UNIVERSITY OF WASHINGTON
ADDENDUM CONSENT FORM
Severe Chronic Neutropenia Tissue Repository Study
dbGaP Sub-Study
Addendum Consent/Assent for participants 12 years of age or older

Researchers:
David C. Dale, MD  Professor, Medicine  206-543-7215
Audrey Anna Bolyard, RN, BS  Research Nurse, Medicine  206-543-9749

24 hr. Emergency Contact: Hematology MD on call 206-598-6190 or Dr. Dale’s pager 206-743-7096

Researchers’ statement
We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called “informed consent.” We will give you a copy of this form for your records.

PURPOSE OF THE STUDY
You or your family member has a condition that causes very low numbers of white blood cells, cells necessary to prevent and fight infections. The condition is called “neutropenia.” You are already enrolled in a research study called “Severe Chronic Neutropenia Tissue Repository,” a study to find the causes of neutropenia. Your blood and DNA (inherited material) continue to be studied by researchers to find the causes for this disorder. We are asking your permission now to allow us to take advantage of new DNA technologies to expand our research. Previously, we were only able to look at very small portions of DNA. New technologies allow us to study much larger portions. We are also asking you to allow us to share your genetic information with other qualified researchers in hopes of increasing our understanding as to why this disorder appears to run in families.

PROCEDURES
For the new phase of this research, we may need an additional blood sample (up to 2 tablespoons or 30 milliliters), unless the sample we previously collected is sufficient. The blood test samples will be done when they are part of your regular medical care. After we analyze the DNA in the expanded way, we want to share that information with other investigators. The National Institutes of Health (NIH) have set up a health research database of genetic information (the genotype or DNA information) and clinical information (the phenotype-information such as laboratory test results and history of infections). The purpose of this database is to allow multiple researchers access the data to study how genes interact in human health and disease. This national database is designed to increase efficiency and save money in the study of diseases related by genetics. These data will be kept indefinitely. Qualified researchers who receive permission to access and share these data may be from other universities or from commercial companies. Your name or contact information, or any identifiers will never be released to the
databank. However, because genetic data is considered unique to each individual, it could theoretically identify you. We need your permission to allow your data to be included in the national genetic database (dbGaP; the NIH database for genotype and phenotype). You can withdraw your consent anytime if you do not want your data in the national databank. However, data from the database that has already been sent to researchers will not be able to be retrieved.

**RISKS AND DISCOMFORTS**

Drawing a sample of blood causes a short period of pain at the place of the needle stick. There is a chance that a small bruise or infection will occur there also.

There is a possible risk of loss of confidentiality. Your privacy will be strictly protected, but we cannot absolutely guarantee there will be no breach of confidentiality. There is a small chance that your genetic information could be shared with others by mistake. If your information was mistakenly shared and if it were linked with a medical condition, this could affect your ability to get or keep your insurance. There is the risk that coded data could be released to the public, insurers, employers, or law enforcement agencies. If family members were to see this information it could also affect them. This could hurt family relationships. It is also possible that you could be identified from the sample if someone has another DNA sample from you. The two samples could be matched to identify you from the sample given for this study. There is also the risk that a breach of computer security could release information. There may be other risks that are unknown at this time.

We are double coding all information sent to this national database to lessen the chance that you could be identified. The NIH will assign yet another code to the data we send there to add a further layer of protection from disclosure.

**NEW INFORMATION**

Our studies may take years to complete. We may never, in fact, identify the genes responsible for severe neutropenia. You will not be told about any research information that might be discovered in this study. If medically important information becomes known to us from this research, we will attempt to contact you.

**BENEFITS OF THE STUDY**

You are not likely to benefit personally from participating in this research. However, we may be able to answer why some people have severe neutropenia while others do not. We are hopeful that future generations may benefit from the scientific and medical knowledge we gain from your participation. We believe that this research will lead to better methods to treat or prevent disease. This knowledge may help society by leading to effective treatments or cures.

**COSTS/ PAYMENTS**

You will not be charged for any study procedures. Your insurance company will not be billed for any study procedures. You will not receive any payment for participating in this research.

**ALTERNATIVE TO PARTICIPATION**

This is not a treatment study. Your alternative is not to participate in this study.
CONFIDENTIALITY

We will keep your participation in this study confidential. Sometimes, government or university staffs review studies to make sure they are being done safely and legally. If a review happens, your records may be examined. The reviewers will protect your privacy. Your name will not be given on any scientific presentation or publication.

SOURCE OF FUNDING FOR THE STUDY

The National Institutes of Health primarily funds this research. Gifts and grants from other sources may also be used to support the work.

FINANCIAL INTEREST

Dr David Dale has a financial or leadership relationship with Amgen, the company which manufactures filgrastim or Neupogen, a drug used for the treatment of neutropenia. Amgen provides filgrastim free of charge to patients in the United States who are enrolled in the Severe Chronic Neutropenia International Registry (SCNIR) under a contractual agreement with the University of Washington. Dr. Dale is the Principal Investigator for this agreement. Amgen supported development of the SCNIR and the Repository described in this consent form, but these activities are now primarily supported by a grant from the National Institutes of Health; Dr. Dale is the Principal Investigator for this grant. Dr. Dale also serves as a consultant and advisor to Amgen and receives compensation for this activity in addition to his salary from the University of Washington. This financial interest and the design of the study have been reviewed and approved by the University of Washington for possible conflict of interest. A Management Plan was developed to minimize any possible effect of this financial interest on your safety or welfare. The Plan will also protect the quality and reliability of the research.

QUESTIONS

Contact Dr. David Dale, MD at 206-543-7315 for any of the following reasons:
  • if you have any questions about this study or your part in it
  • if you feel you have had a research-related injury
  • if you have questions, concerns or complaints about the research

Printed name of study staff obtaining consent  Signature  Date

Severe Chronic Neutropenia Tissue Repository Study

Addendum Consent Form

Page 3 of 4
August 8, 2018
Subject’s statement

This study has been explained to me. I volunteer to take part in this research. I agree to have my coded genetic information shared with qualified researchers. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206-543-0098). I will receive a copy of this consent form.

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When subject is a minor, Signature of Parent:

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Copies to Researcher and Subject