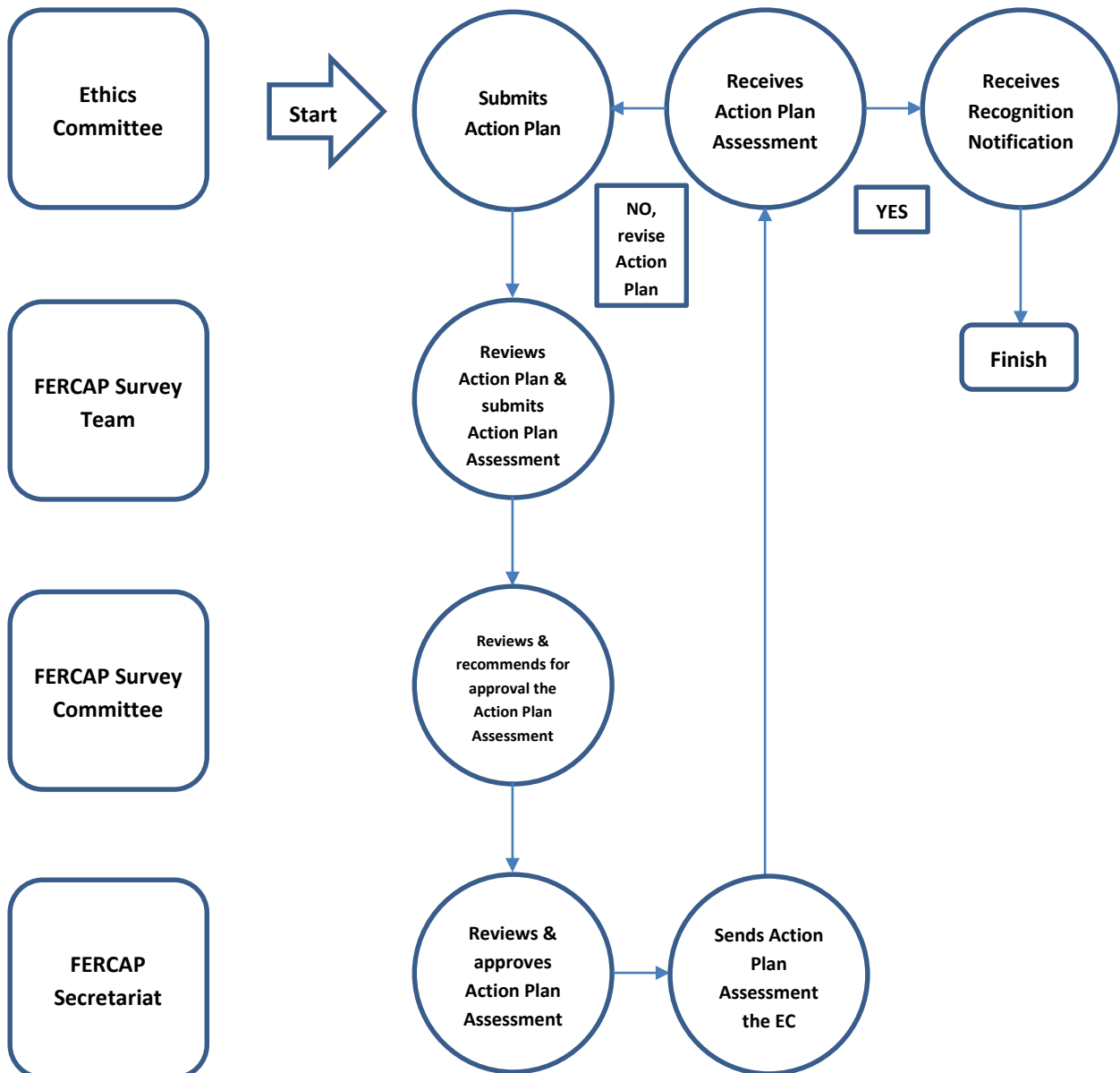
## 1. OBJECTIVE


The objective of this Standard Operating Procedure (SOP) is to describe the processes in decision-making on recognition.

## 2. SCOPE

This SOP covers the processes in decision-making on recognition.

## 3. RESPONSIBILITY AND WORKFLOW



	<b>SIDCER-FERCAP Survey SOP o8</b>	SIDCER-FERCAP Survey SOP o8 Version 4.0  Effective Date: 30 April 2020
	<b>Decision-Making on Recognition</b>	Page 45

## 4. DETAILED INSTRUCTIONS

### 4.1. Submission of the Action Plan

- The Ethics Committee (EC) submits the Action Plan (SIDCER-FERCAP Survey Form 26) one month after receiving the Final Survey Report.
- If the EC is unable to comply with the timeline for the submission of the Action Plan, it may request the FERCAP Secretariat for an extension of submission. The FERCAP Secretariat may grant extension of no more than one year. After one year, a Re-Survey is required.

### 4.2. Assessment of the Action Plan

- The FERCAP Survey Team reviews and provides inputs to the Action Plan submitted by the EC.
- The FERCAP Lead Surveyor prepares, consolidates inputs to, and finalizes the Action Plan Assessment.
- The FERCAP Lead Surveyor submits the Action Plan Assessment (SIDCER-FERCAP Survey Form 26) to the FERCAP Survey Committee within one week after receiving the Action Plan.

### 4.3. Recommendation for Approval of the Action Plan Assessment


- The FERCAP Local Coordinator (as part of the FERCAP Survey Committee) reviews the Action Plan Assessment for any local concerns and issues.
- The FERCAP Local Coordinator recommends for approval the Action Plan Assessment and submits it to the FERCAP Secretariat within three days after receipt from the FERCAP Survey Team.

### 4.4. Approval of the Action Plan Assessment

- The FERCAP Coordinator or FERCAP Program Manager (as part of the FERCAP Secretariat) reviews the Action Plan Assessment for clarity, consistency, and compliance.
- The FERCAP Coordinator or FERCAP Program Manager approves the Action Plan Assessment and sends to the EC within two weeks after receiving the Action Plan.

### 4.5. Decision-Making on Recognition

- If the Action Plan Assessment is not favorable, the EC needs to submit a Revised Action Plan. The Revised Action Plan undergoes the same process.
- If the Action Plan Assessment is favorable, the EC receives a Recognition Notification (SIDCER-FERCAP Survey Template 13).

	<b>SIDCER-FERCAP Survey SOP o8</b>	SIDCER-FERCAP Survey SOP o8 Version 4.0  Effective Date: 30 April 2020
	<b>Decision-Making on Recognition</b>	Page 46


- The EC receives the Recognition Plaque/Certificate (SIDCER-FERCAP Survey Templates 14-15) during the FERCAP General Assembly with validity for three years. In some cases, depending on the national requirements, the validity of recognition maybe four years.
- Recognition maybe withdrawn when the FERCAP Secretariat receives an identifiable written complaint related to a SIDCER-FERCAP recognized EC. In such a case, the FERCAP Secretariat undertakes an investigation and/or other probable actions. Only the FERCAP Steering Committee can withdraw recognition. A major breach of the 5 SIDCER-FERCAP Standards, as confirmed by the investigation, is one of the criteria for withdrawal of recognition. The FERCAP Steering Committee may also withdraw a recognition given to an EC, due to the following reasons:
  - a) Consistent non-submission of Annual Progress Report
  - b) Major issues from the Annual Progress Report
  - c) Consistent non-compliance with other requirements for SIDCER-FERCAP recognized EC (*e.g.* consistent non-payment of Annual Institutional Fee)

## 5. DOCUMENT HISTORY

Version/Year	SOP Code	Revisions
1.0/2005	FERCAP SRP 06	Initial SIDCER-FERCAP Survey SOP.
2.0/2007	FERCAP SRP SOP006	Procedures and workflow were elaborated according to practice.
3.0/2010	SIDCER-FERCAP Survey SOP008	Coding was changed to SOP008. Procedures and workflow were elaborated according to practice.
4.0/2020	SIDCER-FERCAP Survey SOP 08	Format was changed. Procedures and workflow were revised. Responsibility (in the workflow) and references were added. Annex codes were revised.

## 6. ANNEXES

- SIDCER-FERCAP Survey Form 26 - Action Plan
- SIDCER-FERCAP Survey Template 13 - Recognition Notification
- SIDCER-FERCAP Survey Template 14 - Recognition Plaque
- SIDCER-FERCAP Survey Template 15 - Renewal of Recognition Certificate

	<b>SIDCER-FERCAP Survey SOP 09</b>	SIDCER-FERCAP Survey SOP 09 Version 4.0  Effective Date: 30 April 2020
	<b>Submission of Annual Progress Report</b>	Page 47

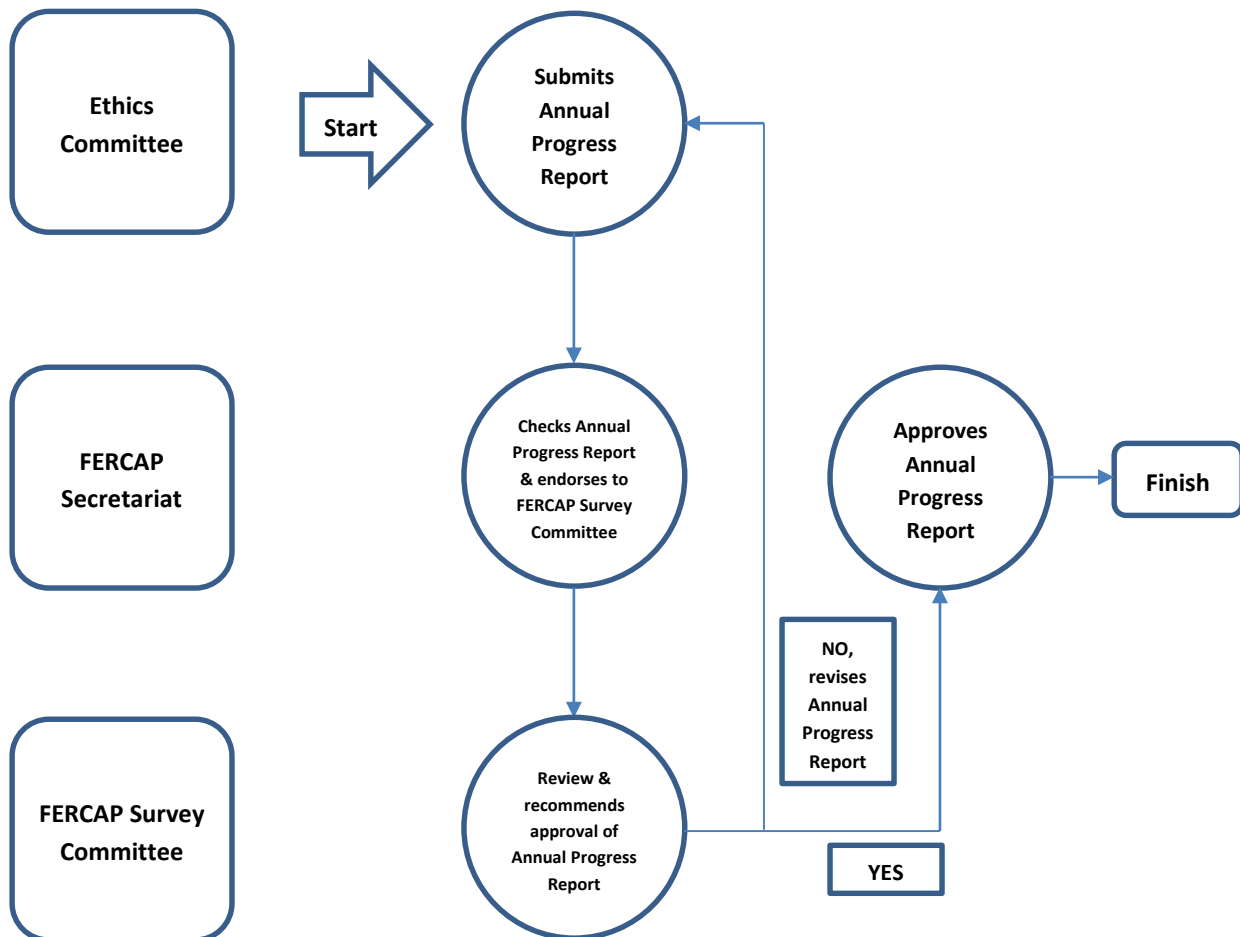
### 1. OBJECTIVE


The objective of this Standard Operating Procedure (SOP) is to describe the processes in the submission, review, and approval of Annual Progress Reports.

### 2. SCOPE

This SOP covers the processes in the submission, review, and approval of Annual Progress Reports.

### 3. RESPONSIBILITY AND WORKFLOW



	<b>SIDCER-FERCAP Survey SOP 09</b>	SIDCER-FERCAP Survey SOP 09 Version 4.0  Effective Date: 30 April 2020
	<b>Submission of Annual Progress Report</b>	Page 48

## 4. DETAILED INSTRUCTIONS

### 4.1. Submission of the Annual Progress Report

- The Ethics Committee (EC) submits the Annual Progress Report (SIDCER-FERCAP Survey Form 27) together with the updated Action Plan in response to the most recent Survey Report before the end of each year. The EC provides information on the full compliance with the updated Action Plan either through the submission of documentary evidence or through the conduct of Post-Recognition Follow-up Site Visit.
- If the EC is unable to comply with the timeline for the submission of the Annual Progress Report, it may request the FERCAP Secretariat for an extension of submission. The FERCAP Secretariat may grant extension of no more than one month.

### 4.2. Recommendation for Approval of the Annual Progress Report

- The FERCAP Local Coordinator (as part of the FERCAP Survey Committee) reviews the Annual Progress Report for any local concerns and issues.
- The FERCAP Local Coordinator recommends for approval of the Annual Progress Report and submits it to the FERCAP Secretariat within two weeks after receipt from the FERCAP Secretariat.


### 4.3. Approval of the Annual Progress Report

- The FERCAP Coordinator or FERCAP Program Manager (as part of the FERCAP Secretariat) reviews the Annual Progress Report for clarity, consistency, and compliance.
- The FERCAP Coordinator or FERCAP Program Manager approves the Annual Progress Report and sends the approval to the EC within one month after receiving the Annual Progress Report.

## 5. DOCUMENT HISTORY

Version/Year	SOP Code	Revisions
1.0/2005	FERCAP SOP SRP 07	Initial SIDCER-FERCAP Survey SOP.
2.0/2007	FERCAP SRP SOP007	Procedures and workflow were elaborated according to practice.
3.0/2010	SIDCER-FERCAP Survey SOP009	Coding was changed to SOP009. Procedures and workflow were elaborated according to practice.




	<b>SIDCER-FERCAP Survey SOP 09</b>	SIDCER-FERCAP Survey SOP 09 Version 4.0  Effective Date: 30 April 2020  Page 49
	<b>Submission of Annual Progress Report</b>	

4.0/2020	SIDCER-FERCAP Survey SOP 09	Format was changed. Procedures and workflow were revised. Responsibility (in the workflow) and references were added. Annex codes were revised.
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**6. ANNEX**

- SIDCER-FERCAP Survey Form 27 - Annual Progress Report

	<b>SIDCER-FERCAP Survey SOP 10</b>	SIDCER-FERCAP Survey SOP 10 Version 1.0  Effective Date: 30 April 2020  Page 50
	<b>Evaluation of Surveyors</b>	

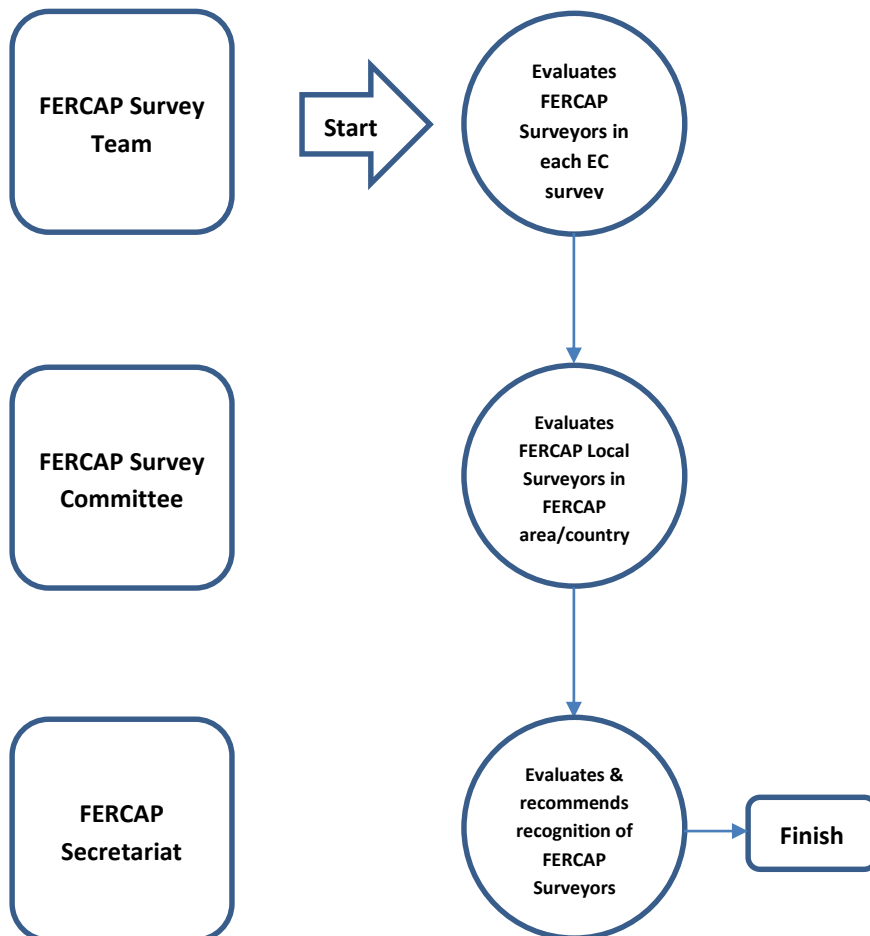
## 1. OBJECTIVE


The objective of this Standard Operating Procedure (SOP) is to describe the processes in the evaluation of FERCAP Surveyors.

## 2. SCOPE

This SOP covers the processes in the evaluation of FERCAP Surveyors.

## 3. RESPONSIBILITY AND WORKFLOW



	<b>SIDCER-FERCAP Survey SOP 10</b>	SIDCER-FERCAP Survey SOP 10 Version 1.0  Effective Date: 30 April 2020
	<b>Evaluation of Surveyors</b>	Page 51

## 4. DETAILED INSTRUCTIONS

### 4.1. Evaluation of FERCAP Surveyors in each Ethics Committee Survey

- The FERCAP Survey Coordinator (as part of the FERCAP Survey Team) evaluates the FERCAP Surveyors in each Ethics Committee (EC) survey and submit its feedback to the FERCAP Survey Committee using the Surveyor Evaluation Form (SIDCER-FERCAP Survey Form 21) within three days after the Site Visit.
- The FERCAP Survey Committee collates all evaluation of FERCAP Local Surveyors from all the EC surveys in the FERCAP area/country.

### 4.2. Evaluation of FERCAP Surveyors in the FERCAP Area/Country

- The FERCAP Local Coordinator (as part of the FERCAP Survey Committee) reviews all evaluation of FERCAP Local Surveyors from all the EC surveys in the FERCAP area/country and submit its feedback to the FERCAP Secretariat using the Annual Surveyor Evaluation Form (SIDCER-FERCAP Survey Form 29) within one month after the last EC survey for the year in the FERCAP area/country.
- The FERCAP Secretariat collates all evaluation of FERCAP Surveyors from all the EC surveys for the year.

### 4.3. Evaluation and Recognition of FERCAP Surveyors Every Year

- The FERCAP Coordinator or FERCAP Program Manager (as part of the FERCAP Secretariat) reviews all evaluation of FERCAP Surveyors from all the EC surveys in and submit its feedback to the FERCAP Steering Committee using the Annual Surveyor Evaluation Form within one week before the FERCAP Steering Committee Meeting and FERCAP General Assembly.
- The FERCAP Secretariat recommends to the FERCAP Steering Committee the Surveyors for recognition during the FERCAP General Assembly.

## 5. DOCUMENT HISTORY

Version/Year	SOP Code	Revisions
1.0/2020	SIDCER-FERCAP Survey SOP 10	Initial SIDCER-FERCAP Survey SOP.

## 6. ANNEXES

- SIDCER-FERCAP Survey Form 21 - Surveyor Evaluation by the Survey Coordinator
- SIDCER-FERCAP Survey Form 28 - Annual Surveyor Evaluation

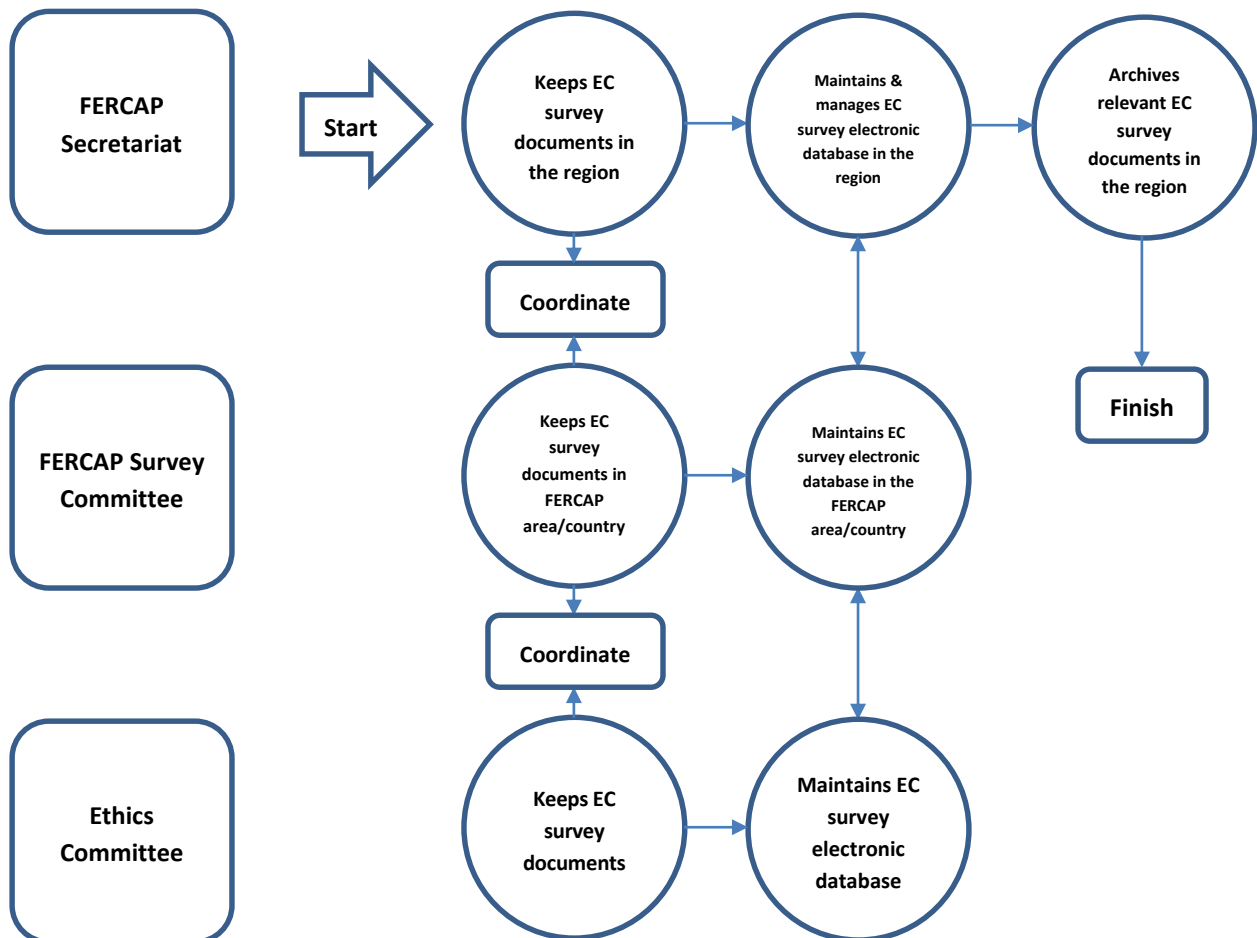
### 1. OBJECTIVE


The objective of this Standard Operating Procedure (SOP) is to describe the processes in documentation and archiving.

### 2. SCOPE

This SOP covers the processes in documentation and archiving.

### 3. RESPONSIBILITY AND WORKFLOW



	<b>SIDCER-FERCAP Survey SOP 11</b>	SIDCER-FERCAP Survey SOP 11 Version 4.0  Effective Date: 30 April 2020
	<b>Documentation and Archiving</b>	Page 53

## 4. DETAILED INSTRUCTIONS

### 4.1. Keeping Documents Related to EC Surveys


- The FERCAP Secretariat keeps all documents related to EC surveys in the region. The FERCAP Secretariat keeps electronic files of the following:
  - a) SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, and SIDCER-FERCAP Survey Forms
  - b) EC Files (from EC Application Form to EC Annual Progress Report)
  - c) FERCAP Surveyor Files (*e.g.* CV)
  - d) Other documents
- The FERCAP Secretariat backs-up electronic files before the end of each month.
- The FERCAP Local Coordinator (as part of the FERCAP Survey Committee) coordinates with the FERCAP Secretariat and the ECs and keeps all documents related to EC surveys in the FERCAP area/country.
- EC coordinates with the FERCAP Secretariat and FERCAP Local Coordinator and keeps all documents related to their EC survey.

### 4.2. Maintenance and Management of EC Survey Electronic Database

- The FERCAP Secretariat maintains and manages EC survey electronic database in the region. The FERCAP Secretariat keeps electronic database on the following:
  - Survey Schedule
  - Recognized EC List (SIDCER-FERCAP Survey Form 29)
  - Surveyor List (SIDCER-FERCAP Survey Form 30)
- The FERCAP Secretariat uploads the updated Recognized EC list and Surveyor list on the FERCAP website before the end of each year.
- The FERCAP Local Coordinator (as part of the FERCAP Survey Committee) maintains EC survey electronic database in the FERCAP area/country.
- EC maintains EC survey electronic database related to their EC survey.

### 4.3. Archiving of FERCAP Documents

- The FERCAP Secretariat archives the files of ECs that have been inactive for ten years.
- The FERCAP Secretariat archives the files of Surveyors that have been inactive for five years.


	<b>SIDCER-FERCAP Survey SOP 11</b>	SIDCER-FERCAP Survey SOP 11 Version 4.0  Effective Date: 30 April 2020  Page 54
	<b>Documentation and Archiving</b>	

## 5. DOCUMENT HISTORY

Version/Year	SOP Code	Revisions
1.0/2005	FERCAP SOP SRP 08	Initial SIDCER-FERCAP Survey SOP.
2.0/2007	FERCAP SRP SOP008	Procedures and workflow were elaborated according to practice.
3.0/2010	SIDCER-FERCAP Survey SOP010	Coding was changed to SOP010. Procedures and workflow were elaborated according to practice.
4.0/2020	SIDCER-FERCAP Survey SOP 10	Format was changed. Procedures and workflow were revised. Responsibility (in the workflow) and references were added. Annex codes were revised.

## 6. ANNEXES

- SIDCER-FERCAP Survey Form 29 - Recognized EC List
- SIDCER-FERCAP Survey Form 30 - Surveyors List

	<b>SIDCER-FERCAP Survey SOP 12</b>	SIDCER-FERCAP Survey SOP 12 Version 1.0  Effective Date: 30 April 2020
	<b>Review and Revision of Survey SOPs</b>	Page 55

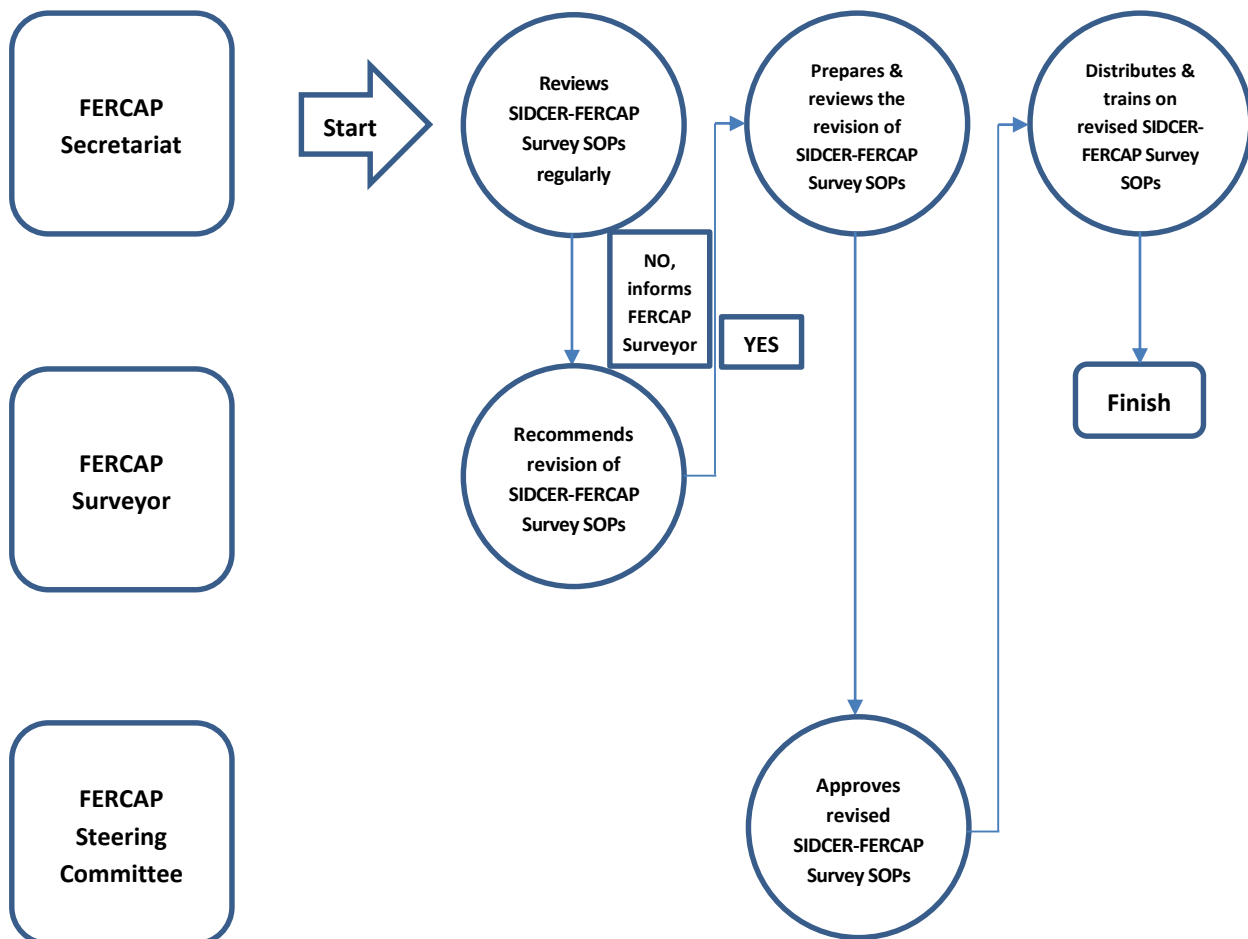
## 1. OBJECTIVE


The objective of this Standard Operating Procedure (SOP) is to describe the processes in the review and revision of the SIDCER-FERCAP Survey Terms of Reference (TOR), SIDCER-FERCAP Survey Standard Operating Procedures (SOPs), SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates.

## 2. SCOPE

This SOP covers the processes in the review and revision of the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates.

## 3. RESPONSIBILITY AND WORKFLOW



	<b>SIDCER-FERCAP Survey SOP 12</b>	SIDCER-FERCAP Survey SOP 12 Version 1.0  Effective Date: 30 April 2020
	<b>Review and Revision of Survey SOPs</b>	Page 56

## 4. DETAILED INSTRUCTIONS


### 4.1. Review of the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates

- The FERCAP Secretariat conducts a regular review of the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates every three years.
- The FERCAP Secretariat documents the regular review and if applicable, the need to review the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates.

### 4.2. Revision of the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates

- The FERCAP Secretariat or any FERCAP Surveyor can request to revise the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and/or SIDCER-FERCAP Survey Templates using the Survey SOP Revision Form.
- The FERCAP Secretariat makes a decision on the need to revise the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and/or SIDCER-FERCAP Survey Templates.
- If the FERCAP Secretariat does not agree with the need to revise the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and/or SIDCER-FERCAP Survey Templates, the FERCAP Secretariat provides the FERCAP Surveyor with the reason.
- If the FERCAP Secretariat confirms the need to revise the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and/or SIDCER-FERCAP Survey Templates, the FERCAP Secretariat asks the FERCAP Program Manager to prepare the revision or development of a new document.
- The FERCAP Program Manager (as part of the FERCAP Secretariat) prepares the revision of the SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and/or SIDCER-FERCAP Survey Templates and consults with FERCAP Local Coordinators and/or FERCAP Surveyors about the revision.
- The SIDCER Coordinator (as part of the FERCAP Secretariat) reviews the revised SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and/or SIDCER-FERCAP Survey Templates.



	<b>SIDCER-FERCAP Survey SOP 12</b>	SIDCER-FERCAP Survey SOP 12 Version 1.0  Effective Date: 30 April 2020
	<b>Review and Revision of Survey SOPs</b>	Page 57

**4.3. Approval of the Revised SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates**

- The FERCAP Secretariat recommends the revised SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and/or SIDCER-FERCAP Survey Templates.
- The FERCAP Chairperson (as Head of the FERCAP Steering Committee) approves the revised SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and/or SIDCER-FERCAP Survey Templates. The effective date of the revised SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and/or SIDCER-FERCAP Survey Templates is the approval date as signed by the FERCAP Chairperson on behalf of the FERCAP Steering Committee.

**4.4. Distribution of the Revised SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates**


- The FERCAP Program Manager (as part of the FERCAP Secretariat) uploads the revised SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and/or SIDCER-FERCAP Survey Templates on the FERCAP website.
- The FERCAP Program Manager (as part of the FERCAP Secretariat) informs FERCAP Surveyors about the revised SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and/or SIDCER-FERCAP Survey Templates.
- The FERCAP Program Manager (as part of the FERCAP Secretariat) marks old SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and/or SIDCER-FERCAP Survey Templates as “CANCELLED” and moves the documents to the Archives section of the FERCAP website.

**4.5. Training on the Revised SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and SIDCER-FERCAP Survey Templates**

- The FERCAP Secretariat includes the training on the revised SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and/or SIDCER-FERCAP Survey Templates in the FERCAP Surveyor Trainings prior to EC surveys.
- The FERCAP Secretariat includes the training on the revised SIDCER-FERCAP Survey TOR, SIDCER-FERCAP Survey SOPs, SIDCER-FERCAP Survey Forms, and/or SIDCER-FERCAP Survey Templates in the update FERCAP Surveyor Trainings.


**5. DOCUMENT HISTORY**

Version/Year	SOP Code	Revisions
1.0/2020	SIDCER-FERCAP Survey SOP 12	Initial SIDCER-FERCAP Survey SOP.

	<b>SIDCER-FERCAP Survey SOP 12</b>	SIDCER-FERCAP Survey SOP 12 Version 1.0  Effective Date: 30 April 2020  Page 58
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**6. ANNEX**


- SIDCER-FERCAP Survey Form 28 - Survey SOP Revision

	<b>SIDCER-FERCAP Survey TOR &amp; SOPs</b>	SIDCER-FERCAP Survey TOR & SOPs Version 4.0  Effective Date: 30 April 2020
	<b>Glossary</b>	Page 59


EC	An ethics committee. It is also known as ethical review board (ERB), ethical review committee (ERC), human research ethics committee (HREC), independent ethics committee (IEC), 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 Administrative Officer	A FERCAP Office Staff that assists the FERCAP Secretariat in administration and office management.
FERCAP Chairperson	The head and presiding officer of FERCAP.
FERCAP Coordinator	The coordinator of the activities of FERCAP.
FERCAP Finance Officer	A FERCAP Office Staff that assists the FERCAP Treasurer in financial management.
FERCAP Foreign Surveyor or FERCAP International Surveyor	An experienced FERCAP Surveyor who is not from the area/country of the EC being surveyed.
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.

	<b>SIDCER-FERCAP Survey TOR &amp; SOPs</b>	SIDCER-FERCAP Survey TOR & SOPs Version 4.0  Effective Date: 30 April 2020
	<b>Glossary</b>	Page 60

FERCAP Local Surveyor	A FERCAP Surveyor from the area/country of the EC being surveyed.
FERCAP Office Staff	Composed of the FERCAP Finance Officer and FERCAP Administrative Officer that assists the FERCAP Secretariat.
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 Steering Committee	Composed of Representatives of FERCAP areas/countries with SIDCER-FERCAP recognized ECs, the SIDCER-FERCAP Foundation President, and the SIDCER Chairperson that serves as the highest governing and policy-making body of FERCAP.
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 Coordinator	An experienced FERCAP Surveyor who supervises the FERCAP Survey Team.
FERCAP Surveyor	A person who heads a group of Surveyor Trainees and responsible for the completion of the various SIDCER-FERCAP Survey Forms during the Site Visit. Maybe a FERCAP Foreign Surveyor or FERCAP Local Surveyor.
FERCAP Survey Team	Composed of a FERCAP Survey Coordinator, a FERCAP Lead Surveyor, and two other FERCAP Surveyors tasked to conduct the EC survey.
FERCAP Treasurer	The chief financial manager of FERCAP.
FERCAP Vice-Chairperson	The deputy head of FERCAP who assists the FERCAP Chairperson and performs the responsibilities of the FERCAP Chairperson in the latter's absence and in case of conflict of interest (COI).

	<b>SIDCER-FERCAP Survey TOR &amp; SOPs</b>	SIDCER-FERCAP Survey TOR & SOPs Version 4.0  Effective Date: 30 April 2020
	<b>Glossary</b>	Page 61

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).
SIDCER Chairperson	The head and presiding officer of SIDCER.
SIDCER Coordinator	The coordinator of the activities of SIDCER.
SIDCER-FERCAP Foundation	The SIDCER-FERCAP Foundation is an independent institution promoting quality ethical review in health research that provides administrative, financial, and secretariat support to SIDCER-FERCAP.
SIDCER-FERCAP Foundation President	The head and presiding officer of the SIDCER-FERCAP Foundation.
Surveyor Trainee	A potential FERCAP Surveyor undergoing training.

	<b>SIDCER-FERCAP Survey TOR &amp; SOPs</b>	SIDCER-FERCAP Survey TOR & SOPs Version 4.0  Effective Date: 30 April 2020
	<b>References</b>	Page 62

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