

14 years of age-17 years of age: Assent and Parental Permission Form

The Ohio State University Assent to Participate in Research

Study Title: Genetics, Molecular Diagnostics, and Mechanisms of Juvenile Cobalamin Deficiency

Researcher: Stephan Tanner, PhD

Sponsor:

- You are being asked to be in a research study. Studies are done to find better ways to treat people or to understand things better.
- This form will tell you about the study to help you decide whether or not you want to participate.
- You should ask any questions you have before making up your mind. You can think about it and discuss it with your family or friends before you decide.
- It is okay to say “No” if you don’t want to be in the study. If you say “Yes” you can change your mind and quit being in the study at any time without getting in trouble.
- If you decide you want to be in the study, an adult (usually a parent) will also need to give permission for you to be in the study.

1. What is this study about?

Some people have trouble digesting a vitamin, called B12, and this can result in the person developing infections or feeling sick. In this study, we are trying to understand why some people do not absorb vitamin B12 the way they should.

We all have inherited traits, such as our eye color. DNA helps determine our traits. Our DNA is inherited from our parents. Sometimes changes in the DNA code can also cause medical conditions. This research is being done to help us better understand the changes in the DNA code that might lead to problems absorbing vitamin B12.

2. What will I need to do if I am in this study?

If you are in this study, you will need to provide a blood or cheek cell sample. If you choose to give blood, a small needle will be inserted into a vein in your arm and about 4 tablespoons of blood will be taken. If you do not wish to give a blood sample, you can give a cheek cell sample instead by either spitting into a small cup, rubbing a soft brush on the inside of your cheek, or rinsing your mouth with a mouthwash (like Scope) and

spitting it back into a cup. These samples can be collected at home or at Ohio State University Medical Center. You and your parent(s) will need to let us know which option you prefer.

Your sample will be sent to a laboratory at The Ohio State University. Scientists will use your sample to look for changes in the genetic code that may be responsible for problems that you, or a family member, have in absorbing vitamin B12. Other family members (like your brothers, sisters, mother, or father) may also choose to give a sample for this study.

3. How long will I be in the study?

You will only need to have your blood drawn one time, or donate one cheek cell sample, to be in this study. It should only take a few minutes for you to donate blood or provide the cheek cells. It will take several months (likely 2-6 months) to get results from this study. Your sample will be kept until 2015.

4. Can I stop being in the study?

You may stop being in the study at any time. If you turn 18 while the study is being done, the researchers will try to contact you so that you can decide whether or not you want to continue to be in the study. If you decide to continue to be in the study, you will be asked to sign a new (adult) consent form. If you decide you do not want to be in the study, we will destroy any samples (such as blood or saliva) and information that we had previously obtained about you. If we are unable to find you, your sample and information will continue to be used until the study is complete.

5. What bad things might happen to me if I am in the study?

You might have some pain or discomfort when your blood is drawn. You might get a small bruise in the place that the needle was inserted. There is a very small chance that you could get an infection after getting blood drawn.

6. What good things might happen to me if I am in the study?

If you choose to be in the study, we may be able to find the change in your DNA code that has led you, or a family member, to have problems absorbing vitamin B12. This information may also help researchers develop a new test, which can be offered to people in your family or around the world, to see if they have a higher chance to have problems absorbing vitamin B12.

7. Will I be given anything for being in this study?

You will not be given anything for being in this study. However, you do have the option to get your test results, or have them given to your parents and/or your doctor. You can tell us below what you would like to do (check and initial all that apply).

- _____ I would like to know the results of my testing.
(initial)
- _____ I would like for my health care provider to be told the results of my testing.
(initial)
- _____ I would like my parents to know the results of my testing.
(initial)
- _____ I do not want to know the results of my testing.
(initial)

8. Who can I talk to about the study?

For questions about the study you may contact Amy Sturm at (614) 293-6694 or 1-888-329-1654 (toll free).

To discuss other study-related questions with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

