

Assent to Participate in a Research Study

Who are we and what are we doing?

We are from the **University of Utah and Primary Children's Hospital**. We would like to ask if you would be in a research study. A research study is a way to find out new information about something.

Why are we asking you to be in this research study?

We are asking you to be in this research study because you are very sick with trouble breathing because of asthma. A medicine called magnesium sulfate (Mg) may help your trouble breathing with asthma and we want to learn more about how it works in your body. Being in this study is not part of your regular medical care.

About 30 children between the ages of 2 and 17 will participate in this study at **Primary Children's Hospital**.

What happens in the research study?

If you decide to be in this research study, this is what will happen:

- We will have your nurse place an intravenous (IV) line to give the study medicine, which is a small amount of fluid given right into one of your veins, usually on your arm or hand.
- Your nurse will give you a small amount of study fluid over 20 minutes, which may or may not have the study medicine (Mg).
- We will collect a small amount of blood from your IV at three time-points:
 - Before you are given the study fluid
 - After you are given Mg:
 - 30 minutes
 - 2 hours or before discharge
- If you are a female 12 years old or older, we will do a pregnancy test (blood or urine) to make sure you are not pregnant before getting the study medicine. You must not be pregnant to participate in this research study.

Will any part of the research study hurt you?

There is a chance that during this research study you could feel afraid, uncomfortable, or hurt. We will try to help you feel better if this happens. Some children who receive Mg feel warm or have an upset stomach. This should go away as soon as we stop giving the medicine.

Blood draws: During the study you will have blood samples taken. Extra blood will be collected from the same line used to give you the study fluid.



Will the research study help you or anyone else?

About 2 out of every 3 children in this study will receive Mg. The other children will receive a small amount of water and salt. Mg could help you breathe easier. It is possible that we could learn something to help other people being given Mg in the future.

Who will see the information about you?

Only the researchers or others who are doing their jobs will be able to see the information about you from this research study. We will talk about this information with you, your doctors, and your parents.

What if you have any questions about the research study?

It is okay to ask questions. If you don't understand something, you can ask us. We want you to ask questions now and anytime you think of them. If you have a question later that you didn't think of now, you can call **Michael Johnson at (801) 935-0503** or ask us the next time we see you.

Do you have to be in the research study?

You do not have to be in this study if you don't want to. Being in this study is up to you. No one will be upset if you don't want to do it. Even if you say yes now, you can change your mind later and tell us you want to stop. You can take your time to decide. You can talk to your parent or guardian before you decide. We will also ask your parent or guardian to give their permission for you to be in this study. But even if your parent or guardian say "yes" you can still decide not to be in the research study. Your doctors will continue to take care of you even if you decide not to be in this research study.



Agreeing to be in the study

I was able to ask questions about this study. Signing my name at the bottom means that I agree to be in this study. My parent or guardian and I will be given a copy of this form after I have signed it.

Printed Name

Sign your name on this line

Date

Printed Name of Person Obtaining Assent

Signature of Person Obtaining Assent

Date

The following should be completed by the study member conducting the assent process if the participant agrees to be in the study. Initial the appropriate selection:

_____ *The participant is capable of reading the assent form and has signed above as documentation of assent to take part in this study.*

_____ *The participant is not capable of reading the assent form, but the information was verbally explained to him/her. The participant signed above as documentation of assent to take part in this study.*

