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Editorial

Practical precautions when submitting a project to the research ethics committee

Cuidados práticos ao submeter um projeto ao comitê de ética em pesquisa

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Gilmara Holanda da Cunha[1]
Fernando Antônio Frota Bezerra[1]
Maria Elisabete Amaral de Moraes[1]

[1]Universidade Federal do Ceará.
Fortaleza, CE, Brazil.

Corresponding author:
Gilmara Holanda da Cunha
Rua Alexandre Baraúna, 1115, Rodolfo Teófilo.
CEP: 60430160. Fortaleza, CE, Brazil.
E-mail: gilmaraholandaufc@yahoo.com.br

EDITOR IN CHIEF: Ana Fatima Carvalho Fernandes

Each research ethics committee (REC) has its own routine and documentation models for the submission of projects for evaluation. However, regardless of their location and whether they are part of a university or a health institution, laws, resolutions, letters, and circular letters in effect in the country must be respected. Thus, some common mistakes delay the process of project assessment, while making it more difficult to issue opinions. This editorial is about the most common issues in this context, which must be observed when submitting a project to a REC.

RECs are interdisciplinary and independent collegiates. They are consultive, deliberative, and educational bodies of public relevance, created to stand for the interests, integrity, and dignity of those who participate in research, contributing to the ethical development of research[1]. Therefore, this type of informative piece is important, as it is part of the educational activities that a REC must develop. RECs can also help members of ethics committees to evaluate projects, improving their workflow.

Beginning with the title, it is important to note that it must be standardized, being the same in Plataforma Brasil and any attached documents: research project, letter of submission to the REC, institutional authorizations, budget, schedule, declarations from the researchers participating in the study, informed consent, informed agreement, trustworthy depositary form, and any other necessary documents that may be required by the institution.

An authorization from the setting of the research must be attached to Plataforma Brasil. Fur-

thermore, participating institutions, that is, any public or private organizations, legitimately constituted and qualified, in which any stage or phase of the research is developed[1], must be documented via Plataforma Brasil.

The objectives of the study must be clear and standardized in both research project and Plataforma Brasil. The methodology of the project must describe: the type of study, the setting of the research and the period during which it will be conducted, its population and sample, participant selection, and the criteria for inclusion, exclusion and withdrawal, or discontinuity, if applicable. The study must be designed including all data collection stages, procedure descriptions, interventions, and instruments to be applied. It is important to describe when, exactly, the participant will sign the informed consent. If the research involves minors, it should explain how their guardians will sign the informed consent, and how the minors will sign the informed agreement. All logistics of data collection should be detailed, so the evaluator can understand what the participant will go through during the study. Avoid using the term "subjects"; use research "participants" instead.

Still regarding methodology, the steps that will be employed for data analysis must be described. Regarding ethical aspects, laws, resolutions, letters, and circular letters in effect, as well as consent forms and agreements, risks and benefits of the study, should all be mentioned. It is important to describe how risks will be minimized, and what will be the conduct in case of alterations or disturbances caused by the research. In case of studies that identify participants with health alterations, there should also be orientations regarding proper referral.

The informed consent and agreement must indicate all procedures from the study in a language accessible to the participant. This involves describing the procedures, be it in person or online, explaining which and how many forms will be applied, as well as the number of questions, mean time required, and whether the environment will be private or there will be a group. If there are follow-up sessions, later evaluations, group activities, phone calls, photographs, or recordings, they must be described, as well as the equipment used to produce them. If it is a randomized clinical trial, the participant must know that they may be included in any of the groups, and know the respective procedures. The risks and benefits must be described in the consent and agreement forms and standardized in the research project and in Plataforma Brasil.

It is important to be clear regarding risks, according to the procedures carried out in research. The real risks of the study must be described, such as time demands, psychological discomfort, stress, embarrassment, and eyes train. If it involves any invasive procedure, describe the potential occurrences, collateral effects, and adverse events. Do not use vague or nonspecific sentences or simply state that there are no risks. It is worth noting that the risk is associated with the participant, meaning that, if there is more than one type of participant, the risks for each type of sample must be specified.

Since the pandemic of the new coronavirus, the cause of COVID-19, researchers carried out in part or in full within virtual environments have become more frequent. To enable that, a circular letter presented guidance regarding procedures for researches which have any stage conducted in a virtual environment[2]. These elements are relevant, as they show that the documents follow epidemiological changes and the development of science. They also show that researchers must be attentive, in order to guide their studies in the best possible way.

Finally, in addition to knowing the method used, the researcher must be up-to-date in their knowledge of laws, resolutions, letters, and circular letters in force in the country[1-3], always seeking autonomy, non-maleficence, beneficence, justice, and equality, in order to ensure the rights and duties of each participant of the research, the scientific community, and the State[1].

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