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HUMAN PERSON IN EXPERIMENTATION

Ethical Issues and Concerns

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1. Introduction

Advances in biomedical science and technology and their applications in the practice of medicine are a cause of anxiety among the public at large. The society is confronted with a number of ethical problems due to the abuses committed in scientific investigation and biomedical research. The methodology of biomedical research is itself a cause of concern and fear for the society at large. The researchers test their hypotheses by experimenting on animals. However, to be clinically useful, experiments must be performed on human persons and this entails some risk to the subjects. Although biomedical research may cause some risk to its subjects, it is said to be largely beneficial to the subjects as well as the society at large.

'Research' means an inquiry or examination or a critical and exhaustive investigation or experimentation which aims at discovering and interpreting new facts. However, 'biomedical research' refers to health-related research which aims at the advancement of the goals of medicine. While defining research, the Declaration of Helsinki reads as follows: "The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the etiology and pathogenesis of disease..."[1]

Concern for the interests and wellbeing of the human person must always prevail over the interest of science and society. The physician can conduct research with the aim of acquiring new medical knowledge only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient. The physicians who engage in research projects involving human persons should take care to see that the hazards involved do not outweigh the potential benefits.

The history of human experimentation is as old as that of medicine itself: "... man is an inveterate experimenter, and man has been the chief

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[1]Dianne N. Irving, "Biomedical Research with 'Decisionally Incapacitated' Human Subjects: Legalization of a Defunct Normative Bioethics Theory," www.all.org.

experimental animal both as experimenter and as subject."[2] The central fact of any human experimentation is that one person is being used as a means for the benefit of others. This poses an ethical dilemma. It is necessary to distinguish between beneficial experimentation and non-beneficial experimentation. Beneficial or therapeutic experimentation is that which benefits the human subjects. However, non-beneficial experimentation aims at the advancement of knowledge and not improving the subject's condition. Experimentation enables medicine to yield better means of preventing illness, diagnosing diseases and therapy. However, the "do not harm" rule should be followed when the human person is made a subject of the experiment.

2. Basic Requirements for Experimentation Involving Human Persons

There are three basic requirements for experimentation.[3] Firstly, experiments should be conducted on non-humans, namely, animals. It is only later on that the research can be conducted on human persons, provided the required conditions like taking informed consent, etc., are met. Secondly, the experiment should involve proper scientific and medical procedures. Thirdly, the experiment should be undertaken by scientifically qualified persons.

Besides these scientific requirements, certain ethical requirements must also be met. Firstly, an assessment has to be done of the foreseeable risks as well as benefits to the human persons and the society at large and science itself. It must be seen that the benefits outweigh the risks. The most important requisite of experimentation is that the voluntary and informed consent of the person subjected to research must be obtained. Research activity requires that there should be a healthy relationship between the investigator/researcher and the participant/subject. The National Committee for Ethics in Social Science Research in Health (NCESSRH), India, has succinctly put it: "Participants should be seen as indispensable and worthy partners in research."[4]

Paul M. McNeill points out that the "history of unethical experimentation is an appalling account of 'man's inhumanity to man'.

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[2]Gert H. Brieger, "Human Experimentation: History," in Warren T. Reich, ed., *Encyclopedia of Bioethics*, New York: The Free Press, 1978, 2:684.

[3]Alexander M. Capron, "Human Experimentation: Basic Issues," *Encyclopedia of Bioethics*, 2:696.

[4]Amar Jesani and Tejal Barai-Jaitly, eds., *Ethics in Health Research: A Social Science Perspective*, Mumbai: Centre for Studies in Ethics and Rights, 2005, 44.

One of the commonalities across many of the experiments ... is an attitude of superiority in the experimenters towards their human subjects."[5] It is mostly the socially powerless and disadvantaged who are subjected to unethical research. Besides the superiority element, the researchers are indifferent to the risk of harm or deliberate infliction of harm on others. In this context, Macfarlane Burnet holds that "any group of men directly concerned in the success of an enterprise will be inclined to minimize the danger and to resent any safety precautions which will impede the enterprise."[6] In the context of research, the outcome of the project is more important than the risks of harm to the lives of the persons involved. The scientists should not be allowed to conduct experiments on human persons without adequate protective measures.

3. Ethical Principles of Human Experimentation

As per the Belmont Report, all research involving human subjects should be conducted in accordance with three basic ethical principles, namely, respect for person, beneficence, and justice. "Respect for persons ... incorporates at least two basic ethical convictions: first, that individuals should be treated as autonomous agents and, second, that persons with diminished autonomy are entitled to protection."[7] In practice, the respect for autonomy translates into the requirement of informed consent. In order to respect research subjects as persons, investigators must obtain their informed consent. Those who are dependent or vulnerable must be given security against harm or abuse. For example, children lack maturity and independence and, hence, are not regarded as autonomous. Sometimes an injury or illness may reduce one's capacity to make autonomous decisions. Hence in such cases, the subjects should be given protection.

The second principle of research ethics identified by the Belmont Report is the principle of beneficence. This principle gives rise to two obligations: 1) Non–malfeasance or do not harm. Non–malfeasance extends beyond physical harm to include protection from psychological, social, and economic harm. 2) Beneficence or maximize possible benefits

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[5]Paul M. McNeill, *The Ethics and Politics of Human Experimentation*, Cambridge: Cambridge University Press, 1993, 35.

[6]McNeill, *The Ethics and Politics of Human Experimentation*, 36.

[7]P. Boleyn-Fitzgerald., "Experimentation on Human Subjects," in F. G. Frey and C. H. Wellman, eds., *A Companion to Applied Ethics*, London: Blackwell, 2003, 413.

and minimize possible harms. The investigators should prevent harm, remove harm and promote good.

The final principle is the principle of justice. Justice refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. In the context of research, this principle refers to distributive justice, which requires the equitable distribution of both the burdens and benefits of participation in research. As justice is "rooted in ideas of 'fairness and desert'; people should be treated fairly and disinterestedly, and should be given what they deserve in the sense of what they have earned."[8] The primary application of the principle of justice to human experimentation has been in the area of subject selection. Historically, human experimentation has drawn people from socially and economically disadvantaged background. The abuses of patients have occurred mostly among the poorer patients with low status. The selection of subjects should be fair both to individuals and to the classes in society. As a principle of social justice, there should be preference for using some classes ahead of others. For example, in most cases adults should be used as subjects of research rather than children. Prisoners and mentally infirm persons should be avoided as subjects of research. They could be involved in research only if the research is directly related to their conditions or there are no alternative people who could serve as subjects.

These three principles outlined in the Belmont Report provide a framework for resolving ethical issues. These principles are incorporated in government regulations, professional codes and theoretical models. These principles were significant in terms of protection of the human subject. Respect for persons focused on informed consent so that individuals are protected from coercion, fraud, etc. Beneficence protects individuals from unwarranted risks. Justice focuses on protection of persons from exploitation. These principles constitute a protective ethic and help in preventing the abuses perpetrated in the name of scientific advancement.

4. Significance of Informed Consent

For all types of biomedical research involving human persons, one of the most basic requirements is to obtain the informed consent of the prospective human subject or, in case the human person is not capable of giving informed consent, the proxy consent of a properly authorized

[8]McNeill, *The Ethics and Politics of Human Experimentation*, 148-9.

representative. 'Informed consent' is treated as "infallible dogma in biomedical research ethics."[9] It is the consent given by a competent individual after receiving the relevant information from the researcher. He should have understood the information and then arrived at a decision to participate in the research out of his own free will and not due to any coercion or influence or inducement.

The foremost grounding for seeking consent is the ethical principle, "respect for persons." Informed consent protects the person's freedom of choice and respects his autonomy. This principle ensures that the person is treated as an 'end' and not as a means to another's end. The requirement for seeking consent also has a religious basis. The Judeo-Christian tradition affirms that "each human life is a gift from God and is of infinite and immeasurable worth... The infinite worth of the individual requires that persons treat each other with respect and not interfere in each others lives without consent."[10]

Consent obtained by the researcher is valid only if (1) the person is competent to consent, (2) the consent is not under coercion, and (3) the consent should be informed, namely, the person who is the subject of research should be provided with the relevant information about the research to be conducted and this information has to be understood by the subject before giving his consent. Consent may be indicated in a number of ways. The consent could be expressed orally or in writing, that is by signing a consent form. As a general rule, the person should sign a consent form or, in case he is incompetent to do so, by a legal guardian or other duly authorized representative.

Before obtaining the person's consent to participate in research the researchers should provide the subject or person with the following information either verbally or in writing in the language that he or she is capable of understanding:

(1) The goal and objective of research should be explained.
(2) Names and addresses of researchers, institutions and the main person of the ethics committees / ethical review board should be provided.
(3) Reasons or methods for selecting the particular locality or community or individual or groups for participating in the research must be revealed.

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[9]Justine Burley and John Harris, eds., *A Companion to Genethics*, New York: Blackwell, 2002, 83.

[10]Karen Lebacqz and Robert J. Levine, "Informed Consent in Human Research: Ethical and Legal Aspects," *Encyclopedia of Bioethics*, 2:756.

(4) The possible, anticipated, and potential benefits or harms (direct/ indirect, immediate/long term) of research must be explained.
(5) There must be commitment to maintain privacy, anonymity, and confidentiality of the data obtained from the subjects.
(6) The future possible use of the information and data obtained, like using as a database or recordings for educational purposes, should be made known to the human subjects. However, such use should be anonymous so that the privacy and confidentiality could be maintained.
(7) Persons should also be informed of their right to decline in participating in the research or to withdraw consent at any stage of the research.
(8) The subject and subject's family should be informed whether there will be compensation for any disability or death or injury arising in the process of research.

In some specific situations and research issues, it is not practically possible to carry out research if all the details are revealed to the subjects. If all the details are revealed, there may be difficulties in assessing participants, possibility of affecting change in behaviour or responses of the participants. Hence, it may not be possible to reveal all the information mentioned earlier. In such cases, the following should be done: (1) A detailed justification for not revealing all the information must be provided in the research proposal which has to be reviewed by the peers and ethical committees. (2) The subject's right to privacy, anonymity, and confidentiality must be safeguarded in such cases, as they do not know fully the real purpose for which they are providing the information. (3) Though it may be accepted that some information may not be revealed, the rest of the information should be provided particularly with respect to the physical risks, discomfort, or unpleasant emotional experiences that the subject could face.

The informed consent procedure is, however, significant as it helps in promoting individual autonomy, encourage rational decision making, avoid fraud and duress, involve the public and encourage self scrutiny by the researcher as well as reduce the civil and criminal liability of the researcher and his or her institution. Informed consent safeguards the rights and welfare of the persons. By obtaining informed consent, the subjects "are not being 'used' but instead they... become 'co-adventurers'. The consent requirement, thus, affirms a basic covenantal bond between the researcher and the human subject and ensures respect for the subject as an end, not merely a means."[11] The ideal human subjects, therefore, are themselves researchers.

[11]Lebacqz and Levine, "Informed Consent in Human Research," 756.

Though informed consent is very significant, there are certain class of people like children who are incapable to give their consent. In case research is to be conducted with children as subjects, then proxy consent must be obtained from the parents/guardians; further, in the case of mentally ill persons who are not competent of consenting, consent should be obtained from the person who is the guardian or next friend or like. There are also unconscious, semi-conscious or critically ill patients from whom or on whose behalf consent cannot be obtained for treatment or research.

5. Guidelines Laid Down by Indian Council for Medical Research (ICMR) for Conduct of Research with Human Persons

Ethical guidelines on biomedical research involving human persons were finalized by ICMR in 2000. The general principles, as stated in the document, are that the research must be essential; voluntary and informed consent must be obtained from the person or subject of research. Participants should not be exploited, their privacy must be respected. The risks involved in the research should be minimized. The researchers should be well qualified and competent. These guidelines, however, do not refer to the gender and class inequalities prevalent in India. These guidelines are devoted to ethics of research in genetic testing, organ transplantation and assisted reproductive technology, though there is very little original research in these areas. On the other hand, the frequently researched areas like use of drugs and vaccines are not given much importance. The guidelines do not directly address laboratory based research that makes use of established drugs or procedures, as well as invasive and possibly risky procedures. The codes whether at the national or international level are not sufficient to safeguard research subjects and ensure ethical experimentation. There needs to be some mechanisms for ensuring that the rules stated in codes are adhered to.

In India, it is recommended that the ethics committee should include clinicians experienced in clinical research, an expert on drugs, one or two non-medical persons who could provide guidance to the committee in the matter of ethics and law. These non-medical persons could be a lawyer or a judge. The committees should consist of five to seven members who should meet at least once in every three months. A research ethics committee of one of the research institutes, namely, All India Institute of Medical Sciences considers between forty to fifty research proposals every year. The committee functions in a similar manner as in other countries wherein the

research proposals are reviewed by the members and, subsequently, meetings are held to discuss these proposals. If necessary, the researchers are asked to defend their proposals. There are approximately one hundred institutional ethical committees throughout India. However, these ethics committees function poorly. The committee members do not have training, time or interest to fulfil their responsibilities. The proceedings of committee meetings are kept confidential preventing transparency in functioning. As per the ICMR, many of its affiliated institutions do not have active ethics committees and the ICMR also does not have the infrastructure necessary to monitor their functioning.

Amar Jesani and Tejal Barai-Jaitly[12] have mentioned that the researchers, before taking up any research involving human beings, should ask themselves whether the research is necessary and relevant to the community being studied, whether the researcher is qualified and competent to undertake the research, what are the risks which the subjects may face in course of the research, whether informed and voluntary consent from the subject is obtained. In India, it is found that researchers do not give significance to these issues. Reflection on ethical issues involved in medical research involving human beings is not of serious concern to the researchers. Obtaining informed consent is not given importance. Though informed consent is crucial in research it becomes difficult to obtain informed consent from the poor either because of the literacy level or because they become vulnerable to the need for healthcare. Researchers also do not respect the person's right to privacy and confidentiality. Sometimes in medical conferences and seminars, confidential information is revealed, thus, violating the subjects' right to privacy. Any researcher ought to have follow-up of participants. But it is found that, in India, the researchers do not maintain long term contact with participants. Many times poor Indians cannot benefit from the results of the research undertaken. For example, they cannot afford the drugs being tested on them.

6. Ethical Issues Involved in Human Experimentation

Medical research, which typically begins in a test tube or petri dish, moves on to animal testing, and, eventually, ends in human experimentation. Medicine requires constant experimental inputs to solve problems and

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[12]Amar Jesani and Tejal Barai-Jaitly, eds., *Ethics in Health Research: A Social Science Perspective*, Mumbai: Centre for Studies in Ethics and Rights, 2005, 77-87.

make progress. Most experiments are thoughtfully designed and most researchers desire to do good to the experimental subject. However, during the past century, serious abuses of subjects have taken place. In this context, it is important that researchers who help in the advancement of medical knowledge should be aware of ethical issues involved in research with human persons.

One of the ethically important issues in research is informed consent. The significant question is whether research is unethical in all those cases where consent cannot be obtained. Before answering this question, it is pertinent to see why informed consent is essential in research. Informed consent protects the rights of the human persons and prevents the researchers from using them as pure means to further their own ends.

The basic concern of medical practice was to protect the person and promote his wellbeing regardless of all implications. Biomedical research, however, developed interests sometimes contrary to the medical practice and at times the interest of advancement of medical knowledge at all cost became the credo. Under these conditions physicians involved in biomedicine began to regard patients as 'guinea pigs'. Whether it is Nuremberg Declaration or Helsinki Declaration, the main objective of such documents was to ensure that no exploitation of patients is carried out in the name of experimentation. Even if experimentation is deemed necessary, then informed consent is to be procured. Legislation controlling research and experimentation and institutionalisation of controlling bodies came into existence to ensure that the fundamental objective of medical profession is upheld.

Medicine today is an enterprise pursued by physicians and researchers who develop only transient and temporary relationship with the experimental subjects. It is in this context that patient autonomy and informed consent are seen as 'antidotes' to arrogant researchers and necessary mechanisms for protecting the rights and freedom of the human persons.

While it is argued that persons who are experimental subjects have freedom to participate or not to participate in research, the question whether this freedom is respected in medical research has been debated. In biomedical research this freedom has been threatened and subjects are compelled to assert the freedom as freedom from interference legitimized by informed consent. The researcher is aware of the fact that any research does involve certain risks. As such the researchers in their own interest and for the sake of the human subjects should inform the subjects about the

pros and cons of research. In view of negligence and malpractices in biomedical research, a dire need is felt to protect the human person.

However, in spite of this, consent in the fully informed sense may not always be obtainable. The researcher knows that if the person is always fully informed he may not agree to participate in the research for the sake of the advancement of medical knowledge. If the risks and hazards to the human persons are not very serious and life threatening, then the informed consent need not be obtained. However, this decision should not be left to the individual researcher alone but be decided by a body such as ethical research committee or the like.

Another issue of moral concern is when experimentation is conducted on human beings by giving them financial benefits or payment. Many times the persons or subjects who are exploited are from the lower socio-economic strata. It is these subjects who due to financial crisis agree to participate in the research. It is unethical that medical research which should be carried out for the highest and purest motives is using money to lure people to participate in experiments.

The defenders of the medical research activity hold that experimentation is necessary for the progress of medicine. They argue that the subjects participate in the research of their own free will and even give their consent in writing. They add that the experiments conducted on these human subjects are first conducted on animals. Hence, the actual and possible effects and consequences are known and tested on living creatures.

However, in spite of these arguments, experimentation where human subjects are paid does exhibit a number of morally objectionable features and is, thus, criticized as being unethical. Most of the human subjects are from the economically backward section; hence, the responsibility of medical research and human welfare is not being evenly shared among the people at large. A large section of the society is not involved in the experimentation. Thus, a few persons face the hardships and consequences for the benefit of the society as a whole.

7. Conclusion

Though medicine needs to progress, human person needs protection and care. The researcher should see to it that while discharging his obligation to medical research and human health, the human subject is not exploited and harmed. Research should be conducted on ethical grounds so that the adventure of experimentation becomes a joint venture characterised not by arrogance and domination but respectful co-operation.