

# The experience of the research ethics committee at a public university in the state of Minas Gerais, Brazil

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## Abstract

The article reports the experience of the Research Ethics Committee at the State University of Montes Claros, MG, Brazil, in the period from 2000 to 2009. Desk research, case study method were employed, and the significance level was set at  $p < 0.05$ . Of 1,751 projects, 95.8% were approved. Problems in preparing the statement of informed consent were among reasons for disapproval. The health sciences area of knowledge stood out at 60.8%. The average time between submission and ethical review was 11 days. The area of knowledge influenced the average time between submission and ethical assessment ( $p < 0.05$ ), but did not affect the time to approval of the research project. Conclusion: the local committee followed the standards for ethical assessment in accordance with Resolution 466/2012, in view of the fact that it rejected projects with shortcomings in the statement of informed consent, thus protecting the subjects of the research.

**Keywords:** Ethics. Research. Research ethics committees.

## Resumo

### Experiência do comitê de ética em pesquisa de uma universidade pública de Minas Gerais, Brasil

O artigo relata experiência do Comitê de Ética em Pesquisa da Universidade Estadual de Montes Claros, MG, Brasil, no período entre 2000 e 2009, com base em pesquisa documental, na modalidade estudo de caso, com nível de significância  $p < 0,05$ . De 1.751 projetos, 95,8% foram aprovados e, entre os motivos de reprovação, estão problemas na elaboração do termo de consentimento livre e esclarecido (TCLE). A área de conhecimento mais destacada foi ciências da saúde (60,8%). O tempo médio entre submissão e avaliação ética foi de 11 dias. A área de conhecimento influenciou no tempo decorrido entre a submissão e a apreciação ética ( $p < 0,05$ ), mas não na aprovação do projeto. Concluiu-se que o comitê local segue as normas de apreciação ética de modo a atender a Resolução 466/2012, uma vez que reprovou projetos com falhas no TCLE, protegendo os sujeitos pesquisados.

**Palavras-chave:** Ética. Pesquisa. Comitês de ética em pesquisa.

## Resumen

### Experiencia del comité de ética en investigación de una universidad pública de Minas Gerais, Brasil

El artículo informa sobre la experiencia del Comité de Ética de Investigación de la Universidad Estadual de Montes Claros, MG, Brasil, en el período del 2000 a 2009, con base en investigación documental, en la modalidad de estudio del caso, con un nivel de significación  $p < 0,05$ . De los 1.751 proyectos, 95,8% fueron aprobados y, entre las razones de la desaprobación, están los problemas en la elaboración del Término de Consentimiento Informado. El área de conocimiento más destacada fue el de las ciencias de la salud (60,8%). El tiempo promedio entre la presentación y la evaluación ética fue de 11 días. El área de conocimiento influyó en el tiempo pasado entre la presentación y la valoración ética ( $p < 0,05$ ), pero no en la aprobación del proyecto. Se concluyó que el comité local sigue las normas para la consideración ética para cumplir con la Resolución 466/2012, una vez que reprobó proyectos con fallas en el Término de Consentimiento Informado, protegiendo a los sujetos.

**Palabras-clave:** Ética. Investigación. Comitês de ética en investigación.

## Aprovação CEP Unimontes 1.661/2009

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Declararam não haver conflito de interesse.

Research Ethics Committees (REC) have shown that ethical advances in the evaluation of researches involving human beings. They represent the interests of the society in establishing ethical criteria for research, regulating the ethics in research in order to avoid abuse to the physical, psychic and moral integrity of people who participate in the studies. The approval by local committees in institutions aims at protecting the individuals in the research, who may require clarifications about the studies they take part in, or even complain about their participation<sup>1,2</sup>. By approving the research project, the committee becomes responsible for ethical aspects, however, without exempting the researchers of their ethical responsibility, which is *inalienable and non-transferable*<sup>3</sup>.

REC is a multi- and transdisciplinary. It includes the participation of professionals of several areas such as health, social sciences, human sciences and community representatives. Being independent, it manifests itself on behalf of the society to analyze and guarantee that the participation in a research does not cause any harm or impairment to the individual. The committee insures respect to the individuals, considering their needs and rights. Therefore, it is an organized way of social control of scientific practices, based on internationally accepted standards.

Thus, this work has the purpose of describing the experience of REC of Universidade Estadual de Montes Claros (Unimontes), MG, Brazil, from 2000 to 2009, aiming at analyzing institutional experiences during this period, as well as stimulating the improvement of the process to protect the investigated individuals.

## Materials and Methods

By Reading the article “Ethical conduct in research involving human beings in Brazil: Diagnosis of research ethics committee”, written by Novaes, Guilhem and Lolas, came the interest to develop a similar research in the university where the researchers came from, considering the importance of this topic in the scientific scenario<sup>4</sup>.

Therefore, this study was conducted by the Research Ethics Committee of Universidade Estadual de Montes Claros (Unimontes), located in Montes Claros, in important city in the north of the state of Minas Gerais, Brazil. The design of the study was transversal and documental, in the form of a “case study”.

The research was conducted by means of evaluating documents filed in the REC of Unimontes, substantiated opinions and title pages of protocols of research projects submitted to the evaluation of REC from January 2000 to December 2009. The research project follow the recommendations of the resolution 196/1996 of “Conselho Nacional de Saúde” (National Health Council) existing at that time. The opinions on research projects was evaluated to identify both the percentage of projects approved and also the projects that were reproved, in addition to identifying the reasons for reproval of the researches.

From the title pages, it was possible to identify the area and the sub-area of knowledge of the studies. The evaluation of both documents allowed the identification of the proposed setting to conduct the study (research setting) and the time required, in days, between the submission of the proposal to the REC and the conclusion of the ethical evaluation. For the data collection, a proper form was developed, previously tested in a pilot study with 10 research projects which were not part of the sample for this study.

The collected data were released in the program SPSS, version 18.0, for statistical analysis. For the descriptive analysis, measures of central tendency were used (such as arithmetic means, standard deviation and quartiles), as well as calculating ratios. For the association among the variables of the study, the variable “area of knowledge” is classified in three categories: exact sciences, sciences of the earth and engineering; human sciences, applied social sciences, linguistics, languages and arts; health sciences and biological sciences. The variable “sub-area” is classified in two categories: health and others. Finally, the variable “setting” – that is, the one proposed for the scientific investigation – was classified in two categories: “hospital” and “other settings”.

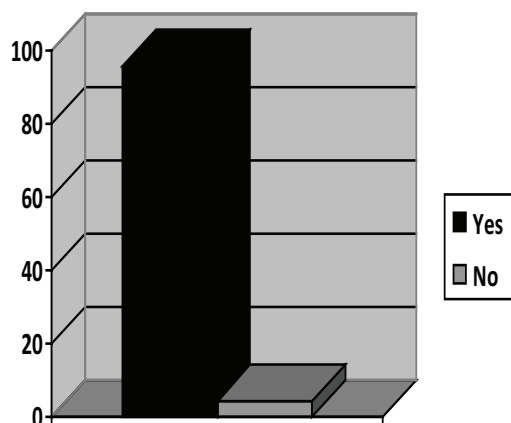
Tests used to compare the mean times – time between the submission and the analysis of the projects, of different groups – were Mann-Whitney’s test and Kruskal-Wallis’s test, considering that there was no normality of the analysis variable by the Kolmogorov-Smirnov’s test ( $p < 0.001$ ). For the association among variables, Pearson’s chi-square test and its alternative test, the likelihood ratio test, were used. The latter was used when over 25% of the cases had a score that was lower than 5. In all of the statistical tests,  $p < 0.05$  was considered as the level of significance and the confidence interval was 95% (CI 95%).

## Results

One thousand seven hundred and fifty-seven documents of REC of Unimontes, from 2000 to 2009, were used. The mean time between the submission and the ethical evaluation was 11.07 ( $\pm$  5.413) days, median and mode 11 days, percentile 25% equal to 9 days and percentile 75% equal to 14 days. The maximum period was 26 days.

Most substantiated opinions (95.8%) received ethical approval for the study to be conducted. This is because the scientific method did not compromise ethical principles of the research involving human beings. Thus, only a small percentage of projects (4.2%) was reproved by the REC of Unimontes, according to Chart 1.

**Chart 1.** Distribution of studies according to approval by the REC of Unimontes, 2000/2009



The reasons to reprove a Project are due to several problems. Among them, the most prominent are those related to the elaboration of a free and informed consent form, corresponding to 1.4% of the projects; problems in the formation on the research schedule (1.7%); in the informed consent and in the schedule simultaneously (0.3%); in the informed consent and in the methodology simultaneously (0.2%); in the title page (0.3%); and in the methodology (0.2%) of research projects.

Projects evaluated by the REC corresponded to several areas of knowledge: exact sciences and Earth sciences, biological sciences, engineering, health sciences, applied social sciences, human sciences and linguistics, languages and arts. The most highlighted one was the health sciences (60.8%). The condition to approve projects was not associated with the areas of knowledge, falling into three categories:

exact sciences, health sciences and human sciences ( $p = 0.415$ ).

When the three categories of the areas of knowledge were associated to the time between the submission and the evaluation of the project, it was verified that the mean time for exact sciences was 13.00 ( $\pm$  4.83) days, for health sciences it was 10.91 ( $\pm$  5.18) days and for human sciences it was 11.69 ( $\pm$  5.99) days, with a significant difference in the time needed for the analysis of projects according to the area of knowledge ( $p = 0.001$ ), as it is shown in Table 1.

**Table 1.** Mean, standard deviation and confidence interval of 95% (CI 95%) of time between submission and evaluation, according to the area of knowledge of the study. REC Unimontes, 2000/2009

Time between submission and ethical evaluation				
Area of knowledge	Mean	Standard-deviation	CI 95%	p*
Exact sciences	13,00	4,83	5,31-20,69	0,001
Health	10,91	5,18	10,61-11,21	...
Human Sciences	11,69	5,99	11,14-12,25	...

\* Kruskal-Wallis's test.

Out of the 40 sub-areas highlighted in the documentation evaluated, the most frequent ones were nursing (25.4%), social service (13.1%), dentistry (9%), collective health (6.5%), physical education (8.0%) and medicine (3.6%).

Among places where the studies were carried out, the hospital was the most common one, representing 414 (23.6%) scientific researches; "Estratégia Saúde da Família" (Family Health Strategy) was the setting of 187 (10.6%) projects; different educational institutions had 139 (7.9%) studies; and the higher education institution (Unimontes) was the setting of data collection of 139 (7.9%) studies. There was no significant difference ( $p = 0.089$ ) between the means of days equivalent to the period of submission and the ethical evaluation of projects according to the proposed setting for the research (research setting).

The condition to approve research projects of the REC was associated with the proposed setting for the research, as well as the area of knowledge of the study. The approval of the studies was seen not to be associated with neither the setting nor the area of knowledge ( $p > 0.05$ ), as shown in Table 2.

**Table 2.** Bivariate association between the condition of approval of a research project and the setting and the area of knowledge. REC Unimontes, 2000/2009

Variables		Approval			Test
		Yes N(%)	No N(%)	Total N(%)	p
Setting	Hospital	401(97,3%)	11(2,7%)	412(100%)	0,067*
	Others	1.261(95,2%)	63(4,8%)	1.324(100%)	...
	Total	1.662(95,7%)	74(4,3%)	1.736(100%)	
Area	Exact Sciences	4(100%)	0(0%)	4(100%)	0,490**
	Health	1.081(96,1%)	44(3,9%)	1.125(100%)	...
	Human Sciences	4.28(94,8%)	23(5,1%)	451(100%)	...
	Total	1.513(95,8%)	67(4,2%)	1.580(100%)	

\*Pearson's test. \*\* Likelihood ratio.

## Discussion

The large number of projects analyzed by REC of Unimontes depicts the importance of the local committee to preserve reference ethical principles, which are fundamental to the research involving human beings. The results was higher than that of the study that evaluated the experience of the Research Ethics Committee of "Secretaria de Estado de Saúde" (State Health Department) of Distrito Federal – REC/SHD/DF, Brazil, from 1997 to 2007, analyzing 1,129 projects <sup>4</sup>, corresponding to 64.48% of the projects evaluated in the current study, at the same time interval.

The role of the REC is important in the regulation and supervision of the production of researches in Brazil, but it is important to point out that the role of the government and of editors of scientific journals, who, as those in charge of the dissemination of research results, should establish detailed ethical recommendations. Thus, REC, the government and editors need to realize the extent of their responsibilities to the general community, particularly the scientific community. Because of the existing inequalities in Latin America and in the Caribbean, it would be up to the database in health sciences to promote actions aiming to comply with the laws of each country, protecting the science, individuals and animals against inadequate scientific practices <sup>5</sup>.

The short time period to submit a research project to appreciation shows the commitment of the local committee to evaluate all documents received in this instance. Meetings of the REC studied take place monthly and are previously scheduled every year. Dates are published on the website of Unimontes. The deadlines to send documents needed to submit a research project to be evaluated by the local committee are also published on the web-

site. Thus, researchers may organize the delivery of all the material timely for the ethical analysis in the following meeting of the committee.

The time between submission and the evaluation of projects at Unimontes was less than that presented by the study carried out at CEP/SES/DF, whose time to approve projects varied from 30 to 60 days <sup>4</sup>. As for the fact that the highest mean of time for the approval of projects related to exact sciences, has the justifying hypothesis of having less representativeness of this area in the local committee, which would demand more time to analyze the Project by professionals with degrees in other areas.

Most research projects received a favorable opinion to carry out the proposal, which means they respected research ethical principles involving human beings. This result corresponds to that found in the study of CEP/SES/DF, which presented a percentage of approval of 90.4% of the projects evaluated <sup>4</sup>. It is important to highlight that every research ethics committee becomes responsible for the research projects they approve <sup>6</sup>.

For the approval if projects, the evaluation of the informed consent is extremely important, since its document ensures the understanding of the study by each participant, insuring respect to the autonomy, ethical principle that arose as a reference to self-management or to the self-government. Currently, the informed consent comprises the rights of freedom, privacy, individual choice, individual choice and the freedom will. It includes some rules as for the respect to privacy; the protection of confidential information and obtaining consent for the intervention in the patients. The research in human beings should always have to protect people in their significance, respect their autonomy and defending its vulnerability <sup>7-10</sup>.

In this study, the reproval of projects occurred for several reasons, among them flaws in the elab-

oration of the informed consent. It is also observed that the reapproval of some projects occurred because of more than one problem, with flaws in the informed consent and in the schedule or flaws in the informed consent and in the methodology. In general, the most notable flaw was that related to the informed consent. This result was also verified in the study of CEP/SES/DF, which considered the consent term was the most frequent pendency among the projects evaluated 4.

The informed consent was also considered as the main reason of the reapproval of research protocols in projects analyzed by the CAPPesq (Comissão de Ética para Análise de Projetos de Pesquisa) (Ethics Committee for the Analysis of Research) of the complex of Hospital das Clínicas of Faculdade de Medicina of Universidade de São Paulo, with about 25% of reapprovals. It is responsibility of the REC to audit the conduction of the research and the review the informed consent based on the results of the research 11.

The consent, in addition to being informed, has to be free, with no type of limitation to the decision made by the individual to consent, and informed because the commitment with the investigated individual is not only to inform him/her but also to clarify them. REC should be extra careful with the protection of vulnerable groups, those with a reduced self-determination capacity, as in the case of those who are under 18 years of age, pregnant women, socioeconomically disadvantaged, indigenous people, prison inmates, employees, students, disabled people and elderly. In the report issued, the committee evaluates if the project is feasible, verifying the adequacy of the free and informed consent and eventual conflicts of interest 6. Thus, the capacity of the individual of the research to give his/her consent becomes an important factor to approve projects, which is why doubts should be cleared up by the researcher of the study, in order to avoid flaws in the process of understanding and consent by the patient 12.

The researcher should do his/her best for its elucidation, using a language that is colloquial and understandable for the participant, so that the consent is, actually, free and informed. The disapproval of projects by issues related to informed consent in the current study may be linked to the use of inadequate language for the target population of the research. In addition, the large number of researchers that are carried out in the health area and in hospitals requires the members of the local committee to be very careful in the ethical review of the informed consent, since individuals admitted

to hospitals are in a situation of vulnerability, even if temporarily.

The informed consent is a document that is adopted worldwide. In a study carried out in 40 local ethics committees in medical sciences universities in Iran, supported by the World Health Organization (WHO), it was verified that in 95% of the committees evaluated, the informed consent was maintained available to the researchers 13. The REC of Unimon-tes also provides a model of informed consent to researchers, having the recommendations of “Comitê Nacional de Pesquisa” (Conep) (National Research Committee) as a base. The availability of models of this document helps the researcher to build a free and informed consent according to current ethical guidelines, such as information on the objectives of the study, risks and benefits.

The process of free and informed consent has the purpose of allowing the individual invited to take part in the research to understand procedures, risks, discomforts, benefits and rights involved in the study, leading him/her to make an autonomous decision. Obtaining a free and informed consent is the researcher's duty and it is a sign of respect for the people involved in the project 14. Therefore, the informed consent is a document, which authorizes the participation of the individual in the research 1. The individual, when adequately informed, makes his/her choice freely between either participating or not participating in the study 15. That is why an informed consent in disagreement with ethical principles leads the project to receiving an unfavorable opinion, that is, being disapproved by the committee. In this study, as previously shown, most disapprovals have been due to problems identified in the informed consent.

Researchers should guarantee that data will be used just for scientific purposes, thus preserving the privacy and reliability of the research individual. Images will be only identified and used with the authorization of the investigated individual 14. Regarding the research, both for the biomedical and the social research, terms “anonymous” and “confidential” are commonly used as synonymous, although they have different meanings. Both have in common the fact that they refer to a certain piece of information that should be protected so it does not harm its holder. In several cases, investigated individuals are promised to be kept anonymous in the research, but it is impossible that this promise is honored 16.

Other ethical principles, in addition to the respect to the autonomy, are considered for the ap-

proval of projects, among them are the principle of non-maleficence that determines the obligation of not harming intentionally. That principle is closely related to norm according to which no one should be harmed, or that potential damages should be prevented. Another principle mentioned is beneficence, for which it is not enough to just treat the individual as an autonomous one, but also to contribute to his/her well-being. This principle, in addition to compassion, benignity, altruism, and love, should be considered so that it includes all forms of actions that benefit other people. Risks and benefits should be evaluated, both real and potential ones, as well as individual or collective ones, and search for the maximum of benefits and the minimum of risks as possible. The principle of justice comprises equality, merit (what is merited) and prerogative (what someone has the right to). It implies in a fair, equitable and appropriate treatment. It is important to consider what is someone's right. According to this principle, the research should have social relevance, with significant advantages to the investigated individuals, and to minimize the burden for the vulnerable ones <sup>7-10</sup>.

In this study, most projects are in the area of health sciences, among them the most common ones were from the nursing area, which may explain the largest number of researches conducted in hospitals.

We may state that the ethical evaluation of a project in the health area, and also in other areas is based on at least four key points: 1) qualification of the team of researches and of the project; 2) evaluation of the risk-benefit ratio; 3) informed consent; 4) previous evaluation by an ethics committee <sup>14</sup>. The previous evaluation of research projects carried out by a REC aims at ensuring the adjustment of ethical and methodological aspects of the study. Due to its social and academic independence and representativeness, the committee will guarantee that studies have an institutional endorsement, in addition to the liability insured by the researchers <sup>17</sup>.

Based on the above mentioned, we may state that the role of the REC is inserted into the mechanisms of social control, to enable a humanized treatment to the investigated individuals. The mission of REC is to protect people involved, guaranteeing their interests have priority over scientific or societal interests <sup>3</sup>.

Although Brazil currently occupies a prominent position in Latin America by having a well-defined regulations about research in human beings, such as resolution 466/2012 of "Conselho Nacional de Saúde" (National Health Council) (NHC), study pub-

lished in 2010 verified that most studies presented in the "XVIII Congresso Pernambucano de Cardiologia" (XVIII Congress of Cardiology in the state of Pernambuco), in 2008, did not conform to the resolution of NHC 196/1996, existing at that time <sup>18</sup>. Ethical review in research is an important process, intended to protect participants in a medical research. Nevertheless, it is criticized for not meeting objectives <sup>19</sup>.

In a research carried out in two universities of dentistry in the Middle East to evaluate the knowledge, consciousness and attitudes of the faculty regarding ethics in research and in ethics committees, it was verified that almost half (44.0%) of the interviewees considered that ethics committees delayed the scientific research, and only 36.8% of the interviewees had had previous training in ethics in research <sup>20</sup>. These results have shown the existence of gaps in knowledge of ethics in research even among professionals of higher education institutions. And, in the present study, the lack of knowledge on the part of the researcher may have been the factor responsible for flaws in the methodology and make an informed consent.

In a research carried out in dentistry schools in Brazil, it was verified that 31.3% of them had the discipline of Bioethics in their curriculum. In general it is taught in the first or in the last year of the course <sup>21</sup>. This discipline is appropriate to introduce ethical dilemmas included in the research with human beings, in the Brazilian regulations, in the role of the REC, in the bioethical principles of the research, among other topics related to the investigation involving humans, as well as animals.

The participant, as a patient of health care services, may supply the needs and interests of the investigator in health research. This may generate evident conflicts, such as what happens in research projects involving clinical assays in developing countries. The participation of target-populations of developing countries in a research project may be a strategy from the poor access to health care services, little understanding of the risks involved in the studies, as well as the little ability of the population to legally claim for some kind of compensation in situations of impairment <sup>22</sup>. In this context, the ethics committee plays a fundamental role of ethically evaluating a health research project, thus preventing the exploitation of participants, particularly those who are more vulnerable and live in developing countries.

In developed countries, the informed consent is based on the autonomy, being authenticated by

the signature of the participant and supervised by research ethics committees. In developing countries, the decision-making initiative to obtain the informed consent is usually invested in the community, rather than in the individual. Challenges of developing countries are exacerbated by the fact that people at a higher risk of disease are usually illiterate, have little experience with the Western medicine and little understanding of the scientific rationale for the studies proposed<sup>23</sup>. In his study, Lorenzo argues that, in addition to the informed consent, it is necessary to expand strategies to obtain informed consent for the research, considering that illiteracy is common in these countries, thus, limiting the value of signatures in the documents<sup>24</sup>.

In response to the growing number of researches undergoing today in developing countries, several research ethics committees have been established; but, in certain countries, the quality of the system of ethical review remains unknown. Accordingly, researches proposed a tool aimed at a self-evaluation of the committees, with the purpose of reviewing their policies as for internationally recognized ethical standards. Developed and evaluated by REC members and researchers from the Middle East, the self-evaluation tool reflects pragmatic aspects of protection of human beings, based on international standards<sup>25</sup>.

A study conducted in the Dominican Republic also aimed at describing the situation of seven research ethics committees, as for the organization and composition, as well as activities and needs to train their members and following recommendations provided by International Ethical Guidelines for Biomedical Research involving Humans. Results have shown the complexity of the situation of committees in the Dominican Republic and the efforts needed to better follow the international recommendations<sup>26</sup>. In a certain way, results from this study contribute to the reflection of local committee members, to identify that most projects in the health area show the importance of permanent education actions aimed at REC members.

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By being funded by transnational corporations, the research is often subjected to standards imposed by the market, in the name of merely economic interests, which ends up compromising the integrity and the relevance of the scientific research, in addition to interfering with the final results of the study. The economic interest conditions the investigation, which should be conducted with total neutrality and always guided towards the collective good<sup>27</sup>. This reinforces the importance of the REC to carefully evaluate research projects, before they are carried out.

This study has the limitation of being conducted from secondary data; thus, although data are in accordance with records observed in the documents assessed, the risk of bias in the obtained information should be considered. The absence of information in one part of the documents is another limitation inherent to any study based on documents. However, researchers have attempted to compensate for these limitations by data being collected by only one researcher, concomitant evaluation in more than one type of document and percentage adjustments of results disregarding missing information.

## Final considerations

With this study, it is concluded that, by improving research projects due to flaws in the informed consent, methodology and schedule, the local committee of Unimontes judgment was built on guidelines based on research involving human beings. Ethical evaluation was established on fundamental principles of bioethics: *autonomy, beneficence, non-maleficence* and *justice*. Therefore, the local committee skillfully played its role to protect the ethics and the participant of the research. In addition, results from this study have shown that REC of Unimontes was resolute in the evaluation of projects, once it required little time from submission to the final report.

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#### Participation of the authors

The authors participated equally in all phases of the research and production of this paper. All of them approved the final version of the article and are equally responsible for all the aspects of the work, including the assurance of its accuracy and integrity.

Recebido: 29. 5.2014

Revisado: 13. 8.2014

Aprovado: 6.11.2014

