to, or beyond, an intolerable level. The ethical conflict that arises from the following evidence demonstrates that motivation of subjects enrolling in Phase I oncology trials takes a variety of forms, such as "hope for improvement of their condition, by pressure exerted by relatives and friends, or simply because they felt they had no choice" (61).

X. DECISION AIDS

An instrument called a "decision aid" is sometimes used in conjunction with consent forms. Decision aids can be used, in conjunction with a consent form, in the context of conventional medical care, as well as in clinical trials. Decision aids are not standard with the pharmaceutical industry. Using a decision aid is a matter of the investigator's digression and of the available budget (62). The decision aid, as well as the consent form, needs to be approved by the Institutional Review Board (IRB), or other ethics committee.

Decision aids take the form of literature, audiotapes, and videotapes. A decision aid can even take the form of verbal counseling (63). According to Sawka et al. (64) decision aids improve general patient knowledge, result in more realistic expectations by patients, increase active patient participation in decision making, and reduce indecisiveness.

A decision aid can take the form of a card to help understand specific parts of the clinical trial. For instance, a decision aid may outline the "Schedule of Events" and help the subject to understand the number of visits to the clinic, and what each visit entails (65). One goal is to enable the potential subject to determine if he or she can afford the time or want to undergo all the necessary procedures.

Elwyn et al. (66) warn that decision aids should be unbiased, and that the motivation to draft and use a decision aid should arise from motivation is to rectify variations in practice due to poor comprehension. In particular, these authors warn that use of "patient stories" can have undue influence on the patient. Patient stories can introduce bias since decisions by the patient are strongly influenced by identification with patients featured, for example, in video presentations.

Waljee et al. (67) find that, with a decision aid, improved "health literacy is correlated with improved patient outcomes, and patients with inadequate knowledge

[61] Daugherty CK. Impact of therapeutic research on informed consent and the ethics of clinical trials: a medical oncology perspective. *J Clin Oncol*. 1999;17:1601–1617.
[62] Mosher KA. E-mail of October 21, 2010.
[63] Brehaut JC. E-mail of October 22, 2010.
[64] Sawka AM, Straus S, Brierley JD, et al. Decision aid on radioactive iodine treatment for early stage papillary thyroid cancer – a randomized controlled trial. *Trials*. 2010;11:81.
[65] Mosher K. E-mail of October 21, 2010.
[66] Elwyn G, O'Connor A, Stacey D, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *Brit Med J*. 2006;333:417.
[67] Waljee JF, Rogers MA, Alderman AK. Decision aids and breast cancer: do they influence choice for surgery and knowledge of treatment options? *J Clin Oncol*. 2007;25:1067–1073.