NATIONAL COMMITTEE FOR ETHICS IN SOCIAL SCIENCE RESEARCH IN HEALTH (NCESSRH)

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The year 2000 was significant for the health research in India. Two ethical guidelines were finalised and published in that year. In September 2000 the Central Ethics Committee on Human Research (CECHR), under the Chairpersonship of Honourable Justice Shri M. N. Venkatachaliah, appointed by the Indian Council of Medical Research (ICMR), New Delhi published the “Ethical Guidelines for Biomedical Research on Human Subjects”. This was an elaborate follow up by the ICMR of its document titled “Policy Statement on Ethical Considerations Involved in Research on Human Subjects” brought out two decades earlier, by the Committee Chaired by Honourable Justice Shri H. R. Khanna. On the other hand, a parallel exercise focusing on the ethics in social science research, particularly in the field of health, was commenced in early 1998 at the Centre for Enquiry into Health and Allied Themes (CEHAT), Mumbai. In 1999, a National Committee for Ethics in Social Science Research in Health (NCESSRH) was constituted. The NCESSRH formulated the draft guidelines for discussion, and after national level consultation, including a national meeting of concerned experts in May 2000, the revised and final draft of the guidelines was adopted by the NCESSRH and published by the CEHAT in November 2000, under the title “Ethical Guidelines for Social Science Research in Health.”

These guidelines for health research were widely distributed in India and internationally, the printed copies as well as in electronic format through the Internet. The NCESSRH guidelines are now being reprinted as by mid-2003 all 2000 copies of the first print were exhausted, and there is an increasing demand for more.

In India for long time the discussion on ethics in social science research in health has been limited by two factors. One factor originates from the inadequate discourse on ethics in the social sciences and their neglect in teaching social science research methodology. The social science institutes have not come under public pressure or pressure of sponsor or government regulations to institutionalise ethics review of research in the form of Institutional Ethics Committee or Review Boards. As a consequence the specific ethical concerns of health research are still struggling to be a part of the mainstream social science discourse. Another limiting factor is from the biomedical research side where the institutionalisation of ethics review has relatively advanced in the form of Institutional Ethics Committees. However, these committees, so used to reviewing proposals for invasive and “high risk” biomedical research, often or almost invariably, find the proposals for social science research in health posing even less than “minimal harm”. The invasion of “privacy and social/personal life” and extent of “social risk” are yet to find appropriate place in moral assessment of research enterprise in bio-medical field. And as a consequence, the biomedical research discourse is also slow in integrating specific ethical concerns arising from the social science research in health.

However, in last three years, these two limiting factors have evidently undergone some changes.

Interestingly, in the year 2000, few months before the NCESSRH guidelines were published, the social science research received a major jolt by the public controversy on the reporting of the findings of sexual behaviour study for understanding risk factors for spread of the HIV infection by an organisation, Sahayog, in Almora area of Uttaranachal. While the political mobilisation against the report centred around the outcry on the violation of the conservative cultural and sexual norms of people of the area; the violation of confidentiality of the villages and some of the participants in the report also came under close scrutiny. Clearly, the activists researchers had neglected ethics both in the conduct of the study
and also in the way the information was communicated and published. The subsequent events, dominated by the right-wing political mobilisation against the activist/researchers, vandalism of their offices, and imprisonment of the office bearers of the organisation for forty days on charges such as obscenity and pornography, increased the complexity of the situation – the violation of ethics getting enmeshed with the gross violation of the human rights of the researchers. This went to such an extent that the researchers were threatened with the imposition of the National Security Act in order to keep them in the prison for the longest duration of time possible and in an act in violation of their ethics, the local lawyers not only refused to provide them with legal defence, but actively canvassed for denying them the right to such a defence.

Although Sahayog episode generated more debate on the human rights than ethics, it did shook up the social science and biomedical researchers in two ways. Indeed, the social science research cannot be called “risk-free” or having “less than minimum harm” if it could, in some cases, lead to direct physical attacks and long incarceration in prison for the researchers. The social risks involved in research and ensuring the social safety in addition to the safety of the body and mind of the participants, were instantly recognised as important legitimate ethical issues needing full deliberation prior to commencing any research. In addition, the concerns of communities and culture; and their place in designing, conducting and communicating research found recognition not only in social sciences research but also in the biomedical and public health research. Secondly, it made some of the institutional and funding agency sponsors of research a look at the process of ethics review, the inaugurating some institutionalisation of ethics review of the social science research in health.

In last three years several institutions doing social science research in health have taken steps to establish formal or informal process of ethical review of the research proposals and/or research process, and increasing number of institutions are gradually moving towards the establishment of such processes. The reasons for such development are both intrinsic to the institutions as well extrinsic. The institutions coordinating research in several parts of the country with the help of other institutions and NGOs have found it useful to subject the process to some type of formal ethics review in order to ensure that; the larger research process does not get derailed by the controversy, and/or to improve the adherence to methodology and improve quality of data collection. While the penetration of formal ethics review process or what we call, institutionalisation of ethics review of social science research in health is very uneven and slow across the country, there is no doubt that there is increasing awareness among the social science researchers about the ethics and about the need for ethics review. Experience teaches us that increasing awareness and acceptance could only accelerate the process of diffusion of ethics review mechanism in various institutions across the country.

I must also acknowledge and thank the ICMR for the recognition and support provided to the NCESSRH guidelines. In various ethics training workshops in last three years, the ICMR kept a separate session on social science and behavioural research in health and recommended the NCESSRH guidelines to the trainees for their reference. This only increased the awareness of the biomedical and public health researchers about the existence of such guidelines and encouraged them to use them. In addition, I also acknowledge thank the Harvard School of Public Health for recommending these guidelines and for putting them on its website almost at the same time as was done by the CEHAT. All those institutions, the nationally coordinated projects, the fellowship programmes and sponsoring organisations that made the review of research projects necessary using these guidelines are also hereby thanked. Needless to add that their experience in using these guidelines would contribute immensely in updating and refinement of the existing guidelines in coming time.
Three years is not a long enough period for making an assessment on the impact of the NCESSRH guidelines on social science research in health in India. This period is also not long enough for commencing updating or revision of the guidelines in order to overcome the limitations encountered while using them. However, more and more experience is getting accumulated in the use of these guidelines and perhaps in the next two years we may have enough to undertake an exercise in the updating of the guidelines. Till then, this reprint of the year 2000 guidelines would make them more accessible to many researchers and we hope that more and more of them would benefit from their use.

December 21, 2003

Amar Jesani
Mumbai.

INTRODUCTION TO THE FIRST EDITION

Ethics is concerned with the conduct of human beings. All scientific activities, including those by the social scientists, are conducted with the participation of human beings or have an impact on human beings or on the wider society and environment. Therefore, it is essential that scientists/researchers understand ethical issues and the implications of their scientific work and act accordingly. For making ethical judgement, the scientists/researchers rely upon various standards of ethics, which could be universal or specific to the culture(s) or localities. Indeed, it is essential that researchers share and discuss the ethical issues in their work and evolve collective standards of their own.

Self-regulation and ethics have been issues for debate within research more often in medicine than in social sciences. The Second World War and the Nuremberg trials of doctor-researchers exposed the horrors of the fascist politics as well as unethical biomedical research. In the post World War period, therefore, the scientists paid increased attention to ethics in biomedical research. In the process, the quality and validity of unethical research was questioned, the human rights of participants recognised and ethical codes formulated. The Nuremberg Code (1947) was followed by the Declaration of Helsinki in 1964, which was amended subsequently (WMA, 1989). The Council for International Organisations of Medical Sciences (CIOMS) and the World Health Organisation (WHO) (1993) also proposed guidelines in 1983 and adopted them in 1992. These international developments followed as well as inspired several such initiatives at the national level and in various specific fields of biomedical research. India, too, did not remain unaffected. In 1980, the Indian Council of Medical Research formulated “Policy statement on ethical considerations involved in research on human subjects” and in 1997, it brought out the draft of “Consultative Document on Ethical Guidelines on Biomedical Research Involving Human Subjects”.

INTRODUCTION TO THE FIRST EDITION
The issue of ethics in social sciences, unlike in medical research, has been given less prominence in India. Although many social scientists have paid serious attention to the appropriate conduct of research and set personal examples, they are often not discussed as ethics and no efforts are made to formalise some guidelines based on such experience(s). Our national councils for social science research and their institutions have many guidelines either as administrative orders or for improving the quality of research but enough efforts have not been made to bring them together as comprehensive ethical guidelines. Besides, in the absence of such comprehensive guidelines, ethics are hardly there in the social science education curriculum.

However, this situation in India is definitely not due to lack of attention to ethics in social sciences in other countries. In fact, in the post World War period, there has been growing pressure on social science professionals to self-regulate and evolve their own codes of conduct. There has been a continuing debate between the view of making the social sciences “value free” and “objective” and the view that social scientists could not remain value free simply because they deal with contemporary society and because there is an explicit connection between research and social action or political viewpoint. The former tries to make social scientists attain a status of professionals and often puts them in ivory tower situations, while the latter tries to make them aware of the impact of their activities on the society. However, in both cases the ethics of the social inquiry and the application of the expertise of social science to current social problem need to be dealt with.

Internationally, the associations of applied anthropology and the psychologists formulated their codes as early as in 1940s and 1950s. The controversy around the Project Camelot and its cancellation in 1965 led to increased discussion on ethics among the social scientists and eventually prompted most of the major social science associations to formulate their guidelines (Barnes 1979). The universities have also tried to establish formal guidelines to protect student research and their exploitation by the teachers. Our survey of ethical guidelines in the social sciences in different developed countries showed, to our surprise, that most associations of sociologists, anthropologists, political scientists, psychologists, etc. have formulated and refined their ethical guidelines in last three decades. Besides, in last one and half decades there have been attempts by the associations of different science and social science disciplines to combine their efforts and evolve joint guidelines. The most important effort made so far has been the joint efforts for evolving common ethical guidelines by medical, social science and natural science disciplines. For instance, the Medical Research Council of Canada, the Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada appointed a joint committee (called Tri-Council Working Group) to formulate “The Code of Ethical Conduct for Research Involving Humans”. In 1997, these three councils adopted the Tri-Council report as a common code of ethics. Apparently some similar processes are also on the USA. In essence, these developments emphasise that the principles governing all research on humans by all disciplines of sciences have many things in common. And the researchers need to respect and protect human rights of the participants of research.

The present effort to formulate ethical guidelines for research in social sciences and health in India began in 1998. After a rigorous documentation of the guidelines for medical as well as social science research in India and outside, a multi-disciplinary national committee was constituted in 1999. As is evident from their backgrounds (see Appendix for brief outline on each member of the committee), they brought together vast experience of last few decades in social science and health research and activism. The committee met twice to prepare the drafts of the guidelines and the final draft was mailed to over 100 researchers and institutions in different parts of the country to get their feed back. Besides,
it was directly presented at six institutions to teachers, researchers and students. The feedback thus obtained from all over the country was summarised in a paper, which, along with the draft of the guidelines were then thoroughly discussed in a national meeting of researchers and activists from social science and health fields in May 2000. (See Appendix for the list of participants at the May 2000 meeting.) The draft of the guidelines discussed at this meeting was again revised, discussed and adopted by the committee after the meeting. The final guidelines thus formulated are given in this document.

In brief, we have made all possible efforts to consult the social scientists and health researchers from different parts of the country. Our objective was to incorporate available experience, expertise and concerns on ethics in the guidelines so that, they could be used by more and more researchers across the country in their work. We are aware that any effort (more so if it is voluntary effort) in formulating comprehensive guidelines for such a vast field of research in such a vast country like ours is not going to be adequate. However, the feedback received from the community of researchers suggests that this is a good beginning and we hope that as more researchers and institutions use these guidelines, they will get further refined and become more comprehensive. Perhaps it is true that real improvement in the standards of quality of and ethics in research in our country need more effort than the mere drafting of ethical guidelines. The guidelines presented here provide an ethical framework based on four moral or normative principles and ten principles relevant for ethics in research in India. The ethics are after all arrived at on the basis of the context of the situation, and the principle-based framework assists the

researchers in developing their moral arguments for choosing the most appropriate and ethical action in the given situation. In that sense, the guidelines are not administrative rules, but they are approximate standards informing the choice of action in a concrete situation. Fundamental to understanding and applying ethical principles and guidelines is the concern for and protection of the human rights of the participants. Further, the guidelines formulate rights and responsibilities of the four major actors in research endeavour; namely, the researchers, the institutions, the sponsors and funders, and the gatekeepers.

Lastly, the development of organisational mechanism for ethics in social science research in health has been kept as an open process to be evolved by the community of researchers and institutions. The national meeting of researchers in May 2000 correctly felt that such a mechanism could be different for different types of institutions and projects; and that only by practising ethics within institutions could we arrive at appropriate models for the organisational mechanism. Indeed, such a process would also create a critical mass of individuals and institutions having experience in integrating ethics and guidelines in their institutional environment and the research process. Of course, this is a collective endeavour of networking, sharing, discussing and providing assistance to each other. We hope that the publication of this document will help in consolidating the process started while formulating it.

References


CIOMS (Council for International Organisations of Medical Sciences) and (WHO) World Health Organisation (1993), “International Ethical Guidelines for Biomedical Research Involving


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Section 1

PREAMBLE

1.1 There has been a steady growth of research in the social sciences and in social science research in health in India. A wide range of research topics and issues including those that have the potential to seriously invade the privacy and security of individuals are being studied. Methodologies employed for such research have also expanded in range and depth. There is a considerable increase in the types and numbers of individuals and institutions1 undertaking such research and those sponsoring and funding it.

1.2 While it is encouraging that social science research and social science research in health are getting the attention they deserve, the growth of research without social and ethical commitment could adversely affect the credibility of research, the autonomy of researchers,2 the quality of research and the rights of participants3. In fact, there is a growing concern about indifference to ethics in some social science research in the field of health in India.

1.3 Social and ethical commitment and self-regulation are, therefore, imperative for all parties in research, namely, institutions undertaking research, researchers, funders/sponsors4 and those who publish material generated from research. Their individual and joint efforts are needed in order to achieve consensus on a common framework for

1 Institution is any organisation (public, private or voluntary) undertaking research.
2 Researcher is any individual directly involved in research or a research project.
3 Participants are individuals or groups from and/or on whom the researchers collect information for research.
4 Funders/Sponsors are individuals and organisations (public, private or voluntary) providing full or part funding and/or sponsorship for the research.
research, and to improve and strengthen the system and environment in which research is conducted. Enunciation of ethical principles and formulation of necessary guidelines for research are, therefore, a part of such a process, and also a necessary and desirable step.

1.4 This document contains ethical principles and guidelines formulated by a national committee with the additional inputs of individuals from different institutions and disciplines. While it has immediate specific applicability for social science research in health, it is relevant for social science research in other fields as well. For medical and clinical research some of the ethical guidelines may be different.

1.5 The ethical principles and guidelines for social science research in health, given in this document, are developed for the following purpose:

1.5.1 To sensitise and protect researchers who are often under pressures from various quarters/forces while undertaking research.

1.5.2 To preserve and promote the autonomy of research through the observance of ethics, ethical values and ethical self-regulation.

1.5.3 To protect and promote the human rights of participants and to sensitise and encourage researchers and organisations to respect participants’ rights and needs.

1.5.4 To improve quality, legitimacy and credibility of social science research in health.

1.5.5 To make ethics an integral part of the planning and methodology of research, and to enable organisations and individuals to develop appropriate mechanisms for ethical self-regulation.

1.6 The ethical principles and the guidelines given in this document do not, by themselves, resolve all ethical problems and dilemmas, which may confront researchers. For each dilemma and conflict they face, researchers may be required to balance the demands made by moral principles of research. The resolution of the dilemma may best be arrived at in concrete relation to the context and circumstance(s); it may involve a decision privileging one principle over another.

1.7 The experiences in using this document may be shared. Keeping in mind the immediate and long-term interests of the larger sections of people and the autonomy of researchers, the ethical guidelines given in this document may be refined through periodic reviews.
Section 2

ETHICAL PRINCIPLES FOR RESEARCH

2.1 Four well-known moral principles constitute the basis for ethics in research. They are:

2.1.1 The Principle of Non-maleficence: Research must not cause harm to the participants in particular and to people in general.

2.1.2 The Principle of Beneficence: Research should also make a positive contribution towards the welfare of people.

2.1.3 The Principle of Autonomy: Research must respect and protect the rights and dignity of participants.

2.1.4 The Principle of Justice: The benefits and risks of research should be fairly distributed among people.

2.2 Ten general ethical principles, presently relevant for social science research in health in India, are as follows:

2.2.1 Essentiality: For undertaking research it is necessary to make all possible efforts to get and give adequate consideration to existing literature/knowledge and its relevance, and the alternatives available on the subject/issue under the study.

2.2.2 Maximisation of Public Interest and of Social Justice: Research is a social activity, carried out for the benefit of society. It should be undertaken with the motive of maximisation of public interest and social justice.

2.2.3 Knowledge, Ability and Commitment to do Research: Sincere commitment to research in general and to the relevant subject in particular, and readiness to acquire adequate knowledge, ability and skill for undertaking particular research are essential prerequisites for good and ethical research.

2.2.4 Respect and Protection of Autonomy, Rights and Dignity of Participants: Research involving participation of individual(s) must not only respect, but also protect the autonomy, the rights and the dignity of participants. The participation of individual(s) must be voluntary and based on informed consent.

2.2.5 Privacy, Anonymity and Confidentiality: All information and records provided by participants or obtained directly or indirectly on/about the participants are confidential. For revealing or sharing any information that may identify participants, permission of the participants is essential.

2.2.6 Precaution and Risk Minimisation: All research carries some risk to the participants and to society. Taking adequate precautions and minimising and mitigating risks is, therefore, essential.

2.2.7 Non-exploitation: Research must not unnecessarily consume the time of participants or make them incur undue loss of resources and income. It should not expose them to risks due to participation in the research. The relationship within the research team, including student and junior members, should be based on the principle of non-exploitation. Contribution of each member of the research team should be properly acknowledged and recognised.

2.2.8 Public Domain: All persons and organisations connected to research should make adequate efforts to make public in appropriate manner and form, and at appropriate time, information on the research undertaken, and the relevant results and implications of completed research.
2.2.9  Accountability and Transparency: The conduct of research must be fair, honest and transparent. It is desirable that institutions and researchers are amenable to social and financial review of their research by an appropriate and responsible social body. They should also make appropriate arrangements for the preservation of research records for a reasonable period of time.

2.2.10  Totality of Responsibility: The responsibility for due observance of all principles of ethics and guidelines devolves on all those directly or indirectly connected with the research. They include institution(s) where the research is conducted, researcher(s), sponsors/funders and those who publish material generated from research.

Section 3

RIGHTS AND RESPONSIBILITIES OF RESEARCHERS AND INSTITUTIONS

3.1.  Relationship Between Researchers and Institution

3.1.1  Institutions have a responsibility to respect the autonomy of researchers and the ethical guidelines for research.

3.1.2  Institutions should create and maintain an environment with adequate support systems to enable researchers to follow ethical guidelines.

3.1.3  Institutions have a responsibility to take appropriate and adequate steps for protection against pressures inimical to the observance of ethical guidelines for research.

3.2.  Protection and Promotion of Integrity in Research

3.2.1  Researchers have a right, as well as a responsibility, to refrain from undertaking or continue undertaking any research that contravenes ethical guidelines, violates the integrity of research and/or compromises their autonomy in research, including design methodology, analysis and interpretation of findings and publication. If they feel that their rights are being violated, or that the study is unethical, they should make all possible efforts at making corrections. In the event of failure of remedial measures they should exercise their right to terminate the study or to opt out of it.

3.2.2  Researchers should undertake only such research that according to their understanding will be useful to society or for the furtherance of knowledge on the subject.

3.2.3  Researchers should not undertake secret or classified research,
any secret assignment under the garb of research nor research whose findings are to be kept confidential. Researchers have a right as well as responsibility to make all necessary efforts to bring the research and its findings to the public domain in an appropriate manner.

3.2.4 Researchers have a responsibility towards the interests of those involved in or affected by their own work. They should make reasonable efforts to anticipate and to guard against possible misuse and undesirable or harmful consequences of research. Researchers should take reasonable corrective steps when they come across misuse or misrepresentation of their work.

3.2.5 Researchers should ensure that there is honesty and transparency at every stage of research as these are indispensable for good and ethical research.

3.2.6 Researchers should ensure that there is no fabrication, falsification, plagiarism or other unethical practices at any stage of the research; and that the findings of research are reported accurately and truthfully. They should also ensure protection of historical records and preservation of study material.

3.2.7 All parties involved in research and dissemination of its findings should inculcate and practice sensitivity and respect for culture and other aspects of the group or community studied.

3.2.8 Researchers must ensure respect, protection and promotion of rights of participants. Criteria for the selection of participants of research should be fair, besides being scientific.

3.2.9 Peer review should be an essential part of every research endeavour or initiative, and should be sought at various stages of research.

3.3 Relationship Among Researchers

3.3.1 Principal researchers are responsible for the ethical conduct of research by all juniors, assistants, students and trainees. At the same time juniors, assistants, students and trainees have an equal responsibility for ethical conduct and observance of ethical guidelines.

3.3.2 The juniors, assistants, students and trainees have a right to receive, and principal researchers have a responsibility to provide/impart, proper training and guidance regarding all aspects of research, including ethical conduct. The principal researchers should delegate to the juniors, assistants, students and trainees only those responsibilities that they are reasonably capable of performing on the basis of their education, training or experience, either independently or under supervision.

3.3.3 No researcher should engage, personally or professionally, in discriminatory, harmful or exploitative practices, or any perceived form of harassment. Nor should the researcher impose views/beliefs on or try to seek personal, sexual or economic gain from anybody, including other researchers, juniors, assistants, trainees and students.

3.3.4 Researchers should not deceive or coerce other researchers, including juniors, assistants, trainees and students into serving as research subjects/participants, nor use them as cheap labour.

3.3.5 Researchers should be co-operative, responsive, honest and respectful about the interest, opinion/view, capability and work of other researchers, including juniors, assistants, trainees and students.

3.3.6 While working in the team on a research project, at the outset, all members of the team have a right to know and document all aspects of research including ownership of the data. This procedure also applies to the participation of students doing their own research in a project team.
Students should have the right to opt out of a research project without having to face adverse consequences.

3.3.7 In addition to researchers, other individuals such as administrative staff of the organisation conducting research or that of the research setting, etc may be associated, in some way, with the research. All of them should be briefed on ethical issues and the guidelines, including the need to protect the rights of participants and the confidentiality of identifiable data.

3.4 Data Sharing

3.4.1 Sharing of data should be done in a form, which is in consonance with the interests and rights of the participants. Researchers who have conducted the study and the institution where the study is conducted are fully responsible for ensuring the protection and promotion of the interests and rights of participants while sharing or making public available data in any form.

3.4.2 The researchers involved in a particular research and the institution where the research is conducted, have a joint right over and ownership of all raw data, including those identifying the participants. Along with this right, they are fully responsible for ensuring that when such data, including those that identify participants, are shared with other researchers, all necessary measures are taken and followed to maintain confidentiality, by those researchers with whom data are shared.

3.4.3 Data that do not identify participants and their whereabouts, in the form of anonymous or abstracted facts, may be commonly shared, if necessary even before the publication of the study, among researchers, peer reviewers, or may even be made available to the public.

3.4.4 As far as possible, researchers and institutions should ensure that relevant summary findings of the research are taken back to the research participants in a form and manner that they can understand. In this process they should take into consideration the possible social harm that such information might cause to the research participants.

3.5 Reporting and Publication of Research

3.5.1 Reporting of research and its results is the right as well as duty of every researcher and institution that conducted the study. When they agree to delegate this responsibility to funder(s)/sponsor(s) or any other individual(s)/organisation(s), they should do it only if they have received mutually agreed and expressed commitment to publish/disseminate the results/report within a stipulated period.

3.5.2 The results should be reported irrespective of whether they support or contradict the expected outcome(s). Researchers should also disclose in their publications, the source(s) of funding and sponsors, if any, unless there is a compelling reason not to do so. The findings should also explain the methodology used, as well as how, in actual practice the ethical guidelines were followed, ethical dilemmas encountered and resolved, etc.

3.5.3 Authorship Credit: The following guidelines should be followed for giving authorship credit while reporting the research in any form:

3.5.3.1 Authorship, and its sequence in case of more than one author, should be based on the quantum of contribution made in terms of ideas, conceptualisation, actual performance of the research, analysis and writing of the report or any publication based on the research. Authorship and its sequence should not be based on the status of the individual in the institution or elsewhere.

3.5.3.2 All other individuals not satisfying the criteria for authorship but whose contribution made the conduct and completion of research or publication possible should be properly acknowledged.
3.5.3.3 A student should be listed as principal or first author on any multiple authored publication that substantially derives from the student’s dissertation or thesis.

3.5.3.4 Appropriate credits should be given where data or information from other studies or publications is quoted or otherwise included.

3.5.4 Researchers should avoid dissemination of the results of research before they are peer-reviewed or published in appropriate journals. When such results are disseminated through the popular media, extra care should be taken to ensure that even those media persons not specifically trained in social science and health issues and research, are able to comprehend the limitations and implications of research results. Journalists and the media that publish these research results have a responsibility to do so truthfully and honestly.

3.5.5 When institutions and/or researchers publish a report or any other documents based on research, they should make adequate efforts to ensure their easy availability and accessibility.

Section 4

RIGHTS OF PARTICIPANTS

4.1 Relationship With the Participants

4.1.1 Participants should be seen as indispensable and worthy partners in research. Researchers should recognise and ensure that respect, protection and promotion of the rights of participants are made intrinsic to every stage and level of research undertaken by them.

4.1.2 Research undertaken should not adversely affect the physical, social and/or psychological well being of the participants. The risks and benefits of the research to the prospective participants must be fully considered; research that could lead to unnecessary physical harm or mental distress should not be undertaken. Researchers should make adequate provision for the comfort of the participants as well as for protection against all possible and potential risks.

4.1.3 The criteria for selecting research participants should be fair. The easy accessibility of the participants alone does not constitute a fair criterion for their inclusion in research as that will make them bear an unfair share of the direct burden of participation. At the same time, it should be borne in mind that no particular group or groups should be unfairly excluded from research, as that could well exclude them from the social understanding of their situation, and can also unfairly exclude them from direct, indirect or potential benefits of research.

4.1.4 Unless consent on mutually beneficial arrangement is obtained, institution and student should not use community or research setting as a constant and long-term resource for data collection for curricular research or training in an institution.
4.1.5 The relevant social, cultural and historical background of the participants should be taken into consideration and given appropriate importance in the planning and conduct of research.

4.1.6 Researchers should not impede the autonomy of participants by resorting to coercion, promise of unrealistic benefits or inducement. Participants and communities should not be exploited and the time taken for data collection from these sources should not be inordinately long.

4.1.7 Participants are autonomous agents and must have the right to choose whether or not to be part of the research. They also have the right to change their decision or withdraw the informed consent given earlier, at any stage of the research without assigning any reason.

4.2. Informed Consent

4.2.1 Voluntary and informed participation of individuals or communities is necessary for research. Their participation should be based on informed consent; the greater the risk to participants, the greater is the need for it. Informed consent is essential to protect the participants, not the researchers and institutions.

4.2.2 Consent for participation in research is voluntary and informed only if it is given without any direct/indirect coercion and inducement, and is based on adequate briefing given to the participants about the details of the project. The briefing should be given both verbally and in writing in a manner and language that the participants know and understand. In the prevailing circumstances in India, often, it may not be possible to obtain signed informed consent of the participants in social science research in health. It is however essential that the participants are furnished with written information giving adequate details of the research. Researchers have a duty to ensure that the participants comprehend the information given.

4.2.3 The verbal and written briefing of the participants, in the manner and language they understand, should include the following details:

4.2.3.1 Purpose of Research: The goal and objective of research should be presented in simple local language.

4.2.3.2 Identity of the Researchers: Name and address of researcher(s), the institution(s) and the main person of the ethics committee/ethical review board or any such ethics group of the institution.

4.2.3.3 Identity of Others Associated With the Research: Name(s) and address of chief consultant(s), funder(s) or sponsor(s), etc., if any.

4.2.3.4 Why Selected: Reasons or method for selecting the particular locality, community and/or any other setting; and individual(s) or group(s) within that, for participation in the study.

4.2.3.5 Harms and Benefits: The possible, anticipated and potential benefits and/or harms (direct/indirect, immediate/long term) of research and their participation.

4.2.3.6 Privacy, Anonymity and Confidentiality: Information on the extent of privacy, anonymity and confidentiality that will be provided to participant(s). This must include, at least, the firm commitment that privacy, anonymity and confidentiality of data identifying participants will be strictly maintained. In case the data identifying participants is to be shared with or made available to individuals/organisations not in the research team, information about them (their names, addresses etc.) should be provided.

4.2.3.7 Future use of Information: The future possible use of the information and data obtained, including use as a database, archival research or recordings for educational purposes, as well as possible use in unanticipated circumstances, like its use as secondary data should be made known to participants. Such use should be only of anonymous or
abducted information and data, and should in no way conflict with or violate the maintenance of privacy, anonymity and confidentiality of information identifying participants.

4.2.3.8 Right not to Participate and Withdraw: Participants should also be informed about their right to decline participation outright, or to withdraw consent given at any stage of the research, without undesirable consequences, penalty and so on. The participants should be informed that they are free to object to and refuse to allow the use of data gathering devices, such as camera, tape recorder, etc.

4.2.3.9 Right to Get Help: The researcher should try and get all the possible help that the participants might require. The researcher also has a responsibility to help the participant(s) in cases of adverse consequence or retaliation against the participant(s) by any agency due to their participation in the research. Information, which may contribute to the improvement of quality of life of the participants, should be passed on to concerned person(s), official(s) or the agencies.

4.2.4 If the data collection from the participant(s) is done in more than one sitting or contact and there is a long time period between the sittings/contacts, informed consent should be sought each time.

4.2.5 In some cases, revealing the identity of the group of participants, groups, village(s), neighbourhood(s), etc, in the report could have an adverse effect on members/residents there. Sometimes the researchers are not able to anticipate the possibility of adverse effect at the time of conducting research and publishing reports. Researchers should take care that the study communities and/or localities are not identified or made identifiable in the report unless there are strong reasons for doing so. If the researcher(s) and institution intend to identify them in the report, participants’ informed consent allowing such disclosure should be obtained.

4.2.6 Non-disclosure of all information: In some specific situations and research issues, it is not practically possible to carry out research if all the details of the study are revealed to participants. This may be due to genuine difficulties in accessing participants, possibility of affecting change in behaviour or responses, etc., when the details are revealed. Thus, it is not possible to obtain the informed consent in the same way as described above. In such cases, the following should be done:

4.2.6.1 A detailed justification for not revealing all necessary information must be provided in the research proposal and methodology and should be subject to peer and ethical reviews. Only on approval in peer review, should such research be undertaken.

4.2.6.2 The participants’ right to privacy, anonymity and confidentiality gains additional importance in such cases as they do not know fully the real purpose or objective for which they provide information.

4.2.6.3 Even if through a peer review process it is accepted that some of the information about the study need not be revealed, participants must be provided the rest of the information. Under no circumstance should the researchers withhold the information regarding physical risks, discomfort, unpleasant emotional experiences, or any such aspect that would be a major factor in taking the decision to participate.

4.2.6.4 As far as possible, debriefing should be done with the participants after completion of the research, giving reasons for not providing full information. As a part of the debriefing process, it might often be necessary to provide services such as counselling and referral.

4.2.7 Consent where gatekeepers5 are involved: In some situations there may be a need to obtain permission of the ‘gatekeeper’ to access the participants for research. The following care must be taken in such situation:
4.2.7.1 Permission obtained from the gatekeeper must not be substituted for the need to take separate and full informed consent of the participants. The rights of participants in such situation are the same as in all other cases and need determined protection.

4.2.7.2 For obtaining permission of the gatekeeper, no pre-condition demanding sharing of information or data obtained should be accepted.

4.2.7.3 In the process of research or data collection, adequate care should be taken to ensure that the relationship between the gatekeeper and the participants is not jeopardised.

4.2.7.4 Greater care should also be exercised in protecting participants and their interest while publishing and disseminating results of research.

4.2.8 Informed consent in the case of research with children (below the age of fourteen years) should be sought from the parents/guardians as well as the children themselves. Where the parents/guardians consent to participate, and the children have declined, the rights of the children should be respected. The consent from parents/guardians should be waived only in special cases such as child abuse. Peer review is indispensable and the protection of children especially from the immediate consequences of research gains prime importance.

4.3 Privacy, Anonymity and Confidentiality

4.3.1 Anonymity and confidentiality are the inherent rights of all participants. The right whether to remain anonymous or to be identified lies with the participant. It becomes all the more important in research projects dealing with stigmatised, sensitive or personal issues and information.

4.3.2 Possibility of the breach of confidentiality and anonymity should be anticipated, addressed and explained to the participants.

4.3.3 Appropriate methods should be devised to ensure privacy at the time of data collection. These methods are also essential to ensure the validity of data.

4.3.4 The obligation to maintain privacy, anonymity and confidentiality extends to the entire research team, other researchers in the institution, the administrative staff, and all those (from or outside the institution) not directly associated with the research who may possibly have access to the information.

4.3.5 While deciding on what information should be regarded as private or confidential, the perspective of the participant(s) on the matter should also be given adequate importance.

4.3.6 Researchers should maintain appropriate anonymity and confidentiality of information in creating, storing, accessing, transferring and disposing of records under their control, whether these are written, automated or in any other medium.
Section 5

RIGHTS AND RESPONSIBILITIES OF PEER REVIEWERS/REFEREES

5.1 The purpose of peer review and refereeing is to improve and advance research, and facilitate observance of ethics. Researchers should be encouraged to make themselves available for such work and subject their own work to such a process.

5.2 Researchers should accept the role and duties of peer reviewer and referee only for the research in the fields they have adequate knowledge and expertise. They must also be fully aware of the ethical aspects of research and publication.

5.3 When called upon to act as peer reviewer and referee, researchers have an ethical duty to undertake it objectively, impartially and constructively.

5.4 If the peer reviewers/referees have any actual or potential conflicts of personal or professional interest with the work under review, they should either disclose the same or decline to review the work concerned. In such situations, their role should be decided on the basis of the type and severity of the conflict of interest.

5.5 When malpractice in research or violation of ethics are discovered, the researcher/peer reviewer has the ethical responsibility to take appropriate steps to report it.

Section 6

RIGHTS AND RESPONSIBILITIES OF EDITORS AND PUBLISHERS

6.1 Before accepting the research based articles for publication, editors and publishers have the right and duty to ensure that such material is, duly reviewed by referees deemed by the publication to have the relevant expertise and knowledge in the particular field.

6.2 As social scientists and as journalists, editors are responsible for ensuring that the editorial policy and instructions to authors reflect the ethical concerns and the guidelines for research. Referees and editorial staff should be made aware of the editorial policy including the need for articles/papers to adhere to prescribed ethical norms. Contributors should be informed that the material submitted for publication should carry appropriate credits. Fabricated, falsified or plagiarised information should not be entertained.

6.3 If, after the publication of material, any doubt is raised about its ethical status or ethical conduct of the study on which the said material is based, editors should take appropriate corrective steps.
Section 7

RIGHTS AND RESPONSIBILITIES OF FUNDERS AND SPONSORS

7.1 Funders and sponsors have the right to expect that researchers and institutions report the progress of their work and submit a copy of the final report on results of research as per the schedule agreed in advance.

7.2 Funders and sponsors have a right to get a copy, if any, of the ethical guidelines for research followed by the researchers and institutions. They also have a right to expect that the research proposal submitted for funding or sponsorship by researchers and institution contains necessary information on ethical issues in and ethical conduct of the particular research proposed.

7.3 The funders and sponsors of research should respect the ethical guidelines for research and should not expect researchers and institutions to undertake research or conduct it in any way contrary to the ethical guidelines.

7.4 Where sponsors and funders also act, directly or indirectly, as gatekeepers and control access to the participants, researchers should not devolve onto the gatekeeper their responsibility to obtain separate and full informed consent from participants and protect all rights of the participants.

Section 8

ORGANISATIONAL MECHANISM FOR ETHICS

While ethical guidelines are not administrative rules and the conscience of researchers may be the best guide for ensuring that ethics are followed in research and for resolving ethical dilemmas, conduct of research cannot be completely left to the discretion of individual researchers. Institutions and researchers involved in social science research in health should create appropriate institutional or research project based mechanisms to ensure ethical conduct of research and implementation of guidelines.
Appendix: 1

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Ashok Dayalchand is a medical doctor with a degree in public health from Johns Hopkins University, USA. He has established a number of institutions, including the Navjeevan Rugnalaya, a forty bed rural hospital; Institute of Health Management, Pachod (IHMP); and the Centre for Health Policy and Promotion, IHMP, Pune. His areas of special competence include Planning and implementation of primary health care programmes, training in community health and health management, Research and Policy Advocacy.

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Lakshmi Lingam is currently a Reader in the Unit for Women's Studies at the Tata Institute of Social Sciences, Mumbai. She is also the Co-ordinator for the Centre for Health Studies and the General Secretary of the Indian Association for Women’s Studies. She has a Masters in Sociology from Andhra University, Visakhapatnam, and a Ph.D. from Indian Institute of Technology, Mumbai. Her major areas of research include women’s work and health, women and migration, globalisation and impact on health. She has published papers in national and international journals.

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Radhika Chandiramani is a qualified clinical psychologist. She works with TARSHI on sexuality and reproductive health, and has a particular interest in issues of rights and ethics. Radhika is also a Trustee of the Psychological Foundations, a Trust that facilitates the work of psychologists in clinical practice.

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Thelma Narayan is a medical doctor, trained in epidemiology with a doctorate in health policy analysis. Her research has been in medical
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*Amar Jesani* is a medical doctor doing social science research in health and health care since 1979. He worked at the Foundation for Research in Community Health, Mumbai/Pune from 1979 to 1993. As a part of the Anusandhan Trust he was involved in establishment of CEHAT, Mumbai/Pune and was its first Coordinator from 1994 to 1999. He has authored three books and over a dozen research reports and monographs; and researched topics ranging from community health and NGOs in health care to ethics and human rights. He is a social and health activist with involvement in campaigns for medical ethics and health and human rights.

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APPENDIX: 2

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