

Vulnerability and Protection in Research: Is it Ethical to use Prisoners as Research
Subjects?
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Abstract

This paper reviews the basis for and the literature pertaining to the ethical issues surrounding the use of the vulnerable population of prisoners as subjects for research protocols. The foundation for the development of ethical guidelines to protect this population comes from the exploitation of vulnerable populations including prisoners in the Holocaust, totalitarian regimes, and even in countries with long histories of democracy. The main ethical issues relevant to research with prisoners are respect for persons, justice, and the theory of Utilitarianism. Within the ethical guidelines there is a conflict between protecting prisoners from exploitation in research and prisoners right to participate in research. Therefore, many ethical codes attempt to safeguard this especially vulnerable group without completely restricting them from the benefits of research.

Background

Within medical research and healthcare certain groups are offered special protections and services because they are considered “vulnerable” (Ruof, 411). Vulnerable populations include but are not limited to prisoners, women who are pregnant, children, and minorities. The CIOMS International Ethical Guidelines for Biomedical Research define “vulnerable persons” as “those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests” (Macklin, 474). Therefore, there are specific guidelines designed to protect the rights and welfare of vulnerable persons by requiring special justifications for involving vulnerable individuals in research. In medical research and healthcare, “vulnerability” is a vague concept that has substantial effects both for those labeled vulnerable and for those not. It is essential for policy makers, healthcare workers, and researchers to properly identify vulnerable subjects in order for resources to be allocated appropriately and in order to ensure that those who are entitled to special protections and socialized benefits are afforded these protections and benefits (Ruof, 412). There has been a struggle to define vulnerability, and this has led to arguments about its value as a qualifying factor in the allocation of health resources and its appropriateness as a guiding principle in bioethics.

History

The exploitation inherent in the use of human research subjects in recent history highlighted the need for a code of ethics protecting human research subjects. In Nazi Germany, the Imperial Japanese Army in Asia, totalitarian regimes, and even in countries with a long tradition of democracy wealthy or powerful individuals or agencies took “advantage of the poverty, powerlessness, or dependency of others by using the latter to serve their own needs (those of the wealthy and powerful) without adequate compensating benefits for the less powerful or disadvantaged individuals or groups” (Macklin, 475).

In the first third of the 20th century there was a significant increase in popularity of theories based on eugenics. As a consequence of this pseudoscience, the Nazi government introduced a policy of “racial hygiene,” which had harmful political, social, and scientific consequences. Rooted in the Darwinist concept of natural selection, the aim of this policy was to enhance the reproductive rate of the “Aryan race.” Prominent scientists and geneticists promoted eugenics and this “racial science,” thereby medicalizing racism and anti-Semitism (Lopez-Munoz 794).

When Adolf Hitler came to power he implemented a series of laws promoting racial segregation and the protection of the “superior race.” These laws were created in collaboration with part of the German medical community. One of the first laws enacted was called the Sterilization Act, which enforced the sterilization of subjects with certain medical and mental diagnoses in order to remove a complete generation of subjects with genetic deficiencies to purify the gene pool and thereby improve the “German race.” The scientists involved in implementing these laws justified their actions, arguing that they were performing these procedures “for the benefit of the nation and the health of

subsequent generations, and not for the individual patient.” They believed they were part of a “holy mission” to benefit society as a whole (Lopez-Munoz 795).

In addition to the Sterilization Act, the German medical community was involved in implementing the Nuremberg Laws, which were enacted for the purpose of “purification of the blood of the German people.” The medical communities involvement in implementing these laws demonstrates the relaxation of ethical principles. In addition to prohibiting the marriage between Jews and Aryans, these laws required that couples undergo premarital medical examinations in order to prevent the spread of “racially damaging diseases.” In addition, as the war was approaching the Germans needed to free up hospital beds for wounded soldiers, and thus, medical professionals were instructed to implement ‘euthanasic death’ to incurable patients. Also, medical professionals were responsible for implementing the Euthanasia Programme, which led to the “mass extermination of patients with ‘deficiencies’ or mental pathologies” (Lopez-Munoz, 796). This program was ultimately extended to include the extermination of those who constituted a threat to society, those with links to criminality, those who behaved antisocially, prostitutes, drifters and homosexuals. Finally, this practice of mass extermination served as the model for the “Final Solution,” which was executed to wipe out an enormous amount of Jewish victims. In addition to these overt methods of elimination, the German medical community played a large role in more covert procedures that took place in healthcare institutions. These included killing patients through malnutrition, turning off the heat in hospitals during the winter, and injecting patients with drugs in order to speed up the death process (Lopez-Munoz 797).

The most concerning manifestation of the connection between doctors and the Nazis was the use of human beings as research and laboratory subjects, not only among the atrocities of the death camps, but also in hospitals and universities. In addition to Jews gypsies, Slavs, homosexuals, and physically and mentally disabled persons were recruited as victims for these horrific experiments. Just as they justified carrying out the Sterilization Act and the Nuremberg Laws, by arguing that they were for the benefit of society, so too the medical personnel who carried out these activities justified them by arguing, “ if the sick have to die anyway, as a result of the expert assessment of one of my colleagues, why not make use of them while alive or after their execution for research” (Lopez-Munoz, 798)?

Human experimentation performed by the Nazis extended to the field of neuropsychiatry. For example, they conducted research projects on various forms of mental retardation and epilepsy. These projects involved a long-term neuropsychological and physiological study and assessment of living patients, which culminated in the examination of the subjects’ brains after their death in accordance with the Euthanasia Programme. In addition, the Nazi doctors carried out experiments with electroshock techniques and drugs. For example, they performed brainwashing experiments, in which they administered chemical compounds to patients. From these examples it is clear that German doctors during this time neglected their duty as doctors and rejected the ethical principles intrinsic to the practice of their profession (Lopez-Munoz, 799).

Like the Nazis, their Asian allies utilized a similar method. The Imperial Japanese Army developed a series of medical research units that conducted horrific experiments with human prisoners. Unit 731 was set up for bacteriological research using prisoners of

war, political detainees, and mentally ill and disabled Chinese subjects. They injected the subjects with various diseases, which subsequently caused the deaths of up to 10,000 people (Lopez-Munoz, 799). Such practices also took place in other countries that had totalitarian regimes such as the former Soviet Union, China, and Chile. However, these methods were also used in democratic countries such as the United States, Great Britain, and Australia (Lopes-Munoz, 801).

In the Soviet Union, institutional psychiatric abuse was not motivated by eugenics or “racial hygiene.” Rather, it was used as a weapon for removing various forms of dissension and unacceptable social behaviors. Despite differing motivations, the Soviet Union’s methods were similar to those of the Nazis. There was collaboration between the state psychiatric machinery and the police who tortured prisoners. Psychiatric abuse was extended to nationalists, potential emigrants, and those with religious beliefs. These people were confined to institutions that were considered “psychiatric prisons” after being falsely attributed with psychiatric disorders. In these institutions doctors used drugs for disciplinary purposes (Lopez-Munoz 801). The administration of psychotropic drugs to religious and political dissenters in totalitarian states was for the purpose of admitting patients to psychiatric institutions, as a disciplinary tool, as tactic to force the dissenters to denounce their anti-governmental ideas and activities, and as a form of torture (Lopez-Munoz 801).

Psychiatric and psychopharmacologic exploitation by government institutions has also taken place in non-totalitarian states. From the mid 1900’s, both the Central Intelligence Agency and the US Army performed various experiments with several chemical agents under the direction of leading psychiatrists. In addition to

experimentation of different groups, the CIA recruited prostitutes who would trick businessmen into visiting brothels. Once there, the men were covertly injected with LSD and their behavior was then observed. Also, they injected subjects with drugs for the purpose of attaining certain responses to guided interrogation. Many subjects died as a consequence of these experiments. It came out later that participants in these experiments “were exposed to serious danger of death or injury without their informed consent, without medical supervision and without the necessary monitoring to determine possible long term effects” (Lopez-Munoz, 802). In addition, prestigious healthcare and institutions and universities, as well as well-known neurosurgeons, psychologists, and psychiatrists worked with the Army and CIA on experiments for studying amnesiac states induced with psychoactive drugs.

Review of Ethical Guidelines

As a result of these horrors and the exploitation inherent in the use of prisoners as research subjects, ethical codes were written in an attempt to protect this population in addition to other populations classified as vulnerable, “a group of persons who, in virtue of some feature they share, such as limited cognitive abilities or unequal social circumstances, are deserving of special protection in research,” from being maltreated and exploited. The various codes of ethics that have been drawn up demonstrate that when vulnerable groups such as prisoners serve as research populations, special principles and a heightened degree of care must be employed to deal with them (Nickel, 245).

As a reaction to the atrocities carried out by the Nazi doctors and scientists in the field of human research that were revealed during the Nuremberg war crimes trials, the Nuremberg code was published in August 1947. It is the first international code for research with human beings, and it is based on the Hippocratic oath of “first do no harm.” It was created to prevent any repetition of the calamity resulting from the extremely cruel attacks on human wellbeing and human rights. It put forth rules that should govern the use of human beings for experimentation. The need to obtain informed consent is emphasized, and it has since been regarded as the key issue of patients’ rights protection. The code consists of a declaration of ten principles, generally focusing on the protection of the rights of persons participating in medical research. It requires that in addition to the requirement for researchers and clinicians to protect their patients’ rights, the subjects themselves also actively participate in their own protection.

The Nuremberg Code has not been formally implemented as a legal norm in any nation or medical association. However, it has had an extreme impact on the area of human rights and bioethics, since its fundamental requirement, informed consent, has been accepted all over the world, is preserved within several international laws regarding human rights, and is the foundation of the International Ethical Guidelines for Biomedical Research Involving Human Subjects, published in 1982 (Lopez-Munoz 800).

In 1964, the Eighteenth World Medical Assembly meeting in Helsinki adopted an ethical code to guide physicians and other investigators who conduct medical research involving human subjects. This code has been amended several times. The Declaration of Helsinki developed the ten principles first addressed in the Nuremberg Code and tied them to the Declaration of Geneva, a statement of a physician’s ethical duties. Thus, it

has many points in common with the Nuremberg code; most essential is the requirement for Informed Consent. However, they do have various differences. First, the Declaration of Helsinki points out that some, but not all medical, research is combined with medical care. Consequently, it puts forth, in addition to basic principles for all medical research, a set of principles for medical research combined with medical care or therapeutic research. Second, while the Nuremberg Code does not address research on subjects who are unable to provide informed consent, the Helsinki Code addresses such research, asserting the ethical acceptability under certain conditions of “proxy consent.” Despite the Declaration of Helsinki not being regarded as a binding instrument in international law, it is significant because it was the first significant effort of the medical community to regulate research itself, and forms the basis of subsequent ethical codes (Lopez-Munoz 803).

In the 1970s, the World Psychiatric Association (WPA) was concerned that there were no specific texts requiring the use of ethical procedures in psychiatry. One issue that particularly made the psychiatric community aware of the problem and led to the composition of such a document was the political abuse and improper use of psychiatry and its applications in countries such as the former Soviet Union, Rumania and South Africa. Thus, in 1977 in Hawaii the WPA General Assembly adopted a Declaration of ethical principles, which was amended in 1983. The Declaration of Hawaii became the first document created by the psychiatric profession on ethical questions, and incorporated, in relation to human experimentation, the explicit requirement, for the first time, of obtaining informed consent before involving a patient in a research study (Lopez-Munoz, 802).

Prompted in part by problems arising from the Tuskegee Syphilis Study, and protests taking place in the United States in support of the right to protection of participants in drug trials the Department of Health revised and expanded its regulations for the protection of human subjects. Due to the possible threat to civil rights and human values involved in the drug trials, in 1974 Congress appointed a commission called The National Commission for the Protection of Human subjects of Biomedical and Behavioral research. This was done in order to assure respect for the rights of subjects. This commission drafted The Belmont Report in 1978 in Baltimore. The report is not a set of regulations, but a framework for identifying, discussing, and settling ethical matters. This report stated that three basic ethical principles should direct all clinical pharmacological research with human beings and its applications. These are the principle of respect for persons and their autonomy, the principle of beneficence, and the principle of justice. Even though the Report ties the requirement to protect autonomy of persons with diminished capacity to the ethical principle of respect for persons, it addresses the concept of vulnerability in the framework of the principle of justice. This principle requires the distribution of the benefits and burdens of research. This code of ethics asserts that vulnerable groups may continually be sought out to participate in research because of their “ready availability in settings where research is conducted,” however, they should not shoulder unequal burdens in research. If they do take part in research, they require special protections because of their frequently compromised capacity for free consent and their dependent status (Levine, 45). The Belmont Report is an essential reference for institutional review boards that review research proposals of research

involving human subjects, in order to ensure that the research meets the ethical foundations and regulations (Lopez-Munoz, 802,803).

In 1993, the Council for International Organizations of Medical Sciences put forward international ethical guidelines pertaining to research with human subjects. These guidelines, the International Ethical Guidelines for Biomedical Research Involving Human Subjects, which were originally 15 guidelines but after having been adapted in 2002 are now 21, try to balance both protection from abuse in research and access to new, experimental treatments for the vulnerable (Ruof, 411). The recently revised CIOMS guidelines include a guideline pertaining to research involving vulnerable persons. It states that, “special justification is required for inviting vulnerable individuals to serve as research subjects, and, if they are selected, the means of protecting their rights and welfare must be strictly applied” (Macklin, 474). The most important characteristic that defines an individual as “vulnerable” is the “limited capacity or freedom to consent or to decline participation in research.”

Federal Regulations to protect human subjects of research were established in 1974 and adapted and codified in 1981. The regulations were revised in 1991 as the U.S-Code of Federal Regulations for the Protection of Human Subjects also known as the Common Rule. However, unlike other ethical guidelines it does not define vulnerability. Instead, it provides special protections for “particularly vulnerable populations.” These include pregnant women, human fetuses and neonates, prisoners, and children (Levine, 45). These regulations define research as a “systematic investigation” designed to advance or add to “generalizable knowledge.” This includes research development, and testing and evaluation (York 55).

Subpart A of the Common Rule states two major requirements for all human subjects research. The first is that anyone participating in research that falls under the definition stated above must go through an informed consent process that includes a written consent that has eight required elements. The second is that all research studies must be reviewed and approved by the Institutional Review Board, a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of research subjects (Chwang, 14). Subparts B, C, and D express further conditions for research with a variety of vulnerable populations: B is for pregnant women, fetuses and neonates, C is for prisoners, and D is for children. Subpart C, instructs that prisoner research must focus on possible causes, effects, and processes of incarceration, prisons as institutional structures or prisoners as incarcerated persons, conditions particularly affecting prisoners as a class, or practices that have the intent and reasonable probability of improving the health or well-being of research participants (Chwang, 15). Under Subpart C, research must result in no more than minimal risk, which is defined as “the risk or harm normally encountered in their daily lives in their daily lives or in the routine medical, dental, or psychological examination of healthy persons” (Gostin, 737).

Review of the Current Literature

Lawrence Gostin in his article entitled *Biomedical Research Involving Prisoners* discusses the ethical values and legal regulations regarding research studies that involve prisoners. He mentions that many companies including the US Army and major pharmaceutical companies performed a wide variety of research on prisoners up

until the early 1970s. This was due to their easy accessibility, vulnerability, and captivity. In many cases researchers did not obtain informed consent and failed to treat the prisoners properly for the pain they endured. Ultimately, in the mid 1970s research of this kind declined due to publicized knowledge of the exploitation of prisoners and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created. Federal regulations that protected human subjects were adapted several times and came to be known as the Common Rule. This code of ethics applies to research funded by the department of Health and Human Services, to private institutions that assume a Federal-Wide Assurance of Compliance, and with exceptions, to 16 other Federal Agencies (737).

The Common Rule contains requirements for institutional review board review, informed consent, and risk-benefit analysis. It also offers additional protections for vulnerable populations. Subpart C that refers to prisoners has not been taken on by many federal agencies because it is too restrictive. Part of subpart C stresses that research on prisoners can present no more than minimal risk, which means risk of harm normally encountered in their daily lives. However, this definition is very narrow and ambiguous. Thus, research subject to subpart C is frequently avoided. Since these restrictions pertain only to a few federal agencies and institutions that act in accordance with them through Federal-Wide Assurance Compliance, the bulk of research on prisoners is performed outside the statute of subpart C. "Federal oversight of research in prisons, therefore, is either too restrictive (effectively impeding responsible research) or inapplicable (opening the door to exploitation or abuse)." Thus, the DHHS requested that the Institute of

Medicine consider the need for creating a new ethical framework for prisoner research and to identify regulatory safeguards (737).

In recent years the amount of prisoners in correctional facilities has greatly increased. Thus, correctional facilities are overcrowded and many inmates are subject inadequate treatment including limited access to programs, services, and health care. In addition to their poor health and low socioeconomic status, prisoners are considered vulnerable due to their limited liberty and autonomy. They may not be capable of providing informed consent and may not have a practical expectation of privacy within prison settings. In this environment, prisoners may not be capable of meaningfully choosing between participating in research and not participating (738).

A compromise between promoting beneficial research and protecting prisoners is difficult to achieve and it is politically controversial. The author suggests a few proposals that he believes solve this difficulty. Firstly, he suggests that the definition of prisoner be extended to include all individuals whose autonomy and liberty are limited by the justice system. Next, he recommends that all research on prisoners be regulated consistently, irrespective of the source of funding, supporting agency, or type of correctional facility. The third proposal is to create a national database for prisoner research. This would ensure greater accountability, provide a scientific method for measuring the success of research projects, and assist the implementation of beneficial research findings to prisoner populations. Another suggestion that the author makes is a shift from category-based to a risk-benefit approach to research review. He argues that that categories of allowed research set up under subpart C do not offer reliable, consistent, or adequate safeguards for prisoner research. Thus, a risk-benefit approach that offers a range of

protections depending on the harshness of the correctional setting is a more sensible approach for guaranteeing that research involving prisoners will be ethical and safe. Under this guideline, research with prisoners as research subjects should be performed only if it presents a markedly favorable benefit-to-risk ratio and not due to the easy accessibility to prisoners or their lack of therapeutic treatment. In addition, the author proposes that the ethical framework be updated to include collaborative responsibility. If possible, everyone involved in the research, including the prisoners should take part in the design, planning, and implementation of the research. This would ensure that everyone involved would have a part in guaranteeing that the research is responsible. Finally, research should include enhanced systematic oversight. Protections beyond the variable review of the IRB should be strengthened, made consistent, and be applied to all degrees of risk and liberty constraints experienced by prisoners who are subjects in research (738, 739).

In his article entitled *Against Risk-Benefit Review of Prisoner Research*, Eric Chwang discusses the some of the weaknesses of the Common Rule. He mentions the recommendations of the Institute of Medicine's Ethical Considerations for Research Involving Prisoners. The suggested five changes to the current United States regulations on prisoner research. These are: to broaden the definition of "prisoner," to guarantee universally and consistently applied standards of protection, to move from a category-based to a risk-benefit approach to research review, to revise the ethical framework to include collaborative responsibility, and to improve systematic oversight of research involving prisoners (14). The IOM report maintains that the category-based constraints stated in the Common Rule are deficient since they are too subject to interpretation and

do not attend to actual prisoner vulnerabilities. Thus, the IOM report recommends that the category-based constraints be replaced with risk-benefit constraints. However, the author disagrees and thinks the Common Rule and IOM recommendations should be combined into an ethical framework. He suggests that additional risk-benefit restrictions on research are redundant and that the current Common Rule regulations excluding category-based constraints, but compounded with the IOM's four other recommendations, guarantee that prisoner research is as ethical as non-prisoner research. Chwang argues that the reason for the IOM's insistence on risk-benefit constraints is that the IOM compares the vulnerable population of prisoners to the vulnerable population of children, for whom research is regulated on the basis of risk-benefit restrictions. However, while children are not competent to give rational consent and rely on adults to determine whether or not they should serve as subjects in research, most prisoners are adults and can thus make rational decisions about participation in research (15).

Chwang argues that even though the implementation of risk-benefit restrictions was designed to solve certain problems inherent to prisoners, there are several reasons why it was not successful in its attempt. First, risk-benefit constraints seem appropriate because they protect against the lack of autonomy inherent to prison life due to prisoner's lack of freedom. They live in a coercive environment in which their lives are highly regulated, and therefore, it can be argued that prisoners cannot freely choose whether or not to participate in research. However, while it seems that prisoners living in a coercive are completely unfree meaning all of their decisions are made under "duress" then this is claim is false. Even though in this coercive environment many of prisoners' decisions are subject to interference, this does not necessarily mean that every choice they make is

subject to coercive interference. Another argument is that even if prisoners can make some free choices the choice to participate in research will always be coerced. Yet, coercion is prohibited by Subpart A of the Common Rule, which applies to research with all populations. In addition, risk-benefit constraints do not alleviate these concerns about coercion since passing the research through a risk-benefit filter would not make it any more ethical to coerce prisoners into participating in research. The author suggests that the right response is to ensure that the research study is not coercive to begin with. The solution is not to add a risk-benefit analysis to the process; the solution is to make certain that the constraints already established for research are followed (17).

In addition to risk-benefit analysis not being a suitable solution for the problem of coercion it is not a solution for the problem of undue inducement. Undue inducement is an inducement to participate in research that inappropriately influences the subject to enroll. Prisoner research seems susceptible to undue inducements; however, this concern is not resolved by additional risk-benefit constraints. Firstly, the IOM report is concerned with risk-benefit analysis because it wants to guarantee that the benefits of prisoner research are great enough to offset the risks. Yet, it does not mention the threat of undue inducement as a motivating factor for its suggestion of risk-benefit restrictions. Also, undue inducements are no more problematic for prisoners than they are for the general population and the Common Rule already prohibits undue inducement. Therefore, it is essential that the constraints already in place are strictly followed, not the addition of new constraints (18).

Finally, while additional risk-benefit restrictions might seem to help solve the issue of exploitation of prisoners they in fact do not. This is partly due to the fact that

calculating the degree of exploitation is controversial. In order to eliminate exploitation, we would have to figure out not just whether the benefits of participation outweigh the risks. Rather, we would also have to figure out whether the net benefits are sufficiently high. This may depend on comparing those benefits to the benefits to the researcher and to society. We would therefore require an expected benefit calculation. This idea, that we must guarantee that the allocation of benefits is not exploitative is not part of the IOM report's suggestion. Even if they did incorporate this calculation, it would still be problematic because the calculation can yield incorrect results. In addition, exploitation is a problem for all research not just for research involving prisoners. Exploitation should be prohibited and more rigorous guidelines should be implemented for all research. Thus, we do not need additional restrictions for prisoner research. What is needed is better supervision to guarantee that more general constraints, which apply to all research, are followed (20).

David Thomas in his article entitled *Prisoner Research- Looking Back or Looking Forward* discusses the issue of what he calls "prisoner's right to research", which refers to the concept of a prisoner's right to participate in medical research as a subject. The author argues that this issue has been rarely addressed. While the IOM recommendations advocates for prisoners and allows research on prisoners it does not advocate for the concept of a prisoner's right to research (23). There are a variety of therapies in current medical care that change with great rapidity. Unlike a non-incarcerated person who could readily access therapies and receive treatment if needed, in a prison environment the only way to gain access to these therapies is to participate in a clinical trial. Thus, refusing prisoners the advantages of modern therapies would be equivalent to restricting their

rights due only to their incarceration. Courts have commonly held that the punishment is imprisonment. Forms of imprisonment that extend beyond humane confinement may defy the 8th Amendment ban against cruel and unusual punishment. In addition, denying incarcerated persons therapy by virtue of their incarceration creates an unequal state of affairs that imposes upon the essential issue of justice as articulated in the Belmont Report (25). Research involving prisoners with suitable protections that gives prisoners the accepted standard of care, should not be denied (26).

In addition to the IOM recommendations, Julio Arboleda-Florez, in his article *The Ethics of Biomedical Research on Prisoners* suggests other rules to ensure the protection of prisoners involved in research. First he recommends that external rewards should not be used as inducements to participate in research. Medical care, healthy food, reduction in sentence, or an increase in visiting hours should not be used to persuade prisoners to be involved in research. Next he suggests that therapeutic research should be distinguished from nontherapeutic research. This is necessary so that prisoners will not be denied eventual health benefits that could result from involvement as a subject in research. In addition the author insists that the Institutional Review Board must have a role (516). Finally, he proposes that increased external governance should be introduced. This is due to the trouble that results from lack of oversight. Efficient means for the supervising and monitoring of continuing projects must be implemented by prison administrators in cooperation with external agencies (517).

Carol Levine et al. in *The Limitations of "Vulnerability" as a Protection for Human Research Participants* addresses the concept of vulnerability in a different way from the authors previously mentioned in this paper. She discusses the limitations of

classifying a person or group as vulnerable. The concept of vulnerability has three major problems. First, so many categories of people are now considered vulnerable that practically all possible human subjects are included. If everyone is vulnerable then the concept becomes too tenuous to be significant. Apparently, the purpose of labeling a group as vulnerable is to give additional protections above those required for all human participants. As more and more groups come to be designated “vulnerable,” the consequence is that every research protocol requires some type of special attention and the IRB has no guidance on where to focus their limited attention and resources. The second problem is that “if the concept of vulnerability is too broad, it is also too narrow. An almost sole emphasis on group characteristics that presumably undercut or eliminate the capacity to give consent can deflect attention from aspects of the research itself, the environment, or the social and economic context that can put participants in harms way. While consent is in fact an important concern, the root of the concept of vulnerability lies in the risk of physical harm (46). Finally, labeling groups and individuals as vulnerable stereotypes whole categories of individuals without differentiating between individuals in the group who actually might have special characteristics that need to be taken into consideration and those who do not. Furthermore, some individuals may be vulnerable in some circumstances and not in others. Thus, a person’s needs for particular protections in the research context depend not only on that individual’s inclusion in a group, but also on the specific characteristics of the research project and the environment in which it is taking place (47)

In the article entitled *Protecting Prisoners from Harmful Research: Is “Being Heard” Enough?* Mobley et al. questions the recommendations of the IOM despite the

improvements that they have made on prisoner protection in research. In this article the author specifically addresses the IOM recommendation that refers to the role of the prisoners in the process of their own protection. He questions “whether having a formal position, as a prisoner representative, regardless of the institutionally prescribed role in the process, is effective as a means of protection from exploitation, harm, or elevated risk for harm.” This proposal, even though a major improvement over their exclusion, may function to include the “symbolic” voice of prisoners, but to exclude the “content” of their valuable contribution. This is due to the concern that prisoners’ empirical knowledge will be overlooked relative to the professionals’ opinions. Thus, the research collaboration process is unreliable. Without a way to include prisoners’ voices into the actual research process, such that the result is significantly shaped by his or her contribution, all efforts to include the human subject’s voice may be negated (43).

Ethical Analysis

As can be seen from the literature previously discussed, there has been an ongoing debate regarding the ethical issues surrounding the use of prisoners as subjects of research studies, and the proper course of action to take in order to ensure prisoners’ protection from exploitation and coercion while at the same time maintaining their autonomy. According to the various codes of ethics the requirement to protect the autonomy of persons with diminished capacity, such as the vulnerable population of prisoners is linked to the ethical principle of respect for persons. Also, various codes of ethics address the concept of vulnerability within the framework of the principle of

justice. Finally, the most commonly offered justification for human research is Utilitarian in nature.

According to the principle of respect for persons an individual should be treated as an autonomous agent and a person with diminished autonomy is entitled to protection. In prison environments, the constraints on prisoners' voluntariness, and concerns about whether they are truly free to make informed consent decisions about participation in research projects lead them to be labeled as "vulnerable." Inmates have diminished liberty and autonomy, and in the prison environment there are poor quality health care systems and thus, prisoners may be subject to coercion and may volunteer to participate in research simply to gain access to basic medical care. Also, it is common for inmates to have their participation as research subjects bought by means of small, but in the prison environment significant rewards such as food, or better sleeping conditions. And even in some cases substantial rewards such as reduced sentence, improved healthcare, or large payments. In addition, they might not receive effective treatment for harms that result from the research study. Therefore, many argue that research studies should be restricted from prison environments. However, despite the risks, research studies can also confer many benefits to inmates. Certain research might be able to improve the health of prisoners and their living conditions. In addition, prisoners can benefit from research in the altruistic sense of finding purpose and satisfaction in their contribution to a greater good and a sense that they are still regarded as useful and contributing members of society. Another argument against the restriction of research in prison settings due to reduced autonomy is that some (like Chwang) argue that even though inmates have diminished autonomy in terms of restricted liberty or freedom, they are still adults who

can make rational decisions. In addition, their diminished range of daily choices that is inherent to prison life does not necessarily denote that they are incapable of making all decisions and does not mean that all of prisoners' decisions are coerced.

In addition to the safeguarding prisoners as individuals with limited autonomy and liberty, ethical guidelines stress the protection of prisoners along the lines of the principle of justice. This ethical principle calls for distributing the benefits and burdens of research. Vulnerable populations, such as prisoners may continually be sought as research subjects because of their easy accessibility, which as mentioned previously has frequently occurred in distant and recent history. In addition, incarcerated persons are often specifically denied access to cutting edge therapies by virtue of their incarceration increasing the gap between the haves and have-nots. This creates an unequal situation that impinges upon the fundamental issue as articulated in the Belmont Report. Various ethical guidelines therefore emphasize that prisoners should not bear disproportionate burdens in research. If they do participate, they require special protections. The IOM recommended particularly strict protections such as research should be limited to phase 3 trials that offer potential benefits to the research participants and not simply to prisoners as a class or the public at large. Further, the ratio of prisoner to non-prisoner research participants should not exceed 50% to guarantee a fair distribution of research burdens. Also, the IOM recommends the use of risk-benefit analysis to ensure that the benefits of the study outweigh the risks. However, the use of additional risk-benefit constraints to protect prisoners from harm such as coercion and exploitation are in fact treating mentally competent adults as if they were children incapable of making rational decisions. As Chwang points out, the only way for risk benefit constraints to eliminate

the exploitation of prisoners and from the harms that could be conferred from bearing the burden of research, the benefits to the inmates must be significantly high enough to exceed the risks they are subject to as societal benefits increase. If society stands to gain a great deal, then subjects must all benefit to a greater degree, in order to prevent the exploitation of prisoners for that societal gain. In addition, under one or another of the ethical guidelines, nearly everyone may be considered “vulnerable” and deserving of special protections, especially since the benefits of research can never be guaranteed in advance. In this case, the concept of vulnerability becomes too vague to be meaningful. Along the same lines, not all member of a group are necessarily vulnerable and thus, the protections that would exclude them from the harms or benefits of research would be inaccurately applied.

Finally, a justification for the use of human beings as research subjects stems from the ethical theory of Utilitarianism. Utilitarianism’s principle of utility articulates that one should choose those actions that will yield the greatest amount of benefit to the most people. According to this theory an individual’s rights may be infringed upon in order to benefit the greater population. In this case, the theory of utilitarianism does not seem to require the use of informed consent as other ethical principles do. If more good will come of forcing, coercing, or exploiting individuals to participate as subjects in a research study, according to this principle it is legitimate and justified. The utilitarian conclusion is that research on human beings is not only permissible, but also morally required to benefit the common good. It argues that the future benefits and prevention of harm to many that result from human experimentation will far outweigh the potential harmful consequences to research subjects. However, it is this mentality, the sacrifice of

the few for the good of the many that led to the atrocities of the Holocaust and the horrors committed to other prisoners and vulnerable individuals. It is the reason for the development of ethical guidelines to protect such groups from being exploited for the benefit of the greater population.

Position Statement

Based on the ethical arguments mentioned previously in this paper, I believe that prisoners should not be restricted from participating in research studies based on their designation as a “vulnerable population.” Regarding the IOM’s proposal for additional risk benefit constraints due to prisoners supposed lack of capacity to supply informed consent to research, I think it is wrong to assume that prisoners need similar constraints to those of children. Adults must protect children by determining what is in their best interest. Prisoners on the other hand, are adults (aside from minors or those who are mentally incompetent, who would require additional constraints) and can make their own rational decisions, in this case particularly regarding whether or not to participate in research. I agree with Chwang’s argument that the additional constraints suggested by the IOM committee do not address the problems that prisoners face more frequently than non-prisoners do, such as coercion, undue inducement, and exploitation. However, I do think that research on human beings in general does need specific safeguards. Therefore, there is no need for additional risk-benefit constraints on prisoner research. Rather, better oversight is needed to guarantee that the appropriate constraints on all research are followed even when the subjects are prisoners. Excluding prisoners from research based on the history of exploitation of this population would leave prisoners without the

benefits of modern science that could improve the quality of their lives and the conditions of the prison environment. With proper and efficient oversight, respect for human beings and scientific advancement do not have to be incompatible.

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