

# Code of Ethics for Health Research

*Social science research involves certain vital ethical issues – respect for all those involved in research, their rights and protection. Ensuring ethics in research, as the ethical guidelines seek to do, would help complement research, rather than hinder it. A debate on the draft code of ethics held in May 2000 sought to evolve a consensus among researchers across the country. These initial steps would help fill long-perceived lacunae as well as seek to resolve ethical dilemmas plaguing researchers.*

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Ethics in social science research is about addressing crucial issues of respect for all those involved in research, their rights and their protection. Dilemmas and questions are asked. Is focus group discussion the best suitable methodology to research issues related to reproductive health? What are the ethical problems and dilemmas that could arise? Can children have their own right to participate or decline participation? Can they veto the consent given by their parents? Can communities be made identifiable? What if the information associated with this community could prove harmful or cause disgrace to the community, in which case, does the use of pseudonyms suffice? Is not increasing knowledge one of the many aims for undertaking research? Thus not making research available and accessible, defeat one of its main purposes? These and other issues can cause harm or damage not just to the participants of research but to the entire discipline. Not addressing these issues effectively, time and again, can someday lead to an outrage from the participants of research. Moreover, the credibility of social science research can get affected, hindering research. This is contrary to the belief that ethical guidelines could come in the way of doing research. Ethics in research should be seen as complementing research, since that is what it is.

The fact that social science research is a study of human beings by human beings, where the circumstances of research, the background of the participants, the kind of study, the issue being researched, the

value system of the participants and that of the researchers themselves, gives social science research the characteristic of giving rise to a myriad of complexities. Some of these complexities could be as methodological or technical, while others ethical. With more and more research conducted in the social sciences today, and the kind of issues that researchers dwell to research in, ethical dilemmas are not only going to arise, but with time even these are bound to get more and more complex. However, this does not imply that these issues have never been considered and that the work done by researchers till date has been unethical. However, what is now required and what is lacking is a common base and similar thinking on these issues, something that has a collective consensus on ethics in research, not only to guide research, but also to anticipate and solve dilemmas.

To be able to comprehend, let alone anticipate, ethical complexities and dilemmas is a mammoth task. Evolving ethical guidelines that aim to anticipate and enable us to address these issues effectively is an even bigger task. An attempt in that direction was recently made.

## The Initial Steps

The National Meeting to discuss 'The Draft Code of Ethics for Research in Social Sciences and Social Science Research' was held on the May 29 and 30, 2000. The drafting process of the guidelines took about a year. The process began with the research secretariat (comprising Amar Jesani and Tejal Barai) undertaking a detailed scrutiny of ethical codes in the social sciences from across the world.

These include codes of ethics in psychology, sociology, anthropology, among others.

Any ethical guidelines in social science research would have to necessarily address and cope with the research atmosphere and conditions with all the inherent complexities that exist in our country. Thus, simultaneously a review of research studies in India from 1950s onwards, and concentrating on the past decade, was undertaken. This helped us become more aware of the varying circumstances that researchers in our country work in together with the problems that could arise.

A committee<sup>1</sup> was formed. The members of the research secretariat and the committee met twice and discussed and debated draft guidelines (*EPW*, March 18-24, 2000).

The guidelines consist of four sections, Section I – The Preamble; Section II – The Principles; Section III – Ethical Guidelines and Section IV – Institutional Mechanism for Ethics. The guidelines are general and broad in character. This was specifically done to facilitate their use and adoption in various research areas. It is also necessary that the individual guidelines are not seen in isolation.

The preamble lays down the need and the purpose for the guidelines. A consensus is required for the need to observe ethics in research. It is a call for social science researchers to collectively evolve guidelines. It is required for the education and empowerment of researchers. The preamble also proposes the formation of a network of institutions that can be formed to share experiences in solving ethical dilemmas as well as problems associated with the implementation of the guidelines. The principles have been drawn up keeping in mind the broader principles of non-maleficence, beneficence, autonomy, confidentiality and justice. The principles thus read – the principle of essentiality; protection of autonomy, rights and dignity of the participants, accountability and transparency, totality of responsibility among others.

The guidelines have been specifically drawn up for the purpose of making the principles operational, making them more practical for use during the practice of research. To cite an example, the principle of non-exploitation can be seen operationalised throughout the guidelines. In the form of guidelines it stands for the protection of the rights of researchers,

seen in the form of protection of their autonomy, as well as participants or subjects of the study and rights of juniors and students. The principle of totality of responsibility can be seen in the form of the guideline that specifically lays down that students, juniors as well as all those associated with the research, including administrative staff, all of whom should be given proper guidance with respect to ethics in research. Moreover, it can also be seen in the form of informing funders and sponsor about ethical guidelines followed by the researchers or the organisations. An attempt has been made to try and evolve ethical guidelines for all stages of research, from conception of research problem to publication of research, encompassing all those areas that could raise ethical dilemmas.

To get a collective consensus on the draft from researchers from across the country was of prime importance. The first step was thus to have a national level meeting.

### **The National Level Debate**

We began with extensive dissemination of the draft. The draft was not only sent across to the participants of the national meeting, but also to a large number of other institutions, organisations and researchers. A member of the research secretariat also undertook presentations of the guidelines. Feedback in terms of their practicality and its usefulness in anticipating dilemmas was sought. The feedback received through these various attempts was documented. The documented feedback together with some papers that were commissioned for the purpose set the background to the national meeting.

The meeting was a two-day workshop. It began with a plenary given by Ghanshyam Shah. He touched upon various issues plaguing research in India today. The circumstances of research have changed today. These changes are related to the autonomy of researchers and even the utilisation of research findings; the narrowing down of the concept of applied research together with the sharp decline in the funds for academic research. There has also been a change in the kind of issues that are being researched today, from study of marital and sexual relationships to ethnic identity and domestic violence. Participants of research are often taken for granted. A code of ethics should create sensitivity,

commitment and responsibility, without limiting good research.

The entire group of participants was divided into three groups. Researchers discussed each section from their own perspective and in the light of their own experiences. Each of the sections are handled separately below, and consists of the gist of issues that were discussed and some recommendations given during the two days.

Research is any activity that involves humans, and an intervention undertaken by an NGO would then be considered as research. A code of ethics that deals with social science research and a code that deals with social science research in health, have a totally different scope. The title of the revised draft should thus look into the scope of the guidelines and thus name it accordingly.

The introduction should not only look into issues such as the scope of the guidelines, but should also reflect the ideology of the makers, research settings under which it can be used, reflect the Indian context, propagate bad research as unethical, use of the guidelines as an advocacy tool – for upholding the rights of the participants as well as the researchers, and the reasons for the increased ethical concerns today. Moreover, as more and more doctors are getting into social science research, the line between social science research and medical research is fast diminishing. Thus, eventually, down the years, any draft would need to address these simultaneously. The preamble should look into the issue of relevance of research, based on the prioritisation and not exclusion.

The principle of 'precaution and risk minimisation', should also address the issue of mitigating of risks. Moreover, the principle of 'Knowledge, ability and commitment to do research' states that, though research is not the monopoly of any individual or group, every researcher must acquire adequate knowledge and ability and should have commitment to do research. A doubt was raised as to who would decide as to what constitutes adequate knowledge and ability and commitment to do research? Would it be the organisation/s that fund the research? Or the person/organisation which grants the permission to undertake the said research? There were views against the funding agency as being the decision-maker. The principle is very crucial in the light of the fact that a researcher, who has been doing

extensive research in poverty, would like to conduct a research on sexuality, thus acquiring knowledge in the specific area is indispensable.

Accountability and transparency of research should be given prime importance. Researchers are not only accountable to their peers, but also to the participants. Thus accountability is professional, social, and financial. Moreover, both social and financial audit of their work should be stressed. Utmost priority should be given to sharing of the findings with the people. The participants felt that along with these issues, we need to formulate a guideline for premature termination of research, i.e., if at any stage of the research, it is felt that the rights of the participant community or the researcher are being violated then the researcher should have a right to terminate or opt out of such research.

It is not only the publication of the report which should be available in the public domain, but one also needs to ensure accessibility to such material, especially to researchers, funders, sponsors, institutions where research is conducted and various persons, groups or undertakings who sponsor, use or derive benefit from research.

Keeping with the spirit of the guideline emphasising the integrity of researchers, it was felt that researchers should definitely not take up studies where the pre-conditions lay down that the research results are not to be laid in the public domain. Concern was also raised where the funding agencies disseminate research results without acknowledging the source.

The guidelines regarding training of juniors and students regarding all aspects of research was well appreciated. However, it was felt that often mutually beneficial long-term interventions are undertaken and that these should not be seen as exploitation and hence seen as unethical.

While addressing the issues of the relation between the researcher and the participant, it was felt that apart from anticipating and addressing harms (or risks, as was suggested at the meeting), participants should be provided with specific safety nets and space for comfort. Further, efforts should also be made to mitigate risks.

The process of informed consent, it was stressed, should not be a one-step agenda, it should be a process. Participants should also be able to comprehend the information that they have been given at the time of briefing. Moreover, where the partici-

pants have been given a right to withdraw at any stage, what can then be done with the information already collected. Are the researchers permitted to use it? Some participants may also have conflicting interests vis-a-vis certain members of the community. In this light, disclosure of information selectively needs to be considered. Where there is a long gap between two sittings with the participants, informed consent should be sought again.

Issues related to ethics in research with the mentally ill should be addressed independently, and there should be no proxy consent for research with the mentally ill. There was a debate about what should be the age of the child, when informed consent from parents was not required. It was agreed that when a child has reached the age of 14 years, consent from parents is not required. Further, a child below the age of 14 years can veto the consent given by the parents/guardians.

Privacy, anonymity and confidentiality are the inherent rights of all participants. The guidelines do not simply state that privacy should be ensured, it goes beyond and says that appropriate methods need to be devised to endure privacy. Moreover, what is important are that these concepts need to be viewed from the participants' perspective. Though it was felt that ensuring privacy was a difficult possibility in our country, it was agreed upon that it cannot be excluded from any ethical guidelines.

Publication of research should not just involve publishing. It also means easy accessibility of research results and reports. Authorship credits, apart from what is laid down in the guidelines, should also be based on the quantum of contribution made in terms of ideas, methodology solving of problems and actually doing research.

The Section IV of the guidelines gives certain suggestions with respect to the implementation of these guidelines. It was felt that institutions and organisations that would be going in for the formation of ethics committee should do so on a participatory basis. Its role should be consultative, educational and regulatory (but not punitive). A strong need was felt for a network on institutions, as expressed in the preamble. It would also help institutions that may not have the capacity to implement the guidelines and form an ethics committee. The proposals should anticipate and address the ethical issues

in the light of these guidelines, mid-term analysis or consultation can be undertaken. However, it may not be possible to anticipate all ethical issues that may arise during the course of the study. Thus the need for the ethics committee to play an ongoing consultative role. The committee should comprise of a core group of experts. The scope of the committee should also be well defined.

It was strongly felt that reports and published material should mention that the study was carried out in consonance to the guidelines. Where the study has also been screened by an ethics committee, mention the same in the report along with the names of the members of the committee.

## Conclusion

A lot of discussion took place as to what can be done at the end of the two-day workshop. It was felt that we need to build an environment conducive to ethical discussions. Attempts should be made to integrate the guidelines with the educational curriculum. The participants as a group committed themselves to follow and forward the guidelines. They would also carry the discussions back to their respective organisations and other forums. Donors and funders should be informed of the guidelines endorsed by the researchers and organisations. Care should be taken in collaborative research that ethical concerns are not diluted.

The suggestions for the networking of institutions was called for and appreciated. It would put pressures on institutions, and enable the guidelines to be accepted as widely as possible. It would thus act as a 'peer pressure'. The participants strongly felt the need to assert themselves as a social

science community, especially when it comes to unethical practices and threats and unreasonable restrictions on their autonomy. It was felt that one of the purposes of the meeting was to sensitise ourselves, and the government and funders. Trial and error method would be the best way to learn how to use and to implement the code.

Since different institutions and researchers could interpret and use the guidelines in a different way, participants can come back and discuss these within the network of institutions formed. Workshops can be held and models can be evolved to suit various situations, based on experiences in using these guidelines.

It was decided that the research secretariat would revise the guidelines and meet with the committee to finalise them. It would also be published a volume together with background papers and other material on ethics in research. Extensive dissemination of the revised draft was also suggested. Funders, organisations, researchers should all be encouraged to adopt them.

It was felt that the present code has certain basic values and concepts and it can thus be applied to a very wide variety of research issues, including interdisciplinary research. The draft guidelines received the consensus that was aimed for. The draft thus fills the existing lacuna to guide researchers and help them resolve ethical dilemmas. **EPW**

## Note

- 1 Ghanshyam Shah, Lakshmi Lingam, V R Muraleedharan, Padma Prakash, Thelma Narayan, Ashok Dayalchand, Manisha Gupte, Sarojini Thakur, Geetanjali Misra, Radhika Chandiramani.