

We are IntechOpen, the world's leading publisher of Open Access books Built by scientists, for scientists

6,900

Open access books available

186,000

International authors and editors

200M

Downloads

Our authors are among the

154

Countries delivered to

TOP 1%

most cited scientists

12.2%

Contributors from top 500 universities



WEB OF SCIENCE™

Selection of our books indexed in the Book Citation Index
in Web of Science™ Core Collection (BKCI)

Interested in publishing with us?
Contact book.department@intechopen.com

Numbers displayed above are based on latest data collected.
For more information visit www.intechopen.com



Nature of Vulnerability in Biomedical and Psychosocial Research

Pablo Alejandro Millones Gómez

Additional information is available at the end of the chapter

<http://dx.doi.org/10.5772/intechopen.70186>

Abstract

This chapter explores the ethics of research as one of the requirements in daily work, considering the protection of the dignity of subjects and the publication of information. It identifies which are the most vulnerable populations as well as the conflicting ones and the ambiguity in the decision making, which in many occasions recurrently appear in the review of the literature on human research. Also, it described strategies to overcome the ethical difficulties encountered in the call and follow-up, with a cultural sensitivity.

Keywords: vulnerability condition, biomedical, psychosocial research

1. Introduction

Often, ethics committees or thesis jury members are in the uncertainty whether to approve or not some work involving the study in humans under so-called vulnerable conditions. And to what extent this could limit or surpass the rights of study subjects. It is necessary to know in detail what the characteristics of these populations are as well as the strategies to overcome these limitations considering the ethical and moral aspects that allow them. The objective of this chapter is to show basic concepts of studies in vulnerable populations, as well as their most relevant characteristics.

2. Vulnerability condition

It begins by defining vulnerability to disability or disability—temporary or permanent, individual or group—to make a valid assessment of the risk-benefit relationship in the context of

an investigation. It is essentially a condition that compromises the exercise of autonomy. The vulnerability condition is dual, which speaks of the reciprocity of actions between the investigator and the participant. Research becomes vulnerable to the extent that one of its actors exhibits limitations for the full protection of personal integrity.

Vulnerable people have limited capacities to consent; this can be given by the absence of power of choice and decision, as in prisoners; legal capacity to consent, for example, in minors; or ability to understand, as it occurs in people with mental illness. A researcher is also vulnerable when choosing a special population. Ethical shortcomings in the recruitment process or in the same experiment can seriously compromise the generalization of the results to other populations, thus fulfilling the biostatistics conditions. In addition, the criminal and civil consequences that involve the fissures in the ethical structure of a research.

The researcher who includes a special group has to recognize that this fact implies a greater sharpness and refinement in the devices that he uses to obtain his results, and even in the long-term follow-up of those who have been his participants. The Bioethics Committee, for its part, has to monitor and advise with particular rigor the protection of the interests of the people linked to the investigative process.

The Helsinki Declaration of the World Medical Association of October 2000 adds, "Medical research on human beings should be carried out only by scientifically qualified persons and under the supervision of a clinically competent physician. The responsibility of human beings must always rest with a person with medical training, and never with the participants in the research, even if they have given their consent." This warning regarding medical research serves to emphasize the need for the appropriate professional qualification of researchers as a means of reducing the vulnerability inherent in the personnel conducting the study.

Often reflection on vulnerability is concentrated on the participants and the analysis of the conditions of the researchers is neglected. In recent years, proposals have been presented to ensure the ethical transparency of research projects. One of the central points in this order of ideas is the declaration of conflicts of interest. A researcher becomes a vulnerable individual when he or she does not fully state the economic, political, or other interests that may substantially compromise his or her ability to make decisions in the course of research. This is a mode of vulnerability that is just beginning to be explored "researchers must be aware and obliged to declare, not only to the Research Ethics Board, but also to the research subjects, any conflict of interest that they may have and any financial gain they expect to obtain per patient as a result of the recruitment." To this point, it is advisable to make a point the researcher, and of course his work group, can also acquire the condition of vulnerability essentially due to deficiencies in training professional and scientific and also for the partial declaration of conflicts of interest.

Bioethics Committees should be alert to the cautious reviews of protocols that focus exclusively on potential organic damage and do not address the likelihood of moral damage. Written registration in the consent of measures such as limits of confidentiality or the means of communication for the call and follow-up denote the interest to prevent the increase in vulnerability derived from participation in the study.

3. Level of dependency

For special and vulnerable populations, their relationship with the biomedical and psychosocial research apparatus determines another criterion for evaluating the conditions for the granting of valid informed consent.

Ethical tension is heightened when research is merged with medical care. "Intimidation, in any way that is done, invalidates informed consent. Potential subjects, who are both patients, often depend on the physician/researcher's medical care, which therefore has some credibility before their eyes, and whose influence on them can be considerable, particularly if the protocol of study has a therapeutic component. They may fear, for example, that refusal to participate would damage the therapeutic relationship or mean the omission of health services. The physician/investigator must assure them that their decision to participate will not affect the therapeutic relationship or other benefits to which they are entitled. In this situation, the ethics review committee should consider whether informed consent should be sought by a neutral third party" [1].

The type of link between the researcher and the participant can increase the vulnerability in a bidirectional way. The researcher may feel more comfortable with people who have already been approached clinically and with whom recruitment is usually easier given prior recognition. However, there are several risks such as intimidation, undue influence and even the introduction of statistical bias due to limitations in sampling, which in turn ethically compromise the study by obtaining restricted results in its generalization.

On the patient/participant front, the situation is also equally complex. People can remain in an investigation, against their personal desire, only to avoid a loss or deterioration in the therapeutic attention they are receiving "even a fully capable person may have difficulty objecting to following a project due to their dependence on the relationship medical, and the vulnerability inherent in such dependence" [2].

Additionally, it should be noted how deficiencies in assertiveness can lead to vulnerability in participants. This becomes more prominent in some Latin American populations where the figure of medical personnel is inserted in a paternalistic model of care that confers an almost absolute power in the therapeutic relationship.

Extending the concept of dependence out of the therapeutic context are similar ethical difficulties in doubles as employer/employee or teacher/student. Dependency is connected to subordination. Faced with economic difficulties or problems in academic performance, linking to a research project, even if it seems voluntary and free, may be the effect of an attempt to please the superior and obtain employment or academic opportunities. A teacher can use his charisma and academic prestige to link his students just as a doctor influences his patients.

The level of dependence marks a criterion of special populations and raises a reflection that must always be present in the formulation and revision of research protocols.

4. Capacity/competence

Capacity and competence criteria have traditionally been reviewed in the field of informed consent. The Nuremberg Code identifies voluntary consent as necessary and essential for the conduct of investigations with persons. Considering the capacity and competence in the discussion of special populations is relevant because precisely their evaluation allows the researcher and the Bioethics Committee to establish whether they have the minimum conditions for obtaining valid informed consent and what kind of additional protective devices should be implemented.

Capacity refers to “the necessary physiological, mental and emotional integrity required to make decisions, and therefore to be considered legally competent” [2]. Capacity is a medical term that results from the evaluation that the investigator or a specialized physician performs, among others, the spheres of mental functioning and the organic state in general.

Capacity may be compromised by fluctuations in a chronic disease or by the intensity of an acute event such as encephalocranial trauma. Similarly, states of limited capacity may be medically induced as during general anesthesia or the use of sedative medication in agitated patients. The ability also refers to the proper integration of external stimuli with the internal mental reality and the behaviors that are executed accordingly. To understand, even more, the concept of capacity is required to integrate variables, which, although they make the analysis more complex, enrich the criteria that base a conclusion, in this order are psychophysiological maturity and sociocultural influences.

For its part, the Competence, a legal term, is “a construction that indicates that a person has the necessary capacity to deal with legally defined acts such as signing contracts, witnessing, being prosecuted or accepting medical interventions.” The link between capacity and competence guides the basic conditions that a researcher must have when working with people belonging to special populations and with vulnerability.

5. Risk-benefit ratio

This relationship is another of the criteria that must be integrated when making the ethical approach of special populations. It was previously defined as vulnerability to disability or disability, temporary or permanent, individual or group, to make a valid assessment of the risk-benefit relationship in the context of an investigation. The logical sequence is then to describe that the distorted evaluation of the risk-benefit relationship generates vulnerability, which in turn results in the condition of subject or special population.

Perhaps the complex of talking about special populations in these times is not so much to identify groups that for decades have been classically recognized as vulnerable. The focus of the discussion should shift to subjects and populations we call “normal” and in which a significant degree of vulnerability is not perceived. The above is mentioned because it is just

the distortion in the assessment of risks and benefits added to the explosion of a plethora of economic incentives that can make that transition in the gray scale from nonvulnerable to vulnerable.

A terrain where the slippery slope of bioethics becomes steeper is that of healthy volunteers. They often participate in research where they are exposed to new drugs or procedures without responding to the reality of a disease or condition that is their own. While recognizing their altruism in exposing their well-being, it is questionable when economic or other rewards motivate their link. The reflection points to the fact that the researcher and the Bioethics Committees recognize in these subjects their vulnerability, despite precisely being "normal."

The issue of vulnerability lies essentially in the area of autonomy and respect for people with diminished autonomy, while that of the risk-benefit relationship corresponds to distributive justice. When applying the principle of justice, it should also be understood that the objectives of the research and its likely outcomes account for a problem that affects the level of well-being and health conditions of vulnerable individuals included. In this way, the expectation of interventions and procedures, which directly benefit their health, would justify their participation.

If we use the principle of beneficence, the researcher and his work group must maximize benefits and reduce risks. However, research with special and vulnerable populations requires additional effort to identify and prevent risks before, during and after the intervention. Precisely the vulnerability increases when the study has concluded the individuals present some damage in their integrity and do not find who respond for damages.

In an attempt to circumvent the difficulties involved in obtaining valid informed consent in special populations, the concept of minimum risk has been introduced to justify interventions or research procedures that have no possibility of direct benefit to their health "Minimum risk means that the probability and magnitude of the predicted harm or discomfort in the research are no greater in themselves than those commonly encountered in daily life or during routine physical or psychological examinations or tests" [2].

At this point, it should be noted that even if the investigative intervention is of minimal risk, or slightly exceeds, this does not exempt from seeking the available channels obtaining consent or assent, if any, for the beginning of the same. Any sign of rejection or desire to leave should be respected without having to request rigorous or extensive explanations about it. In addition, the researcher should question about psychosocial risks such as breach of confidentiality, invasion of privacy, or stigmatization and not focus exclusively on physiological organic risk.

The informed consent process must therefore be particularly rigorous so that individuals or their legal representatives have the option of adequately assessing the benefits of linking them to research in the face of risks.

To summarize, special populations have to be evaluated in the convergence of the criteria of vulnerability condition, level of dependency, capacity/competence, and risk-benefit ratio. With these elements in mind, it is possible to continue the discussion on each particular population group.

5.1. Children

This group includes people who have not reached the age of majority are considered legally incompetent to consent. The extent of this human group and the complexity of its inclusion in research projects deserve a close analysis. The ethical nuclei that guide the evaluation of the protocols and the ethical decision making in this case are condensed in the following three points:

1. Research is aimed at addressing the health needs of children; consequently, it requires that it be performed with this population and not with adults.
2. The parents or legal representatives of the child must authorize their participation.
3. The minor agrees to participate by means of the form of assent and in case of refusal, his decision is respected.

On the other hand, four options have been distinguished for the linking of minors to research projects:

1. The “surrogate” solution allows for investigations with children as with other populations if the parents give consent. This solution can increase the chances of damage if included in high-risk projects. The tutorial and protective role of parents should be guided by the search for welfare for minors; parents do not have the moral authority to enroll their children in potentially harmful research projects.
2. The “non-consent-non-research” solution derived from the Nuremberg code proposal represents the hard line in these solutions. It considers that children are not competent to rationally consent and therefore cannot be recruited into an investigation, even if it provides some benefit to them.
3. The solution “no consent—only therapy” arises from the interpretation of the content of the Declaration of Helsinki. He argues that people with lack of capacity to give consent can only be included in projects that investigate therapeutic options for their disease or condition. However, this proviso does not exclude minors from experiencing discomfort from tests and hospitalizations linked to the therapeutic research. On the other hand, it limits the options of producing and renewing useful knowledge to improve the health conditions of children regardless of a therapeutic objective.
4. The “risk-benefit” solution is governed by United States federal regulations. Investigation with minors is permitted if there are reasonable expectations of direct benefit with a minimized and acceptable level of risk. This modality stresses the need for review by ethics committees, obtaining parental consent and consent. This solution tries to determine if the risks are proportional to the benefits for each participant, it also seeks to strike a balance between the social utility of finding new knowledge and protecting the interests of children undergoing experimentation.

Seeking to protect them has been excluded from research projects, more frequently in studies of new drugs. This has produced a paradoxical situation because the use of drugs in children

ends up being guided by the results obtained in adults, which creates additional risks, unlike projects that are done directly with minors and ethical recommendations. This lack of data and studies with children has led to the formulation of the term “therapeutic orphans” to refer to the situation of inequity in the construction of new knowledge for the therapeutic needs of this population.

Other, more vulnerable subgroups such as fetuses, neonates, and preterm infants can be found in the group of minors. The literature describes cases such as the application of oxygen above the needs of the neonate, leading to blindness and damage to the infant. Crystalline, in therapeutic approaches that were performed without the controlled studies due, it was avoided to perform investigations precisely to not cause damage [3–7].

Researchers must also be alert to expressions of disapproval or refusal of participation by the child, even when parental consent is already available. If it is further considered that the child in question does not have the psychological maturity to accept participation with understanding or giving assent. We are then faced with the figure of deliberate objection. In any case, it should be considered that this does not apply to manifestations such as crying or exaltation to any stimulus. Due to the above, it is also convenient to observe or accompany, if appropriate, a parent while performing the procedures or interventions of the research.

A context in which the vulnerability of minors is multiplied is institutionalization. The formulation and review of research protocols with these children should be especially sensitive to their situation and prevent coercion or undue influence by linking them. They should always be reminded that it is possible to withdraw the research without meaning the discharge of the institution or the loss of special care or care that they require. Researchers must make efforts to explain, as clearly as possible, what the research consists of and how the child’s participation will take place, in understandable terms for their age and their cognitive development.

5.2. Women

The condition of women is often pierced by multiple vulnerabilities. In Latin America and the Caribbean, women and their minor children often suffer from more severe situations of inequity and economic underdevelopment.

Traditionally research with women has taken place to address the health difficulties derived from their reproductive role. Results of research on new drugs, such as those performed with men, have often been generalized without studies being conducted to address the particular physiological and sociocultural conditions of women.

The inclusion of women as a “special” or “vulnerable” population has a record of discrimination, since it seems to presuppose a condition of normality in men and an abnormality in them. “Although women have essentially gained this status as special because they are not men, the fact that they menstruate, become pregnant or experience menopause is highlighted as a reason why researchers need to show special consideration if women who go to be included in the studies” [11]. The work of bioethics must consist precisely in assimilating positive discrimination against women and reorganizing it as a source for overcoming conditions of inequity.

In the 1990s, there was a movement in North America that denounced the scant research being done on the health needs of women. It was proposed, then, the implementation of an already existing policy of inclusion of women in research, which would overcome the low representation in the samples usually selected.

In 1991, the American Medical Association recommended that “the results of medical evaluations made only on men should not be generalized to women without the evidence that these results can be safely and effectively applied to both sexes.” The recommendations have in some cases yielded positive results in the investigation of new drugs, including the study of gender differences, even if costs are increased.

The policy of protectionism or exclusion of women of childbearing age by the risk of becoming pregnant and thus causing harm to the fetus during experiments with new drugs, procedures, or interventions has paradoxically produced a knowledge gap that ends up violating the situation—health of the mother and the fetus. This situation of injustice is added to the restriction on the autonomy of women.

The inclusion of women as research subjects has also had to overcome arguments such as methodological limitations and increased project costs “For the research findings to be meaningful, sample sizes should not only be large enough but also representative of the group to which the findings will be generalized. However, a basic premise for the development of an experimental design is that it uses a sample that excludes subjects whose characteristics may interfere with a clear explanation of the differences between the experimental group and the control.” In some cases, too large samples would be required to detect subtle differences between groups such as gender, age or racial differences. “Consequently, according to the perception that women are special (because of their variable hormonal constitution related to the menstrual cycle, menopause and the use of oral contraceptives or estrogen replacement therapy) they have been excluded from the studies because they control. These variables would require larger and more expensive master sizes.” This methodological justification has been one of the most frequent excuses of the delay in the inclusion of women as research subjects.

The participation of pregnant women in research should be guided by the following recommendations: it should be established whether the research seeks to promote the health of the mother or the fetus and what type of risks it poses for the two. The fetus will be under the minimal risk necessary to meet the mother’s health needs.

Information on the risks to the embryo and the fetus should be included in informed consent if the woman became pregnant during the course of the investigation. The bioethics committee must demand that the appropriate devices be available so that the participating women are informed in a timely manner about the techniques of contraception and the pregnancy report when the situation arises.

In research that seeks to obtain information about the diseases of pregnant women, the health needs of the mother tend to have preeminence with respect to those of the fetus except, perhaps, when the health benefit to the mother is minimal and the risk to the fetus is high. Finally,

in women who are breastfeeding the committee should ensure that they are given adequate information about the risks they run and the nutritional alternatives they have.

5.3. Older adults

Older adults become more vulnerable when they experience cognitive impairment or are institutionalized, often resulting in difficulties in making decisions for themselves in the time required. For the researcher and for the Bioethics Committee, it may be difficult to introduce older adults as a vulnerable population because they can, on the one hand, attend to particular protection needs, but on the other, their self-respecting status may be affected.

Usually, the older adult does not necessarily have to be always considered a vulnerable person. In accordance with the principle of justice, older adults should also be included in biomedical research to share the potential benefits derived from them. On the other hand, the researcher must consider, for example in the case of experimental drugs, the particular physiological conditions that this population group keeps and not necessarily make inferences from the studies carried out in young adults.

The most described limitations for the inclusion of older adults in research are the presence of several chronic diseases for which they receive multiple medications, which represents methodological difficulties and additional statistics in controlled studies; high dropout rate; greater time of dedication to the realization of informed consent due to hearing and visual difficulties, among others; cognitive deficit isolated or associated with a dementia syndrome; and loss of autonomy that is reflected in relationships of dependence with caregivers or entry to asylum institutions.

The CIOMS guidelines of 2002 mention in this regard “Older adults are commonly considered vulnerable. As the age advances, people are more likely to acquire characteristics that define them as vulnerable. They may, for example, be hospitalized or develop various degrees of dementia. It is appropriate to regard them as vulnerable, and treat them as such, only when they have acquired those attributes.” This helps to understand that it is often not the age that marks intrinsically the condition of vulnerability but the pathological or deficient characteristics associated with it.

At the beginning of the chapter, the level of dependency was mentioned as a criterion of vulnerability. To conceptually integrate these elements with aging, I will take the proposal of on the three forms of dependence generated by aging, namely (1) the deficiency or impairment that corresponds to a reversible alteration or at least can be corrected with adaptations in life as with delayed walking; (2) the disability or objective and irreversible impairment in some or several social functions as happens with presbyopia or hearing loss; and (3) the disability that corresponds to a total reorganization of life according to the disabilities or disabilities that are suffered.

“As it is evident that there can be impairments without disabilities and disabilities without disabilities, it is evident that the process of helplessness, incapacity, or incompetence—focused individually and societally—is not biological invariant but biographical development. Being a biography

and not biology, its social construction is a matter related to culture, language and beliefs. It may be argued, however, that there is a quantum of progressive deprivation that is personally and socially estimated and that it constitutes the addition of impairments, disabilities and handicaps and is expressed in different spheres. For example, there is a situational helplessness, which excludes people, according to their age, from certain contexts. There is a cognitive mismatch or incompetence, which allows us to relativize the attentional or anemic yields and even expect a coefficient of functional loss” The central point will then be in the estimation of the quantum of helplessness proposed by this author, which should be part of the work of the researcher and the Bioethics Committee. The level of dependence generates a situation of vulnerability that will be considered in the evaluation of the capacity and competence to give a valid informed consent.

When informed consent is made, researchers should consider more than age, the conservation of autonomy, the level of education achieved, the state of health and the conditions under which it is performed. This is in order to determine the cognitive difficulties that may compromise the ability and competence to process the information provided. It is convenient to link in this process the caregivers or responsible persons with the well-being of the older adult, without this meaning the substitution of the decision-making capacity by the participant.

In the process of informed consent, it is essential to insist on the simple description of the basic conditions of the study and to verify that the information has actually been retained and can be evoked when required. In this sense, some authors recommend to include only those elderly who, after having received an initial information, are able to pass a test about their participation in the study. What is complex for researchers is to establish, what the minimum level of understanding they require in their participants so that consent is valid through the study. It is advisable to reiterate the basic conditions of your participation, emphasizing the risk-benefit relationship and your rights as a patient.

5.4. People with cognitive disabilities

There is an ethical tension between the interests of society and science to gain new knowledge about mental illness and cognitive disorders and the need to fully protect the interests of those who suffer from them. Some authors even point to this tension as the cause of the slowness in the application of modern neurosciences to psychiatric diseases.

To begin with, it is important to define the population group, special and vulnerable, which is included in this category. Cognitive impairment refers to “those persons who have a psychiatric disorder (psychosis, neurosis, personality disorder, or behavioral disorder), an organic deterioration (dementia), or a developmental disorder (mental retardation) that affects cognitive or emotional functions and which Lead to a significant decrease in judgment and reasoning. Other people can also be included as drug addicts or those who are under the influence of substances (drugs, alcohol), people with degenerative brain diseases, terminal patients, and people with severe physical disabilities” [5, 8].

The fundamental criterion that ethically justifies the linkage of people with cognitive disabilities to consent is that the research is oriented to obtain knowledge about diseases or conditions that directly affect them and could not be done with other types of people. The central axis of reflection for researchers and the Bioethics Committee is to determine the ability to

understand the information provided the ability to make a reasonable decision about their participation and the consequences of it. Competition may fluctuate as a function in the natural course of a mental illness, in response to treatment, as medication effect, or as damage to general physical health, among other factors. The competition criteria propped up in deliberation and rationality can in turn be influenced by mood, for example, people with psychotic depression can consent to high-risk research as a way to atone for their guilt.

Not every subject with cognitive defects is necessarily incompetent "... cognitively impaired subjects form a heterogeneous population of patients, and may have, to varying degrees, impaired their ability to give a valid informed consent." Cognitive impairment alone does not disqualify the person to give consent. As a general rule, all adults should be considered competent to give informed consent, regardless of their diagnosis or condition, unless there is evidence of severe mental incapacity to impair judgment and reasoning.

People with cognitive disabilities who are in institutions multiply their special and vulnerable population status. An institutional context may favor conditions for the researcher accessibility to participants, close supervision to control environmental variables and availability of resources for monitoring and emergency care. However, the recruitment of people in these media can compromise the voluntary nature of their participation in the study. Individuals who are totally dependent on an institution may feel pressured to participate in exchange for continuing inpatient care. The recommendation is not to include institutionalized individuals as far as possible.

Now, it is convenient to clarify that not all people by the fact of being institutionalized have simultaneously lost their capacity and competence to give consent. The measures taken in the investigation should be clearly indicated to avoid or reduce the likelihood of adverse reactions, as well as to specify how the privacy of the individuals will be protected and the confidentiality of their information. The effect of institutionalization on the ability to make a free choice (voluntary) should be considered. It is important to protect the privacy of all subjects and the confidentiality of information obtained in research that contains emotionally sensitive topics (sensitive information).

People who are legally the guardians or legal guardians of people with mental disabilities should also be vigilant so that the investigation does not run beyond the minimal risk and avoid causing harm or discomfort. Even in cases of individuals with legal guardians, it is advisable to ask the consent to the people with mental limitation. So, you must respect your feelings, expressed wishes, and the right to exercise deliberate objection.

Summarizes the ethical requirements of research in people with cognitive disabilities as follows: (1) risk is only minimal, (2) research is related to patient problems that cannot be investigated with competent persons, (3) disabled persons by themselves have not verbally or behaviorally objected to their participation, (4) family members agree upon being fully informed, and (5) the ethics committee has given its approval [9–16].

5.5. People in institutions or subordinates

It is a group that each gains more ground in the bioethical discussion of special populations. It includes, among others: prisoners, students, employees, soldiers, and people residing in institutions such as asylums, convents, etc.

The CIOMS guidelines of 2002 refer to this “The quality of consent of potential young subjects or subordinate members of a hierarchical group should be carefully considered, since their acceptance, whether justified or not, may be unduly influenced by the possibility of preferential treatment or for fear of disapproval or retaliation in case of refusal. These groups include medical and nursing students, subordinate staff from hospitals and laboratories, employees of pharmaceutical companies and members of the armed forces or police. Because these people work closely with researchers, they tend to require them mostly to participate as research subjects, and this can lead to an unequal distribution of research burdens and benefits.”

In the following it will be mentioned the prisoners and students as representative of the collective of people in institutions or subordinates.

5.6. Prisoners

Prisoner is understood to mean a person involuntarily confined in a penal institution because he was sentenced according to the codes in force in each country; he is detained and pending judgment or sentence; he is interned by legal mandate for the treatment of drug dependence and alcoholism.

Until the 1970s, researchers used to include prisoners in their experiments because of the facilities in terms of accessibility, permanence, control of external variables, and cost reduction. However, on the obverse are various ethical tensions such as coercion, undue inducement, unbalanced risk-benefit relationship, multiple studies with the same subjects, limitation in the ability to make autonomous decisions, excessive or poor economic remuneration for their participation, and breaches of confidentiality in the prison environment, given the security conditions that are applied. As in other special groups, the researcher must ask himself if his study is designed to respond to a particular situation of this population that can only be clarified with his participation.

Institutions of incarceration are characterized by being “totalitarian” institutions, that is, they have defined the environment and social relations at the service of a central authority, often exert acts of submission or subordination to preserve such control. Under these conditions, it is very complex to establish the voluntariness of informed consent and respect for autonomy, in accordance with the postulates of the Nuremberg Code.

Ethically, difficulties arise in obtaining free consent when healthcare improvements, places of confinement or economic rewards are offered. Some authors defend the participation of the prisoners as one more work that they can carry with their body while they are rehabilitated; However, the current trend is to break this connection “... prisoners may be free enough to consent to prison work but not to consent to an investigation.”

A central issue in analyzing the subject of prisoners is their subordinate nature, so their voluntary participation may be compromised by the relational and authority characteristics of their detention center. Situations of economic demands are often given to prisoners to provide basic conditions such as a mattress or food. The researcher can inadvertently be introduced into this dynamic and favor inequality conditions. The precarious conditions of many detention

centers in Latin America and the Caribbean pave the way for undue influence when financial rewards are offered for participation in experimentation.

The United States Department of Health and Human Services has delimited the participation of prisoners in investigations that as follows (1) inquire into the causes, effects, and processes of incarceration and criminal conduct, and which do not involve minimum risk; (2) study prisons as institutional structures or prisoners as interned; (3) explore conditions that affect them in a particular way; and (4) try therapies that are likely to benefit them directly as inmates [17, 18].

5.7. Students

In the case of students, it is important to distinguish if they are in a position to freely choose their participation in the study. Often their teachers are the same researchers. A rejection of participation could therefore be understood as a lack of cooperation with the very development of the knowledge it is receiving. The situation becomes more complex when the participation is part of the same evaluative process of the course that is advanced. If a student is faced with performing a written assignment or submitting a test, on the one hand, and participating in an investigation, on the other hand, he is likely to be inclined to link to the study thereby ensuring course approval and obtaining teacher complacency.

The researcher may be inclined to take students as participants in the research projects given their accessibility and frequent availability. However, caution should be exercised when working with homogeneous populations (such as university students) as the study findings are not necessarily generalizable to all students and the general population. Another aspect is the so-called Educational Benefit, whereby recruitment into research is understood as an opportunity for practical learning. This argument is particularly delicate because it conflicts with the student's willingness to face his desire for academic training.

In order to make the linkage of students to research projects more transparent and ethically sustainable, a number of recommendations have been formulated. One is to conduct calls for research openly to the entire group of students and not individually. When the request is made individually, there is a risk of undue influence, whether due to the type of relationship (academic or work) that the researcher has with the candidate. The information transmitted should not reduce risks or magnify benefits. Another recommendation is to unlink the research participation of the evaluation process of the subject; the student should be offered alternative activities comparable to the link to the study. The US regulations consider possible economic compensation for the participants as long as it is adjusted to the time spent, the discomfort experienced, and the risk assumed.

In the context of research with student subjects, the mechanisms that protect the collected information, especially sensitive information such as sexual activity, mental health, or drug use, should be considered.

The employees follow ethical guidelines similar to those of the students to guarantee precisely the absence of coercion or undue pressure and the confidential preservation of the data

collected. As in all research with special and vulnerable populations, it must be borne in mind that their design must obey the need to know and improve the particular conditions of the subjects under study.

5.8. People in critical medical conditions or in coma

Often the ability of polytraumatized people with severe life or coma risk is severely compromised. The commitment of the state of conscience or the urgency for the accomplishment of a medical intervention limits the granting of a valid informed consent.

The FDA allows exceptions to informed consent when the investigator and another nonresearch physician can certify in writing that these are life-threatening situations, the participant's consent can not be obtained because of their inability to communicate or give a legally valid consent, there is insufficient time to obtain the consent of a legal representative and there is no alternative or generally accepted or approved therapy offering an equal or greater likelihood of saving life. Documentation of these conditions must be sent to the ethics committee within 5 business days after the event.

On the other hand, there are opinions that defend the exclusion of traumatized subjects or coma in investigations with risk above the minimum if they do not have the proper informed consent or the authorization of a previously authorized legal representative. Otherwise, the person should receive conventional care for their urgent situation.

The Bioethics Committee should establish the risk-benefit ratio and whether the possible benefit is reasonable in relation to the risks involved. When the risk is greater than the minimum, the informed consent of the patient or his/her legal representative must be obtained. However, in the context of emergency care, it may happen that there is no accessibility or time to contact a relative or legal representative who can give the respective consent. In some investigations, it is foreseeable that urgent situations arise or the surgeries of critically ill people are scheduled, in which cases consent must be obtained in advance.

5.9. People with terminal illness

These are people who have a life-threatening disease or deteriorating condition for which there is no effective standard treatment. The terminally ill are a highly vulnerable population in which researchers and the Bioethics Committee should carefully analyze research protocols to avoid coercion and undue influence. Individuals can unconditionally accept treatments or interventions in an ultimate desire to improve or cure their terminal condition.

In developing countries, the situation becomes more complex since entering the research protocols represents for many people the only option to receive medication or some therapeutic modality that can alleviate the difficult situation experienced. People with terminal illness may consider that if they do not agree to participate in an investigation they may lose health care they are receiving or that their doctor would not be interested in other efforts to improve their health conditions. On the other hand, they may also consider receiving the treatment under investigation is better than receiving nothing. Some also understand that their involvement has an altruistic sense to improve the conditions of future patients.

The 2002 CIOMS guidelines state “People who have potentially crippling or fatal serious diseases are highly vulnerable.” As in other cases, research must address the particular conditions and needs in health and quality of life of individuals with the specific disease or condition that the participants have. Their desire to withdraw at any time must be respected, but the necessary information must also be given to assess the risk-benefit ratio.

It is important to make the difference between risks justified by the likely therapeutic benefits of the research and the risks associated with procedures carried out purely for investigative purposes. The subjects must exercise their autonomy based on a sufficient explanation of the risks and benefits and the degree of uncertainty regarding the results; Consent must conform to real expectations so as not to create false expectations or to break down all hope. If it is considered advisable, the informed consent process must be carried out in the company of a family member or legal representative. Particular emphasis should be given to consent to the conditions of eligibility of individuals based on their diagnosis and prognosis, as well as to show the alternative treatments and define the advantages between receiving and not receiving treatment. The ethics committee should also ask why it is appropriate for the treating physician to act as a researcher [5].

5.10. Healthy volunteers

In healthy volunteers, the dual vulnerability between participant-researcher described at the beginning of the chapter is presented. The researcher knows partially the risk-benefit relationship; in fact, to overcome such situation is that research, while the healthy volunteer participates based on the information, usually partial, that they provide. This mutual ignorance of the risks and benefits added to economic, labor, or social pressures has made them increasingly considered as a special and vulnerable group, so much of the pharmacological knowledge of the twentieth century has been built with their participation.

For healthy volunteers, their participation does not result in a direct therapeutic benefit although there are levels of risk that up to that time have not had other human beings. The role of the researcher should therefore be to reduce as much as possible the level of risk, this to establish reciprocity with the altruistic motivation that leads them to bond.

Healthy volunteers should receive available information about the research and reasonably expected results that the investigator believes may be expected. Consent must be free from coercion and undue inducement to participate. The latter is considered mainly in the field of economic remunerations that must be consistent with the time spent, discomfort generated, and risk assumed. In studies with increased risk should be considered that a motivation of volunteers may be precisely the money offered; In this situation, which is frequent in Latin America, a type of vulnerability is derived from economic and educational status that compromises the ability to objectively assess the risks assumed when informed consent.

In this chapter, the special populations of biomedical and psychosocial research have been approached considering the convergence of the criteria of vulnerability, level of dependence, capacity/competence and risk-benefit ratio as a proposal of an approach that favors the inclusion and NOT the exclusion of these people and human groups in the production and transformation of knowledge.

Author details

Pablo Alejandro Millones Gómez

Address all correspondence to: pablodent@hotmail.com

Universidad Católica Los Angeles de Chimbote, Trujillo, Perú

References

- [1] CIOMS. Pautas Éticas Internacionales de las Ciencias Médicas (CIOMS) en colaboración con la Organización Mundial de la Salud-Ginebra 2002. Programa Regional de Bioética OPS/OMS. Santiago: LOM Ediciones; 2003
- [2] Arboleda Florez J. La investigación en sujetos humanos: poblaciones vulnerables. En: Investigación en Sujetos Humanos: Experiencia Internacional. Pellegrini Filho A, y Macklin R, editors. OPS/OMS Serie Publicaciones. Programa Regional de Bioética. 1999
- [3] Real Academia Española. Diccionario de la Lengua Española. Vigésima Segunda Edición. Tomo II. Madrid: Espasa Calpe; 2001
- [4] Drane J. The many faces of competency. In: Mappes Th, Zembaty J, editors. Biomedical Ethics. 3rd ed. New York: McGraw-Hill; 1991
- [5] Reich W, editor. Children: Health-Care and Research Issues. Encyclopedia of Bioethics. New York: Simon&Schuster MacMillan; 1995
- [6] Levine RJ. Ethics and Regulation of Clinical Research. 2nd ed. New Haven: Yale University Press; 1986
- [7] Perlman M. Ethics of research in neonatos. In: Koren G, editor. Textbook of Ethics in Pediatric Research. Malabar: Krieger Publishing Company; 1993
- [8] Gracia D. Ética de los confines de la vida. Ética y vida. Estudios de bioética 3. Bogotá, El Búho; 1998
- [9] Cabello F. Experimentación en humanos y derechos humanos. ¿Está permitida la experimentación biomédica con niños? Revista Medica De Chile. 1986;114:57-60
- [10] Wilson A. Women: Research issues. In: Encyclopedia of Bioethics. Reich WTh/New York; Simon&Schuster MacMillan, 1995
- [11] Sachs G. Aging and the aged: Health-Care and Research Issues. In: Encyclopedia of Bioethics. Reich WTh/New York: Simon&Schuster MacMillan; 1995
- [12] Lolas F. Bioética y Vejez: el proceso de desvalimiento como constructo biográfico. OPS/OMS. Cuadernos del Programa Regional de Bioética. Número 2. Santiago. 1996

- [13] Cuénod M, Passer J. Symposium on consent and confidentiality. Research on the mentally incompetent. *Journal of Medical Ethics*. 2003;**29**:19-21
- [14] Elliott C. Mentally disabled and mentally ill persons: Research issues. In: *Encyclopedia of Bioethics*. Reich WTh/New York, Simon&Schuster MacMillan; 1995
- [15] Lavados Montes M. Aspectos éticos relacionados con la participación de sujetos cognitivamente impedidos en proyectos de investigación biomédica. OPS/OMS. Cuadernos del Programa Regional de Bioética. Número 3. Santiago. 1996
- [16] Wing J. Ethics and psychiatric research. In: *Psychiatric Ethics*. 2nd ed. Trowbridge: Oxford Medical Publications; 1994
- [17] Branson R. Prisoners: Research issues. In: *Encyclopedia of Bioethics*. Reich WTh/New York: Simon&Schuster MacMillan; 1995
- [18] Millar B. Students as research subjects. In: *Encyclopedia of Bioethics*. Reich WTh/New York: Simon&Schuster, MacMillan; 1995

