Ethical guidelines for research on pregnant women and neonates

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١. From a scientific view, research projects should be right and rational. It is necessary to perform preclinical studies on pregnant animals and also clinical studies on non-pregnant women in order to get some information about probable risks of research.

٢. If the study has direct benefit effect for fetus, informed consent should be obtained from both parents. If the father is not available or competent, there is no need for his consent.

٣. No financial encouragement or compulsion should be taken for pregnancy termination.

٤. In cases where neonate survival is not clear, the fetus should not be involved in the study unless:

a. The ethics committee determines that the study may increase neonate' survival and risk probability is the lowest. The goal of the study is to obtain important medical information which is not accessible by other methods and there is no further risk for neonate's participation.

b. Informed consent should be taken from both parents and in case of unavailability or incompetency of one of them, the other one's consent is enough. In case of unavailability or incompetency of both parents, the legal guardian's consent in needed for participating in therapeutic projects but in case of non- therapeutic projects, the neonate may not be enrolled.

٥. Neonates without hope of living can be enrolled in research under all of the following conditions:

a. The researcher is not allowed to keep the neonate alive by mechanical ventilation just for the sake of research.

b. The research should not halt the heart or respiratory function of the neonate.

c. Advancing medical knowledge is not accessible from other methods.

d. Informed consent should be taken from both parents otherwise, one is enough.

٦. Research projects which have to be conducted after delivery on placenta, dead fetus, fetal remnants, cells, tissues or organs, must be approved by legal civil authorities.

٧. If the record and report of the results of studies on placenta, dead fetus, fetal remnants, cells, tissues or organs, lead to recognition of parents, those are known as study participants and all of medical ethics issues must be considered for them.

٨. Delivery time is not a proper time for concentration, so informed consent must not be taken at this time.

٩. In exceptional cases in which giving information before consent is not possible, the ethics committee should evaluate the condition.

١٠. Parents should be informed if research causes some changes in routine examination and treatment plans of pregnant women, the separation process of neonate from mother, or changes in neonates' examination, follow up or treatment.