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Surveying and Evaluating Ethical Review Practices

a complementary guideline to the

Operational Guidelines for Ethics Committees That Review Biomedical Research

Comments and suggestions on all aspects of these guidelines are welcome for consideration in future revisions of this document.

World Health Organization
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PREFACE

In 2000 TDR WHO introduced the *Operational Guidelines for Ethics Committees That Review Biomedical Research*, which has contributed globally to the development of independent and competent ethical review. The *Operational Guidelines* provide essential guidance for the development of the constitution, composition, and procedures of ethics committees (ECs) and ethical review systems. The ethical review of research involving human participants provides an essential measure for safeguarding and promoting the protection of persons and communities.

This guideline on *Surveying and Evaluating Ethical Review Practices* is intended to be complementary to the *Operational Guidelines*. Its purpose is to facilitate and support procedures for assisting the development of quality and transparency in ethical review. The Guideline is developed as a means to contribute to the education of ethics committees through review and evaluation of their practices. It is also intended to contribute to justified public confidence in the ethical review of research involving human participants. Finally, this Guideline is intended to assist public authorities and national associations involved with developing ethical review systems in promoting good ethical review practices.

The ethical and scientific standards for carrying out biomedical research on human subjects have been developed and established in international guidelines, including the Declaration of Helsinki, the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, and the WHO & ICH Guidelines for Good Clinical Practice. Adherence to guidelines, as well as national legislation and other instruments, helps to ensure that the dignity, rights, safety, and well being of research participants are promoted and that the results of the investigations are credible.

This Guideline relies on the established standards for international research ethics and Good Clinical Practice as the primary reference for surveying and evaluating the practices of ECs. In particular, the WHO

& ICH Good Clinical Practice Guidelines provide a fundamental framework for appreciating the role and responsibilities of ECs in the research process. The specific needs for the composition and functioning of an EC are provided in the TDR WHO *Operational Guidelines for Ethics Committees That Review Biomedical Research.* The *Declaration of Helsinki* provides a general ethical framework for all persons engaged in the conduct of biomedical research.

1 OBJECTIVE

The purpose of this Guideline is to contribute to an international framework for surveying and evaluating ethical review practices. Ethical review provides essential guidance on research proposals and helps to ensure the protection of participants. The assurance of research protections for individuals and communities requires the establishment of standards for ethical review and the evaluation of the performance of ethical review systems, including the functioning of ECs.

More recently there is growing national and international interest in ensuring that ethical review achieves the highest standards with regard to the protection of individuals and communities. Some countries and regions are in the process of determining methods for evaluating the performance and quality of ECs. In particular, accreditation systems for ECs based on an evaluation of their constitution, Standard Operating Procedures (SOPs), and practices are under development in several countries. This Guideline provides a common reference point for appreciating good ethical review practices and promoting transparency in the work of ECs.

ECs have a public responsibility whose fulfilment requires good practices for ethical review as well as the ongoing education of their members. As part of good practices, there should be a system of quality assurance for surveying and evaluating the performance of ethical review systems. This involves the development by ECs of internal quality assurance mechanisms, such as self-assessment checklists, designed for self-appraisal. Further measures include independent external evaluations of EC practices designed to advise, educate, and improve the ethical review process.

2 THE ROLE OF AN EC

ECs have been established to provide ethical advice to researchers in order to assist decision-making on the adequacy of proposed research projects regarding the protection of potential and actual human partici-

pants. In order to fulfil this role it is essential that ECs are constituted and perform according to four principles for ethical review: independence, competence, pluralism, and transparency.

The *Declaration of Helsinki,* Good Clinical Practice Guidelines, and other international and national instruments require the ethical review of research prior to its commencement. These instruments also require ECs to perform regular follow-ups to research projects for which they have provided a positive decision. In their decision-making, ECs must be independent of the sponsor, the investigator, and any undue influence.

ECs must be appropriately constituted and adopt written SOPs in order to achieve independence and quality in decision-making.

3 THE PURPOSE OF SURVEYING AND EVALUATING ECs

The purpose of surveying and evaluating ethical review practices is to assist ECs in reviewing their practices and appraising performance while also providing a means to assure the public that the ethical review of research proposals is carried out according to established standards. The survey should establish the basis for an independent evaluation that provides relevant information to parties having a legitimate interest in the appropriate functioning of an EC, as defined within the framework of national legislation or mutually agreed to by the surveying entity and the EC. An independent evaluation should provide an opportunity for an EC to receive advice on its constitution and operation.

In recent years ECs along with health ministries and regulatory authorities have taken measures to improve the process of ethical review. In some instances these measures have included independent reviews and evaluations of ECs as a means to improve practices and achieve more confident results. There has also been an interest on the part of researchers and sponsors to have more information regarding the functioning of ECs.

At present only a few countries have a legal or regulatory framework for assisting in the evaluation of ECs, while the framework for the inspection of clinical trials is well established in some countries. This Guideline suggests a cooperative and educative model for surveying and evaluating the work of ECs, being concerned less with 'enforcement' of standards and more with 'learning' from the review of practices.

4 THE APPROACH TO SURVEYING AND EVALUATING ETHICAL REVIEW

A predefined framework should be established for surveying and evaluating ethical review practices. Such a framework may be established by national health or regulatory authorities, or it may be agreed upon in cooperation with national, regional, or international associations. The framework should define the responsible entities for surveying and evaluating ECs as well as the circumstances and frequency of the reviews. Where no predefined framework exists, ECs should be able to avail themselves of surveillance and/or evaluative processes or other quality assurance mechanisms.

Open and frank communication should characterise the surveying and evaluative procedures, with both the independent surveyor and the EC providing a supportive structure. Independent surveyors should be bound by a confidentiality agreement prior to the commencement of the review procedures.

5 SOPs FOR SURVEYING AND EVALUATING ETHICAL REVIEW

SOPs for surveying and evaluating ethical review practices should be developed in advance of the activities taking place. These SOPs should provide detailed guidance on the requirements for assigning independent surveyors, as well as procedures related to conflict of interest and confidentiality, the development of survey plans, the documents to be reviewed, and the writing of the evaluative report and its distribution. The SOPs should be based on the predefined framework for surveying

and evaluating ethical review systems and/or the actual practices of specific ECs. These SOPs should be flexible, where necessary, in order to meet the needs of specific systems and their ECs while permitting comprehensives reviews.

6 ASSIGNING INDEPENDENT SURVEYORS

Independent surveyors should be appropriately trained and qualified for carrying out the review of ethical review practices. The assignment of an independent surveyor or surveying entity should be based on qualifications expressed in SOPs for a regional, national, local, or specific ethical review system.

Independent surveyors should have experience in working with quality evaluation, preferably within ethical review systems. They should also have demonstrated communication skills and preferably experience in education. Independent surveyors should be thoroughly familiar with the requirements, practices, and needs of ECs, and they should be knowledgeable of the legislative and regulatory framework in which the EC to be reviewed is working.

7 CONFLICT OF INTEREST

The independence of the surveyor is an essential guarantee for the validity of the survey and evaluation findings. Any real or potential conflict of interest on the part of an (candidate) independent surveyor should be declared prior to the review activity to both the entity responsible for assigning the independent surveyor and the EC. A conflict of interest on the part of an independent surveyor may include financial, research, and/or professional involvement on the part of the independent surveyor with institutions or persons submitting applications to the EC or direct involvement of the independent surveyor with the EC. Where substantial conflict of interest is determined, the assignment of the independent surveyor should not take place or be withdrawn.

8 CONFIDENTIALITY IN THE SURVEY AND EVALUATION PROCESSES

The survey and evaluation processes should be designed to guarantee the full confidentiality of patients/research participants, community, and research design and data. The independent surveyor should sign a confidentiality agreement prior to the initiation of any survey-related activities that bars the disclosure of information considered confidential to patients/research participants, communities, researchers, sponsors, or the EC itself. Correspondence and information related to the survey and evaluation processes, including the final report, should not contain confidential information. In addition, the findings as well as the final report should be available only to those parties defined in advance by the entity responsible for conducting the survey and evaluation or otherwise mutually agreed to by the independent surveyor and the EC.

9 WORKING DOCUMENTS

An independent surveyor should review the standards, regulations, guidelines, constitution, SOPs, and/or project specific requirements applicable to an EC. In addition, the working documents of an EC may be reviewed, including meeting minutes and official correspondence.

10 SURVEY PLAN

A survey plan should be designed for each review activity, taking into consideration the reason for the review. The survey plan should be drafted by the independent surveyor and communicated in advance to the EC for agreement. The plan should be designed in accordance with an SOP for surveying and evaluating ethical review practices.

The survey plan should include the following:

10.1 identification and location of the independent surveyor;

10.2 identification and location of the EC, as well as the persons responsible for representing the EC during the survey and evaluation;

10.3 identification of the persons to be interviewed by the independent surveyor;

10.4 reason for the survey and evaluation;

10.5 objectives and scope of the survey and evaluation;

10.6 expected time and duration for each major survey and evaluation activity;

10.7 date(s) and location of the survey and evaluation;

10.8 schedule and purpose of meeting(s) to be held between the independent surveyor and the EC;

10.9 language in which the survey and evaluation is to be conducted and any arrangements for translation;

10.10 confidentiality requirements and confidentiality statements;

10.11 identification of reference documents to be used by the independent surveyor (for example, the applicable standards, regulations, guidelines, SOPs);

10.12 documents of the EC to be reviewed (for example, constitution, SOPs, minutes of meetings, relevant correspondence);

10.13 distribution of the report, if applicable;

10.14 foreseen follow-up actions to the survey and evaluation;

10.15 expected date of the survey and evaluation completion.

11 THE CONDUCT OF A SURVEY AND EVALUATION

The survey and evaluation of an EC should be conducted according to a mutually agreed survey plan that includes the following:

11.1 Opening Meeting

The survey and evaluation begins with an opening meeting between the independent surveyor and the representative(s) of the EC. These representatives should be appointed in accordance with the SOPs of the EC or determined by the chairperson of the EC. It is expected that an

officer (for example, chairperson, assistant chairperson, or secretary) will be present at the opening meeting.

The objectives of the Opening Meeting include the following:

11.1.1 review of the purpose and scope of the survey and evaluation;

11.1.2 review of the survey plan;

11.1.3 discussion of the documents to be reviewed;

11.1.4 discussion of the current practices of the EC;

11.1.5 discussion of any considerations relating to laws, regulatory requirements, or guidelines affecting EC practices;

11.1.6 clarification of arrangements for contacting the representatives of the EC during the survey and evaluation;

11.1.7 confirmation of the time and date for the closing meeting.

11.2 Review of Documentation

The independent surveyor is required to review the constitution and SOPs of an EC. The independent surveyor may also need to consider other working documents of an EC, such as the application form, decision form, specific procedures for reviewing certain kinds of protocols, evaluation forms for reviewing applications, and minutes of meetings. The documents to be reviewed may include the following information:

11.2.1 Documents Referring to the Establishment of the EC

11.2.1.1 the authority under which the EC was established;

11.2.1.2 a statement from the EC indicating the relevant laws, regulatory requirements, as well as appropriate national and international guidelines according to which it operates;

11.2.2 Documents Referring to the Membership of the EC

11.2.2.1 the membership requirements;

11.2.2.2 the terms and procedure for the appointment of members of the EC;

11.2.2.3 the conditions of appointment;

11.2.2.4 a listing of current and previous members of the EC;

11.2.2.5 the curriculum vitae of current and past members of the EC;

11.2.2.6 a description of the requirements for holding EC offices (for example, chairperson, secretary);

11.2.2.7 a description of the responsibilities and duties of the offices of the EC;

11.2.2.8 the quorum requirements;

11.2.3 Documents Referring to Applications Made to the EC

11.2.3.1 the published guidelines for submission of applications for the review by the EC;

11.2.3.2 the required documentation to be included in the application;

11.2.3.3 the registration procedure for applications;

11.2.3.4 the maintenance of records for communications regarding the application;

11.2.3.5 the review procedure timelines;

11.2.4 Documents Referring to Review Procedures of the EC

11.2.4.1 the meeting procedures;

11.2.4.2 the provisions and conditions for expedited EC review and decision;

11.2.4.3 the elements of the review of the application;

11.2.4.4 the decision-making procedure;

11.2.4.5 the procedure for communicating a decision;

11.2.4.6 the follow-up review;

11.2.4.7 the documentation and archiving procedures;

11.2.5 Documents Referring to Actions Taken by the EC

11.2.5.1 the materials submitted by applicants;

11.2.5.2 the correspondence regarding applications, decisions, and follow-ups;

11.2.5.3 the record of incomes and expenses of the EC;

11.2.5.4 the agenda of EC meetings;

11.2.5.5 the minutes of EC meetings;

11.2.5.6 the decisions and advice provided to applicants;

11.2.5.7 interim and annual reports during follow-up;

11.2.5.8 notifications of completion or premature study suspensions/ terminations;

11.2.5.9 final summaries or reports of studies;

11.2.5.10 regular (annual) reports of the EC.

The independent surveyor should also review the manner in which documents are filed and stored, including previous versions of the EC constitution and/or SOPs.

11.3 Survey Observations

All survey findings should be documented. Following the survey, the independent surveyor should review the findings and present an evaluation. The independent surveyor should ensure that these findings are documented in a clear and concise manner, without disclosing any patient/participant, researcher, sponsor, and EC information of a confidential nature. The findings should be, where possible, supported by objective evidence and reference made to the relevant requirements. The evaluation based on the findings should assist the EC in improving its working procedures.

11.4 Closing Meeting

At the conclusion of the survey and evaluation, a meeting should be held with the independent surveyor and EC to review the findings and clarify any misunderstandings. The meeting should be of a mutually supportive nature.

11.5 The Report

The report should reflect the findings and evaluation of the independent surveyor. It should be dated and signed by the independent surveyor and contain, at the minimum, the following items:

11.5.1 identification of the independent surveyor;

11.5.2 identification of the EC and the representative(s) of the EC;

11.5.3 objectives and scope of the survey and evaluation;

11.5.4 survey plan;

11.5.5 identification of the facilities, persons interviewed, and the documents reviewed;

11.5.6 findings of the survey;

11.5.7 the independent surveyor's evaluation based on the findings;

11.5.8 observations and recommendations for corrective actions or areas of suggested revisions in practice;

11.5.9 report distribution list;

11.5.10 signature and date of the independent surveyor.

Both the independent surveyor and the EC should retain a copy of the report for the same time period for which the EC stores essential records.

11.6 Addressing the Independent Surveyor's Findings and Evaluation

The EC is responsible for determining, initiating, and completing the actions required to address the findings and evaluation as presented in the report. These actions and a time period for their accomplishment

should, if appropriate, be communicated to the independent surveyor within a reasonable time period following the receipt of the report.

11.7 Follow-up

A follow-up survey and evaluation may be appropriate. A survey plan should be prepared by the independent surveyor for the follow-up review and agreed to by the EC. The EC is responsible for determining, initiating, and completing the actions required to address the findings and evaluation as presented in the follow-up report.

11.8 Final Report

The independent surveyor should present a final report containing the final set of findings and an overall evaluation supported, where possible, by objective evidence. The final report should be communicated to the entity under which the survey and evaluation takes place, the EC, and others as defined within the framework of national law or as mutually agreed by the surveying entity and the EC.

GLOSSARY

The definitions provided within this glossary apply to terms as they are used in these Guidelines. The terms may have different meanings in other contexts.

Community

A community is a group of people understood as having a certain identity due to the sharing of common interests or to a shared proximity. A community may be identified as a group of people living in the same village, town, or country and thus, sharing geographical proximity. A community may be otherwise identified as a group of people sharing a common set of values, a common set of interests, or a common disease.

Confidentiality Agreement

An agreement signed by the independent surveyor prior to the initiation of a survey or any survey-related activities that bars the independent surveyor, the survey and evaluation process, and the report from the disclosure of any patient/participant, researcher, sponsor, and EC information of a confidential nature.

Conflict of Interest

A conflict of interest arises when an independent surveyor holds any real or potential financial, research, and/or professional interests that may affect the validity of the survey findings and evaluation.

Constitution

A document establishing the authority under which an EC is established, the mandate and remit of an EC, and general provisions for its activities. The term 'constitution' may be replaced at times by other terms, such as 'terms of reference'.

Decision

The response (positive, conditional, or negative) by an EC to an applicant following the review of an application.

Evaluation

The assessment by an independent surveyor of the strong and weak points of an EC's practices based on the findings of a survey.

Findings

The findings of a survey based on the purpose of the survey and the materials reviewed by the independent surveyor. The findings should refer to specific observations made by the independent surveyor and be supported by objective evidence. Findings express the independent surveyor's conclusions regarding specific procedures or systems reviewed according to the relevant requirements. The findings are the basis for the independent surveyor's evaluation of the ethical review practices of an EC.

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and the rights, integrity, and confidentiality of research participants are protected.

Independent Surveyor

The person(s) responsible for carrying out the survey and evaluation of an EC.

Report

A written evaluation by the independent surveyor of the results of the survey and evaluation. The report may take the form of an 'initial report', 'follow-up report', or 'final report'. In all cases the report should not

disclose any patient/participant, researcher, sponsor, and/or EC information of a confidential nature.

Research Participant

An individual who participates in a research project, either as the direct recipient of an intervention (for example, study product or invasive procedure), as a control, or through observation. The individual may be a healthy person who volunteers to participate in the research, or a person with a condition unrelated to the research carried out who volunteers to participate, or a person (usually a patient) whose condition is relevant to the use of the study product or questions being investigated.

Sponsor

An individual, company, institution, or organisation that takes responsibility for the initiation, management, and / or financing of a research project.

Standard Operating Procedures (SOPs)

Detailed, written instructions to achieve uniformity in the performance of a specific function.

Survey

The activity of reviewing ethical review practices, usually those of a specific EC, in order to analyse and evaluate those practices with a view toward quality improvement and transparency.

Survey Plan

A plan setting out the specific practices, resources, activities, and timelines relevant to a particular survey and evaluation.

SUPPORTING DOCUMENTS

Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO). *International Ethical Guidelines for Biomedical Research Involving Human Subjects.* Geneva 1993.

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International Research and Drafting Committee

Francis P. Crawley (Chairman)
European Forum for Good Clinical Practice

Odette Morin Carpentier
International Federation of Pharmaceutical Manufacturer's Association

Chifumbe Chintu
Pan-African Bioethics Initiative

Vichai Chokevivat
Forum for Ethical Review Committees in Asia & Western Pacific

Christiane Druml
Ethical Review Committee, Vienna University School of Medicine, Austria

Elaine Esber
Merck Sharp & Dohme

Dafna Feinholz
Foro Latino Americano de Comités de Ética en Investigacion en Salud [Latin American Forum of Ethics Committees in Health Research] (FLACEIS)

Victoria Hale
Institute for One World Health, USA

Kenji Hirayama
Saitama Medical School, Japan

Greg Koski
Office for Human Research Protections
Department of Health and Human Services, USA

Olga Kubar
Forum for Ethics Committees in the Confederation of Independent States

James Lavery
National Institutes of Health, USA

David Lepay
Food and Drug Administration, USA

Melody Lin
Office for Human Research Protections
US Department of Health and Human Services, USA

Marianne Maman
Novartis Pharmaceuticals

Vasantha Muthuswamy
Indian Council of Medical Research

Sara Radcliffe
Pharmaceutical Research & Manufacturers Association of America

John Richardson
Central Office for Research Ethics Committees, United Kingdom

John Sweatman
European Forum for Good Clinical Practice

Fergus Sweeney
European Agency for the Evaluation of Medicinal Products

Nadia Tornieporth
GlaxoSmithKline Pharmaceuticals

Peteris Zilgalvis
Council of Europe

Secretariat

Juntra Karbwang (Project Coordinator)
TDR/WHO

Howard Engers
TDR/WHO

Christine Encrenaz
Essential Drugs & Other Medicines, WHO

Chen Ken
WPRO/WHO

Adik Wibowo
SEARO/WHO

Comments and suggestions on all aspects of these guidelines are welcome for consideration in future revisions of this document. Please correspond with:

Dr Juntra Karbwang
Clinical Coordinator
Product Research and Development
TDR/CDS/WHO
CH-1211 Geneva 27
Switzerland

Tel (41) 22 791 3867/8
Fax (41) 22 791 4854
E-mail: karbwangj@who.ch