

**Protection Code Of Human Subject
in Medical Research**

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- 1.In all medical research involving human subjects, we must obtain informed consent. In interventional research, written informed consent is necessary.
- 2.We must not limit human subject's right,or make risk for them. Concern for the interests of the subject must always be prevailed over the interests of science and society.
3. If the informed consent be taken under force, threat, allure or temptation; it would be illegal and if the subject harms, the investigator is responsible for.
4. If the subject is in a dependent relationship to investigator, the reason for the subject selection must be approved by the ethical committee.
5. In any research involving human subject, the subject must be adequately Informed of the aims, methods, anticipated benefits and potential risk, and the duration of investigation. Also the investigator must answer subject's questions related to the research.
6. In medical research, all diagnostic and therapeutic sources must be available and if there is any injury/damage/impairment, compensation must be made.
7. The way of publishing research report and result, should be concluded all research element's rights.
8. The investigator should assure the human subject that he could leave the study at any time he prefers. The investigator must inform the subject of any risk of leaving the research.
9. If information provided to the subject may cause any bias for the study, any withdrawal of information from the subject, must be presented to the ethical committee.
10. The investigator personally is responsible for research information to be provided, including when another person does it.
11. It is illegal to make human subject participate in medical research without providing him or her the research information, unless he or she refuses from receiving the information.
- 12.In clinical trial research that we need case and control groups,the investigator must inform the subjects that may be selected in one of those groups randomly.
13. In therapeutic research the magnitude of risk should not exceed that of benefits. The measurement is up to ethical committee after consulting with related expert professional.
14. In non- therapeutic research, the risk must not exceed the everyday risk which subject may be faced.
15. Being practical, easier, faster, cheaper and so on, can not explain the exposure of human subjects to any risk.
16. Ethical committee should make sure that subjects who suffer from social disadvantage (low socialclass, being poor...) are aware of the risk they may be exposed in the study.
17. All data from human subject must be kept as confidential, except where disclosure is otherwise required by law.
18. In studies that the subject doesn't know the kind of used drug, the investigator should let the subject or his/her physician know the related data when emergency.

19. Any body damage and financial loss caused by a research for the subject, must be compensated according to current rules.
20. Carrying out any research against the religious or social values are illegal.
21. In equal situations if we want to select prisoners, special groups (minors, the mentally retarded, the demented, psychotic patients and foetus) from one hand and the rest of the society on the other hand as "subject", the ethical committee is responsible for the preferred selection.
22. In human experimentations which their result belong to the prisoners, could be done when their informed consent is obtained.
23. We can not prefer the prisoners' participation in a research because of their special situation (including accessibility). Meanwhile they must not be deprived of the benefits.
24. Minors, the mentally retarded, the demented and psychotic patients, could participate in human research only when necessary and their parents or legal guardians sign the informed consent. If the competent subject during the research becomes demented or psychotic, the last informed consent should be cancelled and it must be obtained from his/ her legal guardian. Also when these subjects become competent during doing research, a new informed consent must be obtained from themselves.
25. Doing non- therapeutic research on foetus is forbidden. Doing therapeutic research on foetus is permissible when it is beneficial for it and/ or its mother and also no harm is exposed to them. Obviously obtaining written informed consent from the mother and the legal guardian of the foetus would be necessary.
26. Doing research on aborted foetus is allowed when necessary and legal measurements are considered