where we strived to obtain scarce research dollars to pursue research of relevance. Often, the topics of our enquiry stemmed from our work on the ground. Also, research findings got fed back to advocacy campaigns and policy and legal reforms. They had on occasion helped shape healthcare and related services at the grassroots level. Rosanna herself came from a country in Latin America where she was involved in health activism and trained in the critical theory tradition. As a consequence she found it challenging to be in an academic setting which appeared to be so far removed from the ground realities that people are confronted with. It was heart wrenching to learn that research supported with millions of dollars was not necessarily socially relevant, nor did it generate much new knowledge.

The debate around the social value of research is not new (2) and it is not easy to resolve. It is harder to lay down general guiding principles to arrive at fair decisions on the social value of a particular research project. This leaves all stakeholders in the research enterprise with much more accountability for the quality of their own research and the use of scarce research funds.

Postscript: *Rosanna told us that eventually the team undertook a systematic, structured review of literature, spanning several sectors beyond health. Some of us in the group are acquainted with the products of her project. Indeed, these are outstanding and made original contributions to the field in the early 2000s. On the other count, efforts to explore other appropriate REBs from within the academic setting were not encouraged at her institute. To her, this was because REB approval came by quickly through the current arrangement with the current, designated REB.*

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Process, pitfalls and probity: sharing experiences on setting up and running ethics committees in India

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Jesani recently (1) pointed out in his editorial that even after 30 years of having ethics committees (ECs), we still do not have empirical and factual knowledge about how ethics committees function in the country. He rues that information on how "ECs function, the problems and dilemmas faced and experiential sharing is not available in the public domain." Brahme and Mehendale (2) provide one of the few accounts in the literature of characteristics of ECs, focusing on institutions in Pune.

In this article, we describe the framework of a workshop that we organised at the Second National Bioethics Conference in Bangalore in December 2008; we also highlight the challenges in establishing and administering ECs in India identified during the discussion among workshop participants. We believe that our experience will help researchers and institutions better understand how to start and sustain an EC, efficiently and effectively.

Concept and structure of the workshop

The workshop was organised with three objectives: to learn about the requirements for setting up an EC; to identify the potential obstacles to setting up an EC, and to find ways to conduct the day-to-day activities of an EC effectively

The workshop was also conceived as a venue for participants to discuss the problems, pitfalls and processes involved in setting up an EC. This was done through a structured discussion which was initiated during the second half of the workshop. The 35 participants and five facilitators had varying levels of experience in the field of EC functioning.

The workshop began with an introduction to the rationale of the workshop, followed by a presentation on the guidelines for setting up an EC and the challenges in building it from scratch. A discussion with the participants was then started with a focus on the challenges faced in setting up and running ECs, and the responses to these challenges. These were finally distilled and presented as a summary at the end of the workshop.

Highlighting regulatory guidance on ECs and practical tips in running an EC

Following the introduction, one of the facilitators (S Swarnalakshmi) presented guidelines for setting up of an EC. Universally, ECs resemble each other in concept as their focus remains the safety and dignity of human participants in research studies. However, they may be differentiated by regional variations and cultural nuances.

Worldwide, a number of laws, regulations, and guidelines govern biomedical and social science research in health. Researchers from institutions in developing countries such as India often collaborate with researchers from developed countries. In such collaborative research projects, we need to understand the guidelines of both the host and the sponsor countries. In this context, the relevant sections of international guidelines focusing on ECs/Institutional Review Boards (IRBs) – ICH-GCP, 45 CFR 46, 21 CFR Part 56, E6 (R1) (1996), Section 3 (1996), World Medical Association Declaration of Helsinki (2004) - Section B.13, CIOMS International Ethical Guidelines for Biomedical Research involving Human Subjects (2002) - Guidelines 2 and 3, Article 19 of the Universal Declaration on Bioethics and Human Rights of UNESCO – were explained. The relevant website links and sources from which these international guidelines could be accessed were provided. The different situations under which particular international guidelines that govern human subject research in many countries are used were described.

The importance of the EC as per the Indian Council for Medical Research (ICMR) Ethical Guidelines for Biomedical Research on Human Subjects (4) was highlighted. This was followed by a detailed description of Chapter II of the ICMR guidelines, on ethics review procedures. This covered the basic responsibilities of an EC; the composition of the EC including the quorum required for drug trials; type of training required for EC members. Details of the format of the EC application for protocol submissions were also explained. The review procedures to be followed by an EC were elaborated including procedures to be followed for deciding if a proposal is exempt from review, procedures for expedited review and those for research requiring full review. Approaches to monitoring following EC approval and record keeping were described. The administration and management of an EC was outlined. The need for special consideration for research involving vulnerable populations was also briefly explained. The strengths (clear and comprehensive guidelines appropriate for the Indian scenario) and limitations (no mention of funding of ECs, such as for example in terms of percentage of the total project grant; minimum qualification of EC members are not prescribed, and lack of legalisation of the guidelines which limits enforceability) of the ICMR guidelines were discussed.

This was followed by a case study of best practices followed in the EC (the institution uses the term institutional review board or IRB for its EC) of a Chennai-based Indian non-governmental organisation, YRG CARE (http://www.yrgcare.org/). YRG CARE provides a comprehensive range of services in HIV/AIDS, functions in a hospital setting and conducts socio-behavioural research studies and clinical trials on HIV/AIDS. An in-house committee reviews the science of the research proposals and a trained bioethicist (the IRB coordinator) examines the proposal for ethical issues before the proposals are submitted to the IRB.

A key practice in the IRB was the face-to-face interaction between investigators and IRB members during the IRB meeting. This practice reduces delays spent on correspondence and provides a great learning opportunity for IRB members as well as investigators (who better understand IRB concerns). All research projects, including short term studentships, are reviewed thoroughly. The IRB members are kept informed about research outcomes including publications and conference presentations by YRG CARE researchers. The English versions of the informed consent forms are translated in local languages, and the translated documents are "back-translated" to ensure reliability and validity of translated documents. YRG CARE has also instituted a community advisory board (CAB) to provide community inputs for its research, and the IRB and CAB meet on an annual basis to exchange views. IRB members are independent of the institution and this helps reduce possibilities of conflict of interest.

There are clear documentation procedures instituted in the IRB. Access to files is limited only to the IRB desk, and records are kept under lock and key. There is a duly indexed archiving of completed project files in a record maintenance unit. The IRB desk has established good contacts with both the national apex biomedical research body (ICMR) and international/ foreign collaborators, including the National Institutes of Health (NIH) from where clarification is obtained on IRB procedures when needed. A test of understanding is prepared for some trials when there is a possibility that the participants may not understand the complicated procedures involved in the study. Sections dealing with specimen banking forms have been introduced in informed consent forms where relevant.

The presentation concluded with a discussion on how the success of an IRB depends on well-trained and committed EC members, clear and transparent procedures, rigorous documentation, and support from the institute in terms of financial resources, degree of autonomy and investigator adherence to norms.

The participants found the practical experiences in running an IRB successfully very useful.

Key questions used to initiate discussions

After the presentation, a facilitator (Mala Ramanathan, Sree Chitra Tirunal Institute of Medical Sciences and Research, Thiruvananthapuram) led a structured discussion among the participants to identify challenges faced by ECs in the country, and also innovative practices at local EC level.

The key questions used to initiate the discussion were:

A. Questions related to membership requirements in an EC.

What are the skills required for a person to be considered for membership of an EC, given that proposals need to be evaluated from both technical and ethical perspectives?

Since the skills required may not always be available within the same institution, where else could we look for these skills?

Should it be mandatory for members to have an orientation course, as it were, to understand the existing requirements that need to be fulfilled before initiating, and during the process of

conducting, any kind of biomedical research?

B. Questions related to finances for setting up an EC

We need resources to set up and run an EC. When resources for research are scarce, how can we generate resources for the ethical review? Is it possible to:

- Charge all researchers a stipulated EC fee? If yes, what happens to research that is not funded?
- Seek government or other funding for this activity? If yes, will the review really be unbiased and independent?
- Should it be possible to pay for the skills required for EC membership? Would paying for the review create conflicts of interest in reviewing proposals?

C. Questions related to logistics and administrative support

EC meetings need to be convened, conducted and documented. That requires resources, staffing and autonomy. Therefore,

- What kind of administrative and infrastructural support would be needed for ECs to function?
- What kind of staffing would be required?
- From where can we draw properly qualified staff?

Themes identified in the discussion in the workshop

The following key themes emerged during the discussion and provide important insights into ECs in India.

Membership issues: Several participants felt that because EC members often lack training and skills to understand ethical issues and therefore, they need to be formally trained and certified in ethics. The process of training (who, where, how and when) and curriculum was discussed; it was suggested trainings should be periodic like Continuing Medical Education seminars. Online certification of EC members (a mandatory requirement for NIH-sponsored researchers) was also identified as a quick and efficient step.

Participants also mentioned that for a EC to succeed, EC members should be well trained with minimum qualifications, they should have enough time and interest to attend the meetings, and ECs should also actively involve community members and leaders, especially when dealing with community-based research protocols.

Logistics and administration: The EC should:

a. Announce well in advance the date and times for EC meetings and introduce strict deadlines for protocol submissions to provide enough time for members to go through the proposals.
b. Demand and get enough staff, space and infrastructure to run the EC secretariat. It should hire at least one full-time employee for the secretariat.
c. Ensure that the EC secretary gets dedicated time for conducting the EC activities. The post could be rotated among EC members.
d. Actively encourage young researchers interested in bioethics to join and thus reduce the burden on the EC; internships with ethics committees could be developed, paying due attention to confidentiality concerns through prior signed agreements.
e. Should monitor research proposals and, if need be, visit the sites. They should not rely solely on paper-based progress reports.
f. Develop Standard Operating Procedures (SOPs) to serve as a template for EC operations, and to ensure that meetings are conducted according to quorum requirements and proceedings are documented properly.

Financing mechanisms for running ECs: Running ECs consumes time and costs money. While most ECs run as not-for-profit entities in their institutions, there are direct and indirect costs associated with the day-to-day functioning of ECs. Some institutions charge a fixed application fee from research proposals sponsored by funding agencies or pharmaceutical companies. A system of proportionate allocation of funds to ECs from project budgets could thus be put in place. However, it may not be desirable to ask for fees from non-funded or student-initiated research proposals. ECs should ensure that all fees are deposited with their parent institution in a separate designated account.

One of the facilitators brought up the issue of indemnity of ethics committees and pointed out that some ECs were beginning to get insurance for committees in case of any legal claims about decisions being instituted.

Engendering respect for ethics committees on the same level as academic committees among institutional leadership would help in addressing some of these needs.

Accreditation and registration of ECs: A system of keeping tabs on ECs through periodic audits and instituting quality control measures is required. This is only possible if ECs are registered and accredited by a central body. This has been discussed as being a responsibility which the Forum for Ethics Review Committees in India (FERCI) could undertake in collaboration with the Indian Council for Medical Research.

Other issues: A participant felt that we need to introduce bioethics in medical curricula and thus sensitise students of health sciences to ethical challenges in research. Similarly, ECs could also take the responsibility of conducting investigator-targeted courses on bioethics in their institution.

Participants raised concerns regarding dilemmas faced by ethics committees when issues like specimen/tissue banking and long term storage of samples for use in research (and taking consent while collecting samples for unspecified future uses) came up in research protocols. It was stated that word "banking" itself was perhaps inappropriate and the connotations could be misused for exploiting communities and individuals.

It was also suggested that we need research to find out how

much it costs an institution to run an effective and streamlined EC. This information would also be useful for institutions planning to set up ECs.

Limitations

It was challenging to use the limited time we had for conducting this workshop, given the incessant enthusiasm of the participants. We acknowledge that the themes identified and discussion might have been constrained due to paucity of time.

Conclusion

Effectively functioning ECs are crucial for ethical research. This article provides a synthesis of discussions from a workshop at the Second National Bioethics Conference and provides insights about ethics committees in India. We hope that the discussion in the workshop will encourage researchers, heads of institutions and policy makers to identify strategies to further improve the functioning of ECs.

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Use of blanket consent for retrospective research in academic institutions: need for scrutiny and integrating safeguards

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The quantum of research is increasing in most Indian institutions. Linked with academic activities such as postgraduate thesis studies, or with externally and internally funded research projects, this research is often useful in devising better treatment modalities as well as in making policy suggestions. As knowledge about ethical requirements in research becomes commonplace, the need for informed consent (IC) from patients and/or research participants has become the norm. Some institutions have started encouraging researchers to take consent from patients for the use of their samples or case reports for unspecified future research purposes; such consent is often referred to as "blanket consent". Ethicists and researchers in a previous issue have debated whether the use of blanket consent can be justified (1-3). This commentary looks at the concept of blanket consent in the context of research in India. It highlights issues from the perspectives of the researcher and the patient and provides examples of ways to address these concerns.

Informed consent in our context

Obtaining IC is a key component of ethical research and requires that the patient or research participant be adequately informed about the research so that s/he can make a decision about whether or not to participate in the research. This is not just a one-time requirement but a process which is reinforced at the time of subsequent research visits (if these are required by the research protocol). Conventionally, IC requires that all relevant information be understood by the participant, and that the decision to participate be made voluntarily. However there are challenges in obtaining effective consent in our settings due to factors such as low literacy levels and high levels of trust in healthcare providers (4). The quality of IC thus remains an ongoing concern in Indian institutions, whether in the public or the private sector.

Why blanket consent

Often researchers and clinicians do not know in advance what they might want to study in the future, or what might be clinically relevant research in their disciplines. They might be treating a patient or a series of patients with an interesting clinical condition but without the technical knowledge to be able to conduct research on patient samples at that point in time. They may therefore want to preserve tissue samples for possible use in future research. Allowing researchers to store interesting samples will enable them to conduct research and come up with relevant findings once they have new tools or novel research methodologies to apply to the samples. This research could help in the enhancement of knowledge as well as in the discovery of new treatments or research information which might be relevant in treating patients with that clinical condition (including, possibly, the patients to whom the samples belong).