

# Protection of Human Subject

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## EXECUTIVE SUMMARY

*Human subjects research history has always tried to strike a balance between science & safety of research subject. The way of carrying out most experiments in the traditional manner, development of test in most cases were tragic thus needed a lot of morality. Research in contemporary times is guided by principles of autonomy, justice & beneficence that create dignity, inclusion & protection of research subjects. This is no longer the case as it is now the people as the research partners & not the objects of inquiry. However, rapid technological growth & global collaborations present new moral challenges. Emerging domains (genomics, artificial intelligence & data science) have difficult questions that present privacy, consent & equity problems. Those issues imply that there is a need to have hard & yet flexible laws that would enable people to be secured & inventions to be improved. Ethical research does not just establish a knowledge, but also trust, dignity, & ethical responsibility of the society in such a way that science is built in a responsible manner to serve people & society.*

# 1. INTRODUCTION

In medical research, there would not be medical advancement without human beings. It is the largest percentage of the medicines, treatment, procedures undergoing which had been previously experimental because of the experimentation on the human population. Vaccine, imaging technology and bone marrow transplants are some of the examples of the innovations that begin as an experiment and become the normalcy. But there is the dark history of inhumane experiments on human beings that do hold those exploited, abused or even de-dignified in the name of science. The consequences of ethical neglect in cases of failure to be extremely alert of ethical practices in research are quite punitive as indicated in the case of the Nazi medical test, and the Tuskegee Syphilis Study. It is these atrocities that brought about the universal tenets of respect, beneficence, justice and autonomy as the principle of research ethics (Bertholf, 2001; Manton et al., 2014; Xu et al., 2020; Sng et al., 2016; Felzmann et al., 2014).

Medical research did not get under the extremely restrictive scrutiny until later, when the time had passed, the World War II had elapsed. With the demonstration of the free consent, the force is barred by the Nuremberg Code of 1947. This was to be supplemented by the reference of Helsinki (1964) that entails the culpability of the doctors, the well-being of the patient, and the reduction of harm than good. These theories became incorporated in Belmont Report (1979) of the U.S and became the foundation of the institute review boards (IRBs). The theories transformed the paradigm of researches to the participant centred approach founded on rights and well-being (Levine et al., 2004).

It has the issue of dealing with the vulnerable groups. The vulnerable individuals might be characterized as children and prisoners who were economically disadvantaged in the past and such an approach would be likely to lead to the development of the problem of stereotyping. The challenge of the current generation of authors and ethics boards is to discover the trade-off between the indisputable autonomy and the extreme generalization (Levine et al., 2004). One of the most important protective issues can be referred to as informed consent since the participants of the study were the subjects of the study in a voluntary manner at the moment when the concept of the purpose and risk, advantages, and other opportunities were elucidated to them. This must be existent and culture aware and possessed. Nonetheless, the intervention of the vulnerable groups is an ethical peculiarity in that an emergency does not always give the parties the opportunity to negotiate (Manti & Licari, 2018; Parija & Mandal, 2014; Gupta, 2013).

The question of whether science should be held back or hard ethics is not new. The other ones narrate that life-saving procedures were gained following the risky experiment and the other ones narrate that the professional duty can guarantee the

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