

treatments. This study uses two “investigational” drugs, gemcitabine and taxotere. These drugs are “investigational” because they have not been fully tested against other drugs.

Who will be part of this study?

About 1200 patients from many cancer treatment centers will join the study over a period of three years. All patients will have advanced non-small cell lung cancer.

Who is sponsoring the study?

This study is sponsored by the National Cancer Institute (NCI), the Eastern Cooperative Oncology Group (ECOG), and the North Central Cancer Treatment Group (NCCTG). ECOG and NCCTG are groups of cancer specialists from across the country who do studies to find better ways to treat cancer. This study is supported partly by funds from NCI.

Description of Procedures.

What will happen in the study?

If you join the study, you will be treated with two cancer-fighting drugs. Four different combinations of two (2) drugs each will be used in this study. Each of these drug combinations have been used before and have shown some anti-cancer activity. Which two drugs you will get depends on which of four treatment groups you are in. We do not know which, if any, of these treatments is best.

What are the differences between the four treatment groups?

The differences between the four treatment groups are the drugs used in each group and how often they are given. Each patient will get two cancer-fighting drugs. The drugs used in each treatment group are listed in the table below.

Which treatment group will I be in?

If you decide to be part of the study, you will be put into one of the four treatment groups. A computer will pick which group you will be in. This is done by chance, like flipping a coin. You have the same chance of being placed in any of the four treatment groups. Your doctor will tell you which group the computer puts you in. Neither you nor your doctor can pick which treatment group you will be in.

Do these drugs have any side effects or other risks?

Yes. Drugs that are strong enough to kill cancer cells often cause problems in other parts of the body. These added problems are called side effects. We have listed side effects and risks that can be seen in all treatment groups in the study. We have also listed risks and possible side effects for the

drugs that are specific to each of the treatment groups. You may have a few or all of the side effects listed and they may be mild or severe. You also could have other unexpected side effects that are not listed. Side effects differ from patient to patient. Be sure to talk with your doctor about any side effects you have while you are in the study.

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What does signing the consent form mean?

Signing the consent form means that you choose to be part of this cancer treatment study. It means that you have read the consent form, your questions have been answered and that you understand what will happen in the study. A copy of this informed consent form will be given to you after you sign it. If you decide not to take part in the study, just give the unsigned form back to the doctor or nurse.

_____ (Patient’s signature)

_____ (Date)

_____ (Witness signature)

_____ (Date)

_____ (Physician’s signature)

_____ (Date)

c. Comparison of Standard Consent Form With the More Elementary Consent Form

The two consent forms reproduced above were used as part of a clinical trial of lung cancer patients, as reported by Coyne et al. (47). This trial is distinguished from most other clinical trials, in that the investigators administered two different consent forms to different enrollees.

One of the consent forms was standard. The other consent form contained the same information, but it disclosed the information in a step-by-step manner, similar to instructions that come with toys or gadgets to be assembled by children.

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

⁴⁷Coyne 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;21:836–42.