Ethics in social sciences and health research: a draft code of conduct

Self-regulation and ethics have been issues for debate within research more often in medicine than in social sciences. This is, at least partly because historically ethics has been used as a defining principle for medicine. In recent years there has been a steady growth of concern for ethics in medical research in India. Many socially conscious groups (such as women's groups, health activists' groups) have been confronted with issues of ethics in the course of their work. They have had to bring into public focus unethical conduct of medical research. These issues have also attracted media attention. In 1980 the Indian Council of Medical Research (ICMR) adopted its first code of ethics entitled 'Policy Statement on Ethical Considerations Involved in Research on Human Subjects'. These guidelines are currently undergoing revision. A consultative document was published in 1997 but the new guidelines are yet to be formally released.

While it is true that real improvement in the standards of quality and of ethics in research need more effort than the mere drafting of ethical guidelines, the very process of evolving such guidelines has an educational value and often empowers the individual researchers to resist pressures.

In the social sciences, interest in ethics is only now emerging. Although many social scientists have paid serious attention to the appropriate conduct of research and have set personal examples, such important issues are hardly discussed as ethics and little effort has been made to formalise a code of conduct for researchers. As far as we know, neither the national councils for social sciences (the ICSSR, etc), their institutions, nor the national bodies for higher education such as the UGC have published comprehensive guidelines for research in social sciences. Elsewhere however there has been growing pressure on social science professionals to self-regulate and evolve their own codes of conduct. Universities have also made efforts to establish formal guidelines to protect student research and their exploitation by the teachers.

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Our preliminary survey of ethical guidelines in the social sciences in different developed countries, shows that a number of proposed associations of sociologists, anthropologists, political scientists, psychologists, etc, have formulated and refined their ethical guidelines in the last three decades. Not only that, in the last one and half decades there have been attempts by the associations of different social science disciplines to evolve joint guidelines. Most important so far have been the efforts to evolve 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. Similar processes are also underway elsewhere. These developments emphasise the fact that the principles governing all research on humans by all disciplines of sciences have many things in common. And researchers need to respect and protect the human rights of the participants of research.

Currently an effort is being made in India to formulate ethical guidelines for research in social sciences and health. These guidelines are being discussed in different institutions, and we hope some of them will be adopting them (with modifications) formally. They will also be discussed at a national level seminar by social scientists, health activists and the NGOs. A draft of the proposed guidelines is reproduced here to prompt a more broad-based discussion among of the research community.

Preamble

I.1 There has been a steady growth of research in the social sciences, and in health, health care and medicine in India. A wide range of research of topics and issues, including those which have potential to seriously invade the privacy and security of individuals, are being studied. The methodologies employed for such research have also expanded both in range and in depth. There is considerable increase in the types and numbers of individuals and organisations undertaking such research, and those sponsoring and funding it.

I.2 There has been a growing concern for indifference and ignorance of ethics in some of the social science research conducted in India. Inadequate ethical self-regulation could hamper autonomy of researchers, quality of research and violate the rights of participants. In general, it could lower the respect for and social commitment of the social science research in general and health research in particular.

I.3 Enunciation of ethical principles and formulation of necessary guidelines/rules for research are, therefore necessary and desirable.

I.4 The ethical guidelines proposed here are the voluntary effort of individuals involved in social science and health research, and reflects their concern for the prevailing situation and desire to improve it. They are proposed for the following purposes:

(i) To prompt discussions in the society, among the researchers and all others directly/indirectly connected to research for the need to observe ethics in research, and to collectively evolve adequate and practical ethical guidelines as well as some mechanism for ensuring the observance of ethics in research.

(ii) For the education and empowerment of researchers who feel the pulls and pressures of various social forces while undertaking research.

(iii) The ethical conduct of research is one of the components of quality of research, and is essential for making research socially relevant and for upholding human rights of participants.

(iv) To enable institutions and researchers to adopt the ethical principles and guidelines in their work, for constituting institutional or project ethics committees and to help evolve network(s) of institutions and researchers for sharing their experiences in implementing guidelines and resolving ethical dilemmas.

Ethical principles for research

The ethical principles outlined here take into consideration the general or normative principle of ethics, viz, (1) Non-maleficence, (2) Beneficence, (3) Autonomy, (4) Confidentiality and (5) Justice.

***II.1** Essentiality*: Research should be undertaken after giving adequate consideration to the existing knowledge on the subject/issue under the study and alternatives available.

II.2 Precaution and risk minimisation: Every research carries some amount of risk to the participants and to the society and consumes resources. Taking adequate precautions and minimising risks are therefore essential.

***II.3** Knowledge, ability and commitment to do research*: While research is not the monopoly of any group or of only those who are recognised as professionals, every researcher must acquire adequate knowledge and ability, and should have commitment to do research.

***II.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, rights and dignity of participants. The participation of the individual(s) must be voluntary and based on informed consent.

***II.5** Privacy, anonymity and confidentiality*: All information and records provided by participants to researchers or obtained directly or indirectly by researchers on the participants, are confidential. The researchers should not reveal or share any information that could identify participants without the express permission of the participants.

***II.6** Non-exploitation*: Research must not consume unnecessary time of participants, make them incur unacceptable loss of resources and income and should not expose them to risks due to participation in the research. The relationship within the research team should also be based on the principle of non-exploitation and the contribution of each member should be properly acknowledged and recognised.

***II.7** Accountability and transparency*: The conduct of research must be fair, honest and transparent. The researchers are accountable to the research community and the society. Researchers must be amenable to the appropriate and responsible public scrutiny of their work by appropriate and responsible ethics/social body. In such a scrutiny, researchers should make full disclosure on each aspect of the research, conflicts of interest (if any), complete records of research, etc. It is desirable that researchers take steps, on their own, for the periodic research and social audit of their work by independent committee. The researchers should also make appropriate arrangement for the preservation of research records for a reasonable length of time.

***II.8** Maximisation of public interest and of distributive 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 distributive justice.

***II.9** Public domain*: All research being carried out and planned must be brought to the public domain. Researchers must make adequate efforts to make the results of their research public, and to ensure that their reports are peer reviewed and disseminated.

***II.10** Totality of responsibility*: The responsibility for due observance of all principles of ethics and guidelines or rules devolves on all those directly or indirectly connected with the research. They include researcher(s), funder(s) and sponsor(s) of research, institution(s) where the research is conducted, and various persons, groups or undertakings who sponsor, use or derive benefit from research, market the product (if any) or prescribe its use. The totality of responsibility means all associated with research, must monitor, constantly review and take corrective measures.

Ethical guidelines

III.1 *Integrity of researcher*

III.1.1 Researchers should undertake study only if they believe it will be useful to the society or for the furtherance of knowledge. They should bear in mind that research can have the potential of not only affecting individuals but also a larger population, even an entire state or country. Thus, they have a responsibility towards the interests of those involved in or affected by their own work. This also emphasises the need for integrity; continued enhancing of research capabilities and honesty at all stages.

III.1.2 Researchers should anticipate and guard against possible misuse and undesirable or harmful consequences of research. Whenever a researcher comes across misuse or misrepresentation of their work, they should take reasonable steps to correct the same.

III.1.3 Researchers, organisations and institutions should not allow themselves to be put in a position, which leads to compromising their integrity, autonomy or freedom in designing methodology, interpretation of findings and publication. They should not undertake research when its findings are to be kept confidential. Unless there is an established or written agreement on the stipulated time by which the funding/sponsoring organisation will make the research results public and disseminate them, the researcher should not accept the funding/sponsoring organisation's right to publish and disseminate results.

III.1.4 Framing of research questions and agendas should be issue/subject specific and sensitive to the culture or community being studied. The criterion of selection of participants of research should be fair. Easy accessibility of the participants alone does not make a fair criterion for including them 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 can exclude them from the social understanding of their situation, and can also unfairly exclude them from direct, indirect or potential benefits of research. Participants and communities should not be exploited.

III.1.5 Peer review should be an essential part of every research endeavour or initiative, and should be sought at various stages of research. Any research or peer review in which a conflict of interest could arise as a result of a personal or vested interest, should be disclosed prior to undertaking it. Where it is found that such a conflict could lead to the results of research or of its ethical conduct being affected then such an activity should not be undertaken.

III.1.6 Researchers should report their findings accurately and truthfully. There should be no fabrication, falsification, plagiarism or other practices at any stage of the research.

III.1.7 Every researcher has a duty to protect historical records and to preserve materials studied.

III.2 *Relationship between Researcher and Junior researchers/ Students/Trainees*

III.2.1 All juniors and trainees should be given proper training and guidance regarding all aspects of research, including ethical conduct. Senior researchers must bear responsibility for the ethical conduct or misconduct of all junior researchers, research assistants, students and trainees. This, however, does not devolve the responsibility of objective and ethical conduct of research from the students or trainees themselves. They will be equally responsible for any ethical misconduct on their part.

III.2.2 Researchers should delegate to their employees, students, research assistants, only those responsibilities that, in the researcher's judgement, they are reasonably capable of performing on the basis of their education, training or experience, either independently or under supervision, as the researchers deem fit.

III.2.3 No researcher should engage in discriminatory, harmful or exploitative practices, or any perceived form of harassment, personally or professionally. Researcher should never impose views/ beliefs on or try to seek personal, sexual, economic gain from anybody, especially their juniors/trainees/ students, or impose views or beliefs.

III.2.4 Researchers should not deceive or coerce students/trainees/ juniors into serving as research subjects/participants, and they should not be used as cheap labour. Teachers and seniors should be co-operative, responsive, honest and realistic about the students'/trainees' interests, opinions and views.

III.2.5 No unethical practice including that of plagiarism, fabrication and falsification of data should be indulged in with the work of juniors/trainees/students.

III.2.6 For the purpose of student research i.e. data collection for research by the students as a part of their study or training in an institution, no community/research setting should be used as a constant and long-term resource. Moreover, whenever such student research is also a part of externally funded project(s), all aspects of research, including ownership of data, should be laid down and made known at the outset, and the students should have a right to opt out of it without any adverse consequence.

III.2.7 All research team members as well as those individuals who at some level would get associated in some way to the research (such as administrative staff of the organisation conducting research or that of the research setting), should be briefed of the ethical issues.

III.3 *Relationship between Researcher and Participant*

III.3.1 Participants should be seen as indispensable partners in research, and researchers should give due recognition to each other's contribution to research.

III.3.2 Research undertaken should not adversely affect the physical, social, psychological well being of the participants. The harms and benefits of the research to the prospective participants must be fully considered; and research that leads to unnecessary physical harm or mental stress should not be undertaken.

III.3.3 The relevant cultural and historical background of the participants should be considered when research is planned. Researchers should not, in any way, compromise the participant's position in their society/community.

III.3.4 Participants are autonomous agencies and 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.

III.3.5 Researchers should not impede the autonomy of participants by resorting to coercion, deception, or deprivation of essential information, or promise of unrealistic benefits, excessive reimbursement or inducement.

III.4 *Rights of Participants: Informed Consent*

III.4.1 Voluntary and informed participation of individuals or communities is necessary for research and should be based on informed consent and the greater the risk to participants, the greater is the need for it. The need for informed consent is not to protect researchers who are normally in a more powerful position than the participants and would be in possession of information about the participants, but the participants.

III.4.2 Consent for participation in research is voluntary and informed only if it is freely given (without any direct/indirect coercion) and is based on adequate briefing given to the participants about the details of the project. The briefing should be given verbally and details given in writing (in both cases, 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, but it is essential that the researchers furnish the participants written information giving adequate details of the research along with the name/ addresses of people/institution(s) associated with the project.

III.4.3 The verbal and written briefing of the participants, in the manner and language they understand, should include the following details:

(i) *Purpose of research*: The goal and objective of research in simple jargon free language.

(ii) *Who is doing it*: Name(s) and address(s) of principal researcher, the institution and the main person of the ethics committee or ethical review board.

(iii) *Others associated with it*: Name(s) and address(s) of chief consultant, if any, of funding or sponsoring organisation(s), etc.

(iv) *Why selected*: Reasons or method for selecting the particular group or individual(s) in the community or in any other settings, for participation in the study.

(v) *Harms and benefits*: The possible harms and/or benefits (direct/indirect, immediate/long term) of research, as anticipated by the researcher,

(vi) *Privacy, anonymity and confidentiality*: The extent of privacy, anonymity and confidentiality that will be provided to participant. This must include, at least, the firm commitment that privacy, anonymity and confidentiality of all identifiable data will be strictly maintained. In case the identifiable data would be shared with or made available to individuals/ organisations not in the research team, the information on them must be provided.

(vii) *Future use of information*: The future possible use of the information and data thus obtained including being used as database or eventually as archival research or recordings used for educational purposes, as well as possible use in unanticipated circumstances, i e, its use as secondary data. However, this should not conflict with or violate the point (vi), i e, maintaining privacy, anonymity and confidentiality of the identifiable information.

(viii) *Right not to participate and withdraw*: They 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, etc. That the participants are free to reject any form of data gathering devices, such as camera, tape recorders.

(ix) *Right to get help*: The researcher 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. This must be stated in the briefing.

III.4.4 If the data collection from the participant(s) is done in more than one sitting or contact, informed consent should be sought each time. If some significant changes are affected in the aspects of information to be collected, fresh informed consent needs to be taken.

III.4.5 In many cases, revealing the identity of the group of participants, community, village, neighbourhood, 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 doing research and publishing reports. Researcher should take care that the study committees are not identified or made identifiable in the report unless there are strong reasons for doing so. If the researcher intends to identify them in the report, informed consent for the same must be sought.

III.4.6 Researchers should be careful so as not to use up excessive amounts of time of the participants.

III.4.7 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 could be due to genuine difficulties in accessing participants, possibility of affecting change in behaviour or responses, etc, when the details are revealed. In such cases, it is not possible to obtain the informed consent in the same way as described above. The following guidelines are suggested in such cases:

(i) It is necessary that the researchers justify the need for such research – where the full details of the study would not be revealed to participants – to a wider peer group not directly connected to the study. Only when such a peer group of researchers approves it, the research should be undertaken.

(ii) The participants' right to privacy, anonymity and confidentiality gains additional importance in such cases as they do not know the real purpose or objective for which they provided information.

(iii) 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 information regarding significant aspects of the research such as physical risks, discomfort, unpleasant emotional experiences, or any such aspect that would be a major factor in making the decision to participate or not be withheld.

(iv) When certain aspects of research are not disclosed, steps should be taken to avoid, or at least minimise the possible harm, including embarrassment or humiliation.

(v) As far as possible, debriefing should be done with the participants after completion of the research, giving reasons for not providing full information. It might often be necessary to take steps such as counselling as a part of the debriefing process.

III.4.8 In some situations (mental institutions, remand homes, some traditional communities, etc) there may be a need to obtain permission/consent of the 'gatekeeper' to access the participants for research. However, the consent/permission obtained from the gatekeeper must not make the researcher disregard the need to take the informed consent of the participants. Researchers should also be careful so as not to jeopardise the relationship between the gatekeeper and the participants. Researchers should not accept any conditionality which demands the sharing of data obtained from the participants with the gatekeeper as a prerequisite for obtaining permission to access the participants.

III.4.9 Where research participants are critically ill patients and those incapable or rendered incapable or do not have the ability to take a decision, the informed consent from proxies or surrogates (parents, guardians, care-taking institutions, etc) should be taken. Where it can be inferred that the person about whom data are sought would object to supplying certain kinds of information, that material should not be sought from the proxy. In studies using such proxy data, the process of peer review has added importance.

III.4.10 Informed consent in case of research with children 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. Waiver to consent from parents/guardians can be sought only in special cases such as child abuse. Peer review is indispensable, and protection of the children especially from the immediate consequences of research, gains prime importance.

III.4.11 Research by naturalistic observation, not needing identification of participants, does not need informed consent. Research using historical records, archival research does not need informed consent.

III.5 Rights of Participants: Privacy, Anonymity and Confidentiality

III.5.1 Anonymity and confidentiality are the inherent rights of all participants. The right to remain anonymous or to receive recognition lies with the participant. It becomes all the more important in research projects dealing with stigmatised, sensitive or personal issues and information.

III.5.2 Threats to confidentiality and anonymity should be anticipated and addressed. In unanticipated circumstances, which could threaten the promise made to the participants, researcher needs to balance the promise of confidentiality against the possible harm that the situation could cause, keeping in mind applicable law and this code. Peer review should be sought.

III.5.3 Appropriate methods need to be devised to ensure privacy at the time of data collection. This is also essential to ensure the validity of data.

III.5.4 The obligation to maintain privacy, anonymity and confidentiality extends to the entire research team, including the administrative staff, and people though not directly associated with the team may possibly be able to access to the information.

III.5.5 What information is regarded as private or confidential can be determined when viewed according to the participants' perspective, which in turn, is often determined by the culture to which the participants belong or are part of.

III.5.6 Researchers should maintain appropriate anonymity and confidentiality in creating, storing accessing, transferring and disposing of records under their control, whether these are written, automated or in any other medium. The question of anonymity also arises at the time of publication of the findings of the research. As far as possible the publication should give only the relevant information and avoid giving markers that might lead to the possible identification of the participants.

III.6 Data Sharing and Secondary Use of Data

III.6.1 Data are commonly shared among researchers, sometimes, even before the publication of the study, and maybe as an effort towards peer review. Sharing of data should be done in a form consonant to the interests and rights of the participants. Markers or other disclosure avoidance techniques should be used.

III.6.2 Researchers should avoid sharing raw field notes and other preliminary notes, where the names of the participants have not been changed.

III.6.3 Where the participants are prisoners, employees, students, children from a remand home etc, i e, where access to the participants has been obtained through gatekeeper(s), no identifiable data should be shared with the gatekeeper(s).

III.6.4 The wider sharing of data, including making them available publicly, should be of anonymous facts where there are no markers that could lead to the identification of any participant.

III.7 Reporting and Publication of Research

III.7.1 Reporting research is the duty of every researcher. Practices such as plagiarism, falsification, fabrication of data or any misconduct or unethical practice should not be indulged in at any stage of the research.

III.7.2 The results should be reported whether they support or contradict the expected outcome(s). Researchers should also report in their publications, the source/s of funding, sponsors, etc, unless there is a compelling reason not to do so. The findings should also explain ethical guidelines followed and dilemmas encountered and resolved.

III.7.3 Authorship credit:

...guidelines should be followed for giving authorship credit while reporting the research in any form...

III.7.4 The results of research often need to be conveyed/disseminated through the popular media even before they are published in journals. Researchers who choose to do so have a special responsibility to ensure that the ethics is research are not disregarded, and the results of research have been afforded a peer review. Journalists and the media that publish these research results have a responsibility to publish the results truthfully and honestly.

III.8 Role of Editors

III.8.1 Editors have special responsibility both as social scientists and as journalists. Editorial policy and instructions to authors must reflect the ethical concerns of this document, and the peer reviewers/referees and editorial staff should be instructed to scrutinise contributions for adherence to ethical norms.

III.8.2 Editors should make it clear that papers or reports of studies should carry appropriate credits and do not contain fabricated, falsified or plagiarised material.

III.8.3 If, after the publication of material, any doubt is raised about its ethical status or about the ethical conduct of the study on which the said material is based editors should take appropriate steps to correct the mistake.

III.9 Role of Peer Reviewers/Referees

III.9.1 The work of peer reviewing and refereeing are for the improvement and advancement of research. Researchers have an ethical duty to undertake it objectively and impartially when called upon to do so.

III.9.2 When researchers and editors are acting as peer reviewers and referees, they should do it responsibly and constructively. They must also be fully aware of the ethical aspects of research and publication.

III.9.3 If the peer reviewers/referees have any actual or potential conflicts of 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 severity of the conflict of interest.

III.9.4 When malpractice in research or violation of ethics are discovered, the researcher has the ethical responsibility to take appropriate steps to stop or report it.

III.10 Relationship with Sponsors and Funders

III.10.1 Researchers have a responsibility to report the progress of their work and submit a copy of report to sponsors and funders of research as per the schedule agreed in advance.

III.10.2 Researchers should inform the sponsors and funders of research about the ethical guidelines for research followed by them and/or their institution.

III.10.3 Researchers should not accept or imply acceptance to the sponsors and funders the condition(s) which are contrary to the ethical guidelines followed by them or competing commitments.

III.10.4 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 informed consent from and to protect interests of the participants.

III.10.5 Researchers should not undertake secret or classified research, and any secret assignment under the garb of research.

[The proposed code containing ethical guidelines has been formulated by a committee comprising Ghanshyam Shah, Lakshmi Lingam, V R Muraleedharan, Padma Prakash, Thelma Narayan, Ashok Dayalchand, Manisha Gupte, Sarojini Thakur, Geetanjali Misra, Radhikaa Chandiramani. The committee is being assisted by the research secretariat of Amar Jesani and Tejal Barai. This work is being done at the CEHAT, Mumbai with the financial support of the Ford Foundation. The proposed draft does not reflect views of the individual committee members and they will be thoroughly debating it before adopting it.]

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