PROTOCOL TITLE:

Investigating the Impact of Skin to Skin on Preterm Infant Heart Rate Variability

PRINCIPAL INVESTIGATOR:

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VERSION NUMBER:

Version 3

DATE:

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REGULATORY FRAMEWORK:

Please indicate all that apply (please note that the regulatory framework **does not** mean the funding source):

☐	DOD (Department of Defense)
☐	DOE (Department of Energy)
☐	DOJ (Department of Justice)
☐	ED (Department of Education)
☐	EPA (Environmental Protection Agency)
☐	FDA (Food and Drug Administration)
☒	HHS (Department of Health and Human Services)
☐	VA
☐	Other:

FUNDING:

This project is not currently funded. The supplies required to complete this project, including the incentives for participants, will be funded from the fellow's research funds.

CLINICAL TRIALS

Is this a clinical trial per the NIH definition of a Clinical Trial? ☒ Yes ☐ No

PROTOCOL TITLE:

NIH Definition of a Clinical Trial:

"A research study in which one or more human subjects are prospectively assigned to one or more interventions. An "intervention" is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

Use the following four questions to determine the difference between a clinical study and a clinical trial:

1) Does the study involve human participants? ☒ Yes ☐ No
2) Are the participants prospectively assigned to an intervention? ☒ Yes ☐ No
3) Is the study designed to evaluate the effect of the intervention on the participants? ☒ Yes ☐ No
4) Is the effect being evaluated a health-related biomedical or behavioral outcome? ☒ Yes ☐ No

Note that if the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if…

- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention

If yes to all 4 questions, please confirm that the research team is familiar with and agrees to comply with the investigator requirement to register the study on the ClinicalTrials.gov database. Additionally, the approved consent document(s) must be uploaded to the ClinicalTrials.gov database ☒ Yes ☐ No

For any assistance with registration of your trial or the requirements, please contact HSC-CTSCResearchConcierge@salud.unm.edu

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1. Objectives

The objective of this study is to monitor heart rate variability in preterm infants receiving respiratory support, including conventional mechanical ventilation, during skin-to-skin care. We hypothesize that skin to skin care will be associated with a more mature pattern of parasympathetic activity as measured by various domains of heart rate variability. Specifically, the standard deviation of the normal-to-normal interval (SDNN), the root mean squared of successive differences of normal-to-normal intervals (RMSDD), and the standard deviation of deceleration (SDDec) will decrease in infants that are receiving skin-to-skin care across all types of respiratory support compared to infants who are lying in their isolette.

2. Background

Kangaroo Mother Care (KMC), caring for newborns on their mother's chest 24 hours/day, has shown to be effective for thermal control, breastfeeding and bonding in newborns and was initially used in resource limited countries to reduce mortality in low birthweight infants [1]. For infants with a birthweight <2000g born in low- or middle-income countries, initiating KMC within the first week of postnatal life resulted in 51% reduction in mortality [1]. KMC has also been found to decrease health care related sepsis and improve infant growth [1]. Most neonatal intensive care units are familiar with skin-to-skin care, intermittent, usually short-term placement on mother's (or father's) chest, as a means to enhance breastfeeding, attachment and parental self-esteem, and studies have shown that it is safe for both non-intubated and intubated preterm infants to complete skin to skin care [1,2,3].

The autonomic nervous system, comprised of sympathetic and parasympathetic innervations, is incomplete at birth. In premature infants the sympathetic tone is dominant. Improved parasympathetic tone promotes growth and restoration in addition to energy conservation [4].

Heart rate variability (HRV) is the temporal variation between sequences of consecutive heart beats, measured by the normal to normal (NN interval) which is the period between adjacent QRS complexes [5]. HRV measures the balance between sympathetic and parasympathetic mediators of heart rate. HRV increases with gestational age, and lower heart rate variability reflects low parasympathetic activity in infants [7,8]. Studies have shown that reduced heart rate variability in a fetus, which is detectable prior to a change in normally measured heart rate, is a marker of fetal distress [6]. HRV measurements may be useful in capturing clinical dynamic changes in autonomic regulation in response to skin-to-skin care [8,9].

3. Study Design

This will be a prospective crossover study, with each infant serving as their own control. Any infant for whom the parent has consented to participate in the study will have heart rate variability leads applied and be monitored before, during and after a skin-to-skin session with the infant's parent. Due to the nature of the study, blinding is not feasible. Infants will remain on the hospital cardiac monitor during the study to maintain standard of care, and data obtained in this study will not be used for clinical care. All sessions will occur during the infant's NICU admission.

4. Inclusion and Exclusion Criteria

Inclusion Criteria:

- Infants must be ≤ 30 weeks gestational age at time of delivery.
- Both inborn and outborn infants are eligible for this study.
- Infants must be less than 6 weeks postnatal age.
- Infants must have had a cranial ultrasound with results showing no intraventricular severe intraventricular hemorrhage (Grade III or IV) [10].
- Infants must require respiratory support at the time of the first session. This will include mechanical ventilation, noninvasive positive pressure ventilation (NIPPV), continuous positive airway pressure (CPAP), high flow nasal cannula (HFNC) or low flow nasal cannula (LFNC).
- Consenting biological or legal adoptive mother of the infant must speak English. If the study is unable to enroll an appropriate number of patients, will consider including non-English speaking patients. However, due to limited resources for this study, we will start with only English-speaking patients. Biological or legal adoptive mother will provide consent for the infant to participate in this study.
- Biological or legal adoptive fathers of the infant are eligible to complete skin to skin sessions with the infant. As we are not collecting any information from the father, and skin to skin is a part of accepted standard of care, consent will not be obtained from the father.
- Infants of employees are eligible to participate. Undue influence or coercion will not be applied to infants of employees and participation or lack thereof will not affect employment status.

Exclusion Criteria:

- Infants who have not received a head ultrasound.
- Infants with grade III or higher intraventricular hemorrhage identified on a head ultrasound.
- Infants on high frequency ventilation, due to the artifact transmitted to ECG.
- Infants with known genetic disorders or known prenatal chromosomal anomalies.
- Infants with one or more major congenital anomaly.
- Infants undergoing active sepsis evaluation or treatment for infection.
- Infants on blood pressure or cardiac medications or infusions including inotropic mediations.
- Mothers (biological or legal adoptive) that are <18 years of age will not be approached for consent.
- Mothers (biological or legal adoptive) who are unable to provide consent due to having a legal representative will not be approached for consent in this study.
- Mothers (biological or legal adoptive) who are prisoners will not be approached for this study as participation requires multiple skin to skin session with the infant.

Infants will be screened for eligibility by reviewing the Newborn Intensive Care Unit (NICU) census daily. Consent will be obtained after an infant has delivered. No pregnant women will be approached for consent.

Any infant who has been consented for participation and completes at least 1 skin to skin session will be included in the final study sample. As skin to skin is part of standard of care, and information, aside from gender, will not be obtained from the parent, consent will be obtained for the infant to participate in the study. Consent for the parent to participate will not be necessary.

5. Number of Subjects

This is a single site crossover study design. The goal number of patients to be recruited is 10. The number of extremely preterm infants ≤30 weeks gestation born at UNMH averages approximately 60-70 per year. Anticipating that most of these infants will be eligible and the consent rate will be about 50%, as this is not a drug study, we expect to reach goal enrollment within 1 – 1 ½ years.

Previous studies of HRV analysis in preterm infants have found significant differences (alpha of 0.05) when enrolling 10 or more infants in the study[11,12]. Therefore, utilizing this information, the sample size of 10 has been determined for this study.

6. Study Timelines

An infant will participate in the study if the mother consents for participation. Maximum duration of participation is limited to the first 6 weeks of life.

The duration of time to enroll subjects is 18 months. If the goal enrollment is reached sooner, then the enrollment will be stopped. Data will be analyzed after 2 infants have completed the study to make sure data is being captured correctly and on completion of goal enrollment. Data analysis is expected to be completed within three months after enrollment is complete. Total study duration is expected to be 18-24 months.

7. Study Endpoints

The primary endpoint of the study will be obtaining the heart rate variability measurements at three time points. Specifically the standard deviation of the normal-to-normal interval (SDNN), the root mean squared of successive differences of normal-to-normal intervals (RMSDD) and the standard deviation of deceleration (SDDec) measured before, during, and after a skin to skin session.

As this study is no more than minimal risk, a data safety monitoring board will not be required. However, during the enrollment period, a safety review will be completed by the study team after every patient to assess skin integrity and to provide any reports needed to the IRB in a timely manner.

In addition to the aims presented, an exploratory aim will evaluate the differences in heart rate variability of preterm infants between mothers and fathers performing skin-to-skin care. The study will collect the gender of the parent performing skin to skin with the infant for each session.

8. Research Setting

The research will be conducted in the Newborn Intensive Care Unit (NICU) at the University of New Mexico Hospital (UNMH). Patients will be identified after admission to the NICU. The application of the Heart Rate Variability monitor will occur in the NICU as well.

9. Resources Available

Dr. Maxwell is a neonatologist who conducts basic, translational and clinical research when not on service in the NICU. She has dedicated research time, and thus has the availability to complete the proposed project. She is well experienced in caring for this patient population. Her involvement on an IRB committee has significantly increased her knowledge in regard to ensuring that all research is conducted in the highest quality possible. Dr. Maxwell also has experience in utilization of HRV in neonates and can provide expertise in this area.

Dr. Watterberg has over 30 years of experience conducting studies in the newborn population. She is the New Mexico principal investigator for the NICHD Neonatal Research Network, which has multiple ongoing observational and interventional studies. She has mentored fellows, faculty and other learners in research and academic advancement.

Dr. Swieter is a neonatology fellow at UNMH. She has dedicated research time, and thus has the availability to complete the proposed project. Additionally, Dr. Swieter has research funds available to provide monetary support for the project, including the gift cards as described.

All research persons will remain up to date on CITI training and on the most recent version of the IRB-approved protocol for this study. Additionally, research persons have availability to all patients admitted to the NICU that meet inclusion criteria, making the goal recruitment of 10 infants over 1 year feasible.

10. Prior Approvals

The departmental approval has been obtained and is uploaded for review.

11. Multi-Site Research – N/A

12. Study Procedures

Any infant that is born ≤ 30 weeks gestational age and does not meet exclusion criteria as described above will be considered for this study. If an infant is born at another hospital and transferred to UNMH, they will be considered for the study when the mother is physically present to consent if inclusion criteria are met.

The study will be described following the consent script (attached). If consent is given, the infant will then be given a unique study identifier (HRV1, HRV2).

The AcqKnowledge HRV device will be applied 30 minutes prior to a skin-to-skin session with the infant's mother or father (only the gender of the individual will be collected from the caregiver at the time of the session) and remain in place until 30 minutes following the end of a skin-to-skin session. This will allow a minimum of 90 minutes of data collection (30 minutes pre skin-to-skin, 30 minutes during skin-to-skin, and 30 minutes post skin-to-skin), depending on the duration of skin-to-skin time. If the infant is tolerating skin to skin, the session may last longer than 30 minutes. The data output will

not be visible to the clinical team, so there will not be any incidental clinical interpretation of the data.

To apply the device, three leads with a drop of gel on each lead will be applied to the infant. Additionally, the pneumogram will be placed on the skin above the diaphragm. The leads and the pneumogram will be plugged into the HRV monitor, which is connected to a laptop computer and will remain at the bedside throughout the study session. Care will be taken to remove the sensors, using massage oil, following each skin-to-skin session. The sensors will then be discarded after use. The area of application of the sensors will be assessed upon completion to ensure skin integrity remains and there is no/minimal irritation.

Infants will be transferred to their mother or father following the unit protocol for transfer of ventilated infants for skin to skin care. Data will be collected from the infant's medical record. We will collect the gender of the individual completing the skin to skin session so that the exploratory aim can be completed.

Information will be collected from the medical record at time of enrollment as well as at each skin-to-skin session. This information will include the infant's gestational age at birth, postnatal age, birth weight, mode of delivery, infant's sex, any resuscitation required at time of birth, the length and type of breathing support required, any surgeries during the hospitalization, the hospital length of stay, any common complications babies have from being born early including intraventricular hemorrhage (bleeding in the brain), necrotizing enterocolitis (complication in the bowel), current medications, infectious work ups and death during the study period if applicable.

13. Data Analysis

As this study is essentially a pilot study, with goal recruitment of 10 patients, the statistics will be exploratory, but modeled after a Cong et al pilot study that looked at kangaroo care in the preterm infant and heart rate variability in response to a heel stick [13]. We plan to calculate the geometric mean [GM = (a1 · … · an)1/N] instead of the arithmetic mean [M = (a1 + … + an)/N] for calculating HRV indices, because the GM results in an average rate of change. Repeated measures of analysis of variance (RM-ANOVA) will be used to compare HR and HRV across the pre, during and post skin to skin sessions.

The primary endpoint of the study will be to obtain heart rate variability measurements at three time points. Specifically the standard deviation of the normal-to-normal interval (SDNN), the root mean squared of successive differences of normal-to-normal intervals (RMSDD) and the standard deviation of deceleration (SDDec) measured before, during, and after a skin to skin session.

14. Provisions to Monitor the Data to Ensure the Safety of Subjects

This study is seen as no more than minimal risk to the patient population because skin-to-skin care currently occurs within this population. Scientific literature will also be reviewed throughout the study to ensure that the study protocol remains appropriate for the patient population. Any concerns or significant adverse events will be reported to the IRB immediately. As this study is no more than minimal risk, a DSMB is not required.

15. Withdrawal of Subjects

If a parent decides to withdraw the infant from the study, any data that has already been collected will be kept for analysis, unless the PI has been contacted as described in the following sentence. If the mother wishes to remove collected data, then they can contact the PI, Dr. Maxwell, at 630-864-9422 to request all data to be removed; the data will then be removed. No additional data will be collected.

The investigators conducting the study may need to remove the infant from the study if the mother or father completing skin to skin sessions is not able to follow directions or if participation of the infant is found to have more risk than benefit.

16. Data Management/Confidentiality

All data will be kept on a password protected computer or external hard drive in the neonatology fellow office, in a locked cabinet, which is behind a locked office door and a locked hallway. All paper records will be kept in a locked cabinet in the neonatology fellow's office, which has a locked office door and a locked hallway. All electronic data will be de-identified as soon as possible with identifying information stored separately from study data. All de-identified information will be kept until the youngest subject reaches the age of 22, as required by UNM HSC Research Policy, and then destroyed. Upon graduation of the fellow, the study documents will be transferred to Dr. Maxwell's office (BRF 137D) in a locked cabinet, in her locked office. There is also an anteroom to the office that remains locked.

Each patient will be assigned a code at time of enrollment (ie: HRV1, HRV2). This will allow for de-identification of the patient. As protected health information and identifying information will be collected, this de-identification will allow for added confidentiality. The date of birth and medical record number will be the identifying information that is removed from the data collection once the study ID is assigned, and the medical chart has been reviewed for the additional information (see attached excel file for additional information that will be collected). The electronic link between the study ID and the patient identifiers will be kept on a password protected computer in a locked office in Dr. Maxwell's office. This will not be stored in the same computer folder as any other documents pertaining to this study (it will be separated from the data). If the research team needs any of the patient information, they will be required to utilize the computer in Dr. Maxwell's office. No sensitive information will be collected, and a certificate of confidentiality is not required. As this is a single site study, there will be no transfer of the data required. All data will be electronically collected and stored. All data will be kept per the policy HSC-R-801 PR.1, in which research records of minors (under 18 years) must be retained until the minor turns 22 years old; thus, all data will be stored until the youngest participant has reached 22 years of age.

17. Data and Specimen Banking- N/A

18. Risks to Subjects

We expect the risks to the subjects to be minimal in relation to the AcqKnowledge heart rate variability device. The primary risk to the subjects will be skin irritation from the electrode placements. However, this gestational age group at baseline is at high risk

of complications including death, severe brain injury, necrotizing enterocolitis, chronic lung disease, retinopathy of prematurity and sepsis.

The risks that may be present related to the AcqKnowledge HRV device include erythema and irritation of the skin follow electrode lead placement and removal. We will use gel to reduce the risk of skin irritation and gently remove the sensors using massage oil following the end of a skin-to-skin session to decrease discomfort during the process.

As protected health information will be gathered, there is the risk for loss of privacy and/or confidentiality. We will minimize these risks by giving each participant a study ID and removing the identifiers at that time. Per policy, records of participants under the age of 18 years must be stored until the youngest participant receives 22 years of age. All records will be stored either electronically on Dr. Maxwell's UNM issued password protected computer that is stored in her locked office, or paper copies will be stored in a locked cabinet in Dr. Maxwell's office in BRF137D.

Additionally, there is the possibility of unforeseen risks. Any concerns or SAE from the study will be reported to the IRB immediately.

19. Potential Benefits to Subjects

It is unknown if infants participating will benefit from skin to skin contact. However, infants in this study may benefit from increased skin-to-skin time with their mother or father. The benefit of this project will potentially be for this patient population (extremely preterm infants) to have increased skin-to-skin contact with their caregivers. Currently, some facilities across the country are less likely to support or promote skin-to-skin in extremely preterm infants, especially if they are intubated. However, there is benefit in this bonding as described previously. Therefore, the results of this study may reveal the importance of promoting skin-to-skin whenever possible in this high-risk population.

20. Recruitment Methods

Any infant that meets the inclusion / exclusion criteria will be considered for enrollment. The mother will be approached by one of the study personnel that are included on this IRB, and the study will be discussed if they are interested in the study. The consent form has been included to show what the study personnel would verbally state to the mother. The mother may be approached at the infant's bedside or in her hospital room after delivery. If approached at the infant's bedside, the mother will be given the option to go into a family room to discuss the study further for additional privacy. The Powerchart census will be reviewed daily to monitor for admission of infants that would meet criteria. There will be no additional recruitment materials used for this study.

21. Provisions to Protect the Privacy Interests of Subjects

To protect the privacy of the subjects in this study, consent will be obtained in the mother's hospital room if possible. However, if the mother is present at the bedside in the NICU, they will be approached and asked if the study can be discussed in a private location (utilizing a family room or conference room) or at the bedside if the mother desires. If the

mother states they do not want to participate in a study, they will be informed that the infant will continue to receive all appropriate medical care.

22. Economic Burden to Subjects

There is no expected economic burden to the subject. Participation in the study will result in an added mode of monitoring, at no cost to the subject. The information collected from the medical record will be obtained through electronic medical record access. There are no samples that will be obtained, and no cost expected to the participants or a 3rd party payer.

23. Compensation

A Clincard in the amount of $10 will be provided to the mother or father for each skin-to-skin session completed, with a maximum of six sessions for each participant.

24. Compensation for Research-Related Injury

As this technology is used routinely in some NICUs, the study is not expected to be more than minimal risk. Therefore, no research-related injury is expected to occur, and no compensation will be offered.

25. Consent Process

Investigators included on the IRB protocol will be responsible for obtaining consent, and include Dr. Maxwell, Dr. Watterberg and Dr. Swieter.

The consent process will take place in the mother's hospital room if possible, to allow for privacy. The consent process can also take place in a family room in the NICU; the consent would only be obtained at the infant's bedside if the mother requested the conversation to occur in that location. It will be stated during the consent process that participation is voluntary and will have no impact on the infant's medical care or treatment to minimize the possibility of coercion or undue influence. Once the study has been described (using the consent script that has been attached), the mother will be offered additional time to consider participation in the study. The mother will be contacted during the study period to ensure they continue to consent to the study. During the consent process, it will be requested that the mother is able to describe the study with the sensor placement to ensure understanding.

As this study does not involve greater than minimal risk, one parent is able to give consent. This study involves neonates, so they will not be able to provide assent. Consent will be obtained for all neonates participating in the study.

Mothers or fathers are able to hold the infant while data is collected during the study. Only the gender of the individual completing the skin to skin session will be obtained from the caregiver. Detailed information will be collected from the infant's medical record. Therefore, consent will be obtained for the infant to participate, but consent will not be needed for the parent to hold the infant.

26. Documentation of Consent

We will use a consent form that is modified from the HRPO website. It has been attached for review. The signed consent forms will be stored in a locked cabinet in Dr.

Maxwell's office, which is locked and has an anteroom that is locked during non-business hours. We will obtain consent from the mother by providing a written document that will be signed (attached). The study personnel obtaining consent will use the detailed consent form (attached).

27. Study Test Results/Incidental Findings

Test results will not be specifically shared with the participant's families; however, they will be able to see the monitor and the readings while at the bedside. If at any time there are significant clinical changes in the infant during a session, the study will be stopped, and families will be notified immediately at the bedside.

The infant will still have all routine monitoring in place with the heart rate variability monitor in addition. As continuous cardiac monitoring occurs as standard of care, we do not expect any incidental findings.

28. Sharing Study Progress or Results with Subjects

There will not be a summary of the trial progress provided while the study is underway. Also, there will not be a summary of the study results after the study is complete.

29. Inclusion of Vulnerable Populations

This study will include the vulnerable population of neonates. As some of the neonates will be uncertain viability (using the federal research regulations which states "viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration) due to continued need for ventilatory support to maintain respiration, that checklist has been completed.

The population proposed in this study is necessary, as they are the population that has the potential to achieve benefit from this study.

30. Community-Based Participatory Research –N/A

31. Research Involving American Indian/Native Populations

This study will not exclude American Indian / Native populations, nor will it target the population for inclusion. If a woman and infant otherwise meet criteria, they will be approached for consent.

32. Transnational Research –N/A

33. Drugs or Devices

The device that will be used is approved for clinical use in infants. The sensors will be new for each patient and discarded after use. The equipment will be cleaned with Clorox wipes before and after each use.

34.Principal Investigator's Assurance

By submitting this study in the Huron IRB system, the principal investigator of this study confirms that:

☒ The information supplied in this form and attachments are complete and correct.

☒ The PI has read the Investigator's Manual and will conduct this research in accordance with these requirements.

☒ Data will be collected, maintained and archived or destroyed per HSC Data Security Best Practices, including:

1. **Best Practice for data collection** is for it to be directly entered onto a data collection form that is in a secured access folder on an HS drive behind a firewall, or in a secure UNM Data Security approved system such as RedCap.
2. **Data collection of <u>de-identified data</u>**, if done in a clinical setting or other setting that does not allow direct entry into a secured system, may be done temporarily using a personal or university owned electronic storage device or hard copy document. **The important security safeguard is that no identifiers be include if the data is entered or stored using an untrusted device or storage.**
3. **Permanent (during data analysis, after study closure**) storage must reside on HSC central IT managed storage. Processing of data (aggregation, etc.) are to be carried out in such a way as to avoid creating/retaining files on untrusted storage devices/computers. Trusted devices are HSC managed and provide one or more of following safeguards: access logs, encryption keys, backups, business continuity and disaster recovery capabilities.
4. **Alternate storage media** must be approved by HSC IT Security as meeting or exceeding HSC central IT provided security safeguards.

35.CHECKLIST SECTION

This section contains checklists to provide information on a variety of topics that require special determinations by the IRB. Please complete all checklists relevant to your research.

36.Partial Waiver of HIPAA Authorization for Screening/Recruitment

Complete the following additional questions/attestations if the records you will review to identify potential subjects and/or determine eligibility include Protected Health Information (PHI).

A. Will you be recording any PHI when conducting the records review to identify potential subjects and/or determine eligibility?

☒ Yes. Describe: *The study team will review the medical records of infants admitted to the newborn intensive care unit to determine which infants may qualify for the study. This will look at the following items:*

Inclusion Criteria:

- *Infant must be ≤30 weeks gestational age at time of delivery.*
- *Infants inborn and outborn are eligible for this study.*
- *Infants must have had a head ultrasound with results showing no severe intraventricular hemorrhage (IVH Grade III or IV).*
- *Infants must be receiving respiratory support including mechanical ventilation, noninvasive positive pressure ventilation (NIPPV), continuous positive airway pressure (CPAP), high flow nasal cannula (HFNC), or low flow nasal cannula (LFNC) at the time of the first session.*
- *Consenting mother of the infant must speak English*
- *Biological or legal adoptive fathers of the infant are eligible to complete skin to skin sessions with the infant*
- *Infants of employees are eligible to participate. Undue influence or coercion will not be applied to infants of employees and participation or lack thereof will not affect employment status.*

Exclusion Criteria:

- *Infants who have not received a head ultrasound.*
- *Infants with grade III or IV intraventricular hemorrhage identified on head ultrasound.*
- *Infants on high frequency ventilation due to the artifact obtained on ECG.*
- *Infants with known genetic disorders or known prenatal chromosomal anomalies.*
- *Infants with one or more major congenital anomaly.*
- *Infants undergoing active sepsis evaluation or treatment for infection.*
- *Infants on blood pressure or cardiac medications or infusions including inotropic medications*

- *Mothers that are <18 years of age will not be approached for consent.*
- *Mothers who are unable to provide consent due to having a legal representative will not be approached for consent in this study*
- *Mothers who are prisoners as participation in the study requires multiple skin to skin sessions with the infant.*

If the infant is found to meet inclusion criteria, the study personnel will then approach the mother for consent.

☐ No

B. If you answered "Yes" to question 6 above, please describe when you will destroy identifiers (must be the earliest opportunity consistent with the conduct of the research) or provide justification for why they must be retained:

The identifying information will be separated from the rest of the study data once a patient is consented for participation. At that time, the participant will be given a study ID, and the identifiers will be removed. The link for the study ID and identifiers will be kept on Dr. Maxwell's UNM issue password protected computer, stored in her locked office with a locked anteroom. Upon completion of the study, all data will be stored per policy until the youngest participant reaches age 22 years. All identifying information will be destroyed upon completion of the study.

C. The PHI accessed or recorded for identification/screening purposes will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

☒ True

☐ False

37.Waiver of Documentation of Consent N/A

A. Are you requesting a waiver of documentation of consent for some or all subjects? No

B. Do you intend to provide subjects with a written statement regarding the research in lieu of a traditional consent form?

☒No

38.Alteration of Consent- N/A

Note: FDA-regulated research is not eligible for an alteration of consent.

39.Full Waiver of Consent/Parental Permission N/A

Note: FDA-regulated research is not eligible for a full waiver of consent using these criteria. If you believe that your FDA-regulated research may be eligible for a waiver under another

mechanism, such as planned emergency research, contact the HRPO for assistance in determining what information to provide to the HRRC.

40. Full Waiver of Consent/Parental Permission (Public Benefit or Service Programs) N/A

41. Full Waiver of HIPAA Authorization (Checklist)- N/A

42. Other Waiver Types (Checklist) N/A

If you are seeking another waiver type (e.g., Planned Emergency Research, Waiver of Parental Permission to Protect Child Participants, Enforcement Discretion for In Vitro Diagnostics, etc. contact the HRPO office for assistance in determining what information to submit for the HRRC's consideration.

43. Vulnerable Populations (Checklist)

A. Adults with Cognitive Impairments – N/A

B. Children

Complete this checklist if the subject population will include children.

1. Select the category of research that you believe this research falls within and provide justification for any associated criteria. If there are different assessments for different groups of children or arms (e.g., placebo vs. drug), include a memo to provide an assessment for each group.

   ☒Research not involving greater than minimal risk. *(Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)*

   ☐Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

   Provide justification for each of the following criteria:

   (1) The risk is justified by the anticipated benefit to the subjects:

   (2) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches:

☐Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

Provide justification for each of the following criteria:

(1) The risk represents a minor increase over minimal risk:

(2) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations:

(3) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition

C. Pregnant Women and Fetuses N/A

D. Neonates of Uncertain Viability or Nonviable Neonates
Complete this checklist if the subject population will include neonates of uncertain viability.

Provide justification for each of the following:

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

   Prior research has been conducted assessing heart rate variability in preterm infants as well as skin to skin in preterm intubated infants. There have been minimal risks noted to the neonates that have the heart rate variability leads and pneumogram in place.

2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

   Each mother will provide consent and be fully informed. We expect there to be no direct benefit to the neonates in the study, however the results may inform future use in the NICU that may become routine.

3. Individuals engaged in the research will have no part in determining the viability of a neonate.

   The use of this technology will not impact the viability of the neonate, and the research team will not be determining the viability of the neonate in relation to this study.

4. The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, ***or***, the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research

   The results of this study have the potential to increase the utilization of skin to skin care in preterm infants requiring ventilator support. The purpose of this research cannot be obtained by other means and there will be no added risk to the neonate resulting from this research.

E. Nonviable Neonates N/A

F. Biomedical and Behavioral Research Involving Prisoners N/A

44.Medical Devices (Checklist) - N/A

Complete this checklist if the research evaluates the safety or effectiveness of a medical device. If more than one medical device is being evaluated, provide the requested information for each.

A. Device Name:

B. Manufacturer:

C. Does the research involve a Significant Risk Device under an IDE?

☐Yes. Include documentation of the FDA approval of the IDE with your submission. *Acceptable methods of documentation include: (1) FDA letter noting IDE number and approval status; (2) Industry sponsor letter noting IDE number and FDA approval status; or (3) FDA-approved industry sponsor protocol with IDE number noted*

☐No

D. Is the research IDE-exempt?

☐Yes. Include a FDA letter with your submission noting the determination that the research is IDE-exempt or a letter from the sponsor (or sponsor-investigator) justifying why they believe the research is IDE-exempt*.

☐No

E. Does the research involve a Non-Significant Risk (NSR) Device?

☐Yes. Include a FDA letter with your submission noting the determination that the research is NSR or a letter from the sponsor (or sponsor-investigator) justifying why they believe the research is NSR**.

☐No

* This FDA guidance includes a description for when a device study is exempt from the IDE requirements:
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf

**This FDA guidance includes information on how to differentiate between Significant Risk and Non-Significant Risk device studies:
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf

45.Export Control (Checklist)- N/A

Indicate if there will be export control concerns (i.e., select agents or select toxins involved in the project, collaboration with foreign institution or foreign nationals, publication restrictions, foreign travel, etc.). If so, please upload and complete Export Control Exclusion Screening Form.

EC-Screening-Form-FILLABLE 12-1-14.pd

46.Data Transfer/Sharing (Checklist) (required –do not delete even if the answer is "No")

Provide all information requested if the research involves transferring/sharing of data with an external entity (institution, company, etc.).

A. Will data be transferred/shared with an external entity (institution, company, etc.)?

☐Yes

☒No. **The remainder of this section does not apply.**

B. Indicate if the data is incoming and/or outgoing:
C. Provide the name of the entity that data will be transferred/shared with:
D. Provide the contact name, email and phone number with whom data is being transferred/shared with:
E. Who is responsible for transmission of the data?
F. Who is responsible for receiving the data?
G. Describe how the data will be transferred/shared. Please note data cannot be transferred/shared without assistance from UNM HSC IT. **Requesting HSC Central IT Transfer is detailed on the Sponsored Projects website:**
H. For data being transferred/shared with outside locations or entities, describe the following:

- Where is data storage and how will it be maintained in a secure manner (i.e. encryption, password protection, use of Qualtrics or REDCap, etc)?
- What is method in which data will be collected and stored (i.e. electronic, hard copy, etc)?
- How long will the data be stored?
- Who will have access to data?

I. Please list all specific data elements, variables, etc. to be sent out and/or received. Indicate if the data contains identifiers and health information. Please note that identifiers that MUST be removed to make health information de-identified are as follows: Names, All geographic subdivision smaller than a State, All elements of year (except year), Telephone, Fax numbers, E-mail addresses, Social Security, Medical record number, Health plan beneficiary, Account numbers, Certificate/license numbers, Vehicle identifiers and serial numbers, Device identifiers and serial numbers, Web URLs, IP address numbers, Biometric identifiers, full face photographic images, and Any other unique identifying number, characteristic or code.)

J. If the research requires the access, use, or disclosure of any of the 18 individually identifiable protected health information (PHI) identifiers that can be used to identify, contact, or locate a person (e.g., name, medical record number, etc.), are the subjects going to consent to or authorize the disclosure of their individually identifiable health information?
   a. ***Or*** is HIPAA authorization altered or waived?

K. What is the classification of the data (de-identified, limited data set, protected health information, other).

L. Does the request to transfer/share data include clinical data that belongs to the UNM Health Systems?

M. Does the data to be transferred/shared include information about patients seen at external health system or at a third party medical provider?

N. Is the external entity a "covered entity"?

O. Is the data that is going to be transferred/shared owned or partially owned by another party or have any type of restrictions including regulatory restrictions (i.e. HIPAA, FERPA, etc.)?

P. Is the data publically available? If yes, please provide details:

Q. Does the data include information about substance abuse treatment, sexually transmitted diseases, genetic testing results, HIV/AIDS testing results, and/or mental health?

47. Specimen Transfer/Sharing (Checklist) (required –do not delete even if the answer is "No")

Provide all requested information if the research involves transferring/sharing of specimens with an external entity (institution, company, etc.).

A. Will specimens be transferred/shared with an external entity (institution, company, etc.)?

☐ Yes

☒No. **The remainder of this section does not apply.**

B. Indicate if the specimens are incoming and/or outgoing:

C. Provide the name of the entity that specimens will be being transferred/shared with:

D. Provide the contact name, email and phone number with whom specimens are being transferred/shared with:

E. Who is responsible for sending out the specimens? Please note specimens cannot be sent out without a fully executed material transfer agreement.

F. Who is responsible for receipt of the specimens? Please note specimens cannot be received without a fully executed material transfer agreement.

G. For specimens being transferred/shared with outside locations or entities, describe the following:

- *Where is specimen storage and how will it be maintained in a secure manner?*
- *What is method in which specimens will be collected and stored?*
- *How long will the specimens be stored?*
- *Who will have access to the specimens?*

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