Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Parents' or Guardians' Permission for Your Child to Be in a Research Study

In this form "you" means the child in the study *and* the parent or guardian.

- ✓ If you are the parent or guardian, you are being asked to give permission for your child to be in this study.

In this form "we" means the researchers and staff involved in running this study at the University of Virginia.

Participant's Name_____

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study? This research is being supported by the National Institute of Health (NIH)

Principal Investigator:	Lisa Letzkus PhD, RN, CPNP-AC PO BOX 800135 Charlottesville VA 22908 434-924-5392
Sponsor:	National Institute of Health

You are being asked to take part in a research study. You do not have to take part in this study. You should only agree to take part in this study after reading this consent form and discussing it with the study team.
You may also discuss this with your family, friends, health care providers or others before you make a decision.

What problem is this study trying to solve?
Premature infants are now surviving at increasing rates and some of these infants are at higher risk of developing motor problems such as cerebral palsy (CP). Finding out early which babies may be at risk of developing CP is difficult but important in order to improve their outcomes and quality of life.

The goal of this study is to assess the feasibility of early interventions that a parent can provide for their preterm baby. These activities will focus on scheduled, specific caregiver-baby interactions proven to be beneficial to the baby. Those include: vocal soothing, scent exchange, comforting touch, skin-to-skin holding, infant massage, and physical therapy. This type of approach *may* improve outcomes of babies at risk of developing motor problems such as CP.

You are being asked to be in this study because your infant was born prematurely and may be at a higher risk for later development of CP.

If you agree to be in this study, you will sign this consent to give permission for yourself or designated caregiver and your infant to be in this study. No study related procedures will take place before you have signed this consent. Up to 70 infants will be enrolled in this study at UVA. 35 infants will be randomized to receive the intervention and 35 infants will receive standard care. Infants will be randomized once consent is obtained.

Why would you want to take part in this study?
Infants in the NICU and family members are always encouraged to participate in activities appropriate for the developmental stage of the baby. However, these activities are not applied regular basis. Babies in the intervention group will have these activities scheduled daily with a minimum goal of 5 days per week.

Why would you NOT want to take part in this study?
You may not want to take part in this study because your participation would increase the number of days you have to be present at the bedside and may impact your daily life due to the frequency of the intervention.

What is the difference between being in this study and getting usual care?
If you take part in this study, the following things will be done differently than if you do not take part in this study.

Your baby does not have to be in this study. Your baby can get the usual treatment if you choose not to be in this study. The usual treatment would include activities such as skin-to-skin holding of your baby and standard physical therapy at a frequency determined by you and your baby's healthcare provider.

If you are an employee of UVa your job will not be affected if you decide not to participate in this study. If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

What will happen if you are in the study?

If you agree to be in this study, you will sign this consent form before any study related procedures take place.

If you agree to be in the study, we would like you to return (within a maximum of 7 days) to begin the study.

STUDY PROCEDURES

You will be randomly assigned (like the flip of a coin) to 1 of 2 study groups. You have an equal chance of being assigned to any one of the groups. You cannot choose to which group you are assigned.

GROUP 1: If you agree to be in the study and are randomized to the **intervention group**, you as the parent or designated caregiver (such as a grandparent) will be asked to perform several "**activities with your baby"** for a minimum of *5 days per week until NICU discharge* including: vocal soothing, scent exchange, comforting touch, kangaroo care plus, and infant massage. These are described below:

Vocal soothing - you will use your native speech or language to express your feelings and emotions to your baby.

Scent exchange means you will place one cloth under your baby's head and one cloth in your bra. The cloths will then be exchanged on each subsequent visit.

Comforting touch refers to your baby's arms being placed over their chest, and knees drawn upward with your hands placed firmly but gently on top.

Kangaroo care plus is defined as skin-to-skin holding in combination with vocal soothing, eye contact, and gentle touch. Kangaroo care plus can start once your infant has reached 26 weeks post menstrual age (PMA). PMA is your infant's gestational age at birth plus his/her current chronological age.

Infant massage: Lastly, the physical therapists in the hospital will teach you how to perform infant massage. The massage sessions will involve gentle but firm rhythmic motion, as well as flexion extension movements of all extremities (arms and legs) for 15 minutes twice daily. Infant massage can be started once your infant has reached 29 weeks PMA.

Parent/designated caregiver administered physical therapy: 10 minutes interventions promoting postural and head control as well as midline orientation will be conducted by the adult is recommended starting at 33 weeks PMA. The intervention will be monitored by a physical therapist for 3 consecutive sessions and weekly thereafter

Study Diary: All of these activities will be performed by you until your baby goes home. You will be asked to fill out a diary to keep track of each time you complete a study activity with your baby.

Weekly interview: A study team member will touch base with you weekly to see if you have any questions or concerns related to the interventions

GROUP 2: If you are randomized to the **standard care group** the NICU team will continue to encouraged you to touch, hold, and talk to baby. You will be encouraged to perform kangaroo care based on unit guidelines and your availability. All infants in the standard care will have a routine PT consult at 28 weeks' gestation as determined by the healthcare provider. The infants will continue to be followed 2-3 times per week for 10-30 minutes per session by PT until discharge per standard care. We will ask you to maintain a study diary to record these activities throughout your NICU stay.

FOLLOW UP:

At time of discharge standard care will resume for both groups (Group 1 and Group 2) and will include a referral to early intervention and a NICU follow up appointment with developmental pediatrics when your baby is 3 months PMA.

Both groups will have standard of care motor assessments performed prior to discharge from the NICU and at 3 months PMA. The general movement assessment (GMA) and Test of Infant Motor Performance (TIMP) will be done prior to discharge from the NICU. The GMA, TIMP and Hammersmith Infant Neurological Examination (HINE) will be done at 3 months PMA. These instruments are used to look at motor and movement progress in babies.

Study Schedule of Events

		Frequency				
Study Procedures	**Screening**	**Post Consent**	**5 Days Per Week Till Discharge**	**Weekly**	**Pre NICU discharge**	**3 Months Post NICU Discharge**
Eligibility review	**X**					
Consent	**X**					
Collection of information from Medical Record (age, sex, race etc.)					**X**	
Parent or designee activities with baby (with intervention group only)			**X**			
Massage and parent administered PT Instruction by Physical Therapists (with intervention group only)		**X**				
Diary - Parent or designee			**X**			
Interviews (with intervention group only)				**X**		
Final GMA and TIMP assessment (performed as part of standard of care)					**X**	
Follow-Up Visit (as part of rstandard of care includes GMA, HINE and TIMP)						**X**

WHAT ARE YOUR AND YOUR PARENT/LEGAL GUARDIAN'S RESPONSIBILITIES IN THE STUDY?

You and your parent/legal guardian have certain responsibilities to help ensure your safety.

These responsibilities are listed below:

- Follow all instructions given.

- If randomized to the intervention group, perform activities scheduled daily with a minimum goal of 5 days per week.

How long will this study take?

Your participation in this study will last while your infant is in the NICU. The outpatient follow-up visit is part of your baby's clinical care.

If you want to know about the results before the study is done:

The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you can ask for more information about the study results

What are the risks of being in this study?

The risks are minimal to individual participants with a potential benefit to society. There is a risk of loss of confidentiality and privacy. The privacy plan outlined in this protocol minimizes the risk. The risk benefit ratio is acceptable.

Risks related to the Maternal/Designee Activities with Baby:

Rare but serious:

- During Kangaroo Care there is a rare risk that infant may fall or that a tube or line may be dislodged.
- Injury to muscles or bones due to improperly applied infant massage

Could you be helped by being in this study?

You and your baby might not benefit from this study. However, it is possible that the interventions you perform will improve your baby's motor outcomes. Information obtained from this study may help plan standard of care activities for future infants.

Will you be paid for being in this study?

Parents (not the designee) will be paid $ 50 for finishing this study by gift card. You should get your payment after you complete the 3 month follow up visit.

Will being in this study cost you any money?

All of the procedures in this study will be provided at no cost to you or your health insurance. You or your insurance company will be responsible for the cost of physical therapy consultations as this is part of standard of care while in the NICU.

You will be responsible for:

1. the cost of travel to come to visit your baby in the hospital
2. and for any parking costs.

3. You will also be responsible for the cost of travel and parking to come to your baby's follow up visit 3 months after he/she goes home.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

If you decide to stop being in the study, we will continue to encouraged you to touch, hold, and talk to baby. You will be encouraged to perform kangaroo care based on unit guidelines and your availability. All infants in the NICU will have a routine PT consult at 28 weeks' gestation as determined by the healthcare provider. The infants will continue to be followed 2-3 times per week for 10-30 minutes per session by PT until discharge per standard care.

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader may take you out of the study. Some of the reasons for doing so may include:

a) Your baby's physician is concerned about your baby's health
b) New information shows the interventions are not safe for your baby
c) You do not follow the study's instructions
d) The study sponsor closes the study for safety, administrative, or other reasons

If you decide to stop being in the study, we ask that you let the study leader know. This can be done verbally or in writing whichever method work better for you.

Any data collected about you up until the time you leave the study must be kept in order to determine the results of the study.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

Information obtained from you during this study will not be used in future research.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

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

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Your information, collected for this study, will be protected by a Certificate of Confidentiality from the federal government. If UVA receives a subpoena or court order demanding information from the study records that would identify you, we will use the Certificate to resist the demand. However, UVa will not use it in the following cases.

- You have agreed in writing to allow UVa to share the information with your employer, your insurance company for billing purposes, or someone else
- Reports to authorities where there is a danger that you may harm yourself or others, or if there is evidence of probable child or elder abuse or neglect.

In addition, the Certificate does not prevent government authorities who oversee research from reviewing this study. This Certificate does not mean that the government either approves or disapproves of this study. It just helps protect your privacy.

Please contact the Principal Investigator listed earlier in this form to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Lisa Letzkus
PO BOX 800135 Charlottesville VA 22908
Telephone: (434)924-5392

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483, Charlottesville, Virginia 22908, Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent of Adult

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Parental/ Guardian Permission

By signing below you confirm you have the legal authority to sign for this child.

_____	_____	_____
PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE

Person Obtaining Parental/Guardian Permission

By signing below you confirm that you have fully explained this study to the parent/guardian, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING PARENTAL/ GUARDIAN PERMISSION (SIGNATURE)	PERSON OBTAINING PARENTAL/GUARDIAN PERMISSION (PRINT NAME)	DATE

Signature of Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

Please indicate with check box the identified individual(s):

☐ Subject
☐ Parent(s)/Guardian of the subject

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE

Notification of My Health Care Provider

Your health care provider will be notified of your participation in this study.

Leaving the Study Early

If you leave the study early the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

Check one option below:

____ I am withdrawing my consent from the intervention or treatment part of this study but agree to continue to have follow up information about me collected by the study team.

____ I am withdrawing my consent for this study. No additional information may be collected about me including follow up information from my medical records.

Signature From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Signature

By signing below you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Parental/ Guardian Signature

By signing below you confirm you have the legal authority to sign for this child.

_____	_____	_____
PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE

Person Obtaining Signature

By signing below you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE