

Institutional Review Board (MBRU-IRB)

Assent Form for Children below 18 years of age

Title of project:

**Evaluating the Potential of Virtual Reality in Alleviating Pain and Anxiety
Among Thalassemia Patients During Intravenous Cannulation: An
Interventional Cross-Over Study, 2023-2024**

Medical Record Number (MRN): _____

Why are we meeting with you?

We want to tell you about something we are doing called a research study. A research study is when doctors collect a lot of information to learn more about a topic. Dr. Yacine Hadjat, Dr Fatheya and other doctors and nurses from the Thalassemia Center, are doing a study to learn more about how we can reduce pain and anxiety using Virtual Reality technology with a headset during your procedure. After we tell you about it, we will ask if you'd like to be in this study or not.

What is this study about? Why are we doing this study?

We want to find out if we can reduce the pain and anxiety when the doctor or nurse puts a needle in your arm before giving you blood by wearing a Virtual Reality headset and are therefore getting information on this from children like you. Virtual Reality will show you videos and pictures of different places with many colors and soft sounds.

How many children will take part in this study?

In the whole study, there will be up to 50 children who have thalassemia.

What will happen to you if you are in this study?

Only if you agree, the doctor will perform the following:

1. You will wear a Virtual Reality headset for 5 minutes before your procedure and follow the instructions that the headset gives you to help you relax. You can keep the headset on throughout your procedure for 10 minutes and then continue to wear it for 5

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minutes after it is complete. Whether you choose to take part in this study or not, your regular treatment will not be affected.

2. For our research, you will get some questions to answer about your experience with the procedure and headset. The nurse or doctor will also measure how fast your heart is beating throughout the procedure.

Will this study hurt?

No, it won't hurt. We are just using a Virtual Reality headset you can wear during your procedure.

Will you get better if you are in this study?

This intervention might help you reduce pain and anxiety during the procedure. This is what your doctors will assess during the study.

Do you have any questions?

You can ask questions any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else.

Do you have to be in this study?

No, you don't. No one will be upset with you if you don't want to do this. Let us know if you want to or not want to be part of this study. And remember, you can say yes now and change your mind later. It's up to you.

If you don't want to be in this study, just tell us.

If you want to be in this study, just tell us.

The doctor will give you a copy of this form to keep.

PERSON TAKING ASSENT TO FOLLOW THE BELOW INSTRUCTIONS:

Choose one of the two following options. Be sure to delete these directions from the form/include only what is appropriate for the study.

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SIGNATURE OF CHILD/SUBJECT IS NOT REQUIRED, BUT DOCUMENTATION OF ASSENT IS REQUIRED— ON THIS FORM, ON THE INFORMED CONSENT FORM, AND IN THE STUDY RECORDS —INDICATING THAT CHILD HAS BEEN GIVEN ABOVE INFORMATION AND HAS VERBALLY AGREED TO TAKE PART IN THE STUDY.

SIGNATURE OF PERSON CONDUCTING ASSENT DISCUSSION

I have explained the study to _____ (print name of child here) in language they can understand, and the child has agreed to be in the study.

Name of Person Conducting Assent Discussion (print)	
Signature of Person Conducting Assent Discussion	
Date	

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