Assessment 1: Protecting Human Research Participants

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Introduction

In biomedical research, the ethical issues of the use of human subjects have always been under discussion, as many ethical guidelines are based on incidents or research that has violated the human subject causing distress in them. participation of humans in any research has always presented many challenging ethical dilemmas, such as, a person may participate in a study of no benefit and no substantial risk or getting involved in a study with many potential risks or significant benefits (Kapp 2006). Therefore, it mainly represents an ethical dilemma of whether to use human subjects or not. In the nursing world, a similar dilemma has put forward the fundamental ground of many ethical codes. Clinical nurses, always s has a unique position to support the research on the impact of interventions, symptom management, education as well as treatment adherence plan in patients (Breault, 2006). Nursing studies and biomedical research has mostly been based on the outcome of unethical research subjected to human participants such as the Nuremberg Code or Declaration of Helsinki, thus, highlighting how the experimentation in the nursing field emerged issues that were not thought through before and helped in paving ethical standards of conducting researches in the current times while providing ways to minimize the unethical researches and being cognizant while working with human subject participants (White, 2020). This paper is based on the historical development, ethical responsibilities, and legal consideration of the research that involves human participants. The study aims at understanding how historical development has paved the way for ethically responsible research while promoting and elevating the standards of the research communities.

The fire of developing the guideline for the protection of human participants ignited to form controversy over the egregious abuse of human subjects at the hands of research in the famous Belmont Report (1979), providing contemporary regulation designs for the use of human subjects in research. From the late 19th century, the focus of the research drastically

shifted to the participation of groups and communities in research associated with AIDS. As the research progressed, new voices and scientific challenges begin to highlight forcing us to reinterpret the Belmont Report. Gostin (1991) expended the ethical principles of respecting the participants, beneficence (Not to cause harm), and justice to the participating groups and communities. Similarly, Weijer (1999), added another ethical obligation of the "respect of communities", demanding researchers to be aware of the cultural and communal sentiments of individuals to increase the vulnerability while supplementing the atomistic view of the person (Quinn, 2004). This ethical principle acknowledges the dignity and freedom of every person and supports the requirement to obtain informed consent before involving any human in research which addresses one's ability to volunteer the participation independently and autonomously in the study while supporting the mandate that an individual has been fully informed regarding the procedure, risk, benefits, and their rights in the particular study (Mick, 2019). In today's world, this protects human subject as they voluntarily participate and know that they can withdraw or behold any information they think is private and does not want to share. Thus, these rules in the modern era respect one's personal space and justice.

Similarly, the Nuremberg trials (1949-1953), were based on the unethical research performance by the Nazis on the war prisoners during World War II. Through which the ethical codes involving human subjects such as a person being able to freely volunteer for research participants now known as Informed Consent which was supposed to be written in an appropriate reading level and language for the human subjects being involved in the study. Similarly, today's law requires consent forms providing the human participants the complete know-how of the study's intent and procedure. Informed consent has become one of the most essential parts of the study which concisely guide the participant regarding the time that is going to be invested, procedures, confidentiality, potential risk and benefits of the study, giving complete transparency to the participants along with the right to withdraw or behold

any information they feel to while including an ending statement that states that the participation is voluntary after reading and discussing the research (Mick, 2019). This has given rise to the Declaration of Helsinki (1961) and Good clinical Practice guidelines to develop to provide future researchers the ability to behold ethical obligations.

The research world is largely expanding through every domain. Most of the nursing research that requires human subject involvement is mostly drug trials, internet surveys about alcohol consumption, studies based on deception, research on risk-taking behaviors and attitudes, and open-ended interviews that may contribute to the information that may be generalizable. Mostly human research involves human participation when a significant drug, material, or device has to be introduced, or studies that are based on bodily materials or based on human physiology however, the research based on the human subject requires review and approval by the institutional review board through a systematic investigation of the necessity of using the human subjects. Most of the research in such domains is based on intervention including physical procedures or biospecimens that may lead to substantial findings. Significantly, the studies should be aligned with the ethical.

Research-based on human subjects has always been significant to the research world highlighting significant information regarding humans and how different biospecimens-related information changes the context of the biomedical world. Thus, the International Review Board has the primary responsibility of catering to the human subject's welfare and rights to ensure accurate findings while protecting individuals form any unwanted or permanent harm (*Human Subjects Research Determinations | Human Subjects Office*, n.d.). Mostly these international review boards are institutionalized to avoid risk. They are responsible for reviewing a research protocol to assess the balance of benefits and risks, and to ensure that the risk to subjects does not outweigh the benefits. However, it is evident that risk is unavoidable but for sure can be managed or reduced. Therefore, the safety of human

subjects in research is based on addressing the categories of risk exposure and how they can be minimized. Such as, while developing the protocol sometimes, nurses mistakenly assume that there will be no potential risk to the research, but, to minimize any risk there should be an awareness that all the research studies have some level of risk and the nurses should provide complete information in the protocol regarding the procedure and the scientific rationale while using the procedures that are consistent with the research design and does not expose the participant to risk (Mick, 2019). For an instant, to minimize the risk and to provide adequate safeguards for the confidentiality of information such as developing a plan for managing the data. Similarly, other risks can be minimized by providing additive care to the study participants, making sure that drug impact is not lasting and if it is, proper medical or physiological help should be provided to people to take responsibility for the research outcomes and help people who played a role in providing the significant findings.

Moreover, the nursing population needs to understand that research has different procedures, goals, and ethical considerations. Therefore, developing a plan and having an awareness that risk may befall, provides an edge in pre-planning risk management. Furthermore, when dealing with a vulnerable population such as pregnant women, minors, Prisoners, differently abled, or old age people, it is important to re-evaluate the risk before involving them in research. Thus, minimizing the risk and optimizing the benefits is usually conducted by involving them in early or late trial phases, soliciting vulnerable subjects, and utilizing them in rather subjective studies than biomedical studies. For instants, studies based on personal care or hygiene have less risk as compared to involving pregnant females in new medicine that may become harmful to the fetus. Research involving the vulnerable population should adhere to the Federal regulation of research that identifies that all research proposals involving human subjects should be based on the ethical and approved principle of IRB (Mick, 2019).

In conclusion, throughout history, the need for ethical obligations raised through unethical research enlightens future researchers to develop ethical obligations that protect human subjects while being in the research. Informed consent was developed through the Nuremberg trails, which highlighted the importance of giving humans free will to whether they want to participate or not. The Belmont Report highlights the importance of beneficence, justice, and respect for the person. It helps researchers and nurses to understand that informed consent and privacy as two basic tenets of the research protocol that ensure protection and association for participants and the researcher.

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