

**Study Title:** Early genomic testing for Inherited Bleeding Disorders in patients without a diagnosis after first line testing: a randomized controlled trial

**Principal Investigator(s):** Dr. Paula James, MD, FRCPC, Professor, Department of Medicine  
**Phone Number:** XXX XXX XXXX

**Study Coordinator:** Julie Grabell

**Phone Number:** XXX XXX XXXX

### What is a research study?

A research study is a way to test new ideas to see if we can do things better. This research study is a way to learn more about genetic disorders that might affect your health. You do not need to be in a research study if you don't want to.

### Why am I being asked to be in this study?

You are being invited to take part in this research study because you are part of a larger research study looking at people with bleeding problems.

We know that some health problems are caused by changes in genes. A gene is something that is in each cell of the human body. Genes carry the information that decides what is passed to you from your parents, like the colour of your eyes and hair. Genes also seem to be important for many different health problems. In the large study, we will try to find the gene which causes your problems with bleeding or bruising. In this part of the study, we will see if you have genes for other health problems.

### Who will know I am in this study?

This study was explained to your parents/guardians and they said that we could ask you about the study. Your parents/guardians can help you decide if you want to be in this study.

Only the research team and your parents/guardians will know that you are in the study. There may be times where your family doctor will need to know test results performed by this study, for example if you are diagnosed with a health problem.

### If I join this study what do I need to do?

We want to tell you some things about this study. If you agree to take part:

- Talk with someone called a genetic counsellor who will tell you more about the health problems that could be found
- Say if you would like us to look at genes for other health problems

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### Will any part of the study hurt or be scary?

It might feel upsetting to learn about new health problems.

### Will the study help me?

We think that the study might help you by finding if you have other health problems that can be treated.

### Will the study help others?

This study might find out if this type of extra testing is helpful to find other health problems in children. It might also tell us if other members of your family may also have the same health problem.

### Can I say no?

Yes of course, you can decide not to be in the study. It's up to you. No one will be upset if you don't want to do this study. You can tell your parents, grandparents, guardians or your doctor if you do not want to be in the study. If you do join the study, you can change your mind and stop being part of it at any time.

### What choices do I have if I say no to this study?

If you say no to this study, you will still be part of the larger study about bleeding problems.

You can ask us for more information about these other choices.

### Who will see information about me?

The information collected about you during this study will be kept safe and your name will not be kept with this information. The people doing the research will be able to see the information collected about you. If you receive a diagnosis, this information will be given to your parents/guardians. Your parents/guardians will not see your answers to the questions unless you share it with them. The researchers will not tell your friends or anyone else if you decide to join the study or not. If the researchers think that you might need help then they will need to tell someone.

Other people doing studies in the future would have to ask special permission to look at your information. These researchers would not know your name either.

### Do I get anything for being in the study?

You will not be paid to be in this part of the study

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### What if I have questions?

You can ask any questions you want about the study.

### What if I have questions later?

If you have any question about this study that you didn't think of now, either you can call or have your parents/guardians call : Dr. Paula James the study doctor, at : 613 533 6329.

You will be given a copy of this paper to keep.

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Would you like to take part in this study?

Yes, I will be in this research study:

\_\_\_\_\_  
Child's name

\_\_\_\_\_  
Signature (if applicable)

\_\_\_\_\_  
Date

☐ Assent was obtained orally

I have discussed this research study with using language which is understandable and appropriate for the participant. I believe that I have fully informed him/her of the nature of the study and its possible risks and benefits. I believe the participant understood this explanation and assent to participate in this study.

\_\_\_\_\_  
Person obtaining Assent

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

December 5, 2024