

INSTITUTE: National Institute of Child Health and Human Development

STUDY NUMBER: 00-CH-0093 PRINCIPAL INVESTIGATOR: Karel Pacak, M.D., Ph.D., D.Sc.

STUDY TITLE: Diagnosis, Pathophysiology, and Molecular Biology of Pheochromocytoma and Paraganglioma

Continuing Review Approved by the IRB on 7/22/09

Amendment Approved by the IRB on 6/10/10 (ZZ)

Date Posted to Web: 6/15/10

Normal Volunteer/ Urine Collection

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

OVERVIEW OF THE STUDY

This study is performed to better understand the development of metastatic disease in patients with pheochromocytoma and/or paraganglioma related to germline mutation of the succinate dehydrogenase gene. Insight in the differences between healthy control subjects, mutation carriers, patients with non-metastatic and patients with metastatic disease may lead to the development of new diagnostic markers as well as novel therapeutic targets.

URINE COLLECTION

The midstream portion of the second void of the morning will be collected and sent to mosaiques diagnostics and therapeutics (Hannover, Germany) for proteomic analysis. Several conditions can interfere with the test results. Therefore you will have to fast after 12 AM the night before urine collection and can't:

- Take antidepressants, anxiolytics, sleep aids and H2 blocker for 14 days prior to collection;

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- Take tylenol/acetaminophen products for 5 days prior to collection;
- Drink caffeinated or de-caffinated beverages, alcohol or smoke for 24 hours prior to urine collection.

DATA COLLECTION

You will be asked to fill in a questionnaire, asking for prior health issues, including kidney, urether or bladder related conditions. You will also confirm in this questionare that you did not smoke or have alcohol within 24 hours of urine collection. You will also have to list all medications you are taking at the urine collection.

OTHER GENERAL ISSUES RELATED TO THIS PROTOCOL

1. Unanticipated medical information. During the course of this or future investigations, it is possible (although not likely) that we may obtain unanticipated information about your health or genetic background. If this information is considered to be relevant to your health care, we will provide it to you.

2. Participation in other research studies. This consent form specifically refers to your participation in the research protocol described above. In the future, we may invite you to participate in other studies. Even if you sign this consent form, you are not obligated to participate in these other research protocols. If you are asked to participate in these other studies, you will be provided with additional consent forms. As stated in the Introduction to this protocol, you are free to withdraw from any or all research studies at any time without penalty or loss of any benefits to which you are otherwise entitled.

3. Collection, research and storage of biologic material. During your participation in this protocol, samples of your urine will be collected and stored for ongoing and future research purposes. Data about your condition will also be collected. The research carried out on these samples and the data collected will help in understanding how pheochromocytomas develop and how different forms of these tumors, including those that have become malignant, might be better diagnosed and treated. Much of this research using stored human specimens and data will be carried out by NIH investigators under the direction of the Principal Investigator of the protocol. However, some research involving your samples and data collected under the protocol will also be carried out as part of collaborations with investigators at centers outside of the NIH. In the latter situation, your samples will be coded so that your identity as the source of those samples will be protected and remain confidential to the non-NIH investigators directly involved in the research. Any data that is shared will also have identifying information removed before it can be used for collaborative research with investigators at centers outside the NIH.

The urine collected from you will be stored in freezers contained in a secured building on the NIH campus. The samples will be inventoried and stored by codes defined by us.

ALTERNATIVES TO PARTICIPATION IN THIS STUDY AND RIGHTS UPON REFUSAL OR WITHDRAWAL FROM THIS STUDY

The choice to enter or not enter this study is entirely voluntary. Before you decide to enter or not, you should understand what has been explained to you and what you have read about the research study. If you decide not to participate your enrollment in any other NIH protocol will not be affected. If you choose to begin this study you have the right to withdraw at any time.

