

# An IRB's Consent Form Survey

by Jessica H. Lewis

Recently, the University of Pittsburgh's Biomedical Institutional Review Board (IRB) undertook a survey to determine certain aspects of the informed consent procedure. We chose one new protocol from each principal investigator who submitted one or more protocols for IRB approval. The time period surveyed was July 1, 1982, to June 30, 1983, which should have uncovered research recently completed or still active at the time of the survey (March 1984).

One hundred thirty one-page questionnaires were sent out; one hundred responses (77%) were received. Of the latter, 23 had had no subjects entered, usually because the project was not funded. Data from the 77 remaining protocols were analyzed. The number of subjects in each protocol varied from one to one thousand. Eliminating from the calculation the one protocol with 1000 subjects, the total number of subjects was 2371, a mean of 31 subjects per protocol.

To obtain these subjects, some 2929 individuals were interviewed. About 20% refused to enter. The most common reasons given were: lack of interest, too far to travel, no desire to take new medication or try a new device, none given. Once entered into a study, 219 (9%) subjects dropped out. These were from less than half the research protocols. The reasons for the dropouts included patients whose disease had improved so much that they no longer desired medication or had worsened so much that the protocol could not be continued. Side effects caused by experimental drugs was a rare reason for stopping a research study.

Information about the research and request to sign the consent form were usually handled by the same individual or small group. This was the principal investigator alone in 40% of the protocols, and the principal investigator and/or a coinvestigator, fellow, resident, or attending physician in an additional 38%. Specially trained nurses, social workers or laboratory technicians performed these actions in the remaining 22%. Most frequently (57%) the giving of information to the subjects and reading and requesting a signature on the consent form were accomplished at the same session. In another 16% about 24 hours elapsed between telling the subject about the research and requesting the signature. In the remaining (26%) there were more than 24 hours and often as long as two weeks between the informing the subject and requesting the signature.

At our institution each subject is asked to sign three copies of the same consent form—one for the subject, one for the chart (if the subject is a hospital patient), and one for the research file. Our next question was aimed to find out how frequently the subject was asked to sign other consent forms at the same time. The answers were: Never-84%, Occasionally-8%, Always-5%, Don't know-3%. When the answer was "Always," we questioned the types of the other forms signed and found that these were standard hospital forms.

The last question dealt with the principal investigator's conception of the subject's understanding of the consent form. All the investigators felt that the subjects, unless children or mentally incompetent, did understand the protocol, its risks, and their rights.

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