# Parental Permission and Authorization Document

Your child is being asked to take part in a research study. Participating in the study is voluntary, which means you can choose whether or not you want your child to continue. Before you decide it is important for you to know why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you will allow your child to take part in this study. If you decide to allow your child to participate in the study, you will be asked to sign this form.

Your child was severely sick with asthma when you came to this emergency department. This is called severe acute asthma. The doctors and nurses began treatment for asthma right away, but many children who are this sick do not recover completely with the normal treatments including albuterol and steroids. We do not know if another medicine called intravenous (IV) magnesium sulfate (Mg) can help children with severe acute asthma. The purpose of this study is to learn whether IV Mg can help some children get better enough to go home after treatment in the emergency department and avoid hospitalization.

**BACKGROUND**

Most problems related to asthma can be managed with medication at home or during a short period of treatment in the emergency department. For most children, breathing albuterol and swallowing a steroid medicine is enough to improve and go home from the emergency department. About a third of children need to be hospitalized for more treatment. The medicine we are studying, IV Mg, may help the lungs open and the child breathe easier even if other medicines aren't working well. This medicine is promising for children with asthma because it is simply a salt that is already found in the body, it is cheap, it has been used for many years in children with asthma, and it has been safely used and studied in other diseases, including diseases during pregnancy.

We give IV Mg as a liquid through an intravenous line, which is a small tube placed through the skin directly into a vein. This allows it to go quickly into the blood and reach the lungs even if there is trouble breathing or trouble swallowing other medicines. There have been no studies to find out which amount of IV Mg is best to improve breathing or if the medicine works well enough for a child to avoid hospitalization. In this study, we are testing two different amounts of IV Mg against a placebo. A placebo is a small amount of water and salt given just like the medicine through the IV, but without the medicine in it. This is important to understand how children who receive the medicine respond differently to children who don't receive it, and how children who receive a higher amount of medicine respond differently to children who receive a lower amount. Because your child and the other children in this study are sick, it is important that we start these medicines as soon as possible. Part of the purpose of this study is to see if children can be successfully given medicine quickly as part of this study so that a larger study can be performed in the future.

IV Mg is an investigational drug in this study. It has been studied in other trials of children with asthma but has not been approved by the Food and Drug Administration (FDA) for use in children with asthma. Doctors have used IV Mg in children with asthma for many years. Doctors are allowed to, and commonly do, use unapproved medications like this, even if the medicines are not labeled by FDA for that particular use. This study is an important step in understanding the medicine better so that it can be considered for approval by the FDA.

**STUDY PROCEDURES**

**What happens in this study?**

Everyone in this study gets a single dose of a small amount of study fluid given into a vein over 20 minutes, followed by another small amount of fluid mixed with a small amount of salt to flush the IV. Everyone will be randomly assigned to receive either fluid without IV Mg (placebo), fluid with a lower amount of IV Mg, or fluid with a larger amount of IV Mg. Random means assigned by chance, like the flip of a coin. During this study, two of every three patients will get IV Mg.
Neither you or your doctor will know which of the three possible study fluids your child will receive. The doctors caring for your child in the hospital can be told what medicine he/she was given if needed.
Three blood draws, up to 5 ml total of blood (1 teaspoon), will be collected for study purposes. These will be collected through the IV already in place, and will not involve additional needle pokes. To collect blood through the IV, we use a small device that connects to it called PIVO. The company that makes this device, BD Medical, will be providing them for use in this study. This blood will be frozen and sent to a research laboratory at University of California Davis to measure the amount of magnesium in the blood, along with a few other basic blood tests. These test results will not be available while your child is being treated in the Emergency Department and will not be in your child's medical record. After these tests have been completed, any remaining blood in the samples will be destroyed.
No other aspect of your child's routine medical care will be affected by enrollment in the study. As part of your child's regular medical care, he/she may be treated later with IV Mg, or different medicines, but not as part of the study.

**Here is what has happened so far:**

Some medical information about your child and his/her condition has been looked at to decide if it was appropriate to talk to you about this study. A doctor examined your child and started treating him/her medically with standard asthma medications.
The doctor performed a standard clinical assessment of your child's trouble breathing to know that your child is sick enough to be in the study.

**What am I being asked to do?**

Now, you are being asked to decide whether or not your child will participate in this study.

Participating in the study involves placing an IV line, collecting three blood samples at different times through the IV, and giving your child study fluid that may or may not contain IV Mg. If you decide to continue participating, you also allow us to collect some medical information about your child and how he/she is doing until the time they are discharged from the hospital. If you are sent home from the ED, we will contact you about 1 - 2 days later and in one week to find out how your child is doing.
If you decide to continue participating in this study, the researchers will continue to collect your medical information only until you are discharged from the hospital. There is no time commitment being requested from you aside from the one follow up phone calls 1 – 2 days after your child is sent home and one week.

**RISKS**

The medical risks and discomforts of being in the study are similar to the risks of getting standard care. Continued severe acute asthma is associated with serious medical risks. These risks are not affected by participation in the study.

The study medicine, IV Mg, has some known risks at higher doses though these risks are extremely rare at the doses used in this study. The risks of the study medicines are the same whether they are given in the study or for treatment of asthma outside of this study. About 1 out of every 10 children who receive IV Mg have a brief drop in their blood pressure, enough to be measured but not enough to cause any symptoms or need treatment. Mild discomforts are more common, but limited to the 20 minutes while the medicine is being given. These include diarrhea, nausea, facial flushing, and stomach cramping.

Since all of the medications used in this study are routinely used as part of standard care, your child would have likely experienced some of these risks whether or not he/she was in this study. One of the risks of participating in the research is related to the randomization. Because your child's treatment was randomized (like flipping a coin), the doctor did not have a choice as to which treatment your child received. If there had been a problem related to the randomization, your child would have been immediately withdrawn from the study and the doctor would have treated your child as he/she believed was best for your child's condition.

There is also a risk of breach of confidentiality related to participation in the study. We will do our best to keep all of your medical information that we collect confidential. We will keep your study information in a secure location during and after the study. Only the members of the study team and the persons and entities listed below will have access to your medical information for the study.

**REPRODUCTIVE RISKS**

Though IV Mg is approved for use in late pregnancy to prevent and treat seizures in the setting of preeclampsia and eclampsia, it is unknown how it affects pregnancy when given for asthma, especially at other points in the pregnancy. For this reason, we will not include any patients who are pregnant. We

will do pregnancy tests in girls who are 12 years or older. The pregnancy test must be negative to participate in this study.

**UNFORESEEABLE RISKS**

In addition to the risks listed above, your child may experience a previously unknown risk or side effect.

**What are the possible benefits?**
Because we do not know which of the amounts of medicine is better, your child may benefit from receiving a higher amount, but this is not guaranteed. Depending on when your child is enrolled in the study, there may be an increased likelihood of being given the best medication. You may not get any benefit from being in this research study. However, the information that we get from this study may benefit patients in the future.

**What happens if I choose not to continue in the study?**

Being in this study is entirely voluntary. You are also free to withdraw your permission for your child to continue in the study at any time. If you decide not to continue your child's participation, your decision will not affect your child's current or future medical care in any way. You may ask and will receive responses to any questions during the course of the study. If you choose not to continue, no further information will be collected about your child.

**PERSON TO CONTACT**

If you have questions, complaints or concerns about this study, you can contact Dr. Michael Johnson at 801-935-0503. If you think your child may have been injured from being in this study, please call the Primary Children's Hospital Emergency Department at 801-662-1200. The emergency department can be reached at this number during 24-hours a day.

**Institutional Review Board:** Contact the Institutional Review Board (IRB) if you have questions regarding your child's rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

**Research Participant Advocate:** You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

**RESEARCH-RELATED INJURY**

If your child is injured from being in this study, medical care is available Primary Children's Hospital, as it is to all sick or injured people. The University of Utah and Primary Children's Hospital have not set aside any money to pay the costs for such care. The University and Primary Children's Hospital will work with

you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care your child receives. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If your child is injured in this study, and you want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

**RIGHT OF PHYSICIANS TO STOP THE STUDY**

The doctors treating your child can stop the treatment medication if they feel this is best for your child's safety. If this happened, they would treat your child following standard care and best judgment.

**COSTS AND COMPENSATION TO PARTICIPANTS**

You or your child will not be paid to be in the study. The study medicines will be provided free of charge. However, medical care received during this hospital visit will still be billed to you and/or your insurance according to hospital policy. If you received a bill that you believe is related to your taking part in this research study, please contact the study team.

**NEW INFORMATION**

You will be told of any new information discovered during your participation that may affect your choice to continue in the study. We may contact you when the study is completed to share the results.

**NUMBER OF PARTICIPANTS**

About 90 children at 3 hospitals across the United States will participate in this study. Enrollment will take place over about 7 months. About30 children will be enrolled here at Primary Children's Hospital. No one will be included or prevented from participating based on gender, race, color, economic status, or national origin.

**AUTHORIZATION FOR USE OF YOUR CHILD'S PROTECTED HEALTH INFORMATION**

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your child's health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like your child's name, medical record number(s) and contact information

- Related medical information about your child like his/her condition and treatment in the emergency department, medical history, some tests and findings during the hospitalization, adverse events, and the dates of hospital admission and discharge

- All tests and procedures that will be done in the study

**How we will protect and share your child's information:**

We will do everything we can to keep your child's information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your child's medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

To protect your privacy, the information about you gathered for this study will be coded with a special study number. Your name and information that could identify you will be stored securely at the site where you were enrolled or in the study database. In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research, including monitors and others from the study team or other groups with oversight or regulatory responsibilities. These include:

- Members of the research team and University of Utah and/or Primary Children's Hospital
- The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
- Other academic research centers we are working with: Children's Hospital of Philadelphia, Nationwide Children's Hospital, and a research coordinating office: Data Coordination Center of the University of Utah
- University of California Davis
- The study funding agency at National Heart, Lung, and Blood Institute, at the National Institutes of Health, and its affiliates
- Food and Drug Administration
- Study Data and Safety Monitoring Board
- BD Medical, who is supplying the PIVO device for blood collection will receive a de-identified summary of the data pertaining to the collect of blood samples

In addition, records can be opened by court order or produced in response to a subpoena or a request for production of documents.

Your child's records will be kept for as long as necessary for purposes of the research study. During that time they will be kept confidential to the extent permitted by law. The results of this study could be published in an article, but would not include any information that would let others know who you are. Study results will be published by group only and no data shared publicly will include your child's name or identifying information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
If you do not want us to use information about your child's health, your child should not be part of this research.

**What if I decide to Not Participate after I sign the Consent and Authorization Form?**

You can tell us anytime that you do not want your child to be in this study and do not want us to use your child's health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about your child, and your child will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.
This authorization does not have an expiration date.
You have a right to information used to make decisions about your child's health care. However, your child's information from this study will not be available during the study; it will be available after the study is finished.

**CONSENT:**

I confirm that I have read this parental permission document and have had the opportunity to ask questions. I will be given a signed copy of the parental permission form to keep.

The research team for this study is interested in your experience with this consent process and may ask to talk to you about it further now, or in the future, to ask you a few questions about it.

**I agree to allow my child to participate in this research study and authorize you to use and disclose health information about my child for this study, as you have explained in this document.**

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|---|---|
| _____ | _____ |
| Child's Name | Parent/Guardian's Name |
| _____ | _____ |
| Relationship of Parent/Guardian to Child | Parent/Guardian's Signature |
| | _____ _____ |
| | Date Time (24 hr) |

_____
Name of Person Obtaining Authorization and Consent

| | |
|---|---|
| _____ | _____ _____ |
| Signature of Person Obtaining Authorization and Consent | Date Time (24 hr) |

**Informed Withdrawal Addendum**
(Attach to informed consent document only when a participant chooses to withdraw.)

**SIGNATURES:** Sign below if you understand the information given to you about the research and choose **not** to continue. Make sure that any questions have been answered and that you understand the study. If you have any questions or concerns about your rights as a research subject, you may contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

Although you are opting not to continue in the study, we are interested in your experience so that we can learn more about how patients feel about this type of medical research. We may ask to talk to you about your experience further now, or in the future, to answer a few questions about it. Check here if you do not want to be asked. ☐

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| _____ | _____ |
| Child's Name | Parent/Guardian's Name |
| _____ | _____ |
| Relationship of Parent/Guardian to Child | Parent/Guardian's Signature |
| | _____ _____ |
| | Date Time (24 hr) |
| _____ | |
| Name of Person Obtaining Authorization and Consent | |
| _____ | _____ _____ |
| Signature of Person Obtaining Authorization and Consent | Date Time (24 hr) |