
EDITORIAL

**THE PARTICIPATION IN HEALTH-RELATED RESEARCH PROJECTS:
COMPENSATED, REIMBURSED OR GRATUITOUS**José Roberto GOLDIM^a

Health research always poses new challenges. Nursing staff constantly deal with such activities, either as researchers or research team members. The interaction between healthcare and research activities creates situations that are not found in other fields. Research always stems from a researcher's idea, which materializes in a project. Once the project is approved by a Research Ethics Committee (REC), it is presented to potential participants. Such possibility is offered to participants in the form of an invitation, which may be accepted or not. This informed consent process is based on sharing essential information for people to understand what will be taking place in the course of research, ensuring their voluntary participation, and recognizing each person's self-determination. On the other hand, healthcare primarily stems from patients' needs as they seek a health professional or institution to see them. The relationship is established in order to offer help to those asking for it. The professional evaluates the different therapeutic alternatives available and their respective outcomes, whether they are risks or benefits, and shares the decision with the patient. As a result of such need, which may be an illness, for instance, the patient has a vulnerability that must also be taken into account during the decision-making process. By combining healthcare and research, clinical research couples possibilities and needs, the role of participant and that of a patient, a researcher's activity and that of a healthcare professional. Such combination creates very special research situations that must be seen as healthcare also by all those involved. Therefore, nursing staff may interact with research participants even though they are not research team members. The new proposal to amend Resolution 196/96, approved in December 2012 by the Brazilian Health Council (CNS), carries a few issues that should have been further discussed and thought through. One such issue is the possibility to compensate research project participants. Item II.10 of the new resolution 196/96, 2012 version, brings the possibility to pay participants in phase I or bioequivalence clinical research. That regulatory change is quite worrisome as it opens up a possibility not previously provided for or discussed. The version approved by the National Conference of Research Ethics Committees (ENCEP) held in 2012 to evaluate this new document did not contain such possibility. That version, which is still available on the National Research Ethics Committee (CONEP) website, is the one meant to be discussed by the CNS. The 1996 version barred any form of compensation for participating in research projects under its item II.10, which characterized what a "research subject" was. The resolution by the Brazilian Health Control Agency (RDC ANVISA 34 of July 3, 2008), specific for bioequivalence studies, also bars compensating participants. The new resolution 196/96, 2012 version, changes the text and proposes that "participation must be gratuitous, except for Phase I or bioequivalence clinical research." Gratuitous participation means not paying to participate, being gratuitous is characterized by the lack of payment. Not compensating means not paying someone for their specific participation in a research project, while holding on to the possibility of paying in the form of reimbursing the expenses deriving from their participation. This new wording may end up carrying multiple implications. The first and most evident one is that participants in these specific types of pharmacological research – phase I and bioequivalence studies – may be compensated for their participation. Most people participating in these studies, except for a few specific fields like Oncology and Psychiatry, are perfectly healthy people who

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do not have an associated healthcare need. They are merely research participants, not patients. Paying a healthy person to use a new drug from which that person will derive no benefits means expanding the individual's vulnerability. It means adding an economic coercion factor that may compromise the voluntary nature of their consent. This new proposal may lead to an array of other consequences. Who will be considered the payer of these participants: the researcher, the sponsor, the proposing institution, a supporting foundation, or an organization hired for such purpose? Is such payment going to be made for services provided? What about studies involving patients, as in the case of some specialties, will they be given this same type of compensation? Another potentially puzzling issue regarding the replacement of no compensation with gratuitous participation is that projects may no longer be able to reimburse research participants for the expenses deriving from their acceptance, such as transportation and meals. A patient participating in a pharmacological study may have the benefit of continuing to receive a given medication, considering such patient will be having their need, which is prior to the research, met. A new vulnerability is not created in that case. Researchers are simply trying to allay a previously existing vulnerability. The change approved to resolution 196/96, 2012 version, may worsen the participants' vulnerability and impact both research and healthcare. This is an extremely important issue to be discussed and thought through by CONEP and RECs across Brazil.

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