Parental Informed Consent and Authorization

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

KEY STUDY INFORMATION

Your child is being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you and your child.
- Taking part in this research is voluntary. Whether your child takes part is up to you and your child.
- If your child doesn't take part, it won't be held against your child.
- Your child can take part now and later drop out, and it won't be held against your child.
- If you or your child do not understand, ask questions.
- Ask all the questions you want before you decide.

How long will your child be in this research?

We expect that your taking part in this research will last the time it takes for a single blood draw—usually no more than 30 minutes.

Why is this research being done?

Certain individuals with ancestors from Africa or the Middle East often have fewer white blood cells compared to those with ancestors from Europe or Asia. This difference may be linked to the absence of a red blood cell marker known as Duffy. We believe that not having the Duffy antigen leads to lower white blood cell counts, but this is considered normal and does not cause harm. Our goal is to establish a more accurate range for blood counts in individuals without the Duffy antigen. This could result in improved medical care for people lacking the Duffy antigen.

What happens to my child if I agree for my child to take part in this research?

If you decide to join to allow your child to join, they will have a one time blood draw. This can be added on to any blood draw they are already getting from their normal medical care. It can also be a blood draw only for this research project.

Could being in this research hurt my child?
There is a potential risk of a data breach. A data breach is when data are either on purpose or by mistake given to a person or organization not approved by the study. We are careful to prevent this from happening.

Your child may also experience discomfort at the site of the blood draw, possible bruising, bleeding, redness and swelling around the site where the needle is inserted, feeling of lightheadedness when blood is being drawn, and rarely, an infection at the site of the blood draw. We hope to minimize this risk by adding on tubes of blood for this project when your child is already getting a blood draw for your regular medical care.

Will being in this research benefit my child?
Participating in the project might benefit your child if the research team makes their Duffy typing available in the electronic medical record. In this case, your child's doctor may use this data to make healthcare decisions in the future. Joining the project could help others in the future if we better understand the Duffy antigen and the impact on white blood cells.

What other choices does my child have besides taking part in this research?
You may choose for your child not to take part in this research.

What else should I know about the research?
The project only shares de-identified information parties outside of your healthcare system.

Welcome
In this consent form, "the patient" is the child giving blood. "You" is the person providing the information, who may be a parent or guardian who is legally responsible for the care and health of the child.

The consent process is very important. It helps you understand what it means for your child to join the project. If you would like your child to take part in the project, we will need your approval (also called "consent").

Blood Volume and Data
If you decide to allow your child to join the project, you are allowing a one-time blood draw. This blood draw will allow the researchers to analyze your child's neutrophil count (one of the white blood cells) as well as their Duffy phenotype (antigen on the red blood cell). One 3 mL lavender top (EDTA) tube of volume blood will be collected from your child 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. Duffy phenotype or Duffy genotype by sequencing are acceptable methods to obtain typing. We will also collect your child's age, sex, race, and ethnicity. This data will be de-identified which means that it cannot be linked to you.

Data privacy
Data is stored on protected computers. These computers are protected by passwords and stored in the United States. Only approved people may have access to the data.

Your child's record will be closely guarded. People who are approved to access or use the data must follow strict rules. These rules are listed in a contract that is signed before any data is shared. All attempts will be made to protect your privacy.

What will we do?
We will use your child's blood sample and health information to understand the impact of the Duffy antigen on white blood cell count. This will allow us to build reference ranges that are the best possible fit for each individual person. This is a one-time interaction. We will not ask you for more data or for more blood samples.

What are the benefits of joining?
Participating in the project might not directly help your child. You might have access to your child's blood results in their electronic medical record. These results could help you or your doctors make decisions in the future about your child's care.

Compensation
<<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.>>

What are the risks?

There is a potential risk of a data breach. A data breach is when data are either on purpose or by mistake given to a person or organization not approved by the project. If a breach occurs, the team will make every effort to let you know what happened as quickly as possible.

Alternatives
The alternative to joining the project is your child not participating.

You get to choose
Your child's participation is voluntary. No matter what you decide, it will not affect your child's care or their relationship with their doctor.

Participation of minors
For patients below the age of 18, a parent or legal guardian must sign this consent form (and/or assent form) for the child to join the project.

Confidentiality
Medical records with your child's identifiable information and this consent form may be looked at and/or copied for research or regulatory purposes.

Will I receive a copy of this form?
Yes, you will receive a copy of this form.

Who do I talk to if I have a question?
If you have questions, concerns, or complaints about your participation in the project, please talk to your child's doctor. We are also available to answer your questions about the project. You may call or email us at:

Phone (toll-free): <<site completes>>
Email: <<site completes>>

You can also contact the IRB if:
- You have questions, concerns, or complaints.
- You are not getting answers or cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research participant.

Phone: (609) 945-0101
Email: info@wcgclinical.com

By signing this form, I understand that:
- My child's participation is voluntary. I can change my mind at any time.
- All attempts will be made to protect my child's privacy and my family's privacy.
- This is a one-time blood draw with de-identified information from my child's health record.
- My child may not benefit from participating.

I understand the purpose of this form and all my questions were answered.

I had enough time to decide that I want my child to participate in the project.

Signature Page

Child's Printed Name: _____

Child's Date of Birth: ____/____/_____

Parent/Guardian's Printed Name: _____

Signature of the patient/guardian confirming that he/she understood the content of the consent form:

Signature: _____ Date _____

Study team member's name and signature

Name of the person (not relative of the patient) who explained the content of the consent form:

Printed Name: _____

Signature of the person (not relative of the patient) who explained the content of the consent form:

Signature: _____ Date _____

****For Sites in California****

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?

The study doctor and the study staff. [They may also share the research information with [enter SMO company name], an agent for the study doctor. delete if the site does not have an SMO]

Who might get this information?

The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

_____ _____

Signature of Subject **Date**