

Informed are the ethical and moral right of

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Informed consent is a relevant aspect of the process where the participant understands and agree for a study . The informed consent process need to fulfill two main objectives which are the ethical and moral right of autonomy, freedom of choice and the legal authorization for a study. It is not only a legal and ethical concern but a core factor in decisional process. Humans need to be treated as autonomous entities, who are carefree to conduct their lives without other party controlling their life.

subjects are treated as autonomous agents in a study if researcher has informed them about the study, giving them choice to choose whether to take part , and allow them to refuse from taking part in the study, any time with no penalty (Levine, 1986). Informed consent is an important tool before begin a study using human as their subjects . Taking consent involves process of notify the subject about important things such as introduction of study process, statement of the study, purpose, description of risk anddiscomforts , selection of research subjects, explanation of procedures, description of benefits, disclosure of alternatives, assurance of anonymity and confidentiality, offer to answer question, voluntary involved in the study, option to retreat and consent to incomplete disclosure for some studies.

By doing so, taking part and involvement of the subjects in the study is voluntary. There are several issues related to informed

consent regarding research involving human subjects. There is an issue with subjects that having diminished autonomy where they are vulnerable because of legal or mental incompetence, terminally ill or confinement to an institution such as prisoners (Levigne, 1986). These subjects require additional protection of their right to self-determination because of their inability to give informed consent.

Furthermore, these people are exposed to coercion which happens when someone intentionally presents an overt threat of harm or an excessive reward to another to obtain compliance. When a study involved a younger generation under the age of 18, consent has to be obtained from parents or caretakers. Often a child's competence to give consent is operationalized by age, with incompetence being irrefutable up to age 7 (Broome, 1999).

The U. S Department of Health and Human Services (DHHS) regulations require "soliciting the assent of the children and the permission of their parents or caretakers. During a study, the children need to be given a choice to ask questions and to withdraw from study if he or she desires. Language barrier is another issue involving informed consent. Misunderstandings and misinterpretation of information can happen because of incorrect or inadequate language translations.

According to Department of Health and Human Services regulations of US, to protect the human rights, it is mandatory that informed consent information be presented "in language understandable to the subject" and, in most situations, that

informed consent be documented in writing. Subjects who cannot speak English must be presented with a consent document, written in a language that they understand. The purpose of clinical research is to develop and establish knowledge to improve health which valuable to society. Clinical research ethics is about norms, values, right and wrong, good and bad, and what should and should not be done in the context of clinical research. Investigators are responsible for research ethics to ensure that there is no potential for exploitation and /or abuse of human research subjects. Two significant events that have contributed to the development of research ethics; a.

Nazi experiments and Nuremberg Trial 1946, b. Tuskegee Syphilis study. The Belmont Report 1979 has introduced 3 fundamental ethical principles that is now widely accepted.

They are 1. Respect for person 2. Beneficence and non-maleficence 3.

Justice. 1. Respect for person Trial subjects must continue to be treated with respect from the time they are enrolled, throughout their participation and after their participation ends. Respecting trial subjects means; the subjects will be informed of all aspects of the research that are relevant to the subject's decision to participate (informed consent); to protect their confidentiality and privacy; provide opportunity of early withdrawal without penalty; monitor subject's well-being during and after trials; inform subject of new information and re-consent if necessary; inform subject of study results; compensate subject for research injury; all clinical trial information

should be properly recorded, handled and stored; medical records and study data of subjects must confidentially protected.

2. Beneficence and non-maleficence Experiments need to be started and continued only if the benefits are expected to justify the risk. The assessment of risks and benefits of the research lies on the responsibility of International Review Board (IRB) Independent Ethics Committee (IEC) and investigator before embarking on a research. In order to gain interest of science and society, they must important things are to consider on the rights, safety and well – being of the trial subject.

Medical physicians or qualified medical personnel should hold the responsibilities in giving medical care and medical decisions made on behalf on the trial subjects. All trials must have scientifically protocols to ensure research outcomes are accurate and reproducible, there must be adequate preclinical and clinical information, research conducted following and IRB approved protocols and the investigational product must be manufactured and used according to Good Manufacturing Practice (GMP). 3. Justice Trial subjects should be fairly selected.

The selection of subject must be consider of inclusion and exclusion criteria, target group as well as how to approach them. Furthermore, the selection requires a clear scientific objectives of the study and not vulnerability, privilege, efficiency or other factors unrelated to research purposes. Groups of trial subjects must be targeted especially for risky research or research without benefits, just because they are convenient or vulnerable.