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Characterization of research protocols: a study in Paraíba, Brazil

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Abstract

This article provides a description of all the research protocols evaluated by the Research Ethics Committee of the Instituto Federal da Paraíba (the Federal Institute of Paraíba) (CEP/IFPB), from its foundation in 2008 until 2014. A descriptive and documental case study type review was performed. Of 228 protocols considered, 82.02% were approved. The predominant areas of knowledge were Human Sciences (21.05%) and Social Sciences (21.05%). The IFPB Campus in Joao Pessoa (35.52%) approved the most protocols. The researchers responsible for the research protocols were predominantly professors (86.84%) and the majority had post-graduate qualifications (52.63%), with a rate of one protocol per researcher predominating. It was concluded that in assessing the ethics of the protocols submitted, the CEP/IFPB has been acting in the interests of ethical reflection in scientific research, contributing to the development of studies guided by ethical standards and by the need to provide more protection to research participants.

Keywords: Ethics. Ethics committees, research. Protocols.

Resumo

Caracterização de protocolos de pesquisa: um estudo na Paraíba, Brasil

O artigo apresenta a caracterização da totalidade dos protocolos de pesquisa apreciados pelo Comitê de Ética em Pesquisa do Instituto Federal da Paraíba (CEP/IFPB), desde sua fundação, em 2008, até 2014. Trata-se de estudo descritivo e documental, na modalidade estudo de caso. Dos 228 protocolos apreciados, 82,02% foram aprovados. As áreas de conhecimento predominantes foram ciências humanas (21,05%) e ciências sociais aplicadas (21,05%), e o *campus* de João Pessoa, do IFPB, foi o que teve o maior número de protocolos apreciados (35,52%). Os pesquisadores responsáveis pelos protocolos de pesquisa eram, majoritariamente, professores (86,84%), e 52,63% possuíam titulação de mestre, com incidência predominante de um protocolo por pesquisador. Concluiu-se que, ao apreciar a eticidade dos protocolos submetidos, o CEP/IFPB fomenta a reflexão ética nas pesquisas científicas, contribuindo para o desenvolvimento de estudos norteados por padrões éticos e para maior proteção ao participante da pesquisa.

Palavras-chave: Ética. Comitês de ética em pesquisa. Protocolos.

Resumen

Caracterización de los protocolos de investigación: un estudio en Paraíba, Brasil

El artículo presenta la caracterización de la totalidad de los protocolos de investigación examinados por el Comité de Ética en investigación del Instituto Federal de Paraíba (CEP/IFPB), desde su fundación, en el año 2008, hasta el 2014. Se trata de un estudio descriptivo y documental, en la modalidad de estudio de caso. De los 228 protocolos examinados, 82,02% se aprobaron. Las áreas de conocimientos predominantes fueron las Ciencias Humanas (21,05%) y las Ciencias Sociales Aplicadas (21,05%). El campus de IFPB con el mayor número de protocolos evaluados fue el de João Pessoa (35,52%). Los investigadores encargados de los protocolos de investigación fueron, predominantemente, profesores (86,84%) y poseían, en su mayoría, título de maestría (52,63%), con incidencia, principalmente, de un protocolo por investigador. Se concluye que, al examinar la eticidad de los protocolos sometidos, el CEP/IFPB fomenta la reflexión ética en los estudios científicos, contribuyendo al desarrollo de trabajos orientados por patrones éticos y tendiendo a una mayor protección al participante de la investigación.

Palabras-clave: Ética. Comité de ética en investigación. Protocolos.

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Research articles

In Brazil, the ethics review system of research involving human subjects was created by Resolution 1/1988 of the Conselho Nacional de Saúde (CNS)[1] (National Health Council), which aimed to regulate research in the area of health throughout the national territory[2]. In 1995, the CNS initiated the process of revising this Resolution with the objective of bringing it up to date. As a result, the Grupo Executivo de Trabalho (GET – Executive Work Group) was created and consisted of representatives from various social and professional areas, resulting in the elaboration of CNS Resolution 196/1996[3], which covered a broader scope, applying to all research involving human subjects, regardless of the area of knowledge[4].

In 2013, after practically seventeen years in effect, CNS Resolution 196/96 was revoked by CNS Resolution 466/2012[5]; a document that also established guidelines and regulations of research involving human subjects and which came into effect on 13th June 2013, the date of its publication in the Diário Oficial da União (Official Federal Gazette of Brazil). Among the alterations, some which should be mentioned are: the incorporation of new international documents in its introduction; the inclusion of new terms and definitions and the modification of others present in the previous resolution; the alteration of the item "Free and Clarified Consent" to "Free and Clarified Consent Process"; intended to create a complementary resolution to consider specificities of research in the humanities and social areas and others that adopt their own methodologies[6].

According to CNS Resolution 466/2012[5], the comitês de ética em pesquisa (research ethics committees – CEP) are interdisciplinary and independent collegiate bodies, endowed with public relevance and a consultative, deliberative and educational role, which have the mission to protect research participants and collaborate in the development of studies according to ethical standards. Therefore, it is imperative that research involving human subjects is submitted to the evaluation of the system formed by the CEP and the Comissão Nacional de Ética em Pesquisa (National Research Ethics Commission – CONEP), known as the CEP/CONEP system.

The CEP are responsible for evaluating and monitoring the ethical aspects of all research involving human subjects, and its reason for existence is to defend the rights and dignity of the study participants, to contribute to the ethical quality of the protocols analyzed, for discussions about research in the context of institutional development and social progress of the community, as well as for the appreciation of the researchers who receive recognition for having developed ethically adequate studies[7].

According to data from Conep[8], Brazil currently has 727 research ethics committees. However, it is evident that there are still few studies developed within the national scenario that aim to characterize the protocols evaluated by CEP. Studying their peculiarities is an important instrument of planning as the data obtained can be used as input for the preparation of action plans by the committees, which would influence in the improvement of their activities. In addition, these studies have social relevance – since the CEP aim to promote the protection of the research participants – and contribute to the development of the ethical quality of processes.

The importance of this study is in the development of work, the results of which could be used by the Comitê de Ética em Pesquisa do Instituto Federal da Paraíba (Research Ethics Committee of the Paraíba Federal Institute – IFPB) to assist in planning their activities and making decisions, contributing to a better performance of the CEP regarding the protection of participants and promote more ethical quality in research involving human subjects. The study also contributes to the existing literature on the network of CEP/CONEP system institutions.

Within this scope, the central objective of this study was to characterize all the protocols evaluated by the CEP/IFPB – since 2008, the year it was founded, until 2014 –, emphasizing the following aspects: quantity assessed by the CEP; number of projects approved, not approved, withdrawn and archived; large areas of knowledge; campus of origin; professional category and qualifications of the researchers responsible for the protocols; and number of researchers per protocol.

Method

It is a descriptive and documental research in the format of a case study, carried out by the CEP/IFPB. Created on 9th December 2008 by means of Resolution 13/2008 of the IFPB Board of directors, the CEP had its registration approved by Conep on 23rd October 2009.

The sources of data utilized were semiannual reports, consolidated opinions and all protocols of research evaluated by CEP/IFPB, since its founding until 2014, over a period of seven years. In table 1, detailed information about the items discussed in each document type is given.

Table 1. Documental research map

Documents	Items analyzed
Semiannual reports	Activities developed by the CEP each semester; quantity of protocols analyzed; number of protocols approved, not approved, withdrawn and archived
Consolidated opinions	Protocols that received consolidated opinion "pending" before being "approved"
Protocols of research evaluated	Large areas of knowledge; quantity of projects per IFPB *campus* or other institution; professional category and qualification of the researchers responsible; number of researchers per protocol

The documental research was carried out between 11th August 2014 and 30th January 2015. The collected data in the semiannual reports concerning the period 2008-2014, as well as those relating to analyzed research protocols and consolidated opinions issued by CEP/IFPB in 2010 and 2011, were collected from printed documents available in the Committee archives. The data of protocols and consolidated opinions in the period from 2012-2014 were obtained from digital documents and were presented on Plataforma Brasil ("the Brazil Platform").

The data was tabulated on Microsoft Excel 2010 and subsequently analyzed by simple descriptive statistics methods (frequency, mean and percentage), which permitted the characterization of the research protocols. The study was developed in conformity with the ethical principles set out in CNS Resolution 466/2012 [5].

Results and discussion

Research protocols evaluated by CEP/IFPB

Since its founding until 2014, the CEP/IFPB evaluated 228 research protocols, signifying an average of slightly more than 32 per year. Despite having its registration approved by Conep in October 2009, the first research protocols received by CEP are from 2010. Given the period in which CEP effectively performed evaluations, there were an average of 45.6 protocols analyzed per year.

These figures represent important work carried out by the CEP/Conep system throughout Brazil. Through the work developed by a network of institutions, consisting of 727 CEP [8] and by Conep, thousands of protocols are evaluated annually in order to safeguard the rights and dignity of research participants as well as contributing to the development of research in accordance with ethical standards [7].

In 2009, planning meetings were held, and in the first semester of 2010 educational activities with the internal community were developed, standardized documents were produced and the creation of the CEP web page was completed, aimed at making information available to IFPB researchers.

From April of 2009, the Dean's office for Research, Innovation and Graduate Studies of the Instituto Federal da Paraíba (PRPIPG/IFPB – Federal Institute of Paraíba) established that research projects involving human subjects be analyzed by CEP as a prerequisite in order to participate in bids for research grants. If the proposal is considered, receipt of grants and the development of the study is conditioned to prior approval of the project by the CEP. However, this procedure only came into force in 2010, as the registration of the Committee took place in October 2009.

These initial actions were directly responsible for the evaluation of research protocols by the CEP/IFPB, in that the first application occurred on 7th June 2010. The total number of protocols evaluated by CEP in 2010 (25) corresponds to 10.96% of evaluations within the period analyzed.

In 2011, that number increased by more than 50% in relation to the previous year (52). Some factors were crucial in relation to this: the first was the dissemination of the existence of the CEP in the various campi of IFPB. This activity of educational nature, carried out in the form of lectures, also aimed to promote the importance of the committee for research involving human subjects, as well as the procedures required to submit research protocols for evaluation. Another relevant factor was the upholding of the application prerequisite prior to CEP in order to obtain the grant. In addition, different to 2010, a year in which evaluations were only initiated in June, in 2011 they occurred throughout the year. The research protocols evaluated by the CEP in this year correspond to 22.81% of the total evaluated within the period analyzed.

There was a progressive annual increase in the number of protocols submitted for evaluation by CEP, with the exception of 2012, in which a significant decrease of 84.62% can be observed (8 in total), in relation to the previous year. The main factor for this was the change in the submission process of research protocols. Since its creation, the CEP

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followed a standard procedure: the researcher presented the required documentation directly to the CEP. However, by means of Document 327/2011/Conep/CNS/MS [9], Conep defined that from 2012, the CEP should utilize the Plataforma Brasil ("the Brazil Platform") system for receiving research protocols.

It is important to point out that, in the beginning of the first semester of 2012, Conep and the Plataforma Brasil ("the Brazil Platform") support team were requested to register the profile of the CEP/IFPB coordinator in order for the system to be enabled in the committee; however, this was only carried out in October of that year. As a result, the CEP/IFPB was unable to promote ethical analysis of research protocols for nine months, which caused a sharp drop in the number of projects evaluated. The total number in 2012 represented only 3.51%, the lowest of the period analyzed.

In 2013, with the Plataforma Brasil ("the Brazil Platform") already enabled for operation by the CEP/IFPB, the progressive increase of evaluated protocols resumed, corresponding to 27.19% of the period analyzed (62 submissions). Approximately 34% refer to end of course projects of graduates in occupational safety technology on the Patos *campus*, possibly due to the extensive dissemination of the CEP promoted by the coordination of that course.

In 2014, there was a 30.65% increase in the number of research protocols evaluated in relation to the previous year (81), reaching 35.53% of all submissions in the period studied. This significant percentage is due to the continuity of the actions developed by the CEP and PRPIPG, in addition to the continuous promoting of the work of the committee. Another factor was the initiation of promoting the CEP/IFPB by the coordination of technology courses in commercial management (Guarabira *campus*) and food technology (Sousa *campus*).

Among the research protocols evaluated by the CEP / IFPB in the period 2010-2014, there was a project that, as it dealt with international research, following approval of the committee, had to undergo ethical evaluation by Conep. CNS Resolution 466/2012 [5] lists the research that, in addition to evaluation by CEP, also requires analysis by Conep: human genetics; human reproduction; therapeutic equipment and devices that are new or not registered in Brazil; new invasive therapeutic procedures; studies of indigenous populations; protocols involving genetically modified organisms, embryonic stem cells and organisms that have a high collective risk; protocols for the creation and operation of bio banks for research purposes; research with foreign cooperation, with the exception of those sponsored by the Brazilian government; and others that, at the discretion of the CEP, upon justification, require approval of CONEP. Since these are in special theme areas, it is necessary to provide greater protection to research participants, therefore, the CEP/Conep system, by means of double ethical assessment, permits that the study is developed according to the requirements of ethical obligations in relation to human subjects.

The analysis of the quantity of protocols submitted annually for evaluation by the CEP/IFPB makes it possible to identify several institutional initiatives that have proven the implementation and consolidation of the committee to be successful. Firstly, the period of preparation for the initiation of activities, permitting detailed planning and avoiding hastiness, that would probably prevent or hinder the full and effective functioning of the CEP. It is also important to acknowledge the internal training and dissemination of the CEP for the academic community in the various *campi* of the institution. Finally, the essential support of PRPIPG/IFPB, which established the presentation of research projects to the CEP as a prerequisite for submission of projects for the research grant programs.

Approved, not approved, withdrawn and archived protocols

From 2010 to 2014, of the 228 research protocols evaluated by CEP, 187 (82.02%) were approved, 8 (3.51%) were not approved, 20 (8.77%) were withdrawn and 13 (5.7%), were archived.

Among the approved research protocols, 52 (27.81%) received approval on first analysis, and 135 (72.19%) were considered "pending" before being approved. According to CNS Resolution 466/2012 [5], a research protocol is considered "pending" when the CEP identifies the need to correct it, and the responsible researcher must fulfill the rectification requested by the committee within the period established by the regulation in effect. According to Barbosa and collaborators [10], by verifying the necessity to make adjustments to the research protocols, the CEP protects both the research participants and the researchers and also the proponent institution of the project by means of contributing to reducing the incidence of ethical failures that might compromise the parties involved in the research.

Among the approved research protocols, there are also two that were evaluated by the CEP/

IFPB in co-participant assessment. CNS Resolution 466/2012 [5] defines the co-participant institution as one in which any phase or stage of the research is developed. Regarding the procedure, according to Document 0212/2010/Conep/CNS/MS [11], a research protocol that has co-participant institutions will first be evaluated by the committee of the proponent institution, that is the one from which the project is proposed, if the institution has a CEP. Secondly, following this approval, the Project will be evaluated by the CEP of the co-participant institution, which can only issue a decision of "approved" or "not approved". If the proponent institution has no committee, the research protocol will be forwarded, by means of the Plataforma Brasil ("the Brazil Platform"), to Conep, which will in turn indicate a CEP to evaluate the project, preferably that of the co-participant, if this institution possesses a committee. If there is no committee in the institution, Conep will forward the research protocol to the committee closest to the location where the study will be developed.

In the case of the two research protocols with co-participants evaluated by CEP/IFPB, the proponent institutions have a CEP, and the projects received the decision "pending" in the first analysis and were later "approved". Only following this analysis, the CEP/IFPB evaluated the protocols, issuing a decision of "approved". Therefore, these protocols were included among the 135 that received a "pending" decision before being approved.

In the period of analysis, 8.77% of the research protocols evaluated by a CEP/IFPB were withdrawn. Until 2011, according to CNS Resolution 196/96 [3], research protocols were considered withdrawn when the researchers did not manifest regarding the pending issues of the committee within sixty days or when requested by the researcher responsible, upon justification, before the ethical evaluation by the CEP [12]. From 2012, following the revision of the resolution, the only possibility of a protocol being considered withdrawn was when requested by the researcher; the processes in which there was no response to a pendency were then considered archived [13]. Resolution 466/2012 [5], that revoked Resolution 196/96, maintained the guidance, however, the period for the researcher to manifest, instead of sixty days, was to be defined by the operational regulations. For this reason, it was only from 2012 that protocols started to be registered with the status "arquived".

Research protocols that were not approved represent the lowest percentage (3.51%). This number reflects the educational role played by the CEP / IFPB, as the ethical inadequacies identified in the protocols and guidelines to improve the ethics of the research are registered in a consolidated opinion report, and this is forwarded, by means of the Plataforma Brasil ("the Brazil Platform"), to the researcher responsible for the study. This permits that the project can be adapted before submitting it for evaluation again and therefore contributing to the study being approved and developed with ethical quality.

In addition, the CEP also promotes educational activities on the various campi of IFPB, mainly lectures aimed at researchers, as well as making telephone contact, e-mail and consulting rooms available where proponents have access to guidance related to development of research conforming to ethical standards and can obtain guidance about pendencies identified in their protocols.

Large areas of knowledge

The research protocols evaluated by the CEP/IFPB belong to various large areas of knowledge (Tabel 1), with predominance of the humanities, applied social sciences and health, which together, represent 60.52% of the projects studied. It is important to highlight that, regardless of the knowledge area, all research involving human subjects should undergo ethical evaluation in order to protect research participants and promote solidarity and social justice [4-5].

Table 1. Research protocols per large area

Large areas of knowledge	Quantity	%
Exact and earth sciences	14	6.14
Biological sciences	1	0.44
Engineering	10	4.39
Health sciences	42	18.42
Agricultural sciences	19	8.34
Applied social sciences	48	21.05
Humanities	48	21.05
Linguistics, literature and arts	5	2.19
Others	12	5,26
More than one large area	29	12.72
Total	**228**	**100**

Freitas and Hossne [4] point out that, despite trials with human subjects being more visible in the area of health, they also occur in other areas of

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knowledge, and are often not associated with the necessary care related to ethical aspects. CNS Resolution 466/2012 [5] establishes that *all research with human subjects involves risk of varied types and levels*, and therefore, researchers and the CEP should analyze the possibility of immediate or delayed harm to participants, in each specific case, assessing risks that may arise from the study, both on the individual and collective level.

Note that the significant quantity of protocols belonging to the areas of humanities and applied social sciences (96 research projects) contradicts the opinion of some researchers that only protocols belonging to the health sciences should undergo ethical assessment of a CEP. This condition is mainly due to the educational role of the CEP at the various *campi* of the institution, which emphasizes the importance of submission of all protocols involving human subjects to the committee, regardless of the knowledge areas of project.

It is also worth mentioning that the number of CEP / CONEP system member institutions, due to its interdisciplinary nature, is also composed of professionals from various areas of knowledge, and not only the health sciences. This configuration, in addition to contributing to the evaluation of protocols from other areas, permits ethical evaluation from different and distinct angles of observation, which promotes collegial discussion and results in a more comprehensive analysis of the protocols.

Campus origin of the protocols

The majority of protocols evaluated by the CEP/IFPB originated from João Pessoa *campus* (81, or 35.52%). The other *campi* of the institution presented, in descending order, the following results: 50 from Patos (21.93%), 23 from Sousa (10.09%), 14 from Campina Grande (6.14%), 14 from Picuí (6.14%), 9 from Cabedelo (3.95%), 8 from Guarabira (3.51%), 6 from Cajazeiras (2.63%) and 5 from Monteiro (2.19%). No research protocols from Princesa Isabel *campus* were evaluated. There were also 8 research protocols registered which originated from the Rectory of IFPB (3.51%), 9 from other institutions (3.95%) and 1 did not state the proponent institution (0.44%).

The prevalence of the João Pessoa *campus* is due mainly to some peculiarities: it is the oldest of the IFPB, and currently offers three post graduate courses, 13 bachelor courses and eight technical courses, that is, the *campus* has extensive engagement in research activities; and is the *campus* which offers the most grants from the Programa Institucional de Bolsas de Iniciação Científica e Tecnológica (Institutional Scholarship Program for Scientific Initiation and Technology - Pibict) and from the Institutional Research Support Program.

The absense of research protocols from the Princesa Isabel *campus* and the low quantity from the Cabedelo, Cajazeiras and Monteiro campi indicates that the CEP/IFPB should find means to develop and/or reinforce educational activities for researchers of those units, aimed at increasing their awareness of the importance of submitting research projects involving human subjects to the institution committee and, therefore, contributing to the construction and development of scientific knowledge based on ethical analysis. However, in doing this, the CEP may encounter difficulties, such as poor infrastructure, shortage of human resources, a high demand of protocols submitted for ethical evaluation, overload of work for its members, a lack of interest from researchers to participate in the events organized by the CEP and lack of institutional support for the financing of educational activities [14-15].

The low number of research protocols coming from the rectory and Guarabira *campus* is justifiable, as the first, due to its administrative nature, does not develop many research activities, and the Guarabira *campus* was inaugurated recently (in 2011) – its research activities are still in their initial stages and only started being submitted to the CEP/IFPB in 2014.

The CEP/IFPB evaluated nine protocols that belonged to other institutions, that is, the researcher responsible for providing the data on the Plataforma Brasil ("the Brazil Platform"), input an institution that did not have a CEP. There was also an evaluation of one that did not state the proponent institution. In both of these situations, generally, the protocols are forwarded to Conep, which indicates a CEP for ethical evaluation, prioritizing those with the best conditions to monitor the development of the study [6] – in this case, the CEP/IFPB was indicated for these ten protocols.

Professional category and qualification of the researchers responsible for the protocols

It was found that 198 (86.84%) of those responsible for the protocols were IFPB professors and only 20 (8.77%) were administrative staff of the institution. The professional category of 10 (4.39%) researchers that did not belong to the IFPB staff was not identified. This significant number of research protocols submitted by professors of the institution

had as the determining factor, the linkage between teaching and research activities. As for the low number presented by administrative staff, this was due to the fact that these protocols were mainly related to projects for the development of monographs of post graduate specialization courses, as well as guidance for research grant projects.

It was observed that among the 228 protocols evaluated, 120 researchers (52.63%) had master's degrees; 63, doctorate (27.63%); 38, specialization (16.67%); 6, bachelor's (2.63%); and 1, high school (0.44%) – in relation to the last, the registration on Plataforma Brasil ("the Brazil Platform") stated a bachelor's degree, however, the applicant's curriculum stated that the course was ongoing. This fact became evident to the CEP/IFPB during the evaluation of the research protocol, and a "not approved" result was issued, due to the fact that, in order to be the researcher responsible, it is necessary to have at least a bachelor's degree.

The expressive number of researchers with master's and doctorate (80.26%) is a reflection of the policy for qualification of professors and administrative staff at federal institutes. When they qualify, professors have the right to remuneration according to their degree; while administrative staff are entitled to incentives for level of qualification. In an attempt to increasingly consolidate this strategy, the IFPB has entered into partnerships with other institutions with the objective to offer post graduate courses to their employees.

Number of researchers per protocol

Considering the period of analysis, the quantity of researchers that had research protocols evaluated by a CEP/IFPB for the first time was: in 2010, 14 researchers; in 2011, 31; in 2012, 3; in 2013, 29; and in 2014, 41. Note that, each year, new researchers submit protocols to the committee for evaluation, permitting ethical analysis of the project to be carried out by an independent authority. The reduced number related to 2012 is due to the fact that in that year the CEP did not promote the ethical analysis of protocols, as mentioned previously.

The 228 research protocols evaluated by the committee from 2010 to 2014 were submitted by 118 different researchers. The data collected also points out that each researcher presented, individually, the following quantity of protocols: 78 researchers, only one protocol; 19 researchers, two protocols; 6 researchers, three protocols; 5 researchers, four protocols; 5 researchers, five protocols; and 5 researchers presented more than five protocols.

The necessity for submission of research protocols involving human subjects to independent research ethics committees emerged following the updating of the *Declaration of Helsinki*, in 1975 [16]. Therefore, these research protocols should be submitted for consideration, discussion and guidance of a CEP, not leaving the ethical analysis of the project to the criteria of the researcher responsible for the study and the sponsor of the research [4].

Despite this, the CEPs were actually only implemented in Brazil in 1996, following the publication of CNS Resolution 196/96 [3], since CNS Resolution 1/1988 [1] was focused only on research in the area of health care. Resolution 196/96 [3] had a broader scope, establishing that all research involving human subjects should be analyzed by a research ethics committee.

Note that the number of researchers that submitted research protocols to CEP/IFPB has been increasing gradually, which permits us to infer that there is a greater protection of participants in research, as a result of the higher number of projects that undergo ethical evaluation of the CEP/Conep system.

Final considerations

The development of this study permitted a detailed analysis of the profile of the research protocols evaluated by the Federal Institute of Paraíba Research Ethics Committee from 2010 to 2014. Verified that the number of research protocols submitted to the CEP/IFPB has been gradually evolving each year, which demonstrates that the committee contributes to the ethical quality of research developed in the institute.

Despite the majority of the protocols having been approved, 72.19% of them received the analysis result pending before being approved. This fact points out the necessity to encourage educational activities, developed by the CEP/IFPB, aimed at researchers, with the intention of raising awareness of researchers to the importance of submitting research protocols involving human subjects to the institutional CEP in order for them to be carried out according to ethical standards. Another fact that demonstrates this necessity is the significant difference, among the various *campi* of the institute, in the number of research protocols evaluated by the CEP. Regardless of their peculiarities, in some units there should be reinforcement of the educational activities carried out by the committee.

It is also possible to infer that the *campi* with a relatively high number of evaluated protocols have a strong tendency to create their own CEP, mainly due to the increasing annual demand for evaluation by the CEP/IFPB.

The 228 research protocols evaluated by the CEP/IFPB were submitted by 118 researchers with high levels of qualification, belonging predominantly to the professional category of professors. Therefore, it can be deduced that the protocols evaluated by the committee are from well-qualified researchers, which represents a positive factor for the performance of CEP educational activities, strengthening their mission to protect research participants.

In addition, the CEP/IFPB evaluated research protocols in various areas of knowledge, which demonstrates that the committee is in compliance with the guidelines presented in the resolutions issued by the CNS, promoting the ethical evaluation of any research involving human subjects, regardless of the subject being studied.

Given the above, it can be concluded that, by evaluating the ethics of the protocols submitted, the CEP/IFPB promotes ethical reflection in scientific research, contributing to the development of studies guided by ethical standards and respect for the research participants and consolidating, therefore, its fundamental role in the construction and development of scientific knowledge in IFPB.

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