

## Review Article

# Protection of the Research Participants in the Developing Countries: A Personal Concern

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## Abstract

The protection of the study participants is a corner stone of any research-involving human. There are many international ethical codes and guidelines as the Declaration of Helsinki, the Federal Regulations, the guidelines prepared by the Council for the International Organizations of Medical Sciences (CIOMS) and the Islamic Organizations for Medical Sciences (IOMS). All these guidelines indicate how the ethical principles should guide the conduct of biomedical research involving human participants.

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Many of the developing countries-including Egypt- are working hard to build their capacity and strengthen the system for the protection of the research participants. These countries may also have different motivations as attracting external funding, participating in the international clinical trials, which are growingly conducted in the developing countries, and publishing in prestigious journals. Few countries in the Middle East developed their guidelines, which consider their local cultures, norms, and laws. However, most of the countries in the region have started developing their reviewing system, i.e. the Institutional Review Board (IRB)/ Research Ethics Committee (REC). For example and according to the directory of the Egyptian Network of Research Ethics Committee (ENREC), there are

23 committees included in the network<sup>(1)</sup>. The real number may be much more than that mentioned in the directory. In addition, some researchers have received training in the developed countries and worked as professional reviewers and trainers in their home countries.

The raised question: do the developing countries achieve their goal toward protection of the research participants? We heard the different perspectives toward protection of the research participants in Egypt and other developing countries from a wide range of research ethics professionals and researchers. Here is the summary of most opinions. Most of the experts working in the research ethics committees are disappointed especially those who review the proposals of the theses for the junior researchers. The reviewers feel that they

waste their effort and time in the reviewing process and in educating the researchers how to weigh the risks and benefits of the health research, to do a fair subject selection and how to conduct the informed consent process. The reviewers said, “There is a deviation from the main goal of the committee. We are assigned to take the measures for the protection of the research participants. The target of the researchers is to satisfy the institutional paper work, have the ethical clearance, which is used as an official document during the publication in most of the scientific journals. The researchers are not worried about the protection of the research participants. Most of the research participants are exposed to therapeutic misconception. They do believe that they are treated as patients and they do not recognize being research subjects. So, there may be no distinction between the clinical practice and the clinical research”.

To complete the picture, it is needed to identify the opinion of the researchers. We heard the voices of many researchers from the developing countries. Some of them are fellows in the Joint Master of Health Professions Education developed between University of Maastricht and Suez Canal University. Other voices are heard during implementing research ethics workshops in different countries in the Middle East. Asking them about the challenges they face during the application of the ethical standards in human health research, their responses are classified into three categories. The first category is related to the researchers themselves and the research environment. They said, “In developing countries, and due to low pay; we are unmotivated to conduct our research, and there is a Lack of appreciation for the value of health research and its impact on the health

enhancement”. They added, “There is a culture that deepens the mistrust between the research subjects and the investigators. Before asking us to apply the ethical standards in human health research, our institutes should offer us professional training for research ethics”. The second category of the challenges is related to lack of integer reviewing system, national guidelines, and clear standards operating procedures (SOPs) of the research ethics committees. The researchers said, “To have the ethical approval from the REC, we spend a long time and pay a lot of effort to go through this complex process. Also, some of the reviewers lack the required experience”. The researchers extensively described the third group of challenges, which are related to the research subjects. They said, “Many people refuse their participation in the health research because they are not experimental animals”. The researchers also described the difficulties of having a valid informed consent. They said, “Most of people are illiterate, have poor education and it is hard for them to understand the technical terms, the purpose of the research, benefits and risks. It is too hard to explain some concepts like placebo and randomization to them. The patients will be scared and will not be included in the study if we explain the potential risks to them. Other participants believe that they must participate in the study in order to receive medical care or treatment.” They also highlighted the key role of the culture in the developing countries. They said, “We face many culture barriers as the refusal of the research participants to sign the informed consent because many people distrust any signing process. Sometimes, we need the permission of the community leader before the start of the clinical trial. Another problem is the family-centered decision making. Some cultures

require the permission of a woman's husband, if she is married, or her father, if she is unmarried, before she can enroll in a research project.”

At this point, we must direct the attention to the missed voice in the discussion. It is the voice of the research participants and the community. The researchers mentioned that the research subjects are not able to understand the nature of the research because of illiteracy and lack of education. Moreover, the pervasive poverty may motivate them to be recruited in clinical trials to overcome the inadequate access to medical care. This explanation is a reflection of the paternalistic attitude of the physician-patient and the researcher-subject relationship. In the developing countries, we ignore the participatory relationship in both of medical practice and clinical research. It is important to mention that most of the international guidelines promote for the community engagement in human health research. The community engagement will help the research team to respect the culture and increase the acceptability of the research among the potential research participants. We need to consider that the illiterate or low educated person does not mean that s/he is not able to understand. The respect and transparency will build the trust between the investigator and the research subject.

The paternalistic attitude and lack of transparency are clear when we try to compare the researchers' attitude toward protection of the research subjects in developing and developed countries. We used the study tool developed by Kandeel and Silverman, (2011)<sup>(2)</sup> to assess the awareness and attitudes of Egyptian Faculty towards Research Ethics in a similar study in an American College by Ali et al, (2013)<sup>(3)</sup>. On asking both samples “Research subject do

not understand research, so no need to provide them with details”, (35.4%) of the Egyptian researchers agreed versus only (4%) of the American researchers. Another question to the researchers whether the research subject should not be informed about risks as they may not enroll in the study, (12.2%) of the Egyptian sample agrees versus only (2%) of the American sample. It is clear that the Egyptian researchers believe that the research participant should not be informed about the study details because they are not able to comprehend the information.

Other interesting results revealed that nearly (61%) of the Egyptian sample are familiar with ethical principles that govern conducting research involving human subjects versus (80%) of the American researchers. Ninety four percent of both samples agreed that all investigators should have training in research ethics. A considerable proportion of the Egyptian researchers (25.1%) thought that the ethical review should be restricted to international collaborative projects versus (14%) of the American researchers. Also, nearly (33%) of the Egyptian participants and (28%) of the American participants thought that reviewing the research by an IRB/REC would delay research and make it harder for the researcher. We believe that specific steps can be taken to ensure the protection of the participants in the clinical research in the developing countries:

- 1- At the national level: Development of national research ethics guidelines and national standards for RECs<sup>(4)</sup>
- 2- At the institutional level: Development of a monitoring committee. Its role will be integrated with that of the REC. According to the International Conference on Harmonization (ICH) of Good Clinical Practice (GCP) guidelines

- (1996)<sup>(5)</sup>, this committee verify that the rights and well-being of human subjects are protected and the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s). In addition, there should be a clear program for the continuing education for the members of the REC members. The institute need to offer a professional research ethics training for each researcher involved in a human research
- 3- Promotion for the community partnership: This goal could be achieved by increasing the number of non-scientists members in the RECs. These members really have the knowledge and better understanding the local social concepts than others. They may help the committee to take into account the decisional capacity of the individuals, may facilitate the informed consent process. They may also ensure the voluntariness of the research participants and avoidance of coercion or undue-inducement.
  - 4- The research community in biomedical and social sciences may work together to develop a website explaining the difficult terms in a plain language. The researchers will use these simplified terms during writing the informed consent documents to be understood by people with low health literacy.
  - 5- A quantitative and qualitative research is needed to hear the voice of the community and assess its attitude toward the research-involving human. This research will help the researchers to understand what is accepted/not accepted in their local community. It will also recognize the challenges/the

barriers of health research and generate solutions to overcome these barriers. Finally, we need to build the trust between the society and the research community. People need to know that health research is a fundamental pillar in the health system with other pillars as sufficient resources and proper management.

### Disclaimer

The views herein are those of the author based on her experience and her research and do not necessarily outline the view of School of Medicine, Suez Canal University

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### Author' Biographical Sketch

Nahed M. Ali, MD, MS, CHES, is a Professor and Chair of the Department of Forensic Medicine and Toxicology, School of Medicine, Suez Canal

University. She is a certified trainer of research ethics from the University of Maryland, USA and serves as teaching faculty member of Middle East Research Ethics Training Initiative (MERETI). She developed the Research Ethics Committee (REC) in the school and served as a vice chair of the committee. She has numerous national and international activities and research in Research Ethics. Dr. Ali also worked as a part-time faculty at Ithaca College, NY, USA. She has a Master Degree in Health Education and is a Certified Health Education Specialist (CHES) in USA.