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Role of Informed Consent in Medical Experiment in Clinical Trials

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ABSTRACT

In law and medicine, the role of informed consent is very important on that the basic process is set to provide health care education to the research subjects in clinical trials. The researcher must be provided with information about the risks, benefits, and alternative procedures for the research subjects. The subjects of clinical trials must be competent to make a voluntary decision about whether to undergo the procedure or not. In clinical trials, informed consent is a is a legal requirement for new drug discovery and treatment.The Indian Council of Medical Association's makes a requirement for informed consent before undergone the medical treatment for new drug development. Fundamentally, both ethical and legally, subjects have the right to receive information and ask questions about treatment in clinical trials, so that subject can take a decision about clinical trials.

Introduction

In clinical trials, the subject must give informed consent, which is viewed as the same as getting the subject's signature on the consent form. Informed consent can be obtained in a research subject's verbal or written form. Informed consent is only part of the process. Informed consent involves a potential subject with:

- Sufficient information to provide subjects those who are involving clinical trials.
- Recognition and facilitation of the potential subject's understanding of the information about clinical trials.
- The subject should get appropriate time to ask questions and to discuss with family and friends about the clinical trials.
- The research subject must have obtained the potential to ask the question about the clinical trials.
- The clinical trials center must provide continuing information as the clinical investigation progresses to the subject and their relatives. [1]

When some new medicine, cosmetics, or food stuff is to be marketed, its suitability has to be confirmed by applying the invented medicine, cosmetics, or food stuff to human subjects. It becomes necessary that certain types of medicine cannot be experimented on human subjects directly. Such experiments are conducted on animals first, results are analyzed, and if found satisfactory, they are applied to human subjects next. [2]

For testing medicines, human subjects are recruited from both healthy persons as volunteers and from patients who are undergoing treatment in some institution. The patients are selected according to the protocol of the new medicine. Similarly, the introduction of new cosmetics needs experiments on human subjects. Because the product will be rejected by the consumers if there are adverse effects.

Subjects who participate in scientific research are generally of two categories. The first category is healthy volunteers, and the second category is patients. In each category there shall be persons of different age groups, viz., infants, children, adults, and elderly persons.

Healthy volunteers are recruited through advertisements in the media. Apart from recruited volunteers, medical, nursing, and pharmacy institutional students and interns also participate in research studies. These calls from volunteers are the most wanted ones.

Form of consent:

Whether the consent of the subject should be oral or written. The Declaration of Helsinki refers to preferably written consent. German law requires that the consent of the patient must either be in writing or be witnessed independently. In the Republic of Ireland, written consent (subject to certain exceptions) is also required. So far as the UK is concerned, there are no particular legal requirements, although

ethical guidelines endorse the view that consent in writing is preferable. Genuine and effective consent can be given orally, but it is very difficult to prove oral consent. [3]

In many cases, researchers use standard printed consent forms, which may refer the patient to a standard information sheet that should be read before signing. Since an underlying principle or of all research is that the subject must be free to withdraw consent in trials at any time and stage.

Subjects are clinical trials.

Subjects who take part in clinical center studies include:

Children and adults can take part in clinical trials when they want to improve their health. They may be subjects with newly diagnosed medical issues.

Healthy volunteers, if they seek to advance knowledge about causes, progress, and treatment of disease, can also become subjects of clinical research. subjects and healthy volunteers must meet certain requirements, which are different for each study. [4]

The object of a clinical trials study is to make investigational drugs available under certain circumstances to treat subjects with their condition who cannot participate in a clinical trial. [5]

Women:

There is no representation of women at any stage of the research process. Research on conditions specific to females receives low priority, funding, and prestige; various protocols and guidelines have excluded women, especially those who are pregnant, from clinical trials.

Women's reproduction is the issue that primarily affects women and for which massive resources have been devoted. However, contraceptive research is greatly inadequate.

SIGNIFICANCE OF THE CLINICAL TRIAL

The Indian scenario is very different: a non-uniform health care system with different standards practiced in the government and private sectors, desperate poverty and lack of access to health care,

health education, lack of information, and lack of enforcement machinery, which is a major challenge for a program of clinical trials. [6]

In clinical trials in India, someone has to take into account the vast cultural, economic, social, and educational differences that exist. The absence of specific laws and poor enforcement of guidelines can result in exploitation of our vulnerable populations by anyone with a vested interest. [7]

Application for Permission:

In clinical trials, subjects must volunteer to apply for permission to import or manufacture new drugs for sale or to undertake clinical trials with the following data:

1. name of the chemical and pharmaceutical company's information,
2. Clinical Trials subject's data,
3. Human being and animal toxicology data,
4. Human clinical pharmacology data,
5. To follow the complete testing protocol for quality with an impurity profile and release specifications.

However, if the drugs are to be used for life, serious diseases, or diseases of special relevance to the Indian scenario, [8

Clinical trial subjects must be given the following information:

- A statement explaining that the study involves research.
- Clinical trials to develop new drugs for society's development.
- The duration of the clinical trials is not fixed.
- After registration of clinical trials, all legal formalities must be fulfilled.
- Information regarding the clinical trials and consequences must be given to the subjects.
- All legal formalities and procedures for clinical trials that will be completed during the clinical trial.
- Information about any alternative procedures or treatment of clinical trials that might benefit the research subject.[9]

Conclusion:

Participating in clinical trials is voluntary. You have the right not to participate or to end your participation in the clinical trial at any time. Usually, if one is considering participating in a clinical trial, he or she may take the consent document home to discuss with family, friends, or an advocate.

The patient is required to make a valid decision, and hence the process of informed consent demands that the patient should have adequate knowledge about it. It is seen that patients come from varied social and cultural backgrounds, with limited literacy about the process. Hence, it is suggested that innovative communication strategies should be developed to encourage and facilitate informed decision-making in India.

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