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Editorial

Ethical Issues in Biomedical Research

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Department of General Medicine, Glocal Healthcare Systems Pvt Ltd, India

***Corresponding author**

Sujit Kumar Bhattacharya, Department of General Medicine, Glocal Healthcare Systems Pvt Ltd, Kolkata-700156, India, Email: sujitkbhattacharya@yahoo.com

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EDITORIAL

Biomedical research involving human subjects has become an important issue over the last several decades. Even in ancient time it was discussed and documented. Relatively in the past, the Nazi experimentation on human prisoners during the Second World War initiated extremely brutal events in research involving human for research. Experiments were to study the impact of freezing on human; some of their "research" involved infecting people with malaria, using mustard gas on people, forced sterilization, giving prisoners different poisons, infecting wounds with bacteria and filling them with wood shavings and ground glass. Another study was to understand the natural history of Syphilis. The study was carried out when Penicillin was available and the patients were denied of its use to cure the disease. These and other similar brutal human experimentation were done and this prompted to develop ethics guidelines. The fundamental basis of ethical guidelines is to protect the individuals participating in research. A number of ethics guidelines have been developed by World Health Organization and guideline by Indian Council of Medical Research. Currently a number of guidelines are available. The main theme is to do social justice, protect human rights, voluntariness, protection of children and ethnic groups and marginalized communities and confidentiality of the participants. In order to ensure these elements, the pivotal concept is Informed consent. It consists of providing of the anticipated goods and bad of the interment of intervention to the participant in a manner in which he/she is comfortable. It is to be ensured that the prospective participants understand the subject and issues involved in the study. Children, mentally deranged people and others who cannot provide freely their willingness or not to participate in the trial is a difficult issue that needs careful discussion and decision. It is crucial to ensure that the consent should be taken from the participants in own language. Confidentiality of patients information should be given due respect. Informed consent could be taken verbally, in writing or under Video came screening. This is a pre-requisite before individuals can be recruited for the study. Community consent is a difficult issue and needs more clarity. Undue inducement should not be given to influence the decision of the participants. For vulnerable participants like children, pregnant women, and mentally deranged individuals, the consent should be taken which safe guards the individuals to protect no harm to him/her.

Placebo controlled studies are discouraged and rather the new treatment should be considered with the best existing treatment (gold standard). In my own experience, instead of placebo, we used similar other thing to mitigate the feeling of exploitation by the participants. After the trial is over, and if the study shows that the new treatment is superior to the current best treatment, it is essential that those who did not receive the new treatment should be given the opportunity to get the new treatment.

The other issue is randomization which means that the participants will have equal chance to get either treatment. Block randomization means under each block, there will be equal number of participants. Currently, randomization list can be generated with the help of computers. Pharmaco-vigilance is an important part of clinical trial.

There are specific guidelines for ethics clearance of any study. The committee should be headed by an eminent individual; other members will include a law person, a journalist, a lay man, women representative and a subject specialist (who may be co-opted). There should be a member secretary who should be from the institute. Generally, there should be at least 6-7 members. The head of the institute should never be a member of the committee. A number of ethics guidelines are available and may be consulted.