



ROCKEFELLER UNIVERSITY:

Assent Form I (For Proband) (To be obtained from children 7 years or older)

Title of research study: Entrance into the International Fanconi Anemia Registry

Principal Investigator: Agata Smogorzewska, MD, PhD

What will happen to me in this study?

You are being asked to participate in this study because you have Fanconi Anemia or have medical concerns similar to kids with Fanconi anemia. We want to put information about you in a registry. A registry is a collection of information about many people with your disease. When we study many people with Fanconi anemia, we get more accurate information about the disease and how it affects people.

Five things may happen to you if you are in this study:

1. We may take a small amount of your blood with a needle in your arm.
2. We might take a small sample of skin if needed (this is called a skin biopsy). For this, you would be given a shot of numbing medicine. Then, to take a piece of skin, we would use a very small hole punch or take a sliver no longer than one inch. You would get stitches to close the wound and to stop any bleeding that might occur. You don't have to do this to be in the study.
3. We may use a long Q-tip to rub the inside of your mouth or we might ask you to spit into a container. These are both other ways to get the samples we need for the research.
4. You might have a physical exam by a doctor. You can choose whether to have your parent in the room for the exam or not.
5. We will ask you or your parents to answer some questions about your health.

The investigators will help you stay covered as much as possible during the exam, and you may choose whether you have a man or a woman examine you. You can choose whether you want your parent/guardian to be present for the exam, and if you don't, we will provide another chaperone to be present for your comfort.

The samples that you have donated for this study will be stored and can be used by scientists at Rockefeller University and elsewhere. All of the information that we learn about you will be kept on a secure website. Only certain people will be able to look at the information on the website and they will need a password to do so.

Can anything bad happen to me? You may feel bad from the needle stick. The stick from the needle might hurt, but the pain will go away after a while. You should tell us or your parents if

you feel bad. You may get a bruise (black and blue mark) where the blood was taken. If you get a skin biopsy, you may bleed a little bit, or have some redness. You may even get a little scar. Often, this scar fades as you get older. If you notice some redness, bruising, or swelling at or around the skin biopsy place you should tell us or your parents. The rub of the inside of your mouth or the spitting should not cause you any discomfort.

Can anything good happen to me? This study will not make you feel better or get well. But, the doctors might find out something that will help other children with Fanconi anemia later.

Do I have other choices? You can choose not to be in this study.

Will anyone know I am in the study? — Yes. The scientists at Rockefeller University will know you are in this study. There are also other doctors that work with children with Fanconi anemia everyday who will also know you are in the study. But none of these people can tell anyone else that you are in the study without your permission. Other scientists that study Fanconi anemia and other diseases might do tests on the samples that you give us, but they won't know your name or any other information that would tell them who you are. While we do not think that this will risk your privacy, we cannot know how this information will be used in the future.

What happens if I get hurt? — If you get hurt because of the blood draw or the skin biopsy, the principal investigator or her staff will make sure you get medical attention. For any other medical problems, you will go to your own doctor.

Who can I talk to about the study? — You can talk to your parents about this study. You can also call the director of the study, Agata Smogorzewska at 212-327-7850, if you have any questions.

What if I do not want to do this? You do not have to do this study if you do not want to and no one will be mad at you. If you do not want to be in this study, you just have to tell us. If you want to be in this study, just tell us. And, remember, you can say “yes” now and change your mind later. It's up to you.

SIGNATURE CLAUSE

If you have any problems with this study, you may call the Institutional Review Board at (212) 327-8410 or the Office of Clinical Research at (212) 327-8408

Are you willing to participate?

YES

NO



Signature of Child

Date

Person Obtaining Assent

Date