

# Researchers' knowledge about the ethical standards for research involving humans

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## Resumo

O presente estudo descritivo, exploratório, de abordagem quantitativa, objetivou identificar o conhecimento de pesquisadores da área da saúde acerca das normas éticas para pesquisa envolvendo seres humanos. Encontrou-se que 24 (48%) pesquisadores desconhecem os documentos internacionais nos quais a Resolução 196/96 do Conselho Nacional de Saúde se fundamenta, 15 (30%) desconhecem a composição do comitê de ética em pesquisa e 14 (28%) não têm conhecimento adequado sobre as funções da Comissão Nacional de Ética em Pesquisa. Os pesquisadores revelaram conhecimento satisfatório acerca das questões abordadas no instrumento de coleta de dados. A manutenção da resolução por muitos anos contribuiu para que os pesquisadores a conhecessem de modo satisfatório. Entretanto, ainda precisam participar de capacitações voltadas para a atualização das normas de ética em pesquisa, sobretudo, atualmente, quando se vivencia um momento de revisão dos pressupostos brasileiros da ética em pesquisa com seres humanos.

**Palavras-chave:** Ética em pesquisa. Conhecimento. Bioética.

## Resumen

### El conocimiento de los investigadores acerca de los estándares éticos para la investigación con humanos

El presente estudio descriptivo, exploratorio, con abordaje cuantitativo, enfocó identificar el conocimiento de los investigadores en el campo de la salud acerca de las normas éticas para la investigación involucrando seres humanos. Se encontró que 24 (48%) de los investigadores desconocen los documentos internacionales en los cuales la Resolución 196/96 del Consejo Nacional de Salud se fundamenta, 15 (30%) desconocen la composición de la Comisión Ética de la Investigación y 14 (28%) no tienen el conocimiento adecuado acerca de las funciones del Comité de Ética de Investigación Nacional. Los investigadores revelaron un conocimiento satisfactorio acerca de las cuestiones abordadas en el instrumento de recolección de datos. El mantenimiento de la resolución desde hace muchos años ha contribuido para que los investigadores la conocieran de modo satisfactorio. Sin embargo, todavía tienen que participar en capacitaciones enfocadas en la actualización de las normas de ética en investigación, sobre todo, actualmente, cuando se vivencia un momento de revisión de los presupuestos brasileños de la ética en la investigación con seres humanos.

**Palabras-clave:** La ética en la investigación. Conocimiento. Bioética.

## Abstract

### Researcher's knowledge about the ethical standards for research involving humans

The analysis bases in data collected in descriptive, exploratory study with quantitative approach. It is aimed to identifying the researcher's knowledge in the field of health about the ethical standards for research involving humans. It has been found that 24 (48%) researchers don't know the international documents on which the resolution 196/96 of the National Health Council (NHC) is based, 15 (30%) don't know the composition of the Research Ethics Committees Involving Human and 14 (28%) don't have adequate knowledge about the functions of the National Research Ethics. The researchers showed satisfactory knowledge through the content of the issues addressed in the instrument of data collection. The maintenance of the resolution for many years has contributed to the researchers in satisfactorily knowing it, however, they still need to participate in training aimed to upgrade the standards of research ethics, especially nowadays when it experiences a moment to review the Brazilian ethics presuppositions in research involving humans.

**Key words:** Ethics in research. Knowledge. Bioethics.

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The research ethics involving human beings is one of the many topics discussed in bioethics and a matter of great interest to the academic and scientific community. In Brazil, the current legislation is the National Health Council's (NHC, CNS in Brazil) Resolution 466/12, at the Ministry of Health (MH, MS in Brazil), which presents the ethical standards for conducting research involving humans<sup>1</sup>. It is worth noting that this resolution was preceded by Resolution CNS/MS 196/96, which was in force in Brazil for 16 years. Importantly, also, it is to mention that Resolution CNS/MS 196/96 was still in force when this research was carried out.

According to the Resolution CNS/MS 196/96, the researcher who conducts research with humans must be the one responsible to know its provisions. However, it appears that most researchers do not yet know the resolution content or is not attentive to its provisions when preparing research projects. This lack of knowledge may be related to the probable deficiency courses at undergraduate and postgraduate programs in addressing ethical standards in research involving humans; combined with the lack of planning and awareness of the researcher in order to conduct a thorough ethical evaluation of the research project before its submission to the Research Ethics Committee (REC, CEP in Brazil) and even the difficulty of CEP to develop their educational role with researchers.

Thus, this study aimed to identify the researchers' knowledge in the health field about the ethical standards for research involving human subjects, aiming at providing data for training in research ethics involving human beings. Although the results relate to the institution where the study was applied, they can be considered as indicators of the knowledge level of teachers from other educational institutions in Brazil, assisting in the planning of courses aimed at teaching research ethics. It is considered that to deepen knowledge about the rules and guidelines for research involving humans shall facilitate the action of CEP, in addition to providing research participants a moment to assess their knowledge on the ethical regulations in human research.

### Literature review

In Brazil, according to the Resolution CNS/MS 196/96, research involving humans is characterized as one in which the participation of human beings, directly or indirectly, in whole or in part, individually or collectively, occurs; also including the use of infor-

mation or materials<sup>2</sup>. The knowledge among researchers concerning the provisions contained in Resolution CNS/MS 196/96 is extremely important, because besides being an obligation of the researcher who conducts studies involving humans, it also directly contributes to the protection and preservation of the dignity of those participating in these studies.

Whereas human research in Brazil is constantly evolving, it is important to note that there have been some changes of investigative practices mobilized since Resolution CNS/MS 196/96 and its amendments were issued, which were dedicated to the protection of research subjects and the contribution to the quality of the research aimed to be scientifically reliable, methodologically correct, morally acceptable and socially relevant. Based on the key international documents that gave rise to statements and guidelines on research with human subjects, the Brazilian legislation, as well as the theoretical framework of bioethical principlism, through the Resolution CNS/MS 196/96 deals with concepts related to human research, such as risks and benefits of research, vulnerability and disability, and implications of research ethics, going through the requirements related to the term of free and informed consent (TFIC), the research protocol's format, the creation of CEP and the National Commission on Research Ethics (Conep in Brazil)<sup>3</sup> and the representativeness and social control in the decisions to be made, as provided in Law 8.142/90 – which outlines the Unified Health System (UHS, SUS in Brazil) and hence influences the organizational format of CEP/ Conep system, considering its statements concerning social participation<sup>4</sup>.

It is noteworthy that the *Nuremberg Code* of 1947 has been always used as the basis for today's statements on research ethics as it determines the need for voluntary consent of individuals involved in the research, after the project's goals and risks elucidation. This fact has been refined and reaffirmed in 1964 in the so called *Declaration of Helsinki*, which has undergone some changes in the 70s, 80s and 90s. In 1975 it was incorporated a requirement for prior approval of any research project on humans by a REC (Research Ethics Committee)<sup>5</sup>.

Although bioethics is increasing concern about the ethical norms in research with humans, it is noted the persistence of problems and conflicts that have not surpassed yet. Recent research shows flaws in the reporting of information on compliance with ethical issues in the development of human research at the international level<sup>6</sup>. Moreover, the relationships between researcher and researched

have not always taken into consideration aspects being addressed by regulatory standards on ethics in research involving humans<sup>3</sup>.

A study aiming to analyze the adequacy of free papers presented at the XVIII Congress of Cardiology held in Pernambuco to Resolution CNS/MS 196/96 pointed out that the vast majority of authors have never read the aforementioned resolution, nor its amendments and, furthermore, that papers which have been submitted for REC review were more often elaborated by authors who had read such a resolution. These data highlight the importance of knowledge in conducting practice, which can also be demonstrated by the significantly higher proportion of authors with a higher level of technical education, among those who had already read the resolutions on research ethics involving human beings<sup>7</sup>.

Taking into account that the formation of ethical awareness needs to be seen beyond something that happens spontaneously, it is important to note that this capacity for ethical awareness depends on the stimuli promoted by family and social inclusion instruments, especially the school; and ethical behaviors may not be required whether opportunities are not offered to accomplish them. It is important the resumption and recovery of themes concerning the sphere of ethics, as they help defining the behavioral patterns of people<sup>8</sup>.

## Method

This was a descriptive, exploratory study, also transversal and with a quantitative approach, held in federal public university in the city of Divinópolis, Minas Gerais. Actual teachers who were not on vacation or out, experienced in conducting research involving humans and who agreed to participate were included in the study. As an instrument for data collection it was used a questionnaire with closed questions about the participants' profile and also closed questions addressing aspects related to Resolution CNS/MS 196/96. This instrument was developed by the researchers themselves, from the ethical provisions set out in that resolution.

Data collection occurred from March 2012 to January 2013. One TFIC was developed using accessible language, including some aspects of the study, such as its justification and purpose, explaining all procedures to be performed and offering total freedom to research subjects to refuse to participate or to withdraw their consent at any phase of the re-

search, without being penalized or disadvantaged in any way.

It is worth mentioning that when answering the questionnaire the subjects in the research could be directly benefited, as they were able to assess their knowledge level concerning ethical regulations in human research and subsequently they would receive a template containing the answers to the questions contained in the questionnaire. Participants were invited to participate in the study, being duly informed about its objectives, risks and benefits, and then signed the consent form had been prepared in duplicate. Besides the TFIC, other precautionary measures were taken in relation to occurrences of embarrassment or damage.

The questionnaire was administered in a private place and each one was marked with letters. Therefore, the confidentiality and anonymity of the individuals who composed the study sample was assured. Thus, risks relating to the subjects participation were minimal and could arise from the possibility of some sort of embarrassment or discomfort in the quiz – however, the preventive and protective measures were able to minimize or abolish them.

Data were grouped, categorized and presented in tables as well as descriptively. Simple descriptive statistics were prepared by using the software SPSS (*Statistical Package for Social Sciences*), version 17.0.

## Results and discussion

The present study had the participation of 50 professors from a pool of 95, which corresponds to 52.5% of the total. It shall be highlighted that 18 teachers (18.9%) did not participate in the study by being on medical or maternity leave, not being available or have not been found in their respective offices, after several attempts; 27 others (28.3%) reported that they have never conducted research involving humans – reason why the questionnaire was not applied to them.

On the characterization data, it was found that among the 50 interviewees who have answered the questionnaire (52.5%): 16 (32%) were aged between 25 and 34 years; 21 (42%) were aged between 35 and 44 years; 11 (22%) between 45 and 54 years; and only two (4%) between 55 and 64 years.

Regarding the participants' gender, 12 teachers (24%) are male, but the vast majority – 38

teachers (76%) – is female. Research which was conducted aiming at knowing the profile and education of health care teachers who used simulation as a teaching strategy in the laboratory skills (LabHab), Faculty of Medicine, University of São Paulo, showed that 60% of professors are female and 40% male. About the age, the same study showed that 70% are aged 25-50 years and 30%, 51-60 years<sup>9</sup>.

Regarding the level of education, 12 (24%) professors have a master's degree; 33 (66%), PhD; and five (10%) postdoctoral. Research conducted in 2012 in order to study the characteristics and importance of the didactic-pedagogical education of trainers and teachers undergraduates, showed that the majority holds titles of masters or doctors<sup>10</sup>. Postgraduate are in remarkable expansion in Brazil; in 2003 23,000 teachers and 8,000 doctors were formed, and for about 20 years the main professional target of those professionals has been the university<sup>11</sup>.

Regarding the courses in which teachers work and considering that some teachers work in two or more courses, we have found that 17 work in medical school (34%); 33 in nursing (66%); nine in biochemistry (18%); 12 in pharmacy (24%); five in MSc in health sciences (10%); two in MSc in biotechnology (10%); and five (10%) in medical residence in family health – however, it shall be pointed out that some teachers work in two or more courses. The predominance of nurses among the researchers who conduct research with human subjects may be related to the fact that research is growing in nursing. Note also that it has greatly increased the dissemination of research carried out by nurses<sup>12</sup>.

It was identified that five teachers (10%) have 1-3 years of experience teaching in higher education; 10, 3-5 years (20%); 15, 5-10 years (30%); and 20 (40%), more than 10 years. On the type of current or previous experience in the area of research ethics with human subjects, it was found that 48 teachers (96%) have submitted projects to the CEP; nine (18%) have ministered courses focused on this area; six (12%) have been or are members of CEP; and three (6%) have attended refresher courses in ethics. It is known that there are few people who are interested in being a member of CEP, perhaps because it is a volunteer work and a great responsibility; besides, ethics committees are heavily criticized, although essential in the field of research and publications<sup>13</sup>. Moreover, working in CEP requires great knowledge on research and also on significant variety of methodologies.

Considering the level of knowledge of Resolution CNS/MS 196/96, 24 (48%) participants

rated their knowledge as fair; 22 (44%) as satisfactory; three (6%) as unsatisfactory; and one did not answer. In order to evaluate the researchers' knowledge, an objective questionnaire with 12 questions about the ethical standards for research involving human subjects was applied.

Table 1, below, shows the topics covered in each question and the number of hits and errors obtained in each.

**Table 1.** Number of hits and errors in the study "Researchers' knowledge about the ethical standards for research involving humans". Divinópolis/MG, 2012

Q	Subject	Hit	Error
1	Standards for conducting the research	45	5
2	Documents that led to the resolution	26	24
3	Definition of research involving human	41	9
4	Definition of risk	41	9
5	Risk categories	44	6
6	When submitting a project to CEP	50	0
7	Research involving medical records	48	2
8	Research on new drugs	43	7
9	Type of research: literature review	44	6
10	Composition of CEP	35	15
11	Obtaining the term of free and informed consent (TFIC)	41	9
12	Conep's functions	36	14
<b>Total</b>		<b>494</b>	<b>106</b>

On major errors, researchers have found that 24 (48%) participants are unaware of the international documents on which the Resolution CNS/MS 196/96 is based. To understand the sheer importance of the resolution, as well as the importance of CEP in the scientific context, it is of great relevance to resort to the historical aspects that led to the creation of ethical guidelines for research involving human beings up to the resolution's attainment<sup>14</sup>.

It was observed that 15 researchers (30%) were unaware that the CEP's composition should be multidisciplinary, with at least seven members, dis-

tributed in equal numbers. It is important to know the minimum composition because the resolution does not stipulate a maximum number of members or the presence of alternate members, but allows CEP to vary its composition according to institutional needs and the lines of research of the projects to be analyzed<sup>14</sup>.

It was also noticed that 14 researchers (28%) have not correctly pointed out the alternative that best describes Conep's functions, NHC's advisory committee created by Resolution CNS/MS 196/96, which is responsible for implementing the standards and regulatory guidelines for research involving humans<sup>15</sup> – they may be unaware of such functions because they have never developed any research that needed Conep's assessment.

Whereas the mean score obtained with hits was 9.88, scores were established to obtain the evaluation parameter of the researchers' knowledge about Brazilian ethical standards in research involving humans. Thus, as shown in Table 2, researchers who were above average were classified as having a high knowledge; those who stayed on average, satisfactory knowledge; and below average, as having regular knowledge.

**Table 2.** Scores to evaluate the level of knowledge of researchers from the Public University in the study "Researchers' knowledge about the ethical standards for research involving humans". Divinópolis/MG, 2012

Knowledge level	Number of right questions	Percentage of correct answers
High	11 to 12 questions	90% or more
Satisfactory	9-10 questions	75% a 83%
Regular	8 or fewer questions	65% or less

Considering only the questionnaire's questions and the established scores, it was found that 23 researchers (46%) have presented knowledge about the addressed ethical standards; 17, satisfactory knowledge (34%); and 10, regular knowledge (20%). In general, the researcher's knowledge in view of the questions presented to them was rated as satisfactory because, in total, there was 82.33% yield. This data proves to be satisfactory, because the person who conducts a research involving human subjects must meet the provisions of Resolution CNS/MS 196/96<sup>2</sup>. Thus, it was expected that

researchers have presented high knowledge, or at least satisfactory, on the ethical standards for research involving humans.

It is worth mentioning that although researchers have satisfactory knowledge, they have still presented some uncertainty or even doubts concerning the norms, since when assessing their level of knowledge most of the subjects, i.e., 24 (48%) of them, rated their knowledge as regular, and no participants rated their knowledge as high, as it is assumed that each time a researcher submits a research project to CEP, he/she sees the resolution for any questions. This insecurity may be related to the researchers' lack of practical experience as CEP members, considering that only six researchers (12%) reported such an experience. It is noted, however, that although the researchers satisfactorily know about the ethical standards for research involving human beings, they do not feel able to discuss them.

### Final Considerations

Researchers generally showed satisfactory knowledge about the content of the issues addressed in the instrument of data collection and although considerable number of them (24) unknowns historical aspects related to ethical standards in humans research, as well as the composition of CEP (15), and Conep's functions (14), it can be stated that researchers know and dominate the articles of Resolution CNS/MS 196/96 that address the ethical issues related to the practice of drafting and structuring their research projects and their subsequent submission to the same CEP. However, it should be noted that this study did not aim at obtaining generalizations about teacher's knowledge on aspects of Resolution CNS/MS 196/96, but rather to provide, in general, views thereon. It was not obtained generalizations concerning the researchers' knowledge due to the difficulty of covering the various issues involved in the research ethics on human beings and aspects of Resolution CNS/MS 196/96, given that ethics cannot be taken concretely and the said resolution does not answer all the dilemmas arising from the practice of ethics in research involving humans.

The development of this study was important to show that the maintenance of Resolution CNS/MS 196/96 for many years has satisfactorily contributed to the researchers' knowledge. However, the need to attend training sessions aimed at updating their knowledge regarding the ethical standards in

research is still present, greatly in the current context, in which we experience a moment when the assumptions of ethics in human research in the country are being reviewed, since it was made a revision of Resolution CNS/MS 196/96 and published its new version in 2012: Resolution 466/12. This revision was approved after a public consultation that occurred from September 12 to November 10, 2011 and resulted in 1,890 suggestions electronically sent

and 18 documents submitted by mail. It is worth noting that these contributions, duly tabulated, were submitted to the participants of the Extraordinary Meeting of CEP (Encep), occurred in the city of São Paulo. It is also important to emphasize the fact that this study was carried out considering the CNS/MS 196/96 Resolution – not the Resolution 466/12 – what did not influence the results since the evaluated items were not modified in the new resolution.

## References

1. Brasil. Conselho Nacional de Saúde. Resolução 466/12. Trata de pesquisas em seres humanos e atualiza a resolução 196. [Internet]. Diário Oficial da União. 12 dez. 2012 (acesso 13 jun. 2013). Disponível: <http://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf>
2. Conselho Nacional de Saúde. Resolução nº 196/1996. Trata das diretrizes e normas regulamentadoras da pesquisa envolvendo seres humanos. [Internet]. Diário Oficial da União. 10 out. 1996 (acesso out. 2013). Disponível: [http://conselho.saude.gov.br/web\\_comissoes/conep/quivos/resolucoes/23\\_out\\_versao\\_final\\_196\\_ENCEP2012.pdf](http://conselho.saude.gov.br/web_comissoes/conep/quivos/resolucoes/23_out_versao_final_196_ENCEP2012.pdf)
3. Ramos FRS, Finkler M, Gonçalves ER, Caetano JC. A eticidade na pesquisa qualitativa em saúde: o dito e o não dito nas produções científicas. *Ciênc. Saúde Coletiva*. 2010;15(1):1.673-84.
4. Brasil. Ministério da Saúde. Lei nº 8.142, de 28 de dezembro de 1990. Dispõe sobre a participação popular no Sistema Único de Saúde e sobre as transferências intergovernamentais de recursos financeiros na área da saúde, e dá outras providências. [Internet]. 1990 (acesso out. 2013). Disponível: [http://www.planalto.gov.br/ccivil\\_03/leis/l8142.htm](http://www.planalto.gov.br/ccivil_03/leis/l8142.htm)
5. Cabral MML, Schindler HC, Abath FGC. Regulamentações, conflitos e ética da pesquisa médica em países em desenvolvimento. *Rev. Saúde Pública*. 2006;40(3):521-7.
6. Malafaia G, Rodrigues ASL, Talvani A. Ética na publicação de pesquisas sobre leishmaniose visceral humana em periódicos nacionais. *Rev. Saúde Pública*. 2011;45(1):166-72.
7. Lima SG, Lima TAG, Macedo LA, Sá MPBO, Vidal ML, et al. Ética em pesquisas com seres humanos: do conhecimento à prática. *Arq. bras. cardiol*. 2010;95(3):289-94.
8. Pires JR., Garrafa V. Educação: nova fronteira da bioética. *Ciênc. Saúde Coletiva*. 2011;16(1):735-45.
9. Gomez MV, Vieira JE, Neto AS. Análise do perfil de professores da área da saúde que usam a simulação como estratégia didática. *Rev. bras. educ. med*. 2011;35(2):157-62.
10. Borges MC, Aquino OF. A formação didático-pedagógica de professores para maior qualidade de ensino. [anais]. XVI Endipe - Encontro Nacional de Didática e Práticas de Ensino. Campinas: Unicamp; 2012.
11. Velloso J. Mestres e doutores no país: destinos profissionais e políticas de pós-graduação. *Cad Pesqui*. 2004;34(123):583-611.
12. Cardoso MVLML. Produção e divulgação de pesquisa em enfermagem. *Rev. Rene*. 2012;13(2):252.
13. Batista KT, Andrade RR, Bezerra LN. O papel dos comitês de ética em pesquisa. *Rev Bras Cir Plást*. 2012;27(1):150-5.
14. Barbosa AA, Boery RNSO, Boery EM, Filho DLG, Sena ELS, et al. A resolução 196/96 e o sistema brasileiro de revisão ética de pesquisas envolvendo seres humanos. *Rev. bioét. (Impr.)*. 2011;19(2):523-42.
15. Muccioli C, Dantas PEC, Campos M, Bicas HEA. Relevância do comitê de ética em pesquisa nas publicações científicas. *Arq. Bras. Oftalmol*. 2008;71(6):773-4.

### Participation of authors

Camila Maria Pereira Rates participated in the data collection, scientific writing and formatting the article. Juliana Dias Reis Pessalacia has participated on the orientation, scientific writing and the article's final review.

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## Attachment QUESTIONNAIRE

**Characterization data**

1. Initials: \_\_\_\_\_

2. Age group:

- 2.1.  25-34
- 2.2.  35-44
- 2.3.  45-54
- 2.4.  55-64
- 2.5.  >65

3. Gender:

- 3.1.  Female
- 3.2.  Male

4. Level of education

- 4.1.  Bachelor's Degree
- 4.2.  Licensure Degree
- 4.3.  Master Degree
- 4.4.  Doctoral
- 4.5.  Postdoctoral

5. Field of knowledge: \_\_\_\_\_

CODE - AREAS OF KNOWLEDGE
<b>5.1 EXACT AND EARTH SCIENCE</b>
5.1.1 MATHEMATICS
5.1.2 PROBABILITY AND STATISTICS
5.1.3 COMPUTER SCIENCE
5.1.4 ASTRONOMY
5.1.5 PHYSICS
5.1.6 CHEMISTRY
5.1.7 GEOSCIENCES
5.1.8 OCEANOGRAPHY
<b>5.2 BIOLOGICAL SCIENCES (*)</b>
5.2.1 GENERAL BIOLOGY
5.2.2 GENETICS
5.2.3 BOTANY
5.2.4 ZOOLOGY
5.2.5 ECOLOGY
5.2.6 MORPHOLOGY
5.2.7 PHYSIOLOGY
5.2.8 BIOCHEMISTRY
5.2.9 BIOPHYSICS
5.2.10 PHARMACOLOGY
5.2.11 IMMUNOLOGY
5.2.12 MICROBIOLOGY
5.2.13 PARASITOLOGY

5.2.14 TOXICOLOGY
<b>5.3 ENGINEERING</b>
5.3.1 CIVIL ENGINEERING
5.3.2 MINING ENGINEERING
5.3.3 MATERIALS AND METALLURGICAL ENGINEERING
5.3.4 ELECTRICAL ENGINEERING
5.3.5 MECHANICAL ENGINEERING
5.3.6 CHEMICAL ENGINEERING
5.3.7 SANITARY ENGINEERING
5.3.8 PRODUCTION ENGINEERING
5.3.9 NUCLEAR ENGINEERING
5.3.10 TRANSPORT ENGINEERING
5.3.11 MARINE AND OCEANIC
5.3.12 AEROSPACE ENGINEERING
<b>5.4 HEALTH SCIENCES (*)</b>
5.4.1 MEDICINE
5.4.2 DENTISTRY
5.4.3 PHARMACY
5.4.4 NURSING
5.4.5 NUTRITION
5.4.6 PUBLIC HEALTH
5.4.7 PHONOAUDIOLOGY
5.4.8 PHYSICAL AND OCCUPATIONAL THERAPY
5.4.9 PHYSICAL EDUCATION
<b>5.5 AGRICULTURAL SCIENCES</b>
5.5.1 AGRONOMY
5.5.2 FOREST ENGINEERING AND FOREST RESOURCES
5.5.3 AGRICULTURAL ENGINEERING
5.5.4 ZOOTECHNICS
5.5.5 VETERINARY MEDICINE
5.5.6 FISHING ENGINEERING AND FISHERIES RESOURCES
5.5.7 FOOD SCIENCE AND TECHNOLOGY
<b>5.6 SOCIAL SCIENCES</b>
5.6.1 LAW
5.6.2 ADMINISTRATION
5.6.3 ECONOMY
5.6.4 ARCHITECTURE AND URBANISM
5.6.5 URBAN AND REGIONAL PLANNING
5.6.6 DEMOGRAPHY
5.6.7 INFORMATION SCIENCE
5.6.8 MUSEOLOGY
5.6.9 COMMUNICATION AND JOURNALISM
5.6.10 SOCIAL SERVICE
5.6.11 DOMESTIC ECONOMY

5.6.12 INDUSTRIAL DESIGN
5.6.13 TOURISM
<b>5.7 HUMANITIES</b>
5.7.1 PHILOSOPHY
5.7.2 SOCIOLOGY
5.7.3 ANTHROPOLOGY
5.7.4 ARCHAEOLOGY
5.7.5 HISTORY
5.7.6 GEOGRAPHY
5.7.7 PSYCHOLOGY
5.7.8 EDUCATION
5.7.9 POLITICAL SCIENCE
5.7.10 THEOLOGY
<b>5.8 LANGUAGE, LETTERS AND ARTS</b>
5.8.1 LINGUISTICS
5.8.2 LANGUAGE
5.8.3 ARTS

6. Other Courses on campus in which operates:

- 6.1.  Medicine
- 6.2.  Nursing
- 6.3.  Biochemistry
- 6.4.  Pharmacy
- 6.5.  Master – Health Sciences
- 6.6.  Master – Biotechnologies
- 6.7.  Residence – Family Health

7. Time on the job:

- 7.1.  Less than 1 year
- 7.2.  From 1 to 3 years
- 7.3.  From 3 to 5 years
- 7.4.  More than 5 years

8. Time teaching experience in higher education:

- 8.1.  Less than 1 year
- 8.2.  From 1 to 3 years
- 8.3.  From 3 to 5 years
- 8.4.  From 5 to 10 years
- 8.5.  More than 10 years

9. Current or previous experience in research ethics:

- 9.1.  CEP Member
- 9.2.  CEP *ad hoc* Evaluation
- 9.3.  Course teaching or UC
- 9.4.  Submission of projects to CEP
- 9.5.  *Lato sensu* course
- 9.6.  Refresher course
- 9.7. Other: \_\_\_\_\_

10. Level of knowledge that assigns, as to the Resolution CNS / MS 196/96:

- 10.1.  High
- 10.2.  Satisfactory
- 10.3.  Regular
- 10.3.  Poor

**Knowledge about the resolution CNS / MS 196/96**

Resolution CNS/MS 196/96 provides regulatory guidelines for research involving humans. Answer the questions below, based on your knowledge of that document.

1. The National Health Council (NHC, CNS in Brazil), by Resolution 196/96, regarding the research, *states*:

- a) that the standards for conducting research are aimed at protecting the researcher, involved institutions and funding bodies;
- b) the research protocol must contain documents related only to the research development and its fundamental aspects and all information about the research subject;
- c) the responsible researcher will be responsible for the coordination and execution of the research and the integrity and welfare of research subjects;
- d) the subject's participation in research is voluntary, however, after signing the term of free and informed consent (TFIC), which contains all the implications of the research, the subject cannot stop the protocol.

2. Resolution CNS/MS 196/96 is based on the main international documents emanating statements and guidelines on research involving humans. Mark the alternative that points some examples of these *international documents*:

- a) United Nations Charter (1945); Guatemala Convention (2001), Declaration of Helsinki (1964);
- b) Declaration of Human Rights (1948), Declaration of Helsinki (1964), Nuremberg Code (1947);
- c) Nuremberg Code (1947); Sapporo's Statement (2002); Dellors Report (1996);
- d) Declaration of Helsinki (1964); Guatemala Convention (2001); Dellors Report (1996).

3. Under item II.2 of Resolution CNS/MS 196/96, check the alternative that best describes the definition of *research involving human subjects*:

- a) research involving humans directly and invasively, including the handling of blood and other body fluids;
- b) research involving humans holistically, considering their biopsychosocial aspects;
- c) research involving humans, directly or indirectly, in whole or parts thereof, including the management of information and materials;
- d) research involving humans and/or their families directly and specifically, considering their particularities.

4. According to the item II.8 of Resolution CNS/MS 196/96, check the alternative that best describes the definition of *risk* in research involving human subjects:
  - a) possibility of harm to the physical, mental, moral, intellectual, social, cultural or spiritual dimension of the human being at any stage of an investigation, or arising from it;
  - b) immediate or delayed grievance, to the individual or to the community, with proven, direct or indirect causal relationship, based on scientific study;
  - c) probability of damage to the physical realm of the subjects at any stage of a survey, with proven, direct or indirect causal relationship, based on scientific study;
  - d) immediate or delayed grievance, to the individual or to the community, with proven, direct or indirect causal relationship, based on scientific study, provided that the subjects are not envisaged prevention and protection measures.
  
5. Considering the item V of Resolution CNS/MS 196/96, which discusses the risks and benefits of research involving human beings, we can consider the following *risk categories* in research involving human subjects:
  - a) nonexistent; potential; minimum;
  - b) minimum; potential, imminent;
  - c) null; nonexistent; imminent;
  - d) potential; minimum; nonexistent.
  
6. Concerning the *process of submitting* research to the analysis of a research ethics committee (REC), mark true (T) or false (F):
  - a) all research involving humans, directly or indirectly, must be submitted for review by a REC;
  - b) research involving medical records of patients does not require a submission process to a REC;
  - c) in research on new drugs, the protocol must be submitted for review by the REC and also by Conep (National Commission on Research Ethics);
  - d) researches type literature review only does not need to be submitted for review by a REC.
  
7. About the *composition* of an ethics committee on human research, according to VII.4 item of Resolution CNS/MS 196/96, it should be:
  - a) composed of researchers with ethics education and a maximum of 7 members;
  - b) multidisciplinary, with a maximum of 7 members and, of these, at least 4 must have medical education;
  - c) multidisciplinary, with at least 7 members, distributed in equal numbers;
  - d) composed of non-healthcare members, with at least 7 members, and especially members of the community.
  
8. About the *process of obtaining* informed consent, through the Term of Free and Informed Consent (TFIC), select the alternative that best defines this process:
  - a) shall be performed after an information process with an autonomous and capable person;
  - b) shall be performed by a person connected to the research investigator, requesting a written authorization;
  - c) such a process is only applicable to clinical research and should be written in an accessible language;
  - d) this process legitimizes the responsibility of the research subject not to abandon the study in any of its phases.
  
9. Indicate the alternative that best describes the *functions* of the National Commission on Research Ethics (Conep):
  - a) review and approve all research protocols reviewed by registered REC;
  - b) impose penalties on REC that do not fit the Resolution CNS/MS 196/96;
  - c) implement standards and guidelines and approval of research in special areas;
  - d) train registered REC and passes the funds required for maintenance of facilities and remuneration of members.