



SIDCER Recognition Programme

**UNICEF/UNDP/World Bank/WHO
Special Programme for Research and
Training in Tropical Diseases (TDR)**

PROJECT OVERVIEW

BACKGROUND

There has been widespread discussion on the conduct of biomedical research in developing countries in the past several years and much of the concern is focused on developing capacity for ethical review in these countries to ensure the rights and safety of persons and communities participating in clinical research. WHO/TDR has facilitated the establishment of five regional fora around the globe (Asia, Africa, Latin America, North America and Eastern Europe), to strengthen ethical review capacity within countries. These Fora committed to the exchange of information and the development of national guidelines and local standard operating procedures, as well as the establishment of educational activities for members of ethics committees. The fora have worked together across regions to share the complexity of cultural variations, national laws, local medical and research practices, and local knowledge as well as developing similar structured approaches to address their specific needs. It is essential to continue to develop an integrated approach to information gathering and sharing, and capacity building for ethical review practice across the continents to address the fundamental ethical gaps and challenges encountered in global health research. The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) was established in WHO/TDR as a Public-Private Partnership project, the objective was to bring these regional fora together into a global strategic initiative focused on addressing human subjects protections in global health research. SIDCER provides the international community with not only a means to build in-country human subjects protection programmes, but also a way to measure and provide accountability regarding the quality and effectiveness of ethical review worldwide. This is the basis for the initiation of SIDCER recognition programme.

SIDCER VISION

To enhance the protection of human participants in all research endeavors in all countries of the world.

MISSIONS

- 1) To promote the highest ethical and scientific standards for biomedical and behavioral research,
- 2) To ensure the quality and effectiveness of ethics review worldwide, with mutual understanding and respect for cultural, regional and national differences,
- 3) To expand Biomedical Research Ethics Alliance through facilitating Regional and National Network.

OBJECTIVE

The primary objective of SIDCER is to contribute to human subjects protections globally by developing capacity in ethical review and the ethics of health research.

THE METHOD

- 1) Building on ‘grass-roots’ initiatives, fora of ethics committee members committed to improving their own situations
- 2) Building the independence and competence through dialogue, exchange, and education
- 3) Inviting all parties having a responsibility in health research to engage a long-term sustained involvement in capacity-building for decision-making in ethics

TOOLS

- 1) Operational Guidelines for Ethics Committees That Review Biomedical Research
- 2) Operational Guidelines for Surveying & Evaluating Ethical Review Practice
- 3) SIDCER Self assessment tool
- 4) Standard Operating Procedures (SOPs) templates for IEC/IRB

ACTIVITIES THAT SUPPORT IEC/IRB RECOGNITION PROGRAMME

- 1) Human Subject Protection Course
- 2) IEC/IRB SOPs writing workshop
- 3) Site Survey and evaluation

EVALUATING STANDARDS FOR RECOGNITION

Ethics Committee will be recognized on the quality of the committee based on five standards

Standard I. STRUCTURE AND COMPOSITION OF ETHIC COMMITTEE

Structure, composition and skills of the EC and staff are appropriate to the amount and nature of research reviewed

Standard II: ADHERENCE TO SPECIFIC POLICIES

Ethics Committee has appropriate management and operational procedures for optimal and systematic conduct of ethical review

Standard III: COMPLETENESS OF ITS REVIEW PROCESS

EC review protocols and its supporting documents in a timely fashion according to an established procedure to protect the interest of research participants

Standard IV: AFTER REVIEW PROCESS

EC should adequately and effectively communicate its decision to investigators

Standard V. DOCUMENTATION AND ARCHIVING

Ethics Committee systematically documents and archives its activities for a good time period

RECOGNITION CERTIFICATE

A certificate of recognition will be issued to an IEC/IRB that meets the five criteria standards. Recognition will be granted for a maximum period of 3 years. The SIDCER committee will have the discretion of awarding recognition for a shorter period and can withdraw recognition at any time if it is established that recognition criteria are no longer being met.

SIDCER ACTIVITIES THAT SUPPORT RECOGNITION PROGRAMME

Module 1: Human Subject Protection Course

Length **Topic (Responsible Organization) Notes *Materials***

DAY 1

- 30 mins. **Registration (Host Institution)**
- 15 mins. **Course Orientation (Host Institution)**
- 45 mins. **Topic 1 – History of Bioethics (Forum)**
 WWII Research, Tuskegee, Other Relevant Studies
- 15 mins. **Break**
- 45 mins. **Topic 2 – Origins of International Guidelines (Forum)**
 Nuremberg Code, Declaration of Helsinki
- 45 mins. **Topic 3 – Overview of Good Clinical Practices**
 History and Theory
 ICH E6 GCP
- 45 mins. **Topic 4 – WHO Operational Guidelines for Ethics Committees (Forum)**
 WHO Operation Guidelines
- 1 hour **Lunch (Host Institution)**
- 45 mins. **Topic 5 – Principles of Research Ethics (Forum)**
 Autonomy, Beneficence, Justice
- 45 mins. **Topic 6 – The Informed Consent Process (Forum)**
- 1 hour **Topic 7 – Research Among Vulnerable Subjects (Forum)**
 **Prisoners, Employees & Students, Medically Vulnerable Groups,
 Fetuses & Children, Culturally Vulnerable Groups & Minorities,
 Economically Disadvantaged.**
- 15 mins. **Break**
- 45 mins. **Topic 8 – Conflict of Interest Issues (Forum)**

Module 1: Human Subject Protection Course

Length	Topic (Responsible Organization) Notes <i>Materials</i>
Day 2	
45 mins.	Topic 9 – Privacy and Confidentiality of Health information (Forum)
2 hours	Topic 10 – Research Methodologies and Ethical Issues in Various Types of Health Research (Forum) Biomedical Research, Medical Devices, Genetic Research & Stored Samples, Social Science & Behavioral Research
15 mins.	Break
45 mins.	Topic 11 – Research Ethics Issues in International Health and Collaborative Research Issues (Forum)
45 mins.	Topic 12 – Risk/Benefit Assessment in Ethical Review (Forum)
1 hour	Lunch (Host Institution)
2 hours	Group Discussion (Forum) Case Studies <i>Case Study Descriptions</i>
30 mins.	Break
1½ hours	Group / Case Presentation (Forum)

Module 1: Human Subject Protection Course

Length **Topic (Responsible Organization) Notes** *Materials*

Day 3

1 hour **Topic 13 – Local Laws and Regulations (Host Institution)**
Additional regional requirements beyond WHO/ICH guidelines
Copies of Applicable Local Requirements

NOTE: IF NO SPECIFIC REGULATIONS, TOPIC 13 COULD BE A SESSION ON RESPECTING LOCAL ISSUES AND CULTURAL NORMS and ON MONITORING LOCALLY IN CASE NEW RULES ARE CREATED.

45 mins. **Topic 14 – Introduction to SIDCER Assessment Tools and Criteria of Recognition (SIDCER or FORUM)**
Assessment Tool
Criteria Documentation

15 mins. **Break**

30 mins. **Topic 15 – SIDCER Recognition Process**
Application and Review
Process Flowchart

1 hour **Lunch (Host Institution)**

1.5 hours **Mock Review – Protocol (SIDCER or FORUM)**
Sample Protocol Materials

15 mins. **Break**

1.5 hours **Mock Review – Informed Consent (SIDCER or FORUM)**
Sample Consent Form Materials

15 mins. **Break**

1 hour **Case Presentation (SIDCER or FORUM)**

Module 2: Standard Operating Procedure (SOP) Workshop

Length Topic (Responsible Organization) Notes *Materials*

Day 1

30 mins	Course Orientation - Importance of Standard Operating Procedures for Ethics Committees	(Forum)
30 mins	Topic 1 – Preparing SOPs and Guidelines for Ethics Committees	(Forum)
	<i>1.1 Writing, Reviewing, Distributing and Amending Standard Operating Procedures for Ethics Committees</i>	
	<i>1.2. Preparation of Guidelines</i>	
15 mins	Break	
45 mins	Topic 2 – Constituting an IEC/IRB	(Forum)
	<i>2.1. Constituting an IEC/IRB</i>	
	<i>2.2. Confidentiality / Conflict of Interest Agreements</i>	
	<i>2.3. Training Personnel and IEC/IRB Members</i>	
	<i>2.4. Selection of Independent Consultants</i>	
1 hour	Workshop 1 – Reviewing and Revising Current SOPs and Guidelines of Ethics Committees	
1 hour	Lunch	
1 hour	Topic 3 – Review Procedures	(Forum)
	<i>3.1. Management of Protocol Submissions</i>	
	<i>3.2. Expedited Review</i>	
	<i>3.3. Initial Review of Submitted Protocols</i>	
	<i>3.4. Review of New Medical Device Studies</i>	
	<i>3.5. Use of Study Assessment Forms</i>	
45 mins	Topic 4 - Protocol Amendments, Continuing Review and End of Study Reports	(Forum)
	<i>4.1. Review of Resubmitted Protocols</i>	
	<i>4.2. Review of Protocol Amendments</i>	
	<i>4.3. Continuing Review of Study Protocols</i>	
	<i>4.4. Review of Final Reports</i>	
20 mins	Break	
2 hours	Workshop 2 – Revising Review Procedures	

Module 2: Standard Operating Procedure (SOP) Workshop

Length Topic (Responsible Organization) Notes *Materials*

Day 3

45 mins	Topic 8 – Preparation of Review Meeting Agenda and Communication Records <i>8.1. Agenda Preparation, Meeting Procedures and Minutes</i> <i>8.2. Emergency Meeting</i> <i>8.3. Communication Records</i>	(Forum)
45 mins	Topic 9– Managing Study Files <i>9.1. Maintenance of Active Study Files</i> <i>9.2. Archiving and Retrieval of Documents</i> <i>9.3. Maintaining Confidentiality of IEC/IRB's Documents</i>	(Forum)
30 mins	Break	
45 mins	Maintaining an IEC/IRB Data Base	(Forum)
45 mins	Topic 10 – Evaluating an IEC/IRB <i>Self Evaluation Tool</i> <i>External Evaluation and Audit</i>	(Forum)
1 hour	Lunch	
2.5 hours	Workshop No. 4 – Managing an IEC/IRB	
15 mins	Break	
1 hour	Group Reports	
15 mins	Synthesis	(Host)

Module 3
SIDCER Surveyor Training Course

DAY 1:

Session 1: Practical Challenges to Ethical Review

9:00-9:15 **Course Overview**

9:15-9:30 Current Challenges to Quality Ethical Review in the Region

Session 2: Establishing a Framework for Evaluating Ethical Review Practices

9:30-10:00 The Purpose of Surveying and Evaluating Ethical Review Practices

10:00-10:15 The Role of a Surveyor in Evaluating Ethical Review Practices

10:15-10:30 Coffee & Tea Break

10:30-11:00 Presentation of the Guideline *Surveying and Evaluating Ethical Review Practices* a Companion Guideline to the TDR/WHO *Operational Guidelines for Ethics Committees That Review Biomedical Research*

11:00-11:30 Presentation on the SIDCER Recognition Requirements

11:30-12:00 Presentation on the SIDCER Recognition Process

12:00-13:00 Lunch

Session 3: Understanding procedures in surveying an EC

13:00-14:00 Introduction of the Survey Plan to the Working Group

14:00-15:00 Presentation of the Standard Operating Procedures for SIDCER Survey

15:00-15:30 Coffee & Tea Break

15:30-17:30 **Working Groups: Practical Session I: Preparing for a Site Visit**

1. References, Standards and Applicable Guidelines (Local, National, International)
2. Evaluation Methodology
3. Definition of Scope, Rationale, Objectives
4. Practical Tools (check list)
5. Reporting and Analysis (format for report writing)

SIDCER Surveyor Training Course

Day 2:

Working Groups Practical II: Site Visit Day 1

- 9:00-10:00 Opening Meeting
- Meeting with the responsible EC Officer and Staff
 - Discussion of the purpose and method of the survey and evaluation
 - Review and discussion of the Survey Plan
 - Review of EC documentation available for the survey and evaluation
 - Review of the agenda
- 10.00-10.30 Observe facilities
- 11:00-12:00 Review of the EC's legal and regulatory framework
- Discussion with the responsible member and/or staff of the EC of the applicable laws and regulations of the country in which the EC is established
 - Discussion of the national and international guidance documents under which the EC operates
- 12:00-12:30 Review of the EC Membership
- Examination of the EC list of members
 - Examination of the EC curriculum vitae
 - Examination of the EC members' terms of reference
- 12:30-13:30 Lunch
- 13:30-14:30 Review of the EC Standard Operating Procedures
- Examination of the EC Standard Operating Procedures
 - Examination of documents available to applicants, regulatory authorities, or the authority under which the EC is established
- 14:30-16:00 Review of the EC Meeting Conduct
- Discussion with the responsible member/staff of the EC
 - Review of the agenda and minutes of sample EC meetings
- 16:00-17:30 Summary of the Day's Findings
- A listing of the strengths of the EC
 - Indications of areas for further consideration

SIDCER Surveyor Training Course

Day 3:

Working Groups: Practical Session II: Site Visit Day 2

- 9:00-12:30 Review of Protocols
- Examination of protocols previously reviewed by the EC
- 12:30-13:30 Lunch
- 13:30-16:00 Review of the SAE and Follow-up Procedures
- Examination of the EC procedures for receiving and reviewing SAE reports
 - Examination of EC policy and procedures for SAE follow-up review
- 16:00-17:00 Summary of Findings and Survey Observations
- Draft list of findings and observations

Day 4

Working Groups: Practical Session II: Site Visit Day 3

- 9:00-12:00 Summary of findings and observations during the previous 2 days
- List of findings and survey observations prepared by the surveyors
- 12:00-13:00 Lunch
- 13:00-15:00 Observe Board meeting
- 15:00-15:30 Summary of Findings and Survey Observations
- 15:30-16:30 Closing Meeting
- Discussion of the findings and observations with the responsible EC member and staff
 - Follow-up activities, if any

Session 5: Follow-up of Evaluations of Ethical Review Practices

- 16:30-17:00 Reports and Follow-up Procedures

ANNOUNCEMENT

FERCAP is currently conducting the following training modules for interested organizations and Ethics Committees in Asia and the Western Pacific that wish to improve ethical review practices:

- *Module 1 – Human Subject Protection Course*
- *Module 2 – Standard Operating Procedure Course*

Ethics Committees who wish to be surveyed for compliance with international guidelines may request for the SIDCER Self Assessment Tool before applying for SIDCER Recognition.

Please contact FERCAP for any inquiry or question.

Contact Person:

Prof. Cristina E. Torres, FERCAP Coordinator

torres@fercap-sidcer.org