The free and clarified consent term in research with humans

Item Type	Article
Authors	Maluf, Fabiano;Garrafa, Volnei
Publisher	Conselho Federal de Medicina
Rights	Creative Commons Copyright (CC 2.5)
Download date	2026-07-10 18:22:08
Link to Item	http://hdl.handle.net/20.500.12424/237560

Original Articles

The free and clarified consent term in research with humans: a case study

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Abstract

The consolidation of the Brazilian system of ethical review of researches with humans is the outcome of Resolution 196/96 by the National Health Council, which contributed significantly to bioethics expansion in Brazil. The current paper aims to verify the use of free and clarified consent term (FCCT) in dissertations and thesis defended in Health Sciences graduate programs at the University of Brasilia during the period of August 1996 to December 2006. The outcomes show an awareness landscape in researchers' training regarding effective application of bioethics pillars, more specifically the respect for the principle of research subjects' autonomy.

Key words: Ethics in research. Informed consent. Bioethics.

Approval CEP-FM/UnB No. 37/2007

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Biomedical research has its roots in the last decades of the 18th century, but only from the 19th century on is starts to be developed with due methodological rigor. With the increase in scientific productivity, and due to the fact that it is not restricted anymore to an amateur activity as was initially, nor exclusively at the university ambit, as in the 19th century, biomedical researches have acquired greater visibility in the 20th century [1].

As a result of all this progress and development to the field of ethics in research began to demand better control and above all ethics. In this sense, the role of bioethics is fundamental, guiding the actors who participate in this context to a responsible and transparent conduct in pursuit of achieving the greatest possible benefits, especially for the most vulnerable [2], with respect for the human being in his dignity and integrity.

In the Middle Age, the Catholic Church was against the misuse and indiscriminate use of humans in research

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Engelhardt, in his work *fundamentals of bioethics*, cites a passage contained in the document S*umma armilla*, in 1538, where Bartolomeu Fumus stated that *doctors sin when they provide a doubtful or medicine as correct or they do not practice it according to the art, but wish to practice it according to their own and stupid fantasies, or perform similar experiences and acts by which the patient is exposed to serious dangers* [3].

In 1865, Claude Bernard expressed himself as follows about ethics in research: *The principle of medical and surgical morality is to never perform in a man an experiment that can cause him harm of any kind, even if the result can be highly advantageous to science, that is, for the health of others* [4]. There are, here, the principles of beneficence and non maleficence which, later on, by means of bioethics, shall become widely discussed and consolidated in academia.

Over time, this excessive concern with the number of experiments using human beings has significantly influenced the emergence and development of bioethics. In this context, both at micro and macro, individual and collective, public or private level, bioethics discarded the connotation of ephemeral fad to transcend borders and settle down on an irreversible way as science [5].

Oliveira *et al* [6], under the perspective formulated by Thomas S. Kuhn, stands out as the main axis for the consolidation of that knowledge the discussion and drafting of an epistemological statute, whose core is the bioethics' ontological questioning and its characterization as a field of knowledge. According to these authors, bioethics, according to Kuhn's assumptions, is already science.

Of social concern, bioethics won forum of academic discipline, focused not only on analyzing the theoretical aspects and also providing concrete answers to the questions raised. More than make assertions, the Bioethics raises questions. Presently, it is a field of study, and ethical and moral reflection that involves various movements and subject oriented towards professional acting, respecting human rights and citizenship, in spatial and temporal contexts where people are vulnerable [7].

Bioethics has become in recent decades, with this epistemological statute, a field of knowledge essential to the study and submission of ethical issues related to biomedical research involving human beings. In this respect, from different international efforts in various historic moments in recent years, the modern world has abundant international documentation related to the ethical control of clinical research, mainly in the defense of the most vulnerable populations.

As regards the domestic documentation on the issue of ethics in research, it is opportune to rescue the resolutions issued by the Federal Council of Medicine (CFM) about the theme [4]:

CFM Resolution No. 671/70: recommends applying the Declaration of Helsinki as a guide for the clinical research. It became an initial milestone of the Brazilian medical class discussions about the necessity and relevance of the approach of ethical issues in research involving human subjects;

CFM Resolution No. 1,931/09: approves the Code of Medical Ethics, which contains the ethical standards to be complied by doctors in the exercise of their profession;

CFM Resolution No. 1.931/09: approves the Code of Medical Ethics, which contains the ethical standards to be complied by doctors in the exercise of their profession.

The first document about the subject, published by the Ministry of Health (MOH)/ National Health Council (CNS), appeared in 1988: CNS/MS resolution 1/88. However, its little acceptance and operationality gave rise to CNS/MS Resolution 196/96, currently in force and which provided regulatory standards and guidelines for research involving humans in the country [8]. This comprehensive resolution becomes gradually accepted, then, as reference document to be observed in any type of research with human beings, and not only in the field of health.

Thus, Brazil, by means of committees of ethics on research(CEP) and the National Commission of Ethics in Research (Conep), perfected the social control over the scientific practices, qualifying them from the ethical point of view, preventing induction, enforcement, exploitation of vulnerable, abuse, exposure to unnecessary risks and, above all, predictable damages [9].

The work developed in Brazil, through Conep and CEPs, has been focused on the continuous debate and pluralist participation, with the scope to enhancing the dignity of the human being through the redemption of the ethical and moral values of the Brazilian society' [10]. According to Freitas [11], these instances enforce the standards aimed at the protection of the rights of individuals or communities object of research.

The concern with ethics in research with human beings within the Health Sciences School (FS) of the University of Brasília (UnB) dates back to the end of the 80's. In 1987 it was established the first permanent Institutional Commission of Ethical and Scientific Orientation at the institution, predominantly formed by doctors. After the disclosure of resolution 1/88, regulating research with human beings in the country, said commission started following those standards [12].

In 1990 the first Committee of ethics in research with human beings is established at FS-UnB and, in March 1997, after the adoption of Resolution CNS 196/96, is established the first commission with the designation and duties specific of CEP, who became multidisciplinary, encompassing members from several areas/professions [12]. From this date on, the CEP-FS-UnB remained in continuous operation with only natural changes of coordination and replacement of members, for termination of mandate.

This study aims at verifying the use of the free and clarified consent term of consent (FCTE) in research protocols developed in the graduate program in Health Sciences (PPGCS) of UnB in the period August 1996 to December 2006 that specifically involved human beings in the methodological procedure, using as a theoretical reference the guidelines of Resolution CNS No. 196/96..

Method

The methodological procedure consisted, in a first moment, in the verification and search of all dissertations and theses defended along the PPGCS of UnB, in the period. This is an exploratory, retrospective, descriptive study and of quantitative approach. According to Pereira [13,] this type of study is used for initial assessment of a problem still poorly known and whose features or natural variations have not been adequately detailed.

This form of approach is employed to focus on specific groups of the population or a particular aspect of interest, not properly investigated in quantitative research or which simply need supplementation of information with greater details. Relatively easy to be accomplished and low-cost, this type of research is useful to raise problems, many of which are in addition investigated with the assistance of other methods [13].

In the list of production of PPGCS were found 373 master's degree dissertations and112 PhD theses, but five dissertations were required since they had passed through the validation process, i.e. they were projects carried out at other universities and, therefore, not developed by the program. This list contained, in chronological order, the following information: author's name, job title, name of Advisor and components of the examination bench and date of defense.

Following, a search was performed, at the secretariat of the program, to identify the participation or not of human subjects in the research, herein included the handling of biological material (biopsies), parts or organs of the body (teeth, bones), body fluids (blood, saliva, feces, urine, milk) and diagnostic imaging exams, as well as the use of questionnaires and/or interviews, i.e., research was made *with* human beings and the research *on* human beings. To achieve this step the reading of the summary and the methodological procedure of dissertations and theses was made in order to prove the information.

Subsequently a search was made. on the papers submitted to analysis of the Committee of Ethics in Research of the College of Health Sciences of the University of Brasília (CEP-FS-UnB) or other CEPs. This search consisted in the verification of the opinion of the CEP attached or not to the dissertations and theses. In cases where the opinion was not attached, it was checked whether the works mentioned, in the methodological procedure, the submission of the project to a CEP, as well as use the FCCT.

If the opinion was not attached, nor mentioned the concern with the same, a search was performed to verify if there was any record on the submission of the project in the CEP-FS-UnB files, of the University of Brasília Medical School’s Ethics in Research Committee (CEP-FM-UnB) and the Ethics in Research Committee of the Federal District State Secretariat of Health (CEP-SES-DF). The choice of these three committees was motivated by the fact that they are the CEPs that keep a more direct relationship with the PPGCS of UnB.

The relevance of this work consists of studying the process of awareness about Resolution CNS 196/96 by researchers (Master’s and PhD students) of PPGCS-FS-UnB and their advisors to, through this information, inferring the ethical commitment of the same with the legal enforceability of human beings protection during the execution of the researches undertaken in the program.

Results and discussion

The universe of this study was composed of 68 master's degree dissertations and 112 doctor’s degree theses, defended in the period studied, to be identified and operated in accordance with the objectives of the work.

After the data search, it was found out that 274 dissertations (74.46%) and 90 theses (80.36%) had, during the performance of the work, the direct and/or indirect involvement of human beings as subject of research. It was thus realized, the great involvement of humans in the work developed, making up approximately 3/4 of total production of the program, enabling a look about ethical care and the protection provided to the survey participants by researchers (guiding advisors) of the institution.

The technological development in the area of health comes with numerous research studies involving humans and animals. The need to establish rules for the development of research strengthens the moral and ethical discussions [14]. The rise of guidelines facilitates the ethical analysis of researches, to be made initially by the author himself of the project, and then by the bodies responsible for the assessment, guiding the reflection as the risks and benefits [15].

The establishment of ethical and scientific standards of research is a reason for concern and discussion not only by the scientific community, but also by the society at large, which seeks to protect the freedom, integrity, dignity, rights and well-being of man. All documents drawn up for that purpose result from conquests of humanity and represent most important democratic theses at the world level [10].

Thus, the emergence, diffusion and consolidation of bioethics appear linked to the achievements regarding unavailable human rights and the moral conflicts arising of rapid and constant technological scientific advances. In this context, various searches are inserted, involving r or not the participation of humans and other animals. The global concern with the resumption of ethical reflection has as one of its main foci of attention the ethical conduct in research the situation of vulnerability in which people involved are and, therefore, the obvious need to be respected and protected[10].

A specific aspect, among the main recommendations which deserve emphasis, is the submission of the protocol to a CEP and the preparation and presentation of FCCT during the of research. The FCCT is one of the documents required when there is the need of assessment of projects that involve human beings by a CEP. Absent and neglected in abuses already committed against vulnerable groups, the FCCT is, therefore, referenced in virtually all existing documents, in addition to being considered as a way to strengthen the relationship between the researcher and the research subject.

Table 1 shows the dissertations and theses submitted, while research protocols, the assessment of a CEP.

In the PPGCS-UnB, 73.7% of dissertations and 80% of the theses involving humans

Table 1. Distribution of dissertations and theses involving humans defended in the UnB PPGCS, with and without CEP opinion in the period from August to Dezembro2006

	Dissertations		Thesis	
	Nº	**T**	**Nº**	**T**
With CEP's opinion	202	73.7	72	80
Without CEP's opinion	72	26.3	18	20
Total	**274**	**100**	**90**	**100**

Source: research by authors, 2007.

featured or mentioned the existence of opinion for approval by a CEP. It is important to stress that the results obtained include: dissertations and theses that had attached the opinion of a CEP; those which only mentioned the submission of the protocol and the approval, but not the opinion; and those which, although not having attached the approval by a CEP, had in the files investigated of CEPs visited the protocol of the evaluated research project.

These results ratify the data disclosed in research conducted at the Federal University of Uberlandia, which attests that the largest proportion of works submitted to the CEP of the institution are those related to the obtaining of the title of master and doctor, with the argument of greater rigor applied to the studies for the academic award and by the implied importance that the publication of those research presents to the graduate programs [16].

According to this finding, the dissemination of the ethical posture, an essential condition to grant credibility and legitimacy to the researcher and to the experiment, is the role both of educational institutions and the scientific community, since they are closely held responsible for the formation of future researchers [17].

Tables 2 and 3 show FCCTs distribution between Dissertations and Theses, which had the involvement of humans, with and without CEP's opinion.

It was expected a direct logical relationship between the number of works with opinion from CEP and with FCCT. However, 4.74% of dissertations and 2.22% of the theses showed that, although the works have been appreciated by a CEP, the obtaining of the FCCT was waived by the determination of the latter. This fact can

Table 2. FCCT distribution between dissertations involving humans defended in the UnB PPGCS, with and without CEP's opinion, in the period from August 1996 to December /2006

	Nº	**%**
With CEP's opinion and with FCCT	189	68.98
With CEP's opinion and FCCT waived	13	4.74
Without CEP's opinion and with FCCT	26	9.49
Without CEP's opinion and without FCCT	46	16.79
Total	**274**	**100**

Source: research by authors, 2007.

Table 3. FCCT distribution between dissertations involving humans defended in the PPGCS of UnB with and without CEP's opinion, in the period from August 1996 to December /2006

	Nº	**%**
With CEP's opinion and with FCCT	70	77.78
With CEP's opinion and FCCT waived	2	2.22
Without CEP's opinion and with FCCT	7	7.78
Without CEP's opinion and without FCCT	11	12.22
Total	**90**	**100**

Source: research by authors, 2007.

be explained due to the involvement of research with the use of secondary data, such as hospital patient records, database of public bodies and human teeth previously collected and stored.

This practice, even not directly involving the manipulation of human beings, configures access to confidential information of patients and thus requires ethical evaluation of the project by a CEP and, consequently, at its discretion, the waiving of FCCT due to impracticability of its obtaining.

When, for some reason, it cannot be possible to obtain the free and informed consent, the researcher should notify and explain to the CEP the reasons that made it unfeasible and the committee will define if the study can be carried out without the consent of the participants. Item IV. 3. C of Resolution CNS 196/96 makes absolutely clear that: *in cases where it is impossible to register the free and informed consent, such fact shall be duly documented with the explanation of the causes of impossibility and an opinion of the Ethics in Research Committee* [8].

One aspect that caught the attention was that in 9.49% of the dissertations and 7.78%, the researchers did not mention the project to a CEP, but bother to get from the subject of the search the FCCT, partially contemplating the ethical requirements recommended. The reasons for not forwarding the project to a CEP have not been object of this study; however, the duty of the researcher to obtain consent is a requirement from ethics in research, widely recognized by the national and international guidelines [18].

It is known that the selected participants of the research, mainly in developing countries, belong to social classes with less economic power and low level of education, often excluded from health care system, making it necessary to minimize the risk of exploitation of those individuals[19].

The existence of FCCT does not give ethical support the researcher as to the commitment with ethics in research and neither guarantees him the right not to submit the project to a CEP.

Obtaining the FCCT presumes the establishment of a dialogue between the parties, capable of softening the asymmetry existing in the relationship, making it more horizontal and transparent. However, the existing data suggest that the recruiting of subjects implies an extensive process of approach, during which the information contained in formulas of consent is only a small part of the interaction of researcher and subject of the research [20].

Regarded as the biggest reason of backlogs, the FCCT is the target of criticism as to its actual effectiveness [21]. In some CEPs it corresponds to 80% of the percentage of non-approval [22], due to excessive amount of technical terms and low accessibility to readers/subjects of researches. The attempt of the CEPs to make the FCCT intelligible is due to the fact that the subjects of the research are, generally, people with little education (functional illiterates). Thus, the FCCT can be considered as part of a *process* whereby it is guaranteed in writing that, after having received and understood all the information necessary and relevant, as alternative methods, rights, obligations and responsibilities, the participant voluntarily expresses the intention of taking part of the research[23].

Data found in the present study point out that in 73.7% of the dissertations and in 80% of the thesis there has been submission to the protocols of researches involving human beings and one CEP, with the accomplishment of normative recommendation of Resolution CNS 196/96.

With more than ten years of existence since its publication, the contents and the recommendations contained in this resolution cannot anymore be understood as a bureaucratic process to be accomplished and won among many others. It is necessary its incorporation as part of a process essential for vocational training and the recognition of subject of the research as a peer and, therefore, worthy of respect. According to [24], CNS Resolution No. 196/96, although with legal force, is not a code, or decree or ordinance. And a document of to bioethics nature and the researcher, as well as the CEPs, has the task of, using it as a reference, exercising the ethical evaluation with freedom and responsibility.

Jointly with a better ethical control, the respect and recognition that have reached researches developed by our universities and other public research institutions, through *stricto sensu* graduation programs at the master's and doctoral levels and other activities, reflected in the raising increase of Brazilian scientific publications in respected international journals [25].

Spinetti [26] reviewed scientific articles in the area of public health, involving directly or indirectly humans, published in two Brazilian magazines prior to resolution CNS 196/96. The author examined the process of obtaining informed consent when surveys involved subject with reduced autonomy, image protection, stigmatization and the benefit of return of researches.

Out of 568 analyzed articles, 52.15% involved directly or indirectly human subjects in performed researches. Of these, only 4% had a mention to the word *consent*. The most used locations used for the development of researches were health services and public institutions (186-32.8%), usually centered on needy populations and should require, therefore, attention of researchers as to the perception of the situation of vulnerability [26].

A study conducted by Hardy *et al* [27] about knowledge and opinion of Brazilian researchers about the content of Resolution CNS 196/96 noted that, although the participants are heads and/or researchers linked to a college of medicine or research centre, not all were fully informed about the existence and content of the resolution. According to the authors, this leads to reflect on how they the information in the context of complex systems, such as the area of health and the academia circulate and are assimilated.

According to Araujo [28], scientific researches involving human beings can and must be performed under ethical standards, but the simple observance of ethical standards, laws and recommendations does not guarantee, *per se*, its ethics. The discussion on the topic should be encouraged and be present in undergraduate and postgraduate courses, as well as in events and scientific journals.

Ethics in research with human beings, in different sectors, is a process that requires special concern and constant surveillance, making imperative the involvement of various actors, people being oriented, people orienting and universities willing to collaborate. Therefore, familiarization is required with the rules of ethics in research, so that they can effectively contribute to build a collective, scientific and ethical knowledge, with profound social relevance [22].

It should be recalled that survives without science and technique and its existence does not depend on them; science and technique, however, cannot prescind ethics, under penalty of becoming disastrous weapons for the future of humanity if in the hands of powerful and malicious minorities [29]. In this sense, ethics in scientific research, due to the fascination that the scientific-technical progress allows, requires a practice of moral responsibility and competence which requires the existence of a conscious subject, i.e. the researcher of the professional not subjected to the unrestricted apology of technique [30], as well as the social commitment, attitude behavior expected by society [31].

The scientific activity necessarily undergoes an ethical and legal regulation. However, the freedom of investigation cannot detach from social context in which it occurs. And it is precisely this which refers to an ethical reflection, since, when considering humans free and similar, one cannot submit them to any kind of violence and manipulation by other human beings, as in the case of an experiment.

Final considerations

The challenge to build protocols based on ethical principles requires the solid training of the researcher. The decision-making, which could result in the decrease of conflict situations that appear in many cases due to different interests, intrinsic to human relations, require constant critical reflection. The results found in this study allow inferring the compliance timely increasing of submission of research protocols involving human beings of the graduate program in health sciences at UnB and some CEPs, fulfilling the normative recommendations of CNS Resolution 196/96.

In the area of health, the data shows that the use of humans in researches is high compared to the need for scientific proof and due to impossibility of replacing the model, such aspects reflecting in the academia. The 73.7% results of dissertations and 80% of theses with opinion from CEP enable to infer that there was been a growing assimilation and critical incorporation of the recommendations in CNS Resolution 196/96. The results of dissertations and theses with opinion from CEP associated with the result of the works without opinion from CEP, but with FCCT (83.21% for dissertations and 87.78% for theses), exemplify the building of a bioethical culture, critical to the consolidation of moral values and standards in the academic community.

What is expected from researchers is that they commit themselves with the task of submission and ethical evaluation, not limited to a mere technical action, but that they acquire the ability to scale conflicts in its fair measure, counting with the to realize the place of human suffering, identifying the means to avoid them and fight them. The compliance with ethical benchmarks, here shown, according to the data presented, demonstrates the growing level of maturity reached by the program under examination. This result enables a glimpse, in the near future, that all works involving human beings are referred to the opinion of the CEP, as well as incorporate the use of FCCT.

This article derives from a master's dissertation defended in the graduate program in health sciences of the University of Brasília, with a line of research in bioethics.

Resumo A consolidação do sistema brasileiro de revisão ética das pesquisas com seres humanos é fruto da Resolução 196/96 do Conselho Nacional de Saúde, que contribuiu de forma significativa para a ampliação da bioética no Brasil. 0 presente estudo tem como objetivo verificar o uso do termo de consentimento livre e esclarecido (TCLE) nas dissertações e teses defendidas no programa de pós-graduação em Ciências da Saúde da Universidade de Brasília no período de agosto de 1996 a dezembro de 2006. 0s resultados obtidos mostram um panorama de conscientização na formação dos pesquisadores quanto a aplicação efetiva dos pilares da bioética, mais especificamente o respeito ao principio da autonomia dos sujeitos de pesquisa.

Palavras-chave: Ética em pesquisa. Consentimento livre e esclarecido. Bioética.

Resumen

El término de consentimiento libre y esclarecido en las pesquisas con seres humanos: un estudio de caso

La consolidación del sistema brasileño de revisión ética de las pesquisas con seres humanos es fruto de la Resolución 196/96 del Consejo Nacional de Salud, que contribuyó de forma significativa para la ampliación de la bioética en el Brasil. El presente estudio tiene como objetivo verificar el uso del término de consentimiento libre y esclarecido (TCLE) en las disertaciones y tesis defendidas en el programa de pos graduación en Ciencias de la Salud de la Universidad de Brasilia en el periodo de agosto de 1996 a diciembre de 2006. Los resultados obtenidos muestran un panorama de concientización en la formación de los investigadores en lo referente a la aplicación efectiva de los pilares de la bioética, más específicamente el respeto al principio de la autonomía de los sujetos de pesquisa.

Palabras-clave: Ética en investigación. Consentimiento informado. Bioética

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Received: 11.7.11 Approved: 1.11.11 Final approval: 7.11.11

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Authors' participation in the article

Fabiano Maluf participated in all stages of the research, writing of the article and final revision. Volnei Garrafa oriented the research process and the final revision of the article.