Table 29.3 Comparison of poor language versus good language for consent forms

	Poor	Good
People are not tumors.	You have progressed. You have failed the earlier chemotherapy.	The cancer has grown. The chemotherapy you had received is no longer helping you.
Avoid language that is like an enticing advertisement.	You have been invited… If you are eligible…	This trial might be suitable for you. If the trial is suitable for you…
Address the reader as "you."	Study participants will… Giving study medication intravenously and collecting blood samples might involve temporary discomfort or bruising.	If you choose… If you choose to join this trial, you will have the drugs through a needle in your arm. The doctor will also use a needle to take blood for testing. You might have a bit of pain or bruising from the needle.

Tait (58) finds that intractable pain can impair the ability of a patient to make rational decisions, including decisions to sign a consent form. Patients with severe pain, when confronted with complex information, may be impaired in the ability to make rational decisions. Researchers may fail to recognize such deficits, where this failure may expose the patient to a greater risk. Similarly, Hoffman (59) reports that people who are gravely ill are impaired in their ability to make decisions.

IX. ETHICAL ISSUES SPECIFIC TO PHASE I CLINICAL TRIALS IN ONCOLOGY

In an excellent review, Daugherty (60) highlighted an ethical conundrum that is somewhat specific to Phase I clinical trials, in particular to Phase I clinical trials in oncology. In this type of trial, the chance of therapeutic benefit is usually very low, that is, under 5%. The low therapeutic benefit arises from the fact that the most optimal dose is yet unknown, and from the fact that the goal of Phase I trials is to assess safety (not to assess efficacy or to cure the cancer). Another problem is that Phase I trials may have a study design of the "dose-escalating" or "dose-finding" format, that is, where dosing is increased

[58] Tait R.C. Vulnerability in biomedical research: vulnerability in clinical research with patients in pain: a risk analysis. *J Law, Medicine & Ethics*. 2009;37:59.
[59] Hoffman S. Regulating clinical research: informed consent. *Capital Univ Law Rev*. 2002;31:71–91.
[60] 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.