

**Standards and Guidance for Research Ethics Committees that
Review Health Related Research with Human Beings**

**Draft document
For comments only.**

Version 3, 16th July 2010

**This version in its current form needs both general and
professional editing**

**We would like to acknowledge the contributions of all the experts
who provided valuable comments on the first version of this
document.**

NOT FOR CIRCULATION

PREFACE

This document is meant for Research Ethics Committees (RECs) that review any and all types of health-related research with human beings, including biomedical, behavioural, social science, and epidemiological research involving either direct interaction with human beings or the analysis of biological samples and/or identifiable data derived from human beings. Throughout this document, the term "research" is meant to include and refer to all of these types of human research.

Ethics guidance for carrying out research involving human participants has been developed and outlined by different organizations and agencies at the international, regional and national levels. There are international Declarations and Conventions like *Universal Declaration on Bioethics and Human Rights* (UNESCO, 2005) and the *Oviedo Convention (including The Additional Protocol to the Convention on Human Rights and Biomedicine on Biomedical Research)* which are legally binding, international Declarations and Guidelines like *the Declaration of Helsinki* (WMA, updated in 2008) and the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS, 2002), that are not legally binding, but are widely accepted as the national norm, as well as national regulatory or guidance documents like the *Belmont Report* (U.S. Department of Health, Education, and Welfare, 1979) and *The Ethics of Research Related to Healthcare in Developing Countries* (U.K., the Nuffield Council on Bioethics, updated in 2005). Adherence to these guidelines, and the principles outlined within them, helps to ensure that the dignity, rights, safety, and well-being of research participants are promoted.

Comment [s1]: This para can be further strengthened, if required

A core requirement outlined in all of the international guidelines above is that ethical review of human research by an independent and competent research ethics committee (REC) takes place prior to the commencement of research. Such review is intended to ensure that the ethical principles and practices put forward in international ethics guidelines will be followed in the proposed research, including that the study is scientifically valid, that risks of harm are minimized to the extent possible, that the potential benefits outweigh the risks of harm, that selection and recruitment of study participants are equitable and fair; that participants or their representatives provide voluntary informed consent, and that the goals of research do not significantly compromise the health, rights, well-being, or care of research participants and/or research communities.

In 2000, the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR), published the "*Operational Guidelines for Ethics Committees that Review Biomedical Research*", in response to requests from collaborating researchers throughout the world. These Guidelines were reviewed by multiple experts, stakeholders, researchers, and organizations, including the African Malaria Vaccine Testing Network, Council of Europe, National Institutes of Health (USA), the International Conference on Harmonization, and the World Medical Association, and since then have been widely disseminated and used, having been translated into more than 25 languages and used in more than 100 countries.

Ten years later, in November 2009, WHO organized a consultation of key experts in Geneva, including researchers, ethicists, members and chairs of ethics committees, and representatives of international organizations¹ to discuss what additional guidance, if any, is needed for RECs globally, given that RECs continue to be quite variable in terms of their experience, training, capacity, institutional support, human and financial resources, and expertise. Participants recommended that based on the experience from the field, the 2000 Operational Guidelines have been an invaluable resource, but now should be updated and strengthened. The meeting also recognized that Member States may find it useful to have a set of global *standards* available to help define what quality functioning means for RECs and against which RECs might measure their own performance.

Recognizing that currently available international codes and documents outline certain requirements for committees -- for example, that RECs must be multidisciplinary and reviews should be based on ethics principles -- stakeholders and experts recommended that a comprehensive set of standards for RECs should be created, representing core, non-negotiable aspects of REC governance and operations. Further, such standards and guidelines should be promulgated by international, intergovernmental organizations. The recommendation was made for the World Health Organization to coordinate efforts to draft standards for RECs and to revise the 2000 Operational Guidelines to describe specific procedures to meet the standards.

STANDARDS AND GUIDELINES: Standards are defined as a set of rules for ensuring high quality performance and a common language, that establish parameters against which achievements can be benchmarked (*Provide reference for this definition here*). Standards are generally issued by organizations with credibility within the relevant field after a process of consensus and wide input. The Standards put forward in the current Document do not represent new ideas for REC functioning. Rather, they are based on requirements for RECs delineated in existing international ethical Guidelines, Declarations and Conventions and on policies and regulations for research oversight in many countries of the world. The standards included here are intended to contribute to the quality of ethical review of research and to ensure a shared expectation for RECs at the broadest level. The guidelines that accompany each standard explain the standard and provide commentary on its implementation. While standards are non-negotiable, guidelines allow more discretion at the local level. As such, the guidelines recommend commonly used strategies for implementing and fulfilling each standard, but local context may sometimes suggest a different approach. The guidance points included in this document remain mostly unchanged from the 2000 Operational Guidelines. Where appropriate, guidelines have been updated and the order in which they are presented has been reorganized to accommodate the Standards.

These Standards and Guidelines are intended to complement existing laws, regulations, and practices, and to serve as a basis upon which research ethics committees (RECs) can develop their own specific practices and written procedures. They do not, in any way, purport to replace

¹ Attendees included representatives from UNESCO, the World Medical Association (WMA), Council for International Organization of Medical Sciences (CIOMS), the Council of Europe (CoE), the Nuffield Council on Bioethics, the Wellcome Trust, Council on Health Research for Development (COHRED), and Program for Appropriate Technology in Health (PATH) and REC members or staff persons from Botswana, Brazil, China, India, Morocco, and Uganda.

the need for national and local guidelines for the ethical review of research involving human beings, nor do they intend to supersede national laws and regulations. Indeed, it is hoped that these standards may be useful in drafting national, local, and institutional regulations and policies as needed.

In drafting these standards, we acknowledge that, while REC review is recommended by all international ethical codes and guidelines, more research evidence is needed about how the process protects research participants.

I. The Research Ethics System

The primary purpose of an REC is to help safeguard the rights, safety, and well-being of prospective or enrolled research participants and the communities of which they are a part. RECs also help ensure that the conduct of research is valid and fair.

While the primary focus of this document is standards and guidelines for research ethics committees, there is a growing understanding that RECs are part of a larger system of human research protections, and unless attention is given to that larger system, RECs may become isolated or be unable to perform efficiently or effectively, despite their best intentions.

A systems approach means that:

1. RECs are part of a human participants protection program within the organizations or institutions in which they are situated that also includes training for REC members and investigators and mechanisms to ensure that the REC works efficiently and effectively;
2. Procedures exist to ensure clear and efficient communication, harmonization of standards, networking, and cooperation among national committees and institutional and local committees (or between different levels of committees), as applicable. In addition, procedures exist for the coordinated review of multi-site research, whether within a country or in more than one country.
3. Mechanisms are in place for obtaining community input into the system;
4. Countries have policies requiring all human research to be reviewed by an REC, consistent with international guidance.

At the national level, a research ethics system in addition to the above includes (WE WILL NEED MORE SUBSTANCE HERE) qualified researchers, local legislation to protect the rights and fundamental freedoms during research, the establishment of a national registry of committees and a national registry of all research conducted in that country. .

The standards listed in this document are directed towards the entity that establishes the REC, the REC itself, and the staff that supports the REC.

Add a 'Box' explaining different approaches to ethics review in different countries – in some countries review may occur only at institutional level, in others both at national and at institutional level, and there may be differences in the way that different Committees communicate with each other. Such differences may create difficulties for multi-national research projects, and having a good Systems approach and clear rules of how different Committees within a country interact with each other can facilitate greatly the conduct of international health research, an increasingly common occurrence.

Add another “ Box” explaining types of research studies reviewed by RECs acknowledging that the focus of different types of research is different (research on individuals vs. research on communities, clinical vs. social sciences research, research on patients vs. research on health care providers, clinical research vs. quality improvement research etc.) and that the methodology and the ethical considerations in each type of study is likely to be different and that RECs reviewing particular types of research should be familiar with these differences This would then link or provide an explanation for point 1 under the 1st Standard that RECs should include individuals with scientific expertise relevant to the types of research that the committee is most likely to review.

II. STANDARDS AND GUIDANCE FOR THE ENTITY ESTABLISHING THE REC

STANDARD 1

The research ethics committee must be multidisciplinary and multisectoral, comprised of individuals with varied backgrounds relevant to the areas of research the committee will review, be sensitive to the diversity of local cultural values, must rotate periodically, and must seek to strike a balance with regard to gender.

The entity establishing the REC should appoint members to the REC and should create Terms of Reference for them. The entity should take the following into consideration when appointing members:

1. committee membership should include individuals with scientific expertise relevant to the types of research that the committee is most likely to review, those with social sciences/humanities background, as well as enough members whose background is not in science or research to ensure that such members feel comfortable voicing their views;

Comment [s2]: This sentence requires some professional editing

2. membership should be age and gender balanced

3. except for National Committees and committees that review international cooperative research projects that are conducted in other countries, membership should include lay persons to represent the communities that are taking part in research. Such lay persons should have received basic training in research methods.

4. membership should not include more than 50% of members of the same category or background.

5. in order to enhance independence, committee membership should include at least one member who is not affiliated to the institution where the REC is based;

6. members should be sensitive to the social and cultural values of potential participants.

STANDARD 2

RECs must be supported with adequate staffing, facilities, and financial resources to allow them to carry out their responsibilities

RECs should be established as integral parts of the institution or health system and must be provided with necessary organizational support. This means that RECs should have:

1. adequate support staff for carrying out their responsibilities;

2. adequate resources for support staff to carry out their required functions, including office space to conduct administrative business and to store and lock all committee files and

documents, computers, stationery, communication facilities, photocopying, storage space, , and meeting space for the committee;

3. adequate financial resources to ensure quality assurance of its work;
4. any other resources, as needed, to ensure committee independence (both financial and technical) from other parts of the Organization.

STANDARD 3

Independence in both REC operations and decision-making must be ensured

The entity establishing the REC should have publicly available policies that require that the REC is not pressured to approve or disapprove particular protocols. This means that:

1. the composition of the REC as well as its Terms of Reference should ensure its independence;
2. RECs should operate under policies requiring decision making that is independent and free from bias or influence;
3. investigators and funders should not be involved in decisions about their own proposals or those with which they are directly linked or those submitted by their close colleagues;

STANDARD 4

Training must be provided to REC members when they join the committee and periodically during their committee service. Training should relate to ethics considerations for research and how those ethics considerations apply to different types of research projects.

1. the entity establishing the REC should provide or ensure the provision of training for REC members both when they join and at periodic intervals during service. Training should focus on:
 - 1) ethics principles relevant to research with human beings;
 - 2) how ethics principles apply to different types of research;
 - 3) how different ethics requirements are sometimes in tension and how to resolve the tension;
 - 4) how different scientific designs and considerations affect the ethics of a research study
 - 5) providing those committee members who have little or no background in research, the necessary training in research methodology and design, and why these are used to answer certain types of research questions, in order to assure that each member has a basic competency to understand and assess the acceptability of submitted proposals;
 - 6) how to review research proposals.

2. entities establishing RECs may link with co-operative arrangements with other RECs in the area, the country, and the region, as well as other opportunities for the initial and continued training of REC members.

STANDARD 5

Quality assurance mechanisms must be established and implemented as part of REC operations.

1. The entity establishing a REC should ensure that procedures are in place to evaluate whether the committee routinely follows its own SOPs, for example in how proposals are submitted, reviewed, documented, and whether key ethics criteria outlined in SOPs are being considered and followed, and to measure the extent to which the goals of REC review are actually being achieved;

2. Such evaluations should be conducted at regular, pre-defined intervals, using a pre-defined format, should be independent, and should aim towards assisting the REC in reviewing its practice and appraising performance and impact, rather than apportioning blame;

3. Such evaluations are also a means of assuring the public that the ethical review of research proposals is carried out according to established standards

4. Internal quality assurance mechanisms should be supplemented by independent external evaluations;

5. The entity establishing the REC must have a commitment to follow-up on the recommendations of the internal and external evaluations.

III. STANDARDS and GUIDANCE FOR MEMBERS OF THE RESEARCH ETHICS COMMITTEE

The primary task of an REC is the review of research proposals and their supporting documents. Approval or disapproval will be based on the *ethical acceptability* of the research, including the social value of the research, scientific validity, an acceptable ratio of potential benefit to risks of harm for the participants and their communities, minimizing risks of harm, adequate informed consent procedures including cultural appropriateness and mechanisms to ensure voluntariness, measures to ensure protection of vulnerable populations, fair procedures for selection of participants, and fair benefits for study populations. Reviews should take into account any prior scientific reviews and applicable laws.

STANDARD 6

Ethical criteria and reasoning must form the basis of review decisions

Committees should consider the following criteria in conducting reviews, and develop a checklist that they can use in reviewing proposals to ensure that all relevant criteria are considered during review.

1. Scientific Design and Conduct of the Study

Research is ethically acceptable only if it is scientifically valid. Research that is not valid exposes research participants to risks of harm with or without possible benefit. RECs must have evidence from a prior scientific review, or must themselves determine, that the research methods are scientifically sound, and should examine the ethical implications of the chosen research design or strategy. This means that:

1.1 the study design is appropriate to address the study objectives. Statistical or other analytic approaches are appropriate to answer the research questions, and study methods and proposed sample sizes generally have the potential for reaching sound conclusions;

1.2 the research is based on a review of the relevant scientific literature, other relevant sources of information, and, as appropriate, adequate laboratory and/or animal experimentation;

1.3 research is reviewed by appropriately skilled reviewers or by specialist consultants to ensure that appropriate scientific standards are applied to verify the validity and rigor of the proposal, e.g. qualitative research is reviewed by social scientists, and public health research is reviewed by experts in the field of public health research;

1.4 the investigator has the experience and qualifications to direct the study to ensure that it is conducted in accordance with the study proposal and following the scientific methods described.

2. Anticipated Risks of Harm and Potential Benefits

Ethically acceptable research ensures that the potential benefits and risks of harms are reasonably balanced. The nature of the harm (and benefits) may differ according to the type of research to be conducted, and members of RECs should be aware that the harm may occur in different dimensions e.g. physical, social (e.g. related to stigma), psychological (e.g. related to anxiety or emotional distress), and that one type of harm is not lesser than another type of harm, and in general, all type of harm must be avoided. Further harm may occur either at an individual level or at the population level, as in the case of public health research.

Therefore, when reviewing research proposals:

2.1 RECs should identify ways to minimize risks of harm, to the extent reasonably possible, both by preventing potential harms and minimizing the negative impact of harms should they occur;

2.2 RECs should ensure that there is an appropriate balance between any potential benefits and risks of harm, and that where there is little or no benefit expected to the individual (there may be wider or later benefits to groups or communities), the risks of harm are minimal;

2.3 the following should be considered, as relevant, in determining whether the ratio of anticipated risks of harm to potential benefits is acceptable:

- a) the nature or type of harm (for example, clinical, psychological, social, economic, legal etc.), the probability of the harm occurring, and the severity and permanence of the harm, if it were to occur;
- b) the potential benefits for the research participants and the concerned communities;
- c) measures in place to minimize or respond to harms or adverse events if they occur, including referring participants to healthcare providers when a condition is diagnosed as a result of research intervention;
- d) Will the research directly benefit potential research participants, and/or their communities in both the short and the long terms? And what are the indirect benefits?
- e) What are the risks of harm for the potential research participants to take part in this research? Does the research have the potential to worsen their health, relational,

- economic, social, cultural and political conditions?
- f) what additional safeguards, as appropriate, have been provided for vulnerable populations or those who need special protections e.g. do the results benefit these populations specifically and is there no other way to obtain the results.
 - g) the adequacy of the site, including the supporting staff, available facilities, and emergency procedures;
 - h) the nature of the control in a randomized control trial, and the justification for any plans to withdraw or withhold standard therapies for the purpose of research;
 - i) criteria for prematurely withdrawing research participants;
 - j) criteria for suspending or terminating the research study;
 - k) the adequacy of provisions made for ongoing monitoring and auditing of the research, including the constitution of a data safety monitoring board (DSMB), when applicable;
 - l) any medical or psychological care to be provided to participants either during or after the study, or if they should require it as a direct result of any study interventions, interviews, or procedures;
 - m) steps taken to reduce discrimination or stigmatization posed through genetic or any other type of research that may create social risks to participants or communities;
 - n) any risks of harm posed to family members, communities, institutions, or others through the research, e.g., through generating genetic information, information about communicable or stigmatized conditions, or other research that may reveal information about others;
 - o) steps to be taken if research participants voluntarily withdraw during the course of the research;
 - p) the criteria for extended access to, the emergency use of, and/or the compassionate use of study products, if applicable;
 - q) a description of any plans to make the study product, program, or intervention available to the research participants following the research, if applicable;
 - r) if a clinical trial, require that it will be listed in an appropriate registry before recruitment of the first participant;
 - s) the manner in which the results of the research will be reported and published.

3. Selection of study population and recruitment of Research Participants **(do we need a separate section for social value?)**

Ethically acceptable research ensures that no group or class of persons bears more than its fair share of the burdens of participation in research. Similarly, no group should be deprived of its fair share of the benefits of research; these benefits include the direct benefits of participation as well as the new knowledge that the research is designed to yield.

Fair participants selection requires that the scientific goals of the study, rather than vulnerability, privilege, or other factors unrelated to the research questions, be the primary basis for who is selected for participation.

RECs should examine:

3.1 the characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, and ethnicity);

3.2 the relevance of the research question to the interests of the selected population, particularly if inclusion of a vulnerable or disadvantaged population is proposed;

3.3 inclusion and exclusion criteria for research participants and justifications for same;

3.4 justifications for inclusion of particularly vulnerable populations, especially those with limited decision making capacity or those whose decision on participation may be compromised by their special social, cultural or economic situations, like being employees of sponsors or members of armed forces;

3.5 whether any classes of participants, including women, pregnant women, or children, are systematically excluded, and whether justifications for such are scientifically appropriate;

3.6 whether recruitment of potential participants is occurring in ways that violate the rights of participants or have the potential for stigmatizing individuals or communities, particularly those already considered to be vulnerable to harm or exploitation;

3.7 the means by which initial contact and recruitment will be conducted (e.g., through another health care provider, through flyers, through radio announcements) including its potential impact on voluntariness.

4. Inducements, financial benefits, and financial costs

It is considered ethically acceptable and appropriate to reimburse participants for any costs associated with participation, including transportation, childcare, or lost wages. Many committees also believe it is ethically acceptable to pay participants for their time. Payments should not be so large, however, or free medical care so extensive, as to induce prospective participants to consent to participate in the research against their better judgment or to compromise their understanding of the research ("undue inducement").

RECs should review, as applicable:

4.1 a description of any financial costs to research participants including any medical costs not covered by the study;

4.2 any money, services, medicines, or gifts provided to participants or reimbursement for their time, travel or lost wages;

4.3 the provisions for compensation/treatment in the case of the injury/ disability/ death of a research participant attributable to participation in the research;

4.4 the insurance and indemnity arrangements.

5 Protection of Research Participants' Privacy and Confidentiality

Unauthorized invasions of privacy and breaches of confidentiality are both disrespectful to participants and can lead to feelings of loss of control or embarrassment as well as tangible harms such as social stigma, rejection by families or communities, or lost opportunities such as employment or housing. Researchers must take precautions to avoid unnecessary invasions of privacy and breaches of confidentiality.

RECs should review:

- 5.1 who will have access to personal data of the research participants, including medical records and biological samples;
- 5.2 whether the number of persons with access to personal data has been minimized, to the maximum possible extent;
- 5.3 measures taken to ensure the confidentiality and security of personal information concerning research participants;
- 5.4 measures taken to design recruitment or data collection procedures such that participants cannot be identified in ways that may be stigmatizing or harmful to them;
- 5.5 measures by which data or biological samples to be stored beyond the duration of the study will be protected and who, including those not involved with the initial study, may have access to those data or samples and under what conditions;
- 5.6 any limits of confidentiality that may apply, e.g., mandatory reporting laws.

6 Informed Consent Process (this section needs edition, to separate the informed consent process and its documents)

The ethical foundation of informed consent is the principle of respect for persons. Competent individuals are entitled to choose freely whether to participate in research, and they are able to do so only if they adequately understand what the research entails. Those who are unable to give fully autonomous or adequately informed consent are deserving of additional protection.

As such, RECs must examine:

- 6.1 a full description of the process for obtaining informed consent, including whether informed consent will be oral or written, the language used in the informed consent process, and the timing of the information discussed relative to asking for consent; (the timeline of this process);
- 6.2 who will be responsible for obtaining consent and qualifications of such persons the adequacy, completeness, and understandability of written and oral information to be given to the research participants, and, when appropriate, their legally acceptable representative(s);
- 6.3 the means by which the voluntary nature of participation will be assured, taking into consideration the cultural sensitivity in relation to the understanding of autonomy. The RECs should ensure that individuals are not put at risk while pursuing individual consent, nor is the research perpetuating an imbalanced access to research because of cultural issues.
- 6.4 if a vulnerable population is participating in research, then what specific methods have been proposed by the research team to approach, inform and discuss the research project with these potential research participants, and if necessary, their proxies, families and/or communities? And who is responsible for this continuous process?
- 6.5 if appropriate, measures to assess participants' understanding of the consent process, especially if the study entails more than a moderate increase over minimal risk in a vulnerable community;

6.6 clear justification for the intention to include in the research individuals who cannot give consent, and a full account of the arrangements for obtaining assent from such persons when possible and permission or authorization for their participation from culturally, traditionally, ethically and/or legally acceptable representatives;

6.7 assurances that research participants will receive information that becomes available during the course of the research relevant to their participation (including to their rights, safety, and well-being);

6.8 the provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project;

6.9 the existence and composition of a Community Advisory Board or any type of community intermediaries;

6.10 clear justification for a request to waive informed consent, if applicable, including that such waivers are only requested for research that poses minimal risks of harm to participants;

6.11 procedures for seeking consent for the collection, analysis, storage, or future use of identifiable human material, tissues, blood, or data, if applicable.

7. Community Considerations

Research has impacts not only on the individuals who join but also on the communities where research occurs and/or to whom findings can be linked. Duties to respect and protect communities require examining and minimizing any negative effects on communities such as stigma or draining of local capacity, and promoting, as relevant, positive effects on communities including those related to health effects or capacity development. Researchers should actively engage with the participating communities in decision making while being sensitive to and respecting their cultural, traditional and religious practices.

RECs may want to examine:

7.1 the impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn;

7.2 the steps taken to consult with the concerned communities, if applicable. The process should start with research planning and design, and continue across the entire life cycle of the proposed research, from input into proposal development through to access to any proven and successful product

7.3 the influence of the communities on the ability of individuals to act autonomously.

7.4 the extent to which the research contributes to local capacity building, such as the enhancement of local scientific or other skills development, healthcare, research, and the ability to respond to public health needs;

7.5 a description of the availability and affordability of any successful study product to the concerned communities following the research;

7.6 the manner in which the results of the research will be made available to the research participants and the concerned communities;

7.7 assurance that both positive and negative or inconclusive results will be published or otherwise made publicly available, including mechanisms for avoiding breaches of confidentiality;

7.8 assurance in the case of a clinical trial that it will be registered on a publicly available trials registry.

STANDARD 7

Committees must ensure that research respects the dignity, human rights and fundamental freedoms of all research participants, and ensure that the health and welfare of study participants is maximized in the research.

Consistent with international documents, research must not violate human rights or fundamental freedoms of research participants. Further, research should be respectful of all human beings, including those in situations or political contexts that may not be respectful of their full moral worth, and this is relevant to all aspects of research such as recruitment, informed consent, rights to privacy and confidentiality.

RECs should examine, during the review of a proposal that:

7.1 researchers have taken steps to ensure that participants understand that they are free to agree or refuse participation in research;

7.2 adequate steps have been taken to avoid undue inducement coercion, threats, and the perception of such coercion or threats;

7.3 research is respectful of human rights, and does not expose individuals to human rights abuse;

7.4 research does not expose some or all research participants to scrutiny or oppression by others either due to their gender, race, ethnicity, culture, tradition, religion, political status, or other status such as being confined prison, or suffering from a stigmatizing illness or a communicable disease.

STANDARD 8

Committee deliberation on research proposals must be respectful and inclusive, and procedures in place to manage biases and conflicts of interest.

During meetings of REC, members should engage in discussions to elicit all concerns and opinions related to proposed research. Committees should establish procedures to ensure that discussions are respectful of all opinions and allow for varied beliefs to be aired and heard. One of the roles of the Chair of the REC is to foster a respectful and inclusive tone and to ensure adequate deliberation occurs before decisions are reached.

During Committee deliberations:

8.1 the Chair of REC Meetings should encourage inclusive discussions, allowing for varied points of view to be raised and debated respectfully, and for majority or consensus views to emerge from the discussions;

8.2 there should be a period of discussion that includes only REC members and staff who have no direct conflicts related to the proposal (that is, absent of consultants, investigators, and funders directly associated with the proposal in question);

8.3 decision should be made only by those who were present during the discussion. Decision making must occur absent of investigators, funders, and consultants;

8.4 decision making should occur only when a quorum (see below) is present;

8.5 there should be a predefined method for arriving at a decision (e.g., by consensus, by vote); it is recommended that decisions be arrived at through consensus, where possible; when a consensus appears unlikely, it is recommended that the REC vote.

For lower risk proposals Committees may decide to establish written procedures by which review may occur on an expedited basis, instead of full committee review.

IV. STANDARDS AND GUIDANCE FOR SECRETARIAT OR STAFF FOR THE REC

STANDARD 9

All RECs must have written Standard Operating Procedures that outline specific policies related to membership, Committee governance, review procedures, decision-making, communicating, following-up, and monitoring, documentation and archiving, training, and quality assurance.

It is an institutional responsibility to establish a supporting secretariat or REC staff which is essential for the efficient and effective functioning of a REC. REC/Secretariat staff should work with the representatives of the entity establishing the REC and the REC members to ensure that the committee has written standard operating procedures (SOPs). These SOPs should outline all aspects of REC functioning and operations and should state policies related to training, independence, and quality assurance. SOPs should be distributed to all committee members, should be publicly available, and should be reviewed periodically to determine if any revisions are needed. The SOPs should in general be formally approved by the REC's host institution.

SOPs generally should include procedures and policies to address the following topics:

9.1 Membership of the Committee

a. Authority for appointment of committee members

SOPs will generally address the name or description of the party responsible for making appointments; and have procedures for

- i. selecting and appointing REC chair and members, including the method by which new members are selected (e.g., by consensus, by majority vote, by direct appointment);
- ii. avoiding conflicts of interest in making appointments, but where unavoidable, procedures for disclosures and maintaining transparency.

b. Terms of appointment

(Should 'conflicts of interest' be addressed in a separate, explicit section?)

The SOPs should provide information on members' terms of appointment including:

- i. the duration of an appointment;
- ii the policy for the renewal of an appointment;
- iii the disqualification procedure;
- iv. the resignation procedure;
- v. the replacement procedure.

Staggered, finite terms of appointment should be considered, allowing continuity of some members when other members are newly appointed. Having limited terms also promotes the development of research ethics expertise and greater knowledge of REC procedures among the

larger community of scientists or non-scientists who may rotate through committee service, and allows for input of fresh ideas and approaches to committee deliberations.

c. Conditions of appointment

A statement of the conditions of appointment should be included in SOPS, including:

- i. whether members receive any reimbursement for their work and travel expenses;
- ii. such reimbursements for work and expenses, if any, within or related to an REC shall be recorded and made available to the public upon request;
- iii. REC members shall sign confidentiality agreements regarding meeting deliberations, applications, information on research participants, and related matters;

9.2 Committee Governance

SOPs should define how RECs will establish their offices (e.g. Chair, Vice-Chairs) for the good functioning of ethical review. The selection of the Chair of the committee is often considered particularly important, as the chair sets the tone for committee discussions and ideally should be filled by someone respectful of divergent views, able to encourage and help achieve consensus, and has the time to prepare adequately for meetings. The chair must not be a person who has other members as his/her subordinates. Terms of reference should be established for officers that outline:

- i. procedures for selecting and appointing officers;
- ii. the requirements for holding the office;
- iii. the terms and conditions of each office;
- iv. the duties, responsibilities, and authority of each office (e.g., running the meeting, agenda, minutes, notification of decisions).

9.3 Independent Consultants

SOPs should define whether and/or how RECs may call upon independent consultants to provide special expertise to the REC on specific research proposals, populations, or topics.

When developing the SOPs it must be kept in mind that

- i. these non-voting consultants may be specialists in ethical or legal aspects, specific diseases or methodologies, or they might be representatives of communities, patients, or special interest groups relevant to deliberations about specific proposals;
- ii. independent consultants are generally not considered members of the REC and do not have any voting or decision making authority;
- iii. terms of reference for independent consultants should be established.

9.4 Submissions, Documents Required for Review, Review Procedures and Decision Making

a. Submission procedures

SOPs should describe the requirements for submitting an application for review, including which forms must be completed and which documents must be submitted. Submission requirements and required forms should be readily available to prospective applicants. Application requirements should generally include the following:

1. the name(s) and address(es) of the REC secretariat, offices, or member(s) to whom the application material should be submitted;
2. all written documentation to be submitted as part of the application (see section D4b);
3. the format for submission;
4. the language(s) in which (core) documents are to be submitted;
5. the number of copies to be submitted;
6. the deadlines for submission of the application in relation to review dates;
7. the means by which applications will be acknowledged, including the communication of the incompleteness of an application;
8. the expected time for notification of the decision following review;
9. the time frame to be followed in cases where the REC requests supplementary information or changes to documents from the applicant;
10. the fee structure, if any, for reviewing an application;
11. the application procedure for amendments to the proposal, the recruitment material, the prospective research participant information, or the informed consent form;
12. a check list for above procedures.

b. Documents required for review

All documentation required for a thorough and complete review of the proposed research should be submitted by the applicant. As applicable, this may include, but is not limited to:

- i. signed and dated application form, including signatures of listed co-applicants and institutional officials (e.g. Heads of Departments) where relevant;
- ii. the proposal of the proposed research, clearly identified and dated, together with supporting documents and annexures;
- iii. a project summary or synopsis in non-technical language;
- iv. a description (may be included in the proposal) of the ethical considerations in the proposed research, including specifically how the proposal addresses ethical considerations relevant to the committee's review such as scientific rigor, social value, risks of harm and potential benefits, informed consent process, privacy and confidentiality, and community considerations;
- v. a statement of how the products or procedures that show to be effective will be made available for volunteer/community/country;

vi. background information on previous research in the same area that justifies the conduct of this project;

vii. when the research involves a study product (such as a pharmaceutical or device under investigation), an adequate summary of all safety, pharmacological, pharmaceutical, and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g., recent investigator's brochure, published data, a summary of the product's characteristics);

viii. investigator's current curriculum vitae;

all data collection forms to be used in the research, including but not limited to case report forms, diary cards, questionnaires, interview schedule, etc.;

ix. all forms, documents, advertisements, and the like to be used in recruitment of potential participants.

x. a detailed description of the recruitment process and strategies;

xi. informed consent form(s) in languages and at a reading level appropriate for the potential research participants;

xii. a description of the process used to obtain informed consent;

xiii. a statement describing any compensation for study participants including expenses and access to medical care;

xiv. a description of arrangements for insurance coverage for research participants, if applicable;

xv. disclosure of all previous decisions (e.g., those leading to a negative decision or modified proposal) by other RECs or regulatory authorities for the proposed study, whether in the same location or elsewhere, and indication of modification(s) to the proposal made on that account. Reasons for previous negative decisions should be provided;

xvi. a statement of agreement to comply with ethical principles set out in relevant guidelines.

c. Review Procedures

SOPs should establish the process by which the Committee will decide which proposals should be reviewed by the full convened committee and which proposals may be reviewed through an expedited procedure. SOPs should address who will have the responsibility of making this determination. Generally, committees may decide that proposals of lower risk may be reviewed by an expedited procedure whereby, for example, the proposal is reviewed only by 1-2 members of the committee.

Expedited review

SOPs should specify:

i. the nature of the applications, amendments, and other considerations that will be eligible for expedited review;

ii the number of reviewers required for expedited review.

REC meetings

SOPs should describe the process of setting up meetings, the circulation of the documentation for the meetings, process for inviting non-members of the REC, and any related process issues, including approval of minutes of the meeting. RECs should meet regularly as a committee on dates that are announced in advance. The following should be outlined in SOPs:

- i. frequency of meetings should be based on committee workload, but SOPs should outline maximum timeframe for review after receipt of applications;
- ii. REC members should be provided with all relevant documents in advance of the meetings with enough time to adequately review meeting materials;
- iii. the researcher and/or sponsor of a particular proposal may be invited to present or comment on the proposal in question or on specific issues that relate to it during the meeting, at the discretion of the committee; this practice may be implemented routinely or on a per need basis;
- iv. independent consultants may be invited to the meeting or to provide written comments, subject to applicable confidentiality agreements;
- v. adequately detailed minutes should be kept at each meeting and a process identified for approval of the minutes.

d. Deliberation and decision making

Procedures for deliberation and decision making should be clearly established, that describe

- i. the manner in which the proposal will be presented to the Committee for discussion; the process by which the proposal will be discussed, including who may remain in the room during discussions;
- ii. quorum requirements for making a decision;
- iii. the predefined method for arriving at a decision (e.g., by consensus, by vote), and who may take part in decision making; it is recommended that decisions be arrived at through consensus, where possible; when a consensus appears unlikely, it is recommended that the REC vote;
- iv. clear options for decision outcomes, that might include, for example, approval, conditional approval, revise and resubmit, disapproval. Criteria for each outcome should be described, as should any specific follow up procedures associated with each option including specific procedures for re-review, as applicable;
- v. committee correspondence must make clear to the applicant that no research with human participants can commence before concerns have been satisfied and full approval has been granted.

e. Quorum Requirements

Specific quorum requirements for reviewing and making decisions or taking actions on a research proposal should be clearly established in the SOPs. These requirements should include:

1. the minimum number of members required to compose a quorum (e.g., half of the members, or a simple majority);

2. the distribution of committee composition requirements across the quorum; no quorum should consist entirely of members of one profession or one gender; a quorum should include at least one member whose primary area of expertise is in a non-scientific area, and at least one member who is independent of the institution/research site.

9.5 COMMUNICATING A DECISION

SOPs should describe procedures for communicating the decisions of the REC. SOPs should outline the maximum amount of time between the decision about the proposal and when the applicant is informed. The communication of the decision should include, but is not limited to, the following:

1. Specific identifying information about the proposal, including
 - i. the exact title of the research proposal reviewed;
 - ii. the clear identification of the proposal or amendment, date and version number (if applicable) on which the decision is based;
 - iii. the names and (where possible) specific identification numbers (version numbers/dates) of the documents reviewed, including the potential research participant information sheet/material and informed consent form;
 - iv. the name and title of the applicant or sponsor;
 - v. the name of the site(s);
 - vi. the date and place of the decision;
 - vii. the name of the REC making the decision;
2. A clear statement of the decision reached;
 - 1) In the case of a positive decision,
 - i. communicate that approval is given only for the proposal as accepted by the ERC, and compliance is expected
 - ii. the duration for which the approval is valid, and the procedures to be followed to renew the approval at the end of that period.
 - iii. a statement of the responsibilities of the applicant; for example,
 - confirmation of the acceptance by the researchers of the requirements imposed by the REC;
 - submission of progress report(s) at predefined intervals;
 - **the need to seek further prior approval from the REC** in cases of proposal amendments or deviations (including whether local law or REC policy allows amendments involving only logistical or administrative aspects of the study to be made **without permission of the REC**);
 - **the need to seek further prior approval from the REC** in the case of amendments to the recruitment material, the prospective research participant information, or the informed consent form;
 - the need to report serious and unexpected adverse events related to the conduct of the study;
 - the need to report unanticipated problems involving risks of harm to the participants or others,
 - the termination of the study,
 - significant decisions by other RECs;

- the information the REC expects to receive in order to perform ongoing review; the final outcome summary or final report;
- 2) In the case of a conditional decision, any requirements by the REC, including suggestions for revision and the procedure for having the application re-reviewed;
 - 3) In the case of a negative decision, clearly stated reasons relevant specifically to ethical considerations for the negative decision;
 - 4) Advice or suggestions that are non-binding may be appended to the decision but should clearly be marked as advice separate from any stipulations or determinations of the REC;
3. Signature (dated) of the chairperson (or other authorized person) of the REC.
 4. RECs must determine and include in their procedures whether an appeals procedure is available. If allowed, SOPs should address the process for appeals. Appeals should be made to another independent arbiter rather than to an authority or director of the Body establishing the REC, unless a further secondary appeals process is in place. If appeals will be allowed, SOPs must outline what materials must be submitted, to whom, and who is the decision maker.

9.6 Follow-Up Reviews and Monitoring of Proposals

SOPs should describe the process by which RECs will follow up the progress of all approved studies, from the time the approval decision is taken until the termination of the research. The procedure for follow up review should take the following into consideration:

1. the review procedure, quorum requirements, and communication procedure for follow-up reviews, which may vary from requirements and procedures for the initial review of the application;
2. the follow-up review intervals should be determined by the nature and the events of research proposals, though each proposal should undergo a follow-up review at least once a year;
3. the following instances or events should cause follow-up review of a study to occur in addition to regularly scheduled follow up:
 - 1) any proposal amendment likely to affect the rights, safety, and/or well-being of the research participants or the conduct of the study;
 - 2) serious and unexpected adverse events related to the conduct of the study or study product, and the response taken by investigators, sponsors, and regulatory agencies;
 - 3) any event or new information that might affect the potential benefits or risks of harm involved in the study;
 - 4) decisions made by a DSMB to suspend a study in whole or in part.
4. a decision resulting from a follow up review should be issued and communicated to the applicant, indicating the original decision is still valid, or communicating a modification, suspension, or termination of the REC's original decision;
5. in the case of the premature suspension/termination of a study by any party other than the REC, the applicant should notify the REC of the reasons for suspension/termination; a summary of results obtained in a study prematurely suspended/terminated should be communicated to the REC; the follow up to be provided to enrolled participants and how information on the suspension of the study will be communicated to participants. REC must

have the right of overruling the decision of suspending/terminating a study, if there is sufficient reason to believe suspending or terminating a study is likely to jeopardize the safety or right of research participants;

6. RECs should receive notification from the applicant at the time of the completion of a study and a final summary should be provided to the REC.

9.7 DOCUMENTATION AND ARCHIVING

All documentation and communication of an REC should be dated, filed, and archived according to the committee's written procedures.

Procedures should outline who is authorized to access committee files and documents.

a. Committee Related Documents

Documents that should be filed and archived related to REC operations and procedures include, but are not limited to,

1. the constitution and written standard operating procedures of the REC;
2. the published guidelines for submission established by the REC;
3. annual reports that summarize EC activities. Such a report will promote transparency and will help raise awareness of the EC within its institution or jurisdiction, as well as serving as an ongoing reminder of the resources necessary to run the committee;
4. the curriculum vitae of all REC members;
5. a record of all income and expenses of the REC, including allowances and reimbursements made to the secretariat and REC members and for what purposes;
6. the agendas of the REC meetings;
7. the minutes of the REC meetings;

b. Proposals Related Documents

All documents and materials related to the review of specific study proposals should be filed. Committee procedures should specify length of time documents must be archived. Such policies should be consistent with any relevant local laws or institutional policies. These include but are not limited to:

1. one copy of all materials submitted by an applicant;
2. the correspondence by REC members with applicants or concerned parties regarding application, decision, and follow-up;
3. a copy of initial and follow up decisions and any advice or requirements sent to an applicant;
4. all written documentation received during the follow-up including any advice or requirements sent to the applicant;
5. the notification of the completion, premature suspension, or premature termination of a study;

STANDARD 10

REC staff must maintain all relevant committee files and records using a system that is confidential, retrievable, and accountable.

It is a responsibility of REC staff or Secretariat to follow SOPs for documentation and record keeping of both committee and proposal related files. Staff must be sufficiently trained to understand their responsibilities related to record keeping, retrieval, and confidentiality.

Comment [s3]: This section needs to be written in the same style as the rest of the document.

All REC staff should sign a confidentiality agreement regarding meeting deliberations, applications, information on research participants and information on research projects.

Records could either be paper records or electronic. If records are electronic, sufficient safeguards should be built in (password protection, encryption) to maintain the confidentiality of the files and the documents.

VI. GUIDANCE TO RESEARCHERS - INVESTIGATORS' RESPONSIBILITIES

1. Submitting an Application

1. An application for review of the ethics of proposed biomedical research should be submitted by a qualified researcher, who is directly responsible for the ethical and scientific conduct of the research. In certain situations (clinical trials in certain jurisdictions) the sponsor of the trial is responsible for submitting the research proposal to the REC

2. Student proposals should be submitted under the responsibility of a qualified advisor/faculty member involved in the oversight of the student's work or be in the student's name, co-signed by the qualified faculty supervisor;

3. All documentation required for a thorough and complete review of the ethics of proposed research should be submitted. Information about such documentation is usually provided by the REC and is available in its Standard Operating Procedures.

2. Conduct of Research

1. The research should be conducted in compliance of the proposal approved by the REC.

2. No deviation or changes should be made to the approved proposal, or in following it, without prior approval of the REC, except where necessary to avoid harm or risk to the research participant(s). In such a case, the REC should be informed promptly of the changes/deviations made, and the justification for doing so provided.

3. The REC should be informed of any changes at the research site that significantly affect the conduct of the trial, and/or increase the risks of harm to participants (for example closing down of a health facility at the research site, or lack of available health care that was originally available).

3. Safety Reporting

1. All serious adverse events as defined in the proposal and any unexpected events should be reported to the REC as described in the proposal, and according to the procedures established by the REC. Such events should in general be reported in writing to the REC no less than seven days after occurrence.

2. Any recommendations provided by the REC in response to such reporting should be immediately implemented.

4. Ongoing Reporting and follow-up

1. In the case of the premature suspension/termination of a Study, the applicant should notify the REC of the reasons for suspension/termination; a summary of results obtained prior to prematurely suspending or terminating the study; and describe the care and follow-up plan for the participants already enrolled in the study.

2. The investigator should promptly inform the trial participants, should assure appropriate therapy and follow-up for the participants, and, where required by the applicable regulatory requirement(s), should inform the regulatory authority(ies).

3. RECs should receive notification from the applicant at the time the study is completed or cancelled. If cancelled, the reason for cancellation must be communicated as well as procedures for the orderly closure of the study and disposition of enrolled participants.

4. If the REC terminates or suspends its approval, the investigator should inform the institution under whose authority the research is being conducted, the sponsor of the research, and any other applicable organizations.

5. Information to research participants

The investigators have an obligation to keep the research participants and the communities to which they belong informed of the progress of the research project in which they are enrolled at suitable time frames in a simple and non-technical language but specifically when

1. the research study is modified, suspended, terminated or cancelled;
2. any changes occur in the context of the research study, that result in an altered potential benefit-risk of harm ratio; The latter should include mechanisms to provide results, procedures, products or new knowledge that may be useful for the volunteers or the community.
3. research project is completed.

PARTICIPANTS to the WHO Consultation on Norms and Standards for Research Ethics
Review Committees – November 2009

Name	Contact
Borasky, David	IRB Manager Office of Research Protection RTI International 3040 Cornwallis Rd Research Triangle Park, NC 27709 USA Email: dborasky@rti.org
Callies, Ingrid	Representing the Council of Europe Institut Pasteur Direction médicale 25-28 rue du Dr Roux 75724 Paris Cedex 15 France Email: ingrid.callies@pasteur.fr
Capron, Alexander M.	Scott H. Bice Chair in Healthcare Law, Policy and Ethics, University of Southern California Los Angeles, CA 90089-0071 USA Email: acapron@law.usc.edu
Chaumont, Julie*	Senior Clinical Research Associate Programme for Appropriate Technology in Health (PATH) Ferney Voltaire, France.
Coleman, Carl	WHO Consultant Seton Hall Law School One Newark Center Newark, NJ 07102 USA Email: carlhcoleman@gmail.com
Ecuru, Julius	Assistant Executive Secretary Uganda National Council for Science and Technology Plot 3/5/7 Nasser Road P. O. Box 6884 Kampala Uganda Email: j.ecuru@uncst.go.ug
Forster, David G.	Vice President, Office of Compliance Western Institutional Review Board (WIRB), 535 7th Avenue SW Olympia, WA 98502-5010 USA Email: dforster@wirb.com
Guessous, Nouzha	Professor Biologiste Médicale, Parasitologue Consultante auprès de l'OMS / TDR Chercheure et Consultante en Droits Humains et Bioéthique Les Résidences de la Corniche. Angle rue Jules Verne et rue Regraga, GH4, 5ème étage, N° 17 Casablanca- Maroc (Morocco) Email: nouzhaguessous@gmail.com
Greco, Dirceu	Professor School of Medicine, Federal University of Minas Gerais, Av. Alfredo Balena, 190, 30130-100 Belo Horizonte, MG Brésil

	Email: greco@medicina.ufmg.br
Gutnick, Reva	WHO Consultant, 800 Le Vertes Campagnes 01170 Gex France Email: revagutnick@hotmail.com
Hurst, Samia	Senior Lecturer Université de Genève, Institute of Biomedical Ethics Centre médical universitaire /Rue Michel Servet 1 1211 Genève 4 (External ERC member Email: Samia.Hurst@unige.ch
Ijsselmuiden, Carel	Director Council on Health Research for Development (COHRED) 1-5 Route des Morillons P.O. Box 2100 1211 Genève 2 Email: carel@cohred.org
Jesani, Amar	Centre for Studies in Ethics and Rights (CSER), Anusandhan Trust Sai Ashray, Aaram Society Road Vakola Santacruz East Mumbai 400055 India Email: amar.jesani@gmail.com
Khodeli, Irakli	Assistant Programme Specialist Social and Human Sciences Sector United Nations Educational Scientific and Cultural Organization (UNESCO) 1, rue Miollis 75732 Paris Cedex 15 France Email: i.khodeli@unesco.org
Kloiber, Otmar	Secretary General World Medical Association (WMA) 13, ch. du Levant CIB - Bâtiment A 01210 Ferney-Voltaire France Email: otmar.kloiber@wma.net
Kreutz, Gottfried	Secretary General Council of International Organization of Medical Sciences c/o WHO Avenue Appia 20 CH-1211 Genève 27 Suisse/Switzerland Email: kreutzg@who.int
Luna, Florencia	Professor FLACSO (Latin American University of Social Sciences) University of Buenos Aires

	(UBA) Ayacucho 555 Ciudad Autonoma de Buenos Aires, C1026AAC Argentina Email: florluna@fibertel.com.ar
Leveridge, Jacob	Medical Humanities Adviser (Biomedical Ethics) Wellcome Trust Gibbs Building 215 Euston Road London NW1 2BE, UK Email: J.Leveridge@wellcome.ac.uk
Ndebele, Paul	Assistant Director, Ethics Office of Research and Development University of Botswana Office 152 Block 243 (CCE Building) Corner Mobuto/Notwane Road P Bag UB00708 Gaborone Botswana Email: pndexas@yahoo.com
Socquet, Muriel*	Regulatory Program Administrator Programme for Appropriate Technology in Health (PATH)
21. Speers, Marjorie	Executive Director Association for the Accreditation of Human Research Protection Programme 2301 M Street NW Suite 500 Washington, DC USA Email: MSpeers@aahrpp.org
22. Torres, Christina	FERCAP Coordinator WHO-TDR Clinical Coordination and Training Center Academic Affairs Building Thammasat University (Rangsit Campus) Klongluang, Pathumthani 12121, Thailand Email: torres@fercap-sidcer.org , cristina.torres@yahoo.com
23. Whittall, Hugh	Director Nuffield Council on Bioethics 28 Bedford Square London WC1B 3JS, UK Email: hwhittall@nuffieldbioethics.org
24. Williams, John	Independent expert 825 Grenon Avenue, Unit 19, Ottawa, Ontario K2B 6G1, Canada Email: jrewms@yahoo.com
25. Zhai, Xiaomei	Professor and Executive Director Centre for Bioethics Chinese Academy of Medical Sciences and Peking Union Medical College 5 Dong Dan San Tiao, Beijing 100005 P.R. China

	Email: xmzhai@hotmail.com
WHO REGIONAL OFFICES	
26. Azcuna, Rosebelle	The World Health Organization Regional Office for the Western Pacific (WPRO) P.O.Box 2932 1000 Manilla, Philippines E-mail: azcunar@wpro.who.int
WHO/HQ Av. Appia 20, 1211 Geneva 27 Switzerland	
Bahl, Rajiv	FCH/CAH Department of Child and Adolescent Health and Development (ERC member, & ERC Vice-Chair) bahlr@who.int
Bouësseau, Marie-Charlotte	IER/ETH Department of <u>Ethics, Equity, Trade and Human Rights</u> bouesseaum@who.int
Evans, Timothy	Assistant Director-General, Information, Evidence and Research (IER) evanst@who.int
Ezcurra, Enrique	FCH/RHR Department of Reproductive Health and Research (ERC member) ezcurrae@who.int
Kass, Nancy	IER/RPC Department of Research, Policy and Cooperation ERC Secretariat kassn@who.int
Krech, Ruediger	IER/ETH Department of Ethics, Equity, Trade and Human Rights (Director) krechr@who.int
Laothavorn, Juntra	IER/TDR Special Programme for Research and Training in Tropical Diseases karbwangj@who.int
Matsoso, Precious	DGO/PHI Department of Public Health, Innovation and Intellectual Property (Director) matsosom@who.int
Nkowane, Mwansa	HSS/HRH Department of Human Resources for Health (ERC member) nkowanemwansa@who.int
Okeru, F. Amolo	HTM/HIV

	Department of Prevention in the Health Sector (ERC member) okeroa@who.int
Pang, Tikki	IER/RPC Department of Research, Policy and Cooperation (Director, and Secretary, ERC) pangt@who.int
Saxena, Abha	IER/RPC Department of Research, Policy and Cooperation (ERC Secretariat) saxenaa@who.int
Terry, Robert	IER/RPC Department of Research, Policy and Cooperation terryr@who.int
Thapa, Shyam	FCH/RHR Department of Reproductive Health and Research (ERC member) thapas@who.int
Vanderpoel, Sheryl	FCH/RHR Department of Reproductive Health and Research (Secretariat of the Scientific and Ethical Review Group - SERG) vanderpoels@who.int

