

Ethical review process in Bangladesh: Experiences of internationally funded demographic and health surveys

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Abstract: The function of ethical review committee (ERC) or institutional review board (IRB) has become more complex, particularly to the internationally funded demographic and health surveys (DHS) conducted in developing countries, including Bangladesh. This study aims to explore the governance structure and process of ethics approval of DHS in Bangladesh, emphasizing at the local and international levels. We have reviewed literature and conducted key informant interviews (KIIs). ERC plays a central role both locally and internationally funded DHS, but these surveys are taking place largely without adequate participation of ERC. Internationally funded surveys take the IRB approval from their institutions rather than the local host in Bangladesh. Exercise of influence of external power, inadequate allocation of government funding, irregular ERC meetings, non-availability of more skilled or efficient reviewers to review protocol on time, absence of signed informed consent and lack of initiative to deal with the sensitive questionnaire used in the survey at field level- all these make ethical governance a vulnerable and critical one. As the strength of ERC is insufficient and it has to take effective measures by playing an essential role in protecting the rights of human subjects involved in the DHS.

Keywords: Ethical Review Committee, Demographic and Health Surveys, Bangladesh.

Introduction

International researches and ethics review boards in developing countries have been the subject of attention under neocolonialism. The international research supported by many funding agencies of the developed world remains semi-colonial (Costello and Zumla, 2000). The North-South research partnership is currently overwhelmed by differing interpretations of ethical standards of doing research in developing countries and by inequitable funding where the burden and benefits of doing research should be shared equally by the partners (Edejer, 1999). The research capacity in the developing world remains one of the world's unmet challenges, where domestic budgetary allocation for health and population is poor (Lansang and Dennis, 2004; Nchinda, 2002; Ramsay, 2002). Now-a-days such researches conducted in developing countries are increased and raising numerous ethical and logistical questions (Klitzman, 2012). Some of the debate surrounding the ethical regulation of international research indicates that while the issue of study design, ethical review, and standards of care have been highlighted, the underlying socioeconomic deprivation and inequities are largely ignored (Bhutta, 2002). Individuals or communities in developing countries assume the risks of research, but most of the benefits may accrue to people in developed countries (Benatar, 2000). In order to support health and population research in developing countries that are both relevant and meaningful, the focus must be on developing research that promotes equity and on developing local capacity in bioethics (Khan and Lasker, 2014).

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Although poverty, limited health-care services, illiteracy, cultural differences, and limited understanding of the nature of scientific research neither cause nor are necessary for exploitation, they increase the possibility of such exploitation (Glantz, Annas, Grodin, and Mariner, 1998). Moreover, growing commercialization of research and its effects on the ethical conduct of researchers and the advancement of scientific knowledge is of concern today and need serious critical thought. There is a need for capacity building, which should include greater access to educational opportunities in research ethics for members of institutional review boards (IRBs) and ethical review committees (ERCs) in both resource-poor and resource-rich countries (Marshall, 2007). Ethical review of research protocols in resource-poor settings should be improved. Otherwise, ethical risks may come from international researchers, undermining or not thinking of taking approval from the local ERC or IRB, the multiplicity of ethics review boards, or from scientific colonialism in the developing world (Trostle, 1992; Lansang and Olveda, 1994; Edejer, 1999). Also, locally institutional risks may cause due to lack of a coherent set of criteria, poor governance of ethics review board, absence of independent, competent and transparent ethical review board (Parker and Bull, 2009; Nuffield Council on Bioethics, 2005; Igoumenidis and Zyga, 2011; Bartlett, 2008; Hyder, Wali, Khan, Teoh, Kass and Dawson, 2004). Ethical void of such research projects may create the wrong kind of ethical scrutiny in the research process.

Thus, questions may arise: *What is the governance structure or process of ethics approval locally? Is there any presence of marginalization across the board of national ERB/IRBs in the process of globalization? What are the problems emphasizing at the local and global levels? How does incentivize the ethical review process where both national and international research does not follow the local ERC/ ERB rules, adequately?* To answer these questions, we have taken Bangladesh as a case of a developing country where the demand for health and demographic survey research is continuously increasing. Thus, international collaboration is proliferating because of the high prevalence of infectious diseases, nutrition deficiencies, and family planning and reproductive health problems (Rashid, 2006). This study takes into consideration that researchers or international bodies have to care of taking ethical review committee (ERC) approval following national ethical review committee (NERC) guideline where NERC is responsible for providing protection of dignity, rights, and well-being of potential research participants; ensuring that universal ethical values and international scientific standards.

Data and methods

We used both primary and secondary data for the study. As a part of the secondary source of data, reviews of literature through searching electronic databases and websites have been done. Internationally funded multiple survey reports like the *Bangladesh Demographic and Health Survey (BDHS)*, *Bangladesh Urban Health Survey (BUHS)*, *Bangladesh Maternal Mortality and Health Care Survey (BMMS)*, were carefully reviewed with particular focus to methodology and ERC regulations based on National Research Ethics Committee (NIPORT, MEASURE Evaluation, and icddr,b, 2012; NIPORT, Mitra and Associates, and ICF International, 2016; NIPORT, icddr,b, and MEASURE Evaluation, 2015).

For primary data, we conducted 07 (seven) key informant interviews (KIIs) from September 2016 to November 2016. KIIs were conducted among the persons involved or related to the National Research Ethics Committee (NERC), representatives of Bangladesh

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Medical Research Council (BMRC), National Institute of Population Research and Training (NIPORT), United States Agency for International Development (USAID), Bangladesh (which is the financial and technical sponsor of these surveys) and Population Council (Bangladesh Office). Here it can be stated that BDHS, a nationally representative survey funded by USAID, which is carrying out in Bangladesh since 1993. The BMMS surveys were conducted in 2001 and 2010, which is a collaborative effort of the National Institute of Population Research and Training (NIPORT), MEASURE Evaluation, the University of North Carolina at Chapel Hill, USA and the International Centre for Diarrhoeal Diseases, Bangladesh (icddr,b). The Government of the People's Republic of Bangladesh, the US Agency for International Development (USAID), Bangladesh, the Australian Agency for International Development (AusAID) (currently known as Australian Aid), and the United Nations Population Fund (UNFPA), Bangladesh funded the BMMS. The *BUHS 2006 and 2013*, which is funded by the USAID and the Department for International Development (DFID).

Findings and discussion

The governance structure of ethics approval and problems in Bangladesh

In Bangladesh, most of the universities do not have IRB/ ERC. These institutions follow their own respective departmental or academic committee approval and, in few cases, take approval from the National Ethical Committee (NEC) of the Bangladesh Medical Research Council (BMRC), which serves as National Ethical Committee (NEC) of the Country since 1979. The International Centre for Diarrhoeal Diseases, Bangladesh (icddr,b) has its own Ethics Review Committee, which considers research studies submitted by the scientists of the Centre. The National Health Research Strategy (NHRC) introduced in 2009 mandates that ethical standards must be maintained in conducting all research involving human subjects following the ethical guidelines (CCGHR, 2020). In this regard, the Ethical Review Committee (ERC) of BMRC is responsible for the review of the proposed research proposal before the initiation of the project. They also have the responsibility of regular monitoring of the approved research project to foresee the compliance of the ethics during the period of the project. The ERC provides ethical clearance to research studies not funded by the BMRC involving human subjects to be conducted in Bangladesh by Bangladeshi or foreign researchers (BMRC, 2008). In principle, foreign researches have to take ethical approval from the BMRC following the same guidelines as local. There is no difference between national and international research in terms of taking ethical approval.

The current National Research Ethics Committee, NERC (2016-2019), consists of 17 members (13 medical doctors, one lawyer, one Member of the Parliament, two humanities background professionals (BMRC, 2016). The composition of the previous ethics committee (2013-2016) also indicates the presence of 11 medical doctors and four non-medical doctors (BMRC, 2015). The Committee is formed by the Executive Committee of the BMRC and has tenure of 3 years. The Committee is registered in the Office for Human Research Protections in the USA as an Official Institutional Review Board. Reviewing the documents and considering the responses from KIIs, it has been revealed that behavioral and social scientists are missing as members in the NERC of the BMRC. However, the NERC evaluates research proposals, and it meets an ad-hoc basis as and when necessary. It does not follow any annual calendar. The NERC sends the protocol to the reviewers after receiving the protocol from the researchers or research institutes. Once the review is being completed, the Committee holds a meeting for taking decision based on the reviewer's opinion.

The capability and performances of the ERC of BMRC are not out of criticisms, as reported in the KIIs. As there is no annual calendar plan for holding an ethics committee meeting, it takes a longer time to get the approval of the protocol to conduct proposed studies. The NERC of BMRC is also facing several other challenges while reviewing the research protocol. This study finds that the office of BMRC is responsible for ethical governance, but it lacks enough workforces, which is an institutional lacking of BMRC. Bureaucratic complexities exist while the budgetary allocation received per year from the Government is insignificant (e.g., only 30 million BDT (\$3,78,768) is allocated per year for BMRC, including salaries of employees and all activities). The study finds that sometimes protocols are not submitted to the BMRC, as BMRC takes longer time to provide their decision. Also, the reviewers make delay in giving their comments on time even after reminders, which means problems of their responsibilities.

Getting approval of the foreign funded research from the BMRC is also problematic, as reported in the KIIs. The NERC of BMRC has been constituted with a dominance of medical doctors but lacks relevant experts as members of the committee, e.g., demographer and statisticians, especially for the surveys-BDHS, BMMS, and BHUS. One of the KIIs reported:

“Sometimes, we faced problems, and these were technical. It took 7-8 months to get clearance for the BDHS 2014 survey as BDHS use questionnaire on the reproductive health of women aged 15-49. The ERC of BMRC raised questions on taking an interview of below 18 years of women as the legal age of an adult in Bangladesh is 18 years. Later it took 3-4 months to convince the ERC of BMRC in this regard to approving the protocol.”

In terms of the challenges of the NERC of BMRC, another KII respondent raised the question of its appropriate strength:

“It is irregular, does not follow systematic procedure, takes a long time, and there is no standard timeline. The ERC approval is done through the process of review, but there is a doubt over the competency of the reviewers. Besides, there is a shortage of human resources. Protocols are being reviewed based on medical perspective”.

Presence of marginalization across the board of national ERC

Both national and international researchers are not serious about taking approval from the NERC, as reported in the KIIs. Pressure groups sometimes influence the BMRC to complete the process within 15 days. Lack of knowledge on ethics the policy makers do not try to understand that even some protocols received ERC/IRB approval internationally; these are also required to get approval from NREC and undermines, which reflects marginalization. Moreover, they are not aware of the importance of ethical clearance from the local body. Evidence from a KII shows that a donor funded routine survey once submitted the protocol when the survey was also simultaneously going on at the field level. The NERC of BMRC had no role in stopping that survey due to the pressure from the top policy levels.

While reviewing all the published reports of those surveys (referred to in the method section of this study), this study finds that none of these survey reports mentioned anything about the approval of the study protocols by NERC though they used informed consent form for the respondents with the data collection instruments. Nevertheless, reviewing the list of

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ethical clearance since 1993-2014 in the directory published by NERC, we found that *Bangladesh Demographic and Health Survey* (BDHS) did not take any approval from the BMRC before 2011, but BDHS 2011 and 2014 took the approval. Another foreign funded survey-*Bangladesh Maternal Mortality and Health Care Survey* (BMMS) conducted in 2001 and 2010 also did not take approval from the BMRC. Although ERC approvals are not reflected in the survey reports of *Bangladesh Urban Health Survey (BUHS) 2006 and 2013*, our review of the list of ethical clearance shows that BUHS received approval from the NERC.

Regarding signed informed consent, we found that the *BMRC* guideline refers that the informed consent form should be included signature or thumbprint of the participants are required as there are potential risks to subject, or the privacy of the individual may be involved. However, our review of survey reports indicates the absence of a signed/ thumb print of the participants' rather verbal consents in all the surveys (BDHS, BUHS, BMMS). That means, ERC approvals are taken based on the guidelines of BMRC but in practice are not followed. In this regard, the representatives of the authority responsible for conducting BDHS reported:

“In reality, the implementation of the informed consent form is a challenge, but we try to follow.”

In response to not using inform consent, another KII reported:

“Those surveys take verbal consent, and it is not ethically sound.”

The implication of not taking ethical clearance and maintaining the ethics standard

Globally or internationally funded surveys like Demographic and Health Survey (DHS) follow the standardized questionnaire internationally; there are presences of sensitive questions for the respondents in these surveys, like sexual behavior related questions. These culturally sensitive questions may be necessary for the research, but KII with BMRC representative reported that there is a little chance to monitor whether the questions are being addressed with maintaining adequate privacy. Under such circumstances, the actual response rate of such questions is also questionable to the credibility of the research outcome. Thus, the role of a reviewer is vital to review such a questionnaire. However, internationally funded research takes the IRB approval from their institution rather than the local host where international researches do not think local IRB requires. Globally researchers are going significant cultural divide, and there is a scope to exercise of power, including the determination of topic and the area of research globally rather than locally.

Less policy relevance due to the untimely release of data

This study finds that the NERC or BMRC has no role regarding the availability of data of the foreign funded research. However, the regular interval of survey results and data should be publicly accessible following their institutional rules. Research findings into policy and practice, it is better to release the survey data from the respective institutions as early as possible to generate policy suggestions. *Bangladesh Urban Health Survey (BUHS) 2006* released its data from its implementing partner- MEASURE Evaluation, the University of North Carolina at Chapel Hill (USA) after seven years in 2013, where the question may raise from an ethical point of view to use of such data for policy implication that is for the betterment of the research subjects. However, for BDHS and BMMS, this study finds that data are updated, available at regular intervals, and data are keeping confidential and de-identifiable for public access.

Strengthening the ethical review process

In the absence of IRB/ERB in most of the universities in Bangladesh, NERC under BMRC is the focal point for health and demographic research related ethics in the country where all research projects should go through the NERC and follow the guideline. Thus, to strengthen the ethical review process, both international and national researchers have to be committed about getting local ERB approval but not to exercise an influence of external power. They should consider submitting the protocol through allocating sufficient time. Adequate allocation of government funding to BMRC, frequent or regular ERC meetings, ensuring the availability of more skilled/efficient reviewers to review protocol on time, no absence of signed informed consent and initiative to deal with the sensitive questions at field level- all these will make the ethical governance here reliable and objective one.

Conclusions

Although literally the National Ethical Review Committee (NERC) plays a central role, both locally and internationally funded health and demographic surveys are taking place, mainly without adequate participation of the NERC in Bangladesh. The implications of such practices are varied like violation of standard guidelines of NERC to conduct scientific researches- absent informed consent, violation of privacy, absence of protection of rights of human subjects involved in research projects. Although the strength of NERC of BMRC is insufficient, in Bangladesh, NERC of BMRC has to take adequate measures by playing an essential role in protecting the rights of human subjects involved and should be developed by strengthening models for reviewing the ethics of research. Given the volume of national and international guidance and regulation currently available, it is essential to maintain the rigorous and transparent procedures to inform the movement from theory to practice when determining best practice in conducting the surveys-where foreign institutions or their funds are involved in the health and demographic research in Bangladesh or elsewhere.

References

- Bangladesh Medical Research Council (BMRC), 2008, Ethical issues in health research. Retrieved from <http://www.bmrcbd.org/research.html>. Accessed: 1 December, 2016.
- Bangladesh Medical Research Council (BMRC), 2016, Proceeding of the 95th General Meeting of BMRC. Dhaka: BMRC.
- Bangladesh Medical Research Council (BMRC), 2015, *Directory 2014: National research ethics committee (NREC)*. Dhaka: BMRC.
- Bartlett, E. E., 2008, International analysis of institutional review boards registered with the U.S. Office for Human Research Protections. *Journal of Empirical Research on Human Research Ethics*, 3:49–56. doi: 10.1525/jer.2008.3.4.49.
- Benatar, S. R., 2000, Avoiding exploitation in clinical research. *Cambridge Quarterly of Healthcare Ethics*, 9:562–565. doi: <https://doi.org/10.1017/S096318010000414X>.
- Bhutta, Z. A., 2002, Ethics in international health research: A perspective from the developing world. *Bulletin of the World Health Organization*, 80(2): 114-120.
- Canadian Coalition for Global Health Research (CCGHR), 2020, Bangladesh Research Ethics. Retrieved from <https://www.ccghr.ca/resources/harmonization/bangladesh/bangladesh-research-ethics/> on March 30, 2020.
- Costello, A. and Zumla, A., 2000, Moving to research partnerships in developing countries. *BMJ*, 321: 827. doi: <https://doi.org/10.1136/bmj.321.7264.827>.

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- Glantz, L. H., Annas, G. J., Grodin, M. A., and Mariner, W.K., 1998, Research in developing countries: Taking “benefit” seriously. *The Hastings Centre Report*, 28 (6):38–42. <https://doi.org/10.2307/3528268>.
- Edejer T. T., 1999, North-South research partnerships: The ethics of carrying out research in developing countries. *BMJ (Clinical research ed.)*, 319(7207), 438–441. <https://doi.org/10.1136/bmj.319.7207.438>.
- Hyder, A. A., Khan, A. N., Teoh, N. B., Kass, N. E., and Dawson, L., 2004, Ethical review of health research: A perspective from developing country researchers. *Journal of Medical Ethics*, 30 (1): 68-72. doi: 10.1136/jme.2002.001933.
- Igoumenidis, M. and Sophia, Z., 2011, Healthcare research in developing countries: Ethical issues. *Health Science Journal*, 5(4): 243-250.
- Khan, M.H.A. and Lasker, S. P., 2014, A review of ethics in developing country in perspective of dental research. *Bangladesh Journal of Bioethics*, 5(1):11-19.
- Klitzman, R. L., 2012, US IRBs confronting research in the developing world. *Developing World Bioethics*, 12: 63–73. doi: 10.1111/J.1471-8847.2012.00324.X.
- Lansang, M. A. and Dennis, R., 2004, Building capacity in health research in the developing world. *Bulletin of the World Health Organization*, 82 (10): 764-770.
- Lansang, M. A. and Olveda, R., 1994, Institutional linkages: Strategic bridges for research capacity strengthening. *Acta Tropica*, 57 (2-3):139-45. doi: 10.1016/0001-706x(94)90004-3.
- Marshall, P. A., 2007, *Ethical challenges in study design and informed consent for health research in resource-poor settings*. Geneva: WHO.
- National Institute of Population Research and Training (NIPORT), MEASURE Evaluation, and icddr,b., 2012, *Bangladesh Maternal and Health Survey (BMMS) 2010*. Dhaka, Bangladesh: NIPORT, MEASURE Evaluation, and icddr,b.
- National Institute of Population Research and Training (NIPORT), Mitra and Associates, and ICF International, 2016, *Bangladesh Demographic and Health Survey 2014*. Dhaka, Bangladesh, and Rockville, Maryland, USA: NIPORT, Mitra and Associates, and ICF International.
- National Institute of Population Research and Training (NIPORT), ICDDR, B, and MEASURE Evaluation, 2015, *Bangladesh Urban Health Survey 2013*. Dhaka: NIPORT.
- Nchinda, T. C., 2002, Research capacity strengthening in the South. *Social Science & Medicine*, 54 (11): 1699-1711. [https://doi.org/10.1016/S0277-9536\(01\)00338-0](https://doi.org/10.1016/S0277-9536(01)00338-0).
- Nuffield Council on Bioethics, 2005, *The ethics of research related to healthcare in developing countries: A follow-up discussion paper*. London: Nuffield Council on Bioethics.
- Parker, M. and Bull, S., 2009, The ethics of collaborative global health research network. *Clinical Ethics*. 4(4):165-168. <https://doi.org/10.1258/ce.2009.009025>.
- Ramsay, R., 2002, African health researchers unite [News]. *Lancet*, 360: 1665-1666.
- Rashid, H. A., 2006, Regional perspectives in research ethics- a report from Bangladesh, *Eastern Mediterranean Health Journal*, 12 (Supplement 1): S66-72.
- Trostle, J., 1992, Research capacity building in international health: definitions, evaluations and strategies for success. *Social Science & Medicine*, 35 (11): 1321-1324.