

Part I - Surveying and Evaluating Ethical Review Practices

Date	Name of EC	Contact Persons	Survey Team Members

Forum for Ethical Review Committees in Asia and the Western Pacific



developed within the

Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)

Survey Objectives

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

Scope of Survey Activities

- Review the legal and regulatory framework as well as documents related to the establishment of the EC
- Review EC membership and staff list, terms of reference, and training records

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- Review EC SOPs
- Review the training programme
- Interview EC representatives (members and secretariat)
- Review protocol files, meeting agendas, minutes, and communications
- Review Serious Adverse Events (SAEs) and other follow-up reports
- Observe EC meeting
- Document findings and observations during the survey visit
- Write the survey report

References

- WMA Declaration of Helsinki, 2013
- CIOMS guidelines for ethics review, 2002, 2009, 2016
- WHO standards and operational guidance for ethics review of health related research with human participants, 2011
- WHO surveying and evaluating ethical review practices guidelines, 2002
- ICH-GCP (E-6), 1996, 2016
- SIDCER-FERCAP Survey TOR, 2020
- SIDCER-FERCAP Survey SOPs, 2007, 2010, 2020
- SIDCER-FERCAP Survey Forms, 2009, 2013, 2020
- SIDCER-FERCAP Survey Templates, 2009, 2013, 2020

List of documents to be reviewed during the site visit

- Applicable laws, regulations, guidelines, and organizational policies for the EC
- List of EC members
- EC members' CVs
- EC standard operating procedures
- EC forms for communication with applicants, regulatory authorities, or the authority under which the EC is established
- Agendas and minutes of three EC meetings
- Documents for reviewing serious adverse events (SAEs)
- EC policy and procedures for follow-up review
- Protocol list in the past 3 years
- Protocol files
- Communication Files
- EC database
- Training curriculum and workshops

Part II - International Course on Surveying and Evaluating Ethical Review Practices

Course Description

This course develops local and regional expertise in evaluating ethical review practices. It is based on the WHO surveying and evaluating ethical review practices guidelines. This course targets ethics committee members in the Asia-Pacific region with extensive experience in ethical review. The aim is to lay the foundations for professionals to evaluate and monitor ethical review in the region.

Course Language

The language of this course is English.

Course Objectives

The primary objective of this course is to promote good ethical review practices in health research in the Asia-Pacific region by implementing international criteria for surveying and evaluating ethical review practices. Within this framework, the following specific objectives will be pursued:

- To establish the role of the surveyors and evaluators for ECs in the Asia-Pacific region;
- To implement the WHO surveying and evaluating ethical review practices guidelines;
- To develop surveying and evaluating practices within a framework of international guidelines, including WHO, WMA, CIOMS, and ICH GCP guidelines and national guidelines in the Asia-Pacific region;
- To develop a regionally and internationally appropriate methodology for surveying and evaluating ethics committees;
- To prepare surveyors to work according to the requirements of the local conditions and regulations;
- To prepare national and local ethics committees to work according to international standards in ethical review.

Course Outcomes

This course aims to achieve outcomes in the following areas:

- Training and certification of in-country surveyors of ethical review practices;
- Translation and in-country adaptation of the WHO surveying and evaluating ethical review practices guidelines;
- Development of in-country and regional standards for recognition of ethical review committees;
- Development of international human participant protection standards.

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Course Format

A four-day course consisting of lectures and discussion in working groups, focused on presenting a comprehensive overview of the requirements for surveying and evaluating ethical review practices with an emphasis on developing practical approaches. The following themes are treated:

- Local Environment and Practical Challenges to Ethical Review
- Framework for Evaluating Ethical Review Practices
- Procedures in Surveying ECs
- Site Visit

The course participants will be divided into working groups, each group will have one facilitator. The second, third, and half of the fourth day of the course will consist of site visits. The working groups will carry out an evaluation of the ethics committee at designated sites.

Course Participants

The participants are Asia-Pacific EC members and affiliates.

Survey Trainees:

Name	Discipline/ Expertise	Institution	Position	E-mail Address



Survey Training and Orientation

Training - Day 1

Session 1: Local Environment and Practical Challenges to Ethical Review	
09:00-09:45	Current Challenges to Quality Ethical Review in the Area/Country and National/Local Laws, Regulations, and Guidelines 🌀 FERCAP Local Surveyor/FERCAP Local Coordinator
Session 2: Framework for Evaluating Ethical Review Practices	
09:45-10:15	International Ethical Principles and Guidelines 🌀 FERCAP Survey Coordinator/FERCAP Surveyor
10:15-10:30	Break
10:30-11:30	Purpose of Evaluating Ethical Review and Quality of Ethical Review 🌀 FERCAP Survey Coordinator/FERCAP Surveyor
11:30-12:00	Open Forum
12:00-13:00	Lunch
Session 3: Procedures in Surveying Ethics Committees	
13:00-13:30	Overview of SIDCER-FERCAP Survey TOR and SIDCER-FERCAP Survey SOPs and Roles of the FERCAP Survey Team and Surveyor Trainees 🌀 FERCAP Lead Surveyor/FERCAP Surveyor
13:30-14:15	Overview of SIDCER-FERCAP Survey Methods and SIDCER-FERCAP Survey Forms 🌀 FERCAP Lead Surveyor/FERCAP Surveyor
14:15-14:30	Break
14:30-17:00	Formation of Survey Groups: SIDCER-FERCAP Survey Team Assignments 🌀 Lead Surveyor <ul style="list-style-type: none"> ▪ Grouping the Surveyors and Trainees ▪ Assigning responsibilities to the Survey Groups (Items to Review, SOPs, Interviewees, Board Meeting, Protocols, and Forms)

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Site Visit - Day 1

09:00-10:00	Opening Meeting (with EC Members and Staff) Presentation of EC Profile and Procedures  EC Representative Presentation of Survey Plan  FERCAP Lead Surveyor
10:00-10:15	Break
10:15-12:00	EC Office Visit <ul style="list-style-type: none"> ▪ Discussion on national and international guidance documents under which EC operates ▪ Discussion with responsible Member and Staff of EC about document requirements and procedures ▪ Evaluation of EC documentation and archiving
12:00-13:00	Lunch
13:00-14:30	Review of EC Standard Operating Procedures <ul style="list-style-type: none"> ▪ Examination of the EC Standard Operating Procedures ▪ Examination of documents available to applicants, regulatory authorities, or the authority under which the EC is established
	Review of EC Membership and Training Files <ul style="list-style-type: none"> ▪ Examination of the EC membership list ▪ Examination of documentation of expertise of Members and Staff ▪ Evaluation of EC training curriculum and records
14:30-14:45	Break
14:45-16:30	Review of Protocol Files <ul style="list-style-type: none"> ▪ Examination of protocols reviewed by EC
16:30-17:30	Daily Summary Meeting (Survey Team Closed Door Meeting) <ul style="list-style-type: none"> ▪ Listing of good practices of the EC ▪ Listing of recommendations for the EC

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Site Visit - Day 2

09:00-10:15	Review of Protocol Files (<i>continuation</i>) ▪ Examination of protocols reviewed by EC
10:15-10:30	Break
10:30-12:00	Review of EC SAE Reports and Follow-up Procedures ▪ Examination of EC procedures for receiving and reviewing SAEs ▪ Examination of EC policy and procedures for follow-up review Review of EC Meeting Minutes ▪ Examination of agenda and minutes of EC Board Meetings
12:00-13:00	Lunch
13:00-15:00	Board Meeting Observation ▪ Evaluation of conduct of EC Board Meeting
15:00-15:15	Break
15:15-16:30	Interviews with EC Members and Staff ▪ Discussion with responsible Member and Staff of EC about appointment, qualifications, roles, procedures, quality improvement suggestions)
16:30-17:30	Daily Summary Meeting (Survey Team Closed Door Meeting) ▪ Listing of good practices of the EC ▪ Listing of recommendations for the EC

Site Visit - Day 3

09:00-10:15	Daily Summary Meeting (Survey Team Closed Door Meeting) ▪ Summary of findings and observations
10:15-10:30	Break
10:30-12:00	Daily Summary Meeting (Survey Team Closed Door Meeting) (<i>continuation</i>) ▪ Summary of findings and observations
12:00-13:00	Lunch
13:00-15:00	Closing Meeting (with EC Members and Staff) Presentation of Survey Findings and Observations ☞ FERCAP Lead Surveyor/FERCAP Local Surveyor Response from EC ☞ EC Representative Closing Remarks ☞ EC Representative ☞ FERCAP Survey Coordinator
15:00-15:15	Break
15:15-16:30	Debriefing Session (with Surveyor Trainees) ☞ FERCAP Survey Coordinator