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Article abstract

There is no single institution responsible for research ethics in health sciences in Colombia and there is no specific procedure for securing research ethics approval in the country. However, the Ministry of Health and Social Protection's resolution on health research provides guidance on key ethical considerations in health research and indicates which institutions in Colombia could provide ethics approval. Ethics approval has to be provided either by the researcher's institution of affiliation, the institution in which the research will be conducted, or the health authority responsible for the communities participating in the project. Despite this guidance, our experience with a health systems research project showed that the implementation and practice of research ethics vary between institutions. Attention should be given to ensuring effective implementation of the ethics approval process.

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ÉTUDE DE CAS / CASE STUDY

Seeking Ethics Approval in Colombia: A Health Systems Research Case Study

Juan Carlos Rivillas[1], Marie-Gloriose Ingabire[1]

Résumé
En Colombie, il n'existe aucune institution responsable de l'éthique de la recherche en sciences de la santé et il n'existe pas de procédures spécifiques pour obtenir une approbation éthique pour un projet de recherche. Cependant, la résolution sur la recherche en santé du Ministère de la Santé et de la Protection sociale fournit des conseils sur les principales considérations éthiques de la recherche sur la santé et indique quelles institutions en Colombie pourraient fournir une approbation éthique. L'approbation éthique doit être fournie soit par l'institution d'affiliation du chercheur, l'établissement dans lequel la recherche sera menée, soit par l'autorité de santé responsable des communautés participant au projet. Malgré ces indications, notre expérience dans le cadre d'un projet de recherche sur les systèmes de santé a montré que la mise en œuvre et la pratique de l'éthique de la recherche varient d'une institution à l'autre. Une attention particulière devrait être accordée pour assurer la mise en œuvre efficace du processus d'approbation éthique.

Mots clés
éthique, développement, recherche, santé, Colombie

Abstract
There is no single institution responsible for research ethics in health sciences in Colombia and there is no specific procedure for securing research ethics approval in the country. However, the Ministry of Health and Social Protection's resolution on health research provides guidance on key ethical considerations in health research and indicates which institutions in Colombia could provide ethics approval. Ethics approval has to be provided either by the researcher's institution of affiliation, the institution in which the research will be conducted, or the health authority responsible for the communities participating in the project. Despite this guidance, our experience with a health systems research project showed that the implementation and practice of research ethics vary between institutions. Attention should be given to ensuring effective implementation of the ethics approval process.

Keywords
ethics, development, research, health, Colombia

Background

Countries and institutions are striving to develop and implement ethics guidelines and approval processes to ensure quality and promote excellence in research. Since 1993, the Ministry of Health and Social Protection's resolution Nº 8430 [1] has provided the legal framework for carrying out health research in Colombia. According to the definition in the resolution, health research encompasses the use of social science, science, technology, engineering or mathematics in the delivery of health care. This resolution establishes guidelines to obtain ethics approval, which depends on the institution where research will be conducted, or the health authority responsible for the communities that will be involved. It is the responsibility of these institutions to ensure that ethics reviews are conducted according to their jurisdiction and approvals obtained before research projects are commenced.

Although this resolution outlines the relevant ethical considerations, such as potential risk for research participants, informed consent for participation in research and the confidentiality of research participants, it does not provide a specific process for securing ethics approval. This applies both for researchers in Colombia whose institutions do not have an ethics review process and for researchers from outside Colombia. This case study illustrates how resolution 8430 was implemented in relation to our project as researchers affiliated with an institution outside Colombia.

Presentation of the case

This case study is the result of our experience seeking ethics approval for the health systems research project entitled "Measuring health financing-related inequalities in maternal mortality". The aim of this project was to explain how health financing influences maternal health policy implementation and outcomes. The experience from this study, conducted in Colombia in 2016, is presented to illustrate the challenges, pathways and critical reflections for research ethics review in Colombia. In our research project, we contacted 18 health care facilities in six regions of Colombia to request their support in conducting research in their institutions; only two health care facilities requested to see the ethics approval in compliance with the resolution that requires local institutions to conduct ethics review and provide approval.

In order to facilitate the research registration and to engage local institutions in Colombia, a summary of the research proposal was translated into Spanish and submitted to the Department of Epidemiology at the Ministry of Health and Social Protection in order to register the proposed study. We did this based on our familiarity with the Colombian research context, but it should be noted that this recommended step is not outlined in the Ministry's resolution.

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As part of the registration, ethics approval status is requested. The objective of registration is to inform the Ministry of Health and Social Protection that health-related research will be conducted in the country. Nevertheless, the proof of registration and the ethics approval of the study were instrumental when time came to engage with and obtain support from the institution in which the research was to be conducted and the health authority responsible for the population participating in the research. In our study, the registration and confirmation of ethics approval were considered as a proof that all requirements from the Ministry of Health and Social Protection were met, and this facilitated our engagement with local institutions and authorities and the implementation of the study.

We identified some specific implementation gaps related to limited awareness about the ethical approval process and the capacity to carry out these processes. The observed practice across the institutions we contacted may reflect limited awareness and/or capacity of most health care institutions and health authorities at the local level, which rely on researchers to obtain ethics approval from their research institutions, but where only international research organizations, local universities, and big think tanks have the capacity to do so. Securing ethics approval from the IDRC's Advisory Committee on Research Ethics (ACRE) was therefore critical for us to address all ethical considerations related to the qualitative component of our study, to ensure the timely conduct of our data collection.

Moreover, during the course of our research, we also consulted researchers in universities in Colombia to better understand the ethics approval process in the country. We noticed that some major research institutions have research ethics review bodies but there is minimal capacity at local health facility and community levels. For instance, ethics review boards are well established in Fundación Santa Fe de Bogota [2], Secretaria de Salud de Bogota [3], Colciencias [4], INVIMA [5], Profamilia [6] and most of the universities (e.g., Universidad Nacional de Colombia, Universidad de Antioquia, Universidad de Andes, Universidad CES, Universidad del Valle, Universidad de la Sabana, Pontificia Universidad Javeriana) [7-9], each having clear guidelines addressing research ethics in a coherent way.

Key considerations and conclusions

Based on our case study, it is not clear if the observed practice represents an exception or is consistent across local institutions. To ensure consistency and compliance in ethical practices related to health research, there may be a need in Colombia to establish a new or identify an existing authority with the capacity to provide guidance for ethics review and approval of health research in the case of researchers who are not affiliated with institutions that have ethics committees. Resolution 8430 is a good first step, but more is needed to make research ethics a mandatory requirement across the country. Based on our experience, in order to strengthen the process and facilitate ethics review in health and social sciences, we suggest that the Ministry of Health and Social Protection and Colciencias should assess the capacity for and consistency in ethics review, and address the gaps with capable and accessible new and/or existing institutions that are designated to conduct ethics review and approval.

It is worth mentioning that, in the near future, the Ministry of Health and Social Protection is planning to make mandatory the registration of all health-related research projects in its database to facilitate coordination and management of all research activities in the country, as well as to develop a new bioethical framework for the country. This represents an opportunity for the Ministry of Health and Social Protection to outline the key steps required for all health researchers to secure ethics approval, including designating capable and resourced institutions to conduct health research ethics review.

Meanwhile, based on our case study in Colombia, for researchers in the current environment it remains important to register the research project in the Ministry of Health and Social Protection database and secure ethics approval beforehand from a recognized research institution in Colombia or internationally. Engaging with the Ministry of Health and Social Protection is also critical in facilitating the connection with and involvement of local health facilities or health authorities, if needed.

Even though the institutions involved in our study did not raise any need for ethics approval before we started our data collection, the very few that did raise it were only asking for proof of study registration and ethics approval but they did not conduct a review or additional assessment. This raises potential questions for future research. For instance:

1. To what extent, and using what mechanisms, could the Ministry of Health and Social Protection in Colombia help ensure ethical standards are being met, as per resolution 8430, in the course of research?
2. What is the role of local governments in supporting researchers who do not have affiliations with institutions that have established ethics review processes?

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Conflit d'intérêts
Aucun déclaré

Conflicts of Interest
None to declare

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