

IEC Best Practices: Standard Operating Procedures

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Introduction

- IECs are complex units with multiple moving parts.
- In an IEC humans repeat activities all the time, but not always in a consistent manner.
- Effective IECs minimize human error and inconsistencies by standardizing how they work and documenting the standards.

Learning Objectives

- Identify SOP requirements found in several international standards
- Describe Standard Operating Procedures and differentiate them from other types of guidance documents
- Describe how SOPs can improve the operation of IECs

What are SOPs?

- Detailed, written instructions that describe the steps the ECs follows when conducting their work
- SOPs help the EC to perform its functions consistently.
- SOPs increase efficiency and quality by reducing the chances of human error.

SOPs: ICMR Requirements

- Every IEC should have its own written SOPs according to which the Committee should function.
- The SOPs should be updated periodically based on the changing requirements.
- See reference ***Guidelines for preparing Standard Operating Procedures (SOP) for Institutional Ethics Committee for Human Research.***

SOPs: WHO

- Procedures need to be established for relating various levels of review in order to ensure consistency and facilitate cooperation.
- Recommend “clear procedures” for a number of functions.
- See reference ***Operational Guidelines for Ethics Committees That Review Biomedical Research.***

SOPs: US

- Written procedures... (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject. (46.103(b)(4))
- Written procedures for ensuring prompt reporting ... of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval. (46.103(b)(5))
- See reference ***45 CFR 46 Protection of Human Subjects.***

SOPs vs regulations vs guidelines

- ECs prescribed by international codes (CIOMS) and some national laws
- Codes and Laws incorporate the broad ethical principles
 - Respect for persons
 - Beneficence
 - Justice
- SOPs help define the processes through which ECs follow regulations and guidelines

SOPs Guidelines, Codes and Laws

- SOPs as a way of putting principles, codes and laws into practice
- SOPs derived from codes, laws and guidelines
- SOPs complement codes and national laws

SOPs Promote Principles for Review

- Ensuring Quality in decision making
- Ensure consistency
- Provide a sense of direction
- Reduce confusion and unnecessary delays in the processing of proposals

SOPs support EC reputation

- SOPs provide assurance that the ethical review of proposals is carried out according to established standards:
 - The public
 - Research participants
 - Researchers
 - Other stakeholders
- SOPs promote consistency of EC activities

SOPs and EC AUDITS

- Provide a framework for auditing the activities of the EC
 - They form a standard against which activities can be assessed.
 - Established standards for conducting business and documentation

SOPs promote transparency

- Researchers want to know what is happening behind those closed doors
- SOPs promote efficient communication between the various levels and stakeholders
- SOPs promote a message of integrity of the EC

EC Operating Procedures

- Procedures should be established, documented in writing, and followed, which should include:
 - Determining its composition and authority under which it is established;
 - Establishing what constitutes a quorum;
 - Scheduling, notifying members of, and conducting its meetings;

EC Operating Procedures

- Conducting initial and continuing review
- Determining the frequency of continuing review (no more than 12 months);
- Approval of changes and amendments;

EC Operating Procedures

- Communicating EC decisions to researchers, including the reasons for EC decisions and process for appeal of its decisions.
- Specifying EC reporting requirements:
 - protocol violations
 - all serious adverse events
 - unanticipated problems involving risk to the subject or others
 - other new information that affects the risk / benefit calculation

Reminder

- IECs should have a concise, clear set of SOPs
- All SOPs should be readily available to IEC members and staff, as well as the research community
- SOPs should be reviewed/updated on a recurring basis.