Informed Consent Form: Patient Informed Consent Form (Parental Consent for Child Participation)

Official Title:

Robot Rehab: Animal Assisted Interactions With a Robotic Baby Harp Seal During Inpatient Pediatric Rehabilitation

ClinicalTrials.gov Identifier (NCT Number):

NCT05275543

Document Date:

December 15, 2025 (Version 10)

CONSENT FORM
Parental Consent Form for child participation

Title of this Research Study

Invitation and Summary

You are invited to be in this research study. Taking part in this research is voluntary. You do not have to take part. For the purposes of this document: "You" can refer to:

- Yourself
- The person for whom you are the Legally Authorized Representative (LAR)
- Your child under the age of 19.

"Organization" can refer to: University of Nebraska Medical Center (UNMC), Nebraska Medicine (NM), University of Nebraska at Omaha (UNO) or Children's Nebraska (CN).

Here is a summary of the purpose, methods, risks, benefits, and alternatives, to help you decide whether or not to take part in the research.

Purpose
To learn more about the healing effects of Paro, a therapeutic device that resembles a baby harp seal.

Methods
We will randomly put your child into a study group (intervention vs. control). If they are in the intervention group, they will get to work with Paro during their PT/OT sessions. If they are in the control group, they will do their regularly scheduled PT/OT sessions without Paro.

Participation in this study is expected to last for a maximum of 4 PT/OT sessions. We will collect information about your child's pain, anxiety, mood, opinion on pets, and overall motivation to participate in therapy. We will collect data from your child's personal medical record. If your child is assigned to the intervention group, your child will be asked questions to assess his/her perception of Paro.

Risks
There is a risk of transmission of infectious particles from Paro to your child. There is also a risk that your child could become emotionally attached to Paro.

Benefits

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There may be no benefit to participating in this study. Instead of being in this study, you can choose to not have your child not participate. However, it is possible that your child will experience improved psychological symptoms and experience comfort, relaxation, and a positive mood from their sessions with Paro. Also, if your child the control group and doesn't get to work with Paro, they may benefit from the increased awareness and attention to their needs.

Alternatives
Instead of being in this study, you can choose not to participate.

Why are you being asked to be in this research study?
Your child is voluntarily being asked to participate in this research study because he/she is a patient at Children's Hospital & Medical Center and is 3-18 years of age.

What is the reason for doing this research study?
The purpose of this study is to explore the beneficial treatment effects of Paro during physical and occupational (PT/OT) therapy sessions. Paro is a therapeutic robotic device that resembles a baby harp seal. The United States Food and Drug Administration (FDA) has approved this device.

What will be done during this research study?
If you choose for your child to participate in this study, we will randomly put your child into a study group (intervention vs. control). If they are in the intervention group, they will get to work with Paro during their PT/OT sessions. If they are in the control group, the will do their regularly scheduled PT/OT sessions without Paro. Individual participation in this study is expected to last for a maximum of 4 PT/OT sessions.

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 hospital. We will also ask your child about their opinion about pets and their overall motivation to participate in therapy. If your child is assigned to the intervention group, at the end of the study treatment, your child will be asked questions to assess his/her perception of Paro.

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

Intervention Components	
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. A. Light & Temperature: Paro recognizes light and dark as well as regulates temperature specific to its activity level B. Tactile & Posture: Paro detects pressure, movement, and position. C. Audio: Paro recognizes the direction of voice and words such as its name, greetings, and praise. Paro is covered in fur that has been impregnated with silver and therefore has natural antimicrobial defenses. In addition, the robot can be cleaned with hospital-grade cleaners.	
Categories of Therapeutic Activities	
Speech • Calling Paro's name • Clapping hands to get Paro's attention • Using voice to talk to Paro • Telling Paro stories	**Balance & Endurance** • 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
Memory • Remembering Paro's name, species • Participating activities with a Paro picture book	**Self-Esteem** • 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
Fine Motor • Petting, Brushing. Feeding • Dressing, undressing • Cleaning	**Sensory Stimulation** • Feeling fur and body warmth • Feeling flippers, tail, nose, etc. feet, nails, tails, ears, nose, etc. • Hearing barking and other vocalizations

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 you?

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. Also, if your child the control group and doesn't get to work with Paro, they may benefit from the increased awareness and attention to their needs.

What are the possible benefits to other people?

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What is learned in this research study may help in the treatment of patients admitted to the hospital 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 being in this research study cost you?
You will be responsible for any applicable insurance deductibles and co-payments related to a standard therapy session; however you will not be charged for any research only procedures. 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 be paid for being in this research study?
You and your child will receive a single $25 VISA gift card for participating in the study and completing all follow-up questionnaires.

Who is paying for this research?
This research is being paid for by grant funds from the UNMC Pediatric Cancer Research Group.

What should you do if you are injured or have 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 you be protected?
In the course of this research we may collect information about you. This can be things that could be used to find out who you are (like your name, phone number, birthdate, address). We call this "identifiable private information". We will keep this information as confidential as possible.

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 by us, or by another researcher, without asking you for your permission.

Who can see information about you?

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We also will get medical information about your child (like medical record number, medical history, or the results of physical exams, blood tests, x-rays or other medical or research procedures). We call this "protected health information" or PHI. PHI is protected by a law called the HIPAA Privacy Rule. We will collect the smallest amount of PHI that we can. We will keep your child's PHI as confidential as possible.

By signing this consent form, you are letting us (the researchers listed on this consent form and other people involved in this research at the Organization) have access to your child's PHI. Your child's PHI will be used only for the purposes described in the section "What is the reason for doing this research study?"

You can change your mind and tell us to stop collecting your child's PHI for use in this research at any time by writing to the principal investigator. We can still use the PHI we have already collected. If you tell us to stop collecting your child's PHI, you will have to stop being in this research.

We may share your child's PHI with other groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- The HHS Office for Human Research Protections (OHRP)

We may share your child's PHI with other groups listed below. The HIPAA Privacy Rule requires these groups to protect your child's PHI.

- The Food and Drug Administration (FDA)
- Your health insurance company

You are letting us use and share your child's PHI for as long as the research is going on.

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

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A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen if you decide not 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 participating once you start?
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?
We gave you a copy of *"What Do I Need to Know Before Being in a Research Study?"*

If you ever have any questions about this study, call the Principal Investigator or anyone else listed on this consent form.

What are your rights as a research participant?
You have 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 your rights, or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)

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- 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

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.
- You have been told you can talk to one of the researchers listed below on this consent form if you have any questions during the study.
- 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 subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate

Signature of Person Obtaining Consent_____
Date_____

Authorized Study Personnel
Principal
* Hetland, Breanna

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