

Decision-Making on Recognition

Prepared by: Arthur Navarro

Reviewed by: Juntra Karbwang-Laothavorn

Approved by: Kenji Hirayama

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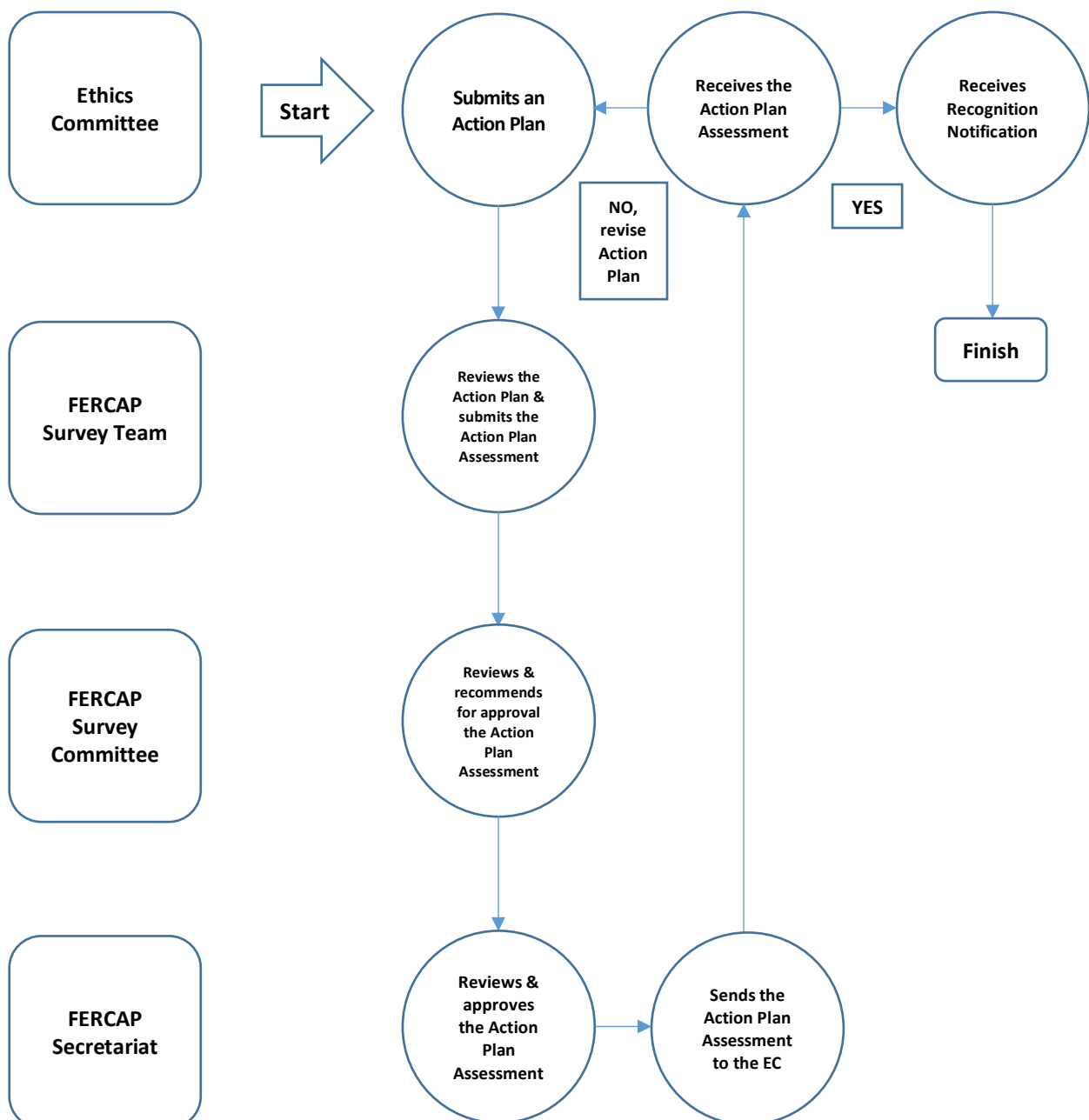
1. OBJECTIVE

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



4. DETAILED INSTRUCTIONS

4.1. Submission of the Action Plan

- The Ethics Committee (EC) submits the Action Plan **at least** 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. The Action Plan Assessment

- 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 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).
- The EC receives the Recognition Plaque/Certificate 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. GLOSSARY

EC	An ethics committee. It is also known as ethical review board (ERB), ethical review committee (ERC), human research ethics committee (HREC), institutional review board (IRB), and research ethics committee (REC). It is a group of individuals who undertakes the ethical review of research protocols involving human participants using agreed ethical principles and guidelines.
FERCAP	The Forum for Ethical Review Committees in Asia and the Western Pacific. It is an organization of ECs within the Asia-Pacific region. It is regional forum under the umbrella of SIDCER.
FERCAP Coordinator	The coordinator of the activities of FERCAP.
FERCAP Lead Surveyor	An experienced FERCAP Surveyor who leads the FERCAP Survey Team and writes the Survey Report.
FERCAP Local Coordinator	A FERCAP Steering Committee Member representing a FERCAP area/country or a Representative of the national accreditation institution (<i>e.g.</i> NECAST, PHREB) or a Representative of the area/country network of ECs (<i>e.g.</i> FERCI, FERCSL, FERCIT, FIRREC, NERCIM, PHREN, TAIRB) who coordinates the EC surveys in a FERCAP area/country.
FERCAP Local Surveyor	A FERCAP Surveyor from the area/country of the EC being surveyed.
FERCAP Program Manager	Manager of the activities of FERCAP.
FERCAP Secretariat	Composed of the SIDCER Coordinator, FERCAP Coordinator, FERCAP Program Manager, and FERCAP Treasurer that serves as the coordinating and managing arm of FERCAP
FERCAP Survey Coordinator	An experienced FERCAP Surveyor who supervises the FERCAP Survey Team.
FERCAP Survey Committee	Composed of the SIDCER Coordinator, the FERCAP Coordinator or FERCAP Program Manager, and the FERCAP Local Coordinator that serves as the coordinating arm in a FERCAP area/country.
FERCAP Survey Team	Composed of a FERCAP Survey Coordinator, a FERCAP Lead Surveyor, and two other FERCAP Surveyors tasked to conduct the EC survey.

SIDCER	The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER). It is a global network of EC fora composed of FERCAP and the Pan-African Bioethics Initiative (PABIN),
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6. 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.

7. 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

8. REFERENCES

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