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Standard 1: Responsibility for establishing the research ethics review system

Relevant authorities ensure that the ethics review of health-related research is supported by an adequate legal framework consistent with the standards outlined in this document. The research ethics committees (RECs) can independently review all health-related research at the national, subnational, and institutional (public or private) levels. An appropriate and sustainable system is in place to monitor the quality and effectiveness of research ethics reviews.

All research with human participants is presumptively subject to REC oversight.

RECs are part of more extensive research participant protection programs that include training for REC members and researchers and mechanisms to ensure that RECs work efficiently and effectively.

Procedures exist to ensure clear and efficient communication, harmonization of standards, networking, and cooperation among national and different levels of committees, as applicable.

Mechanisms exist to ensure that RECs' activities are coordinated with national regulatory authorities' oversight of drugs, biologics, and medical devices, as well as with national and international clinical trial registries.

Mechanisms are in place for obtaining community input into the ethics review system.

Types of research studies RECs may review different types of research studies, including, but not limited to, the following:

• Clinical trials

• Epidemiological research

• Social science research

• Research on medical records or other personal information

• Research on stored samples

• Health systems research

• Implementation research RECs should be familiar with the different methodologies and ethical considerations that apply to each type of proposed research they review

Standard 2: Composition of research ethics committees

The research ethics committee (REC) is constituted according to a charter or other document establishing how to appoint members and the Chair. The appointing entity ensures that the REC has a multidisciplinary and multisectoral membership. Its composition is gender balanced, reflects the social and cultural diversity of the communities from which research participants are most likely to be drawn, and includes individuals with backgrounds relevant to the areas of research the committee is most likely to review.

Standard 3: Research ethics committee resources

The entity establishing the REC supports it with adequate resources, including staffing, facilities, and financial resources, to allow the REC to carry out its responsibilities effectively.

Standard 4: Independence of research ethics committees

Policies governing the REC include mechanisms to ensure the independence of the REC's operations to protect decision-making from influence by any individual or entity that sponsors, conducts, or hosts the research it reviews. Such policies provide, at a minimum, that REC members (including the Chair) remove themselves from the review of any study in which they or close family members have a conflicting interest.

1. The REC's membership includes at least one person with no connection to the organization that sponsors or conducts the research under review
2. Researchers, sponsors, and funders may attend a REC meeting to answer questions about their research protocols and associated documents. Still, they are not present when the REC reaches decisions about their proposed research.
3. Senior decision-makers of REC or any organization that sponsors or conducts the research reviewed by the REC (such as the director of an institution or their agent) do not serve as members of the REC or its Chair.
4. The entity establishing the REC ensures that REC members are protected from retaliation based on positions taken concerning REC-related matters or reviews of research projects.

Standard 5: Training the research ethics committee

Training on the ethical aspects of health-related research with human participants, how ethical considerations apply to different types of research, and how the REC conducts its review of research is provided to REC members when they join the committee and periodically during their committee service.

Standard 6: Transparency, accountability, and quality of the research ethics committee

Mechanisms exist to make REC operations transparent, accountable, consistent, and high-quality.

1. Such evaluations are conducted by knowledgeable and unbiased people at regular, pre-defined intervals using a pre-defined format
2. Internal assessments are supplemented periodically by independent external evaluations.
3. Researchers, research participants, and other interested parties have a means of lodging complaints about the REC; such complaints should be reviewed by an entity other than the REC and should take appropriate follow-up actions.
4. Researchers have a means of discussing concerns with REC members, both on general matters and in response to REC decisions on particular research studies.
5. REC decisions, excluding confidential information, are made publicly available through clinical trial registries, websites, newsletters, and bulletin boards.

Standard 7: Ethical basis for decision-making in research ethics committees

The REC bases its decisions about research that it reviews on a coherent and consistent application of the ethical principles articulated in international guidance documents and human rights instruments, as well as any national laws or policies consistent with those principles.

The REC makes the specific ethical guidelines on which it relies in making decisions and makes them readily available to researchers and the public.

When a REC develops reliance agreements for review of research under its jurisdiction by another REC, it is the responsibility of the delegating REC to assure that the same ethical principles serve as the basis of the other REC's decision-making.

1. **Scientific design and conduct of the study**
   Research is ethically acceptable only if it relies on valid scientific methods. Research that is not scientifically valid exposes research participants or their communities to risks of harm without any possibility of benefit. RECs should have documentation from a prior scientific review or should determine that the research methods are scientifically sound and should examine the ethical implications of the chosen research design or strategy. Unless already determined by a prior scientific review, RECs should also assess how the study will be conducted, the qualifications of the researcher(s), the adequacy of provisions made for monitoring and auditing, as well as the adequacy of the study site (e.g. availability of qualified staff and appropriate infrastructures).
2. **Risks and potential benefits**
   The nature of the risks may differ according to the type of research to be conducted. In ethically acceptable research, risks have been minimized (both by preventing potential harms and minimizing their negative impacts should they occur) and are reasonable about

the potential benefits of the study. REC members should be aware that risks may occur in different dimensions (e.g., physical, social, financial, or psychological), all of which require serious consideration. Further, harm may occur either at an individual level or at the family or population level.

3. **Selection of study population and recruitment of research participants**
   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 (if any) and the new knowledge the research is designed to yield. Thus, one question for research ethics review to consider is whether the population that will bear the risks of participating in the research is likely to benefit from the knowledge derived from the research. In addition, ethically acceptable research includes balanced recruitment strategies that objectively describe the purpose of the research, the risks and potential benefits of participating in the research, and other relevant details.
4. **In documents, financial benefits, and financial costs.**
   It is considered ethically acceptable and appropriate to reimburse individuals for any costs associated with participation in research, including transportation, child care, or lost wages. Many RECs also believe that it is ethically acceptable to compensate participants for their time. However, payments should not be so extensive or accessible as medical care or other forms of compensation so vast as to induce prospective participants to consent to participate in the research against their better judgment or to compromise their understanding of the research.
5. **Protection of research participants' privacy and confidentiality**
   Invasions of privacy and breaches of confidentiality are disrespectful to participants. They can lead to feelings of loss of control or embarrassment, tangible harms such as social stigma, rejection by families or communities, or lost opportunities such as employment or housing. RECs should examine the precautions taken to safeguard participants' privacy and confidentiality.
6. **Informed consent process**
   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 make decisions based on an adequate understanding of the research. Decisions for children or adults who lack the mental capacity to provide informed consent should be made by an authorized surrogate decision-maker. RECs should examine the process through which informed consent will occur and the information that will be provided. RECs may waive the requirement of informed consent only when doing so is consistent with international guidelines and national standards.

7. **Community considerations**

   Research impacts not only the individuals who participate but also the communities where the research occurs and to whom can link fi findings. Duties to respect and protect communities require examining by the REC and, as far as possible, are aimed at minimizing any adverse effects on communities, such as stigma or draining of local capacity.

Standard 8: Decision-making procedures for research ethics committees

Decisions on research protocols designated for review by the convened REC are based on a thorough and inclusive process of discussion and deliberation. Protocols involving no more than minimal risk and burden to research participants may be reviewed on an expedited basis by one or more members (rather than the full committee) if the REC has established written procedures permitting such a procedure.

1. During meetings of the REC, members engage in discussions to elicit all concerns and opinions related to the protocols and the associated documents under consideration. The REC's rules ensure that the discussions are respectful of all views and allow for varied beliefs to be aired. The Chair fosters a respectful and inclusive tone. It will enable adequate time for deliberation, during which only REC members participate, and decisions are made only by those who were present during the entire discussion. The Chair is responsible for the decision-making process, particularly for determining when consensus is needed to achieve the decision. Researchers, funders, or others directly associated with the protocol are absent during committee deliberations.
2. REC members recognize the limitations of their knowledge and seek external input when necessary, particularly in research involving people whose life experiences may differ significantly from those of the committee members.
3. Decisions are arrived at through either a vote or consensus. Consensus does not require that all REC members support the decision but that all members consider the decision at least acceptable, and no member considers the decision unacceptable. A pre-defined method determines when will take votes and how many favorable votes will be needed for the proposed research to be approved.

Standard 9: Written policies and procedures

Written policies and procedures specify the REC's membership, committee governance, review procedures, decision-making, communications, follow-up, monitoring, documentation and archiving, training, quality assurance, and strategies for coordination with other RECs.

1. **Membership of the committee The** REC's policies and procedures delineate the authority, the terms, and the conditions of appointment. Staggered, finite terms of

appointment should be considered, allowing continuity of some members when other members are newly appointed.

2. **Committee governance** The REC's policies and procedures define how the REC will establish its offices (e.g., Chair, Vice-Chairs). The Chair is respectful of divergent views, can encourage and help achieve consensus, and has the time to prepare adequately for meetings. The Chair is not a person who has a supervisory relationship with other committee members.
3. **Independent consultants** The REC's policies and procedures define the circumstances under which a REC may call upon independent consultants to provide special expertise.
4. **Submissions, documents required for review, review procedures, and decision-making** The REC's policies and procedures describe the requirements for submitting an application for review, including the completed forms and the submitted documents. They also specify the process and system for review, the process for coordinating review with other committees, the process for setting up meetings, circulating documentation for the meetings, inviting non-members of the REC, approving the meeting minutes, and any related process issues.
5. **Communicating a decision**
   The REC's policies and procedures describe procedures for communicating the decisions of the REC and specify the maximum amount of time between the decision about the application and when the applicant is informed.
6. **Follow-up reviews and monitoring of proposed research**
   Standard operating procedures describe the process by which RECs will follow up on the progress of all approved studies—from the time the approval decision is taken until the termination or completion of the research.
7. **Documentation and archiving**
   All of the REC's documentation and communication is dated, filed, and archived according to the committee's written procedures. May keep records either in hard copy or electronically. In either case, sufficient safeguards are established (e.g., locked cabinets for complex copy files, password protection, and encryption for electronic files) to maintain confidentiality

Standard 10: Researchers' responsibilities

Research is performed only by persons with scientific, clinical, or other relevant qualifications appropriate to the project and familiar with the ethical standards applicable to their research. who submit the necessary information to the REC for review (including both the research protocol and disclosures of any conflicting interests), and who carry out the research in compliance with the requirements established by the REC.

1. **Applying for review**

An application or review of the ethics of proposed health-related research is submitted by a researcher qualified to undertake the particular study, which is directly responsible for the ethical and scientific conduct of the investigation. In certain jurisdictions, a study sponsor is responsible for submitting the research protocol to the REC.

Student applications are submitted under the responsibility of a qualified advisor/faculty member overseeing the student's work or the student's name, co-signed by the qualified faculty supervisor.

All information required for a thorough and complete review of the ethics of the proposed research is submitted.

2. **Conduct of research**

The research is conducted in compliance with the protocol approved by the REC. The REC is informed of any changes at the research site that significantly affect the conduct of the trial, reduce the protections, decrease the benefits provided, or increase the risk to participants. No deviation or changes are made to the approved protocol or in following it, without prior approval of the REC, except where immediate action is necessary to avoid harm to research participants.

3. **Safety reporting**

All serious, unexpected adverse events related to the conduct of the study/study product or unanticipated problems involving risks of harm to the participants or others are promptly reported to the REC

4. **Ongoing reporting and follow-up**

The researcher submits written summaries of the research status to the REC annually or more frequently if requested by the REC. Researchers inform the REC when a study is completed or prematurely suspended/terminated. In the case of the early suspension/termination by the researcher or sponsor, the researcher notifies the REC of the reasons for suspension/termination.

5. **Information to research participants**

Researchers have a responsibility to keep the research participants and their communities informed of the progress of research by appropriate means, at suitable time-frames in simple and non-technical language, for example, when: a. the research study is terminated or canceled b. any changes occur in the context of the research study that alters the potential benefits or risks c. the research project is completed d. results of the research are available.