

Featherstone and Donovan (76) characterized the patient's confusion about randomization as, "[m]any of these men were struggling to come to terms with different (sometimes competing) views about randomisation."

Flory and Emanuel (77) found that comprehension may or may not be improved by video presentations and that, in contrast, comprehension can be reliably increased by having a study team member or a neutral educator spend more time talking one-on-one to study participants.

XI. DISTINCTION BETWEEN STOPPING TREATMENT AND WITHDRAWING FROM THE STUDY

Fleming (78) provides a fine point regarding dropping out from a study and withdrawal consent form. There are only two valid reasons why a subject can leave a clinical trial; first, withdrawal of consent and second, achieving of all required efficacy and safety endpoints.

According to Fleming (79) it is an unfortunate common practice for Clinical Study Protocols to provide a list of reasons that the subject will be "off study," such as inability to tolerate the intervention, toxicity, physician choice, or need for other therapies. These may be valid reasons for non-adherence (for being off-study treatment), but not for being dropped from the study.

Thus, the Clinical Study Protocol should separately list the two reasons a patient could go "off study" and the many reasons the patient could discontinue the treatment, with an indication that efforts should be made to ensure patients who stop the study treatment be consistently followed for outcomes unless they have withdrawn consent.

XII. CONCLUDING REMARKS

Consent forms are required for clinical trials. The administrative law provides guidelines for writing consent forms. Consent forms may be written by an investigator, medical writer, or attorney, and they must be approved by an Institutional Review Board (IRB) or by an ethics committee.

The primary goal of consent forms, in the context of clinical trials, is to ensure that the potential subject makes an autonomous decision regarding whether to enroll in the trial. Other goals are to promote communication between the study subject and health care providers, promote patient enrollment, reduce drop-out rate, and reduce liability.

⁷⁶ Featherstone K, Donovan JL. Random allocation or allocation at random? Patients' perspectives of participation in a randomised controlled trial. *Brit Med J*. 1998;317:1177-1180.

⁷⁷ Flory J, Emanuel E. Interventions to improve research participants' understanding in informed consent for research: a systematic review. *J Am Med Assoc*. 2004;292:1593-1601.

⁷⁸ Fleming TR. Addressing missing data in clinical trials. *Ann Intern Med*. 2011;154:113-117.

⁷⁹ Fleming TR. Addressing missing data in clinical trials. *Ann Intern Med*. 2011;154:113-117.