UDC 577

Perceptions of Medical Students and Professors Regarding the Free Informed Consent Form and Humanization

[1] Angela Maria Moreira Canuto
[2] Jackson Menezes
[3] Daise Nicácio
[4] José Humberto Belmino Chaves
[5] Rui Nunes

[1] Federal University of Alagoas, Brazil
Masters in the Teaching of Health Sciences from the Federal University of São Paulo, specialized MD recognized by the Brazilian Federation of Gastroenterology, and Assistant Professor University of Porto/Federal Council of Medicine, Brazil, Doctoral candidate in the Program in Bioethics at the School of Medicine
[2] Federal University of Alagoas, Brazil
Medical Student, School of Medicine
[3] Federal University of Alagoas, Brazil
Medical Student, School of Medicine
[4] Federal University of Alagoas, Brazil
Dr. (Bioethics and Medical Ethics), Professor of Gynecology
[5] University of Porto, Brazil
Dr. (Medicine/Bioethics). Full Professor of Medical Sociology/Bioethics

Abstract The aim of this study was to gather information on the perception of the free informed consent form (FICF) and humanization among a population of medical students and professors of medicine. A total of 35 professors of medicine and 56 medical students took part in this study by answering an electronic survey. The collected data were subjected to content analysis using ALCESTE software. The analysis revealed the existence of three different classes: Class 1 designated the "FICF as a guarantee of rights in research"; Class 2 designated the "FICF as informative regarding research procedures"; and Class 3 designated "humanization as a necessary process." The results show a preferential association of the FICF with research, rather than medical care. There was a consensus regarding the importance of humanization; however, a need to increase knowledge of and the possibilities for implementing both the FICF and humanization was also indicated.

Keywords: Behavioral Medicine; Humanization of Care; Bioethics; Graduate Education in Medicine.

Introduction.

FREE AND INFORMED CONSENT, HUMANIZATION AND MEDICAL TRAINING

The free informed consent form (FICF) and the humanization of medical care are topics that currently command great interest because curricular changes have been and are being put into effect in international and Brazilian medical courses. For almost a century, the ideas implemented by Abraham Flexner, who sought to organize American medical education, have been in use as a template for structuring medical courses. The social, political, and economic transformations that occurred in the latter half of the last century, which have been reviewed and expanded in the 21st century, call for deep reflection regarding what sort of medical doctor is currently being trained in this environment. According to Rego[1] (2005), *"Independent of his own personal will, Flexner's name became associated with a rigid model of medical teaching that privileged the highest level of scientific training, the study of the human body through organs and systems, in the belief that men could be understood by studying their parts."* A number of transformations occurred in Brazil following the 2001 Curricular Guidelines[2] highlighting a need for changes in medical courses following the enactment of Law 9131 on the 25th of November, 1995, through Opinion CNE/CES 1.133 from the 7th of August, 2001, Art. 3, which states that *"The Graduate Course in Medicine aims to train students/professionals and doctors of medicine through generalist, humanist, critical, and reflective training who are able to act according to ethical principles in the health-disease process and at its different levels of attention,*

taking actions to promote, recover and rehabilitate health and prevent health problems from a perspective of comprehensive care with a sense of social responsibility and a commitment to citizenship as a promoter of the integral health of human beings."

Canuto[3] (2006) adds that the rise of the contemporary debate on professor-student, doctor-patient, doctor-community, and doctor-health team relationships, wherein the topics of humanism and ethics are of particular importance, undoubtedly confers relevance to these aspects and may also signal that new studies might delve deeper into and review the concepts related to what constitutes a healthy relationship in medical courses. Dantas[4] (2008) performed a systematic review of three original research papers addressing the teaching of deontology, ethics, and bioethics in Brazilian medical schools and stressed that few advances have been made regarding ethics and bioethics in the organizational and educational structures of these courses over the last 30 years. The author also concluded that there were few dedicated professors, few specific courses offered on this subject, and little time devoted to such matters. Kodama[5] *et al.* (2009) recognized that despite the recent recognition of the importance of medical ethics education, the human resources dedicated to teaching medical ethics in Japanese medical schools are both scarce and insufficient. Carneiro[6] *et al.* (2010) claimed that the lack of sufficient studies on this topic emphasizes the need to develop lines of research at the intersection between education and ethics because ethical questions commonly arise while learning clinical practice, and discussing this subject can aid the student in acting responsibly and humanely.

The free informed consent form: a theoretical approach

Sgreccia[7] (2009) claims that bioethics, in its strictest sense, arose in the United States prior to Potter, who coined the original term and provided its original definition. When introducing this concept, Potter emphasized that bioethics should constitute "*a new discipline that combined the knowledge of biology with the knowledge of human values systems*." Potter had effectively identified the perils that the cleavage between two fields of knowledge, scientific and humanistic, could pose to the survival of any ecosystem. Aligning with Potter's ideas, another strong claim came from a Dutch obstetrician, André Hellegers, who founded the Kennedy Institute of Ethics. Hellegers thought that bioethics represented a maieutic, that is, a form of science capable of recovering values from the dialog between medicine, philosophy, and ethics. According to Hellegers, the subject of this new field of study resided in the implicit ethical aspects of clinical practice, thus introducing the term "bioethics" into the academic world.

Regarding the FICF, it is important to remember that biomedical research only began to incorporate rigorous methodology starting in the 19th century. In the 20th century, there was an increase in scientific productivity, with a decrease in the amateurship that characterized this field previously (GARRAFA&LORENZO, 2007)[8]. In the Middle Ages, the Catholic Church took a stance against the indiscriminate and abusive use of human beings in research. Engelhardt[9] (1998), in his Fundamentals of Bioethics, cites an excerpt from *Summa Armilla*, a document from 1538, wherein Bartolomeu Fumus stated that it is sin when doctors "*...practice medicine in a dubious rather than a proper way, or not according to the state of the art, but rather following their own stupid fantasies, or perform experiments or similar acts that lead the patient to be exposed to dangerous perils.*"

Reports were released of terrible experiments involving human beings in Germany, the United States, and, especially, on continents with vulnerable populations that are chronically exposed to extreme poverty, wherein the "scientific" experiments that were performed degraded human dignity. According to Maluf and Garrafa[10] (2011), based on these experiments and with bioethics regarded as an epistemological statute, several different efforts were made at the international level at different times in history providing the modern world with a wealth of international documentation regarding the ethical control of clinical research, particularly that involving vulnerable populations. Brazil joined this movement, and its Federal Council of Medicine (Conselho Federal de Medicina) generated resolutions such as the following:

1) Resolution CFM 671/75: Recommending the application of the Helsinki Declaration as a set of guidelines for clinical research. This declaration became a stepping stone for discussions held by the Brazilian medical class on the need and relevance of ethical approaches in research involving human beings.

2) Resolution CFM 1098/83: Adopting the new provisions of the first revision of the Helsinki Declaration, produced in 1975 in Japan, referring to the basic principles of clinical and non-clinical biomedical research.

3) Resolution CFM 1.931/09: Approval of the new Medical Ethics Code containing the ethical standards that medical doctors should observe in their practice.

The FICF has been well established in research in Brazil. However, in the context of the doctor-patient relationship, there seems to be a lack of understanding of the FICF as a dynamic tool, rather than a legal formality.

According to Muñoz and Fortes[11] (1998), an autonomous individual has the right to consent or deny any preventive, diagnostic, or therapeutic proposition that may lead, in the present or the future, to changes in their physical-psychological or social integrity. The notion of consent to medical activity stems from philosophical perspective regarding the autonomy of the human being and from legal decisions. In the legal realm, the first case addressing consent appears to be Slater vs. Baker & Stapleton, which was decided in 1767 in England; two doctors were found guilty of not obtaining consent from a patient to perform a surgery on a lower limb that resulted in amputation. Consent was already mandatory at the time, not only for legal and ethical reasons, but also resulting from the need for patient's cooperation to perform surgical acts at a time when anesthetic procedures were not sufficiently developed. The notion of consent from an ethical point of view may diverge from the legal perspective. The latter only demands a simple form of consent, meaning a right to refusal. The former demands respect for the ethical principle of autonomy, requiring more than just simple consent, or the right to refusal, and instead requiring free, informed, renewable, and revocable consent. The patient has the moral right to be informed regarding the nature and objectives of diagnostic, preventive, or therapeutic procedures, including their invasiveness, duration, benefits, possible sources of discomfort, and inconveniences as well as the probable physical, psychological, economic, and social risks that may result.

Junges[12] (2007) believes that the principle of autonomy crystallizes in informed consent and that the act of consenting should be genuinely voluntary in nature and based on appropriate disclosure of information. To avoid becoming a mere legal formality, the mode in which consent is obtained is a fundamental requirement in assuring autonomy in the decision. Ricou[13] *et al.* (2004) extols the need for certain conditions to be met to render an informed consent valid. The subject must be competent to act, be in possession of all relevant information regarding the issue at hand, understand the information provided, make the decision voluntarily, and consent to the intervention.

Humanization as an indispensable part of outpatient or hospital medical care

Humanization in medical care appeared to be fated to obscurity because by the latter part of the last century, the human body had been described in great detail following the development of technologically advanced techniques, such as computerized tomography and magnetic resonance imaging, along with the discovery and characterization of the genome and the implicit secrets it contained about each individual. However, contrary to the dominant expectation, these technologies did not replace anamnesis, the doctor-patient relationship, a thorough clinical examination, the formulation of a hypothesis of diagnosis, the requirement for additional exams, or the diagnostic process itself. No machine will ever be capable of conceiving and implementing these steps of medical care with the necessary empathy. In agreement with this statement, Catania and Zagonel[14] claim that: "*...when someone talks about "care", it refers to an attitude as much as an intervention, i.e., the ability to listen to and recognize personal needs and act upon them. Bearing in mind human frailty and the precariousness of life, care is the basis for personal relationships and is particularly important in the doctor-patient relationship, such as in the perception of care that allows a patient to knowingly put his life in the hands of a doctor who may prescribe a treatment that is dangerous or painful.*" In this sense, no matter its level of technological sophistication, no machine can ever replace the level of care that one human being can deliver to another.

According to Brito[15] (2004), the health care professional-patient relationship consists of a relationship between two moral beings interacting with one another as such. Therefore, when addressing the patient, the health care professional should act knowingly, freely, and intently; i.e., he must act as a moral being, both autonomously and with respect for the human individual, and in a moral nature regarding what lies ahead, which can only occur if he respects his own autonomy. Similarly, the patient can only act morally towards the health care professional if he possesses knowledge, freedom, and intent, i.e., if he acts morally, which requires a respect for the health care professional's autonomy. Thus, to sum up the health care professional-patient/user relationship, it should be based on the principle of autonomy. According to Nunes[16] (2011), our society is, or aims to become a plural society, with deep roots in a humanistic view of interpersonal relationships. The

diversity of opinion and ideological, cultural, and religious plurality constitute society's backbone and the foundation of the institutions that support it.

This study was performed in a group of medical professors and students from the School of Medicine at the Federal University of the Brazilian Northeast, and its aim was to gather knowledge about the beliefs/perceptions of the professors and students of a medical course.

Methods

Participants

This study was conducted between October 2010 and May 2011 in a group of professors and students from the School of Medicine of Alagoas Federal University.

The participants included 35 professors of medicine and 56 medical students; 43 of these participants were female, and 48 were male. This group constitutes a non-probabilistic sampling, i.e., a sample of convenience, because the invited participants were given the option to voluntarily decline completing the questionnaire.

This research was presented to the Ethics and Research Committee of Alagoas Federal University and received approval on April 18, 2011 based on item VIII.13b of Resolution 196/96 under protocol number 028748-2010-06.

Instrument

Participants were asked to answer an open questionnaire including the following questions. (1) What is the purpose of free informed consent? Please be as detailed as possible, providing comments on its use during medical acts. (2) How important is free informed consent to you? (3) Do you believe the humanization process is necessary? Please explain your answer. (4) Think about how free informed consent is understood by the medical community. Do you believe that doctors fully grasp its meaning? Please explain your answer. (5) In your opinion, what improvements could be made in the humanization process? (6) Do you believe that free informed consent can be a source of conflict between patients' rights and doctors' duties? Please explain your answer. At the end of this survey, the participants also provided demographic information, such as their age and gender.

Procedure

The questionnaires were provided as an electronic survey sent out as an e-mail invitation to take part in this study with an enclosed link (the electronic address for the questionnaire). The first page of the questionnaire contained a FICF and a question about whether the invited participant would like to take part in the study. This document also informed the participants that the questionnaire guaranteed anonymity and confidentiality. This addition fulfilled the requirements for voluntary participation and respect of the ethical guidelines on research involving human beings.

Data analysis

Computerized content analysis was performed using ALCESTE (*Analyse Lexicale par Contexte d'un Ensemble de Segments de Texte*), which was developed by Max Reinert[17]. This software analyzes text data, such as the content of interviews. It performs calculations based on the co-occurrence of words in text segments with the aim of gathering them into classes according to their similarity or dissimilarity. The goal of this analysis is to obtain a number of classes based on statistical classification of simple utterances from the *corpus* under analysis (in this case, the answers to the questionnaire submitted by the participants) as a function of the distribution of words in the utterances to extract the most characteristic words, i.e., the words with the most significant presence based on the word association coefficient [χ^2 (1) ≥ 3.84, $p < 0.05$] that correlates the word with its position in the text. Additionally, *via* correspondence factorial analysis (FCA), it is possible to graphically represent the relationships and/or conflicts between classes by intersecting the classes with the vocabulary.

To understand this analysis process, a few concepts must be highlighted. First, the Initial Context Unit (ICU) consists of the natural divisions of the *corpus* (i.e., the answers to the open questions from each participant's interview). Second, the Elementary Context Unit (ECU) corresponds to the word/text segment with the greatest semantic weight as a function of text size (ranked as the number of words analyzed) and scoring (within a priority order). Third, the Context Unit (CU) is created by regrouping ECUs that stem from the same ICU until the number of words analyzed is greater than the limit **λ** (*Lambda* – an index of association used to evaluate the relationships among variables, assuming that the data are categorical or nominal, i.e., words). The value is calculated by the software depending on the size of the text being analyzed. The final concept is that of classes, which represents a theme taken from the text; i.e., each class is composed of several ECUs. ALCESTE[18] deconstructs the text into CUs and ranks them according to vocabulary distribution. The early stages of the statistical analysis consist of a

descending hierarchical classification (DHC) with the goal of determining lexical classes and displaying their relationships in a tree (dendrogram)[19]. The DHC is followed by a FCA, which enables the visualization on a factorial plane of the relationships and/or oppositions arising from the DHC. In summary, the automated content analysis organizes the structured content stemming from the statistical analysis into a DHC. The goal of the DHC is to establish a division among classes as clearly as possible. The dendrogram allows assessment of relationships among classes [strong bonds (proximity) or weak bonds (distance)] and the representativeness of each class based on the percentage of explanation of the evaluated *corpus*[20].

In summary, this analysis is comprised of four operational stages: **Stage 1:** text reading and dictionary calculations; **Stage 2**: data matrix calculation and ECU ranking; **Stage 3**: a description of the chosen UCE classes; and **Stage 4**: additional calculations. In the present study, simplified parameterization (*paramétrage simplifié*) was used, and in Stage 2, the option "simple classification into in Elementary Context Units (*classification simple sur les Unités de Contexte Élémentaries* – (UCE[21])) was used.

Results and discussion

The following results refer to the content analysis of the questions posed to medical students and professors of a medical course; i.e., the analyzed *corpus* consists of the answers given by the participants. As such, analysis of the results, consisting of a *corpus* of 546 ICUs, generated 660 ECUs, of which 495 (75 % of the total) were analyzed further; this number represents a significant use of the *corpus*[22].

Three classes were proposed according to the DHC. Figure 1 shows the classes and ECUs that were generated from the first, more concise analysis. The most characteristic word selected from each class, i.e., the word with the highest χ^2 value (sometimes shown as Khi2), possessed the greatest semantic weight within its class, and descriptive names were attributed to each word.

Class 1	
Present	χ^2
research+	189
particip+	136
*p_1	84
subject+	76
free+	53
risk+	47
of	45
*p_2	45
inform+	44
guarant+	37
benefit+	34
over	32
on	24
will	21
knowledge	21
scien+	19
agree+	17
same	15
subjects	14
individu+	13
choice+	13
all	12
humans	12
will be	12

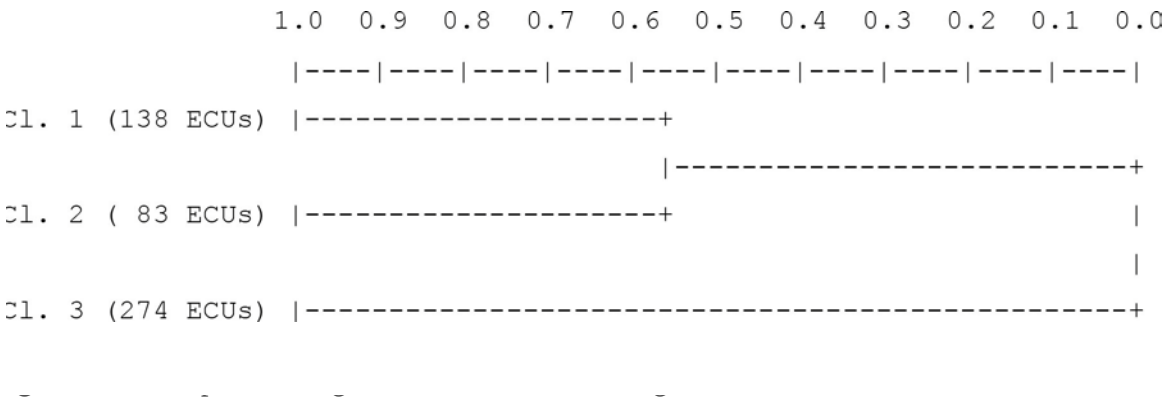
Class 2	
Present	χ^2
patient+	61
doctor+	38
procedure+	36
*p_6	30
perform+	28
know+	28
rigth+	25
right+	23
determin+	18
provide+	17
use+	16
inform+	15
exam+	14
term+	14
refuse+	13
submit+	12
act+	11
submitted+	11
*s_39	10
explain+	9
legal	9
surg+	9
what it is	8
occur+	8

Class 3	
Present	χ^2
*p_5	74
*p_3	46
humaniz+	46
process+	34
health	21
believ+	21
improve+	18
better	17
human+	17
yes	17
educ+	16
understand+	15
form+	14
necessar+	12
work+	12
doctor-relationship	11
however	11
*p_4	11
generat+	10
take+	10
soci+	10
capacit+	9
society	9
opini+	9

Figure 1. Dendrogram summarizing the specific vocabularies belonging to each interview class

Figure 1 describes the signifying words that represent and impart meaning to their respective classes. Additional information and significant indexes of equal importance are presented in the tables corresponding to each particular class (see below). Among the three classes described above,

Class 1, which designated the **FICF AS A GUARANTEE OF RIGHTS IN RESEARCH**, exhibited 138 ECUs (27.88% of the *corpus*); Class 2, designating the **FICF AS INFORMATIVE REGARDING RESEARCH PROCEDURES**, presented 83 ECUs (16.77% of the *corpus*); and Class 3, which designated **HUMANIZATION AS A NECESSARY PROCEDURE**, showed 274 ECUs (55.35% of the *corpus*). The relationship between classes can be visualized in the following dendrogram:



From the initial analysis (a more comprehensive description will be presented at a later in the manuscript), it is evident that Classes 1 and 2 are closely related based on their proximity and the similarity of the listed semantic aspects. Class 3 displays a significant degree of independence when compared to the other two classes due to a more distant relationship, which can be inferred from the figure above and the presence of differentiating semantic aspects. A correlation may still exist between Class 3 and the other two classes, although it is weak when compared to the strength of the relationship between Classes 1 and 2.

Class 3 stands out with the highest percentage of explained variance (55.35%), while Class 2 shows the lowest percentage (16.77%). These additional data are not fundamental because class content will be evaluated focusing on the words and text segments with greater semantic weight. A more thorough and revealing analysis of class constitution is presented next.

Class 1 — The FICF as a guarantee of rights in research

As shown in the summary dendrogram, Class 1 is characterized by signifying words that refer to a belief that application of the FICF represents a research procedure in which both the researcher and research subject should be protected. The particular impact that questions *p_2 [“How important is free informed consent to you?” (χ^2 = 35.47)] and *p_1 [“What is the purpose of free informed consent? Please be as detailed as possible, providing comments on its usage in medical action” (χ^2 = 28.01)] had on this class was also evident.

Based on the students and professors from the School of Medicine who were recruited to answer the questionnaire in this study, the signifying words with the greatest statistical weight (χ^2 or Khi2) mostly refer to the belief that the FICF represents a scientific research procedure [researc+ (pesquis+), χ^2 = 75.46; guarant+ (garant+), χ^2 = 48.08; researcher+ (pesquisador+), χ^2 = 37.93; authoriz+ (autoriz+), χ^2 = 34.54; particip+, χ^2 = 33.54; right+ (direito+), χ^2 = 29.42; ethic+ (etic+), χ^2 = 27.88; inform+, χ^2 = 25.49; document+, χ^2 = 25.49; clarific+ (esclarec+), χ^2 = 18.39; protection (protecao), χ^2 = 18.27; procedure+ (procedimento+), χ^2 = 17.14; user+ (utiliz+), χ^2 = 16.28; sab+, χ^2 = 15.9; term+, χ^2 = 15.46; instrument, χ^2 = 13.79; and explan (explic+), χ^2 = 13.58]. The selected text segments presented in Table 1 also appear to be related to belief that use of the FICF is scientific research procedure.

Table 1. Description of the text segments that represent Class 1

χ^2	**Text segment**
18	The #ficf #serves #guarantee of #the #rights and duties #of the #patient during the #research or #procedure he is undergoing and #guarantee of #protection #to the doctor in #future situations.

14	The #ficf has the #purpose of #guaranteeing #the #patient #the #rights he is entitled to #research subject: confidentiality, #secrecy, and feedback.
14	#guaranteeing #the #rights #of the #patient and #of the #researcher.
13	It is #important #confer #protection and to #register #what is #allowed during #research.
13	The #goal #of the #ficf is exactly #to clarify #the #rights #of the #patient and #the doctor.
12	To provide the #authorization #of the #research subject to #use #their #data for #scientific #purposes.
12	#guarantees #the #rights #of-the #researcher.
10	#inform the #patient and notify the #patient and the professional that this #clarification and consent occurred. In addition to #guaranteeing #the #rights #of the #patient, it also facilitates #ethical analysis #of the #procedure.
10	It is a #document that #grants #protection for both the #researcher and the participant #in the #study.
10	#to-inform the #patient of his #right swhen #involved and of his #freedom to desist at any #moment #of the #duly #explained process.

Note: All forms preceded by # are specific for this class of ECU.

The majority of the text segments in Table 1 refer to a belief that the FICF is a document solely to be applied to research and not as an instrument that guarantees patient rights and the duties of doctors when administering health care. However, two segments contradict the set ("#inform the #patient and notify the #patient and the professional that this #clarification and consent occurred. In addition to #guaranteeing #the #rights #of the #patient, it also facilitates #ethical analysis #of the #procedure." and "The #goal #of the #ficf is exactly to #clarify the #rights of the #patient and the #doctor."). These segments are related to a belief that the FICF is a document that guarantees the rights of both patients and doctors and enables ethical analysis to be performed more readily.

According to Engelhardt[9], the FICF performs its central role not by serving as a commitment to a liberal ideal, but by assuming that a complete overview of health care objectives based on pluralist secular context cannot be found. Obtaining free and informed consent consists of attaining permission from the individuals due to receive care or from the individuals who are responsible for patients who are unable to provide it on their own. Therefore, some medical students and professors believe that the FICF is involved in medical proceedings. However, the majority of opinions indicate a belief that the FICF should apply only to research, which would serve as its sole purpose. The lack of a perception that having respect for autonomy grants important meaning to the FICF may be generalized beyond research. The concept of autonomy in our field is actually quite recent, which is probably why students and professors more readily associate the FICF with research than with an intrinsic, unalienable right of a patient. However, patients themselves do not seem aware that such autonomy or a right to autonomy even exists. The concept of autonomy has been traditionally applied in Greece. According to Beauchamp and Walters[23], "*...when we think of "autonomy" and "respect for autonomy" currently, we are referring to a concept associated with numerous ideas, among which it is difficult to focus on a specific meaning. A conceptual analysis must link the notion of autonomy to concepts such as privacy, willingness, self-determination, free choice, the right to choose, personal choice and moral stance, and acceptance of responsibility.*" It is understandable how difficult it is to apply this concept of autonomy bearing in mind that this study was conducted in the State of Alagoas, located in the Brazilian Northeast, which holds the record for the lowest Human Development Index (HDI)[24] (0.677) among all Brazilian states. The HDI is a metric used by the United Nations to analyze the quality of life of a particular population.

Nieuwkamp[25] believes that the first step toward obtaining free and informed consent is deeply problematic. There is a conflict between the patient's choice and what is in the best interest of the patient. The informed consent doctrine brings to the foreground the disparity in knowledge between the doctor and the patient regarding rights and risks. However, these faults cannot be solely attributed to the physician. What the patient does not comprehend may constitute a gap in information.

According to Figueira[26], *"Informed consent is a fundamental part of the exercise of autonomy by the research subject or healthcare-receiving individual. If one can state that obtaining consent in clinical research is already a routine practice, the same cannot be said of the therapeutic field. This is most prevalent in underdeveloped countries and countries where health care systems are not implemented – i.e., the majority of countries."*

This lack of consent, in turn, leads to the observation that the doctor-patient relationship in general and in private hospitals and public clinics in particular is poor and that obtaining wholly free and clear informed consent is rarely considered to be possible by the majority of medical professionals.

Corroborating this observation, Ceccheto[27] (2007) states that the acknowledgement of the moral right of the patients to be informed of medical decisions is a recent phenomenon in the healthcare field, showing a slow gradual buildup, the end of which is still not clearly visible. When researching the history of informed consent, it is evident that the legal responsibilities of health agents have changed over time. Until the mid-18th century, doctors enjoyed almost total impunity.

In agreement with the aforementioned authors, there is a pressing need for doctors to understand the FICF as an important and essential means to guarantee respect for the patient's autonomy in medical treatment. Regarding medical research, the situation is different because the FICF is already well established as being essential for research.

Class 2 – The FICF as a guideline for research procedures

Based on the summary dendrogram (Figure 1), Class 2 is characterized by signifying words that refer to a belief that application of the FICF is a procedure used to clarify the risks and benefits of participating in research; i.e., the FICF is an informative document that describes the goals and procedures involved in research to the participant and allows them the free and spontaneous choice to participate in the proceedings. The effect that question *p_1 ["What is the purpose of free informed consent? Please be as detailed as possible, with comments on its usage in medical action" (χ^2 = 65.67)] exerts in this class is of particular importance. The signifying words with the greatest statistical weight (χ^2 or Khi2, see Figure 1) refer to a belief that application of the FICF is understood as an informative procedure involved in scientific research [benefic+, χ^2 = 129-42; free+ (livre+), χ^2 = 85.28; risk+ (risco+), χ^2 = 73.22; will (vontade), χ^2 = 54.15; particip+, χ^2 = 47.84; agreem+ (concord+), χ^2 = 44.31; aware+ (cient+), χ^2 = 39.05; researc+ (pesquis+), χ^2 = 38.29; subjec+ (sujeit+), χ^2 = 36.14; same (mesma), χ^2 = 34.11; choic+ (escolh+), χ^2 = 30.15; clarified+ (esclarecido+), χ^2 = 29.15; knowledge+ (conhecimento+), χ^2 = 26.32; possible (possiveis), χ^2 = 23.31; accep+ (aceit+), χ^2 = 21.94; wish+ (desej+), χ^2 = 20.02; and language (linguagem), χ^2 = 20.02]. Note the emphasis on information such as the benefits and risks of participating in research and the the freedom of the participant to participate. As observed from Table 2, presented below, the selected text segments also describe beliefs related to the FICF as an informative document that aims to enlighten the participants in the research about its procedures.

Table 2. Description of the text segments that represent Class 2

χ^2	**Text segment**
32	#to make the #participant #in the research #aware of how it #will #occur (#ocorrer) and from there allow him to #decide whether he #agrees to #participate #in #it.
20	The FICF has the goal of indicating that the #individual is #awar #of the research in which he is #participating and #agrees to do so, #demonstrating that he has #knowledge of its #risks and #benefits.
20	To indicate the #possible #risks and #benefits to be obtained; if the #participant #signs (#assine) the form, he is #agreeing with the goals of his own #free #will.
20	To inform the #subject #of the research regarding how it will be #performed, its goals, importance, #risks, #benefits, the compensation that is #due, and his #free #choice to #participate, respecting the #autonomy of the individual.
19	It is important that the #subject #of the research #may have previous knowledge of what will #happen and be able to express his #willingness to #participate in the event in which he will be enrolled.

18	It #shoul contain and #provide all #information for the #subject #of the research and clarifications regarding the #risks associated with #its #performance.
18	Applying the form #consists of #making the patient #aware #of the research in which he #will #participate, detailing all the #risks and #benefits that #may #occur.
18	It is used in the case that the #participant subsequently feigns a lack of #knowledge about the #risks and #benefits #of the research.
18	I think it is #essential for we researchers #to have a document #proving the #free and #spontaneous #participation of the #subject #of the research.
18	It is my guarantee that the patient or #subject #of the research is participating in the study of his own #free #will and is wholly #aware of #its #risks and #benefits.

Note: Forms preceded by # are specific to this ECU class.

It is evident that medical students and professors hold the belief that the FICF serves as an informative document in the field of research, making clear to research participants the risks and benefits of a study and providing an opportunity to choose whether to take part in it. None of the interviewees correlated the FICF and medical practice; instead, the emphasis was placed on the need for the subject to be knowledgeable about the research and its goals and possible risks and benefits and to allow free and spontaneous participation. Again, the FICF is not perceived as an inherent part of medical practice. It is likely that the massive focus on research presented by the majority of the interviewees is a sign of the current unawareness of the use of the FICF in medical practice and of the limited importance that both students and professors seem to confer upon to the document.

Corroborating this observation, Ceccheto[27] (2007) states that the acknowledgement of the moral right of the patients to be informed of medical decisions is a recent phenomenon in the healthcare field, showing a slow gradual buildup, the end of which is still not clearly visible.

According to Muñoz and Fortes[11] (1998), "*...the patient has the right to be clearly informed of the nature and goals of diagnostic, preventive or therapeutic procedures - to be informed of their invasiveness, the duration of treatments, their benefits, possible sources of discomfort, inconveniences and probable physical, psychological and social risks that may arise from them.*" Such a lack of knowledge regarding the importance of the FICF in medical practice among the students and teachers of medical courses may generate a propagating behavior that regards the FICF as a mere bureaucratic formality.

Once again, attention must be drawn to the fact that respect for autonomy may be relegated to a secondary role should the FICF continue to be applied as a required practice only in research. Junges[12] said, "*The principle of autonomy crystallizes in informed consent, and the act of consent should be genuinely voluntary and be based on appropriate information disclosure. In order for it not to become a mere judicial formality, the way said consent is obtained is fundamental to ensure the principle of autonomy in the decision process.*"

Class III – Humanization as a necessary process

Based on the summary dendrogram (Figure 1), Class III is characterized by signifying words that refer to a belief concerning the need for continuous medical education and a better understanding of the doctor-patient relationship. The effects that questions *p_5 ["In your opinion, what could be done for the humanization process?" (χ^2 = 66.95)] and *p_3 ["Do you believe the humanization process is necessary? Please explain your answer." (χ^2 = 53.08)] have on this class should be noted. The signifying words with the largest statistical weight (χ^2 or Khi2; see Figure 1) refer to a belief concerning continuous medical education and a better understanding of the doctor-patient relationship [humaniz+, χ^2 = 40-93; process+ (processo+), χ^2 = 27.96; health (saúde), χ^2 = 16.89; profession+ (profission+), χ^2 = 15.51; educ+, χ^2 = 14.2; human+, χ^2 = 14.05; understan+ (compreend+), χ^2 = 12.61; doctor_patient_relat (relacao_medico_paci), χ^2 = 11.78; work+ (trabalh+), χ^2 = 11.66; belie+ (acredit+), χ^2 = 11.07; necessar+, χ^2 = 9.98; and relat+ (relac+), χ^2 = 9.36. As observed in Table 3, presented below, the selected text segments also describe beliefs related to the need for continuous medical education and a better understanding of the doctor-patient relationship.

Table 3. Description of the representative Class 3 text segments

23	#changes in #medical #formation #may #improve the #doctor-patient #relationship in the #humanistic #aspect. Exposing the #student to #situations within the #social context to which he belongs #may aid #in-this #process.
18	More than being #required, #I believe that the #humanization process #becomes #essential because a closer #doctor-patient relationship facilitates, among other #things , #quality health.
15	It is #essential to regard the patient in the #most #holistic #way possible with #a #humanized attitude, that #is, regard him as a #human being before #anything else.
14	To improve #medical #education and to invest in updates and #courses that aid in #that #process.
13	No, #I believe that many #doctors, but not all, #regard the FICF as unnecessary, that their #experience as a #doctor will suffice when they #make #decisions, not #taking into account that each patient is different from others and that they #deserve #humane #treatment.
11	#I believe that such a #process is #intrinsic to each individual #personality, and little #can #be-done to improve it. However, I #regard as valid #education #focused on #humanization #through which the student will be #challenged directly with #situations involving this topic.
10	Yes. A #humane #doctor-patient relationship is important because the patient is a being, composed of feelings that #may #cause, worsen or #heal a #disease.
10	#I believe that #doctors #should make #an #adjustment to their attitude, and not only the #doctors, but the whole system.
10	#I believ that only #professional #awareness would constitute a viable method, which in turn is not easy because certain #things related to ethics and #humanization are innate and cannot be added to #an already #formed #personality.
9	Yes, it is #necessary. It #improves the #doctor-patient relationship .

Note: Forms preceded by # are specific to this ECU class.

The emphasis given to beliefs regarding the need for humanization, continuous medical education and understanding of the doctor-patient relationship is remarkable. However, the fatalistic belief regarding the humanization process as a factor in the personality of the individual and not a result of the formation and deontological practice of the medical professional should be noted (e.g., "#I believe that such a #process is #intrinsic to each individual #personality, and little #can #be-done to improve it. However, I #regard as valid an #education #focused on #humanization #through which the student will be #challenged with #situations involving this topic." and "#I believe that only #professional #awareness would constitute a viable method, which in turn is not easy because certain #things related to ethics and #humanization are innate and cannot be added to #an already #formed #personality.").

The importance of humanization in the quality of the doctor-patient relationship is supported by Fortes[28], who states that health and educational policies should be oriented towards decreasing violations of ethical principles by health care professionals, as currently found in daily health care services, pointing towards the development of a health care system committed to more humane practices.

According to Teixeira[29], while certain aspects have been extremely highly valued in the medical system throughout time, the doctor-patient relationship took a secondary role in the biomedical model, thus depriving the modern therapeutic arsenal of a psychoneurophysiological interventions that could aid and complement approaches to solving organic disturbances. This author also states that research concerning medical attitudes, which is permeated by positive events, comments, suggestions, and attitudes, can influence the patient's mental state and elicit neurophysiological responses that can be either favorable or unfavorable, thus acting as a therapeutic or iatrogenic instrument.

Rego[30] states that, in the context of great differences and multiple interactions, the discussion of bioethics and humanization or their contribution to the development of moral and ethical competences cannot be straightforward. To be effective, changes cannot be overly simple and local and cannot focus solely on changing teaching methods.

This study was performed in Alagoas. In this northeastern Brazilian state of 2,800,000 inhabitants (Brazilian Institute of Geography and Statistics - Instituto Brasileiro de Geografia e Estatística - IBGE)[31], whose capital city Maceió currently has 936,314 inhabitants, all initiatives to promote bioethics among medical doctors come from brave, isolated institutions. The first initiatives in this regard came from the Regional Council of Medicine, which offers continuous education, and the Federal University of Alagoas, which implemented curricular measures in 2006 providing some courses, especially in medicine, with some axes considering humanizing disciplines.

Relationships between classes

The dendrograms presented above in Figures 1 and 2 demonstrate the relationships that exist among the three classes based on the DHC, which was implemented with the aim of calculating partitioning into lexical classes and presenting their relationships in the form of a tree (dendrogram). After this step, a FCA permits visualization of these relationships on a factorial plane, as shown in Figure 3.

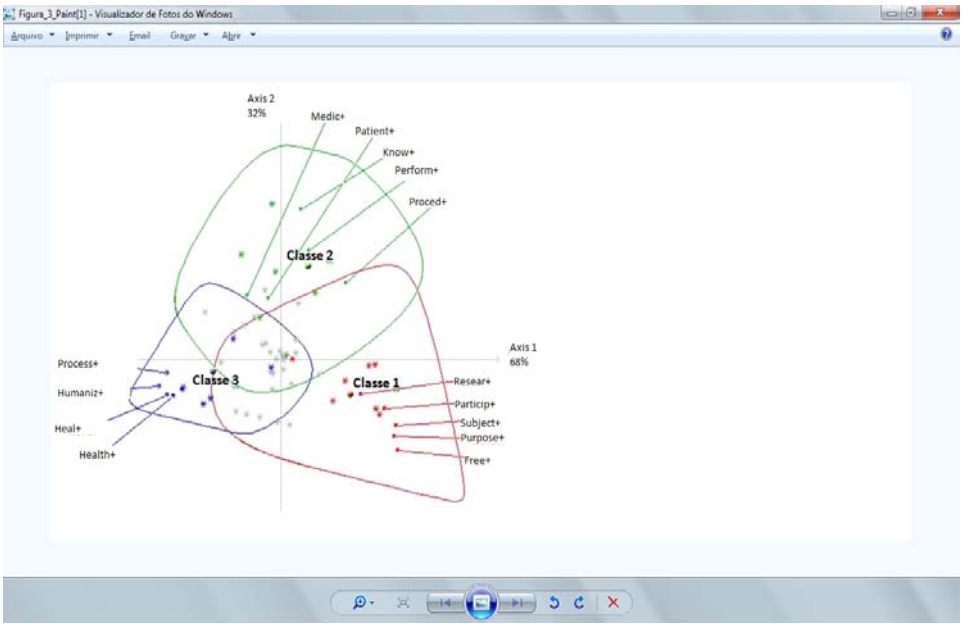


Figure 3. Graphical representation of the factorial correspondence analysis

Class 3 is different than Classes 1 and 2, which exhibit a good degree of correlation because these two classes deal with the FICF as applied to research, while Class 3 refers to the humanization of the doctor-patient relationship. The effect of the questions addressing class constitution should be considered, although it must still be assumed that the FICF will not be applied to the practice of humanization/deontology because Class 3, shown on the left side of Figure 3, is opposed to the other two classes, on the right side.

Based on our own observations, in medical practice in both general hospitals and private hospitals and especially in public clinics, the FICF is rarely employed (with some exceptions), which is far from the ideal situation. It is also not considered for use by the majority of medical professionals in the state of Alagoas and all over Brazil. Possibly contributing to this state of affairs is the fact that the FICF has only recently (in historical terms) been implemented in underdeveloped and emerging countries.

Pernick[32] attempted to establish the degree of social awareness regarding information and consent in medical practices. Over the past two centuries, this author identified three distinct periods: the first period, from 1780 until 1890, is characterized by negligence; the second, from

1890 until 1920, can be associated with assault or coercion; and the third, from 1945 until 1972, is marked by the appearance of voluntary consent and informed understanding. The fact that Pernick's classification ends in 1972 seems to urge researchers to perform a worldwide update of these classifications because the social, technical, and political transformations that have occurred demand a commitment to transform the FICF into an instrument of respect for liberty and, most of all, patient autonomy.

In agreement with this concept, Hatta *et al.*[33] reported that in Japan, use of the FICF is also a recent development, having been introduced in the 1980s. In this country, this instrument is ethically mandatory for clinical trials. Initially, due to its novelty factor, the concept failed for medical and cultural reasons. In the 1990s, studies suggested that the doctor-patient relationship should be discussed under the confidentiality of informed consent in Japan. The authors concluded by stating that, after a period of social and cultural maturation, informed consent became mandatory for clinical trials. In the modern age, with the increase of globalization, both cultural and historical knowledge have been under review with the aim of better understanding the problems posed by informed consent in Japan. Again, in agreement with our findings and those of all of the authors studied, this Japanese author brings to the fore that the FICF, in a technologically evolved country such as Japan, much like in Brazil, is still regarded as a tool mostly employed for research rather than medical practice.

Concluding remarks. In this work, a content analysis addressing the understanding of the FICF and humanization was performed among professors and students of the School of Medicine at the Federal University of Alagoas, Brazil.

We conclude that the FICF is clearly defined as an essential instrument for research, thus contributing to the protection of researchers and research subjects. Regarding the understanding of the FICF in relation to medical care, i.e., clinical, diagnostic, and therapeutic practices, it becomes clear that, in the context studied here, it amounts to nothing more than a bureaucratic tool. It is applied as a rigid document, solely for the duration of a hospital admittance, wherein a patient signs an FICF at the moment of or prior to admittance or before any invasive procedure, with no explanation about its meaning; thus, it solely constitutes a defense mechanism, mostly for the dominant party, which is never the patient (who is usually weakened by disease). Regarding humanization, a significant step forward has been made, and both doctors and students know that this practice needs to be exercised; however, there is still a need to better understand this process. Some of the answers obtained in our survey show a fatalistic belief that humanization cannot be taught because it is inherent to the nature of every individual. We also infer that courses in medicine should strongly invest in continuous education with respect to these two topics: the FICF and humanization.

References:

1. Rego S. Ethical development of doctors: leaving teenhood with (others') lives in their hands. Rio de Janeiro, Editora Fiocruz, 2003.

2. Brazil. National Education Council, Superior Education Chamber. National curricular directives for graduate courses in medicine. Resolution CNE/CES N. 4, Brasilia, November 7th, 1-6, 2001.

3. Canuto A. Faculty of Medicine of Alagoas: a history of struggle and hope. Maceió: Editora Edufal, 2006.

4. Dantas F. Souza EG. The teaching of Deontology, Medical Ethics and Bioethics in Brazilian Medical Schools: a systematic review. Bras Educ Med[internet journal].2008[accessed em 28 jan.2012]32(4):50717.Available at: HTTP://WWW.scielo.br/scielo.php?script =sci_arttex&pid = S0100-55022008000400014&Ing=PT&nrm+isso&tlng=PT.

5. Kodama T. Asay A. Itai K. National survey of medical ethics education at faculties of medicine in Japan. Fonte: Igaku Kyoiku/Medical Education, vol.40,n.1,p.9-17. Japan, 2009. Available at: http://www.jstage.jst.go.jp/article/mededjapan/40/1/9/_pdf Base: Japan Science and Technology Information Aggregator Electronic: J-STAGE .

6. Carneiro L A *et al.* The Teaching of Ethics in Health-related Graduate Courses. Brazilian Journal of Medical Education [Revista Brasileira de Educação Médica], ABEM – vol.1, n.1, p.412-421.Rio de Janeiro: Brazilian Association for Medical Education, 2007.

7. Sgreccia E. Manual of Bioethics. In: Manual of Bioethics – Fundamentals and Biomedical Ethics. Chap. 1: Origin, Diffusion and Definitions of Bioethics. p.14-52, 1st Ed., Cascais, 2009.

8. Garrafa V. Lorenzo C. Moral Imperialism and multi-center clinical trials in peripheral countries. Cad. Saúde Pública.2007;24:2219-26.

9. Engelhardt J.R. Fundamentals of Bioethics. Free and Informed consent, refusal of treatment and the health assistance team: the many faces of freedom. São Paulo: Edições Loyola, 1998. p. 345-445.

10. Maluf F. Garrafa V. The Free Informed Consent Form for research involving human beings: a case study. Rev. Bioética 2011;19(3):725-39. Brasília.

11. Muñoz DR, Fortes PAC. The principle of autonomy and free informed consent. In: Costa SIF, Garrafa V, Oselka G, coords. Initiation on bioethics. Brasília: Federal Council of Medicine; 1998. p. 53-70.

12. Junges, JR. Ethical demands of informed consent. Rev. Bioética**,** Brasília 2007;15(1):77-82.

13. Ricou M *et al.* In: Individual Dependences and Social Values. Nunes R. Ricou M. Nunes C. Alcohol, Pregnancy and Promoting Health. Chap.10, p.111-156 Ed. Gráfica de Coimbra, Lda. Coimbra:2004.

14. Catania C. Zagonel V. Humanism in Oncology "Care and self-care" "god as a mirror of the self". Journal of Cancer Education. Year: 2009 Vol: 24 Nr:1

15. Brito S. In: Individual Dependences and Social Values. Ethics and Autonomy of the subject Chap. 3, p.43- 51. Ed. Gráfica de Coimbra, Lda. Coimbra:2004.

16. Nunes R.; Meli H P. In: Vital Will. Values and Plural Society – personal ethical liberty. p.17-80. Ed. Almedina, Coimbra,2011.

17. Reinert, M. ALCESTE, une méthodologie d'analyse des données textuelles et une application: Aurélia de Gérard de Nerval. Bulletin de Méthodologie Sociologique, Paris, n. 26, 1990, p. 24-54.

18. Reinert, M. La tresse du sens et la méthode Alceste: application aux *Rêveries du promeneur solitaire*, Actes des 5è Journées internationales de l'analyse statistique des données textuelles, Paris, n. 2, Ed. Rajman & Chappelier, 2000, pp. 381-388.

19. Nascimento A. R. A.; Menandro P. R. M. Lexical analysis and content analysis: a tandem application proposal. Studies and Research in Psychology, Rio de Janeiro, year 6, n. 2, 2006, p. 72-88.

20. Ribeiro, A. S. M. Alceste: quantitative analysis of text data (Manual). Institute of Psychology: UNB, 2004

21. Sieguel S. Castellan JR., N. J. Non-parametric statistics for the behavioral sciences [Estatística não-paramétrica para ciências do comportamento]. Translation Sara Ianda Correa Carmona. 2nd ed. Porto Alegre: Artmed, 2006.

22. Reinert, M. ALCESTE: Manuel d'utilisation (Version 4.9 pour Windows). Toulouse: IMAGE, 2007.

23. Beauchamp TL, Walters L., *Contemporary Issues in Bioethics*, 6th ed. (Wadsworth, 2003)

24. Human Development Index (HDI) [Índice de Desenvolvimento Humano (IDH)]. United Nations Organization [Organização das Nações Unidas]. www.pnud.org.br/idh. Accessed 29.01.2012.

25. Nieuwkamp G G A. The theory of Informed Consent Medicine – Problems and prospects for Improvement. Submitted by Garry Anthony Aloysius Nieuwkamp. MB. BS. DA (SA) FACEM MA (Applied Ethics) 2007. A thesis submitted in total fulfillment of the requirements of the degree of School PHD of Philosophy. Australian Catholic University. Research Service.

26. Figueira ACS. Consent and protection of adults and children: common and peculiar dilemmas in developing countries. Revista Bioética, vol.18, nº3 – 2010. Brasília, Federal Council of Medicine.

27. Cechetto SRBB. The informed consent doctrine: incorporating the moral subject in biomedicine. Brazilian Bioethics Society. Revista Brasileira de Bioética, Brasília, vol.3, n.4, 2007. p. 489-507.

28. Fortes PAC. Ethics, Users Rights and Humanization Policies in Health Care. Saúde e Sociedade, v13, n.3, p.30-35, Rio de Janeiro,2004.

29. Teixeira M Z. Psychoneurophysiological bases of the placebo-nocebo phenomenon: scientific evidence to support doctor-patient relationship humanization. Revista Brasileira de Educação Médica; 55(1): 13-18, 2009.

30. Rego S. Gomes AP, Batista RS. Bioethics and Humanization as transversal subjects in Medical Education. Revista Brasileira de Educação Médica. 32 (4): 482 – 491; 2008. 483.

31. Brazilian Institute of Geography and Statistics. www.ibge.gov.br. Accessed 28.01.2012.

32. Pernick, MS. The patient's Role in Medical Decisionmaking: A Social History of Informed Consent in Medical Therapy. In: President's Commission for the Study the Ethical Problems in Medicine and Biomedical and Behavioral Research. Making Health Care Decisions: The Ethical and Legal Implication of Informed Consent in the patient Practitioner Relationship, Washington, v.3, p. 1-35, 1987.

33. Hatta T, Murayama T, Narita K, Sumi E, Yokode M. Trend Analysis of Research on Informed Consent in Clinical Trials: Comprehensive Retrieval via Electronic Databases**.** Japanese Journal of Clinical Pharmacology and Therapeutics. Ano:2011 Vol:42 Nr:1 Pág:21.

УДК 577

Perceptions of Medical Students and Professors Regarding the Free Informed Consent Form and Humanization

[1] Анжела Мария Морейра Canuto
[2] Джексон Менезес
[3] Дайсе Никакио
[4] Хосе Умберто Белмино Чавес
[5] Руи Нуньес

[1] Федеральный университет Алагоас, Бразилия
Специалист в области преподавания наук о здоровье из Федерального Университета Сан-Паулу и доцент Университета Порту / Федеральный совет медицины
[2] Федеральный университет Алагоас, Бразилия
Студент - медик
[3] Федеральный университет Алагоас, Бразилия
Студент о медик
[4] Федеральный университет Алагоас, Бразилия
Доктор наук (Биоэтика и медицинская этика), профессор
[5] Университет Порту, Бразилия
Доктор наук (Медицина и биоэтика), полный профессор

Аннотация. Цель данного исследования заключалась в сборе информации на восприятие свободной формы информированного согласия (FICF) и гуманизации среди населения, студентов-медиков и профессоров медицины. В общей сложности 35 профессоров медицины и 56 студентов-медиков приняли участие в этом исследовании, отвечая на электронные обследования. Собранные данные были подвергнуты анализу с использованием Alceste программного обеспечения. Анализ показал существование трех различных классов: класс 1 Назначенные "FICF как гарантия права в исследованиях", класс 2 назначается «FICF максимально информативным в отношении исследовательских процедур", и класс 3 назначенного "гуманизации как необходимый процесс". Был достигнут консенсус относительно важности гуманизации, однако необходимо увеличить знания и возможности реализации обоих FICF и гуманизации.

Ключевые слова: поведенческая медицина; Гуманизация помощи; биоэтика; Высшее образование в области медицины.