Consent Form Approval: ME-PH2b

Fudan University Medical Center and the University of Colorado Health Sciences Center
Joint Laboratory for Clinical Occupational Studies

Protocol Title: Molecular Epidemiology

Principal Investigators: Professor. Fu Hua; Professor. Richard D. Irons

SUBJECT CONSENT
Patient Urine, Blood and Bone Marrow Donation

Date: February 19, 2004

Description: You have already participated in our research study by allowing us to use your blood in our medical research. Now, you are being asked to further participate in this research project to better understand the health effects of benzene exposure. In doing so you may make a valuable contribution to occupational health and our understanding of the health effects of benzene. Medical research information will be collected to enhance basic medical knowledge, to improve the diagnosis, treatment, and prevention of benzene poisoning. If you agree to participate in this study, you will be asked to supply two small samples of urine (10 ml each); Once at the beginning of your work shift, and again, at the end of the shift. You will also be asked to donate bone marrow and an additional blood sample for these studies. Two hours before the blood donation you will be asked to take a pill containing chorzoxazone. This will allow us to measure your metabolism. Your urine and bone marrow cells will be tested in the laboratory. The procedures performed on your urine will involve testing for the urinary excretion of a benzene-specific break-down product. The procedures performed on your blood and bone marrow will involve the making of slides and the conduct of tests to measure the effects of benzene on your blood cells.

Procedures Involved: If you agree to participate in this study you will be asked to donate urine (20 ml.) and bone marrow (up to 10 ml.). The bone marrow will be taken from your hip. In addition, you will be asked to take a pill containing chorzoxazone. Two hours later blood (18 ml) will be taken from your arm.

Discomforts and Risks: 18 ml of blood will be removed by putting a needle into your vein. This is the standard method used to obtain blood for tests. You will feel pain when the needle goes into the vein. A bruise may form at the site. A total of 18 ml will be taken for research purposes over the course of this study. Bone marrow will be taken by first giving you a numbing medicine and then putting a special needle into the center of the (hip) bone. The bone marrow will be drawn into a syringe. It hurts a lot when the bone marrow is removed but the pain lasts only about 15 - 30 seconds. However, the area may be sore for a day or two. An allergic reaction

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to the numbing medicine is rare (1 in 10,000 cases). - A large amount of bleeding or an infection are possible but almost never happen. There are no known risks for taking one pill of chlorzoxazone.

This study may involve unforeseeable risks.

Benefits: The tests we will perform are in the forefront of medical technology, are more sophisticated than those you routinely receive in the hospital. Information obtained from these tests will be provided to your physician to help in evaluating the status of your health and will also be used for research. The results of tests performed on your urine, bone marrow and blood cells can be used by your physician for the diagnosis and monitoring of any conditions you may have developed as a consequence of benzene exposure. The testing results will be part of your medical records for better health care management. They will also be used to help us better understand the nature and cause of benzene toxicity.

Collaborating Institutions: You are being asked to participate in a collaborative study being conducted by Fudan University Medical Center and the University of Colorado Health Sciences Center, Denver, USA.

Cost to Subject: If you agree to participate in this study, there is no cost to you for these procedures. In addition, you will be contributing to research so you will receive 1500 RMB as a reward for your participation in this study. Your participation in this study requires that you come to the hospital in Shanghai for a few hours. Therefore, we will also provide you with free transportation to and from the hospital, along with hotel lodging and expenses for one day.

Study Withdrawal: You may choose not to enter or withdraw from the study at any time.

Invitation for Questions: The researchers carrying out this study are professor Richard Irons and professor Hua Fu. You may ask any questions you have now. If you have questions later, you may call Liu Jiamin at 86-21-54237202. You will be given a copy of this form to keep.

If you have questions regarding your rights as a research subject, please call professor Ye Zhurong of the Medical Ethic Review Committee Fudan University at 86-21-65643684.

Confidentiality: Your physician/investigator, Fudan University Medical Center, the University of Colorado Health Sciences Center, COMIRB, the Medical Ethic Review Committee of Fudan University and the Study Sponsors will treat your identity with professional standards of confidentiality. However, health care professionals conducting this study have the right to inspect your medical records relating to this research for the purpose of verifying data. Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. However, this information will not be shared with your employer without your permission. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

Injury and Compensation: If you are hurt by this research, we will provide medical care. The cost of medical care will be provided by the study's sponsor.

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Authorization: I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be in this study: I know I can stop being in the study and I will still get the usual medical care. I will get a copy of this consent form. (initial all the previous pages of the consent form). I give my permission for my bone marrow, blood and blood cells to be stored for future use by study investigators in other research projects. I also give permission for the data and results of these studies to be used in other research projects.

Signature: _____/_____ _____
subject print name date

Consent form explained by: _____/_____ _____
signature print name date

Investigator: _____ _____
date

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