

KANSAS CITY CLINICAL ONCOLOGY PROGRAM

CYTOGENETIC STUDIES IN ACUTE LEUKEMIA

You are being asked to participate in a study to determine if patients' responses to treatment are related to particular leukemia cell types. You may also be asked to participate if you have been diagnosed with multiple myeloma. Data obtained at several institutions indicate that acute leukemia patients may be divided into groups based on certain cytogenetic (chromosome) characteristics of the leukemia cells. Investigators are researching similar issues in patients diagnosed with multiple myeloma. Your participation in this study would involve obtaining an additional teaspoon of liquid bone marrow and/or about one tablespoon of blood prior to your treatment, at the time you have achieved a complete remission (that is, when there is no detectable level of leukemia cells), and at the time of relapse (that is, if your leukemia should return). The blood and bone marrow samples we collect would normally be obtained at these times during your treatment and/or routine follow-up. Bone marrow and blood samples for this study will be drawn only when these samples are being obtained for other purposes. Therefore, you will not have to undergo any additional procedure to participate in this study. These samples would be sent to a special laboratory for careful study.

Benefits:

The potential benefits of participating in this study are unknown at this time. As the study progresses, the information obtained may be of value in selecting therapy.

Risks:

Your participation in this study does not involve any additional risk, as blood and bone marrow samples must normally be obtained at the time of diagnosis, at the time of complete remission, and at the time of relapse. When these samples are drawn, additional tubes of blood and bone marrow will be collected for this study. You are being asked to allow the collection of the additional samples. This study will not alter the initial treatment of your leukemia or multiple myeloma.

Patient Protection:

You may contact either the investigator in charge or a member of the human protection committee of _____ Hospital whose names and phone numbers are listed at the end of this form, if at any point during the duration of this treatment you feel that you have been:

a. inadequately informed of the risks, benefits, or alternative treatments,

or

b. encouraged to continue in this study beyond your wish to do so.

Participation is voluntary. You are free to withdraw your consent to participate in this study at any time without prejudice to your subsequent care and continued treatment.

The results of this study may be published but individual patients will not be identified in these publications. However, as required by the FDA and the NCI, medical records may be inspected.

A record of your progress will be kept in a confidential form at _____ Hospital and also in a computer file at the statistical headquarters of the Cancer and Leukemia Group B.

Release

By signing this form you authorize KCCOP to access and obtain information that is required for the study. This may include your medical records, labs, radiologic films, and reports and pathology specimens. This authorization to

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disclose your medical records shall not expire, even upon death, unless specifically revoked in writing by you.

By signing below, you indicate that you have read this form, received acceptable answers to any questions, and willingly consent to participate. You will receive a copy of this form.

(Patient's Signature) (Date)

(Signature of Person Obtaining Consent) (Date)

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