Informed Consent Form: Adult Informed Consent Form

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
Adult Consent for parent/guardian 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 ask you about the nature of your relationship to the child, as well as your current level of stress, anxiety, depression, and emotional distress.

Risks
There are no known risks in regards to your participation in this study.

Benefits
There may be no benefit to participating in this study.

Alternatives

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

Why are you being asked to be in this research study?
You are being asked to participate in this research study because you are the parent or guardian of a patient at Children's Hospital & Medical Center who 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 robot 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?
We will randomly put your child to 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 receive 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 ask you about the nature of your relationship to the child, as well as your current level of stress, anxiety, depression, and emotional distress. If your child is in the intervention group, at the end of the study treatment, we will ask you about your perceptions of the child's interactions with Paro.

What are the possible risks of being in this research study?
There are no known risks to being in this research.

What are the possible benefits to you?
You may not get any benefit from being in this research study.

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 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 take part.

What will being in this research study cost you?

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There is no cost to you to be in this research study.

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 health and safety is our main concern. If you are injured or have a medical problem or some other kind of problem because of the study call someone 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.

Who can see information about you?
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) to have access to your research data. Your research data will be used only for the purpose(s) described in the section "What is the reason for doing this research study?".

You can change your mind and tell us to stop collecting further research data for use in this research at any time by contacting the principal investigator or any of the study personnel listed at the end of the consent form. However, the information which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to take part in this research.

We may share your research data 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)

How will results of the research be made available to you during and after the

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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 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.

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 be in this research study. Deciding not to be in this research will not affect your relationship with the investigator or the organization. You will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop being in this research (withdraw) at any time. Just call the researcher or any research staff.

If you stop being in the research study it will not affect your care or your relationship with the investigator or the organization. You will not lose any benefits to which you are entitled.

Will you be given any important information during the study?
We will tell you right away if we get any new information that might make you change your mind about 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.

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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)
    - 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 deciding whether to be in this research study. Signing 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 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 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

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INACTIVE

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