CONSENT FORM FOR CASES

INTRODUCTION
You are requested to participate in a study to investigate environmental factors and their effects on the health of people. The study is being conducted by the Name of Local Collaborating Center and University of Utah. We obtained your name from your physician, who granted us approval to approach you about this study. Your participation in this study is voluntary. You may refuse to participate or withdraw from the study at any time without this affecting in any way the medical treatment that you are receiving. Please read this consent form thoroughly and ask the hospital coordinator any questions you may have about the study before signing.

EXPLANATION OF PROCEDURES
If you agree to participate in this study, you will be asked to participate in an interview survey and provide blood and pathology tissue samples. In addition, we will ask your permission to collect relevant information from your hospital records. No penalties will result if you decide not to respond, either to the information collection as a whole or to any particular question. You may participate in the interview part of the study and yet decline to have biologic samples collected and stored for research purposes.

Questionnaire:
An interviewer will come to administer the questionnaire while you are in the hospital. The interview takes approximately one hour and consists of questions related to lifestyle, environment and health.

Collection of Blood and Tissue Samples:
You will be asked to donate blood samples while you are in the hospital. A trained nurse will take about 10 ml of blood from your arm in a routine manner. If available, we will request the Pathology Department in the hospital to provide a small sample of tissue.

Biological Sample Analysis
Your blood and pathology tissue samples will be shipped to laboratories for analysis. These samples will be tested for genetic and cellular characteristics that may be related to developing disease. Your samples will be stored for up to 30 years to be used for biochemical and genetic investigations in this study. By agreeing to participate in the biological sampling component of this study, you are granting consent now for future uses of these samples that relate to the purpose of this study. None of these samples will be tested for illegal drugs. Any specific future use of the samples or any follow-up study will be approved by an ethical committee.

NOTIFICATION, COST AND COMPENSATION
Biological samples obtained will be used for research purposes only. Any material not immediately used will continue to be stored to be used in the future to help scientists learn more about environment, genetic changes and health. The research results are not suitable for use as clinical tests for your medical care. Therefore, the results of these studies will not be available to you. There will be no cost to you for participating in this study, other than your time, and there is no compensation or payment for completing the questionnaire and providing biological samples.

POTENTIAL DISCOMFORT AND RISK
During the blood collection, you may feel a little pain or develop a bruise on your arm at the puncture site. It is possible, but not likely, that there may be swelling or bleeding at the puncture site. There may be also uneasiness associated with needles. It is unlikely event of physical injury from drawing a blood sample. If a physical injury occurs, you will be provided with immediate medical treatment by the hospital personnel.
POTENTIAL BENEFITS
This is a research study and there will be no direct benefits to you other than the satisfaction of participating in this research for the possible benefit of future generations. Your participation is very important to the success of this scientific research.

ASSURANCE OF CONFIDENTIALITY
The information concerning your participation in the study will be kept confidential and used only for scientific purposes, in accordance with applicable law of Name of Country. No one except members of the research team will have access to your answers and test results. Your employer will not be given any test results or information you provide us. Your biological samples will not be labelled with your name. Your name will not be used in any report or released in any way.

RIGHT TO WITHDRAW
Your participation in this medical research is voluntary and you may refuse to participate and/or withdraw your consent and discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. If you initially decide to give permission to have biologic samples stored for future research purposes, but later change your mind by written notification of (Name and address of local Principal Investigator), whatever remains of your biologic samples will then be destroyed. Your decision on this matter will not affect your medical care or employment.

CERTIFICATION
I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. By agreeing to participate in this study, I do not waive any rights that I may have regarding access to and disclosure of my records. I hereby consent to take part in the study components marked “yes” and refuse to consent to participate in the components marked “no”. A copy of this consent form has been given to me.

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Signature of Participant        Date                         Signature of Witness       Date
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Print Name                        Print Name

We appreciate your cooperation in this important research project. If you have further questions about this study, you may call Dr. (Name of Local Principal Investigator), at (Local Phone Number) or you may write to him/her at the following address:

Name of Local Collaborating Center and Address
CONSENT FORM FOR CONTROLS

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Questionnaire:
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Collection of Blood and Tissue Samples:
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