INSTITUTE: National Institute of Child Health and Human Development

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

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
Blood Test Adult

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.

Blood Test for Plasma Catecholamines and Metanephrines

Purpose of Study

This study is to diagnose pheochromocytoma, a tumor located in the adrenal gland or outside the adrenal gland. This tumor releases chemicals called catecholamines that can cause high blood pressure. This tumor also produces breakdown products of catecholamines called metanephrines.

Plan

We will perform the blood test for plasma metanephrines and catecholamines on you or your child. We are currently one of only two laboratories in the United States doing the test for plasma metanephrines. The test requires that an intravenous needle be placed in either arm and that you or your child are comfortable and in a lying position for 15-20 minutes after which a 15 ml (1/2 ounce) sample of blood will be drawn. You or your child should not have been taking

any form of acetaminophen in the last week. You or your child should consume no coffee or cola beverages on the day of the test, including decaffeinated coffee. You or your child should also be fasting from the previous midnight until the blood sample is taken.

Explanation of Procedures and Tests

The test may be used to make or reject the diagnosis of a pheochromocytoma. The diagnosis of pheochromocytoma can usually be made on the basis of other tests such as urinary catecholamines or metanephrines. Thus, it may be possible to make the diagnosis of pheochromocytoma without this test.

Hazards/Risks

There is the brief pain of a needlestick and a small risk of a bruise, at the site of the needlestick.

Benefits

You and your doctor will gain additional information as to whether or not you or your child may have a pheochromocytoma. Depending on the results of the blood tests you or your child may be invited for further detailed evaluation to the National Institutes of Health.

Monetary Compensation

We will perform the tests without charge and notify you or your child's doctor of the results and our interpretation of what they mean. While we will only report our results directly to either your doctor or you, we may use these results, pooled with those of others, in scientific reports but always without your name or other identifying information. While we will not charge for our or your child's testing, there may be charges for drawing you or your child's blood and for shipping it to the National Institutes of Health. If so, these charges should be explained by you or your child's doctor and you are responsible for them.

Other General Issues Related to This Protocol

If you still want us to perform the test, you must read and understand this form, approve the taking of the blood sample and the fact that your or your child's doctor will send us certain information about you or your child. Then, you should sign and date this consent form. Your doctor or someone else must sign and date the consent form as a witness. If it is your child who is being tested, then your child will need to read and sign a separate consent form for children. If your child cannot read or understand the consent form then you or the doctor should read to the child the consent form and obtain verbal consent from your child that he or she is willing to have the test carried out. Your doctor will send the signed consent form to us with your blood sample. We may also determine plasma catecholamines in your blood to help interpret our results.

Dr. Karel Pacak at the National Institutes of Health is ready to answer questions from either you or your doctor. Dr. Karel Pacak can be reached by phone (301-402-4594) or by fax (301-402-4712).

OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Karen Pacak, M.D., Ph.D.; Building 10, CRC, Room 1E-3141, Telephone: (301) 402-4594 or Karen T. Adams, CRNP; Building 10, CRC, Room 1E-3141, Telephone (301) 402-7785. You may also call the Clinical Center Patient Representative at (301) 496-2626.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Patient's Consent

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

Signature of Adult Patient/Legal Representative _____ Date _____

Print Name _____

B. Parent's Permission for Minor Patient.

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study.
(Attach NIH 2514-2, Minor's Assent, if applicable.)

Signature of Parent(s)/Guardian _____ Date _____

Print Name _____

C. Child's Verbal Assent (If Applicable)

The information in the above consent was described to my child and my child agrees to participate in the study.

Signature of Parent(s)/Guardian _____ Date _____ Print Name _____

THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM JULY 22, 2009 THROUGH JULY 21, 2010.

Signature of Investigator _____ Date _____

Print Name _____

Signature of Witness _____ Date _____

Print Name _____