Study Protocol and Statistical Analysis Plan

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:

August 19, 2024 (Protocol Version 16)

Biomedical
SECTION I

Therapeutic/Non-Therapeutic
Does your research involve a drug, medical device, technique or other intervention or strategy (including means like diet, cognitive therapy, behavioral therapy, exercise) to diagnose, treat or prevent a particular condition or disease: "THERAPEUTIC RESEARCH"?
Yes

1. Title of Protocol:
Robot Rehab: Animal assisted interactions with a robotic baby harp seal during inpatient pediatric rehabilitation

2. Responsible Personnel:
A. Principal Investigator (PI):
Hetland, Breanna D - CON-Omaha Division - 402-559-5460 - breanna.hetland@unmc.edu - alt #: 309-231-4537 - degree: PhD, RN, CCRN-K - address: CNS 50102 UNMC Midtown (Zip 5330) - phone: 9-5460

B. Secondary Investigator (SI):
Coulter, Donald (Don) W - Pediatrics Hematology/Oncology - 402-559-7257 - dwcoulter@unmc.edu - alt #: 402-559-4925 - degree: MD - address: UT1 5120 UNMC Midtown (Zip 2168) - phone: 9-7257

Kupzyk, Kevin A - CON-Omaha Division - 402-552-7262 - kevin.kupzyk@unmc.edu - alt #: 402-552-7262 - degree: PhD - address: CNS 5091 UNMC Midtown (Zip 5330) - phone: 2-7262

Roberts, Holly Jean - MMI Psychology - 402-559-5762 - hroberts@unmc.edu - alt #: 402-559-5762 - degree: PhD - address: MMI-SCOTT 40154 Off Campus (Zip 5450) - phone: 9-5762

C. Participating Personnel:
Connely, Danielle Marie - Rehabilitation - 3082931776 - dconnely@childrensomaha.org - alt #: 402-955-8355 - degree: OTD, OTR-L

Hoover, Denise M - CHRI Administration - 402-559-0686 - dmhoover@unmc.edu - alt #: 402-559-0686 - degree: BS - address: CN-IHW 8200 Dodge Street, IHW5 (Zip 5456) - phone: 402-981-8010

Kirk, Ashley Nichole - Rehab Services - 4029557389 - akirk@childrensomaha.org - alt #: 402-955-7389 - degree: MS, CCC-SLP

Rogers, Katie - - - karogers@childrensomaha.org - alt #: 402-955-8355 - degree: DPT

Rowberry, Carissa - - - crowberry@childrensomaha.org - alt #: 402-955-8355 - degree: DPT

D. Lead Coordinator:
O'Neill, Sarah M - CHRI Administration - 402-616-0562 - sarah.oneill@unmc.edu - alt #: 402-616-0562 - degree: BS - address: CN-IHW 8200 Dodge Street, IHW-5 (Zip 5456) - phone: 402-616-0562

E. Coordinator(s):
Ellenberger, Laura E - CHRI Administration - 402-559-6709 - lellenberger@unmc.edu - degree: BS, MPH - address: does not work on cam (Zip 4365)

F. Data/Administrative Personnel:
Van Ormer, Matt C - CHRI Administration - 402-559-6709 - matthew.vanormer@unmc.edu - alt #: 000-000-0000 - degree: N/A - address: CN-IHW 8200 Dodge Street, IHW5 (Zip 5456) - phone: 9-2511

G. Are you a student or house officer?
No

3. Funding Source:
Check all that apply and provide the source of the funding.
♦ Cooperative Group: UNMC Pediatric Cancer Research Group
Center for Clinical and Translational Research (CCTR)
Federal (e.g., NIH) Grant - Provide source:
Other Grant:
Departmental funding

Commercial - Provide company name:
Department of Defense
Other - Provide source (e.g. personal funding):

4. Deadline for IRB Approval:
♦ Yes - Explain and provide date: 2/1/2022
No

5. Contract:
Is there a contract associated with this study?
No

6. Agreements
Is there a Material Transfer Agreement (MTA) associated with this study?
No

Is there a Data Use Agreement (DUA) associated with this study?
No

Is there a Data Transfer Agreement (DTA) associated with this study?
No

7. Study Sites:
A. Provide the names and locations of all study sites where this research will be conducted under the oversight of the UNMC IRB or Joint Pediatric IRB.
Children's Hospital and Medical Center (CHMC)

B. Will the research be conducted at external sites under the oversight of an external IRB?
No

C. Does UNMC, TNMC, CHMC or UNO serve as the lead site with responsibility for data and/or safety monitoring?
Yes

List the sites.
Children's Hospital and Medical Center (CHMC)

D. Does this study involve any international sites where the PI will either; 1) conduct 2)

supervise or 3) receive / ship HBM or data to / from UNMC?
No

E. Does this study involve face to face contact with subjects?
Yes

8. Principal Investigator Assurance
The PI understands and accepts the following obligations to protect the rights and welfare of research subjects in this study:
I certify that:

- **I have carefully reviewed this application and all supporting documents. I have determined that the application is accurate, complete and ready for submission to the IRB.**
- **I, and all listed research personnel, have the necessary qualifications, expertise, and hospital credentials to conduct this study in a manner which fully protects the rights and welfare of research subjects.**
- **There are, or will be, adequate resources and facilities to safely initiate, carry out and complete this research at the study sites specified in Section I.7. This includes sufficient staff, funding, space, record keeping capability, and resources necessary to address adverse events and any unanticipated problems involving risk to the subject or others. If the necessary resources become unavailable I will promptly notify the IRB.**
- **All listed research personnel, including external investigators, will be given a copy of the final IRB approved application and any other relevant study-related documents in accordance with their defined responsibilities.**
- **All listed research personnel, including external investigators, will be notified promptly of any changes in protocol, in accordance with their defined responsibilities.**
- **Research personnel, including data and administrative personnel who have access to protected health information (PHI) or subject identifiers will have adequate training in confidentiality and protection of PHI.**
- **The minimum amount of protected health information (PHI) or other identifiers necessary will be used and disclosed to conduct this research study (if applicable). I will implement reasonable safeguards to protect the PHI/identifiers at all times.**
- **I and all other personnel listed in Section I.3A-E of the IRB Application have disclosed all potential financial conflicts of interest as required and are in full compliance with the UNMC Conflict of Interest Policy #8010 and HRPP Policy. I further certify that all potential financial conflicts of interest are appropriately managed in order to ensure protection of the rights and welfare of subjects.**

I recognize that:

- **As the PI it is my responsibility to ensure that this research and the actions of all research personnel involved in conducting the study will comply fully with the IRB-approved protocol (including all amendments), all applicable federal regulations, state laws, and HRPP policies.**
- **It is my responsibility to ensure that valid informed consent/assent will be obtained, as appropriate, from all research subjects or their legally authorized representative(LARs).**

I will:

- **Ensure that all research personnel involved in the process of consent/assent are properly trained and are fully aware of their responsibilities relative to the obtainment of informed consent/assent according to federal regulations, state laws, and HRPP policies.**
- **Promptly inform the IRB of internal adverse events, as well as any unanticipated problems involving risk to the subjects or to others, as required within the time frame defined by HRPP policies. I will analyze each internal adverse event/reported problem to determine if it impacts the risk-benefit relationship of the study, the safety of the subjects, or informed consent.**
- **Analyze each MedWatch/safety report to determine if it impacts the risk/benefit relationship of the study, the safety of the subjects, or informed consent.**
- **Promptly submit external adverse event reports in accordance with HRPP policies.**
- **Promptly inform the IRB if I become aware of 1) any complaints from research subjects, LARs, or others about research participation, 2) violations of federal regulations or state law, 3) violations of the HIPAA Rule, or 4) violations of HRPP policies.**
- **Promptly inform the IRB of the results of external audits performed by sponsors, Contract Review Organizations (CROs), cooperative groups, FDA, or other external groups.**
- **Not initiate any change in protocol without IRB approval except when it is necessary to reduce or eliminate a risk to the subject, in which case the IRB will be notified as soon as possible.**
- **Promptly inform the IRB of any significant negative change in the risk/benefit relationship of the research as originally presented in the protocol and approved by the IRB.**
- **Maintain all required research records on file and I recognize that representatives from the IRB, OHRP, HHS, FDA, and other Federal Departments or Agencies may inspect these records in accordance with granted authority.**

I understand that:

- **Continuing review by the IRB is required at least annually, or as per Federal**

Regulations and HRPP Policy, in order to maintain approval status. I will maintain IRB approval as long as this study is active.

- **I am responsible for appropriate research billing in accordance with UNMC Clinical Trial Professional and Technical Fee Billing Policy #8008 or applicable Children's Hospital & Medical Center policy.**

Failure to comply with the Common Rule, applicable Subparts B, C, and D of HHS regulations at 45 CFR 46, applicable FDA regulations, the HIPAA Rule, applicable state law, HRPP policies, and the provisions of the IRB-approved protocol may result in suspension or termination of IRB Approval of my research project and/or other administrative or legal actions.
Hetland, Breanna D - 2024-08-19 14:48:08.427

9. Principal Investigator Financial Interest Disclosure
A. As the PI, I declare:
♦ I have no financial interest in this research.
I have a financial interest in this research.

B. As the PI, I understand
♦ I must disclose any change in my financial interest during the course of this research within five (5) business days from the time the change becomes known.

C. As the PI, I certify that:
♦ No Responsible Personnel have a financial interest in this research.
The Responsible Personnel listed below have informed me that they have a financial interest in this research.

D. I have informed all Responsible Personnel that if there is any change in their financial interests during the course of this study it must be disclosed within five (5) business days from the time the change becomes known.
Hetland, Breanna D - 2024-08-19 14:48:08.427

11. Resource Review Certification
Resource Reviewer:
Fiandt, Kathryn (Kate) Lee - CON-Omaha Division - 402-559-2238 - kfiandt@unmc.edu - alt #: 409-750-2300 - degree: PhD/APRN-NP - address: CON 2007 UNMC Midtown (Zip 5330)

As the Resource Reviewer,
♦ I do not have a financial conflict of interest associated with this study.

I do have a financial conflict of interest associated with this study.

My signature certifies that:

- **The PI has the necessary qualifications, experience and credentials to conduct this research.**
- **The PI has or will have the necessary funding to support this research.**
- **There is or will be adequate physical space required for the research interventions at all study sites specified in Section I.7.**
- **There is or will be adequate laboratory and clerical support, data storage capability, and any other resources necessary to complete this research.**
- **There is or will be emergency equipment, personnel, or services necessary to respond promptly to adverse events or subject injures at all study sites specified in Section I.7.**
- **I will promptly notify the IRB if the necessary resources to support this research become unavailable.**

Fiandt, Kathryn (Kate) Lee - 2022-01-04 09:16:33.863

Do you have any additional comments that you wish the IRB to consider during the review of this application?
No

SECTION II

PROTOCOL ABSTRACT

1. Provide a brief (less than 2500 characters) abstract of the research protocol. (2500 characters)
This summary should include: 1)) a brief description of the purpose of the study, 2) eligibility criteria, 3) interventions and evaluations and 4) follow-up.
Title: Robot Rehab: Animal assisted interactions with a robotic baby harp seal during inpatient pediatric rehabilitation Purpose: To evaluate the feasibility, acceptability, and preliminary therapeutic treatment effects of PARO, a therapeutic animal robot, on hospitalized children and their parents/guardians during physical therapy and occupational therapy sessions at CHMC. Eligibility Criteria: Pediatric patients enrolled in this study will be: (1) age 3-18; (2) admitted to any of the inpatient units at CHMC; (3) have an available parent or guardian; (4) an active consult request for physical therapy or occupational therapy; (5) awake, alert, and able to follow commands; (6) not delirious; (7) able to understand English; and (8) able to verbalize. Pediatric patients will be excluded from participating in this study if they: (1) have a pacemaker; (2) have open wounds without a covering dressing or a dressing that is visibly soiled; (3) have known adverse psychological reactions to animals; (4) show signs of acute agitation [yelling, screaming, moaning, or is otherwise inconsolable]; (5) have excessive bodily secretions per primary bedside nurse; or (6) report feeling nauseated. Parents/Guardians enrolled in this study will be: (1) the parent or guardian of a child participant; (2) age 19 or older. Parents or guardians will be excluded from participating in this study if: (1) the hospital ethics committee is communicating with the parent/guardian in regards to the patient's case. Interventions and Evaluations: Semi-structured, prescriptive therapy sessions with Paro, a robot seal, focused on speech, balance and endurance, memory, self-esteem, fine motor, and sensory stimulation. Subjects will be evaluated during the study to define or measure patient characteristics, intervention acceptability, activity performance, intervention safety, patient psychological and physiologic variables, and guardian psychological variables. Follow-Up: A semi-structured interview will be conducted with the patients and guardians. In addition, an intervention satisfaction measure will be administered after the protocol is complete [either after 4 PT/OT sessions with PARO or at hospital discharge].

PURPOSE OF THE STUDY AND BACKGROUND

2. Purpose of the Study
What are the specific scientific objectives of the research?
Aim 1: Evaluate the feasibility [consent and refusal rates, attrition rates, length, and number of completed therapy sessions], and acceptability [interviews with children and guardians, overall patient and guardian satisfaction] during inpatient physical therapy (PT) and

occupational therapy (OT) sessions.
Hypothesis 1: Animal-assisted interaction (AAI) with Paro, a robotic baby harp seal, during pediatric inpatient PT/OT sessions will be feasible and acceptable.

Aim 2: Assess preliminary efficacy of AAI during PT/OT sessions with Paro on patient behavior (anxiety and affect) and patient motivation to participate in rehabilitation in hospitalized children.
Hypothesis 2: Pediatric patients who use Paro will demonstrate less anxiety, more positive affect, and greater motivation to participate in therapy than those who do not use Paro.

Aim 3: Test the stress, anxiety, and depression levels of parents/guardians of pediatric patients who use Paro inpatient physical and occupational therapy sessions.
Hypothesis 3: In addition, parents and guardians of pediatric patients that use Paro will report less stress, anxiety, and depression compared to parents/guardians of children that do not use Paro.

3. Background and Rationale
Describe the background of the study. Include a critical evaluation of existing knowledge, and specifically identify the information gaps that the project is intended to fill.
Animal Assisted Interactions (AAIs)
AAI are interventions that intentionally incorporate animals as part of a therapeutic process[1] to promote human health, learning, and well-being.[2] In general, domestic and farm animals such as dogs, cats, birds, equines, guinea pigs, rabbits, llamas, sheep, goats, and pigs are predominantly featured in AAI programs.[3] Animals can be observed, held, and petted, or more actively integrated into specific therapy activities such as brushing with different tools to encourage range of motion and fine motor coordination. AAIs also promote exercise through tandem walking with the animals.[4] Recent literature indicates that AAI can improve reality orientation and attention span, eliminate the sense of isolation, reduce stress and anxiety, enhance communication, promote positive social interactions, and enhance overall quality of life.[5] The use of AAI in hospitalized children has the potential to engage patients, guardians, and healthcare staff in an innovative, holistic approach to recovery.[6]

Benefits of Robotic Animals for AAI in Inpatient Settings
While additional research is warranted to further explore the potential impact of AAI on a variety of clinically meaningful patient outcomes, the highly technical, fast-paced hospital environment and the immunocompromised health statuses of many acutely ill hospitalized patients greatly limit the exploration of AAI in inpatient settings.[6] A new frontier in animal robotics opens a vast array of opportunities to implement AAI in hospitalized populations.

Robot animals may be just as effective as live animals and may provide even more flexibility and tailoring to meet the needs of diverse situations that arise in the hospital. In addition, the infection control risk that live animals pose to hospitalized patients may be significantly lessened.

Applying the P.A.C.E. Model to AAIs in Hospitalized Children

This study is guided by an adapted version of the P.A.C.E. (practitioner, animal, client, and environment) Model (Figure 1 in attached grant application), which establishes a framework to assess the goals, precautions, and objectives of each AAI session.[6] Application of the model to the research helps maintain the quality and reliability of each session. The four P.A.C.E. components must be considered individually and together, as they create a reciprocal and evolving relationship that is unique for each session.

Preliminary Data

We are currently completing a single-arm, pretest-posttest exploratory study that used Paro to facilitate rehabilitation in the pediatric ICU. We presented preliminary study results at the 2020 Midwest Nursing Research Conference.[7] At that time, 11 participants ages five to 17 completed the study protocol for a total of 30 individual sessions. The mean number of sessions per subject was 2.7 (SD=1.3), lasting 36 minutes on average (SD=8.6). No statistically significant changes to psychophysiological variables were noted. Subjective feedback was positive and included statements like, "It was different than normal and It made me feel calm".

CHARACTERISTICS OF THE SUBJECT POPULATION

4. Accrual

A. Is this study conducted solely at sites under the oversight of the UNMC IRB (e.g. UNMC, Nebraska Medicine, CHMC, UNO)?

Yes

1. How many subjects will need to be consented (per group, as applicable) in order to achieve the scientific objectives of the research?

60 patient/guardian dyads total (intervention group: n=30; control group: n=30).

2. What is the statistical or other justification for the total number of subjects described above?

Using this pilot study, we will collect some important information regarding feasibility and efficacy of Paro as a rehabilitation intervention. Given the resources and timeline, we have approximated a sample size of 120 participants (60 patient/guardian pairs), divided equally between each study arm, to enable us to determine effect size of the intervention on the

study variables. Also, according to Hertzog (2008) if the aim of the study is to demonstrate intervention efficacy, a sample in the range of 20-25 will likely be adequate. The effect sizes generated from this research will be used to inform future clinical trials hospitalized children.

3. How long do you estimate it will take to accrue the required number of subjects?
We estimate it will take 12 calendar months to recruit the required number of subjects.

5. Gender of the Subjects
A. Are there any enrollment restrictions based on gender?
No

6. Age Range of Subjects
A. Will adults be enrolled ?
Yes

1. What is the age range of the adult subjects?
Age 19 or older.

2. What is the rationale for selecting this age range?
Parents or guardians of the child participant need to be of the legal age of majority, which is 19 in the state of Nebraska.

B. Will children (18 years of age or younger) be included in this research?
Yes

1. What is the justification for inclusion of children in this research?
Inclusion of children in this research will provide a novel therapeutic intervention (Paro) to hospitalized pediatric patients to help alleviate psychological and physiological symptoms during admission to the hosptial.

2. What is the age range for the child subjects, and what is the justification for selecting this age range?
3-18; Patients admitted to the pediatric intensive care unit at Children's Hospital and Medical Center range from infant to 18 years of age. We will be excluding children under the age of 3 due to the likelihood of their developmental and cognitive limitations in regards to completing the assessment measures.

3. Will this study enroll wards of the state?
No

7. Race and Ethnicity
Are there any subject enrollment restrictions based upon race or ethnic origin?
No

8. Vulnerable Subjects
A. Will prisoners be included in the research?
No

B. Select from the list all of the vulnerable populations that will specifically be recruited to participate in this research.
Decisionally-impaired persons
♦ Critically ill patients
Students of the investigator
Employees of the investigator
Educationally disadvantaged individuals
Socially or economically disadvantaged individuals
Individuals with a stigmatizing illness or condition
Individuals from a marginalized social or ethnic group
Other.
No vulnerable subjects will be specifically recruited

Option chosen: Critically ill patients
Describe the additional safeguards to protect the rights and welfare of the critically ill patients.
We will enroll hospitalized pediatric patients, some of which may have varying degrees of decision impairment due to the severity of their illness and/or the drugs they receive. Research team members will make sure the child is awake, alert, and able to follow commands, free from significant vision or hearing deficits, and able to verbalize.

9. Inclusion Criteria
What are the specific inclusion criteria?
Pediatric Patient Inclusion Criteria:
Age 3-18, admitted to inpatient units at CHMC, have an available parent or guardian, an active consult request for PT or OT, awake, alert, able to follow commands, not delirious, able to understand English, and able to verbalize.

Parent/Guardian Inclusion Criteria:
Parent or guardian of a child participant, age 19 or older.

10. Exclusion Criteria

What are the specific exclusion criteria?
Pediatric Patient Exclusion Criteria:
Have a pacemaker, wounds without a covering dressing or a dressing that is visibly soiled, known adverse psychological reactions to animals, excessive secretions via nose or mouth, report feeling nauseated, or shows signs of acute agitation (yelling, screaming, moaning, or is otherwise inconsolable).

Parent/Guardian Exclusion:
Hospital ethics committee is communicating with the parent/guardian in regard to the patient's case.

11. Pregnancy and Contraception Requirements
A. Are women of child bearing potential (WOCBP) included in this research?
Yes

a. Are there any specific contraception requirements for subjects?
No

1. Provide justification for absence of contraception requirements
♦ There are no interventions that are likely to be of risk to a fetus
Investigational drug(s) is (are) not systemically absorbed
Investigational drug(s) is (are) systemically absorbed, but there is no evidence from human studies, or from clinical experience, that there is risk to a fetus
Other

B. Are pregnant women included in this research?
Yes

C. Are breast feeding women excluded in this research?
No

Provide justification for the inclusion or exclusion of breast feeding women.
No intervention is harmful to a mother or child who is breast feeding.

METHODS AND PROCEDURES

12. Methods and Procedures Applied to Human Subjects
A. Are there any evaluations or tests that will be performed for the purpose of determining subject eligibility which would not be routinely conducted as part of

standard clinical care of the prospective subject?
No

B. Describe the research plan, including all procedures, interventions, evaluations and tests.

Screening and Recruitment:

Physicians who write inpatient rehabilitation orders may contact the PI (Hetland) via email to inform her of pending rehab orders. The PI will share that information with the IRB approved interventionists so they can check to see if the patient is on their clinical list for the day. If the patient is on their list, they will follow our already established protocol and introduce the study when they treat the patient. (see below)

When PT/OT receives a consult for treatment of a hospitalized patient, they will asses if the patient is eligible to participate. If they are eligible, the PT/OT will introduce the study to the patient and guardian. If the patient and guardian express interest in participating, the PT/OT will immediately contact the CHMC support staff research assistant (CHMC RA).The CHMC RA will then make contact with the patient. The CHMC RA will verify that the patient meets eligibility criteria. If the patient is eligible to participate, they will then further explain the details of the study to the patient and their parent or guardian. If the patient is interested in participating, the CHMC RA will seek written informed consent in person with the patient and either in person or over the phone or Zoom conferencing with the patient's guardian. Once the consent forms are complete, the CHMC RA will open the randomization envelope and inform the patient and guardian of the study assignment (intervention vs. control). The CHMC RA and PT/OT will work to coordinate the first study session.

Study Session:

Within 30 minutes of the start of the study session, the CHMC RA will begin pretest data collection. The control group will have standard of care therapy sessions without PARO. In the intervention group, the PT/OT provider will begin the therapy session with PARO. The CHMC RA will remain in the room during therapy session to record field notes. When the therapy session is complete, the CHMC RA will begin posttest data collection. The patient will remain in the study for up to 4 PT/OT sessions or until they are discharged from the hosptial. The PT/OT providers will coordinate all subsequent therapy sessions with the CHMC RA while the patient remains on the study protocol. When a patient completes the study protocol, the CHMC RA will complete the post-study data collection. All pre/post data collection measures with the patient will happen in person, at the patient's bedside. However, pre/post data collection measures that are specific to the patient's guardian may be obtained over email or phone/Zoom per the guardian's preference and availability.

Seal Cleaning Procedures:

We will only enroll 1 patient per seal in the protocol at a time. Therefore, PARO will be dedicated only to a single patient in between cleaning procedures. Prior to a new enrollment, PARO will be deep cleaned per our **Deep Cleaning Protocol** by the CHMC RA. We will then test the cleanliness of the seal by swabbing it with our ATP system, Hygiena System SURE Plus (Hygiena & Siliker Inc. Food Science Report, 2010), in 14 different locations per the National Health System position paper (Dodds, Martyn & Brown, 2017). All tests results must be below the established RLU threshold of 30 (Mulvey, Redding, Roberts, Woodall, Kingsmore, Bedwell, & Dancer, 2011). If any of the areas tested do not meet the threshold, the entire seal will be cleaned again. Once all areas tested fall below the 30 RLU threshold, the seal will be placed in its carrier and considered safe to use with the next enrolled patient.

During the days PARO is being used with a single subject, PARO will undergo daily cleaning per the **Daily Cleaning Protocol** by the CHMC RA. During the protocol, PARO will be kept in a hard-plastic pet carrier. Prior to the start of the PT/OT session, the carrier will be placed in the patients room. PARO will be removed from the carrier. The patient will interact with PARO during their PT/OT session. Once the PT/OT session is done, PARO will be placed on a clean towel while the inside of the carrier is cleaned. Then PARO will be cleaned and placed directly back into the carrier. The carrier will be removed from the room and the process will be completed with that same patient the next day. In the case that the patient completes the protocol or is discharged from the hosptial, the **Deep Cleaning Protocol** by the CHMC RA will then be followed prior to the next patient's enrollment. Our cleaning protocols have undergone a series of laboratory tests in partnership with Dr. Rupp and the Nebraska Medicine Infectious Disease Department. Both the **Deep Cleaning Protocol**and**Daily Cleaning Protocol** have been approved by the infectious disease department at CHMC.

Instruments

Data collected directly from the subjects medical record will include the following:

- *Age*
- *Primary Admission Diagnosis*
- *Variables needed to calculate Pediatric Risk of Mortality: Admission source, Cardiopulmonary resuscitation within 24 hours before PICU admission, Cancer (acute or chronic), low-risk systems of primary dysfunction*
- *Type of respiratory support (airway, mode, oxygen percentage, PEEP, respiratory rate, tidal volume)*
- *Level of Consciousness (Glasgow Coma Score, Type and dose of continuous pain medication, sedation frequency, sedation intensity)*
- *Presence of Lines/Tubes/Invasive Equipment*
- *Pre/Post session vital signs (Heart rate, blood pressure, respiratory rate, oxygen*

saturation)

- *Rates of Central Line Associated Blood Stream Infections (CLABSI), Catheter-Associated Urinary Tract Infections (CAUTI), Enteroviruses, Influenza, Multi-Drug Resistant Organism (MDRO), Surgical-site Infections (SSI), and Ventilator-Associated Pneumonia (VAP)*
- *Activity Performance Form - completed by PT/OT in medical record after each session*

Variable	Measure	Timepoint	Recipient
Patient & Guardian Characteristics	Demographic Form	Baseline	Parent & Guardian
Opinion on pets	Pet Attitude Scale	Baseline	Patient
Guardian Stress	Pediatric Inventory for Parents	Baseline, post-study	Guardian
Guardian Anxiety & Depression	Hospital Anxiety and Depression	Baseline, post-study	Guardian
Physiologic Indicators	HR, BP, RR, O2 saturation	Pre-session, post-session	Research Staff, PT/OT
Pain	Wong-Baker FACES pain scale	Pre-session, post-session	Patient
Anxiety	Children's Anxiety Meter-State (CAM-S)	Pre-session, post-session	Patient
Mood/Affect	10-PANAS-C	Pre-session, post-session	Patient
Motivation to participate in therapy	Pediatric Motivation Scale for Rehabilitation	Post-session	Patient
Sedatives Used	Sedative Exposure Instrument	Post-session	Research Staff
Activity Performance	Activity Performance Form	Post-session	PT/OT
Intervention Satisfaction	Semi-structured interviews, Patient Satisfaction Measure	Post-study	Patient & Guardian

C. Select any of the following that apply to the research:

Phase I study

♦ Randomization

♦ Placebo (or non-treatment arm)

Washout

Sensitive surveys or questionnaires

None of the above

Option chosen: Randomization

Describe randomization process and schedule

This study will use simple randomization. Subjects will be randomized upon enrollment.

Do all arms get at least "standard care"?

Yes

D. Identify:

1. All procedures, interventions, evaluations and tests performed solely for research purposes (eg, administration of an investigational drug or a new psychological assessment instrument; randomization)
All therapeutic procedures involving the PARO robot, the evaluation of patients and guardians in both the intervention and control groups, and the extraction of patient data from the electronic medical record are soley performed for the purpose of research.

2. All procedures, interventions, evaluations and tests performed for clinical indication but more frequently than they would be if the subject was not participating in the research (eg, extra blood tests; additional radiology exams)
We will measure vital signs (heart rate, blood pressure, and respiratory rate) more frequently than if the subject was not participating in the research. Typically, these values are assessed once every 4 hours. We will assess them before and after each therapy session (in addition to the once/every 4 hours standard of care).

E. Describe briefly the statistical methods used to analyze the data (or reference the appropriate section of the detailed protocol or grant).
Descriptive statistics will be calculated on all study variables. T-tests or chi-square tests will be used to assess differences in baseline variables across treatment groups. Randomization should provide balanced conditions, but if any differences are observed then those variables will be considered for inclusion as covariates. Outcome variables measured pre-and post-session will be plotted across all times points and assessed for normality. Transformations may be applied if distributions are found to be non-normal. Mixed or hierarchical linear models will be used to determine changes across time within and between groups. Three-level models will be performed with time of session (pre and post), nested within sessions (up to four sessions), nested within patients. Randomization will occur at the patient level so the treatment group will be a level three predictor. Two different group-by-time interactions will be tested. First will be group-by-time of session to test for differences in pre- to post-session change across groups. A group-by-session interaction will test group differences in trends across the course of the study. IBM SPSS Version 28 will be used for data management and basic statistics. SAS Version 9.4 will be used for hierarchical linear models.

F. Does this study involve the collection of blood, urine, saliva or other human biological material (HBM)?
No

DRUGS, BIOLOGIC DRUGS AND DEVICES

13. Drugs and Biologic Drugs

1. Does this research involve the use of drugs or biologics?
No

14. Devices
1. Does this research involve a medical device(s) (including an in vitro device [IVD] (assay), and medical software)?
Yes

A. Check all that apply:
♦ FDA approved (or cleared) device
FDA unapproved device
In Vitro Device (IVD)

1. Describe the device
PARO™, a baby harp seal, is an advanced interactive, therapeutic robot developed by AIST, a leading Japanese industrial automation pioneer. It allows the documented benefits of animal therapy to be administered to patients in environments such as hospitals and extended care facilities where live animals present treatment or logistical difficulties.

2. Specify the manufacturer of the device.
PARO Robots U.S., Inc.
150 E Pierce Road, Suite 550
Itasca, IL 60143
Phone: 847-241-6692
Fax: 847-660-2912
sales@PAROrobots.com

3. Does this research involve collection of safety or effectiveness data for this device?
No

CONFIDENTIALITY AND PRIVACY

15. Confidentiality and Privacy
A. Describe where research data will be stored. Check all that apply.
♦ On a secure server at UNMC, CHMC, Nebraska Medicine, and/or UNO (including REDCap)
♦ On a secure cloud server - Specify the secured cloud serve: UNMC secured Box
♦ On a firewall protected database accessible through the internet - Specify who has administrative responsibility for maintenance of the server: Stephen Bonasera, Joe

Ziskovsky, Chris Hanna, Michael Gleason, Ashok Mudgapalli, Leela Krishna Golla
On an encrypted, password protected local hard drive
On an encrypted, password protected portable computer
On an encrypted, password protected flash drive
♦ In hard copy
Other

a. Please provide justification for use of hard copies
We will use hard copies for participant consents.

b. Will hard copies will be transported from one site to another, on or off campus?
Yes

c. Describe how they will be secured during transport
The PI or RAs will directly transport data in a locked briefcase from the site of collection to the research office at CHMC. Once the study has been completed, all consents and copies will be securely transferred in a locked box from the research office at CHMC to the PI's locked office at UNMC's College of Nursing.

B. Will any of the following subject identifiers be recorded (at any time) in association with the research data?
Yes

1) Indicate the subject identifiers that will be recorded. Check all that apply.
♦ Name
♦ DATES (e.g. date of study visit, date of sample collection, birth, admission, discharge)
♦ Postal address information: street address, city, county, precinct, ZIP code
♦ Telephone numbers
Fax numbers
♦ Electronic mail addresses
Social Security numbers
♦ Medical Record numbers
Health plan beneficiary numbers
Account numbers
Certificate/license numbers
Vehicle identifiers and serial numbers, including license plate numbers
Device identifiers and serial numbers
Web Universal Resource Locators (URLs) Internet Protocol (IP) address numbers
Biometric identifiers, including finger and voice print

Full face photographic images [and any comparable images]
No Identifier

2) Will a unique subject identifying number (e.g., S1, S2, S3), characteristic or code be used to link data to any of the identifiers listed above?
Yes

a. Where will the key (that links the unique subject identification code to the subject's name or other identifier) be stored?
All the information that could identify subjects will be kept strictly confidential. Participants' names and other PHI will be kept in a locked file cabinet in in the research office at CHMC. Once the study has been completed, all consents and copies will be securely transferred in a locked box from the research office at CHMC to the PI's locked office at UNMC's College of Nursing. Only research personnel will be able to access data. Identifiers will be kept separate from the data.

b. Does the code number include the subject's initials or other subject identifier as part of the code?
No

3) What is the justification for recording the specific subject identifiers listed above? Check all that apply.
♦ Schedule appointments
♦ Collect continuous clinical information from the medical records
♦ Follow-up with subjects
Link stored tissue with subject identification for it to be withdrawn in the future if requested
Compensation
Other. Explain.

4) How long will the subject identifiers be maintained in association with the research data?
All data will be collected specifically for the proposed research project. At the end of the dissemination of this study, this confidential data will be destroyed.

5) How will all of the identifiable research data be destroyed (e.g., all identifiers stripped from the data and destroyed, hard copies shredded etc) when the identifiable data is no longer required?
When research data is no longer required for evaluation and dissemination, paper copies will be shredded. An appointment with Information Technology services at UNMC will be

made for proper disposal of electronic information. Destruction of the hard drive will be witness by research personnel. A certificate of destruction will be obtained from the IT department.

C. Will research data that contain subject identifiers be disclosed to:
Other investigators at UNMC, NM, UNO or CHMC who are not listed in Section I of this application?
No

2. Investigators outside of UNMC, NM, UNO or CHMC?
No

3. Will research data that contain subject identifiers be disclosed to any commercial sponsor or contract research organization (CRO), or to any other external organization or entity (e.g., NCI cooperative groups)?
No

D. What provisions will be in place to protect the subject's privacy? Check all that apply.
♦ Ensuring that only personnel listed on the IRB application Section I.3(A-E) are present during the consent process.
♦ Ensuring that the fewest number of individuals possible are aware of the subject's participation in the research.
♦ Ensuring that the research activities are performed in as private of a place as possible.
Other. Explain.

E. Does this research involve data banking at UNMC, NM, UNO or CHMC, or by an outside organization (e.g. NCI Cooperative Group, pharmaceutical company) for future research that is not related to this study?
Yes

a. Does the data include subject identifiers, or a unique subject identifying number, characteristic or code that can be used to link data to any of subject identifier?
Yes

RISK/BENEFIT ASSESSMENT

16. Potential Risks
What are the potential risks associated with each research procedure, intervention,

evaluation and/or test? If data are available, estimate the probability that a given harm may occur and its potential reversibility.
The main potential risk of the animal robot is the transmission of infectious particles, however, with proper ATP testing procedures, we will be able to monitor infection risk in real time before each PT/OT session. Dr. Mark Rupp, Chief - Division of Infectious Disease at Nebraska Medicine has been notified of the project, participated in laboratory testing of cleaning protocols, and has approved the procedures for this study.

There is a risk that the pediatric patient or the parent/guardian may become emotionally attached to the PARO robot. To minimize this risk, the length of the study will be fully explained to the patients and their guardian.

The loss of confidentiality is always a possibility, but measures to protect the participants' identifiable and research data as described above minimize that risk to the extent possible. There are no known risks to the subjects completing the questions. Subjects are free to withdraw from the study at any time.

17. Risk Classification
What is the overall risk classification of the research?
♦ Minimal risk
Greater than minimal risk

18. Minimization of Risk
A. Describe how the subjects of the research will be monitored by the investigators and other research personnel to ensure their safety.
To protect agains possible risk to confidentiality, research data will be stored in a locked cabinet in the research office at CHMC only by study personnel. Once the study has been completed, all consents and copies will be securely transferred in a locked box from the research office at CHMC to the PI's locked office at UNMC's College of Nursing. Only identification numbers will be used on questionnaires. Subject' names and other contact information will be kept in a locked file accessible only by research personnel. Only research personnel will see these patient record, and upon receipt, the records will be coded with study identification numbers and kept in locked filed in a locked research office. All research related files will be stored in a UNMC sponsored Box account. All study personnel will be CITI trained. Study personnel will be involved in meetings and training sessions regarding data collection procedures in which procedures to ensure confidentiality will be covered.

B. Describe how the data collected will be monitored to ensure the safety of subjects. Identify who will perform the ongoing data and safety analysis, and describe the frequency of data analysis. If there is an independent Data and Safety Monitoring Board

(DSMB) provide the charter, or describe (1) the composition of the DSMB membership, (2) the frequency of DSMB meetings and reports.
The PI will review data weekly. Dr. Kevin Kupzyk, Statistician at the College of Nursing will prepare the data reports.

C. Describe the auditing plan for research conducted. Identify who will conduct the audits and specify the audit frequency.
The PI will review data weekly. Results of any protocol violations or unanticipated problems will be reported promptly to the IRB.

D. Describe the specific subject withdrawal criteria.
Once enrolled, subjects will not be withdrawn by investigators. If subjects withdraw consent, they will be removed from the research study, and they can withdraw consent at any time.

E. Describe the stopping rules for the research (e.g., the specific criteria for halting or early termination of the study).
There are no criteria for halting or early termination of the study.

F. Describe plans and resources available to promptly address any subject injury.
Subjects will be closely monitored by the investigator and study team for any adverse events during participation in the clinical trial. Immediate medical care will be provided at CHMC in the event of an injury. Emergency contact information is provided to each subject should any questions or problems arise.

19. Potential Benefits to the Subject
Is there the prospect for direct benefit (eg, research on diagnosis or treatment of disease)?
Yes

Describe potential benefits to the subjects that may reasonably be expected from participation in the research, if any. If there are therapeutic and non-therapeutic components of the research, address anticipated benefits to subjects that may reasonably be expected from each of these components.
Hospitalized patients in the intervention group may experience improved psychological and physiological symptoms. Parents/guardians of children in the intervention group may also experience improved psychological symptoms associated with seeing their child interact with the robotic animal during therapy sessions.

Subjects randomized to the control group may benefit from the increased awareness and attention to their inpatient rehabilitation experience.

20. Potential Benefits to Society

Describe the potential benefits to society that may reasonably be expected to result from this research.

This study will provide new information regarding the use of AAI with robotic therapy animals to facilitate inpatient rehabilitation. The results from this study may open up a new frontier for this novel intervention and ultimately improve patient outcomes. The investigator plans to use the data from this pilot RCT to support a future federally funded clinical trial

ALTERNATIVES TO PARTICIPATION

21. Alternatives to Participation

1. Describe the likely care the subject would receive at this institution were he/she not to participate in the research. If there are more than one reasonable courses of treatment briefly describe.

Patients no participating in the research would still receive the standard of care for physical therapy sessions.

2. Is the potential benefit of the research at least as good as the potential benefits of the alternatives described above?

Yes

3. Are there any reasonably available alternatives outside this institution which would have the potential for providing benefit to the subjects outside the research context?

No

4. Would any of the study procedures or courses of treatment in the protocol be available to the subject if they elected not to participate?

Yes

a. Explain.

Standard of care courses of treatment would be available to the prospective subject if they elected not to participate.

5. Would the research intervention be available outside the context of research?

No

6. Are there any treatments that the subject would be denied as a consequence of participating in research that he/she would have received had he/she not participated?

No

7. How do the risks of the research compare with the risks of alternative procedures or courses of treatment described above?
Admission to the hospital, as well as physical therapy sessions can elicit physical symptoms such as pain, thirst, and fatigue, Psychological symptoms like anxiety, spells of terror, social isolation, disturbed sleeping patterns, restlessness, fear, confusion, and loss of control are also sometimes experienced in the hospitalized patients because patients often have limited mobility, decreased capacity to communicate, and reliance on healthcare providers for survival.

FINANCIAL OBLIGATIONS AND COMPENSATION

22. Financial Obligations of the Subject
A. Who will pay for research procedures, interventions, evaluations and tests? Check all that apply.
Sponsor
♦ Grant
CRC, CCTR
Costs or fees waived by Nebraska Medicine, UNMC- P, CHMC or CSP
Department/Section funds
Other. Explain

B. Will any of the research procedures, interventions, evaluations and tests described above be charged to the Subject, the Subject's health insurance, or Medicare/Medicaid?
Yes

1. Provide additional detail and justification for charging as noted.
The subject or their insurance will be responsible for standard charges for PT/OT sessions but will not be charged for any research only procedures.

C. Are there any other financial obligations that the subject will incur as a result of participating in the study?
No

23. Compensation to the Subject for Participation
A. Will the subject receive any compensation for participation?
Yes

1. Describe the form of compensation, dollar amount (if applicable) and the prorated

compensation plan (if applicable).
Each family will receive a $25 VISA gift card for participating in the study and completing all follow-up questionnaires.

Small plush seals will be given to all pediatric participants after completion of all study related activities.

PRIOR REVIEW

24. Prior IRB Review
A. Has this study (or one substantially similar) been previously submitted to the UNMC IRB (or the Joint Pediatric IRB) and then withdrawn by the investigator for any reason?
No

B. To the best of your knowledge, has this study (or one substantially similar) been considered by another IRB and disapproved?
No

SUBJECT IDENTIFICATION & RECRUITMENT

25. Method of Subject Identification and Recruitment
A. Will prospective subjects learn about the research and then contact the investigator about participation (for example, in response to a print, electronic, radio or television advertisement; referral by a clinician or other specifically for this research)?
No

B. Will the investigator make the initial contact with the potential subject to tell him/her about the research (for example, by contacting existing or past previous patients or research participants; or by contacting prospective subjects thru school records, or thru support groups or other Interest Groups; or thru use of the Hospital Opt-In Database)?
Yes

1. How will prospective subjects be identified?
Through an official consult to PT/OT when the patient is hospitalized.

2. Will potential subjects be screened for eligibility prior to informed consent?
Yes

a. What information will be collected prior to informed consent?

Age, admission status (inpatient vs. other), guardian availability, PT/OT consult status, mental status (awake, alert, able to follow commands), ability to understand and speak English, adequate ability to see, hear, and verbalize.

b. By whom?
The PT/OT assigned to the patient's case. Then verified through verbal confirmation with the patient by the CHMC RA prior to seeking informed consent.

c. Does that person have ethical access to information about potential subjects?
Yes

i. Describe
The PT/OT have ethical access through their clinical roles as inpatient care providers on the patient's team.

3. How will potential subjects be approached and invited to participate?
Initially approached by the PT/OT. Then if interested in participating, the CHMC RA will follow up with additional information.

a. Describe the process of initial contact
If the subject is eligible, the PT/OT will introduce the study to the patient and guardian. If the patient and guardian express interest in participating, the PT/OT will immediately contact the CHMC support staff research assistant (CHMC RA).The CHMC RA will then make contact with the patient to verify eligibility and interest in study participation.

b. Who will make the initial contact?
Initially contact made by the PT/OT. Then if interested in participating, the CHMC RA will follow up with additional information.

c. Does that person have ethical access to information about potential subjects?
Yes

i. Describe
The PT/OT have ethical access through their clinical roles as inpatient care providers on the patient's team.

C. Will this study be listed in the clinical trial registry at www.clinicaltrials.gov?
Yes

1. Provide the NCT#.
NCT05275543

2. Identify who holds the NCT#
♦ PI
Sponsor

OBTAINMENT OF INFORMED CONSENT

26. Waiver or Alteration of Informed Consent
A. Is a complete waiver or alteration of consent requested?
No

27. Waiver of Signed Consent
Is a waiver to obtain signed consent requested?
No

28. Child Assent
A. Is a waiver of child assent requested?
No

29. Process of Informed Consent
A. When will the prospective subject/parent(s)/guardian(s)/LAR be approached relative to their/the subject's actual participation in the study?
When PT/OT receives a consult for treatment of a hospitalized patient, they will asses if the patient is eligible to participate. If they are eligible, the PT/OT will introduce the study to the patient and guardian. If the patient and guardian express interest in participating, the PT/OT will immediately contact the CHMC support staff research assistant (CHMC RA).The CHMC RA will then make contact with the patient. The CHMC RA will verify that the patient meets eligibility criteria. If the patient is eligible to participate, they will then further explain the details of the study to the patient and their parent or guardian. If the patient is interested in participating, the CHMC RA will seek written informed consent in person with the patient and either in person or over the phone or Zoom conferencing with the patient's guardian.

B. Where will informed consent be obtained, and how will the environment be conducive to discussion and thoughtful consideration?
The research project will be explained and informed consent will be obtained in the privacy of the patient's room or via private phone call, or using Zoom conferencing. The room will be quiet, private, and conducive to discussion and thoughtful consideration of study

participation. Questions will be thoroughly answered. The phone call or Zoom video conferencing technology will provide the same level of privacy to patient's and their guardians.

C. Who will be involved in the process of consent and what are their responsibilities?
Research personnel are CITI trained. The CHMC RA will seek signed informed consent after thoroughly explaining the study, which may be done face-to-face, over the phone, or using Zoom video conferencing. After informed consent is obtained, the RA will begin pretest data collection. Then, the PT/OT provider will begin the therapy session with PARO.

D. Is there any limitation on the amount of time allotted to the process of consent?
No

E. How will the process of consent be structured for subjects who are likely to be more vulnerable to coercion or undue influence?
Subjects will be given the opportunity to discuss the participation with their families or healthcare provider. Consents will be read to participants if needed and time will be allotted to answer all questions.

F. Will non-English speaking subjects be enrolled in this research?
Yes

Describe the plan to conduct the process of informed consent in the language of the subject/parent(s)/guardian(s)/LAR
CHMC translator will be used, if an in-person translator is not available, a tablet will be used to call a remote translator. All consent forms and parent information sheets will be provided in Spanish. Parents and subject will be given as much time needed to go over consent forms before signing. The teach-back method can be used with the translator.

G. How will it be determined that the subject/parent(s)/guardian(s)/LAR understood the information presented?
Subjects will be given time to ask questions about the study. When the subjects have no further questions, subjects will be asked to describe the study, study procedures, and their rights as a research subject.

30. Documentation of Informed Consent and Assent
Select who will obtain consent from the subject/parent(s)/LAR.
Ellenberger, Laura E

Hetland, Breanna D

Hoover, Denise M

O'Neill, Sarah M

31. Consent Forms and Study Information Sheets
Indicate the type of consent forms and study information sheets to be used in this research. Check all that apply.
♦ Adult consent form
Legally authorized representative (LAR) consent form
♦ Parental/Guardian consent form
♦ Youth study information sheet
♦ Child study information sheet
Adult study information sheet (decisionally-impaired)
Screening consent form
Addendum consent form
Other. Explain.

32. Information Purposely Withheld
Will any information be purposely withheld from the subject during the research or after completion of the research?
No

RESOURCES

33. Describe the resources available to safely conduct this study at <u>each</u> study sites specified in Section I.7.
The study will occur at the bedside, in the patient's private room at Children's Hospital and Medical Center. Data collection prior to the start of the study and after the protocol with the patient is completed at the bedside. Data collection prior to the start of the study and after the protocol with the guardian will be completed at the bedside or done via email, telephone, or via Zoom video conferencing. Data storage and security will be through REDCap and Box. The necessary funding includes the UNMC Pediatric Cancer Research Group grant that has already been awarded (grant application is attached). Emergency equipment and personnel are available to respond promptly to adverse events or unanticipated problems.

LITERATURE REVIEW

34. References

Provide a full listing of the key references cited in the background (Section II.3). The references should clearly support the stated purpose of the study.

1. Fine AH. Handbook on Animal-Assisted Therapy: Theoretical Foundations and Guidelines for Practice. 4th ed. Burlington, MA: Academic Press; 2015.
2. Bailey T, Christenson G, Lust K. The role of an animal-assisted interaction (AAI) program as a means of reducing stress and anxiety within a college community. Oxford, UK: Inter-Disciplinary Press.
3. Bailey T. Animal-assisted interactions (AAI): a creative modality to support youth with depression. In: Brooke SL, Myers CE, eds. The Use of the Creative Therapies in Treating Depression. Springfield, IL: Charles C. Thomas; 2015:269.
4. Burres S, Edwards NE, Beck AM, Richards E. Incorporating pets into acute inpatient rehabilitation: a case study. Rehabil Nurs. 2016; 41(6):336-341.
5. Tatla SK, Jarus T, Virji-Babul N, Holsti L. The development of the Pediatric Motivation Scale for rehabilitation. Can J Occup Ther. 2015;82(2):93-105.
6. Hetland B, Bailey T, Prince-Paul M. Animal-Assisted Interactions to Alleviate Psychological Symptoms in Patients Receiving Mechanical Ventilation. J Hosp Palliat Nurs. 2017; 19(6): 516-523.
7. Wawers, A., Bach, C., Heusinkvelt, J., Moody, A., Kinsella, S., Haefner, H., Kupzyk, K., Hetland, B. (2021, March). Animal assisted interactions with an animal robot during physical and occupational therapy sessions in the pediatric ICU: A feasibility study [poster]. Midwest Nursing Research Society, Kansas City, MO. (Virtual)
8. Herzog MA. Considerations in determining sample size for pilot studies. Res Nurs Health. 2008; 31(2): 180-191

SECTION III

SUBMISSION DEADLINE

A. Full Board Review:
The IRB meets twice monthly, on the first and third Thursday of the month, with the exception of January and July when the IRB meets only on the third Thursday of the month. No more than 15 applications (e.g., initial review of a new study, re-review of a tabled study) will be reviewed at each meeting. All reviews are performed on a first-come first-served basis. The IRB meeting schedule and deadline dates can be found on the IRB website at www.unmc.edu/irb.

B. Expedited Review
Applications that qualify for expedited review have no submission deadline and can be reviewed independent of the IRB meeting schedule. Call the Office of Regulatory Affairs for assistance in determining if your study meets the requirements for expedited review.

ADDITIONAL REVIEW REQUIREMENTS

Final IRB approval and release of studies is contingent upon approval by the following UNMC committees or departments. Check the appropriate boxes:
UNMC and NM - Pharmacy & Therapeutics (P&T) Committee (Required for studies involving drugs)
Fred & Pamela Buffett Cancer Center Scientific Review Committee (SRC) (Required for studies involving cancer)
Institutional Biosafety Committee (IBC) (Required for studies involving the use of gene transfer and vaccines)
Investigational Device Review Committee (IDRC) Review by the IDRC is required for all protocols involving the use of investigational or marketed devices
Billing Grid (Required for all studies involving billing for hospital/clinic services)
Coverage Analysis (Departments requiring this analysis have been specified by the Organization)
Conflict of Interest (COI) Management Plan (Required for all studies with declared COI by study personnel)
Sponsored Programs Administration (SPA)/UNeHealth grants and contracts
Pathology approval for collection of tissue samples required for this study
Radiation Committee Approval
UNO Investigational Device Committee
UNO Conflict of Interest Committee

Other Review

- **None of the above organizational requirements apply to this study**

SECTION IV

COVID-19

Human Subjects Research Safety Plan
You have indicated in section I that this study involves face to face contact with subjects. Before final approval and release of this study will be issued, a Human Subjects Research Safety Plan found at unmcredcap.unmc.edu/redcap must be completed and submitted to the Human Subject Research Safety Review Committee (HSRSRC) for review and approval.

♦ I acknowledge this requirement.

ADDENDUM B
Research Involving Pregnant Women, Fetuses and Neonates of Uncertain Viability or Non-Viable

Title of Protocol

Robot Rehab: Animal assisted interactions with a robotic baby harp seal during inpatient pediatric rehabilitation

Principal Investigator

Hetland, Breanna D - CON-Omaha Division - 402-559-5460 - breanna.hetland@unmc.edu

1. Preclinical Studies and Studies on Non-Pregnant Women [45 CFR 46.204(A)]

A. Will Pregnant women/fetuses be included in the research?

Yes

B. Have scientifically appropriate preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, been conducted?

No

C. Do these studies provide data for assessing potential risks to pregnant women and fetuses?

No

2. Risks and Benefits to the Pregnant Woman or Fetus which are Associated with the Research [45 CFR 46.204(B)]

A. Is there *any prospect* of direct benefit for the woman or the fetus?

Yes

1) Describe the anticipated benefit(s), if any, to the pregnant woman.

Pregnant women may experience comfort, relaxation, and a positive mood from interactions with PARO as either a patient or a parent/guardian.

2) Describe the potential benefit(s), if any, to the fetus.

Not applicable, there are not any anticipated benefits to the fetus.

3) Describe any risks to the fetus and/or the pregnant woman.

There is a risk of transmission of infections particles from PARO to the pregnant woman.

There is also a risk that the pregnant woman may become emotionally attached to the device.

4) Are there any risks to the fetus which are caused by interventions or procedures that *do not* hold out the prospect of direct benefit for the pregnant woman or the fetus?
No

3. Minimization of Risks to the Pregnant Woman and Fetus [45 CFR 46.204(C)]
A. Describe how the risks to the pregnant woman and fetus are minimized to the greatest extent possible consistent with the objectives of the research.
There are no additional risks to the pregnant woman or fetus.

4. Pregnancy Termination and Determination of Viability [45 CFR 46.204(H-J)]
A. Will the research involve termination of a pregnancy?
No

5. Consent of the Pregnant Woman and Father [46.204(B), 205(B), 205(C)]
Information Only

	BENEFITS				
RISK TO FETUS		**NONE**	**TO MOTHER ONLY**	**TO MOTHER & FETUS**	**TO FETUS ONLY**
	MINIMAL	**Consent of mother**	**Consent of mother**	**Consent of mother**	**Consent of mother AND father***
	GREATER THAN MINIMAL	**Not allowable**	**Consent of mother**	**Consent of mother**	**Consent of mother AND father***

***Except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence or temporary incapacity or the pregnancy resulted from rape or incest.**

6. Research Involving Neonates of Uncertain Viability [45 CFR 46.205]
A. Will the research involve neonates of uncertain viability?
No

7. Research Involvng Nonviable Neonates [45 CFR 46.205(c)]
A. Will the research involve nonviable neonates?
No

ADDENDUM I
UNMC Registry and Data Banking Addendum

Title of Protocol
Robot Rehab: Animal assisted interactions with a robotic baby harp seal during inpatient pediatric rehabilitation

Principal Investigator
Hetland, Breanna D - CON-Omaha Division - 402-559-5460 - breanna.hetland@unmc.edu

Subject Identifiers
1. Will a unique subject identifying number, characteristic or code be used to protect the confidentiality of the data? This includes codes assigned by the investigator to link data to other identifiers like the subject's name or medical record number.
Yes

a. Where will the key, that links the unique subject identification code to the subject's name or other identifier, be stored?
The key to the subject codes will be kept on the PI's secure UNMC hard drive.

2. Will the key to the code ever be released to any investigator who requests data from the registry?
No, the key will never be released to any investigator.

Methods and Procedures
3. What data will be collected and maintained in the registry?
Caregivers' names and contact information (telephone number, email address) will be kept and maintained in a registry. The purpose of collecting and maintaining this data is to allow caregivers to opt in to being contacted for potential participation in future research studies.

4. Will existing data be obtained for the registry?
No

5. Will data be obtained prospectively for the registry?
Yes

Confidentiality and Privacy
6. Is the location of the data registry external?

No

7. Is the location of the data registry at UNMC?
Yes

a. Who is the information custodian for this database/registry?
The PI will be responsible for the creation, maintenance and security of the registry.

b. Who is the system administrator for this database/registry?
UNMC ITS will be responsible for configuring administering, and maintaining hardware and operating systems.

c. How will the research data be archived or destroyed when the data is no longer required?
The PI will work with UNMC ITS to ensure proper archival and disposal of the research data.

d. Will registry data be stored:
1) On a secure server at UNMC/TNMC/CH&MC/UNO?
Yes

2) On a local hard drive?
No

3) On a portable computer?
No

4) On flash drive?
No

5) In a database accessible through the internet?
Yes

a) Describe the location of the server.
Box will be used. Box is a secure, HIPAA-compliant cloud content management and file sharing system. This server is accessible from the UNMC domain and the external network.

b) Describe the firewall.
Box is a HIPAA-compliant storage and collaboration service that gives faculty, staff and

students the ability to access, store, and share an unlimited amount of content securely - anytime, anywhere, on any device. The PI has an established Box.com account that was set up and will be managed by the Research Information Technology Office at UNMC.

c) Identify who has administrative responsibility for maintenance of the server.
Stephen Bonasera, Joe Ziskovsky, Chris Hanna, Michael Gleason, Ashok Mudgapalli, Leela Krishna Golla.

6) In hard copy?
No

7) Other.
No

D. Will this registry involve transfers of information (files) outside the organization?
No

E. Will the sponsor or others not associated with UNMC require remote access to the registry database?
No

F. Does this registry involve transfer of data between stand-alone networks and the UNMC network?
No

G. Are all UNMC network computers updated regularly with current operating system patches, Microsoft Office patches, and anti-virus software?
Yes

H. Are all operating and application software appropriately licensed and in compliance with copyright laws?
Yes

Release of Date from the Registry
8. Who will be able to use data from the registry? Check all that apply.
♦ Principal or secondary investigators (listed in Section I of the corresponding IRB application).
Other specific UNMC investigators (identify by name).
Other UNMC investigators not currently identified (e.g., investigators who will apply for

access to stored data sometime in the future.
Specific external investigators (identify by name and institution).
Other external investigators not currently identified (e.g., investigators who will apply for access to stored data sometime in the future).

9. Describe the process for investigators to obtain stored data from the registry.
The PI is the only individual who will have access to the stored data in the registry. Other investigators will not obtain stored data from the registry.

10. Describe the requirements for protection of confidentiality when data is released from the registry.
The PI will not be releasing any data from the registry.

11. What records will be kept regarding release of registry data?
The PI will not be releasing any data from the registry, therefore, no records will be kept.

12. What is the procedure for a registry participant to withdraw his/her data?
In order to have personal data withdrawn from the registry, participants must provide the PI with a written request for data to be deleted. Once a written request is provided, the PI will delete all data associated with the participant. The written request will be kept on file in a locked cabinet in the PI's office.