AsiaLymph Study: Informed Consent Form for Cases

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Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of study participants are protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the study at any time. Refusal to participate will not affect your benefits in any way. The information collected in this study will be kept private to the extent provided by law. Names and other identifiers will not appear in any report of the study. Information provided will be combined for all study participants and reported as summaries. You are being contacted in-person to complete this instrument so that we can conduct our research study to compare the effect that different types of occupational and environmental exposures have on health.

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project

INTRODUCTION

You are being asked to participate in a research study that is being conducted by the [insert local hospital name] and the United States National Institutes of Health. Your participation in this study is completely voluntary. You may refuse to participate and/or withdraw your consent and discontinue participation at any time without any penalty or loss of benefits to which you would otherwise be entitled. No matter what you decide to do, it will not affect your medical care. The purpose of this study is to compare the effect that different types of occupational and environmental exposures have on health. To understand the health effects of these exposures on health, it is important to collect information on the types of jobs you have had over the course of your life and where you have lived, as well as additional factors that may influence your health. These include lifestyle factors (e.g., your diet) and inherited differences in genes that you were born with. Biologic samples including blood and buccal cells (e.g., mouth cells present in saliva) will be collected to measure your exposure to several types of exposures that may affect health. Also, we will carry out analyses to determine the genetic contribution to health using your blood or buccal cell sample, as well as to determine if variation in your genes is associated with increased or decreased risk of health effects from occupational and environmental exposures and lifestyle factors. Approximately 10,400 hospitalized men and women from Hong Kong, Chengdu and Tianjin, China, and Taiwan will participate in this study. If you agree to participate, you will be asked to complete the following study activities.

PROCEDURES

If you agree to participate in the study, you will be asked to participate in an interview. The interview will take approximately 90 minutes to complete. In addition to the interview, your permission will be requested to collect blood and buccal cell samples. The minimum requirement for enrollment in this study is to provide consent to participate in the interview or to provide either a blood or buccal cell sample.

Collection of Blood, Buccal Cell, and Tissue Specimens

You will be asked to donate a 30 ml blood sample (about 6 teaspoons) and one buccal cell sample collected by swishing water in your mouth for about a minute. It will take about 15 minutes to collect these biologic samples. The blood collection will be carried out by a person who is trained and experienced in drawing blood, and will be collected at the same time as your routine clinical blood draw if possible to minimize any discomfort or adverse effects. Also, if you give permission, a tissue sample that has been obtained from you as part of your regular care at the hospital also will be collected.

The blood, buccal cell, and tissue samples will be kept in storage indefinitely so that we may use them for this study and for other types of health research of importance to people living in Hong Kong, Chengdu and Tianjin, China, and Taiwan. This means that your samples may be used both now and in the future for other types of health research, including genetic studies.

Medical Records

If you give permission, medical records from the hospitals and clinics where you were treated will be scanned and uploaded into our confidential study management system. The medical records will be used to verify and provide more information about your health. The scanned medical records may be used to obtain information related to your current diagnosis. Further, if you give permission, your treatment data and health status will also be collected from your medical records in the future so that we can study how occupational and environmental exposures, lifestyle, and genetic variation contribute to your future health.

BENEFITS

You will not benefit directly from participating in this study. However, your participation will benefit the general population by increasing knowledge related to the health effects of environmental and occupational exposures.

RISKS

There are no known risks involved with this study. The collection of blood may cause a small amount of pain and/or temporary bruising at the site of collection.

COMPENSATION

You will be paid $22.50 for completing the interview, and for donating buccal cell, tissue, and 30 ml of blood.

NOTIFICATION

Because the importance, meaning, and clinical significance of the research is not known at this time, the results from the research tests using your blood, buccal cell, and tissue samples will not be given to you, your doctor, or any irrelevant persons. However, your doctor will be informed if clinically relevant information is obtained from study review of your tissue sample.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW

The choice to participate in the questionnaire interview, and the collection of blood, buccal cell, and tissue samples, is up to you. You may choose to participate in some parts of the study, but refuse to participate in others. You may refuse to answer any specific questions in the questionnaire. You may refuse to participate and/or withdraw your consent and discontinue participation at any time without any penalty or loss of benefits to which you would otherwise be

entitled. No matter what you decide to do, it will not affect your medical care. You may also change your mind at any time about the use of your blood, buccal cell, and tissue samples, as well as any data collected from the interview or from medical records. If you decide later that your blood, buccal cell, tissue samples, or any collected data cannot be kept for research, you should contact [insert local hospital contact name], the leader of the study in [insert local hospital name], at the telephone number or address provided in the "Contact and Questions" section below. The researchers will then destroy any of your blood, buccal cell, and tissue samples that remain in storage. Otherwise, the blood, buccal cell, and tissue samples may be kept until they are used up. Your blood, buccal cell, and tissue samples will only be used for health research and will not be used for any commercial activities. The authority to collect this information is under 42 USC 285.

CONFIDENTIALITY

All information that is obtained in connection with this study and that could identify you will remain confidential and used only for scientific purposes, in accordance with applicable [insert country] and United States laws. Only grouped data will be used in analysis, and no individuals will be able to be identified in the results. None of your biological samples will be labeled with your name or other personally identifiable information at any point. Biological samples will be labeled with only a study ID number. Any records that include your name will be kept in locked file cabinets at [insert local hospital name]. Access to these records will be restricted to the designated staff in [insert local hospital name].

CONTACTS AND QUESTIONS

Please feel free to ask questions about the study. If our study staff cannot answer your questions, you may contact [insert local hospital contact name and contact information]. Or, you may contact [insert respective study center contact name and contact information].

Now please read the following statements and circle the answer that is right for you. You will be asked to provide consent to each study activity separately.

(Yes = Agree to the statement; No = Do not agree to the statement).

1. **I have read the above information about this research study or it has been explained to me and I have had the opportunity to ask questions. I understand what will be involved to participate in the study. I voluntarily agree to participate in this study.**
   Yes **No**
2. **I agree to answer questions for the questionnaire part of the study.**
   Yes **No**
3. **I agree to make my current medical records available for the study.**
   Yes **No**
4. **I agree to make my future medical records available for the study.**
   Yes **No**
5. **I agree that my buccal cell sample may be collected for use in the study.**
   Yes **No**
6. **I agree that my tissue samples may be used in the study.**
   Yes **No**
7. **I agree to provide a 30 ml blood sample (about 6 teaspoons) for use in the study.**
   Yes **No**

Please sign here after you respond to the above statements.

_____ _____

Signature of Study Subject **Date**

_____ _____

Signature of Person Obtaining Consent **Date**

ID number _____