The reader might want to compare the content of the two consent forms with the content that is suggested by FDA's Guidance for Industry E6. For example, it can be seen that both consent forms state that enrollment in the clinical trial is voluntary. Both consent forms state that enrollees are randomly assigned to the different treatments. Guidance for Industry E6 suggests that the consent form reveals the number of subjects enrolled in the trial. Only the second of the above two consent forms of Coyne et al. (45) contains this particular number.

Coyne et al. (46) did not find any significant differences in comprehension of the two consent forms. But this lack of difference may have been due to the relatively high education level of the subjects. Higher education has been correlated with better understanding of consent forms (47).

Coyne et al. (48) did observe a general issue with both of their consent forms. In obtaining feedback from the patients, about half of the patients did not understand the fact that the clinical trial was not likely to result in a cure for their cancer. About one third of the patients did not understand that the goal of the trial was to find a cure for lung cancer.

## d. Analysis of consent forms by the medical community

Most consent forms adequately disclose the purpose of trial, and refrain from creating expectations of benefit.

In an analysis of a large number of consent forms (272 forms) used in oncology clinical trials, Horng et al. (49) found that most consent forms adequately reveal that the purpose of the trial was to test for safety, that subjects had the right to withdraw from the trial, and that the trial involved risk of severe or permanent harm.

These authors found that most forms were adequate or appropriate in acknowledging uncertainty of benefit, in refraining from promising a cure, and in refraining from downplaying risks. Another good point is that only one out of the 272 forms mentioned that the subject should "expect" any benefit. Horng et al. (50) also found certain deficiencies to be common in consent forms. The deficiencies were that the forms tended to use the term "treatment." Treatment is not a good term since it implies hope for recovery. Better terms are "investigational treatment," "experimental treatment," and "research drug."

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[50] Horng S, Emanuel EJ, Wilfond B, et al. Descriptions of benefits and risks in consent forms for phase 1 oncology trials. *New Engl J Med*. 2002;347:2134–2140.