Partners HealthCare System
Research Consent Form

Subject Identification

Parent Template
Version Date: January 2019

Protocol Title: Transcutaneous carbon dioxide monitoring in neonates receiving therapeutic hypothermia for neonatal encephalopathy

Principal Investigator: Mohamed El-Dib, MD, FAAP

Site Principal Investigator:

Description of Subject Population: Infants with neonatal encephalopathy undergoing therapeutic hypothermia

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about giving permission for your child to take part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you decide to give permission for your child to take part in this research study, you must sign this form to show that you want him/her to take part. We will give you a signed copy of this form to keep.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Mohamed El-Dib, MD is the person in charge of this research study. You can call him at 571-201-6409. You can also call Eniko Szakmar, a co-investigator in this study at 617-480-5638 with questions about this research study.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

Why is this research study being done?

We are doing this research study to find out more about brain health in newborn babies undergoing therapeutic cooling (hypothermia) for risk of brain injury, called neonatal encephalopathy. One of the factors which could affect the health of the brain of these babies is the level of carbon dioxide (CO_2) in their blood. Currently, clinicians use repeated blood samples to measure CO_2 levels every few hours. However, since extreme levels of CO_2 may have a significant effect on brain health, it is important to have a method for continuous measurement of CO_2 levels. In this study, we will use a clinical device to non- invasively and continuously measure the partial pressure of CO_2 on the skin's surface as an estimate of CO_2 in the blood. A~~n~~ small attachment ring and a sensor will be applied to the skin of the abdomen and/or inner or outer thighs to measure skin CO_2. The carbon dioxide monitor is approved by the U.S. Food and Drug Administration (FDA) to monitor CO_2 in neonates. This device is used routinely in our Unit. However, its feasibility has not been tested in infants receiving therapeutic hypothermia.

Who will take part in this research?

We are asking you to take part in this research study because your baby needs therapeutic cooling for neonatal encephalopathy. About 100 babies will take part in this research study. We will enroll them only at BWH.

What will happen in this research study?

If you decide to give permission for your child to join this research study, the following things will happen. A trained health care professional will apply a small attachment ring and a sensor to the skin of the abdomen and/or inner or outer thighs of your baby. The sensor of the device is warmed to improve the ability to estimate the CO_2 level on the skin's surface. We will change the sensor site as often as every 8 hours during the time of the routine nursing care in order to

minimize the risk for skin irritation. The CO_2 levels will be continuously measured until the end of therapeutic hypothermia treatment. It will take your child about 84 hours (during hypothermia treatment, including the rewarming phase) to complete this research study.

If your baby is receiving breathing support, your child will have CO_2 skin monitoring as well as blood gases for clinical purpose regardless of whether or not you choose to participate in the study. If clinical blood gases are not ordered, we may use up to four small samples (0.2 ml) from the daily routine clinical blood draw ordered by the clinical team (most often from a central line already in place) to check CO_2 levels in the blood for research.

If your child is not receiving breathing support, we will also obtain up to four blood gases from the routine daily clinical blood draws, in addition to applying the CO_2 skin monitor. Further blood sample collection will be based on the decisions of attending physicians, as usual for care.

As part of the study we will collect data from monitors connected to your child for clinical reasons. We may need to apply an additional pulse oximetry probe to non-invasively measure the amount of oxygen in the blood. The pulse oximeter is approved by the U.S. Food and Drug Administration (FDA) to monitor oxygen saturation in neonates. There are no specific risks or discomforts related to the potential application of an additional pulse oximetry probe.

In addition, we will collect data from the medical record including demographic, clinical, laboratory and imaging information.

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

A notation that your child is taking part in this research study may be made in his/her electronic medical record. Information from the research that relates to your child's general medical care may be included in the record (for example: skin CO_2 values). Please ask your child's doctor if you have any questions about what information will be included in his/her electronic medical record.

How may we use and share your child's samples and health information for other research?

The samples and information we collect in this study may help advance other research. If your child joins this study, we may remove all information that identifies you (for example your child's name, medical record number, and date of birth) and use these de-identified samples and

data in other research. It won't be possible to link the information or samples back to your child. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these us.

Will you get the results of this research study?

No. The research study we are doing is a stepping stone in understanding neonatal encephalopathy**.** Therefore, no information about the results of this research study or the results of your child's individual participation in the research study will be given to you or your child's doctor.
However, data from continuous skin CO_2 monitor will be available to your baby's clinical team and they might want to use it to help guide management.

What are the risks and possible discomforts from being in this research study?

Taking part in this research study has some risks and requirements that you should consider carefully. Possible risks and discomforts to know about include the minimal risk of skin injury due to the warmed sensor of the device attached to the skin. We will change the sensor site as often as every 8 hours during the routine nursing care in order to minimize the risk for skin irritation. In previous studies skin complications were reported very rarely.

Risk of breach of confidentiality

There is also a small, potential risk of breach of confidentiality associated with any research study. To minimize this risk, your baby's information will be given a unique study ID number. A master list linking the ID number and your identity will be kept separate from the research data in a password protected database on an encrypted server. Only study team members will have access to the list.

There may be other risks that are currently unknown.

What are the possible benefits from being in this research study?

Your child will not benefit from taking part in this research study. When we finish the research, we hope that we will know more about the relationship between brain injury and CO_2 levels. Our goal is to test our device to see if and how it can be used by doctors and nurses to guide clinical care in babies undergoing therapeutic cooling. Other infants with similar medical conditions may benefit in the future from what we learn in this study.

What other treatments or procedures are available for your child's condition?

If your baby has neonatal encephalopathy, your baby does not have to take part in this research study to be treated for this. The study will not change the care plan for your baby.

Can your child still get medical care within Partners if s/he doesn't take part in this research study, or if s/he stops taking part?

Yes. Your decision won't change the medical care your child gets within Partners now or in the future. There will be no penalty, and your child won't lose any benefits your child receives now or has a right to receive.

We will tell you if we learn new information that could make you change your mind about your child taking part in this research study.

What should you do if you want your child to stop taking part in the study?

If your child takes part in this research study, and you want him/her to drop out, you should tell us. We will make sure that your child stops the study safely. We will also talk to you about follow-up care for your child, if needed.

Also, it is possible that we will have to ask your child to drop out of the study before s/he finishes it. If this happens, we will tell you why. We will also help arrange other care for your child, if needed.

Will you or your child be paid to take part in this research study?

You and your child will not be paid for taking part in this research study.

What will you have to pay for if your child takes part in this research study?

The study has no study-related items or services that incur additional costs. We bill your health insurer for, among other things, routine items and services your child would have received even

if s/he did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care.

If you have any questions about costs to you that may result from your child taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if your child is injured as a result of taking part in this research study?

We will offer your child the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care your child gets for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or your child or give you other compensation for an injury, should one occur. However, you or your child are not giving up any of your legal rights by signing this form.

If you think your child has been injured or has experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If your child takes part in this research study, how will we protect your child's privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about your child from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your child's identifiable information and why they may need to do so:

- Partners researchers and staff involved in this study

- The sponsor(s) of this study, and the people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to your child or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other:

Some people or groups who get your child's identifiable information might not have to follow the same privacy rules that we follow and might use or share your child's identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your child's identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your child's identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your child's privacy. The sponsor has agreed that it will not contact you or your child without your permission and will not use or share your child's identifiable information for any mailing or marketing list. However, once your child's identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your child's identifiable information. Your permission to use and share your child's identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your child's name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Child's Privacy Rights

You have the right **not** to sign this form that allows us to use and share your child's identifiable information for research; however, if you don't sign it, your child can't take part in this research study.

You have the right to withdraw your permission for us to use or share your child's identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, your child cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your child's identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Parent(s)/Guardian for Child:

I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Parent(s)/Guardian for Child | Date | Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the parent(s)/guardian and child.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent | Date | Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the parent(s)/guardian, I interpreted, in the parent(s)/guardian's language, the researcher's presentation of the English consent form. The parent(s)/guardian was given the opportunity to ask questions.

Hospital Medical Interpreter | Date | Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the parent(s)/guardian, I represent that the English version of the consent form was presented orally to the parent(s)/guardian in the parent(s)/guardian's own language, and that the parent(s)/guardian was given the opportunity to ask questions.

Name	Date	Time (optional)

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