Informed Consent in Developing Countries

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In recent decades, there has been a significant increase in biomedical research being conducted in developing countries. Institutes like the Bill and Melinda Gates Foundation, and the US National Institutes of Health have begun funding medical research in numerous countries in Africa and other struggling parts of the world. Research programs have started outsourcing to these areas for multiple reasons, including reduced costs and direct access to affected populations. Conducting research in developing nations can have tremendous benefits for the medical field, and in many cases, it is the best way to develop new treatment techniques, medications, and vaccines. It often makes the most sense to test new drugs or therapies on the target populations that are intended to benefit. Performing medical research in developing countries offers advantages for those conducting the research, but these efforts often fall short of the ethical standards in the US and other areas of the developed world. Research trials in previous years have often violated the ethical rights of at risk populations in developing countries. These violations most often begin with obtaining proper informed consent from the individuals participating in the study. But when researching vulnerable populations, or performing clinical trials in these areas, there are additional ethical concerns that must be taken into consideration. New guidelines and methodologies have enhanced the protection of these groups in recent years, but the ethical violations continue. In order to safeguard the rights of these populations, researchers must fully inform participants about the risks and procedures of the research and receive direct verbal or written consent from them or the responsible party.

Obtaining proper informed consent from a participating individual can be problematic even in the United States, so when different cultures and languages get added to the mix, things

can become complicated. When I was growing up in the small country of Malawi in southern Africa, I experienced this stark difference between cultural backgrounds. I spent many days playing with the young children who lived in my neighborhood and walking through the dusty, colorful markets scattered through the hills. I often asked my parents why the other children were allowed to stay out and play later than I was, as I was jealous they could continue to roam after dark. I soon found out that many of the young boys I played soccer with would return to the orphanage late at night, or to a home where the mother was busy tending to three crying babies. These children were forced to fend for themselves on a daily basis with very little guidance as to how to progress through a healthy life. After spending time with these young Malawians, I have come to realize the importance of protecting these people's natural rights, especially when they have no one to help them. *The Belmont Report*, written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, outlines principles and guidelines that best protects the rights of human participants involved in research, young and old. This report breaks down the notion of informed consent into three primary components, information, comprehension and voluntariness (*The Belmont Report*, blackboard).

Each of these three points brings up issues that researchers have encountered numerous times when designing research trails in developing nations. Each contributes to the autonomy of the individual, something that is recognized as a right by many developed countries and organizations around the world, such as Amnesty International, and the World Health Organization (Krogstad, 2010). But this is something that already brings new issues to the table, as the notion of autonomy is variable throughout different cultures. In the US and other developed countries, the idea of consent is attributed to the individual participant, unless they are minors or legally unable to decide for themselves. But for many communities in developing

nations, consent begins with the community, not the individual. This is common in areas of sub-Saharan Africa, South Sea Islanders, and for tribes in the Amazon (Krogstad, 2010). Obtaining informed consent from these people requires a specific knowledge of the customs and practices of those groups. Village leaders or head of households must often be consulted before the individual participant is approached. Because of this, it is easy to accidentally violate the communal rights of these people, thus undermining the ethical basis of the study.

Similarly, obtaining consent from young and impoverished or homeless individuals can be a difficult problem. Children are often a vital component of important research, as preserving the health of new generations can ensure the future prosperity of these vulnerable groups. Normally, obtaining consent to research children begins with the parents or guardians, as they are responsible for the child's safety. But when dealing with impoverished populations, the question of consent for a child becomes complicated. For example, the Congo has alarmingly high numbers of orphaned children living in the slums of its cities. These children are often diseased, with a high prevalence of HIV and other problematic health conditions, and research on this population is important in order to improve public health throughout the country. But most of these children are orphans living on the streets of the nation's capital, Kinshasa, without any shelter or legal guardian (Mupenda, 2012). How should one approach the issue of informed consent with this test group? Finding a home, shelter or education for these young people might lead to possible solutions, but those aren't always viable options. These are the kinds of issues that researchers face when studying disadvantaged groups.

Properly informing research participants about the risks, benefits and other aspects of a study is another area that can result in a violation of an individual's rights. Language barriers, translation problems, illiteracy, and documentation problems can leave the subject with a flawed

understanding of what they are agreeing to (Krogstad, 2010). They might sign their name, or initial a document, but this often doesn't prove the individual is properly informed and knowledgeable about the purpose and dangers involved with the research. This can lead to problems in gathering data for the study, as someone might not have fully understood what information they might need to provide the researchers, or the extent of certain tests. It can also have ramifications down the line during the evaluation and publication of that data, as some participants might not have known the extent to which their information would be used and seen by other people (de Vries, 2015). While these issues are discussed in *The Belmont Report* and other documents from ethical review boards, researchers must be much more detailed when informing participants about their involvement, and better equipped to obtain proper consent from individuals wishing to participate in research.

Another common issue with consent that can occur with research in these low-income countries is compensation. Many impoverished individuals volunteer for these studies in order to receive money for their participation. This is a common practice for most research programs in the US and abroad but deciding what the proper reward should be has long been a problem for ethical review boards. Providing too high of a reward for participation will draw in poor individuals with little regard for their own safety. Giving excessive reimbursement can also be seen as coercion, as it may not only encourage individuals to participate in something they wouldn't normally agree to, but also entice them to lie about their information in order to gain access to the benefits of the study (Fried, 2007). This can both undermine the ethical basis of the study and skew the data as a result of false information. Providing little to no compensation is also harmful as it can either waste people's time, or disincentivize individuals from joining the study (Krogstad, 2010). Finding an ethical balance is important for maintaining proper informed

consent, as going too far in either direction will most likely reduce the individual's understanding of the parameters of their participation.

Obtaining true informed consent from individuals participating in a research study is vital to the ethical validity of the project. Many cases of unethical research begin with populations that have not been fully informed about the extent of their participation, or with individuals who have not given their full, voluntary consent to be a part of a research study. People in developing or impoverished countries are at the greatest risk for these ethical violations, something I have observed in my own experiences growing up in Malawi. It is important that we continue to scrutinize researchers throughout their experimentation to ensure that abuses to informed consent do not occur, especially in at risk populations.

August Kublin

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