IRB Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
AS MODIFIED
August 10, 2023

Adult Informed Consent and Authorization

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

IRB PROTOCOL NO.:

SPONSOR: American Society of Hematology

<<CF-Main Header Block - Investigator>>
PRINCIPAL INVESTIGATOR:
Name
Address
City, State Zip
Country

KEY STUDY INFORMATION
You are 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.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I 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?
Some people with ancestors from Africa or the Middle East are known to have lower white blood cell counts than people with ancestors from Europe or Asia. This may be in part because of the absence of a red blood cell marker called Duffy. We think that not having the Duffy antigen causes lower white blood cells than people who have the Duffy antigen, but is normal and of no harm. We hope to make a better blood count range for many people of who do not have the

Duffy antigen. This could provide better medical care for people who do not have the Duffy antigen.

What happens to me if I agree to take part in this research?
If you decide to join, you will have a one time blood draw. This can be added on to any blood draw you are already getting from your normal medical care. It can also be a blood draw only for this research project.

Could being in this research hurt me?
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.

You 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 you are already getting a blood draw for your regular medical care.

Will being in this research benefit me?
Participating in the project might benefit you if the research team makes your Duffy typing available in your electronic medical record. In this case, your 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 do I have besides taking part in this research?
You may choose 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, the "patient" is the person giving blood. "You" is the person providing the information.

"You" may be the patient, a family member, or someone who is taking care of a patient.

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

Data
If you decide to join the project, you are allowing a one-time blood draw. This blood draw will allow the researchers to analyze your neutrophil count (one of the white blood cells) as well as your Duffy phenotype (antigen on the red blood cell). We will also collect your 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 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 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 you. You might have access to your blood results over the electronic medical record. This results could help you or your doctors make decisions in the future about your care.

Compensation
Compensation protocols may differ among various locations for those intending to provide payment.

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.

The research team will make every effort to protect your privacy and your family's privacy.

Alternatives
The alternative to joining the project is not participating.

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

Confidentiality
Medical records with your 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 doctor. We are also available to answer your questions about the project. You may call or email us at:

- **Phone (toll-free):**
- **Email:**
- **Website:**

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.

By signing this form, I understand that:
My participation in this study is voluntary. I may decide not to participate, or I may leave the study at any time. My decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

My participation in this study may be stopped at any time by the study doctor or the sponsor without my consent for any reason, including:

- If it is in my best interest.
- I do not consent to continue in the study after being told of changes in the research that may affect me.

I understand that:

- This is a one-time blood draw with de-identified information from my health record
- All attempts will be made to protect my privacy and my family's privacy.
- I 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 to participate in the project.

Signature Page

Patient's Printed Name: _____

Signature of the patient confirming that he/she/they 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 _____

<<CF-Main California HIPAA>>

****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**