An analysis of India's 2017 National Ethical Guidelines for Biomedical and Health Research Involving Human Participants: The Social and Behavioural Sciences aspect

Article *in* Indian Journal of Medical Ethics · August 2018

DOI: 10.20529/IJME.2018.067

CITATIONS
0

READS
44

2 authors:

David Nderitu
Egerton University
13 PUBLICATIONS **1** CITATION
SEE PROFILE

Eunice Kamaara
Moi University
28 PUBLICATIONS **124** CITATIONS
SEE PROFILE

An analysis of India's 2017 National Ethical Guidelines for Biomedical and Health Research Involving Human Participants: The Social and Behavioural Sciences aspect

DAVID NDERITU, EUNICE KAMAARA

Abstract

In this commentary on Section 9 (Social and Behavioural Sciences Research for Health) of the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017) by the Indian Council of Medical Research (ICMR), we appreciate that the guidelines clarify that human beings are "research participants" and not merely "subjects". Further, we appreciate and commend the ICMR for: i) contextualising the guidelines to India's unique sociocultural and economic situation and ii) affirming the multidisciplinary nature of health research and the wide scope of social and behavioural research. However, we question the prominence given to the difference between biomedical research and other aspects of health research and the description of social and psychological risks and discomforts as minor risks. Finally, we suggest that the guidelines would express greater value and diversity of the social aspects of health if they recommended wider representation of these aspects in the composition of research ethics committees.

Introduction

The Indian Council of Medical Research (ICMR or "the Council") has a longstanding engagement with bioethics in general and more specifically with health research ethics. As early as 1980, the ICMR developed and released the Policy Statement on Ethical Considerations Involved in Research on Human Subjects (1). The ICMR has since revised the policy statement: in 2000, it was released as the "Ethical Guidelines for Biomedical Research on Human Subjects" (2), and in 2006, it was released as the "Ethical Guidelines for Biomedical Research on Human Participants" (3). Eleven years later, in 2017, the Council released the "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants" (4).

These revisions underscore the dynamic nature of bioethics in the context of rapid scientific and technological advancements and the accompanying social, cultural, religious, economic, legal, political, and environmental changes.

Authors: **David Nderitu** (david.nderitu@egerton.ac.ke), Lecturer, Department of Philosophy, History and Religion, Egerton University, P.O. Box 536-20115, Egerton, KENYA; **Eunice Kamaara** (ekamaara@gmail.com), Professor, Department of Philosophy, Religion and Theology, Moi University, P.O. Box 3900-30100, Eldoret, KENYA

To cite: Nderitu D, Kamaara E. An analysis of India's 2017 National Ethical Guidelines for Biomedical and Health Research Involving Human Participants: The Social and Behavioural Sciences aspect. *Indian J Med Ethics*. 2018 Jul-Sep;3(3) NS:210-14. DOI: 10.20529/IJME.2018.067

Manuscript Editor: Sunita VS Bandewar

As observed in the preface, changes in human contexts across the world present new concerns, new responsibilities, and new challenges in health research (4: xii). Unsurprisingly, not only have the guidelines been updated, expanded, and reorganised, but new issues have also been added as new sections or subsections. While the 2006 guidelines had eight chapters, the current revised version has twelve sections. This commentary focuses on Section 9 of the 2017 version of the guidelines: Social and Behavioural Sciences Research for Health. The section presents issues that are specific to social and behavioural science research for health including: considerations for appropriate design and conduct of studies; informed consent, ethics considerations by ethics committees for ethics review; and various types of deception.

Use of language as reflective of standpoint

First and foremost, we appreciate that the ICMR has negotiated the title of the ethics guidelines with each revision. Therein, we see systematic development towards integrating social and behavioural sciences research for health in the guidelines. When the first document was developed in 1980, it was merely a policy statement titled "Policy Statement on Ethical Considerations Involved in Research on Human Subjects". In 2000, the Council revised the document to release "Ethical Guidelines for Biomedical Research on Human Subjects". Common to both titles is the use of the term "human subjects" to refer to persons involved in research.

The 2000 document came well after a standing advisory group on consumer involvement in the National Health Service (NHS) research and development programme recommended a "firm commitment to involving consumers in research—not as 'subjects' of research, but as active participants in the process of deciding what research should take place, commissioning research, interpreting the results, and disseminating the findings" (Standing Advisory Group on Consumer Involvement in the NHS Research and Development Programme. Aims and values. Leeds: NHS Executive; 1998).

In November 1998, the *British Medical Journal* (*BMJ*) changed its policy: "We will be changing from 'subjects' to 'participants', except in rare cases where 'participant' would be inappropriate. The new policy will be phased in from now." (5)

The term "human subjects" does not feature in later versions of the ICMR guidelines after 2000. This is commendable, especially because many biomedical researchers continue to use the term even after various literature have pointed at the indignity of referring to people as subjects (5,6). It is important to avoid

the term "human subjects" in favour of "persons involved in research","informants","respondents," or "participants" (5,6).

It may be argued that the difference between the disciplines in the use of terminology may be attributed to the way data is collected from those involved in research: Biomedicine has traditionally been identified as a positivist science whose philosophical underpinning is that truth is one, objective, and empirical—independent of the researcher and the researched (7). Using experiments and clinical trials, which are the most common research designs in biomedical research, a single truth is accessed, for example, that drug A has greater efficacy than drug B. This truth is not something that the researcher or the researched can influence. In other words, regardless of who is doing the clinical trial and regardless of who the drugs are administered to, in general, drug A will always have greater efficacy than drug B. Biomedical research often involves human biological materials as parts rather than whole persons; in many cases, the person may long be dead. The involvement of the researched is therefore interpreted as a passive subject that a researcher manipulates to a desired end. However, this still does not justify the use of the dehumanising term "subject" as even deceased persons have dignity.

On the other hand, social and behavioural sciences adopt an interpretivist approach whereby truth is often multiple and subjective. Essentially the realm of social and behavioural sciences research is that of human perceptions, attitudes, beliefs, and behaviour, as individuals or as groups. For example, a behavioural scientist may be interested in exploring people's perspectives on the colour of a drug. For various reasons, people's perspectives vary, and therefore, what is acceptable to one person or one group may not be acceptable to another. Perspectives will also vary in terms of what makes the colour of the drug acceptable, even from one individual to another within the same group. The different perspectives are all true. This kind of information may not be accessed easily in any way without active involvement of the researched. The term "human subjects" is therefore rarely used in social and behavioural sciences.

An analysis of the historical development of the title of the ICMR guidelines points to the general perception globally that the dichotomy between biomedical sciences on one hand, and social and behavioural sciences on the other, has been on the decline. In 2006, the ICMR revised and released the Ethical Guidelines for Biomedical Research on Human Participants. We interpret this title as acknowledging persons involved in research as participants, albeit half-heartedly: the researched are now referred to as participants, but research is done *on* them, not necessarily *with* their active participation. In 2017, the Council released the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. From this title, we observe a further shift by the ICMR to almost bridge the gap between biomedical and social and behavioural sciences research. The title acknowledges that human participants are not subjects to be read and manipulated with drugs. They are active participants in the process of generating new knowledge.

Yet we observe a conceptual hiatus in efforts to bridge the gap between biomedical and behavioural sciences in the ICMR guidelines. Note the assumed distinction between biomedical and health research in the title of the 2017 guidelines. Was it necessary to highlight biomedical research? Is biomedical research not health research? Wouldn't the distinction made by presenting public health research and social and behavioural sciences research in different sections be enough? Would the ICMR have missed out anything if they called the document the "National Ethical Guidelines for Health Research Involving Human Participants"? Of course, the fact that this document was authored by the ICMR may account for the highlighting of biomedical research.

Nevertheless, it is possible that by giving this title to the 2017 version, the ICMR may have been keen to highlight that the new guidelines are not only expansive in scope but also that ICMR recognises the shortcomings of the preceding ones. This is desirable departure from the usual situation where health research guidelines tend to limit researchers, reviewers, and ethics committees to a small scope of a wider field of health research. Perhaps the ICMR might soon consider coming full circle to partially borrow from the 1980 title and release the "National Ethical Guidelines for Health Research Involving Human Participants".

Suitability to the research context

International guidelines have been criticised for being incognisant of and insensitive towards cultural diversities and for ignoring the interests of the Global South. For example, UNESCO's Universal Declaration on Bioethics and Human Rights (8) is considered incognisant of cultural diversities, including religious, spiritual, moral, and philosophical world traditions, to the detriment of "developing" countries (9). The Good Clinical Practice, Belmont Report, and Common Rule documents have also had more or less similar criticism (10).

Notably, the 2017 National Ethical Guidelines for Biomedical and Health Research Involving Human Participants is effectively contextualised to the Indian situation, affirming the importance of cultural contexts in research ethics. As the guidelines acknowledge (in the Preface on page xii), India is dotted with unique sociocultural, economic, legal, and religious realities, made complex by the diversity and conservativeness characterising its culture. The caste system, for example, is globally peculiar to India. Other aspects characterising India are the historical realities of colonialism and Western imperialism, which continue to impact the current context just as in other former European colonies. Additionally, India has some of the poorest resource contexts in the world, and the country is classified among the so-called low and middle-income countries (LMICs). These contexts and challenges have an impact on the health research situation in India. It is therefore gratifying to observe that they attract significant consideration in the formulation of the guidelines by the ICMR (4: pp 22, 24, 30, 49, 95, 104, 106-109, 130).

The Council draws the value of social and behavioural sciences research for health, bearing in mind how culture, attitude, and mindset influence participants' response in research (and also healthcare), particularly in the Indian context, which is characterised by sociocultural and economic diversity. Emphasis is laid on respect for culture in terms of understanding the cultural context under which research is conducted and adjusting to the situation of a certain indigenous context, for example, by interpreting research into a local language (4: Sec 9.2). One specific issue that we would have liked to see elaborated on here is the need to respect group perspectives on their own attitudes, beliefs, and practices and to address them sensitively. Taking cognisance of the diversity of the Indian context, the guidelines avoid issuing general and arbitrary guidance on such issues and instead insist on a case-by-case evaluation (4: Sec 9.2.2).

Nevertheless, we note that the guidelines exhibit some ignorance of what social and behavioural sciences constitute. It is assumed that social and behavioural sciences are one discipline or even one specialisation. In outlining the composition of an ethics committee in Table 4.1, the guidelines call for "an individual with social/ behavioural science/ philosophy/ religious qualification and training and/ or expertise and be sensitive to local cultural and moral values (4: p. 28). The person can be from an NGO involved in health-related activities." It would be extremely rare for one individual to have even half of these qualifications. Strangely, this is the only category of membership that is accorded a single position with no possibility of having a second member.

Instead, social and behavioural sciences are cross-cutting disciplines; often, social and cultural issues interact with all aspects of research to create ethical issues, challenges, and dilemmas. Take the case of Sarah Baartman, in which three core elements are at play: imperialism, biomedicine, and popular culture (11).

Contextual considerations for informed consent

One of the universal principles of research ethics is respect for persons. This principle is assumed to be upheld through the informed consent process. Informed consent presupposes knowledge, comprehension, and voluntariness. However, certain factors in specific contexts impair or enhance knowledge, comprehension, and voluntariness. It is therefore necessary to address these factors in their specific contexts. No wonder one of the most discussed issues in research ethics in the last decade is the need to have proper and valid informed consent that fits various contexts, particularly in LMICs. While this has remained largely theoretical, India has enacted in the ICMR guidelines. The section on informed consent in social and behavioural sciences research on health (4: Sec 9.2.6) is outstanding in its emphasis on considering various approaches to consent: community consent, gatekeeper consent, and individual consent.

Dominant international guidelines insist on individual consent because they are by and large inspired by the Western individualistic world view. There has often been an impasse when this concept is applied in certain contexts, particularly in LMICs where communalism tends to be the dominant world view (12). Other important aspects of consent in contexts of close social and kinship ties (as in India) are often not accounted for in international research ethics guidelines. These include issues such as that of relational autonomy, which has been addressed in the new Indian guidelines. The 2017 National Ethical Guidelines for Biomedical and Health Research Involving Human Participants has an expanded view of informed consent to accommodate what the ICMR refers to as relational autonomy. Relational autonomy has to do with the ontology of personhood and the subsequent principle of autonomy in such contexts where the meaning of personhood is intrinsically attached to society. A valid consent requirement must thus be fashioned with the moral imperative of social justice in mind, as the guidelines suggest (4: Box 9.4).

Further on contextualisation of consent, the dominant international guidelines tend to emphasise a written and signed informed consent process. This requirement is largely influenced by Western literal culture. But many countries, India included, come from the backdrop of an oral culture. This culture, combined with the European colonial experience where families lost autonomy and property after appending their signatures to a piece of paper, often makes it difficult to access written signed consent. The ICMR guidelines have explicit provision for other means of consenting "when written consent may not be possible" (4: Sec 9.2.12), especially for qualitative research.

Box 9.4 appropriately presents ethical issues specific to informed consent in social and behavioural research, all of which are geared to ensuring culturally sensitive and relevant informed consent. Social and behavioural sciences often involve the study of human behaviour in natural settings. However, humans can change their behaviour when they know they are being observed. In such situations, different forms of deception may be allowed on a case-by-case basis to allow for collection of valid data. Box 9.5 presents three forms of deception: active deception, incomplete disclosure and authorised deception. In so doing, the guidelines bring out some issues that may arise in social and behavioural sciences but may not arise in biomedical research.

Understanding of "harm"

In Table 2.1 categories of risk are given as i) less than minimal risk; ii) minimal risk; iii) minor increase over minimal risk or low risk; and iv) more than minimal risk or high risk (4: p.6). The description of "minor increase over minimal risk or low risk" presents social risks, psychological harm, and discomfort as falling within this category. We take issue with this placing as social risks, psychological harm, and discomfort may fall into any of the four categories given in the table. For example, if research makes a person lose self-esteem to the point of death from reckless living as in the case of Saartje (Sarah) Baartman (11,13), would this be classified as minimal risk? Sarah Baartman was a poor, black woman with large buttocks and

elongated labia. Because of these features, she was exhibited as a freak show attraction in Europe. When she died, her body was dissected and used in research to illustrate racist and sexist ideas of African diminished intelligence and enhanced sexuality. Would anthropological studies that supported medical studies that suggest black persons are less intelligent than white persons and justify colonialism be minimal risk? The ICMR falls into the very pitfall that it warns against: "Risks are non-measurable and dynamic in nature and therefore might be misconstrued as no/minimum risk research." (4: Box 9.1)

Multidisciplinary aspects

In devoting a special section to social and behavioural research for health, the guidelines appropriately recognise that these sciences address different realities compared to other types of research and that different ethical issues may therefore arise (4: Sec 9.2.2). Section 9 recognises that social scientists are not always positivists and therefore may not always have a hypothesis at the beginning of the research. Inclusion of a hypothesis in research infers that the study is fixed, and this is not always the case with social and behavioural research. Unlike in biomedical research, where standardised research tools are developed well before the study, in social and behavioural sciences research, tools and even research questions may be developed during the course of the research. And the tools may be reflective, changing as the research progresses. In this case, the guidelines direct that the ethics committee be kept informed about these changes and appropriate consent be taken from participants (4: Sec 9.2.6). The guidelines specifically acknowledge that these research initiatives are not only relevant in the mid to long term for knowledge production, science, and society (4: Sec 9.0) but may also have immediate relevance. Others may be a precursor to major interventional biomedical research.

Indeed, some ethical issues are unique to social and behavioural sciences. The ICMR presents some of these in Box 9.1. It presents also consideration of appropriate design for social and behavioural studies in Box 9.2. But to complement this, Box 9.3, which lists considerations for ethics committees during ethical review (4), should also require ethics review to consider the safety of the study team. Like public health researchers, social and behavioural health researchers often have to visit participants in their communities or homes where they can turn hostile towards the researchers, for example, in studies on home-based counselling and testing. Such aspects are not exhaustively brought up in the guidelines. For example, social science research ought to be gendered because human beliefs, attitudes, practices, norms, and so on are gendered. Gender-insensitive research is unethical because it can intentionally or unintentionally lead to or promote gender-based discrimination, exploitation, and violence.

Expansive elaboration on vulnerable populations and the concept of risk

More often than not, LMICs borrow concepts from international guidelines without tailoring them to their particular context. For example, some aspects of the Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya are borrowed from international guidelines and policies without much contextualisation (14). Some countries in the African continent, such as Ghana, do not have national regulations and rely on international guidelines[1]. In such cases, the guidelines may fail to address contextual issues because their prototypes may not have been conceptualised with the respective situations in mind. This is not the case with the ICMR guidelines. The concepts of risk and informed consent have been incorporated in a manner relevant to the Indian context; the understanding of risk has been effectively tailored to address the wide range of potential harms specific to the sociocultural realities in India. Recognising this possibility the Guidelines caution "it is important to protect study participants from potential future risks and harm by establishing culturally sensitive and context specific safeguards" (4: Sec 9.2.7). While the concept of risk is generally understood to refer to probability and magnitude of harm—with emphasis on physical and psychological harm (14,15)—the ICMR guidelines have expanded the perception of risk. Risk has been explained in the guidelines to include harm to dignity, psychological and emotional harm, social harm, and informational risk.

We like that vulnerable populations have been expanded to include socially and economically disadvantaged persons, especially those below the poverty line, sexual minorities, and women participants. Recognising resource poverty as a situation that creates vulnerability, especially in the context of international research, is a critical ethical issue. As Mariner observes, "risk of exploitation looms large when researchers from a wealthy, predominantly white country seek to conduct research in a poorer, predominantly non-white country, as will be the case for HIV vaccine trials" (16). Also, sexual minorities in India, as in African countries, are stigmatised and vulnerable compared to general populations.

The scope of research ethics

Impressively, the ICMR guidelines acknowledge capacity building as a research ethics issue (4: Sec 10.15.3). Often, LMICs have little or no capacity in terms of structures and human resources for research ethics review. Yet, with globalisation and the consequent internationalisation of higher education, and in view of the need to bridge the 10/90 gap,[2] research funded and executed by researchers from the Global North is increasingly being done with LMICs as the research field (17). The very provision for international collaborations in Sustainable Development Goal 17[3] points at increasing demand for research ethics around this practice. But the expansion of international research presents an obligation for research capacity building in the global South.

In these guidelines, privacy is defined as "the right of an individual to control or influence the information that can be collected and stored and by whom and to whom that information may be disclosed or shared" (4: Sec 2.3). But this is not accurate. This definition relates more to confidentiality

than to privacy. While privacy and confidentiality are closely related, they are distinct. Privacy applies to a person—in this case, the participant—rather than to data. It relates to whether other people can tell who is participating in a study depending on the place where data collection takes place and the method of data collection employed. For example, interviewing participants on a sensitive subject in a public place where other people can tell who is being interviewed on what denies the participant their right to privacy and, by their very nature, focus group discussions cannot be private, but one-on-one interviews can and ought to be. On the other hand, confidentiality refers to the researcher's obligation to ensure safety of data by protecting them from "unauthorized access, use, disclosure, modification, loss, or theft" (18).

Conclusions

By and large, we wish to commend the ICMR for effectively adapting international research ethics guidelines to publish the 2017 National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. The guidelines represent systematic development towards integrating social and behavioural sciences with health research as well as the systematic contextualisation of international guidelines to India's unique sociocultural and economic situation. There is conceptualisation of risk and provision for both oral and written consent in keeping with the sociocultural realities of the caste system and of illiterate populations. Simultaneously, in line with global trends, the guidelines affirm the multidisciplinary nature of health research, which includes biomedical, public health, and social and behavioral health research. Without necessarily pointing to weaknesses in the international guidelines, the National Ethical Guidelines for Health Research Involving Human Participants is a resourceful document and is of great relevance for many contexts in and outside India.

Conflicts of Interest: *The authors declare no conflicts of interest.*

Notes

[1] See the Harvard Global Ethics Research Map at https://webapps.sph.harvard.edu/live.gremap/view.cfm and an interactive map of health research ethics review capacity and drug regulatory capacity in Africa (developed by the MARC project) at http://www.researchethicsweb.org/hrweb/

[2] This refers to the fact that only 10% of total world's health research budget is spent on diseases that affect 90% of the global population.

[3] The Sustainable Development Goals are a set of 17 global goals laid out by the United Nations in 2015. Sustainable Development Goal number 17 is directed towards international cooperation and collaboration for development, emphasising on the development needs of developing countries and the support needed from more developed countries and the international community.

References

1. Indian Council of Medical Research. *Policy statement on ethical considerations involved in research on human subjects.* New Delhi: ICMR; 1980. [Not archived online.]
2. Indian Council of Medical Research. *Ethical guidelines for biomedical research on human subjects.* New Delhi: ICMR; 2000. Available from: http://www.kem.edu/wp-content/uploads/2013/08/ICMR_ethical-guidelines-2000-1.pdf
3. Indian Council of Medical Research. *Ethical guidelines for biomedical research on human participants.* New Delhi: ICMR; 2006. Available from: https://icmr.nic.in/ethical_guidelines.pdf
4. Indian Council of Medical Research. *National ethical guidelines for biomedical and health research involving human participants.* New Delhi: ICMR; 2017. Available from: https://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
5. Boynton PM. People should participate in, not be subjects of, research. *BMJ*. 1998 Nov 28;317(7171):1521.
6. Chalmers I. People are "participants" in research. *BMJ*. 1999 April 24;318(7191):1141.
7. Walsh B, Gillett G. Is evidence-based medicine positivist? *Int J Person Centered Medicine*. June 2011;1(2):232-9.
8. UNESCO. (2006). Universal declaration on bioethics and human rights. Paris. June 2006 at http://unesdoc.unesco.org/images/0014/001461/146180E.pdf.
9. Chattopadhyay S, De Vries, R. Bioethical concerns are global, bioethics is Western. *Eubios J Asian Int Bioeth*. 2008 Jul 1;18(4):106-9.
10. Bandewar SV. CIOMS 2016. *Indian J Med Ethics*. 2017 Jul-Sep;2; 2(3):138-40.
11. Chauveau M. The Hottentot Venus: The objectification and commodification of a Khoisan woman at the crossroads of imperialism, popular culture and science [thesis]. Tilburg: Tilburg University; 2012.
12. Andoh CT. Bioethics and the challenges to its growth in Africa. *Open J Philos*. 2011;1(2):67-75.
13. Qureshi S. Displaying Sara Baartman, The 'Hottentot Venus'. *Hist Sci*. 2004 June; 42(2):233-58.
14. National Council for Science and Technology. Guidelines for ethical conduct of biomedical research involving human subjects in Kenya. NCST No. 45; Nairobi: NCST; 2004. Available from: https://www.healthresearchweb.org/files/Kenya_Guidelines_Ethical_conduct_of_research_involving__human_subjects.pdfhttp://ethics.iit.edu/ecodes/sites/default/files/GUIDELINES%20FOR%20ETHICAL%20CONDUCT%20OF%20RESEARCH%20INVOLVING%20HUMAN%20SUBJECTS%20IN%20KENYA.pdf
15. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979). *The Belmont Report: ethical principles and guidelines for the protection of human subjects of research*. DHEW Publication No. (OS) 78-0013; Washington, DC: U.S. Government Printing Office; 1978. Available from: https://videocast.nih.gov/pdf/ohrp_belmont_report.pdf
16. Mariner WK. Taking informed consent seriously in global HIV vaccine Research. *J Acquir Immune Defic Syndr.* 2003 Feb 1;32(2),117-23.
17. Kamaara EK. Challenges of obtaining informed consent n international HIV research in Western Kenya [thesis]. Eldoret: Moi University; 2014.
18. UCI Researchers [Internet]. Privacy vs. confidentiality: what is the difference? Available from: https://research.uci.edu/compliance/human-research-protections/docs/privacy-confidentiality-hrp.pdf