

ADOLESCENT ASSENT FORM FOR YOUTH AGES 12-17

TITLE: Validating and Developing Duffy Null Specific Absolute Neutrophil Count Reference Ranges for Adults and Pediatrics

IRB PROTOCOL NO.: TBD

SPONSOR: American Society of Hematology

PRINCIPAL INVESTIGATOR: Name
Address
City, State Zip
Country

Your parent has given permission for you to be in a project called a research study. But first, we want to tell you all about it so you can decide if you want to be in it. If you do not understand, please ask questions. You can choose to be in the study, not be in the study, or take more time to decide.

What is the name of the study?

Validating and Developing Duffy Null Specific Absolute Neutrophil Count Reference Ranges for Adults and Pediatrics.

Who is in charge of the study?

The American Society of Hematology.

What is the study about?

We're trying to figure out what's normal for the number of white blood cells in everyone's body. Some people, especially those with ancestors from Africa or the Middle East, may have a marker on their cells (called Duffy null) that makes their white blood cell counts lower than people with ancestors from Europe or Asia. We want to help doctors understand what's normal for all the people they take care of, including you.

Why are you asking me to be in this study?

You are being asked to be in the study because you are between the ages of 12 and 17 and do not have any diseases that would impact the white blood cells in your body.

What will happen to me in the study?

If you decide to be in the study, here is what will happen:

- You will have a one-time blood draw to look at your Duffy antigen and your white blood cell counts. We hope to add this onto any blood draws you already need for your regular medical care to avoid extra needle pokes.
- The risk of joining the study is the discomfort of drawing blood and having your information shared with people outside of the study team.

Blood Volume

One 3 mL lavender top (EDTA) tube of volume blood will be collected from you to perform Duffy genotyping, phenotyping, and absolute neutrophil count (ANC) analysis. Some labs require two separate 3 mL lavender top tubes: one to perform ANC analysis and one for Duffy typing.

Will I be paid to be in this study?

<<Compensation protocols may differ among various locations for those intending to provide payment. Sites should complete this section based on the amount they intend to compensate participants.>>

Do I have to be in the study?

You do not have to be in the study if you do not want to. If you are in the study, you can stop being in it at any time. Nobody will be upset with you if you don't want to be in the study or if you want to stop being in the study. The doctors and nurses will take care of you as they have in the past. If you have any questions or don't like what is happening, please tell your doctor or nurse.

What are the bad or harmful things that could happen in this study?

Blood draws can be uncomfortable. There is also a risk that your private data is given by mistake to an organization that is not approved, but we are careful to prevent this.

What are the good things that could happen in this study?

You and your doctor may know if you have the Duffy antigen or not which could help your doctor give you advice in the future about your health.

Who will see your information?

The study staff may see your information but will protect you by removing information such as your name, address, and other information that could potentially "identify" you or your family. This information is "de-identified" because your direct identifying information has been removed.

Who can answer questions about this study?

The study staff can answer any questions you have about this study.

You have had the study explained to you. You have been given a chance to ask questions. By writing your name below, you are saying that you want to be in the study.

Name of Adolescent (Print)

Date

Signature of Adolescent

Name of Person Obtaining Assent (Print)

Date

Signature of Person Obtaining Assent