



The free and clarified consent and research subject's vulnerability

Mary Lee dos Santos
Adauto Emmerich

Abstract

The Resolution CNS 196/96 of the Brazilian Health Ministry establishes conditions for research involving human subjects and it establishes subject's protection with free and informed term of consent (FITC). The paper investigated subjects' profile, establishing the relationship between subjects' knowledge about the research and their social background. To safeguard confidentiality and privacy of researchers, the institutional ethics committee invited researchers to participate in the study, but only released their contact information upon their acceptance to be in the study. The population more frequently investigated includes patients, health workers, health course students and elderly both from groups of patients and from nursing homes. 75% of subjects were from lower income classes (D and E) and despite higher education of 49% of subjects, 60% never read the informed consent. It is necessary to renew the importance of informed consent as to educate volunteers, including information about their health conditions, thus allowing for better communication between subjects and researchers and further consideration of social vulnerability.

Key words: Bioethics. Human research subjects. Informed consent.



Mary Lee dos Santos
Physiotherapist at Higher School of Sciences of the Holy Mercy House, expert in Ethics and Master in Collective Health at the Federal University of Espirito Santo, working on her PhD in the Bioethics, Applied Ethics, and Collective Health graduate program at the National Public Health School, Federal University of Rio de Janeiro, State University of Rio de Janeiro, Federal Fluminense University (ENSP/UFRJ/ UERJ/UFF), professor at Federal Fluminense University (UFF), Niteroi, Rio de Janeiro, Brazil

The search for new knowledge that can bring benefits for society is part of an intricate network of relationships established in parameter as much human as perverse. Much of this perversity manifests over the more fragile members of society, the sick or forsaken, included in this group the mentally disabled, children, senile, and those institutionalized of any order ¹.

In international consensus, contemplated in Resolution 196/96 ², the more vulnerable populations, traditionally comprised by children and adolescents, carriers of mental disorder or mental disease, and subject in situations of substantive diminished consent capability, demand additional protection. In the same situations are included adults and *capable exposed to specific conditionings or to authority's influence, particularly students, military, employees, prisoners, interns in rehabilitation centers, shelter homes, asylum, religious associations, and similar* ². However, the domestic resolution does not contemplate vulnerability due to economic or educational disadvantage, a criterion established already in other countries ³.





Adauto Emmerich

Dentist at the Federal University of Espirito Santo, post- doctorate at the Federal University of Rio de Janeiro, professor and head of Social Medicine University at the Federal University of Espirito Santo, Vitoria, Espirito Santo, Brazil

There are not valid universal protocols to evaluate vulnerability of research voluntaries or designed to assure the adequate clarification for the full exercise of their autonomy. Such evaluation, although it is not a requirement of the process, should be routine part of getting the free and clarified consent term (FCCT), which should be written in clear language, in layman's terms, making available pertinent information of the research project. Paradoxically, the same protection mechanism, that is, confidentiality of protocols of the study, makes research subject to remain anonymous and unknown, in addition to be impersonally described in projects. Who they are, how they live and what do they think regarding researches of which they are crucial parts, are scarce information in current literature.

Studies undertaken in Europe and in the United States ^{4,5} on clarified consent term show that many volunteers, after signing the document, do not understand the study on which they participate or of their rights. Difficulty is greater in developing countries, with poor volunteers with lower educational level, little or no familiarity with usual procedures of medical research and with own ideas about the origin of the diseases ³.

Detecting vulnerability after getting the FCCT meets three basic purposes: a) evidencing the circumstance(s) that may devaluate or invalidate consents ⁶; b) determine additional protection measures in view of found vulnerabilities; and c) to provide theoretical basis to ensure understanding about the research ⁷.

The present study proposes to know academic research landscape in a higher education institution in health



area from research projects approved the ethics in research committee (CEP) of the institution. The first relevant aspect is the considerable increase in number of projects, mainly academic research, which coincides with research legal requirement the domestic undergraduate courses.

The study sought to know the final understanding of the subject about the research⁴, if they understand the relevance of their participation, and if there is interference of social factors⁵ in the comprehension about their role. The project did not evaluate the research or the relationship between researchers and subjects or other aspects contemplated in the consubstantiated opinion issued by CEP approving the project.

Results and conclusion

Based in methodology used in the study, 12 projects were selected from a stratified sample. Introspective studies, reported cases, invasive procedures were excluded, and it was considered the location where the Project was undertaken, which determined the selection of only one project for each location as well as inclusion of just one research by the same author. The study identified most frequent volunteers: a) health workers (hospital and health unit) = four projects; b) student from the institution = 1 project; c) patients from the institution = 1 project; d) patients from the institution in modality of group assistance, and elderly groups (including seniors living in long stay institutions) = 6 projects.

From this volunteer population, 50 individuals were selected by probabilistic sampling through simple randomness technique to comprise the sample. One realizes that recruitment falls on more available individuals and groups with which academic and scientific communities have greater familiarity, independently of their vulnerability level. Designing of studies varies, but it implies contact with research subjects, even if just of short term.

Age shows that 37.2% are between 18 and 40 years old; 27.4% between 41 and 60 years old, and 35.2% are 61 years old or over. On gender, 76.4% are women, and concerning color or race, 35.9% are white, 14% blacks, and 51% declared themselves as dark-skinned.

In order to analyze distribution of sample by social class, parameters of study undertaken by the Getulio Vargas Foundation⁹ were used, which establishes threshold for household total monthly income: a) class E, between zero and R\$ 768; b) class D, between R\$ 768 and R\$ 1,064; c) class C, between R\$ 1,064 and R\$ 4,591; d) class B, with income higher than R\$ 4,591; and class A, with values above R\$ 6,563. The figures obtained show that among subjects there absence of class A, and deviated distribution by classes D and E, corresponding to 75% of volunteers.

Main occupation of 60% of volunteers concentrates in the services sector, 15% are in farming and 25% are divided between industry, trade or abstained to reply; total of 100% of employees.



Analysis of schooling reveals that 12% of participants are illiterates, 21.6% have up to eight years of schooling; 15.7% up to eleven years of schooling, and 49% over 11 years of schooling.

Considering the household unit, 68% of subjects have families with up to Five members; and 32% have families with up to eight members. The household units have good spatial distribution with two members by dormitory, been headed in equal proportions by man and woman (47% women and 53% men). All have pipe water, sewer, garbage collection, and electricity.

Among the interviewed, 43.13% have access to other health service in addition to that where they were recruited for the research. Concerning the age of those who do not have access to other health service, the majority, 44.84% is older than 61 years, while the remnant of the sample is equally distributed in age ranges of 18 to 40 years old, and 41 to 60 years old.

Subject that read the FCCT (48%) did it once, alone, and they stated that after reading it they understood the research better. However, they expect to benefit from the study, although none of projects included in it brought them immediate benefit. Despite reading, they did not know the basic information about the research, such as, for example, its duration. Although less vulnerable, participants with more schooling years, when questioned about FCCT and its function, they did not show more knowledge about than the average of all participants, and they attribute

importance to their participation and to the research itself. Out of those that did not read the FCCT (52% of the study sample), 40% did not read it because they do not know reading, 35% did not present any reason for not reading the document, and the remnant justified that the document “was too large”, or “the physician explained well”, or “were not interested”. The survey reveals that 48% of total interviewed individuals, in addition to not knowing project duration, they were not capable either to inform on its results, what suggests that communication with subject ceases, in most of the times, with data collection.

In vulnerability evaluation, 100% declared not fearing that their refusal in participating in the study could bring them difficulties in assistance. They were all aware that it is a voluntary activity, and that it could be interrupted without personal consequences. This is the sole unanimous aspect to all interviewed and it deserves to be investigated better due to the constraining risk, since anybody left the projects before its ending nor manifested the desire of doing it. For Biondo-Simoes *et al*¹⁰, the subjects for the research should be those with better education, used to reading, easiness to access to the Internet, and higher incomes. Although this profile be coherent with the volunteers from the group of health sector professionals and undergraduate students in the same área, the current study shows that 100% of this group did not red the FCCT and, consequently, ignored information.





Thus, one realizes that the research involves doubts, and with undertaking of personal vulnerability aspects that cannot be detected by the interviews for FCCT information and signing. CEPs or realized by researchers, such as, for The educational role attributed to CEP bring examples, the schooling years criterion, of access these experiences closer, not common in the to other health services, and volunteers' decision of domestic scenario, to the ideal that inspired not reading attentively the FCCT. How to ensure Resolution CNS 196/96 –which guides research less vulnerability of subjects without changing the in Brazil.

methodological and ethical evaluations to which projects are submitted? Is it feasible to impose stricter control and restrictions to research? And, if this is the way to assure less vulnerability to volunteers, should this greater control be in charge of CEP/Conep system? These are some of the questions raised by the present study and which should not be ignored or considered a punctual case, without similarity in the national landscape.

Although it is a major tool of change, it is naive to think that health education or as it is proposed herein, *in research*, be the ideal solution for vulnerability situations. Predisposition to vulnerability is a health literacy phenomenon¹³, a different concept from the traditional Idea that health education, crucial for improving the health of people. The expression health literacy translates into a set of individual notions regarding health and care, about which the individual bases himself for decision making about his own health.

Social control is one of the most important in the CEP/Conep system. The ideal associated to social control is that of responsible and proactive participation. Therefore, it is from this theoretical axis that should originate solutions for difficulties unique to the system. One should seek answers inside the system itself, strengthening and rescuing already available and effectively proven tools. Lacativa e al¹¹, as well as Goldim¹², point to, in this sense, effective communication with the subject in order to give potential to FCCT protecting action. Experiments are successful information processes, undertaken in group, with multimedia resources to make relevant and needed data available for understanding the research, in suitable language, sheltering environment and appropriate to clarify

It is necessary to acknowledge that the scientific community is not responsible for inequality, but it needs to consider that volunteers do not dispose of needed competences and skills to find, understand, evaluate, communicate, and use information and concepts about health. It is in this recognition that researcher's ethical stand establishes itself¹².

Systemizing educational actions for research subjects is consonant proposal to the Brazilian format for ethical evaluation of research. It is possible, to this end, to



transpose to research the theoretical Nevertheless, closer contact with volunteers landmark of other successful actions, such as at the initial stage of the study allows the Back School model developed in 1969, in researcher to recognize this condition and to Switzerland by the physiotherapist Mariane seek alternatives to clarify participants Zachrisson-Forssell. Her program - better. It is obvious that dedicating more time internationally consecrated as postural training to volunteers' clarification increases the method – consists in four meetings, twice weekly, duration of research and it places a burden to lasting 45 minutes and with participation of six to researchers with one more task. The twelve people. The first two classes are advantage of this proposal – mainly in academic theoretical, the third is practical, and the last a research, when the objective is to train practical review of approached content ¹⁴. professionals with a critical vision and respect

The Back School model can be applied to research – is to enable the development of an inform subjects on the project, presentation of efficient communication and the strengthening procedures to be undertaken, and to clarify of the sacred bond with the other volunteers about the importance of their (subject/future patient), and may be presented participation, as well as about the factors that to young researchers as part of learning. qualify them for the study. Consequently, it may

contribute also for knowledge of their health Education and research, in addition to set a conditions, in addition to set a forum for binomial in knowledge production, also enjoy a appropriate to manifestations of information, reciprocal relation. Thus, the need to incorporate inclusively establishing a timetable for contacts the education strategy to the research act, to be fulfilled after completion of study to extensive to all involved, inclusively volunteers. communicate the outcomes. Therefore, it is not enough that researcher

study to research and acquire new knowledge about the object of study. It is It is important to respect volunteers privacy necessary as well for those that establishing *a priori* that only general information contribute in knowledge production will be made available collectively, owing their to be part of the process and to adherence to collective meeting be voluntary. to benefit from knowledge brought in Furthermore, each volunteer, isolatedly, will make by the research. contact with researchers to solve his doubts and to

communicate his decision to participate or not in the study. Despite these measures, many To invest in research volunteer's volunteers may not assimilate provided clarification and autonomy, through information educational activities, developed during selection of subjects, is a measure of easy installation and intrinsically associated to academic environment.

Disseminating it, stimulating ~~as~~ more they are able to attribute new undertaking and contributing for its meanings to subject's protection and to implementation is the task of entire realize the complexity of his participation in scientific community, but to acknowledge the search for responses that will benefit its importance is CEP role, which the more the entire society. ripe ethical reasoning and analysis, the

Resumo

O consentimento livre e esclarecido e a vulnerabilidade do sujeito de pesquisa

A Resolução CNS 196/96 normatiza a pesquisa envolvendo seres humanos e estabelece a proteção do voluntário com o termo de consentimento livre e esclarecido (TCLE). O trabalho investigou o perfil de sujeitos de pesquisas de uma instituição de ensino buscando estabelecer relação entre sua condição socioeconômica e o entendimento sobre a pesquisa. O CEP intermediou o contato entre pesquisadores, revelando apenas a identidade dos que aceitaram participar da investigação. Os voluntários mais frequentes são pacientes, trabalhadores dos serviços públicos de saúde, estudantes da instituição e grupos de idosos e residentes de instituições de longa permanência. Destes, 75% pertencem às classes D e E, e apesar da alta escolaridade de 49% dos voluntários, 60% não leram o TCLE. Os resultados apontam a necessidade de resgatar o valor do TCLE mediante ações de educação, tornando a comunicação mais eficiente entre pesquisador e voluntário, além de propiciar maior consideração à vulnerabilidade social.

Palavras-chave: Bioética. Sujeitos da pesquisa. Consentimento livre e esclarecido.

Resumen

El consentimiento libre y esclarecido y la vulnerabilidad de los sujetos humanos de investigación

La Resolución CNS 196/96 regula la investigación en seres humanos y proporciona protección a los voluntarios con consentimiento informado. El estudio investigó el perfil de los sujetos de investigación de una institución de enseñanza para establecer la relación entre sus condiciones socio-económicas y la comprensión de la investigación. El CEP medió el contacto entre investigadores, revelando solamente la identidad de los que aceptaron participar en la investigación. Los voluntarios más frecuentes son los pacientes, los trabajadores de los servicios de salud pública, los estudiantes de la institución y grupos de ancianos y residentes de instituciones de larga permanencia. De éstos el 75% pertenecen a las clases D y E, y pese al alto nivel de escolaridad del 49% de los voluntarios, un 60% de ellos no había leído el TCLE (Término de consentimiento libre y esclarecido). Los resultados indican la necesidad de recuperar el valor del TCLE mediante actividades de educación, haciendo la comunicación más eficaz entre los investigadores y voluntarios, además de dar propiciar mayor consideración a la vulnerabilidad social.

Palabras-clave: Bioética. Sujetos de investigación. Consentimiento informado.

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Contacts

Mary Lee dos Santos - maryleedossantos@gmail.com

Adauto Emmerich - adautoemmerich@terra.com.br

Mary Lee dos Santos - Av. Desembargador Cassiano Castelo, 70, Manguinhos CEP 29173-037. Serra/ES, Brasil.

Authors participation in the article

Mary Lee dos Santos developed the article from its Master's degree thesis and Adauto Emmerich was her advisor.

