**A Qualitative Study of IEC Member’s Understanding of Research Guidelines, Privacy, and Challenges to Privacy Protection**

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**ABSTRACT**

Right to privacy of health-related information is a foundational bioethical principle. In India, the importance of protecting privacy is included in law and ethical guidelines. Institutional Ethics Committees (IEC) are entrusted the responsibility of protecting fundamental ethical principles including privacy and confidentiality. The present qualitative study was designed to understand ECs’ privacy-related obligations, and their experience implementing ethical guidelines and privacy protections in their institutions. An interview guide was prepared regarding knowledge of ethical guidelines. Interviews of nineteen EC members were recorded, transcribed and translated. Interviews were analyzed using thematic analysis. Themes related to following issues were extracted after analysis: awareness, understanding, and implementation of ethical guidelines; understanding of privacy-related obligations and their implementation; juridical risks to privacy of patients and research participants. There was limited knowledge of ethical guidelines and members did not visualize any role in monitoring of the studies. These results suggest that training programs and awareness workshops should be organized for ethics committee members for protection of rights of research participants.

**INTRODUCTION**

Recognition of the right of privacy regarding health-related information is a corollary to the foundational bioethical principle that people have the right to give informed consent/refusal to control access to their bodies. The right to privacy refers to the right to limit “access of others to one’s body or mind … through physical contact or disclosure of thought or feelings” (1). The related right of confidentiality, and the concomitant obligation to maintain it, arises in a fiduciary relationship, often a professional relationship, like that between patients and clinicians, or research participants and investigators. It requires that the professional maintain the privacy of information revealed by or about the patient or research participant. Patients’ and research subjects’ trust that their privacy will be protected and that information disclosed will be held in confidence facilitates their truthful and frank disclosures to those who seek to help them or who rely on such information in research (2). Privacy is also valued for its own sake as a prerequisite for individuals’ autonomy and constitutive element of their flourishing as unique individuals (3). The right to privacy enables people to keep “disruptive material out of the public arena” and protects “private life from the crippling effects of the external gaze” (4), particularly where those “crippling effects” include discrimination, stigmatization, and censure.

In India, the importance of protecting privacy is enshrined in law and ethical guidelines. Interpretation of Article 21 of the *Constitution of India – Right to Life and Personal Liberty* has established a penumbral right of the privacy or the right to be free from encroachment on private life (5). The Medical Council of India Code of Ethics Regulations states that confidences entrusted to physicians by their patients should not be revealed unless compelled by law (Article 2.2) (6), though the Code’s next Article also suggests in apparent contradiction, that physicians need to share the patient’s prognosis with family members when doing so will serve the best interests of the patient *and the family* (emphasis added; https://cis-india.org/internet-governance/health-privacy.pdf). The fourth principle of the Indian Council for Medical Research (ICMR) *Ethical Guidelines for Biomedical Research on Human Participants year* articulates privacy protections that are to be implemented by Institutional Ethics Committees (IECs) to protect the interests of research participants.

In this paper, we report the first empirical study in the Indian context examining IEC members’ awareness of ICMR’s *Ethical Guidelines*, how they understand their privacy-related obligations, and their experience implementing ethics guidelines and privacy protections in their institutions. Then, we report IEC members’ views regarding the *Right to Information Act 2005* and the *Persons with Disabilities Act* (1995), which have been shown to present risks to patients’ and research participants’ privacy (7)(8).

**METHODOLOGY**

**Recruitment and informed consent**

Following approval for this interview-based study by the IEC of PGIMER-Dr. RML Hospital, New Delhi, a letter explaining the study was sent to members of the 22 IECs in the National Capital Region Delhi (i.e., Delhi and surrounding area) whose addresses were publicly available (n=55). With a goal of enrolling and interviewing a maximum of two members from each IEC, by a combination of random and snowball sampling, IEC members were approached for their individual consent to be interviewed. Although IEC approval was obtained to interview as many as 45 IEC members, the actual number interviewed was determined by the goals of maximizing the diversity and range of responses and reaching “saturation” in the data collected. Data saturation (or redundancy in information gathered) is the goal for collecting data for the qualitative research method of thematic analysis employed in this study (9).

**Data collection and analysis**

Between March 2010 and May 2011, IEC members were interviewed using semi-structured interview guides. Interviewees were given the option of conducting the interview in either Hindi or English. All but one chose English. Interviews were audiotaped, professionally transcribed, translated into English as necessary, and coded by the principal investigator (NNM) and one co-investigator (TB), who conferred to ensure inter-coder reliability.

As is typical when employing thematic analysis, data collection and analysis were integrated. The interview guide was continually revised to explore emerging concepts and themes. Interview responses were systematically analysed to identify responses clustering around common themes. Analysis proceeds through a series of sequential steps (Rubin & Rubin, 2011): repeated close reading of transcribed interviews, followed by coding of interview data and verification of inter-investigator reliability in coding. In this case, the final step involved normative analysis of the themes or concerns identified. Reporting of the results of this thematic analysis is thus integrated with the normative analysis or discussion of the themes identified.

**RESULTS AND DISCUSSION**

Demographic information about those interviewed is presented in Table 1. It is noteworthy that while all IECs are required to have at least one community representative (10), the one community representative interviewed had a PhD and experience as a psychiatric social worker. Thus, all IEC members interviewed have graduate degrees and experience working in healthcare institutions.

**Table 1: Enrolment and demographic details of IEC/IRB members**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Approached via mail | Agreed to be contacted | Finally enrolled |
| IEC/IRBs Contacted | 22 | 15 | 11\*#$ |
| IEC/IRB Members | 55 | 32 | 19 |
| Gender M/F | - | - | 13/6 |
| Average age in years | - | - | 55 |
| School years | - | - | 16\*\* |
| Experience | - | = | 6 to >10 years |

\*6 at government hospitals, 4 at private hospitals and 1 a private IEC

# clinicians 12, Specialists 4, Law graduates 2

$6intervieews served more than one IEC and two IECs had only one member interviewed in the study

\*\*one was Ph.D. in psychology and worked as psychiatric social worker but was considered a community representative

**Awareness, understanding, and implementation of ethical guidelines**

Of the nineteen IEC members, only three expressed less than full awareness of the ICMR Ethical Guidelines for Research, (10), which guide their review and monitoring of research protocols. One of these three expressed familiarity with guidelines from the United Kingdom and had a preference for following them, while stating that “there is not a set protocol or a set guideline that is followed” on the IEC. A second referred to a lack of occasion to become familiar with the ICMR’s *Ethical Guidelines*, and the third expressed having no knowledge of them: “we have been going by general perception. We have not been given any guidelines for this.” A fourth interviewee reported that the committee mainly relies on the *ICMR Guidelines*, but noted that guidelines from the Department of Science and Technology are sometimes used and that there is “not much difference between them.” Still another commented that the ICMR’s *Guidelines* are “the law of the land, and they are accepted by NIH of USA; they are as good as any international guideline as of now.”

Interviewees were also asked about their familiarity with international research guidelines, such as the *Declaration of Helsinki* orCouncil for International Organizations of Medical Sciences (CIOMS) guidelines. While a third of those interviewed were not familiar with any international research guidelines, just over half were conversant with international guidelines and said that they referred to these to evaluate research protocols. One IEC member discussed that the International Organization for Standardization has guidelines focused on medical laboratories (ISO 15189) to be used for development of quality management systems and laboratory assessment. He observed that the laboratory assessment process requires assessors to sign a pledge that they will maintain confidentiality, and suggested that such a confidentiality agreement should be in place for every research project. IEC members with less than a year’s experience had less familiarity with the ICMR *Guidelines* and did not know of the international documents.

Some IEC members expressed the common concern, documented in the bioethics literature internationally , that there is a preoccupation with written documentation and the “letter” of consent forms and guidelines, rather than their substance and “spirit” (11). One IEC member with legal background commented: “The consent form is just being used to get the sign of the patient; they are not reading out the contents, clause by clause. Most of these forms are not in vernacular language. It has to be read out to the patient that after the completion of the project, this information has to be shared with other doctors or scientists or even with the media, so is the patient prepared for that. This is not being told to the patient at the time of enrolment by the clinical trial researcher.”

Reflecting another common concern that time constraints are a barrier to obtaining truly informed consent, he explained that “most of the doctors are full time employees of the hospital, and research is additional work, so there is lack of time.” This IEC member saw a hands-on role for the committee in training investigators: “Before a particular project is approved by the ethics committee all have to be trained. I have even suggested that … every member of ethics committee take a separate subject and let him explain to the researcher, like somebody has to deal with the compensation part, … insurance, privacy etc. It has been decided to organize a seminar or workshops on these topics by the ethics committee and impart training.”

However, contrary to the provisions of the ICMR *Guidelines*, the same IEC member does not see a role for the committee in monitoring conduct of research or management of information: “See we have no role to play, we only approve the project. … we only see if that agreement, the consent form, adheres to the various clauses, but thereafter we have no role to play. Once the trial is approved by the ethics committee, the role of the ethics committee is over. We do not pay any attention if the records are being properly maintained or not in the respective hospital. It is the job of the administration; it is not our job. We can suggest to the hospital authorities that the records are to be properly maintained even after the completion of the project. … Our work is only restricted and confined to approve the proposal. … the implementation part is based on the faith that the researchers shall follow all the guidelines issued by the ICMR or any other national or international body. … After the completion of the project a report is submitted to the ethics committee for information sake, … What happens to the data thereafter, it is the administrative matter and it does not fall within the purview of the ethics committee.”

In contrast, another member from the same IEC referred to a monitoring role, as well as to having faith in the conduct of investigators, who “have to present a paper to our ethics committee for our approval, and we see that all these aspects have been properly described in that declaration… Usually the researcher is from our own institution so we also have faith that they shall be following what they commit on that paper. Once approved, thereafter during the study also we intermittently investigate and inspect if they are following those steps properly.”

**Understanding of privacy-related obligations and their implementation**

All nineteen IEC members interviewed expressed a fundamental commitment to protecting the privacy of patients and research participants. All stated that information regarding a patient’s or research participant’s disease and other personal information shared during treatment or research should be kept confidential, and considered it their responsibility to help maintain confidentiality. Some interviewees demonstrated a rather sophisticated understanding, specifically distinguishing between privacy and confidentiality, and explaining confidentiality as arising with regard to information shared within a professional relationship. Others used the two concepts interchangeably. One of those with less than a year’s experience on the IEC referred to the non-instrumental value of privacy: “no patient wants [that] his ailment shall become a topic for broadcast and gossip; it does not matter if that brings him some benefit or not. Patients always want to keep personal health information within a limited space.”

Many IEC members were themselves clinicians; indeed, all but two of our interviewees had provided clinical care. Moreover, in the absence of the clinical ethics-focused hospital ethics committees or consultation services that are common in, for example, the US (12), IEC members are occasionally called upon by colleagues or hospital leadership to step outside their prescribed research oversight role to provide clinical ethics advice on an *ad hoc* basis. Therefore, inspired by Mark Siegler’s influential study of confidentiality and of how many individuals had access to a patient’s hospital record during a typical hospital stay in the United States (13, 14), we asked IEC members: “During a routine hospital visit, how many people have access to a patient’s record or health information?”

Echoing findings in Siegler’s early study, one respondent emphasized that while a large number of people have access to a patient’s private information, that access must be based on its contribution to the patient’s benefit: “At present, anyone can go and have it. The records are … supposed to be with the nurses, and it is the nurses’ discretion with whom to share it … and it is by and large accessible to other doctors because there are lots of doctors looking after the same patient … and there are cross referrals that are being made for the patient. … it would become very difficult to treat the patient if the records are not accessible. But I think primarily it is accessible to the medical fraternity. Others who may be perhaps not directly involved with it [perhaps not], but it is accessed easily by the people who are directly involved. … It depends on why the person is looking it and what are his intentions.”

Demonstrating that both the requisite motive of benefitting the patient and the authority of the patient’s physician to determine that benefit constrain access to patients’ confidential records, another respondent referred to the proceedings of her own IEC and its access to patient records: “Minutes are … kept … confidential. We have a medical record section. If we want to have a file then we will have to give it [a request] in writing. I cannot just access anybody’s file except my own patients and even if we want to have another’s file then we will have to take permission from them even as a senior doctor in this hospital.”

IEC members discussed methods for protecting the security of health information of both patients and research participants. The interviewee who articulated most clearly a monitoring role for the IEC also referred to ensuring that information is stored in a locked fashion as the key means to protect private information from being publicized.

Others expressed the need for higher technology ways of protecting privacy of stored information: “Information that is keyed in is not available to any unauthorized person that is one thing. Secondly they should see that there is [an] adequate security setup built in the database, so access becomes limited. It [adequate security] has yet to happen in India but surely there is a need to do that primarily because more and more information is getting into computer systems. Especially in computers that are networked, it should be made sure that it cannot be accessed by anybody else outside the system. There are so many ways of ensuring this, like password protection at each level, and read or write authorization to make sure that privacy is maintained. It is possible but we have to put it in a larger way in our country.”

IEC members also referred to security measures taken by investigators: “Some of them keep it as simple as … lock and key kind of security. Some of them have it in their computers with proper passwords, well coded, or some of them may go even into higher levels of security, … We have not had one case up to now which has said that there has been a breach in the information that has been collected.” Although assignment and use of codes may be considered preferable, another IEC member described and approved of both investigators and IEC members referring to patients and participants by initials or medical record numbers, rather than full names.

**Juridical risks to privacy of patients and research participants**

IEC members demonstrated varied levels of appreciation for the risks to patient and participant privacy presented by India’s *Right to Information Act 2005* and *Persons with Disabilities Act* (1995)(15, 16). In the case of the former, it is misunderstanding of the Act’s provisions that risks breaches of patient privacy. In contrast, the *Persons with Disabilities Act* does require those seeking its benefits to compromise their privacy.

The *Right to Information (RTI) Act 2005* provides citizens the right to access information under the control of public authorities in order to promote transparency in government, counter corruption, and make government more accountable (Ministry of Law and Justice, 2005; Mishra et al, 2008). All but three of the IEC members interviewed incorrectly believed that India’s *RTI Act* requires and allows disclosure of an individual’s health information to a third party who invokes the *Act* to request it. Three correctly realized that the *RTI Act* does not require or permit disclosure of health information, though such information can be subpoenaed by a court or disclosure can be required in the interests of protecting public health. One commented that the *Act* was the topic of many educational workshops which clarified that under the *RTI Act* otherwise private information may be disclosed, but only in cases where the larger public interest warrants it as verified by an appropriate legal authority. Another commented that sometimes employers will seek mental health information about employees, and that this can only be disclosed with the explicit consent of the employee.

Interestingly, because transparency has been such an important goal in Indian public life partly to combat corruption, our questions about the confidentiality of a patient’s health information sometimes prompted responses asserting a patient’s right to know his/her own health information, the idea that such information should not be kept confidential *from* the patient. This suggests a confusion on the part of some IEC members regarding patients’ rights to privacy and confidentiality and their right to know their personal health information including prognosis and test results. In contrast, the chairperson of one IEC, a physician, expressed “confidence” in “two points,” clearly distinguishing the two rights: first, “the patient should have access to the files and there nothing could be kept confidential.” Second, “we [must] make sure that the files do not fall into the other people’s hands. … Otherwise, anybody will come and have that file … in this Indian set up, first of all, the habit of Indians giving bribe has not gone. Someone has bribed the ward boy and bribed the midwife to show the file of this bed number. And, the doctor will not be always there to see. … It is not common. I am saying that this is a possibility, and who will get blamed? Doctors.” Here the interviewee elaborated on the perceived climate of potential corruption that necessitates both privacy protections and the demand for transparency afforded by the *Right to Information Act*.

India’s *Persons with Disabilities Act* (1995) enables those of India’s roughly 70 million disabled persons who meet particular criteria to obtain some benefits in employment and some governmental services, transportation concessions, and tax rebates (15). Its implementation, however, requires that individuals seeking benefits obtain a disability certificate from a government healthcare provider and that the certificates themselves display a photograph, name, and address of the disabled individual, as well as the diagnosis, duration of illness, and degree of disability. To receive benefits, the individual must show the certificate to relevant officials in government offices, as well as the ticket counters and checkers at railway stations. Elsewhere we have analyzed problems with the Disability Certificate and argued for particular improvements that would better protect patient privacy .

Although seven of the 19 IEC members were aware of India’s *Persons with Disabilities Act* (1995) (15), only two immediately recognized that using a Disability Certificate can violate or limit a person’s privacy. One of them commented that, for instance, a patient with a mental disability would have to appear before a panel of doctors, his name would be known, and then he would have to carry a certificate listing the nature of his disability. In contrast, another who worked with neurologically disabled individuals initially failed to see a risk to privacy: “*I have not thought about it, but certainly yes now [that] we are raising this question … I have been involved with neurology disability certificates where we write diagnosis and we write the extent of disability. So [back then], at least, I had not thought about it.”*

Focusing more often on physical disabilities (e.g., mobility or blindness), as is common (15) , most IEC members expressed a lack of concern about the impact of the Certificate on individuals’ privacy; for example, one member said: “*most of the times, this disability certificate is given to persons who are already having 60% to 80% disability so it is very apparent*. … *To a medical person, most of the disabilities are very obvious, it may not be just at the first sight and even without the certificate we know about it.*” Upon questioning about non-obvious disabilities like mental illness, however, the member admitted “*there the confidentiality is much more needed.”*

Further, although this IEC member recognized that nonmedical personnel do not have the same training regarding privacy protection as medical professionals, she downplayed the risk to privacy. “*We expect that in our profession, people are more thorough about their professionalism.”* In contrast in transportation and other, those who see the Certificates do not have a fiduciary relationship with the Certificate holder; instead the relationship is one of gate-keeping power. “[Patients] *are showing the disability certificate to the persons who are giving them some benefit, and those persons at those posts know about the role of confidentiality, most of the people. But sometimes … there may be some manipulations, some power politics to cause a leakage as some opposite party wanted to know the weakness [the disability], so there may be issues, but it is very rare and not so common.”* Some IEC/IRB expressed that disabled individuals willingly accepted this trade-off between privacy invasion and material benefit of the Certificate’s use. One member commented: “*they are getting some advantages because of this certificate, so that is why they are disclosing*” the health information it contains when they use it. Another said, “*I think [the patient] is not really bothered about the privacy aspect because the certificate leads to some benefit … If they are going to use that somewhere, obviously it is not going to be confidential. If it says it is 60% or more of disability, which gets them much more benefits than a person who has 20% to 30% disability but he is voluntarily coming out of the no confidentiality clause I guess because he is putting it in black and white that he is disabled*.”

These members did not focus on how truly willingly the patient sacrificed his privacy, saying for example, “*No, I think if the patient voluntarily says that he is say 60% disabled to get the benefits, why does he need a confidentiality clause? He is trying to prove that he is disabled. So I do not think when you are getting a certificate for a benefit, where does the confidentiality stand. I do not think the question comes in at all at that time.”* Another member explained that it was precisely because seeking the Certificate is initiated by the patient that its privacy implications were of less importance: “*I think here the benefit to the people is overriding. Here the patient is walking to the hospital and asking for a disability certificate. … where people are poor … if government provides some facility to them, personally, I feel that is the overriding factor here.”* It is perhaps disturbing that IEC members, who are charged with ensuring that informed, *voluntary* consent is obtained from research participants, are not more deeply reflective about the conditions required for true voluntary decisions.

Further, most of those interviewed were not particularly insightful about ways to address the violations of privacy required by use of the Disability Certificate. However, when asked whether there was some modification of the Certificate that would protect privacy while still affording benefit, one committee member suggested use of a smart card: *“Hav[ing] a smart card that means you have all the data there in the chart, but [only] some data is accessible to some people. All the data is not accessible to everybody. So we have firewalls. You work in silos; the same smart card works in all compartments. So everybody knows information on a need to know basis. If I am the railway clerk who is to give a railway ticket for the individual who has the disability, I really should not be concerned about what disability he has and to what extent the disability is. I should be concerned this … individual today is in front of me. This is his photograph. This is biometric mark and he has come for a claim which I need to want knows. What is his disability is not my concern.”* Even if such technological fixes as a smartcard are currently only at planning stages , the underlying rationale expressed by this interviewee could be implemented in a lower tech manner. Disclosure of diagnosis could be required by the *Act* on a need-to-know basis. Only those certifying a person as disabled and thus entitled to a range of benefits would need to know the nature of the individual’s disability. Just as the handicapped signs that people in the United States are provided to place on their motor vehicles to entitle them to preferential parking access do not specify the nature of their disability, in India the Disability Certificate itself need not display that information. (Drivers may have a handicapped sign in the US because conditions ranging from asthma to neurological or cardiac conditions to a leg injury can impair their ability to walk from car to destination.) It is perhaps unfortunate that the sole suggestion to revise the Disability Certificate was articulated in terms of relying on technology not widely available in India.

Why should it be hoped that IEC members, charged with protection of the interests of research participants, would have knowledge of privacy-related problems associated with the Disability Certificate and insight into ways to address those problems? Admittedly such ethical concerns are beyond the purview of an IEC. Nevertheless, IEC members are typically viewed as their institutions’ ethics experts, are sometimes called upon to develop or interpret ethical policies not related to research, and most importantly, must have a nuanced understanding of concepts like voluntariness and privacy in order to interpret and apply ethical guidelines governing research, as per their mandate. Indeed, one IEC member commented that *“generally all across the board, in India privacy is not given sufficient thought,”* and suggested that legislators “*should consult ethics experts and redraft the law* [regarding the Disability Certificate] *… to protect the privacy and confidentiality of an individual*.” As perceived ethics experts, IEC members may indeed be called upon to suggest revisions or protections in this and other contexts.

**CONCLUSION**

Given the Supreme Court of India decision that recognizes a right of privacy to be a “guaranteed fundamental right” (5, 17), and its recognition that privacy is not an absolute right, the need may be all the more for pressing for nuanced interpretation both regarding the spheres of life that should be protected as private and balancing the right of privacy against other rights. As public awareness and assertion of the right of privacy grows, it is likely that IEC members will be increasingly be called upon within their institutions to help interpret its requirements. Moreover, as healthcare institutions are increasingly required/called upon to establish institutional ethics committees—and even as India may move toward the US model of establishing clinical ethics-focused committees and offering clinical ethics consultation to clinicians, patients, and their families—the empirical study reported here suggests where strengths and weaknesses in IEC members’ awareness of guidelines and of the demands of ethics may lie. Moreover, the study was conducted in 2011, the scenario may have changed after Supreme Court verdict 2013(18) on clinical trials and after mandatory registration of ethics committees. These results may be used to inform educational workshops for IEC appointees, committees own self-education activities, and education that they may provide to colleagues within their institutions.

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