

Table 29.1 Comparison of terms used in the consent form, with corresponding medical terms used by physicians

Layperson's term in the consent form	Corresponding medical term
Change in sense of taste	Hypogeusia or hypergeusia
Loss of appetite	Anorexia
Side effects	Adverse drug reactions
Hair loss	Alopecia
High blood pressure	Hypertension
Numbness in the hands and feet	Paresthesia

a. Example of a contemporary consent form (reproduced in full) (39,40)

Patient Consent Form (E1594)

Research Study

I, _____, willingly agree to participate in this study which has been explained to me by Dr. _____. This research study is being conducted by the Eastern Cooperative Oncology Group and by _____ (Institution).

Purpose of the Study

It has been explained to you that you have advanced non-small cell lung cancer. Your physician has decided that chemotherapy is the best option available. You have been invited to participate in this research study. This study involves treatment with four drug regimens, Arm A (taxol + cisplatin), Arm B (gemcitabine + cisplatin), Arm C (taxotere + cisplatin), and Arm D (carboplatinol + taxol). The drugs gemcitabine and taxotere are considered experimental. Each of these regimens has been used and demonstrated activity (responses) in non-small cell lung cancer. The purpose of this study is to slow or stop the growth of your disease, define the side effects of each treatment arm, and to see if one regimen is better at controlling lung cancer than the others.

Description of Procedures

This study involves treatment with four drug regimens, Arm A (taxol + cisplatin), Arm B (gemcitabine + cisplatin), Arm C (taxotere + cisplatin), and Arm D (carboplatinol + taxol). It is not clear at the present time which of the therapies is better. For this reason, the therapy which is to be offered to you will be based upon chance, using a method of selection called randomization. Randomization means that your physician will call a statistical office which will assign one of the treatments to you, and the chances of your receiving any one of the therapies are approximately equal.

If you are assigned to Arm A, you will receive taxol and cisplatin. Taxol is given by vein over 24 hours on day one. On day 2 after the taxol is given, you will receive

³⁹ Cella D. Consent form was developed by Peter Raich for an ECOG study. E-mail of November 9, 2009.

⁴⁰ Coyne CA, Xu R, Raich P, et al. Randomized, controlled trial of an easy-to-read informed consent statement for clinical trial participation: a study of the Eastern Cooperative Oncology Group. *J Clin Oncol*. 2003;21:836-842.