Review Article

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# Informed Consent through Community Engagement in Collaborative Research in Developing Countries

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## Abstract

Multinational nature of research activities has been growing increasingly through collaboration that involves a developing country and a developed country. However, several scandals have been reported to date in such research done by the western authorities in the name of collaboration, development, or health improvement in different developing countries especially revolving informed consent and protection of the participants. Those incidences tend to create distrust and may result in non-cooperative attitude among developing countries in further collaboration. This paper aims to discuss how much an informed consent is really informed and how community engagement can make it more meaningful and ethical by respecting the values of any society (i.e., participating developing country). Evidence suggests that there are essential interdependence and overlapping between consenting process and community engagement in that collaborative research. Community engagement is able to provide a meaningful insight that helps in formulation of context-specific consent process. It also helps to regulate and monitor consenting procedure, withdrawal from participation, and any relevant changes while research is ongoing. Moreover, as a sign of showing respect to the participating group in research, community engagement has been found instrumental in making research more acceptable and mutually beneficial.

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## Introduction

Organized and systemic efforts for protection of the human participants in scientific experiment or social science research started within the last sixty years, while history of such human experimentation have been going on for several centuries.[1-3] The Nuremberg Code, as being effective since 1947, first ever barred forced experiments on humans;[4] later in history of science and research, from the Declaration of Helsinki (1964)[5] to the latest CIOMS guideline (2016),[6] all such declarations and guidelines created a similar havoc on human experiments. Those landmark statements grabbed the attention and support from general people, intellectual communities, and researchers as well leading to the universal adoption of the informed, individual, independent and voluntary consent in

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any research. However, this idea of consent and achieving benefits or ensure protection in human involved research is widely variable across countries and culture.[1,3,7,8] Therefore, informed consent and its dimensions have become interesting topics of discussion on the table especially in the field of "multinational nature of research activities" which have been growing increasingly over decades through collaboration that involves a developing country and a developed country.[9]

National and international cooperations have been in action over the past decades to facilitate the developing countries resulted in collaboration in research especially in clinical trials performed in developing countries. International agencies such as the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), the Food and Agriculture Organization (FAO) and national agencies like the United States Agency for International Development (USAID), the Canadian International Development Agency (CIDA), the Agency for Technical Cooperation in Germany (GTZ), the Department for International Development (DFID) of UK, Japan International Cooperation Agency (JICA) and many others have been funding the scientists from developed countries to work on and specialize in research questions specific to least developing countries of Africa, Asia and South America for decades.[3] For example, Ebola epidemic and the global AIDS situation grew up interest of the research groups from the developed countries for collaborative research in those affected developing countries on the proposition that there are many challenges common to many countries and significant potential benefits through joint research enable further research growth, as well as capacity building to tackle common challenges across the globe.[10,11] Nonetheless, advances in transportation and communications increased the opportunities for scientific exchange tremendously between those countries in collaboration.[3] Moreover, a growing interest of the private sectors like pharmaceutical industries from developed countries to fund research in developing countries have some motions. Those include regulatory demands for local data, available participants, cost advantages, enhance the corporate image and advancement of science. Besides, large corporations utilize prevailing research practices in many developing countries in terms of flexibility, and less control on research data, flexibility in research regulations and low economic power.[1-3,9]

We understand the necessity and prospects of collaborative research between the north and the south. However, several scandals have been reported to date in such research by the western authorities in the name of collaboration, development, or health improvement in different developing countries. For example, in the 1960's and 70's, the white minority government in Rhodesia (currently known as Zimbabwe), a clinical trial of Depo-Provera was done on black women; the drug was used as a birth control measure. "Women on white-run commercial farms were coerced to accept" that injection; the drug was banned in the country 1981.[12] Recently, in 2019, Wellcome Sanger Institute, a genomic research center in U.K., was accused of commercializing a genetic chip developed from the donated DNA of African people; it lacks the consent of those African research participants.[13] In recent times, during the COVID-19 pandemic, in a televised discussion in Europe, a couple of scientists suggested that COVID-19 vaccine trials should be done in Africa because "there are no

masks, no treatment, nor intensive care",[14] which was regarded as an attempt to implement substandard and/or exploitative research in that region.[14] Such notion reflects the existence and persistence of colonialism and systemic racism that have created health inequities and continued to manifest in many developing countries to date. Unfortunately, all those controversies, scandals and misuse were done by the scientists of developed countries in collaborative research and thus, created questions on ethical integrity especially on autonomy (i.e., informed consent) of the participants from the developing countries. The discussion of this paper is based on that issue – how much an informed consent is really informed and how community engagement can make it more meaningful and ethical by respecting the values of any society (specifically in developing countries).

## Principles Involved in Collaborative Research

A report published in 2001 by the United States National Bioethics Advisory Commission (NBAC) stated that more than 90 documents from government, non-government, and international organizations were identified and reviewed which were concerned with ethical guidelines for different human research in collaboration with another developing country.[15] However, those documents primarily reflected ideas, beliefs, and principles prevalent in the western world and obviously difficult to ascertain whether any inputs from and specifically relevant to developing countries were included. Based on those documents, a considerable consensus was reached by NABC on the following principles for any research involving humans:[15]

1. The research protocol must be reviewed and approved by an independent research ethics board (REB);
2. Maximum efforts must be in place to minimize the risk to the research participants;
3. A reasonable risk-benefit ratio i.e., an equitable distribution of the burden and the benefits, must involve in the research;
4. Adequate plans must be presented for care and compensation of the participants for any harm/injury and further medical care, if it is directly related to the research;
5. Individual informed consent must be obtained from all participants; and
6. Equal consideration and care must be ensured for all research participants.

Similarly, some other available guidelines emphasized all those issues in collaborative research.[7,8,16,17] Nonetheless, the most important among the issues in collaborative research is informed consent. This consent processes must ensure appropriate and detail information. Information provided about the research should be understandable to the intended participants, and above all, participants should willingly accept or decline to participate in research.[7,8,15-19]

## Problems with Obtaining Informed Consent

Despite broad support among scientific communities, researchers, and policy makers for ensuring written informed consent in collaborative research, several obstacles exist in practice to the achievement of this specific and crucial requirement.[18,20]

Stakeholder in research have the common agreement about the necessity to respect

autonomy and dignity of the participants through a transparent practice of informed consent; however, many studies on the topic revealed that how subtle and complex the ways are that research participants understand provided information about the whole research and make decisions about each component of that research – purpose, design, data collection and security, dissemination of results.[18,20,21] It is very true that international collaborative research covers a broad spectrum of topics of interest, varied research designs, methods, and collaborative research strategies.[2]

Research ethics in the developing countries are influenced by the social structure, religious beliefs, cultural values, and education as well as economic conditions which are also true for both researchers and the population.[2,18] Hence, considerable controversies remain on obtaining real informed consent in collaborative research that is sponsored or conducted by the groups from developed countries and carried out in groups living developing countries. Evidence suggests that research participants living in developing countries often fail to understand: i) the difference between research and medical care,[22] and ii) what are meant by placebos and randomization,[23] as they lack education or exposure to the Western concepts in biomedical research and some terminologies.[21] Therefore, information given in writing may be inappropriate in populations of low literacy – as we have seen in many cases, those consent forms are required, but described contents are overly technical and detailed, too. Moreover, some ethnicities uphold a higher value on communal decision rather than on individual's and rely mostly on advice and collective opinion of their leaders. In a study done in India showed that during its interview session, most of the respondents actually decided on taking part in clinical trial after discussion with their community members.[24] Similar evidence has been found in people living in different parts of Africa.[25,26] Such approval by the community may constitute an additional value through collective consent and strengthen the protection of individuals from research risks along with individual's consent.[26-28]

One of the arguments in favour of the debate on group consent is the awareness about any possible harm to any individual may also lead to affecting the whole group. This concern also capture attention to relevantly special types of groups as research subjects. For example, Africans were tested for sickle cell anemia and who tested positive were reportedly stigmatized socially and in workplaces; that stigmatization was negatively associated with all domains of health-related quality of life.[29] Similarly, Hantavirus pulmonary syndrome was termed as Navajo flu caused stigmatization to the Navajo community.[30]

Last but not the least, evidence shows that several independent mediators defended the rights and interests of local community population and their collective participation in research, and thus gain their trust which could take on a power balance between two parties (for example, local research regulators, human rights agencies, etc.).[27,28]

**Obtaining Informed Consent through Community Engagement**

Here the words "community engagement" and "community participation" will be used interchangeably. Multiple interplay has been identified between community participation and individual consent. Marsh *et al.*[31] described the

links between these two and argued that "community understandings, beliefs, and attitudes influence perceptions of personhood, independent decision making, and views on risks and benefits of research". In some cases, it helps only gathering and recruiting participants. In other cases, it helps in formulation of context-specific consent process which might be helpful for both individual and the community. Community engagement also helps to regulate and monitor consenting procedure, withdrawal from participation, and any relevant changes while research is ongoing.[1,28,31]

The importance of community participation or engagement lies on that it can provide better insights into populations' perspectives: local priorities and needs for research, their perception in consent process and whole of the research activities, the type and bulk of information they need to understand a study and make decisions.[28,32-34] Hence, early consultation with the community members may lead to modify a research proposal which will help become more culturally appropriate. In other way, focus group discussion with the community leaders help develop a culturally appropriate protocol that strengthen the quality of research, appropriate consent process, and other requirements.[28,32-34] Thus, community engagement may play a crucial role to become instrumental in getting approval from the REBs.[30,32]

In here in our discussion, we would like to mention two possibilities (types) of relevant to informed consent. The first one is termed as group or collective consent. As in developing world perspective, this is important. In some research settings, it is obligatory and, therefore, appropriate to obtain community or group approval for enlisting any individual belonged to that community or group to participate in a study.[34] This usually means that researchers need to take permission from the community/local authorities prior to inviting that individual person. However, it does not replace the necessity of an individual's own consent to take part in the study.[15]

Secondly, a special topic related consent by women – it is also a crucial point of interest in developing country's perspective. Some cultures demand that for wife's participation in a research, her husband's permission is mandatory. However, this practice could only be acceptable under the following conditions:

1. If it is impossible to perform the study without those married women;
2. If this research results are important to the community and any failure to conduct the research may deprive those women from getting potential benefit in healthcare perspective;
3. To uphold those woman's autonomy to consent are undertaken with all possible measures;
4. Individual consent remains mandatory, even if husband insists on his wife's participation in the study. (Adopted from NABC, 2001)[15]

We know that the western society gives much more emphasis on the value of individual freedom and autonomy as well as individual rights than that of collectives. Similarly, their federal rules and regulations of research on human participants aim to protect the personal wellbeing of each of the participants in research.[2] In contrast, Brugge & Missaghian[30] described that in collaborative research, how community participation approach can protect individual's wellbeing by ensuring group rights by a process

of group consent along with other measures.[30]

Group rights may include a right to give voluntary consent to take part in research and in a broader sense, a right to protect group's vested interests, e.g., maintaining group's image or reputation, preventing harms, and wellbeing of the group or its members.[30,33,34]

Another important aspect is community discussions prior to a study recruitment have a very useful two-way learning process. Researchers come to learn about culture and values relevant to that community and its members and possible implications of that research for them. We know that there is always a distinction between understanding and acceptance. Through community discussion, potential participants learn about the value and implications of taking part in the research and consent procedures associated with it. It gives them better understanding and more chances to accept.[28,32-34]

Community engagement or participation in collaborative research has been promoted as a "core value in participatory health research" over decades. In the context of challenges in seeking consent at community level, such community engagement has recently begun to be promoted as a helpful measure in the research process.[1,26,33,34] Community engagement upholds individual and collective empowerment of the participant from the community, eases the research process and increases its quality.[26,28]

We have seen that tension still prevails between respecting community values and culture (the community's interest) and honoring individual autonomy (the individual's interest). Researchers have their concerns on voluntary participation of individuals questioning whether it is truly voluntary when they discuss or take opinions from the community leaders. On the other hand, they also felt the necessity of community engagement as an effective mechanism for gathering potential research participants and engage them in discussion.[35]

While many AIDS research projects have already been conducted and also going on in different parts of Africa for decades, UNAIDS strongly recommends community engagement as lessons learned from those research projects.[36] Such community engagement has been playing its role for decades in multiple stages of research, ranging from conception and design to preliminary information session, to gathering participants, to communicating results and collecting feedback and of results.[36] This is how in health research community participation is increasingly encouraged and promoted; however, the concept of community engagement (its universality) and its implementation in practice are still contested and need further research.[32,35,37]

Apart from Africa, in the Tri Council Policy Statement – 2 of Canada, both the informed as well as the community consent have been shown as "indispensable elements for the collection, processing, use and transferal of indigenous samples and data".[38] Similarly, emphasis has been given on such adaptation to specific regional cultural particularities to maintain the quality of all research procedures within effective standards.[16,27,39] We believe that such notion is also helpful for ongoing and future multinational research conducted in a developing country like Bangladesh.

## Conclusion

Community engagements help collaborative research to be carried out in a respectful manner where social values of the community that is participating in research are maximized. Innovative participatory approaches could include, for example, bringing together community liaison officers and community members/representatives from different sites to discuss on-the-ground realities, with inputs from ethicists and academics. This discussion emphasized on “community engagement in consent process”, which is not established as an absolute problem-solving measure, rather suggests a way to enhance trust and confidence, prevent exploitation of people/community living in a country that is poorer, less powerful, and therefore, more vulnerable in the context of collaborative research. We believe that community engagement in consent process has enormous potential to propagate substantial benefits for both the sides.

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