

MEDICAL RECORD	MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • Attach to NIH-2514-2, Consent to Participate in a Clinical Research Study
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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 Minor

PEDIATRIC ASSENT FORM FOR BLOOD TEST OF PLASMA METANEPHRINES (for use in centers outside the NIH)

The passage below is to be read aloud to all minors between 4 and 7 years of age, or any minor who can not read. A parent or guardian must be present. The procedures will be done only after receiving verbal assent by the child and written permission by the parent or guardian

There is a possibility that you may have a growth in your body that produces things that can make you feel sick.

To establish whether you do or do not have this growth we would like to take a small amount of your blood to test for the presence of these things.

To take the blood, you lie down for about 20 to 30 minutes, or about the same amount of time as a TV show like Sesame Street.

We put a rubber band strip around your arm (*show the tourniquet*), so that we can see a vein that contains the blood in your arm. Then we place a small needle into the vein in your arm (*show the butterfly i.v. set*).

This will hurt or sting a little bit for a second or two, but then the stinging goes away.

We connect the needle to a bag that has some liquid in it, and we put the liquid into the needle in your arm, to keep the needle from clogging up. After about 15 minutes, we take a small amount of your blood into this tube (*show the 8 to 10 cc Vacutainer tube*).

Once we have the blood in the tube, we take the needle out, and that's the end of the test. You may have a small black and blue mark where the needle was. If so, the mark will turn to a greenish color over a few days and then disappear.

Your mother (or father) will be with you the whole time, and if at any time you want us to stop the test, just let us know and we'll stop it.

PATIENT IDENTIFICATION	MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY NIH-2514-2 (10-09) P.A.: 09-25-0099 File in Section 4: Protocol Consent (4)
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We have to know that you understand what we plan to do. Do you understand what we plan to do? If so, say yes.

You do not have to do this if you or your parent/guardian do not want you to.

We have to have your permission to have this test. If you allow us to do the test, say yes.

I have had this study explained to me in a way that I understand, and I have had the chance to ask questions.
I agree to take part in this study.

Signature of Minor Patient: _____ Date: _____

Print Name: _____

Signature of Investigator: _____ Date: _____

Print Name: _____