Monitoring Informed Consent Procedures: An Exploratory Record Review

by Ruth R. Faden, Carol Lewis, and Barbara Rimer

Probably no aspect of the ethics of human research has received closer review by institutional review boards (IRBs) than that of informed consent. In a recent nationwide survey of IRB practices, modification of consent forms was found to be the most frequent substantive change requested of investigators.[1] However, this survey also found that IRBs were largely ineffective in improving the quality of consent procedures. IRB proposals for modification were largely limited to the content of consent forms. These modifications were found not to enhance either the completeness or the readability of the forms.

One mechanism for upgrading the performance of IRBs in relation to informed consent would involve periodic IRB monitoring of the consent process. At present, most IRBs have no mechanism for monitoring the consent procedures they approve, nor do they generally require investigators to conduct internal consent audits. However, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research recommended in its report on IRBs that on a discretionary basis but particularly in high-risk studies IRBs appoint representatives to observe the recruitment of subjects, interview research subjects, and review consent-form records.[2] This recommendation has been incorporated in DHEW's (now DHHS's) recent proposed amended regulations, which grant IRBs authority to monitor the consent process.[3]

The conditions under which IRBs ought to undertake such quality control procedures have not been well specified. It could be argued that procedures involving subject interviews or actual, direct observations of the consent process ought not to be widely implemented. Such procedures could seriously intrude on the research process, possibly compromising the overall effectiveness of IRBs in working with the research community. Moreover, the procedures could pose additional inconveniences, and possibly additional risks, for research subjects. By contrast, review of consent records appears to be a less intrusive and thus, a more acceptable monitoring mechanism. However, it is not clear that anything useful would be gained by reviewing consent forms, given the limited information such forms usually contain.

This paper reports one recent exploratory record review that directly addresses the issue of the utility of examining consent forms. Our record review was a relatively simple effort, with modest objectives but encouraging results.

Methodology

The record review was conducted at the Johns Hopkins Oncology Center, where we had been working together with the medical staff on improving consent and patient education procedures. The consent records of all patients enrolled in collaborative clinical protocols (N=28), as well as every fourth patient involved in independent clinical protocols (N=188). Over a three-year period (March 1976-March 1979) were systematically abstracted. These consent records contained the original consent forms as well as information identifying the person who had solicited consent.

Consent forms were reviewed for completeness. The following information was collected: (1) who solicited consent; (2) where and when consent was obtained; (3) whether the consent form was witnessed, and by whom; and (4) the protocol number. Additional information was requested, for a random half of the sample, through the Oncology Center's computerized data banks. This information included age, race, sex, and disease site.

Simple forms were devised for recording these data. When the signature of a witness could not be identified readily, a staff member of the Oncology Center familiar with faculty, housestaff, and ward personnel was consulted. If a witness was not identified through this process as Center staff, the witness was presumed to be a friend or relative. In many cases, the "relative" status could be identified by the surname.

A time record was kept to assess the staff hours needed to conduct consent-form record reviews. The entire study, including statistical analysis, required about 160 hours. If certain changes had been made in the record-keeping system, and consent forms for different protocols had followed a standardized format, the audit process could have been more efficient. Also, the audit could easily have been conducted by any center staff member with access to patient records.

Results

The subgroup for whom demographic variables were examined could generally be described as white (78%) and between the ages of 40 and 69 (69%). Fifty-seven percent of the sample, was female.

Of the 199 consent forms obtainable and available for review, consent was solicited most often by fellows (63%),[4] next often by faculty (29%), least often by housestaff (7%), with 1% unknown. Prior to this study, there had been some concern that a trend toward delegating the responsibility for obtaining consent to housestaff was developing. This was found not to be true, nor were there any significant differences in terms of who solicited consent by the age, sex, or race of the patient, time period when consent was obtained, or 1ocation where consent was obtained.

Eighty-three percent of the forms contained a line for the signature of an auditor witness and were signed. Examination of witness signatures revealed the only notable problem identified in this consent-form review. While there is disagreement about who may qualify as an auditor witness (e.g., physician or lay person), there is general agreement that the auditor witness should be a person without a vested interest in the study.[5,6,7,8] Nevertheless, in 27% of the "witnessed" forms, the witness signature was that of the physician who had solicited consent. Another 36% of the signatures in the auditor witness line were those of hospital staff, mostly nurses. It is not clear whether these were nurses with a conflict of interest, but in a research-oriented cancer facility, nursing and research roles are commonly blurred. On the other hand, 13% of the auditor witness signatures were obviously those of family members (based on surname), while an additional 24% were unidentified signatures, making it likely that about one-third of the auditor witnesses at minimum were appropriate.

Conclusion

This latter finding has encouraged the Oncology Center to review its policies regarding auditor witnesses. Also under consideration is the possibility of including on the consent form a signature line for the physician soliciting consent. It may be that the physicians who sign on the auditor witness line are reflecting a natural inclination to share in the contractual arrangement implied in the consent process.[9]

Since this limited, inexpensive, and nonintrusive consent-form review provided useful information about consent procedures, we are encouraged about the potential for improvements in the consent process that might be gained by minimal monitoring practices. Consent-form reviews such as we have described could be conducted directly by IRBs. They could also be required routinely of investigators as part of the continuing review process of approved research. It is unlikely that major ethical, empirical, and educational issues concerning informed consent can be resolved through monitoring procedures. However, relatively simple auditing procedures may improve the effectiveness of informed consent as a mechanism for respecting and protecting patients.

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