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# Enhancing Research Ethics Committees in Egypt

## Guidelines for Standard Operating Procedures

Standard Operating Procedures (SOPs) describe the policy and procedures that guide Research Ethics Committees (RECs) and . . . serve to enhance the consistency and efficiency of the RECs' ethical review of biomedical research.

Several international guidelines have developed the ethical and scientific standards for carrying out biomedical research involving human subjects.[1,2,3,4] Compliance with these guidelines helps to ensure the dignity, rights, safety, and well-being of subjects who participate in research. These guidelines also require that an independent ethics review committee perform an ethical and scientific review of biomedical research. Such review committees are commonly called Research Ethics Committees (RECs) or Institutional Review Boards (IRBs). Review of research by an independent committee ensures that the review process is performed free from political, institutional, professional, and market influences. Several countries have developed regulations that require the existence of RECs to ensure the protection of the rights and welfare of subjects who participate in research.[2,5] Despite the absence of national regulations addressing the need for RECs, these committees have existed in Egypt for several years.

Recently, the World Health Organization (WHO) issued guidelines for the establishment of standard operational procedures (SOPs) for RECs.[6] SOPs describe the policy and procedures that guide RECs and ensure transparency of how they operate to both the members of their institution and the public. SOPs also serve to enhance the consistency and efficiency of the RECs' ethical review of biomedical research.

At the time of the development of the current project, none of the RECs in Egypt had written SOPs. Guidelines for SOPs would assist individual Egyptian RECs in writing their own SOPs and ensure consistency between existing and future RECs in Egypt. Additionally, SOPs need to be established in accordance with applicable local laws and regulations as well as the customs and cultural traditions of countries in which RECs review research. Accordingly, our aim was to develop model guidelines for SOPs that are relevant to Egypt, which

*Due to space limitations and in order to provide access to these documents, the Appendixes are being provided as part of the online version of the December 2006* Monitor. *To access the online issue, go to www.acrpnet.org, log on as a member, and click on the link to the December 2006 issue.*

could then be further adapted to the local context—that is, institution and community.

## Methods

The working group to develop the SOPs consisted of candidates and faculty participating in the two-month Health Research Ethics Training Initiative in Egypt (HRETIE) research ethics certificate course held at the University of Maryland School of Medicine in Baltimore, Md.[7] Individuals from Egypt consisted of eight physicians and two nurses, representing different sectors of the healthcare profession and institutes in Egypt: the Ministry of Health (S. Hammouda, M. Hassan), the Egyptian Medical Syndicate (R. Afifi), Cairo University (S. Lashin), Ain Shams University (M. El-Setouhy), Alexandria University (H. Kassem), Mansoura University (N. Kandeel, A. El-Nemer), Suez Canal University (N. Moustafa), and the American Navy Medical Research Unit (I. Nakhla).

At the start of the certificate course, the candidates were divided into two working groups representing simulated RECs. Their first task was to develop SOPs for their respective simulated RECs, adapted to existing laws and customs in Egypt. Using the WHO guidelines as a baseline, the working groups provided further specification for many of the WHO statements to develop their respective SOPs. They modified the WHO guidelines when necessary to ensure relevance to the conditions in Egypt. The participants and faculty discussed both sets of SOPs at a general session and subsequently combined them into one document. After the course, the consensus process continued over the next three months through informal e-mail discussions to develop the final model SOPs and associated forms.

## Recommendations

The HRETIE Model SOPs are shown in **Appendix I**, and **Appendixes II–VI** show the forms:

- Investigator Submission Form (App. II)
- REC Protocol Review Form (App. III)
- Informed Consent Checklist (App. IV)
- Conflict of Interest Disclosure Statement (App. V)
- Statement of Confidentiality (App. VI)

An important element of the SOPs is a statement of the authority under which an REC is established. To ensure that their decisions are authoritative, RECs must receive a mandate from a high-ranking institutional official (e.g., Dean, President, or Minister of Health). In addition, the SOPs should state their authority to review, make decisions (including approval and disapproval) regarding the acceptability of the research, and monitor the ongoing research activities.

Independence and competence are the two hallmarks of an REC. Hence, RECs should be multidisciplinary and multisectorial in composition. Members need to be independent from political, institutional, professional, and market influences, and they must demonstrate competence and efficiency in their work.

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Guidelines on the qualifications, appointment process, duties, and terms of appointment for the chair, vice chair, and members need to be explicit. As a general rule, high institutional officials (e.g., Dean, President, etc.), should not be included as members of the REC to ensure the committee's political and institutional independence. There also need to be statements regarding member orientation and education, as well as information regarding the definition and management of potential conflicts of interest.

The SOPs should define the REC's review and evaluation process, including information regarding the frequency of the meetings, quorum requirements, guidelines to investigators concerning submission of applications for initial and continuing reviews, the criteria the REC will use to review and evaluate research, the mechanism for decision making, the types of decisions to be rendered, the method for communicating decisions to investigators, and the opportunity for appeals by investigators. The REC should also define investigator obligations regarding submission of reports, such as adverse events, protocol changes, unanticipated problems, and safety reports. Finally, the REC must define its record-keeping process and documentation methods.

The model SOPs provide further specifications of the WHO guidelines rather than a mere reiteration of the guidelines. These specifications take into consideration the conditions existing in the Egyptian legal, academic, and community environments. For example, the model SOPs state specifically the persons (Dean, President, etc.) under whose authority the REC was established (App. I, B.1). Regarding the constitution of the REC, the model SOPs specify the appointment process and qualifications of the chairperson (App. I, D.1a,b,c) and recommend that high-ranking officials not be members to ensure independence of the REC from institutional influences.

The model SOPs also specify the appointment process and qualifications of the REC members. With the exception of the initial appointment process, high-ranking officials are not involved with the appointment of subsequent REC members and should have no authority regarding disqualification of existing members. The SOPs specify that a consensus process be used to appoint members rather than direct appointment. Such recommendations ensure independence from institutional influence.

Other specifications include the following:

- the different levels of risk assigned to a protocol and the requirement that protocols assigned a level of risk that is "too risky" should be disapproved (App. I, E.4b)
- documentation of the informed consent process (App. I, E.4b)
- the REC responsibilities regarding externally sponsored research (App, I, E.4b
- types of REC decisions allowed (App. I, E.5e)
- recommendations for short-form consent procedures (App. I, G)

Several specifications reflect exigencies influenced by conditions in Egypt. For example, the WHO guidelines state that a quorum should include at least one member whose primary area of expertise is in a nonscientific area and at least one member who is independent of the institution/research site. The HRETIE working group decided that a quorum requirement including both members might be difficult in a country in which RECs are a relatively new phenomenon. Hence, the model SOP requirements for a quorum include the presence only of one member who is not affiliated with the institution.

Another specification inspired by the Egyptian environment involved requiring that the REC consider the assessment of the study design by a separate research committee, if one exists in the institution. Many Egyptian institutions have separate research committees, and the HRETIE working group thought that the REC should work with them for efficiency and political reasons.

Finally, the SOPs specify that there be a mix of junior and senior members on the REC, because there is a tendency in Egypt that only senior members serve on important committees.

To enhance the efficiency of the application and review process of new protocols, we have included examples of an investigator submission form, an REC protocol review form, and an informed consent checklist (Appendixes II, III, and IV). The completion of the REC protocol review form ensures that all of the essential items in the review process have been considered. This form also contains elements that are specifically relevant to research sponsored by external sponsors (items # 2, 6, and 22). The completion of an informed consent checklist ensures that the informed consent forms include the necessary elements of informed consent; research ethics committees have a tendency to omit some of these elements.[8]

## Discussion

We have developed model SOPs for RECs in Egypt. Participants also developed several forms (see Appendixes II-VI) that can help the administrative and review aspects of RECs. The development of SOPs for RECs represents an important administrative process that can contribute to the transparency, independence, quality, consistency, and efficiency of the ethical review of research. We expect that these guidelines for SOPs will be helpful for RECs in Egypt as well as in other developing countries.

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The importance of having written SOPs is witnessed by the many guidelines that have mentioned their value, the frequent development of such documents in other countries, and the announcement of conferences on developing SOPs during the last several years in different parts of the world.[9,10,11] All of these events represent a global phenomenon regarding the importance of SOPs.

The model SOPs clearly define the role and authority of RECs regarding the protection of the rights and welfare of research subjects. The SOPs make transparent the authority of the RECs and their review mechanism. Such transparency ensures the development of trust between RECs, the research staff, and the community they serve. Written SOPs also enhance the likelihood that the RECs will be consistent in their procedures and be free from personal bias in their review process. In addition, for a developing country like Egypt, the SOPs help to clarify the function of RECs regarding their role in the protection of Egyptian citizens against exploitation in collaborative international research funded by external sponsors.

Because the HRETIE model SOPs do not represent the mere reiteration of the WHO guidelines, they reflect the conditions existing in the legal, academic, and social fabric of Egyptian society. Other developing countries might find several aspects of these SOPs to be relevant to their research environment as well.

A frequent concern of investigators is the perceived administrative shortcomings of having another committee review their research, which can lead to delays in the start of research and increase the administrative burdens for investigators. The associated investigator submission and REC protocol review forms should improve the efficiency of the RECs as well as enhance the protection of the rights and welfare of the research subjects.

A potential shortcoming of the model SOPs is that they were developed by a small group of individuals that might not have been representative of those who constitute the many different RECs existing in different parts of the country. However, they should serve as a template for individual RECs as they begin to write their own SOPs. The final SOPs

should be adapted to the institutional and community context in which the REC exists. Hence, RECs in Egypt are urged to use these model SOPs, but also to focus on the sections that need to be sensitive to the local context. Feedback from existing RECs in Egypt on the relevancy of these SOPs would help refine further iterations of this first attempt to develop model SOPs.

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