

**CONSENTIMIENTO INFORMADO, EN INVESTIGACIÓN, EN
CIRCUNSTANCIAS PARTICULARES**

**Looking for Ways to Avoid Deception in the Pursuit
of Science”.**

**Archives of Internal Medicine 2005;165: 1199-1200
[Editor’s Correspondence -In reply-]**

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Looking for Ways to Avoid Deception in the Pursuit of Science

We read with interest the commentary on “Deception in the Pursuit of Science,” by Wendler and Miller.¹ As members of the Institutional Review Board (IRB) and the Health Care Ethics Committee of the Hospital Privado de Comunidad in Mar del Plata, Argentina, we wish to briefly comment on our experience with a situation we were confronted with 6 years ago as a result of a research protocol submitted to us in March, 1998, by researchers at our institution. The study was a fourth-phase, open, prospective, multicentric study of an antihypertensive medication that consisted of 2 distinct phases. The first phase included a placebo, without informing the patients (simple blinding), whereas the second (with the drug) was characterized as the “titration and maintenance” phase. The proposed information brochure for the patients did not make any mention of the possibility of receiving placebo at any time during the study.

Our committee recognized the need for the initial placebo phase, but it was believed that there was a clear situation of withholding information that might induce confusion, error, or deception, thereby invalidating the exercise of free choice or full autonomy. Based on our federal and provincial legislation and the Helsinki Declaration, we urged the sponsoring pharmaceutical company to modify the information sheet to include the possibility that there may be a placebo phase in some stage of the study. The text of the brochure was thus modified by the company for all the institutions participating in the study, including the phrase: “. . . as a part of the process, at some stage of the study you will receive placebo pills.” This would be an early example of the “authorized deception” consent form proposed by the authors of the article. We

¹ Wendler D, Miller FG. Deception in the pursuit of science. *Arch Intern Med*. 2004;164:597-600.

should note that the original protocol had been accepted by several of the IRBs at other hospitals.

This example shows that deception can be missed easily when reviewing research protocols. The Commentary by Wendler and Miller¹ is indeed a welcome warning for the many IRBs pledged to protect our patients from undue or incomplete information.

Maria I. Hechem, MD

Sergio Gonorazky, MD

Correspondence: Dr Hechem, Chair, Health Care Ethics Committee, Hospital Privado de Comunidad, Córdoba 4545, 7600 Mar del Plata, Argentina (o.dalisca@ozu.es).

