Doing Research on Human Subjects in Ethical Way

The process of "Research" is an activity the purpose of which is to either develop new knowledge or contribute to already existing facts, that can be generalized. Such a process can be applied to many scientific fields including social sciences.[1] Those studies that relate to human subjects, whether conducted for physical or mental illnesses, fall into category of biomedical research. This is a special type of research that is related to human health. It is given a special status because with expected noble goal that it addresses there is potential threat to human subjects, as harm may occur or can be intentionally provoked.

In past 4 – 5 decades there has been a gradual shift in research ethics from researcher centered approach to the one where research participants are given priority. This paradigm shift brought forward new ethical research guidelines in the form of Helsinki Declaration, CIOMS guidelines etc that have been revised based upon emerging issues.[2] All this was an effort to prevent any possible harm in the name of research to participants especially vulnerable groups, who can not protect themselves.

In recent years the research focus has shifted from advanced countries to developing countries. Many pharmaceutical industries are now bringing their businesses to developing world. They have major shares in global wealth. There is great danger that third world countries may become a research lab to these giants in pursuit of their interests. There is lack of monitoring on part of health ministries of developing countries coupled with corruption, poverty, political instability, illiteracy, and power relation between rich and poor countries, where former has authority over the latter, every possibility of potential harm being inflicted is there.

In order to meet such challenges we need to develop a system where checks should be placed upon such activities. The purpose is not to put hurdles but to make research an ethical activity in pursuit of greater good for mankind. An Institutional Review Board (IRB) is one such filter. This is an independent committee that oversees all research proposals before being implemented. Its members are chosen from all walks of life. It usually includes physicians, community representatives, lawyers, religious scholars, lay people. The only aim is to ensure that trial is conducted ethically and at the same time the rights of study participants are protected.[3]

1. CIOMS Guidelines. Available from http://www.cioms.ch/frame_guidelines_nov_2002.htm.
2. World Medical Association Declaration of Helsinki. Available from: http://www.wma.net/e/policy/b3.htm
3. Shamoo AE, Resnik DB. Strategies to minimize risks and exploitation in phase one trials on healthy subjects Am J Bioeth. 2006;6:W1-W13.

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