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WALKING A FINE LINE: ETHICAL CONFLICTS ANDCLINICAL RESEARCH ON VULNERABLE POPULATIONS

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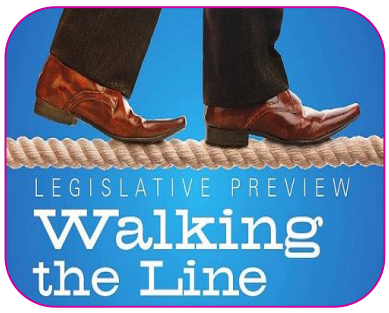
ABSTRACT



Clinical research on vulnerable populations, whose informed consent is problematic, has produced some amazing results. In fact, research in the 19th and 20th centuries has led to medication, vaccinations, treatments and surgery that have extended the average human lifespan.But research is not without controversy, and these improvements are not without a dark side. These developments of clinical research forced us to consider ethical, legal, social and biomedical issues such as: How can we ensure that clinical research on vulnerable populations studies provide the most good to the greatest number of patients? How can we protect vulnerable populations while they are part of a study?The four pillars of medical ethics i.e. autonomy, justice, beneficence and nonmaleficence can be applied to difficult ethical situations in different context of practice and research. Again consequentialism and deontology are the two ethical theories cited to defend different positions in vulnerable populations' research. Kant's principle of respect for persons as autonomous ends-in themselves is at the core of the deontological traditions. On the other J.S.Mill's principle of liberty is at the core of liberal tradition. In this point Nuremberg Code, Belmont Report, Declaration of Helsinki etc. guidelines are important.

The present paper is focused on some ethical requirements to protect vulnerable populations' research subjects, and try to understand why vulnerable populations are used in research and how to ensure that they are treated in an ethical manner and why some people are opposed to using it.

KEYWORDS : *Clinical research, Vulnerable population, , Consequentialism, Deontology.*

INTRODUCTION:

Did you ever put baking soda in a glass and add vinegar to make a mini volcano, when you were a kid? This was an elementary science experiment which has no ethical conflict. But situation and things are different with clinical trials; they are experiments on human beings. Actually clinical research on human subjects is disarray with a history of scandal which often shapes society's views of the ethics of research.[1] On the other hand ethics occupies a very significant place in society because it deals with the morality of human

[1]Angell M, (2015).*Medical Research: The Dangers to the Human Subjects*, the New York.

conduct and the value of life will become nothing more than an animal life which is not quality living. It is fascinating to note that clinical trials and research has given us more useful treatments and drugs for diseases which has found curse for some, invented ways to diagnose problems earlier and offers hope for the future. But research is not without controversy, and these improvements are not without a dark side.

In this point, special populations or vulnerable populations plays a burning roll in medical research. Actually in recent years, controversy over "vulnerable populations" in clinical research forced us to consider ethical , legal, social and biomedical issues such as : Is it permissible to allow human subjects to participate in clinical trials when it puts them at risk and offers them no direct benefit? How can we ensure that these studies and doctors, Scientist and researches provide the most good of the greatest number of patients? How do we determine whether one medical intervention is better than another, whether it offers greater clinical benefit and/or poses fewer risks? Actually there are several types of harm that can come to medical research in vulnerable populations. The central challenge in clinical research in vulnerable populations is that it exposes people to risks that must be justified by benefits to society or science in the form of medical knowledge. To respond to these questions, we need to appeal to ethical theories in giving reasons and arguments to justify a particular policy. Ethical theories provide a framework that enables us to critically reflect on and refine the intuitions generated by issues and reasons determine which actions or policy are obligated, permitted or prohibited in the process of justification.

Meaning and facts of Vulnerable Population in Clinical Research:

'Vulnerability' is a comparatively new and one of the least examined concepts in contemporary global bioethics as well as medical ethics. Vulnerable group simply means the group of people who could easily be harmed physically, mentally or emotionally.[23] Vulnerable populations are those patients for whom obtaining informed consent is problematic because they either lack mental capacity to understand or because they lack freedom in some way. These groups are also called vulnerable subjects because they are unable to protect their own interest. Structural components, age, disability and discrimination etc. are some factors which are responsible for these multiple socio- economic disadvantaged vulnerable populations. The very poor, illiterate patients, comatose patients[4], children, prisoners, foetuses, pregnant women, human in vitro fertilization,[5] terminally ill patients,[6] unorganized workers, people living with HIV/AIDS,[7] military persons, students in hierarchical organizations, , physically and intellectually challenged individuals, ethnic minorities, sexual minorities (LGBT)[8] and healthy volunteers,[9] are examples of vulnerable population.[10]

When conducting any clinical research on pregnant women, pre-clinical studies must be performed first. Informed consent for pregnant women is more complicated than informed consent for other research participants. Pregnant women are vulnerable because the foetus may be harmed. Again children are specially vulnerable because they are growing quickly and may be more sensitive to drugs and other treatments. Experimental treatment may be the only hope for some children with terminal illness. This raised an ethical dilemma for the doctors and the parents.[11] The mentally ill constitute another vulnerable group in research.

[2]https://dictionary.cambridge.org/dictionary/english/vulnerable

[3]https://www.collinsdictionary.com/dictionary/english/vulnerable

[4]A coma is a deep state of unconsciousness. It can happen as a result of a traumatic accident. A person who is comatose is in a coma, unconscious and unable to communicate, often for long periods of time.

[5]In vitro fertilization techniques were initially adopted for the treatment of couples in which the female suffered from inoperable tubal blockage.

[6]Terminal illness is a status assigned to a person who has been diagnosed with an illness and is expected to die within a short period of time.

[7]HIV stands for human immunodeficiency virus which harms your immune system by destroying the white blood cells that fight infection. AIDS stands for acquired immunodeficiency syndrome which is the final stage of infection with HIV.

[8]LGBT stands for lesbian, gay, bisexual and transgender and along with heterosexual.

[9]Someone with no known significant health problems who participates in research to test a new drug, device, or intervention is a "healthy volunteer" or "Clinical Research Volunteer".

[10]Larkin M., (2009). Vulnerable Groups in Health and Social Care, SAGE Publications.

[11]Kopelman, L.M., (2000). *"Children as research subjects: A dilemma,"* Journal of Medicine and Philosophy, 25: 745–64.

Like children, they cannot voluntary decisions about whether to participate in research testing new drugs or surgical treatments. Again poor volunteers in research are vulnerable in different respects because many of them lack of medical insurance and access to basic healthcare. The economically disadvantaged are thought of as "venerable" to exploitation, impaired decision making, or both, thus requiring either special protections or complete exclusion from research.

Moving From Lab Experiments to Research on Humans:

We know most drugs and treatment are first experiment in the laboratory using cell and tissue. Usually animal testing is the next step. When a treatment or drug is first developed, researchers are not sure what, if any, side effects it will have. First on animals it is considered more ethical to experiment and then on human beings. In this context it is remarkable that medical research using animals follows basic guidelines called the three Rs: reduce, replace, and refine.[1213] Medical research in the lab at the secular label and on laboratory animals provides clues to the efficacy of a new treatment. These experiments prove that the new treatment is effective and will no harm an organism. After this is established, these new treatments are tested on human beings. So it is remarkable that, research involving human participants starts from a position of ethical tension. Interventional and observational are the two types of clinical research[14]. A clinical study where doctors, scientist and other researchers can evaluate the effects of the interventions on biomedical or health-related issues due to vulnerable participants are allocate to receive one or more interventions or no intervention. In this procedure vulnerable participants may receive diagnostic, therapeutic, or other types of interventions. On the other hand a clinical study in which vulnerable participants identified as belonging to study groups are appraise for biomedical or health issues. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not ascribe vulnerable participants to explicit interventions.

The history of good clinical practice as well as good clinical research regulation footprint back to one of the earliest abiding traditions in the history of medicine: The Hippocratic Oath. [15] As the regulating ethical code it is principally known for its decree to do no harm to the vulnerable participants. Sadly, a "dark side" of clinical research endeavor has been more and more recognized, although not always fully acknowledged. Our modern society has experienced that blind trust of doctors, scientist and other researchers must have its limits due to examples from the notorious Tuskegee syphilis incident,[16] to worry with the purposeful infection of children with hepatitisat Willowbrook,[17] and more freshly , to the unsuitable inclusion of a young man in a gene therapy trial that resulted in his death.[18] Again it is also true that , based on newly advanced biotechnology, treatment and many new drugs have been developed for improving patient treatment issues. As clinical research and trials involve vulnerable populations in research, the protection of vulnerable participants is essential not only for the participants' safety but also for future patients.

[12]Balls M. (2009) *The Three Rs and the Humanity Criterion. An Abridged Version of The Principles of Humane Experimental Technique by WMS Russell and RL Burch*. Fund for the Replacement of Animals in Medical Experiment (FRAME) Nottingham UK.

[13] Three Rs meaning: researchers must reduce the number of higher species used in experiments , such as horses, dogs and cats and reduce the number of animals used in any experiment. Animal should be replaced with other research methods when possible. And researchers should refine experiments and tests so the research parameters are humane.

[14]Parker,R. A.,(2016), *Planning Clinical Research*, Cambridge University Press,pp 47-61

[15]Hippocratic Oath is a moral code for ethical conduct and practice in medicine, established according to the ideals of Hippocrates which follows that I will use treatment to help the sick according to my ability and judgement, but never with a view to injury or wrongdoing.

[16]http://www.socialworker.com/feature-articles/ethics-articles/The_Tuskegee_Syphilis_Study_and_Its_Implications_for_the_21st_Century/

[17]Ward,R., Krugman, S., Giles, J., P., Jacobs, A., M., Bodansky, O., (1958). *Infectious Hepatitis: Studies of Its Natural History and Prevention*, 258 New England, p 407, 412

[18]Fink, M., Hayes M.,(2008), *Classic Papers in Critical Care*, Second Edition, Springer-Verlag London Limited.

Guiding Principles of Ethical Studies in Clinical research:

Ethics in a clinical trial is not the same as in clinical practice with enough evidence. Clinical research on human subjects is reflection to be essentially ethically demanding, challenging, and moral standards to guide researchers as well as mistakes and ratification of research proposals from independent committees. Hence, the whole procedure of a clinical trial should be well organized, scientifically and ethically planned, and monitored properly by an Institutional Review Board (IRB) which also known as research ethics board's (REBs), or Research Ethics Committees (RECs).The representatives of these boards must make sure that the trials as well as the clinical research assemble the highest ethical standards possible.[19] The safety of the vulnerable participants must be at the top of the list and scientific integrity must be cultivated. The board not only reviews and approves the research before its begins, but it also must review the research as the trial proceeds. In this context, IRB identifies several types of risk of harm that can come to trial vulnerable participants. Such as: 1. Social harm which is defined as invasion of privacy and confidentiality that could end stigma or embarrassment. 2. Psychological harm which include mood alternation from drugs or feelings of guilty, depression and stress. 3. Physical harm: including injury and dis comfort that may be serious or mild. Patients have died while participating in clinical trials. 4. Economic harm which could be the result of employment loss or future ineligibility for insurance.[20] It is remarkable that some of the influential codes of ethics and regulations that guide ethical vulnerable populations' clinical research which include:

1. **Nuremberg Code (1947)**
2. **Declaration of Helsinki (1964)**
3. **Belmont Report (1979),**
4. **U.S. Common Rule (1991)**
5. **CIOMS (1982**)

Nuremberg Code (1947): The Nuremberg Code is a set of research ethics principles for human experimentation set as a result of the subsequent Nuremberg trials at the end of the Second World War which established the requirements for informed consent, properly formulated scientific experimentation, absence of coercion, and beneficence towards experiment participants and ensure the rights of the vulnerable participants in clinical research.[21]

Declaration of Helsinki (1964): The Declaration of Helsinki is a set of ethical principles regarding human experimentation developed for the medical community by the World Medical Association (WMA). Declaration of Helsinki states that medical research involving a underprivileged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of that population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.[22]

Belmont Report (1979): The Belmont Report also known as *"The Belmont Report – Ethical Principles and Guidelines for the Protection of Human Subjects of Research"* was written by the national commission for the protection of human subjects of biomedical and behavioural research. This Report identified three principles essential to the ethical guidance of clinical research with humans which are respect for persons, beneficence, and justice. These were workable in the form of informed consent, assessment of risks and benefits by ethics committees and selection of subjects. Vulnerability is mentioned under each of the three applications. In the segment on informed consent, it is argued that the element of voluntariness of the consent process can be compromised through inappropriate impact. The second reference to vulnerability is in the on assessment of risks and benefits. The principle of justice addresses the distribution segment of the

[19]https://en.wikipedia.org/wiki/Institutional_review_board
[20]https://research.uci.edu/compliance/human-research-protections/irb-members/assessing-risks-and-benefits.html
[21]https://www.sciencedirect.com/topics/medicine-and-dentistry/nuremberg-code
[22]Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. Adopted by 18th WMA General Assembly, Helsinki, Finland, June 1964. https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/

troubles and benefits of vulnerable populations' research and assuring justifiable, non-exploitative, and well-considered procedures are administered fairly.[23]

U.S. Common Rule (1991): The Common Rule or The Federal Policy for the Protection of Human Subjects is a 1981 rule of ethics regarding biomedical and behavioral research involving human subjects in the United States and was adopted by a number of federal agencies in 1991[24]which specifies how research that involves human subjects is to be conducted and reviewed, including specific rules for obtaining informed consent. The Common Rule defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge".[25]

CIOMS (1982): The Council for International Organizations of Medical Sciences (CIOMS) is an international nongovernmental organization established jointly by WHO and UNESCO in 1949 which published the International Ethical Guidelines for Biomedical Research Involving Human Subjects in 1982. [26] The CIOMS guidelines set in an appropriate context the challenges of present-day clinical research, by addressing complex issues including HIV/AIDS research, availability of study treatments after a study ends, women as research subjects, safeguarding confidentiality, compensation for adverse events, as well guidelines on consent. It serves the scientific interests of the international biomedical community in general and has been active in promulgating guidelines for the ethical conduct of research, among other activities.[27]The UNESCO declaration on bioethics and Human Rights, adopted in 2005, is the first international document that articulates respect for vulnerability as an ethical principle. [28]At the same time, the scope of vulnerability is broadened: it is no longer only relevant for medical research but for healthcare as such.

Underlying Ethical Principles:

After the above discussion it is clear that clinical research as well as medical research is a huge subject in its own right but most authorities refer to the basic principles of health care ethics when evaluating the merits and difficulties of medical procedures. Ideally, for a clinical trial on vulnerable populations to be considered "ethical", it must respect all four of following principles,[29] such as: **1. Respect for autonomy** where autonomy refers to the capacity to think , decide and act on vulnerable participant's own free initiative **2. Beneficence** demands that there be a likelihood of some benefits to trial participants and to the larger community through scientific discovery. **3. Justice** which concerns the distribution of scarce health resources and the decisions of who gets what treatment and **4. Nonmaleficence**which requires that a procedure does not harm the patientinvolved or others in society. In this point, it is also important that there are some related principles around which clinical research area revolves. Such are **informed consent, confidentiality** etc. Much of the modern medical ethics deals with the moral dilemmas arising in the context of patient's autonomy and the fundamental principles of informed consent and confidentiality. Inform consent follows from the principle of patient autonomy and a process by which a vulnerable participant understands the purpose, benefits, and potential risks of a medical or surgical intervention, including clinical trials, and then agrees to receive the treatment or participate in the trial. Again confidentiality is an important provision in a clinical trial agreement and also a form of the doctor-patients relationship. It implies respecting the patient's privacy, encouraging them to seek care preventing discrimination on the basis of vulnerableparticipants' medical condition.

The Need For Ethical Theories:

Ethical theories provide a framework that enables us to critically reflect on and refine the institutions generated by issues and cases. This process will enable us to give reasons for or against a position. An

[23]https://www.sciencedirect.com/topics/medicine-and-dentistry/belmont-report
[24]http://www.imarcresearch.com/blog/the-common-rule-1991
[25]https://en.wikipedia.org/wiki/Common_Rule
[26]Council for International Organizations of Medical Sciences, 2002.International ethical guidelines for biomedical research involving human subjects. Geneva: CIOMS.
[27] Ibid.
[28]http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html
[29]https://depts.washington.edu/bioethx/tools/princpl.html

argument can be understood as a consistent set of reasons logically leading to a conclusion. In most cases, the reasons one give will be motivated by one of the four ethical principles (autonomy, Justice, beneficence and nonmaleficence). In the process of justification , reasons determine which actions or policies are obligated, prohibited or permitted.

Clinical Research which is a part of medical ethics is a species of practical normative ethics. It is the study of what one is obligated or permitted to do, or prohibited from doing, in different contexts of medical research, medical practice. Like normative ethics, medical ethics focuses on the meaning of terms like "right", "wrong", "good" and "bad" and on the form of arguments used to justify actions. Actually medical ethics is a practical normative enterprise; it cannot be divorced from metaethics. Again consequentialism and deontology are the two ethical theories most frequently cited to defend different positions in special population research as well as biomedical research. The four principles (autonomy, Justice, beneficence and nonmaleficence) are representative of these two theories. Beneficence and nonmaleficence are consequentialist principles concerned with benefiting and not harming patients in bringing about the best outcome of a treatment. Again autonomy is a deontological principle concerned with such things as a patient's rights, value and dignity, as well as healthcare provider's corresponding duty to respect them. This does not mean that consequentialists completely ignore autonomy nor does deontologist completely ignore consequences. Consequentialism defines the wrongness or rightness of an action in terms of its consequences. [30]

Again deontology defines the rightness or wrongness of an action in terms of obligation or duty to respect the rights and values of persons. Despite their differences, consequentialism and deontology both prescribe principles telling us what we should do. In consequentialism, the obligation is to promote good outcomes. In deontology, the obligation is to respect personas as end –in-themselves. The most well-known deontologist, Kant held that there is one fundamental principle of morality, the categorical imperative. According to Kant, we are autonomous in the sense that we have the capacity for reason and can apply the moral law to ourselves.[31] On the other hand , John Stuart Mill's principle of liberty says that, a person is sovereign over his or her body and mind.[32]It says that an individual's freedom can be restricted only when its exercise would harm other. For these reason, there are consequentialist and deontological arguments for and against permitting vulnerable populations to be research subjects. For instance, according to deontologist children, mentally ill individuals cannot give informed consent and many cases childrenare being treated only as a means and not also as an end–in–itself. Thus the participations of these vulnerable groups in research should be prohibited. On the other hand, consequentialist view is that it is permissible, when a child's or mentally ill individual's participation in research serves greater good. Instead the reason for participating in research and sacrificing some of one's own interest is to minimize harms and maximize benefits for patients in general. Thus clinical trials will help to better understand the causes of diseases. It is also important point is that without appropriately conducted clinical trials, harmful side effects of drugs and new treatments would appear later and adversely affected more people.

CONCLUSION:

Finally, itcan be said that clinical research has the potential to create huge benefits to society. In this point, some determination must be met for vulnerable population research and trials to be ethically acceptable. These are firstly - voluntary informed consent must be earned from vulnerable populations or individual, secondly - the research and trial must comprise a beneficial benefit risk ratio, and thirdly - the privacy and confidentiality of the vulnerable populations or individual must be protected. At the same time it also can be said that, ethical conflicts and concerns are part of the day to day practice of doing all kind of research. On the other hand, many of the norms of research promote a variety of other important moral and social values, i.e. human rights, social responsibility, public health, welfare, compliance with the law and safety. The usage and knowledge of normative ethical theories can play some crucial aspects, such as promoting in the introductory awareness and identification of the ethical challenges, assisting in the scrutiny and argumentation, sharing to a

[30]LaFollette, H., ed.(2000).*The Blackwell Guide to Ethical Theory, Malden*, Mass: Blackwell.
[31]https://www.bartleby.com/essay/Clinical-Trials-A-Kantian-and-Utilitarian-Point-F3ENGGSTJ
[32]Mill, J. S.,(1869). *On Liberty*, Page reference to Stefan Collini (ed.), *On Liberty and Other Writings*, (2005). Cambridge, Cambridge University Press, 12th edition.

robust proceeding and dialogue, and heartening a sentiment of reflexivity. After the above discussion, it is clear that research on vulnerable populations can produce thoughtful harm and there are such field to envisage i.e. respect of a person's autonomous dignity and rights, privacy and confidentiality, protection from physical, mental and emotional harm, voluntary informed consent, right to safeguard integrity, right to end participation in research at any time, access to information regarding research, evaluating risks versus benefits and conflict of interest. In this context, the National Institute of Justice in the United States published recommended rights of human subjects in 2010.[33]Actually clinical research involving vulnerable populations, doctors, scientist and other researchers have a duty to treat this subject not only as means, but also as end- in – themselves. Although so many of the improvements in survival of terminal conditions are due to the willingness of vulnerable individual or group and their families to take in clinical research. We owe a great debt to them.

REFERENCES:

1. Angell M., (2015).*Medical Research: The Dangers to the Human Subjects*, the New York Review of Books, 2015.
2. Beauchamp T, Childress J. (2013).*Principles of Biomedical Ethics*, 7thÂ Edition. New York: Oxford University Press.
3. *Belmont Report. Ethical Principles and Guidelines for the protection of human subjects of research,* The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, April 18, 1979.https://www.sciencedirect.com/topics/medicine-and-dentistry/belmont-report
4. Balls M., (2009).*The Three Rs and the Humanity Criterion. An Abridged Version of The Principles of Humane Experimental Technique* by WMS Russell and RL Burch. Nottingham UK: Fund for the Replacement of Animals in Medical Experiment (FRAME)
5. Brody, B.A., (1998). *The Ethics of Biomedical Research: An International Perspective,* Oxford: Oxford University Press.
6. Fink, M.,Hayes, M., Soni, N., Ed., (2008), *Classic Papers in Critical Care*,Second Edition, Springer-Verlag London Limited.
7. Council for International Organizations of Medical Sciences, 2002. International ethical guidelines for biomedical research involving human subjects. Geneva: CIOMS.
8. *Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects.* Adopted by 18th WMA General Assembly, Helsinki, Finland, June 1964. https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/
9. Fink, M., Hayes M.,(2008), Classic Papers in Critical Care, Second Edition, Springer-Verlag London Limited.
10. Frankena, WK., (1973).*Ethics*, 2nd Edition. Englewood Cliffs, NJ: Prentice-Hall.
11. Gardiner.P., (2003).*A virtue Ethics Approach to Moral Dilemmas in Medicine*, Journal of Medical Ethics.
12. Harris, J., (1985).*The Value of Life: An Introduction to Medical Ethics*,Routledge, London, UK.
13. Harmon, A., (21 April 2010). "*Indian Tribe Wins Fight to Limit Research of Its DNA,*" New York Times.
14. Indian Council of Medical Research Ethical Guidelines for Biomedical Research on Human Participants, New Delhi, 2006
15. Jonsen, A.R., Siegler, M., Winslade, (2002). *Clinical Ethics: Practical Approach of Ethical Dimentions in Clinical Medicine*, Fifth Edition, New York, McGeaw Hill.
16. Kopelman, L.M., (2000). *"Children as research subjects: A dilemma*", Journal of Medicine and Philosophy.
17. Larkin M., (2009). *Vulnerable Groups in Health and Social Care*, SAGE Publications,
18. LaFollette, H., Ed., (2000).*The Blackwell Guide to Ethical Theory*, Malden, Mass: Blackwell.
19. Raphael, D.D., (1981). *Moral Philosophy*, Oxford University Press, Oxford, UK.
20. Parker,R. A., (2006). *Planning Clinical Research*, Cambridge University Press.

[33]National Commission for the protection of human Subjects of Biomedical and Behavioral Research, (1979).*The Belmont Report*, US Government Printing Office, Washington, DC.

21. Mill, J. S.,(1869).*On Liberty*, Page reference to Stefan Collini (ed.), *On Liberty and Other Writings*, (2005). Cambridge, Cambridge University Press, 12th edition.
22. Ward,R., Krugman, S., Giles, J., P., Jacobs, A., M., Bodansky, O., (1958). *Infectious Hepatitis: Studies of Its Natural History and Prevention*, 258 New England,
23. Wellford, C.F., Chemers, B.M., Schuck,J.A., Ed., (2010).*Strengthening the National Institute of Justice,* National Research Council,The National Academies Press,Washington, DC.
24. National Commission for the protection of human Subjects of Biomedical and Behavioral Research,(1979). *The Belmont Report,* US Government Printing Office, Washington, DC.
25. World Medical Organization, 1996. Declaration of Helsinki, British Medical Journal,
26. Wikipedia, the free encyclopedia.
27. https://www.bartleby.com/essay/Clinical-Trials-A-Kantian-and-Utilitarian-Point-F3ENGGSTJ
28. https://www.collinsdictionary.com/dictionary/english/vulnerable
29. https://dictionary.cambridge.org/dictionary/english/vulnerable
30. https://www.sciencedirect.com/topics/medicine-and-dentistry/belmont-report
31. http://portal.unesco.org/en/ev.php
32. https://depts.washington.edu/bioethx/tools/princpl.html
33. https://en.wikipedia.org/wiki/Institutional_review_board
34. https://en.wikipedia.org/wiki/Common_Rule
35. https://research.uci.edu/compliance/human-research-protections/irb-members/assessing-risks-and-benefits.html
36. http://www.imarcresearch.com/blog/the-common-rule-1991

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