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Principals of Research Ethics

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ABSTRACT

The horizons of medical research has increased greatly during the current decade, motivated by the need to improve health. As medical research involves human participants, research fundamentally needs to be guided by ethical principles to ensure the protection of participants rights, integrity and welfare. In addition, international standards mandate the review of research by Research Ethics Committees. Thus it is a necessity that the researchers should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable to international requirements. The inception of ethical guidelines which primarily includes Nuremberg Code (1948), Declaration of Helsinki (1964), Belmont report (1979) and Council for International Organizations for Medical Sciences (CIOMS) can be traced back at the time when Nazis did atrocious human experiments at the time of II World War and Tuskegee syphilis study. Despite the availability of these guidelines violations of the rights of research participants continue to occur in both higher and lower income countries. According to consciences the research ethics are basically guided by four pillars which are regarded as: respect for the individual; beneficence, non-maleficence and justice.

Keywords: ethical principles, human participants, consent, research.

Introduction

Research ethics pertains to anyone who is involved in conducting scientific research. Knowing what constitutes ethical research is important for all researchers including students and professionals who work in the field, work in a Lab, or work with animals or human subjects. They should be familiar with the basic ethical principles and have up-to-date knowledge about policies and procedures designed to ensure the safety of research subjects and to prevent sloppy or irresponsible research, because ignorance of policies designed to protect research subjects is not considered a viable excuse for ethically questionable projects. Therefore, the duty lies with the researcher to seek out and fully understand the policies and theories designed to guarantee upstanding research practices (http://www.ushmm.org/research/doctors/Nuremberg_Code.htm). Research ethics not only provides guidelines for the responsible conduct of biomedical research but also ensure a high ethical standard (http://ohsr.od.nih.gov/helsinki.php3).

"Research misconduct" is the process of identifying and reporting unethical or unsound research" according to United States' Office of Scientific and Technology Policy (OSTP) (2000). Research misconduct includes not only fabrication, falsification in proposing, performing, or reviewing research, or in reporting research results, but also include plagiarism. **Fabrication** is making up data or results and recording or reporting them. **Falsification** is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit (http://www.ostp.gov/html/001207_3.html).

Research misconduct can also be the result of mistaken, negligent, unintentional, lazy, or sloppy research practices. In these instances of research misconduct, the use of outside research evaluators (like the IRB) and the process of peer review helps to maintain and safeguard scientific integrity (Schachman, 1997). The issues concerning research with human subjects involve topics ranging from voluntary participation in research to fair selection and justice. This variety makes the topics surrounding research ethics with human subjects a challenging but important charge.

The birth of modern research ethics began with a desire to protect human subjects involved in research projects. The first attempt to craft regulations began after the Doctors Trial, 1946-47. That was a segment of the Nuremberg Trials for Nazi war criminals. 23 German Nazi physicians were accused of conducting abhorrent and torturous "experiments" with concentration camp prisoners being crippled, and murdered in the name of research (http://ohsr.od.nih.gov/helsinki.php3). That is why the Nuremberg Code was developed with a list of ethical guidelines for the conduct of research. The Nuremberg Code consisted of ten basic ethical principles that the accused violated that include (http://ohsr.od.nih.gov/mpa/belmont.php3):

1. Research participants must voluntarily consent to research participation
2. Research aims should contribute to the good of society
3. Research must be based on sound theory and prior animal testing

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4. Research must avoid unnecessary physical and mental suffering
5. No research projects can go forward where serious injury and/or death are potential outcomes
6. The degree of risk taken with research participants cannot exceed anticipated benefits of results
7. Proper environment and protection for participants is necessary
8. Experiments can be conducted only by scientifically qualified persons
9. Human subjects must be allowed to discontinue their participation at any time
10. Scientists must be prepared to terminate the experiment if there is cause to believe that continuation will be harmful or result in injury or death.

The Nuremberg Guidelines paved the way for the next major initiative designed to promote responsible research with human subjects, the Helsinki Declaration. It was developed by the World Medical Association and has been revised and updated periodically since 1964, with the last update occurring in 2000 (www.research.umn.edu/curriculum). ***The Helsinki Declaration*** contains all the basic ethical elements specified in the Nuremberg Code but then advances further guidelines specifically designed to address the unique vulnerabilities of human subjects solicited to participate in clinical research projects including (www.icmje.org):

1. The necessity of using an independent investigator to review potential research projects
2. Employing a medically qualified person to supervise the research and assume responsibility for the health and welfare of human subjects
3. The importance of preserving the accuracy of research results
4. Suggestions on how to obtain informed consent from research participants
5. Rules concerning research with children and mentally incompetent persons
6. Evaluating and using experimental treatments on patients
7. The importance of determining which medical situations and conditions are appropriate and safe for research.

Following the Helsinki Declaration, the next set of research ethics guidelines came out in the ***Belmont Report of 1979*** from the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The report outlines:

1. The ethical principles for research with human subjects
2. Boundaries between medical practice and research
3. The concepts of respect for persons, beneficence, and justice
4. Applications of these principles in informed consent (respect for persons), assessing risks and benefits (beneficence), and subject selection (justice)

The Nuremberg, Helsinki, and Belmont guidelines provided the foundation of more ethically uniform research to which stringent rules and consequences for violation were attached. Governmental laws and regulations concerning the responsible conduct of research have since been developed for research that involves both human and animal subjects (www.icmje.org). Although there is consideration debate about the theoretical basis of morality with lots of ethical dilemmas, a number of principles and the concepts derived from them are commonly accepted and taken into account. Principles are basic ideas that serve as starting points for both understanding and working through problems (American academy of pediatrics, 2001). Ethical principles are guidelines that can apply to situations to decide whether they are moral or immoral in practice as they can direct or govern actions (Beauchamp & Childress, 2001). They include:

The principle of autonomy recognizes the rights of individuals to self-determination with respect for individuals' ability to make informed decisions (Jordan, 1998). Competent individuals have the right to choose actions consistent with their values, goals, and life plan, even if their choices are not in agreement with the wishes of family members or the recommendation of the physician. **Informed consent** exists to ensure that all research involving human subjects allows for voluntary participation by subjects who understand what participation entails and the concept of consent arises from the ethical principle of autonomy and basic human rights. Informed consent means that people approached and asked to participate in a research should be fully-informed about and understand the potential benefits and risks of their choice study must: a) know what they are getting involved with before they commit; b) not be coerced or manipulated in any way to participate; and, c) must consent to participate in the project as a subject (Engelhardt, 1996).

The Belmont Report of 1979 outlines the three requirements for informed consent. The first requirement is that information disclosed to research participants must include, "research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research" (http://206.102.88.10/ohsrsite/guidelines/belmont.html). The second requirement for informed consent is comprehension. The concept of comprehension requires researchers to adapt information to be understandable to every participant. This requires taking into consideration different abilities, intelligence levels, maturity, and language needs. Finally, the third requirement for informed consent is **voluntariness**. Informed consent can be neither coerced nor improperly pressured from any participant (http://206.102.88.10/ohsrsite/guidelines/belmont.html).

Beneficence is a principle used frequently in research ethics. It means, "doing good" (Churchill, 1995)." Biomedical research strives to do good by studying diseases and health data to uncover information that may be used to help others. While research findings may one day help do well, they may also cause harm to today's research participants. Researchers must never subject research participants to more risk than necessary, be prepared to cease research if it is causing harm, and never put participants at a level of risk disproportionate to the anticipated benefits (Churchill, 1995). Some scholars, such as Edmund Pellegrino, claim that beneficence is the only fundamental principle of ethics (Veatch, 1981). It requires that the procedure be provided with the intent of doing well for the individuals involved. Demands that researchers develop and maintain skills and knowledge, continually

update training, consider individual circumstances, and strive for net benefit (Engelhardt, 1996).

The concept of non-maleficence is embodied by the phrase, "first, do no harm". It is not only more important to do no harm than to do well; it is also important to know how likely it is that your treatment will harm. So the principle of non-maleficence is not absolute, and must be balanced against the principle of beneficence (Pellegrino & Thomasma, 1988).

Privacy and confidentiality are very important components for research involving human subjects. People have a right to keep information about themselves private. The information gathered from people in biomedical studies has a unique potential to be particularly embarrassing, harmful, or damaging. Confidentiality involves a respect for autonomy and also beneficence towards the patient and a desire to act non-maleficently. Confidentiality is not an ethical principle in itself. It can be characterized as a duty by some health professionals (Quill & Brody, 1996).

Principles that should be followed on allowing breach of confidentiality (Siegler, 1982):

- It must be to proper authorities.
- Not beyond what is required or relevant.
- Reason for disclosure must be documented in the medical records.
- Patients are informed about such disclosure.

The principle of justice means fairness is the basis for the obligation to treat all patients equally and fairly. Justice is the foundation for decisions about resource allocation throughout a society or group (Ahmed, 2005). Provision of treatment should not be based on sex, age, race, and socio-economic status, religious or cultural background. Unfortunately, resource limitations and distributions constrain society's ability to do all that is necessary for every person. The principle of justice is not easily applied and does not provide specific guidelines by which to measure equality (Gibbard, 1982).

Veracity means truthfulness (neither lying nor deceiving others). Deception can take many forms: international lying, non-disclosure of information, or partial disclosure of information (Sterba, 1998).

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