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Importance of consent in the research

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Research involving human participants needs to be scientifically valid and should be conducted according to accepted ethical standards. Research ethics provide guidelines for responsible conduct of research on human participants. It primarily protects the human participants of research and also educates and monitors researchers conducting health research to ensure a high quality of ethical standard.[1]

Consent is a research process of information exchange between the researcher and the human participants of research. Information provided to the human participants of research should be adequate, clearly understood by the participant of research with decision-making capacity and the research participant should voluntarily decide to participate. Respect for persons requires that the participants of research should be allowed to make choices about whether to participate or not in the research.[2]

The doctor patient-professional relationship is founded on mutual consent and governed by a multitude of laws and regulations. It is necessary for all phases of the doctor-patient relationship. Consent means a willful agreement by a patient to a doctor. The reason is that the physical touching of the body, from the angle of civil, tortuous and criminal liability is illegal unless there is free consent or a reasonable excuse. Treatment against patient's wish is illegal even if it is administered with the best of intention.

The consent can be classified as follows:[3-5]

1. No consent (indirect/ emergency):
   There will be no consent to save the life, to prevent deterioration endangering life and just adequate and standard treatment of a patient.
2. Proxy consent:
   Proxy consent will be taken if the patient is unconscious/ minor/ mental patient. It may be taken from family members or relatives or next to kin or parents or legal guardian.
   a. Legal state
      District court/ superintendent of Police/ other authority
   b. Professional/ Social
      Hospital authority/ Professional committee/ Husband/ Wife
3. Participant's / Patient's consent
   i. Implied consent
      In implied consent, participation in the study is proof of consent. The acceptable consent for the research is that which provides anonymity. The content of consent should be clearly stated that by filling it, the participant consents to participate in the research, but does not wave any of their rights as the research participant. Research using implied consent should use the consent statement provided in their proposal. It provides active implied consent.
   ii. Active consent
      Participants show a desire to participate in the research by agreeing to a specific statement. Then the participants are included in the research. This is the commonly used and recommended consent to conduct the research.
   iii. Passive consent
      The research participants are informed about the research. They are considered to agree to participate in the research unless they specifically deny including in the research. This type of consent is mostly used in schools. The consent forms sent to parents asking them to allow their children to participate in the research.

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iv. Explicit consent
Explicit consent is also known as express or direct consent. The participants of research are given right to agree or disagree with the collection, use, or disclosure of personal information. Participants give consent means the willingness to participate in research and ready for answering the questions.

v. Informed consent
Informed consent is documented using a written, signed and dated in the form. This form is required
a) When the research participants are patients, children, incompetent/ incapacitated persons, healthy volunteers, or immigrants.
b) When the research uses or collects human genetic material, biological samples or personal data.

The informed consent form must be written in the local language easily understood by the participants. It must minimize the possibility of undue influence. The participants must be given sufficient time to participate in the research. However, informed consent is not only a form that is signed by the participants but also a process in which the participant has an understanding of the research and its risks.It is described in the medical ethics and regulations for human participants in the research.

Importance of informed consent to researchers[4,5]

The concept of consent comes from the ethical issue of respect for participant's integrity as well as self-determination. Every human being has a right to decide what should be done with his body. The operation performs by the surgeon without taking the patient's consent commits an assault for which he is liable in damages. Besides the legal implications, a researcher or doctor is required, as part of his duty of care for his patient, to explain, what he intends to do and the implications involved, in the way in which a responsible researcher or doctor in similar circumstances would have done.

Researchers or doctors may do nothing to the participants or patients without valid consent. This principle applies also to surgical operations. It is also applicable to all forms of medical treatment and to diagnostic procedures that involve intentional interference with the person.

Valid Consent [5,6]

Valid consent consists of three related aspects: of voluntariness, capacity and knowledge.

1. Voluntariness: Participant or patient should give consent completely voluntarily without any compulsion either from a doctor or any third party.
2. Capacity: The Participant or patient should be in a position to understand the nature and implication of the proposed research method/treatment, including its consequences.
   a. Age of Consent: A person who is major by law above 18 years of age can give valid consent for the treatment.
   b. Mental capacity: It is well accepted that a person should be mentally capable to give consent for his or her treatment. The mentally retarded or mentally incapable participants or patients may not be capable of giving their consent. Consent from the legal guardian is essential in these cases.The validity of consent is liable to be questioned if the participants or patients are under the influence of alcohol or drugs or suffering from extreme pain.
3. Knowledge
   The pivotal points of the matter regarding the consent are
   a. Nature of diagnosis
   b. Nature of treatment planned
   c. The foreseeable risk involved in the treatment.
   d. Prognosis, if treatment is not carried out.
   e. Any alternative therapy available.

A doctor must disclose all these points to the patient, so that patient may exercise his right to self-determination about the proposed course of treatment.

Consent is based on the basic principle of inviolability of the person, that is, the right at all times, of every individual not to have his body tempered with or without his permission or agreement, and to be the whole decision-maker on matters that affect his physical integrity. This right is not absolute and it may be abrogated by the state of health or judicial reasons in exceptional circumstances or the person may not be in a position to exercise as in case of unconsciousness or because of mental disability.

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