

Abstract:

Ethics in Demographic Survey Research: Is the Minimal Risk Approach Sufficient in the Indian Context?

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In the Indian context, health research involving human subjects is guided by two guidelines the ICMR guidelines for biomedical research and the NCESSRH guidelines for social science research in health. These guidelines list four major principles of ethical research that are relevant for the protection of human subjects, viz. the principles of autonomy, non-maleficence, beneficence and justice. However, much of demographic research in India consists of surveys that are considered minimal risk research and therefore subjected to expedited review processes. Is the assumption of minimal risk tenable in all circumstances? This paper attempts to explore the potential for harm to human subjects who participate in such surveys in terms of violation of these four major ethical principles. It also proposes some possible remedies in keeping with the ideas based on the Certificates of Confidentiality under the US – Common Federal Regulations and the Census of India Act of 1948.

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Role of Ethics in Demographic Research

Much of health research globally has been gradually brought under the ambit of ethical review processes. Ethical reviews in research are the consequence of violations of rights of the participants in many research settings across the world. A few stark reminders of these violations include the Nazi medical experiments that used prisoners to test human capacity to tolerate loss of oxygen in aviation experiments and Tuskegee Syphilis study, wherein more than four hundred African Americans were followed up over a period of more than forty years to document the natural history of Syphilis, long after Penicillin was invented. Awareness of these horrifying events and concern that such violations not be repeated resulted in the development of the Nuremburg code for human experimentation.

Concern for the protections of human subjects in scientific experimentation and the need for scientific evaluation that respects the human participation resulted in many countries developing their own guidelines for ethical review or using the universal guidelines provided either from the Helsinki Declaration of the World Medical Association or from the Council for International Organisations of Medical Sciences and the World Health Organisation (CIOMS guidelines). In the Indian context, the ethical guidelines governing the conduct of biomedical research is known as the ICMR guidelines that were revised in 2000. Simultaneously, in the same year, a consortium of social scientists in India developed Ethical Guidelines for Social Science Research in Health (NCESSRH, 2000).

Most of the guidelines in ethics are guided by four major principles of ethical research that are relevant for the protection of human subjects, viz. the principles of autonomy, non-maleficence, beneficence and justice. The ICMR guidelines for biomedical research in India go further in this context and list twelve guiding principles for the protection of human subjects. These include the principles of essentiality, principles of voluntariness, informed consent and community agreement, principles of non-exploitation, principles of privacy and confidentiality, principles of precaution and risk minimization, principles of professional competence, principles of accountability and transparency, principles of the maximization of public interest and distributive justice, principles of institutional arrangements, principles of public domain, principles of totality of responsibility, and lastly principles of compliance (ICMR, 2000).

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Regardless of the guidelines being followed, the underlying rationale for following ethical principles in research remains the protection of human subjects of scientific experimentation.

Much of demographic research involves the conduct of surveys that do not seek to directly perform any invasive procedures on the human body not does it hold the promise of any direct therapeutic benefits for the participants. It is for this reason that much of this research passes under the category of minimum risk. Such a categorization facilitates an expedited review that is quick, simple and does not call for a full ethical review that much of medical research is subject to. This is true in settings across most countries, including India.

Objectives

Is this assumption valid? Can almost all demographic surveys pass for minimal risk or are there particularities that should be of concern? What guidance can we obtain from the history of censuses in India and recent controversies in the US Census wherein special tabulations were provided to the US security agencies regarding –Arab Americans(Hubermann, date not known, El Badry and Swanson , 2005). Is there a need for careful data stewardship with respect to large-scale demographic surveys? This paper attempts to explore the potential for harm to human subjects who participate in such surveys in terms of violation of the four main principles of ethical research. It also proposes to suggest some possible remedies in keeping with the ideas based on the Certificates of confidentiality under the US – Common Federal Regulations and the Census of India Act of 1948.

Discussion

As part of an effort towards obtaining fertility and mortality and morbidity estimates in both urban and rural areas, large-scale surveys have been conducted in India. This is in continuation with similar exercises initiated globally through the aegis of the World Fertility Surveys that provided estimates of fertility for most developing countries and provide useful estimates for planning and policy making. One of the more recent examples of such surveys are the National Family Health Surveys and the Reproductive and Child Health Surveys that have become routine exercises within the country with three rounds of the National Family Health Surveys being completed.

While the purpose of these surveys are widely understood to be to facilitate effective planning, the potential for harm through other surveys that could collect information on sexuality related matters, as has become common in recent times can be problematic. This is because of the potential for criminal prosecution under the statutes of the law with respect to specific sexual behavior – particularly related to sexual identities within the country.

The principles approach

Autonomy: All of these surveys have build up mechanisms of addressing the principle of autonomy by seeking informed consent from the participants prior to participation. This does indeed facilitate informed decision making by the participants. In so far as any of the information being reported does not touch upon any behavioural aspects that may serve to criminalise or stigmatise, obtaining the informed consent may be sufficient. However, in the Indian context, barring the census, no other information provided is actually protected from use in criminal or civil procedures against the participant (<http://www.censusindia.net/census2001/history/index.html> accessed on Feb 27, 2007) . The Census of India Act, 1948 alone offers such a guarantee for information provided as it also requires all citizens to exercise due diligence in the provision of such information to the Census authorities. Section 15 articulates this protection and clearly protects any citizen from having the information provided to the Census authorities from being used in any criminal of civil procedures against him or her (<http://www.helplineaw.com/docs/thecensusact1948chapter1> accessed on Feb 27, 2007)

15.Records of census not open to inspection nor admissible in evidence:- No person shall have a right to inspect any book, register or record made by a census-officer in the discharge of his duty as such, or any schedule delivered under section 10, and notwithstanding anything to the contrary in the Indian Evidence Act, 1872, no entry in any such book, register, record or schedule shall be admissible evidence in any civil proceeding whatsoever or in any criminal proceeding other than a prosecution under this Act or any other law for any act or omission which constitutes an offence under this Act.

Such guarantees are not accorded to large-scale surveys and there is no anticipated individual risk in providing information on personal attitudes and practices. These results in the view that this research can be graded as minimal risk – defined as no more risk that that which in encountered during the course of every day life events.

Non-malficience and/or beneficence: Provision of information about one’s identify, beliefs and practices with respect to countable events such as number of pregnancies, births, etc are seen as fairly innocuous. However, how tenable is that belief in light of the fact that same information can be categorized into analytical categories by socio-economic status including religious identity, marital status (if available, as most surveys of fertility in the Indian sub-continent are restricted to marital fertility), demographic status including age, migrant status and so on. Such information with respect to individual identity that is aggregated has not always been apolitical, even though the process of collection of demographic data has been seen as a scientific nationalistic exercise. This is evident in the current discourse on religious group linked growth or fertility rates. Demographic data collection exercises have always been identified with state authority even though the processes may be privatized. As such, these processes can be viewed with some suspicion by marginalized groups within the country, particularly when their historical experiences may justify such intense suspicion. This is because demographers and demographic data collection exercises have remained relatively apolitical processes and curiously naïve with respect to the potential political-economy of the discourse of power surrounding such processes. However, the use of such data has not been as politically naïve. Examples of religious identity linked growth rates in population, exhortions to women to have more children by religious groups abound in the socio-political arena. Such depictions of group behavior and its recognition by the nation

state can affect public policy and its implementation for these sub-groups as is expected. This potential use of innocuous ‘ individual demographic data’ is not anticipated and therefore not reflected in the consent processes. However, it has the potential to cause collective harm by way of reallocation of existing state resources to the detriment of the group.

Surveys are also routinely used to collect information on gender based violence, child labour, sex preferences for family building, sexual identity and expressions of sexuality and so on. The issue of beneficence is also relevant in such surveys that collect information on issues that attract criminal penalties under the state’s laws. For example, sexual behavior has the potential to attract criminal liability under some provisions related to sexual identity (Article 377 of the Indian Penal Code criminalizes ‘unnatural sexual acts’ in general and homosexuality in particular). Therefore information relating to sexual behavior has the potential to directly harm the individual.

It is in this and other similar contexts that the research participant would have to be cautioned about the limits to confidentiality under Indian law – all information collected in surveys can be called for legal scrutiny under the law. Demographers have to be careful about the risk of potential harms to those who provide information – the research subject who deserves to be protected could be at risk of potential harms and there are no legal remedies available to keep the confidentiality, except to not collect such information. Considering most nation states’ ambiguous engagement with sexuality and sexual rights (Correa and Parker, 2004), or even socially contentious issues like child labor or public health problems like gender based violence or sex preferences and the related selective abortions, this is a definite risk.

Justice: It is in this context of the potential use of demographic data that issues relating to justice come to the fore. The principle of justice calls for fairness in the selection of participants for the studies and this can be scrupulously adhered to in terms of the chance of being selected for participation. But this process will not address the issue of how the various groups, particularly marginalized ones are going to be presented in the research findings. State representations of group identity are largely shaped by such information and the groups concerned are left out of the process of creating this form of ‘group identity’. In terms of research ethics, there may not be any violation of fairness in selection of participants for these surveys. However, the potential use of the information some groups without the skills get left behind and often these are groups also without the capabilities to influence their collective representation in the public domain.

Possible protections for research participants

One possible means of protecting potential participants who participate in such surveys is to actually train demographers to recognize the collective harm that could result to individuals. Secondly to prevent direct risks to participants of behavioral and other research that has the risk of criminalizing them, to have a provision of ‘certificates of confidentiality’ as is available under the Office of Human Research Subjects Protections is useful. This allows for research on topics that have the potential to cause direct legal

sanctions or other harms to befall participants to be protected from being produced in a court of law against such participants. This concept is not entirely new in the Indian context as the Census Act of India, 1948 does recognize this form of protection as being necessary for the collection of accurate data for planning.

Conclusions

In the context of possible threats of violation of the rights of individuals and groups with linked identities, there is a need to further protect participants of demographic survey research by explicitly recognizing the direct and indirect harms to which human participants could be subject to. To prevent the harms accruing to potential participants from the creation of group identities there is a need to train demographers about the potential political use of ‘innocuous’ demographic data. This would enable a more cautious approach towards data stewardship amongst them and also facilitate ethical reviews that go beyond the minimal risk approach that is currently in vogue. To prevent individual harms that could result for individuals who practice specific behaviors, particularly those that are criminalized, there is a need to move beyond this and work towards policy provisions that facilitate the collection of accurate data that facilitates development of well informed public policy.

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