Title of the Research Study:
RESTORE Resilience in Critically Ill Children – R2: Research Phase

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Your child may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You may decide to discuss the study with your family, friends or family doctor. Please ask the research team questions about any medical language you find difficult to understand regarding the study. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

Why am I being asked to volunteer?
You are being invited to participate in a research study because your child is receiving medical care in the PICU at *Children's Hospital of Philadelphia (CHOP)*, is between the ages of 6 months and 18 years, was diagnosed with acute respiratory failure, and requires a ventilator (breathing machine).

You may find some of the medical language difficult to understand. Please ask the research team about any questions you may have about this study. If you decide to allow your child to participate, you will be asked to sign this form, and a copy will be given to you. Keep this form so that you can find important contact information and answers to questions about the study.

Who is conducting this research?

This research study is a collaboration between the University of Pennsylvania and *CHOP.* This study is supported by a grant from the National Institute of Child Health and Human Development.

What is the purpose of the study?

This is a pilot study. The purpose of this pilot study is to improve the care, environment, daily routine and sleep patterns of children in the PICU. The goal of this study is to learn what can be improved to support a critically ill child's healing and circadian rhythms (the 24-hour internal clock in the background of your brain and cycles between sleepiness and alertness at regular intervals).

How long will I be in the study?

You and your child's study participation will take place while he/she is in the PICU or up to 28 days, whichever occurs first.

How many other people will be in the study?

We expect about 60 other children to participate in this study, 30 at CHOP and 30 at Johns Hopkins Bloomberg Children's Center. Each site will enroll 10 baseline subjects followed by 20 interventional subjects.

What will I be asked to do?

Some of the procedures in this study will be repeated several times. Tests that are part of your regular, routine medical care will continue to be performed. In addition, you and your child may receive a collection of activities **usually but not consistently implemented at the same time** in the PICU called RESTORE resilience or R2. The study involves the following tests and procedures as well as recordings of the room environment during your stay in the PICU:

Test or Procedure	Purpose	Main Procedures	When and Duration
Light and Noise levels	Assess the possible disruption of rest	Continuously monitored light and noise levels by *Quietyme* system sensors plugged into outlets around the room	Ongoing while in PICU
Cycled Light and Sound	Possibly improve sleep-wake patterns	A laptop in the room that will assist you and the study team to view light and sound levels and make changes to match home routines. Window shades or ambient lighting and shutting room doors will match your preference by cycled lighting and sound in your room.	Ongoing while in PICU
Saliva Samples	Check the circadian rhythm (sleep/rest/wake patterns)	Melatonin secretion levels in saliva will be taken by a cotton swab placed under the tongue for 60-90 seconds to collect saliva	8 oral samples taken on both Day 2 & Day 5
Actigraphy Monitor	Monitor wake and sleep patterns	Small monitor (looks like a wrist watch) placed on the wrist or ankle	Ongoing while in PICU
Electro-	Monitor sleep patterns	Electrodes that look like tiny suction cups about the size of a	Ongoing while in

encephalogram (EEG)		dime placed on skin of the head.	PICU until breathing tube removed
Receive one of three PICU Up! Physical activity programs	Early activity and mobility program	Based on their age, ability and severity illness one of three PICU Up! Physical activity that includes physical therapy and progressive mobility/exercise	Ongoing while in PICU Several times each day.
Sedation plan	Possible improved level of comfort while using a decreased total sedative exposure	Sedation plan will be managed using the RESTORE algorithm	Ongoing while in PICU
Same Care Nurse each shift (when possible)	Provide continuity of care and possible comfort of the same caring staff personnel	The charge nurse will work to limit the number of different nurses assigned to care for you	Ongoing while in PICU
Daily Activity Log	To compare information from both study groups for possible differences	Check off and written information completed by nurse or parent/ guardian that includes naps/bedtime, physical activities, therapy, quiet time, diversional activities and parent presence	Ongoing while in PICU, once each shift 5 minutes
Diary	To compare information from both study groups for possible differences	Collect information as to your thoughts, questions for your medical team, and any events that take place each day	Daily 5 minutes
Initial Daily Routine Survey	Used as a template for your child's daily schedule while in the PICU; like their feeding schedules/ eating, wake time/naps/bedtime, hygiene, daytime activities (physical activity/play, computer/ TV), and bedtime/arousal routine	Complete "*Child's Daily Routine and Sleepy Survey"*	Completed once at the start of the study 5-10 minutes
Survey at PICU Discharge	To measure your experiences with nursing care while you were in the PICU	Complete check off and written information survey	Completed once at PICU discharge 5 minutes

Monitoring:

- The light and noise levels. This information is collected by using *Quietyme* sensor system while in PICU.
- Actigraphy monitor (looks like a wrist watch). The actigraphy watch will be placed on a wrist or ankle that is not occupied by medical devices and will remain on for the duration of your PICU stay. The watch is waterproof and can remain on for baths/showers. It can be removed as needed for routine medical care, such as magnetic resonance imaging or surgery.

Procedure/Test:

- EEG (Electroencephalogram). We will describe the procedure thoroughly to you. We will closely involve you during the application of electrodes, and ask for your opinion regarding the best way to approach the EEG initiation.
- Saliva Samples. If a child does not want to keep the cotton swab in his/her mouth, it will be removed, and the child will be given a break before reattempting.

Logs/Surveys:

- Daily log
- Diary
- Survey at start of study and at PICU discharge

What are the possible risks or discomforts?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor. While in this study, you are at risk for the following side effects or risks:

There are minimal risks or discomforts to you or your child from participating in this study. These include the time burden imposed by completing the survey, diary, and reviewing the room light and sound information on the laptop.

Noise and light level data will be collected using *Quietyme* system, however there is no speech or video recordings. These data will be continuously collected, time coded and downloaded to a password-protected secure server.

There are no risks related to routine EEG monitoring of sleep. In rare situations, electrode placement may lead to a minor skin reaction that is most often self-limited. We will describe the procedure thoroughly to you. We will closely involve you during the application of electrodes, and ask for your opinion regarding the best way to approach the EEG initiation. We will be sure to answer all of your questions.

The actigraphy watch for activity will be placed on a wrist or ankle that is not occupied by medical devices and will remain on your child for the duration of their PICU stay. The watch is waterproof and can remain on for baths/showers. It can be removed as needed for routine medical care, such as magnetic resonance imaging or surgery. A member of the study team will monitor the watch daily while your child is in the PICU to ensure it is functional and positioned appropriately. There are no risks associated with wearing the watch unless it is worn too tightly and constricts the wrist or ankle.

Salivary melatonin measurement is a reliable, non-invasive alternative to serum sampling for characterizing the circadian rhythm of melatonin secretion. There is no risk or discomfort associated with salivary melatonin sampling. If a child does not want to keep the cotton swab in his/her mouth, it will be removed, and the child will be given a break before reattempting. The cotton swabs used are highly absorbent and resistant to breakage; therefore, they present no risk of choking.

Another important risk is related to potential loss or release of confidential (private) information. Anytime confidential information is collected, there is a risk that the information will be unintentionally released. Any information about you or your child obtained from this research will be kept as confidential as possible.

What if new information becomes available about the study?

During the course of this study, we may find out more information that could be important to you and/or your child. This includes information that, once learned, might cause you to change your mind about your child being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

No direct benefit from study participation is expected. Participation may result in the improvement in the environment, daily routine and sleep patterns of children during a stay in the PICU. The findings from this study will increase clinical knowledge regarding the care of critically ill children and how best to preserve and/or restore a child's circadian rhythm. The possible benefits of this study outweigh the risks to participation We expect these results will contribute to education of pediatric health providers, care of all pediatric patients with acute respiratory failure, and future studies evaluating the effects of environment and care.

What other choices do I have if I do not participate?

Your alternative to being in the study is to not be in the study. Your participation is voluntary. You do not have to take part in order to receive care at CHOP. There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you, or would come to you in the future.

Will I be paid for being in this study?

No. There is no compensation for participation in this study.

Will I have to pay for anything?

There will be no cost to you for your child to be in this research study. Care that would be given if your child was not in this research study will be charged under your usual payment method. There will be no charge to you or your insurance company for any of the costs directly related to this study. The study sponsor is providing financial support and material for this study. The following research procedures and study procedures will be paid by study sponsor:

- Actigraphy monitor
- EEG
- Melatonin samples

Who is funding this research study?

The National Institute of Child Health and Human Development is providing funding for this study. Please ask Dr. Zuppa if you have any questions about how this study is funded.

What happens if I am injured from being in the study?

You do not waive any legal rights by signing this form. In the event that you or your child are hurt or injured as a result of participation in this research study, please contact the investigator listed on the first page of this form. It is not expected that any injury will occur from participation.

When is the study over? Can I leave the study before it ends?

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your or your child's future care. You do not have to give a reason.

This study is expected to end after all information has been collected and reviewed.

Can the study doctor take me/my child out of the study early?

This study may also be stopped at any time by your child's doctor, the study Principal Investigator or the study Sponsor (National Institutes of Health) without your consent because it is necessary for your or your child's health or safety, you cannot meet all the requirements of the study, or new information suggests taking part in the study may not be in your/your child's best interest. Such an action would not require your or your child's consent, but you will be informed if such a decision is made and the reason for this decision.

Who can see or use my information? How will my personal information be protected?

Your and your child's personal information from medical records, results of testing, and responses to questionnaires will be reviewed by study personnel at your testing site (the clinic), as well as study investigators. We will do our best to make sure that the personal information in your child's medical record will be kept private. However, we cannot guarantee total privacy. Your child's personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your/your child's name and other personal information will not be used.

What information about me or my child may be collected, used or shared with others?

This part of the form gives more detailed information about how you/your child's personal health information may be used and disclosed by University of Pennsylvania and the individual Principal Investigator, subject to University of Pennsylvania procedures. The following information will be collected:

- Name, address, telephone number, date of birth, email address
- Medical Record Number
- Personal medical history
- Current medications and therapies
- Information from the medical record related to physical examination and results of tests and procedures

Sharing Data with the National Institutes of Health (NIH)

Why will my data be shared with the National Institutes of Health (NIH)?

The NIH is funding this study. The NIH's goal is to maximize the benefits that come from the research. The NIH intends to share the collected information with other researchers. The researchers who receive data must promise to keep the data confidential and to use it only for the purpose approved by NIH. They must also promise to not try to re-identify anyone.

Risks Associated with Sharing Data with the NIH

There are risks associated with sharing your data with the NIH but they are very unlikely to occur. There is only a very small chance that someone could find out that the data came from you. If that happened, it's possible that someone could deny you a job or health insurance. Or you could experience stress, anxiety or embarrassment.

Benefits Associated with Sharing Data with the NIH

Sharing your information for future research will not directly benefit you. It is hoped that it will lead to a greater understanding of the interaction between genes and health. This knowledge could help others in the future.

Consent to Share Data with the NIH

Please indicate whether you will allow us to share your information with the NIH by putting your initials next to one of the following choices:

_____ (initials) No, I do not consent to sharing my de-identified information with the NIH

_____ (initials) Yes, I do consent to sharing my de-identified information with the NIH for controlled access

Consent for Use of Data or Specimens for Future Research
As part of the study, we will collect saliva samples and study data from you. By agreeing to participate in the study, you agree to give these samples and information to CHOP for research purposes.

We may wish to use this information or saliva in a future study about PICU environment and critically ill children's reaction to hospitalization. The information and samples will be given a unique code and will not include information that can identify you. A Master List will be kept that links the data or specimens to the subject, will be held in the Critical Care Medicine Research offices in password protected computer database. Information that can identify you or the saliva samples may be kept permanently in the Zuppa Biometric Laboratory at CHOP.

Only the study doctors and those working with them on this study will be able to see information that can identify you.

If you leave the study, you can ask to have the data collected about you removed or the samples destroyed. You can also ask us to remove information that identifies you from the data or samples.

Please indicate whether you will allow the data or samples to be used for future research by putting your initials next to one of the following choices:

_____ (initials) The data and/or saliva specimens may be used for this study only.

_____ (initials) The data and/or saliva specimens may be used for other future research studies. If the data or saliva specimens are shared outside of CHOP, no identifiable information will be included.

Why is my child's information being used?
Your child's information will be used by the research team to contact you/your child during the study. Your child's information and results of tests and procedures are used to:

- Do the research
- Oversee the research
- To see if the research was done right

Who may use and share information about my child?
The following individuals may use or share your child's information for this study, in order to conduct the research described in this form:

- The investigator for the study and the study team
- Authorized personnel at *CHOP*

Who, outside of the University of Pennsylvania, might receive my child's information?

- The University of Pennsylvania School of Nursing (the coordinating center)
- The study sites: Children's Hospital of Philadelphia and Johns Hopkins University
- Children's Hospital Boston (the lead data coordinating center)
- The funding sponsor (National Institutes of Health) and organizations supporting the sponsor

Oversight organizations

- The Office of Human Research Protections

Once your child's personal health information is disclosed to others outside University of Pennsylvania, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your child's active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your/your child's privacy.

What if there is a Certificate of Confidentiality for this Study?
The NIH has given us a Certificate of Confidentiality for this study. This Certificate provides some additional protection for research information that identifies you. The Certificate allows us, in some circumstances, to refuse to give out information that could identify you as a research subject without your consent, when such information is sought in a federal, state, or local court or public agency action. Still, we may disclose identifying information about you if, for example, you need medical help.

We may also disclose identifiable information about you as described in Section 12 of this form or in other cases. For example, the government may see your information if it audits us, and the research team will voluntarily comply with reporting requirements to the appropriate local or state authorities:

- if they suspect abuse, neglect or abandonment of a child or vulnerable or dependent adult;
- if certain diseases are present; and
- if the team learns that you plan to harm someone. In this case, the team also may warn the person who is at risk.

Even with this Certificate in place, you and your family members must continue to protect your own privacy. If you voluntarily give your written consent for an insurer, employer, or lawyer to receive information about your participation in the research, then we may not use the Certificate to withhold this information.

This Certificate does not mean the government approves or disapproves of this research project.

How long may the University of Pennsylvania use or disclose my child's personal health information?

Your authorization for use of your child's personal health information for this specific study does not expire.

Your child's information may be held in a research database. However, the University of Pennsylvania may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my child's information?

Yes. You may withdraw or take away your permission to use and disclose your child's health information at any time. You do this by sending written notice to the investigator for the study, using the contact information listed on the first page of this form. If you withdraw your permission, your child will not be able to stay in this study.

What if I decide not to give permission to use and give out my child's health information?

Then your child will not be able to be in this research study.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on the first page of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs at the University of Pennsylvania with at (215) 898-2614 or the CHOP IRB office at 215-590-2830.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation. You are also agreeing to let CHOP use and share your child's health information as explained above. If you don't agree to the collection, use and sharing of your child's health information, your child cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Name of Subject

Name of Authorized Representative (if different than subject)	Relation to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date