

Attachment 5: Consent Forms for Patients and Next-of-Kin

Consent form for follow-up Study of Cases in the Central and Eastern European RCC study

INTRODUCTION

You are being asked to participate in a study to follow-up cases that were previously enrolled in the European Kidney Cancer Case-Control Study. The purpose of this study is to investigate lifestyle factors, medical conditions, occupation and diet, and their effects on the outcome of kidney cancer patients in Europe. The study is being conducted by the Name of Local Collaborating Center and the International Agency for Research on Cancer located in Lyon, France EU and the National Cancer Institute, National Institutes of Health in Bethesda, MD, USA. Your participation in this study is voluntary. You may refuse to participate or withdraw in this study at any time without this affecting in any way, the treatment that you receive. Please read this consent form thoroughly, and ask the interviewer any questions that you may have about the study before signing this form.

EXPLANATION OF PROCEDURES INVOLVED IN THE STUDY

If you agree to participate in this study, you will be asked to participate in an interview survey that will not take more than 60 minutes. In addition, we will ask your permission to collect relevant information from your hospital and cancer registry records. No penalties will result if you decide not to respond, either to the information collection as a whole, or to any particular question.

QUESTIONNAIRE

An interviewer will come to administer the questionnaire while you are in the hospital or at home. The interview takes approximately 40 minutes and consists of questions related to your lifestyle, environment, and health. We will study your answers, your medical records, and the genetic and other information we found out from the earlier study. This will help us learn more about kidney cancer outcomes.

NOTIFICATION, COST, AND COMPENSATION

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 the study, other than your time, and there is no compensation or payment for completing the questionnaire.

POTENTIAL DISCOMFORT AND RISK

During the interviews, you may feel some discomfort when asked some questions. If you feel this way, you may refuse to answer them.

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 (Czech Republic, Poland, Romania, or Russia) and the United States state and federal law. 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 questionnaire will not be labeled with your name. Your name will not be used in any report or released in any way. Any information that links your study identification number with your name will be kept under lock and key at all times.

RIGHTS AS A PARTICIPANT

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. Your decision on this matter will not affect your medical care or employment. While the information collected as part of this research study continues to be linked to personally identifying information, it will be protected from access by anyone except those directly responsible for patient recruitment and contact. After this study is completed, all personal identifiers will be removed in place of study identifiers. Any documents containing linkage between identifiers with the study identifying codes will be kept under lock and key at the International Agency for Research on Cancer, and destroyed as soon as the study has been completed.

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.

YES	NO	Study Component
<input type="checkbox"/>	<input type="checkbox"/>	Interview
<input type="checkbox"/>	<input type="checkbox"/>	Access to hospital records

Signature of Participant Date Signature of Witness Date

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 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 follow-up Study of Next-of-Kin: Follow-up Study the Central and Eastern European RCC study

INTRODUCTION

You are being asked to participate in a study to follow-up cases that were previously enrolled in the European Kidney Cancer Case-Control Study. The purpose of this study is to investigate lifestyle factors, medical conditions, occupation and diet, and their effects on the outcome of kidney cancer patients in Europe. The study is being conducted by the Name of Local Collaborating Center and the International Agency for Research on Cancer located in Lyon, France EU and the National Cancer Institute, National Institutes of Health in Bethesda, MD, USA. His/her participation in this study was voluntary and you are being asked to participate in this follow-up study to, answer questions about your family member, as they are no longer able to do so. You may refuse to participate or withdraw in this study at any time. Please read this consent form thoroughly, and ask the interviewer any questions that you may have about the study before deciding to sign this consent form.

EXPLANATION OF PROCEDURES INVOLVED IN THE STUDY

If you agree to participate in this study, you will be asked to participate in an interview survey about your family member that will not take more than 40 minutes. In addition, we will ask your permission to collect relevant information from your family member's hospital and cancer registry records. No penalties will result if you decide not to respond, either to the information collection as a whole, or to any particular question.

QUESTIONNAIRE

An interviewer will come to administer the questionnaire while you are in the hospital or at home. The interview takes approximately one hour and consists of questions related to your family member's lifestyle, environment, and health. We will study your answers given about your next-of-kin, their medical records, and the genetic and other information we found out about them from the earlier study. This will help us learn more about kidney cancer outcomes.

NOTIFICATION COST, AND COMPENSATION

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 the study, other than your time, and there is no compensation or payment for completing the questionnaire.

POTENTIAL DISCOMFORT AND RISK

During the interviews, you may feel some discomfort when asked some questions. If you feel this way, you may refuse to answer them.

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 (Czech Republic, Poland, Romania, or Russia) and the United States state and federal law. 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 questionnaire will not be labeled with your name. Your name will not be used in any report or released in any way.

RIGHTS AS A PARTICIPANT

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. Your decision on this matter will not affect your medical care or employment. We will keep all information we obtain from this interview secure and safe from access or use for any other intent but this research study. While the information collected as part of this research study continues to be linked to personally identifying information, it will be protected from access by anyone except those directly responsible for patient recruitment and contact. After this study is completed, all personal identifiers will be removed in place of study identifiers. Any documents containing linkage between identifiers with the study identifying codes will be kept under lock and key at the International Agency for Research on Cancer, and destroyed as soon as the study has been completed.

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 family member's 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.

YES	NO	Study Component
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<input type="checkbox"/>	<input type="checkbox"/>	Interview
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[] [] Access to hospital records

Signature of Participant Date Signature of Witness Date

Print Name

Print Name

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

Name of Local Collaborating Center and Address