PARENTAL CONSENT - CLINICAL BIOMEDICAL

Animal assisted interactions with an animal robot during physical and occupational therapy sessions in the Pediatric ICU: A feasibility study (PCRG)

Title of this Research Study

Animal assisted interactions with an animal robot during physical and occupational therapy sessions in the Pediatric ICU: A feasibility study (PCRG)

Invitation

You are invited to allow your child to take part in this research study. You have a copy of the following, which is meant to help you decide whether or not to allow your child to take part:

- Informed consent form
- "What Do I need to Know Before Being in a Research Study?"
- The Rights of Research Subjects

Why is your child being asked to be in this research study?

Your child is being asked to participate in this research study because he/she is a critically ill patient in the pediatric intensive care unit (PICU) who is 5-18 years of age.

What is the reason for doing this research study?

The purpose of this study is to explore the calming effect of PARO™ during physical therapy and occupational therapy (PT/OT) sessions with critically ill patients in the PICU. PARO™ is a relaxation electronic device that resembles a baby harp seal. PARO™ has been approved by the United States Food and Drug Administration (FDA).

What will be done during this research study?

If you choose for your child to participate in this study, he/she would remain in the study for up to 7 PT/OT sessions with PARO™ or until he/she is discharged from the PICU. Information about your child's pain and anxiety will be collected 30 minutes prior to and within 30 minutes after each PT/OT session with PARO™.

Study Investigators will make sure your child is awake, alert, and able to follow commands, free from significant vision or hearing deficits, and able to verbalize. We will be collecting data from your child's personal medical record. We will record information related to their oxygen needs, vital signs, how awake and alert he/she is, the types and amount of soothing and pain reducing drugs he/she receives, the length of each therapy session and his/her activity performance, the types of equipment used to provide the care your child needs, and the information about the

medical conditions he/she had prior to coming to the intensive care unit.

The following table includes a description of PARO™s components and a detailed list of the calming activities that may occur during your childs PT/OT sessions with PARO™.

<table>
<tr><th colspan="2">Intervention Components</th></tr>
<tr><td colspan="2">PARO™ has five kinds of sensors: tactile, light, auditory, temperature, and posture. These sensors allow it to perceive people and its environment in real time.
1. Light & Temperature: PARO™ recognizes light and dark as well as regulates temperature specific to its activity level
2. Tactile & Posture: PARO™ detects pressure, movement, and position.
3. Audio: PARO™ recognizes the direction of voice and words such as its name, greetings, and praise. It learns to behave in a way that the user prefers, and to respond to its name.
PARO™ can be cleaned with hospital grade cleaners while the devise also contains silver for sanitation purposes.</td></tr>
<tr><th colspan="2">Potential Calming Activities that we may do with in the PICU with Paro™</th></tr>
<tr><td><u>Speech</u>
• Calling PARO™'s name
• Clapping hands to get PARO™'s attention
• Using voice to talk to PARO™
• Telling PARO™ stories</td><td><u>Balance & Endurance</u>
• Reaching to PARO™ from right or left side across the body
• Moving PARO™ from one surface to another while sitting or standing
• Pushing PARO™ while PARO is in a cart (attached to walker)
• Walking while holding PARO™</td></tr>
<tr><td><u>Memory</u>
• Remembering PARO™'s name, species
• Participating activities with a PARO™ picture book</td><td><u>Self-Esteem</u>
• PARO™'s total acceptance of disability and/or appearance
• Empowerment in getting a response to movement or voice
• Increased social interaction with others because of PARO™</td></tr>
<tr><td><u>Fine Motor</u>
• Petting, brushing, feeding
• Dressing, undressing
• Cleaning</td><td><u>Sensory Stimulation</u>
• Feeling fur and body warmth
• Feeling flippers, tail, nose, feet, nails, tails, ears, nose, etc.
• Hearing barking and other vocalizations</td></tr>
</table>

At the end of the study treatment, your child will be asked questions to assess

his/her perception of PARO™. Your child will also be asked to rank his/her satisfaction with PARO™ from 1-5 (1=not at all, 3=somewhat, 5=very much).

What are the possible risks of being in this research study?
There is a risk of transmission of infectious particles from PARO™ to your child. There is also a risk that your child may become emotionally attached to the PARO™ robot. There is a small risk of loss of confidentiality.

It is possible that other rare side effects could occur which are not described in this consent form. It is also possible that your child could have a side effect that has not occurred before.

What are the possible benefits to your child?
Your child may not get any benefit from being in this research study.

It is possible your child may experience improved psychological symptoms and experience comfort, relaxation, and a positive mood from their sessions with PARO™

What are the possible benefits to other people?
What is learned in this research study may help in the treatment of patients admitted to the PICU in the future.

What are the alternatives to being in this research study?
Instead of being in this research study you can choose not to allow your child to participate.

What will allowing your child to be in this research study cost you?
You will be responsible for any applicable insurance deductibles and co-payments. If you wish to speak with a financial counselor about your child's insurance coverage and benefits, let the investigator or other study personnel know. A contact for personal assistance will be made available for you.

Will you or your child be paid for being in this research study?
Neither you nor your child will be paid to be in this research study.

Who is paying for this research?
This research is being paid for by grant funds from the UNMC Pediatric Cancer Research Group. The Institution receives money from the UNMC Pediatric Cancer Research Group to conduct this study.

What should you do if your child is injured or has a medical problem during this research study?
Your child's welfare is the main concern of every member of the research team. If he/she is injured or has a medical problem or some other kind of problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

How will information about your child be protected?
Your child has rights regarding the protection and privacy of his/her medical information collected before and during this research. This medical information is called "protected health information" (PHI). PHI used in this study may include his/her medical record number, address, birth date, medical history, the results of physical exams, blood tests, x-rays as well as the results of other diagnostic medical or research procedures. Only the minimum amount of PHI will be collected for this research. Your child's research and medical records will be maintained in a secure manner.

Who will have access to information about your child?
By signing this consent form, you are allowing the research team to have access to your child's PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at the Institution.

Your child's PHI will be used only for the purpose(s) described in the section "What is the reason for doing this research study?"

You are also allowing the research team to share his/her PHI, as necessary, with other people or groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Federal law requires that the subject's information may be shared with these groups:
    - The HHS Office of Human Research Protections (OHRP)

You are authorizing us to use and disclose your child's PHI for as long as the research study is being conducted. You may cancel your authorization for further collection of your child's PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, your child will no longer be able to participate in this research.

At some time in the future, we may take the identifiers off the information. It is

possible that this information without identifiers could then be used for other research studies by us, or by another investigator, without asking you or your child for permission.

How will results of the research be made available to you during and after the study is finished?
In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your child's identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address: *985330 Nebraska Medical Center, Omaha, NE 6818-5330*

What will happen if you decide not to give permission for your child to be in this research study?
You can decide not to give permission for your child to be in this research study. Deciding not to be in this research will not affect your child's medical care or his/her relationship with the investigator or the Institution. Your child's doctor will still take care of him/her. Your child will not lose any benefits to which he/she is entitled.

What will happen if you decide to stop your child's participation once it starts?
You can stop your child's participation in this research (withdraw) at any time by contacting the Principal Investigator or any of the research staff. Deciding to withdraw will otherwise not affect your child's care or relationship with the investigator or this institution. Your child will not lose any benefits to which he/she is entitled.

Any research data obtained to date may still be used in the research.

Will you be given any important information during the study?
You will be informed promptly if the research team gets any new information during this research study that may affect whether you would want your child to continue being in the study.

What should you do if you have any questions about the study?
You have been given a copy of *"What Do I Need to Know Before Being in a Research Study?"* If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent

form or any other documents that you have been given.

What are your child's rights as a research subject?
Your child has rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning his/her rights or complaints about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
    - Telephone: (402) 559-6463.
    - Email: IRBORA@unmc.edu
    - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
    - Telephone: (402) 559-6941
    - Email: unmcrsa@unmc.edu

Optional Banked Data (Registry)
As part of this study, the study investigator will collect contact information about the person signing the consent form. This includes the caregivers name, telephone number, and email address. The investigator would like to store this information for future research studies. This data will be stored at UNMC in a secure location. The study investigator will be the only person with access to this data. By agreeing to this optional portion of the study, you will agree to allow the study investigator contact you for participation in future studies that may be applicable to either you or the subject in this study. You do not have to agree to participate in this portion of the study. Your decision not to participate will not influence your ability to participate in the main study.

Storage of contact information for future studies (Initial and Date):

_____ You agree to allow the investigator to maintain your information for future studies.
_____ You do not agree to allow the investigator to maintain your information for future studies.

Documentation of informed consent
You are freely making a decision whether to give permission for your child to be in this research study. Signing this form means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to permit your child to be in the research study.
- If you have any questions during the study, you have been directed to talk to one of the investigators listed below on this consent form.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Parent/Guardian _____
Date _____

You are agreeing to be in this research study. You have had someone explain the study to you, and answer your questions.

Signature of Subject _____
Date _____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the parent(s)/guardian(s) of the subject. In my judgment, the parent(s)/guardian(s) possesses the legal capacity to give informed consent for the subject to participate in this research and is voluntarily and knowingly giving informed consent.

Signature of Person obtaining consent _____
Date _____

Authorized Study Personnel
Principal
* Hetland, Breanna
phone: 402-559-5460
alt #: 309-231-4537
degree: PhD, RN, CCRN-K

Participating Personnel
* Bach, Christina
phone: 402-559-6561
alt #: 904-238-0551
degree: BSN

* Coates, Allison
phone: 402-559-1633
degree: BS

* Rubenfeld, Ellie
alt #: 402-559-1633
degree: BSN

* Wawers, Abigail
alt #: 403-559-1633
degree: BSN

What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

How is this research different than the care or treatment I would get if I wasn t in the research? Are there other treatments I could get?

Does **everyone** in this research study get the same treatment?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? Will the doctor still take care of me if I say **no**?

Can I **stop** being in the research once I ve started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

Make sure all your questions are answered before you decide whether or not to be in this research.

THE RIGHTS OF RESEARCH SUBJECTS
AS A RESEARCH SUBJECT YOU HAVE THE RIGHT

to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

to freely decide whether or not to take part in the research.

to decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

to ask questions about the research at any time. The investigator will answer your questions honestly and completely.

to know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

to privacy and confidentiality. The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

to be treated with dignity and respect at all times

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.