with weak regulatory systems where these can serve as useful learning tools. Lower operational costs, recent regulatory reforms and several logistic advantages make India today an attractive destination for conducting clinical trials (13, 14). However, it must be remembered that future clinical trials are likely to become more complex both in design and execution. Thus maintaining high ethical standards, continuous capacity building of both investigators and IRBs and stringent quality assurance will become exceedingly important to ensure that WLs are minimised and the rights, safety and well being of participants in research are protected.

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Survey of ethics committee protocol approval letters: compliance with Schedule Y / ICMR Guidelines 2006

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Abstract

A study was carried out to determine the extent to which ECs comply with format requirements given in guidelines and regulations. ECs were sent a written communication requesting them to permit investigators to study their approval letter for compliance with the ICMR Guidelines and Schedule Y, using a pre-designed proforma. Of the 60 ECs approached, only 20 agreed to participate. Legal experts and social scientists were not present at the approval meetings of most of the ECs. Only 7 ECs had a quorum according to Schedule Y. Several ECs did not state whether documents such as the clinical trial agreement and insurance policy were reviewed. Delays in sending approval letters could be shortened with efficacious operating of ECs. There is a need to train EC members and create a better awareness of regulatory requirements. There is also a need to evolve a mechanism to monitor EC functioning.

Introduction

Ethics committees (ECs) in India are expected to work within the framework of the Ethical Guidelines for Biomedical Research on Human Participants of the Indian Council of Medical Research (ICMR) (1) and the Amended (2005) Schedule Y of the Drugs and Cosmetics Act, 1945 (2). The Act and the Guidelines, among other documents, have provided the format in which ECs are supposed to issue letters of approval for proposals submitted for review. Approval letters are expected to mention the names of the members who attended the meeting (which reflects the quorum), and the details of the documents reviewed, thus reflecting the functioning of the EC (1, 2).

There is very sparse data available on the functioning of ECs in India. We decided to carry out a study to determine the extent to which ECs comply with the requirements mentioned in the guidelines and regulations while issuing letters of approval for proposals they review.

Material and methods

An observational, retrospective study was carried out after receiving approval from the Institutional Ethics Committee (IEC). The contact details of ECs were obtained from the EC approval letters of other centres in the IEC records for research projects submitted between January 2006 and August 2009. The investigators signed a declaration assuring the IEC that the names of institutions to which the ECs belong would be kept confidential. The identified ECs (n=60) were sent a written communication stating the purpose and methodology of the research project and were requested to permit the investigators to study the EC approval letter for drug trials issued by them for compliance with requirements enunciated in the ICMR guidelines (2006), and Schedule Y (2005). A single approval letter of each EC that consented to participate in the study was assessed for compliance with the requirements, using a pre-designed proforma and check-list as shown in Table 1.

Results

Only 20 of the 60 ECs (33%) that were approached for participation consented to have their approval letters studied. Of the 20 approval letters studied, 4 were not issued on a letterhead. Only 11 of 20 approval letters provided the list of EC members who attended the meeting specifying their designations on the approval letters. Of these 11, only 7 had a quorum satisfying the Schedule Y requirements (2). It was noted that neither legal experts nor a social scientist, a theologian, or an ethicist were present at the approval-granting meetings in most of the ECs. The method for patient accrual, and the insurance policy and clinical trial agreement were not mentioned among the documents reviewed by most ECs. The member secretary signed 12 EC approval letters and the chairman signed 6. There was an average gap of 9 days (range 1-60 days) between the date of project review and approval letter date.

The items studied and the number of compliant ECs are summarised in Table 1.

Discussion

Ethics committees are the custodians of the safety of research participants. The ICMR guidelines (1) and Schedule Y of the Drugs and Cosmetics Act (2) are amongst the documents that lay down standards related to the composition of the EC and the procedures that should be followed while reviewing and approving research projects concerning human research. Many aspects of the functioning of an EC are not amenable to a general audit. This is understandable to some extent, as the confidentiality of research participants and proposals needs to be safeguarded. Further, ECs expect investigators to faithfully document everything that happens during a trial. However, our study showed that many ECs were deficient in several aspects related to documentation in their approval letters.

The regulations also prescribe a format for approval letters so that sponsors, investigators and regulators are assured, to a certain extent, that the EC adheres to prescribed norms on its composition, quorum and review procedures, and is diligent about documentation related to the documents reviewed.

In our study the only aspect that ECs consistently mentioned was the name of the EC and the title of the protocol reviewed. The format for EC approval given in Schedule Y requires the name of the EC to be mentioned in the approval letter. As the EC is independent of the institution, the EC should have a name to maintain its own identity.

Table 1: Compliance with ICMR guidelines and Schedule Y requirements

Sr. No.	Item	Number of ECs complying (n=20)
1.	Letterhead of EC used	16
2.	Name of EC given	19
3.	Details of EC meeting given	
	a. Date	19
	b. Time	6
	c. Venue	6
4.	Complete title of the research protocol given	20
5.	List of documents reviewed	
	a. Protocol date and version no	20
	b. Patient information sheet (English & vernacular)	20
	c. Informed consent form (English and vernacular)	18
	d. Investigator's brochure (date and version no)	16
	e. Method for patient accrual	5
	f. Principal investigator's curriculum vitae	20
	g. Insurance policy / compensation	10
	h. Clinical trial agreement	8
	i. Investigator's undertaking	11
6.	EC members present	
	a. Name	16
	b. Designation	11
	c. Quorum met	7
	d. An EC member involved in the trial voted for it	0
7.	Criteria for EC composition were met	4
8.	The EC asked the PI to report to it about	
	a. Progress of the study	17
	b. Periodicity of report	5
	c. SAEs	14
	d. Protocol amendments	11
	e. Final report of the study	14
9.	Date and number of approval letter given	13
10.	No gap between date of review and approval date	3

Among the documents reviewed, the participant information sheet (PIS) was the only document mentioned by all ECs. Two committees did not specify that they reviewed the informed consent form (ICF) although all mentioned the PIS. It is possible that these committees included the ICF when they mentioned PIS. Ideally these are separate documents and need to be mentioned separately. If not, the document is conventionally referred to as an "informed consent document".

In all other aspects, serious deficiencies were noted. Up to 20% of approval letters did not mention the names of members of the EC attending the meeting.

The quorum was not met in four ECs although the problem may be larger as half the letters did not carry the names of those who attended the meetings and therefore could not be assessed. As per Schedule Y, a lack of quorum would invalidate the approval and the study should not have been initiated. Similar observations have been made in a study carried out in Pune (3).

Most approval letters did not mention the presence of a legal expert or social scientist /ethicist. The participation of legal experts and a social scientist or ethicist is crucial in the review of and decision making on projects. The legal expert is expected to look at legal requirements and issues related to provisions for compensation.

The other common observations included not mentioning the venue and time of the meeting, and not stating the method of patient accrual. Patient accrual methods (including advertisements, letters to colleagues or any other methods) must be reviewed by ECs as these have important implications for the ethical conduct of clinical trials. Several ECs did not state if documents such as the investigator's undertaking, the clinical trial agreement and insurance policy documents were reviewed. The insurance documents must be reviewed as per Schedule Y in order to ensure that the sponsor has given adequate cover to the research participant in case of research-related injury.

In this study, only one-third of ECs approached provided consent. The experience of the ICMR has not been different. In 2002, 35 of 71 institutions did not participate in the ICMR-conducted survey of ECs, even when the ICMR was the sponsor (4).

The study is limited by the small numbers involved, but it identifies important issues regarding the functioning of ECs. There is a need to train EC members and create a better awareness of regulatory requirements. There is also a need to evolve a mechanism to monitor EC functioning, which is crucial in ensuring the ethical conduct of research.

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Considering ethics in community eye health planning: perspectives from an existing model

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Abstract

Despite the widespread acceptance of the principles of the Alma Ata Declaration of 1978 and the subsequent amendments, health for all has remained a distant dream in many parts of the developing world. Concerns such as the economic efficiency of health systems and their reach and coverage have dominated discussions of public health, with ethics remaining at best a shadowy set of assumptions or at worst completely ignored. Similarly, questions of ethics have been taken for granted and rarely addressed directly in the design of public health models across sectors and are rarely explicitly addressed. This paper uses the experience of the L V Prasad Eye Institute's (LVPEI) pyramidal model of eye healthcare delivery to explore ethical issues in the design and implementation of public health interventions. The LVPEI model evolved over time from its beginnings as a tertiary care centre to a network that spans all levels of eye care service delivery from the community through primary and secondary levels. A previously published analytical framework is applied to this model and the utility of this framework as well as the ethics of the LVPEI model are interrogated. An analytical and prescriptive framework is then evolved that could be used to build in and evaluate ethics in other public health delivery models.

Introduction

Among the most significant achievements of modern medicine is the possibility of making good healthcare available to all people at a reasonable cost. While this has been underwritten in large part by advancements in science and medical technology, no less important have been the political and social perspectives that inform contemporary societies. These perspectives have in turn led to the creation of equitable systems of distribution of goods and services. The distribution