

*Concerns of potential
participants: are the ICMR
guidelines 2000 adequate?*

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Objectives

- To identify the concerns of potential participants in biomedical research processes with respect to the protections offered by the ICMR guidelines, 2000

Note: The data collection for this study was done in April-May 2005. The revised 2006 guidelines were not available then

Research questions

- What are the perceptions of the 12 guiding principles for research elaborated in the ICMR guidelines?
- Is the ethical review process through an IRB sufficient for scrutiny of a study proposal?
- If not, what additional safeguards are needed?

Methodology

- Focus group discussions – 4
- Participants: above 21 years of age, have at least 12 years of school education and conversant in English from Trivandrum District, Kerala
- Exclusion criteria: Biomedical training
- Viewing of 36 minute film on IRBs ‘Balancing Society’s Mandates: IRB Review Criteria’
- Rationale for participant selection: FGDs were done in English as translating many of the concepts in the guidelines into Malayalam the language of Kerala was difficult and the language used in the film was English

Participants

- Expected – 12 per FGD, total of 48
- Actual – 36 with 24 men and 12 women
- Educational level – Masters and above
- Occupational profile – majority of them were basic scientists or social scientists

Analysis

- Thematic analysis – manually done
 - Developing codes and memos
 - Identifying the various thematic clusters and their ordering
 - Identifying key emerging themes
 - Validating by cross checking with original codes and memos



Key themes identified

Nature of information provision to potential participants

- Provision of information regarding possible harms that could be caused by research
- Provision of information about benefits to society
- Available redressal mechanisms for subjects

‘If I am studying the life style of sex workers, at least some aspects of it and this may not improve their health care access or their legal access and there may not be any benefits for the sex workers then, you have to say it. You can very well say that you are not going to be able to do that. Even then, you are asking them to participate’

-Social Scientist, Trivandrum

‘I do not think that there is the option for complaints!’ (for the participant/in this process of review that you showed)

-Social Scientist, Trivnandrum

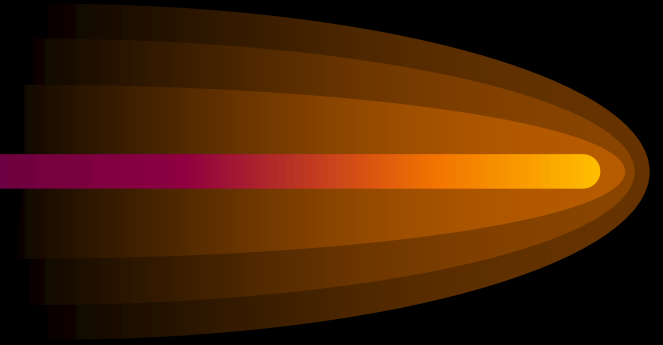
Roles of the IRB

- Evaluation of proposals and monitoring of the research, particularly the processes
- Protection of subjects, particularly those vulnerable (children and those who have impaired comprehension)
 - Prevent exploitation of subjects by recognising unequal power relations between developing countries and developed countries
- Protect vulnerable researchers
 - Researchers in developing countries are also vulnerable due to the same unequal power relations
- Ensure cultural compatibility through building sensitivity to these issues

‘As a social scientist, I am suspicious about why anyone locates a study in a particular region..in biomedical research, one may not find the funds to undertake research and so agree to do research (with developed country researchers) which they won’t allow in their own country’

‘The selection of the location, social contexts, and the financing are all unfair because of the existing unequal power relations. It is too universal a thing to ignore’

- social scientists, Trivandrum



Additional concerns regarding protection of subjects

- Protection of human subjects in govt. data collection processes
- Limits to Confidentiality of information given in Govt. surveys (census protections not available)

Pre-requisites for effective IRB functioning

- Scope for making independent decisions
- Functioning independent of the institution (head of the institution should not be head of IRB)
- Democratic functioning (all members should have their say)

Compensations for harms and Reimbursements for costs

- Compensation for harms
 - Rehabilitation
 - Protection against harms caused by study processes
 - Care for the problems caused by experiment
- Reimbursement for costs–It should not be an incentive for participation and it should be for loss of time, wages, travel

‘Money is not the main thing. Something helpful. If in an experiment – operation the patient dies, money can’t bring her back’

-Scientist, Trivandrum

If there is fits, cardiac arrest, when these things happen(if they are due to the study), we have to have a mechanism. Probably these guide(line)s do not cover it

- Social Scientist, Trivandrum

Protections in the ICMR Guidelines 2000

- Principle of non-exploitation
 - Each research shall include an in-built mechanism for compensation for the human subjects either through insurance cover or any other appropriate means to cover all foreseeable and unforeseeable risks by providing for remedial action and comprehensive after-care, including treatment during and after the research or experiment, in respect of any effect that the conduct of research or experimentation may have on the human subject and to ensure that immediate recompense and rehabilitative measures are taken in respect of all affected, if and when necessary.

Perceptions of potential participants -1

- The risk of participation and exploitation are issues of concern
- Therefore the potential participants highlight the nature of protections to be offered
 - Care for the possible hazards and compensation in situations where care is not possible

The perceptions of the participants - 2

- Role of the IRB
- The scope of the IRB's mandate to protect against exploitation seems to be extended to include the researchers as well within its ambit

Preliminary conclusions

- Potential participants recognise the need for independent review of research as a mechanism of protection offered to them
- Most of the concerns identified are already addressed in the ICMR guidelines
- Scope for compensation more clearly defined as care in case of health hazards and compensation for other harms
- Mandate of protection against exploitation should include the researchers also



Thank you