**Ethics and Governance in Socio-Cultural Research**

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1. Introduction

In this paper I want to discuss the governance of socio-cultural research involving human beings. There is a growing set of regulations that are applied to socio-cultural research, many are direct extensions of governance systems that were developed to protect subjects of biomedical research (Dalglish, 1976). There are a number of ethical issues raised by any research, and the same is true of social science research (Citro et al., 2003; Homan, 1991; Punch, 1986). These issues include deception, informed consent, vulnerable populations, confidentiality and survey research, court subpoena of data, to mention a few (Sieber, 1982; Van den Hoonaarad, 2002). The consideration of the ethical issues has been emerging over the past decade, though there are trends in the considerations of what is an ethical dilemma (Barnes, 1963; Cassell, 1980; Whittaker, 1981).

From a regional perspective we can ask whether there is any characteristic bioethic of Asia or the Pacific, and how research ethics has evolved over the past century. Ethics is a concept balancing benefits and risks of choices and decisions. The underlying heritage of ethics can be seen in all cultures, religions, and in ancient writings from around the world (Macer, 1994). We in fact cannot trace the origin of bioethics back to their beginning, as the relationships between human beings within their society, with nature and God, are formed at an earlier stage then our history would tell us.

There are at least three ways to view ethics (Macer, 1998).

1. **Descriptive ethics** is the way people view life, their moral interactions and responsibilities with others in their life. Information we gather is used to describe many things, and there are many ethical issues related to gathering information and storing information.
2. **Prescriptive ethics** is to tell others what is ethically good or bad, or what principles are most important in making such decisions. It may also be to say something or someone has rights, and others have duties to them. It is related to policy making and law.
3. **Interactive ethics** is discussion and debate between people, groups within society, and communities, and clearly information ethics is central to shaping the types and forms of interactions that are possible. There may be ethical issues that emerge during the conduct of the research, so ongoing analysis and discussion is important (Lee-Treweek and Linkogle, 2000). Descriptive bioethics is important to inform us of how people really think. This approach to bioethics was developed in *Bioethics for the People by the People* (Macer, 1994). It allows us to attempt to answer the questions above. There are several possible strategies. Firstly we can look at the use of organisms and new products in different groups inside each society and between them, for example, do people eat beef or do they not? Do they farm animals in open spaces or in factory
farms? We have to standardise for environmental and economic conditions, and also look at the religious traditions. The religious traditions include guidance on ethical issues, answers to problems that are faced around the world. In one sense looking at the end result of choices, the adoption of science and technology products, consumption, is the best description of acceptance of science and technology. In addition this type of knowledge is publicly available, so many guidelines do not require any governance of acquiring that knowledge.

However, if we only look at the statistics we may still not understand the reasons behind the choices, and whether, for example, there was really much free choice for the consumer given the prevailing norms of their home environment, medical system, and society. The ideal model would say a consumer will determine what products are best, but this is arguably never seen in a world dominated by large commercial interests, trade groups and associations, and connections between producers, retailers and regulators.

There are many unethical episodes in Asian research ethics. One is the wartime experiments conducted on prisoners in Manchuria China, while China was under Japanese occupation in World War II. At least 3,000 persons, mainly Chinese but some Korean, were murdered by or after vivisection and other experiments in facilities under Unit 731 at several locations in China. The functions included vivisection practice for newly qualified army surgeons, intentional infection of diseases, trials of non-standardized treatments, and discovering the tolerances of the human body (Tsuchiya, 2000). Neither Japanese nor Chinese bioethics has sufficiently analysed these experiments and the ethical issues they raise (Morioka, 2000; Tsuchiya, 2000; Macer, 2001; Nie, 2001), in contrast to the German preoccupation with their war crimes. Because of the opportunity to have access to the best medical research facilities in Asia, many physicians went to the Unit, and after the war it was only in the mid 1990s that some members of the Unit started to confess and apologise for their actions, as they reached old age. However, the discussion of the issues in medical ethics has only recently begun. Since the best medical students often trained in Unit 731, because it was the best equipped research laboratory in Asia at the time, the preoccupation with technical as opposed to spiritual issues of medicine is consistent with mentality of medical experimentation that lead to such extremes.

There are numerous examples in every country, even to the current times, of unethical research. There have been a number of codes developed, from the Nuremburg Code (1948), the Belmont Report (1979) in the USA, to modern research codes with detailed explanation such as the Ethical Guidelines for Social Science Research from the Indian National Committee for Ethics in Social Science Research in Health (see Appendix 1). UNESCO has also drafted a Universal Declaration on Bioethics, which is expected to be adopted by the UNESCO General Conference in October 2005 (Appendix 2).

2. Cultural variation and ethical principles of research

One of the current issues in cross-cultural ethics is whether respect for individual autonomy and informed consent should be universal? The issues are faced in not only Japan or Asia, but in most traditional societies. Compared to 50 years before the modern response is to reject “paternalism” and over-dominant
professionals and governments who make decisions for citizens without adequate respect for their voices and values.

There are some accepted common ethical values behind governance systems and these include (TCPS, 2002):

a) **Respect for Human Dignity:** The first principle of modern research ethics aspires to protecting the multiple and interdependent interests of the person -- from bodily to psychological to cultural integrity.

b) **Respect for Free and Informed Consent:** Individuals are generally presumed to have the capacity and right to make free and informed decisions. Respect for persons thus means respecting the exercise of individual consent. In practical terms within the ethics review process, the principle of respect for persons translates into the dialogue, process, rights, duties and requirements for free and informed consent by the research subject.

c) **Respect for Vulnerable Persons:** There are greater ethical obligations towards vulnerable persons -- to those whose diminished competence and/or decision-making capacity make them vulnerable. Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination. There are often special procedures to protect their interests.

d) **Respect for Privacy and Confidentiality:** Respect for human dignity also implies the principles of respect for privacy and confidentiality. Standards of privacy and confidentiality protect the access, control and dissemination of personal information.

e) **Respect for Justice and Inclusiveness:** Procedural justice requires that the ethics review process have fair methods, standards and procedures for reviewing research protocols, and that the process be effectively independent. Justice also concerns the distribution of benefits and burdens of research. On the one hand, distributive justice means that no segment of the population should be unfairly burdened with the harms of research. It thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests in order to ensure that they are not exploited for the advancement of knowledge. Distributive justice also imposes duties neither to neglect nor discriminate against individuals and groups who may benefit from advances in research.

f) **Balancing Harms and Benefits:** The foreseeable harms should not outweigh anticipated benefits. Harms-benefits analysis thus affects the welfare and rights of research subjects, the informed assumption of harms and benefits, and the ethical justifications for competing research paths. Research often involves uncertainty about the precise magnitude and kind of benefits or harms that attend proposed research. There are obligations on the prerequisites, scientific validity, design and conduct of research.

g) **Minimizing Harm:** Non-maleficence is the duty to avoid, prevent or minimize harms to others. Research subjects must not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientifically and societally important aims that cannot be realized without the participation of human subjects. The principle of minimizing harm requires that the research involve the smallest number of human subjects and the smallest number of tests on these subjects that will ensure scientifically valid data.

h) **Maximizing Benefit:** The principle of beneficence imposes a duty to benefit others and, in research ethics, a duty to maximize net benefits. Human research is intended to produce benefits for subjects themselves, for other individuals or society as a
whole, or for the advancement of knowledge. In most research, the primary benefits produced are for society and for the advancement of knowledge.

The most recent exposition of universal ethical principles is in the UNESCO Universal Declaration on Bioethics (see appendix 2). In order to assess how these ethical frameworks should be applied at the community level in research, we need in-depth cross-cultural dialogue and study rather than defining one ethics as Asian and one as not. The interesting point for cross-cultural ethics is at what point do you call something distinctly “Japanese” or “Asian” or “Tongan”. The answer to this may depend upon what literature and practices we are familiar with. Tsai (1999) and others have shown that ancient Chinese medical ethics may follow a four principles approach, but with more emphasis on beneficence than autonomy.

Over time, the existing systems and patterns which are seen in the relationships in communities, for example, between patients, families, health professionals, and the society in general have changed. At the same time, as technology was transferred, some values were also imported beyond the general acceptance that new technology must be better than old (Macer, 2005). A number of countries in Asia and the Pacific were colonized, and a few communities and Islands exist still as colonies, which has significantly influenced their values and the practice of medicine.

One approach I favour for future study is exploring the question of whether “Bioethics is love of life” (Macer, 1998). From the past years of research across many countries I think “love” can be a fruitful language for debate in bioethics, despite its ambiguity. We can consider the four principles of love bioethics, as self-love (autonomy), love of others (justice), loving life (non-maleficence) and loving good (beneficence). I argue that love is not only a universally recognised goal of ethical action, but is also the foundation of normative principles of ethics. These fundamental principles of ethics may not have changed over time, but the emphasis placed on them has shifted. There was more beneficence 150 years ago and now more precedent to autonomy. As for the importance of justice and non-maleficence the trends in different localities are more difficult to determine.

There are other key words that emerge from Asia, such as harmony and tolerance, respect and reverence, and ambiguity (Macer, 1999). There is diversity within every society over the bioethics that each person has, and the relationships that shape the balancing of principles or ideals. While Asia and the Pacific have a rich tradition in views of life, there continues to be a gap between the real world and the ideal. Few of the ideals of respecting life are actually applied to everyday applications, and to deciding how to use medical technology. However, this may not be so different from the real world of the clinic in most societies, and probably there is less gap now than 150 years ago.

The media is clearly a major factor in influencing bioethical decisions in all countries. The discussion of bioethics can transform the whole style of society. The bioethics debate may be the catalyst required to transform countries from paternalistic feudalism through paternalistic democracy into democracies. People of any country may resist the rapid change and globalization of ethics, ideals, and paradigms as ethnic and national identities may be changed, or lost, especially countries with such a
long history of culture. How countries approach globalization is a fundamental question, but many individuals in countries with access to common news media have already answered the question by their converging lifestyles and values. To the extent that human rights and the environment are more respected, this trend is to be encouraged.

3. Whose Perspective in Research Ethics?

When we consider what a global perspective on human subjects protection is we first have to ask whose perspective are we considering? We could consider taking global views inside one particular community, for example, involving the patient, family, local community values, researchers, doctors, etc. If we are considering research that involves genetics, then because genetics is of familial importance we can envisage conflicts between different members of a family. This means that although one person may volunteer to be involved in the human research project, the results of that research when it disclosed to that family member may have implications for the health of other family members. There is a growing recognition of the duty to inform not only the subjects of the research about the health implications of their sample analysis, but also a recognition that there may be duties to inform other members of the family about the avoidable conditions which the tests undertaken as part of the research project have revealed.

If the research involves a pregnant woman, imagine a situation where there is a conflict between a fetus and the mother. For example, if there is an indication that the fetus should undertake surgery in order to be able to survive when it is born, then if the mother does not wish to undergo this type of therapeutic intervention, a conflict between the fetus and the mother might occur later. In almost all countries around the globe, we find that no physician would undertake the treatment of the fetus without the free and informed consent of the mother.

Perhaps more commonly across a broad range of research fields and therapeutic situations is the conflict between the patients and the medical professional in societies which are still moving from a paternalistic system towards a system of informed consent and which may not have yet reached a paradigm of informed choice for medical treatment. This conflict between patient and medical professional could also come up, for example, when the interests and goals of research scientists differ from each other from their patients or when a particular hospital, or even a country, begins to wish to be involved in particularly new and exciting research for a variety of reasons. The reasons could one or several including academic recognition of a hospital in a country where recognition is related to the number of clinical protocols for research, and/or very innovative research in new therapies. Certain countries as a whole may also attempt to become one of the top countries known for new therapeutic innovations. In any of these cases, the interest of the patient may begin to differ from the real interest of the investigator.

If we attempt to take a global perspective, we must start with the premise that not all members of the global community have the same paradigm for what the best option is. There are diverse views of what healing and health is. Although these also differ within a community, we can find within certain communities that have not yet joined the global culture of the 21st century that there may be paradigm of disease, life, and death that we may not have considered. It may very well not be the goal of
living as long as one can with the best quality of life that one can. Therefore, when international research protocols are being designed, we must take into account the possibility that the assumptions that one can make in a small community is that everyone wants to get better may not be valid under certain circumstances.

4. Current concerns over governance of socio-cultural research

There is much research that does not risk personally harm human subjects (Gray, 1982), however in a growing number of countries such research is subject to ethical review. There has been concerns expressed about the suitability of the review systems for social science research (e.g. American Association of University Professors, 2000; Brainard, 2001; Singer & Levine, 2003). Evidence of current concerns was cited in the testimony of three researchers in April 2000 before the U.S. National Bioethics Advisory Commission, which was charged with examining the adequacy of the federal system for protecting human subjects involved in research. The testimony included comments such as:

“The problems that emerge within anthropological research . . . have to do with human beings, not just as physiological specimens, but as social creatures living in families, clans, groups, tribes, or nations . . . The risks and benefits to the people [that anthropologists study] are very different from those faced by subjects of biomedical research.”

“Researchers who are not particularly sophisticated . . . [and] have not been through [the IRB] process feel confused and cynical, distrustful of the IRB and regulatory process because it really does not seem to apply to them. And, unfortunately, there are unsophisticated IRBs that are readily confused, very risk averse, very heavy handed.”

“Historians report that they have been told by IRBs to submit detailed questionnaires prior to conducting any interviews; to maintain narrator anonymity both on tape and in their published work; and to either destroy their tapes or retain them in their private possession after their research project is completed. Each of these requests misconstrues oral history and violates fundamental standards of historical practice.” (NBAC, 1999)

One of the dramatic changes is the decrease in trust and respect towards professionals and governments recently. In the International Bioethics Survey conducted in 1993 in ten countries across Asia and the Pacific, Japan was found to be the least trusting of statements by doctors (Macer, 1994). Arguably, the lack of trust has been a barrier in the implementation of some techniques, such as organ transplants (Macer, 1992).

One of the features of an Ethics Committee that can make it more trustworthy its membership. Among different countries there is quite a different range of committee members, not only in terms of their gender ratio and ages, but also in terms of who is considered a lay person. Often these lay persons are not academics; they are not specialists in a particular discipline. Rather they are people from the community who are willing to think independently about the clinical research protocol. In New Zealand the majority of the Ethics Committee members and its chairperson must be lay persons. However, in Japan it is very rare to find any member of the committee who is not associated with a medical school or whose chair is not the Dean of a medical school.
In many Institutions in Asia we find that one person on the Ethics Committee should not belong to the hospital. While this represents some progress from a totally internal institutional committee, it is still a long way from a truly independent Ethics Committee. We need to have the bioethics for the people by the people, and understand that all members of the community can make educated and good decisions over difficult questions regarding human subject research. Some scientists may claim that the scientific details are too complex for an ordinary person to understand, however I would always argue that unless the science can be made simple so that an ordinary person can understand it, it is not good science. It would seem very difficult to obtain true informed consent from the general member of the public if science could not first explain its work the members of an Ethics Committee.

A broad category of research that raises particular concerns is that conducted on children. There is a recent report on that by Schenk and Williamson (2005).

5. Who Can We Trust?
Public trust is critical for the subjects involved and the communities as a whole. Opinion surveys have shown that when asked to choose who they would trust, a majority of persons trust the United Nations organizations, for example the World Health Organization, rather than their own governments and their own national regulatory authorities. For example, in surveys conducted in Japan and New Zealand in the late 1990's we see over 60 percent of those questioned said they would trust the United Nations for information about the safety of biotechnology, whereas only a around 10 percent would trust their own government authorities (Macer, 1994; Macer, 2004) Scientific organizations are trusted a little bit more than governments, because scientists are perceived to be experts independent of the government. Independent ethics committees are also trusted more than government authorities, and this may be particularly relevant to the discussion of today's international symposium. Because an Institutional Review Board is a form of an Ethics Committee, it is essential that it is well trusted across the community. Ethics committees are relatively new invention, so it is interesting that they have already reached a good reputation in countries that have established ethics committees independent of authorities. This is especially true when those authorities, meaning the industries, physicians, or governments, are perceived by the people to have a conflict of interest. It is a very important principle for a successful institutional review board that they are seen to be independent and that they can be trusted to say yes or no to a research protocol without being manipulated by those who have particular interests in conducting the research protocol. The people conducting the protocol could possibly have a conflict with the best interests of the persons, patients, or local community involved.

There are several examples of international or global bioethics committees, and for different situations we may use different models.

Council of Europe Bioethics Convention and the Council of Europe Steering Committee on Bioethics
The Council of Europe includes nearly 50 members from countries across Europe, and has been able to reach a consensus on the Convention on Human Rights and Biomedicine that has been ratified by member countries. The Convention has been ratified by 19 countries (Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Georgia, Greece, Hungary, Iceland, Lithuania, Moldova, Portugal, Romania,
San Marino, Slovakia, Slovenia, Spain and Turkey). In many other countries who signed but have not ratified yet (13) the principles of the Convention are used, even though there are still controversial issues including human embryo research or how consent is obtain from persons who may not understand what is involved, for example, mentally handicapped persons or children.

Basic articles like number 2 assert “The interests and welfare of the human being shall prevail over the sole interest of society or science.”

Professionalism is also important as stated in article 4, “Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.”

**UNESCO International Bioethics Committee**

UNESCO, an international agency of the United Nations established the International Bioethics Committee in 1993. For the first five years the committee focused on developing the Declaration on the Human Genome and Human Rights, which was unanimously adopted by all member countries of UNESCO in 1997. This Declaration represents a global bioethics consensus on the way that research in human genetics should be conducted.

In 1998 a new committee was formed to focus on implementing the Declaration and continue developing some statements and reports on particular issues in bioethics. The first Committee, which had 50 members from a wide range of countries and which performed its role from 1993 to 1997. The members were appointed to act as individuals, not representative of their governments. The second committee has 36 members, one member per country. Also in 1998, UNESCO established another committee, the Inter-governmental Bioethics Committee, to officially represent their government views. These committees represent the globalization of the concept of Bioethics.

6. **Education for a Bioethically Mature and Responsible Societies**

I would call a mature society a society that can balance the benefits and risks of different choices, one which can debate these choices in public, and one which can accept that different members may make different choices, and these choices will be tolerated within general limits of medical law. In order to ensure an informed and bioethically mature society, we need to have public education and patient education. We need to empower persons to move from beyond paternalism through informed consent to informed choice. There is a role for every professional in this transfer of decision making power, because such an empowerment is a natural extension of the recognition of human rights and human dignity, and loving our neighbor as ourselves (Macer, 1998).

One way to accomplish this education is to target all of society through school education and community health centers. Patient groups and families to support these persons also need to be closely involved, as do associations of aged persons who are often seen in hospitals. There are many approaches and methods that can be used and it is important to attempt many types of measures. One step for immediate action is a disclosure of information about the activities of institutional review boards and how they proceed on the Internet. It is not enough to provide information through public
meetings and secondhand reporting by the media. It is also important for the committee to provide information directly to society, and the Internet is one modern ways that the ill have been empowered.

An important aspect of this is professional responsibility. The 1997 UNESCO Declaration reads: “13. The responsibilities inherent in the activities of researchers, including meticulousness, caution, intellectual honesty and integrity in carrying out their research as well as in the presentation and utilization of their findings, should be the subject of particular attention in the framework of research on the human genome, because of its ethical and social implications. Public and private science policy-makers also have particular responsibilities in this respect.”

There are international norms of good practice by scientific researchers, and they apply to design, conduct, analysis and reporting of results. These international norms must be followed by professionals in research and also by clinicians in the clinic. These professional norms do not only consist of requiring excellent scientific and clinical practice, they also include respecting all persons' human values and rights.

Human subjects protection committees are also a method of quality control that is essential for developing trust in an area of medicine that has so often been abused in the past (Tsuchiya, 2000; Nie, 2001). Some lessons for ethics committees from the surveys are:
• The purpose of regulation is to avoid doing harm, loving life. At the same time, loving good also demands us to do good, and people express support for both ideals.
• We need to educate people how to exercise informed choices in medical therapy, restricting choice only if this will harm others or society in general.
• Members of ethics committees need to consider whether they can limit choices that people make for themselves or their family?
• They also need to limit access to dangerous research interventions (mental and physical) because sick people may grasp at everything because of the common image to prolong live by all means, reinforced by the media.
• Education is necessary and cooperation between all sectors of society to understand medicine and genetics. Ethics committees can play a role.
• An ethics committee should build consensus between persons, but empirical studies show that there is no predictor of a persons’ views based on a group they can be categorized into. Every group is pluralistic when resolving moral dilemmas.

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**APPENDIX 1: ETHICAL GUIDELINES FOR SOCIAL SCIENCE RESEARCH IN HEALTH**

The Indian National Committee for Ethics in Social Science Research in Health (NCESSRH) welcomes your feedback on this latest edition of the guidelines -- comments may be e-mailed directly to Ms. Tejal Barai , tejalba@rediffmail.com These guidelines were developed with the support of CEHAT (the research center of Anusandhan Trust) and the Ford Foundation.

**Table of Contents and Introduction**

Introduction
Section I --Preamble
Section II --Ethical Principles for Research
Section III --Rights and Responsibilities of Researchers and Institutions
INTRODUCTION

by Amar Jesani Tejal Barai

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".

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.

But 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 feedback. 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. But at the same time the very process of drafting, discussing, adopting and ultimately using guidelines have not only an educational value, but they also contribute the larger process of improvement. The guidelines would also provide a means to individual researchers and institutions to resist pressures to undertake research that might compromise their ethics.

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.

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Section I
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 institutions 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, the quality of research and the rights of participants. In fact, there is a growing concern about indifference to ethics in some the 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/sponsors 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 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 follow purpose:

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

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

(iii) To protect and promote the human rights of participants and to sensitise and encourage researchers
and organisations to respect participants' rights and needs.

(iv) To improve quality, legitimacy and credibility of social science research in health.

(v) 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.

I.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.

I.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 II
Ethical Principles for Research

II.1. Four well-known moral principles constitute the basis for ethics in research. They are:

(i) The Principle of Non-maleficence: Research must not cause harm to the participants in particular and to people in general.
(ii) The Principle of Beneficence: Research should also make a positive contribution towards the welfare of people.
(iii) The Principle of Autonomy: Research must respect and protect the rights and dignity of participants.
(iv) The Principle of Justice: The benefits and risks of research should be fairly distributed among people.

II.2. Ten general ethical principles, presently relevant for social science research in health in India, are as follows:

(i) 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.
(ii) 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.
(iii) 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.
(iv) 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.
(v) 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.
(vi) 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.
(vii) 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.
(viii) 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.
(ix) 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.

(x) 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 III
Rights and Responsibilities of Researchers and Institutions
III.1. Relationship between researchers and institutions

III.1.1. Institutions have a responsibility to respect the autonomy of researchers and the ethical guidelines for research.

III.1.2. Institutions should create and maintain an environment with adequate support systems to enable researchers to follow ethical guidelines.

III.1.3. Institutions have a responsibility to take appropriate and adequate steps for protection against pressures imimical to the observance of ethical guidelines for research.

III.2. Protection and promotion of integrity in research

III.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.

III.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.

III.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.

III.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.

III.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.

III.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.

III.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.

III.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.

III.2.9. Peer review should be an essential part of every research endeavour or initiative, and should be sought at various stages of research.

III.3. Relationship among researchers

III.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.
III.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.

III.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.

III.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.

III.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.

III.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.

III.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.

III.4. Data Sharing

III.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.

III.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.

III.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.

III.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.

III.5. Reporting and publication of research

III.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.

III.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.

III.5.3. **Authorship credit:** The following guidelines should be followed for giving authorship credit while reporting the research in any form:

(i) 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.

(ii) 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.

(iii) 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.

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

III.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.

III.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 IV**

**Rights of Participants**

IV.1. **Relationship with the participants**

IV.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.

IV.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.

IV.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.

IV.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.

IV.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.

IV.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.
IV.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.

IV.2. Informed consent

IV.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.

IV.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.

IV.2.3. 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 should be presented in simple local language.

(ii) **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.

(iii) **Identity of others associated with the research**: Name(s) and address of chief consultant(s), funder(s) or sponsor(s), etc., if any.

(iv) **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.

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

(vi) **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.

(vii) **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 abstracted information and data, and should in no way conflict with or violate the maintenance of privacy, anonymity and confidentiality of information identifying participants.

(viii) **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.

(ix) **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.

IV.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.

IV.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.

IV.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:
(i) 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.
(ii) 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.
(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 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.
(iv) 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.

IV.2.7. **Consent where gatekeepers 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:
(i) 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.
(ii) For obtaining permission of the gatekeeper, no pre-condition demanding sharing of information or data obtained should be accepted.
(iii) 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.
(iv) Greater care should also be exercised in protecting participants and their interest while publishing and disseminating results of research.

IV.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.

**IV.3. Privacy, anonymity and confidentiality**

IV.3.1. Anonymity and confidentiality are the inherent 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.

IV.3.2. Possibility of the breach of confidentiality and anonymity should be anticipated, addressed and explained to the participants.

IV.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.

IV.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.

IV.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.
IV.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 V
Rights and Responsibilities of Peer Reviewers/Referees
V.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.

V.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.

V.3. When called upon to act as peer reviewer and referee, researchers have an ethical duty to undertake it objectively, impartially and constructively.

V.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.

V.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 VI
Rights and Responsibilities of Editors and Publishers
VI.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.

VI.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.

VI.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 VII
Rights and Responsibilities of Funders and Sponsors
VII.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.

VII.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 institutions contains necessary information on ethical issues in and ethical conduct of the particular research proposed.

VII.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.

VII.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 VIII
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.