Abstract

Does waiver of written informed consent from the institutional review board affect response rate in a low-risk research study?

Krousel-Wood M, Muntner P, Jannu A, Hyre A, Breault J.

BACKGROUND: Requiring written informed consent for a minimal-risk survey may result in limited participation rates.

METHODS: Data from a cross-sectional survey of 177 older patients (87 blacks and 90 whites) with hypertension enrolled in the managed care Medicare risk product were used to assess participation rates pre- and postwaiver of written informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorization. Prior to the waivers being granted, patients were contacted two times via mail with an introductory letter and an informed consent document. Those who completed and returned the informed consent document were administered the questionnaire. After 6 weeks, a waiver of written informed consent and HIPAA authorization was obtained from the Institutional Review Board. Nonparticipants were reapproached and asked to complete the questionnaire. Participation rates were recorded before and after receiving the waivers.

RESULTS: Participation rates increased from 21.5% in the prewaiver period to 57.4% in the postwaiver period (p < .001). Prewaiver participation differed by demographic subgroup and was higher among whites (26.7%) versus blacks (16.1%; p = .087), men (31.6%) versus women (16.7%; p = .024), and participants > or ≥ 75 years old (28.4%) versus < 75 years old (14.6%; p = .025). In contrast, the postwaiver participation rate did not differ significantly across race, gender, or age subgroupings. Significant increases in participation rates from the pre- to the postwaiver time period were noted within each demographic subgroup (all p < .01).

CONCLUSIONS: We identified a substantial increase in participation rates postwaiver of written informed consent and HIPAA authorization in a minimal-risk survey. The need for written documentation for minimal-risk surveys may negatively impact recruitment of blacks, women, and patients < 75 years old.

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