DIRECTIONS FOR USE OF THIS TEMPLATE:

- Required sections appear in black font.
- All changes made to this template must be done using tracked edits.
- Sections may be reordered as appropriate.
- Instructions to insert site specific information, contact information or institution name are indicated in italics.
  - hospital name must be the institution where you are recruiting subjects
  - if you are also affiliated with a university, please indicate both institutions on page 1 under “who is leading this research” section
- Do not remove the Version Date in the footer. A local site Version Date may be added if preferred.
- All added text must be written at or below a 6th grade reading level.
- Review italicized instructions and insert requested information where applicable. Delete the instructions once information has been added.
- If a separate HIPAA form is required locally, remove all HIPAA related sections on pages 9-11. Review both documents for redundancy and accuracy.
- If the local site IRB wants to be listed as an entity that can be contacted with question or complains please add the contact information to the final section before signature page

HOSPITAL NAME
Study Title: PRone and OScillation PEdiatric Clinical Trial: PROSpect

Principal Investigator:
Martha A.Q. Curley, RN, PhD, RAAN
University of Pennsylvania
418 Curie Boulevard, #424
Philadelphia PA 19104-4217
Office Phone: 215-573-9449
Email: curley@nursing.upenn.edu

Local Investigator:
insert name, address, phone and email address for local investigator
Office Phone:
Email:

Emergency Contact:
Insert Local Investigator Name, Phone and email address
Phone: [indicate if phone number may be called 24/7 and if not who to contact after hours]
Email:

Why is my child being asked to volunteer?
Your child is being asked to take part in a research study because:
- your child is receiving care in the Pediatric Intensive Care Unit;
- is between the ages of 2 weeks and 17 years old; and
- has severe respiratory distress with a breathing tube.

Your child’s participation is voluntary. If you choose not to take part there will be no loss of benefits to your child. Your child’s doctor feels they are a good fit for this study. Please feel free to discuss participation with your family, friends, or another doctor. Members of your child’s health care team may be involved in this study. They are interested in your child’s health care and in the goals of this study. You do not have to participate in any research study offered by them. If you allow your child to take part, you will be asked to sign this form.

Who is leading this research?
This research study is a collaboration between the University of Pennsylvania and hospital name. Hospital name receives payments from the National Institutes of Health to conduct this study.

Why is this research being done?
This study is being done to learn the best way to help children breathe when they are sick. When children’s lungs are very sick, they are on a machine to help them breathe.

There are different types of breathing machines that can be used. The two types are usual or high frequency:
1) A usual breathing machine imitates a person’s normal breathing.
2) A high frequency breathing machine delivers fast and shallow breaths.
There are also different positions a child can be in while on a breathing machine:
1) Lying on their back with a slight change in position every two hours.
2) Lying on their stomach for at least 16 hours each day with a slight change in position every 2 hours. When needed for medical care, your child will be turned on their back, and then returned to lying on his or her stomach.

At hospital name, we use both types of breathing machines and place children in both positions. The main purpose of this study is to find out if one approach is better than others in reducing the number of days a child spends on a breathing machine. The length of time your child spends on the breathing machine may be shorter or longer from taking part in this study.

**How many children will be in this study?**
At hospital name, we are asking about 24 children to be in this study. The study will ask up to 1,000 children from over 45 hospitals around the world. The study will take up to 4 years to complete.

**How long will participation in this study last?**
For about one year after your child leaves the Pediatric Intensive Care Unit. After leaving the hospital, taking part in the study will be by phone or by email. All contacts with your child will be made through, or in coordination with, a parent.

**What is involved in this study?**
1. Within 4 days of your child being placed on a breathing machine your child will be randomly placed into one of 4 groups:

<table>
<thead>
<tr>
<th>Machine Type</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Usual</td>
<td>a. Lying on Back</td>
</tr>
<tr>
<td></td>
<td>b. Lying on Stomach</td>
</tr>
<tr>
<td>2. High Frequency</td>
<td>a. Lying on Back</td>
</tr>
<tr>
<td></td>
<td>b. Lying on Stomach</td>
</tr>
</tbody>
</table>

Randomization is a tool used in research to place patients in study groups. In this study your child will be randomly placed into one of the 4 groups by chance, like picking numbers from a hat. Neither you, your child’s doctor, nor the researcher’s will choose which study group your child is in. A computer will choose which study group your child receives. After 400 patients have participated and after every 100 patients after that, the chance of being in one of these 4 groups may change. This change may allow more children to be randomly placed in the better group and fewer children to be randomly placed in the worse group.

Your child will remain in their group until:
- 24 hours after stopping a breathing machine or
- your child has been in the Pediatric Intensive Care Unit for 28 days

A member of the care team will observe your child every day until they leave the Pediatric Intensive Care Unit or until day 28. During this time, we will also record information from their medical record. We will continue to record information up until hospital discharge or at day 90.

During this study, your child’s doctor will continue to determine your child’s best care. They may place your child on a different breathing machine or position or remove your child from the study completely. Your child’s doctor will inform you of their decision. If this happens, the study will continue to collect information from your child’s medical record.
2. MEDICATION:
For the first 24 hours of study participation, your child will receive a medication called neuromuscular blockade. This helps keep your child still while the machine helps them breathe. After 24 hours, your child’s care team will determine if it is necessary to continue this medication.

3. BLOOD SAMPLE:
We will collect a blood sample [about one half teaspoon] from your child. The blood sample will be collected from an existing intravenous (IV) line on day 0, 1, 2, 3, 5, 7, 10, 14, 21 and 28. This blood collection will take approximately 2 minutes. Collecting these samples will not require an additional needle stick.

We are collecting these blood samples to better understand why children like yours become so sick. The blood samples are not linked to this study but will be collected and saved for future studies including genetic studies. The study results will not be available to you or your child’s care team.

All other care your child receives will be standard medical care led by your child’s doctor.

4. MEDICAL RECORD:
We will ask the care team to provide details of your child’s health during their hospital stay. This information will be recorded into a secure web-based study form.

If your child tests positive for COVID-19 (SARS-CoV-2) we will also collect information from their medical record about the medications and tests they receive related to their COVID-19 treatment.

5. SURVEY:
You will answer questions about your child’s physical, social and academic work before coming to the hospital. This survey will take you about 10-15 minutes to complete and will be completed on a computer. Your child’s care team will assist you with completing this survey.

How might my child’s treatment during this study at hospital name differ from routine care that they would otherwise receive?
Differences in caring for children with severe respiratory distress may exist. The following parts of the study are not a part of routine care at hospital name:

Note: In this section remove the elements listed below that are routine care at your site. Only keep those items that are NOT routine. For the items you need to include, lay language for each item can be provided:

- Oxygenation goals
- Ventilation goals
- Use of neuromuscular blockade in first 24 hours
- Daily sedation goal
- Daily extubation readiness test
- Daily pressure injury risk assessment
- Initial and ongoing conventional mechanical ventilation settings
- Initial and ongoing high frequency oscillatory ventilation settings
- Prone positioning for 16 hours/day
What is involved after my child leaves the hospital?
We will ask you and/or your child to complete a follow up survey. The survey will be completed four times over one year and takes about 15 minutes to complete. The survey will ask about how your child is doing. Dr. Curley’s research team at the University of Pennsylvania will help you complete these surveys.

The table explains who may complete each survey.

<table>
<thead>
<tr>
<th>What is your child’s age?</th>
<th>Who will complete the survey?</th>
</tr>
</thead>
<tbody>
<tr>
<td>My child is younger than 8 years of age</td>
<td>You will complete the survey by phone or by yourself on a computer.</td>
</tr>
<tr>
<td>My child is between the ages of 8 and 13</td>
<td>You and your child will complete the survey by phone or by computer.</td>
</tr>
<tr>
<td></td>
<td>We will contact you and arrange the best time to speak to your child if the survey will be completed over the phone.</td>
</tr>
<tr>
<td></td>
<td>We will ask you to help your child with accessing the survey if the survey will be completed on the computer.</td>
</tr>
<tr>
<td>My child is 13 years or older</td>
<td>You and your child will complete the survey by phone or by yourself on a computer.</td>
</tr>
<tr>
<td></td>
<td>We will ask you by phone or by email to remind your child to complete each follow up survey on the phone or on a computer.</td>
</tr>
</tbody>
</table>

How will we be contacted for the follow up survey?
Before your child leaves the hospital, Dr. Curley’s research team will contact you to confirm your contact information. Most of the time the research team will reach you by email. If they cannot reach you by email, they will call you. You can then decide the best way to reach you to complete the follow up surveys. If your child is 13 years of age or older they may ask your permission to gather his/her cell phone number and email address.

This study will have a Facebook page and a website. You are welcome to message the research team on Facebook or send them email through the study website.

However, for questions about personal or private matters — such as your child’s health care or symptoms. — we urge you to call your child’s care team at xxx-xxx-xxxx (insert site specific number) so that we can have a private discussion regarding your questions or concerns.

What are the risks of this study?
The procedures used in this study are consistent with the international guidelines for the care of children with severe respiratory distress. Critically ill children with severe respiratory distress are at risk for death. There may be risks or discomforts to your child from taking part in this study. They are the same risks if your child’s doctor chose to treat your child this way and your child was not in the study. These include potential risks related to:

Lying on stomach.
Risks while in this position may include:
- unplanned breathing or other tube removal
- blockage or movement of the breathing tube
- temporary swelling in the face or eyes
- eye scratches

Type of breathing machine:
Risks for each of these study groups may include:
- displaced air in the chest

Lying on stomach and breathing machine
Risks while in these groups may include:
- unstable blood pressure
- heart rhythm abnormalities
- blockage of the breathing tube
- more sedation medication
- pressure sores on the skin

Medication:
Neuromuscular Blockade: Your child’s doctor will choose the medication for neuromuscular blockade. Each type of medicine has different risks. Short-term use of this medication is not expected to cause harm. Your child’s nurses will continue to manage your child’s comfort. After receiving this medication, some children may experience long-term muscle weakness.

Privacy:
Anytime confidential information is collected, there is a risk that the information will be accidentally released. Any information about your child obtained from this research will be kept as private as possible.

Confidentiality:
Do not send any private information by social media or email. Social media or email are not secure. Please review the privacy settings carefully before commenting, posting, or sending a message. Once content is posted or sent, privacy cannot be assured.

Genetic testing:
The collected blood samples may include genetic testing. Even without your child’s name or other identifiers, your child’s genetic information is unique to them. The researchers believe the chance that someone will identify your child is very small. The risk may change in the future as new ways of tracing information are learned.

There can be a risk in knowing genetic information. New health information about inherited traits that might affect your child or their blood relatives could be found during a research study. Even though your genes are unique, your child shares some of the same genes with your blood relatives. Although we are not able to know all of the risks from taking part in research on inherited traits, we believe that the risks to your child and their family are very low, because your child’s samples will be coded. Research results will not be returned to you, your child or your child’s doctor.

Very rarely, health or genetic information could be misused by employers, insurance companies, and others. For example, it could make it harder for your child to get or keep a job or insurance, or life insurance companies may charge a higher rate based on this information. We believe the chance these things will happen is very small, but we cannot make guarantees.
A United States federal law (Genetic Information Non-Discrimination Act, GINA) helps reduce the risk from health insurance or employment discrimination. The law does not include other types of misuse by life insurance or long-term care insurance. If you want to learn more about Genetic Information Non-Discrimination Act, please ask the study team.

Follow up surveys:
Your child may feel embarrassed answering some of the questions on the follow up surveys. These will be questions like those a doctor may ask during a typical medical appointment.

How will my child’s blood sample be protected?
All information that identifies your child (like their name) on the blood sample will be removed. This information will be replaced with a unique code number. When your blood samples are sent to the Children’s Hospital of Philadelphia (CHOP) biorepository they will only have the unique code number.

What will be done with my child’s data and blood samples?
- Your child’s sample will be stored in a biorepository at Children’s Hospital of Philadelphia (CHOP). A biorepository is a collection of samples of blood.
- A variety of different tests may be done on your child’s samples, including genetic tests. Because the field of genetic testing is advancing rapidly, we can’t predict all of the tests that will be done.
- Only with the permission of the lead researchers of this study the samples and test results may be shared with other researchers. Anyone who uses your child’s samples and data for future research will not know who they are. They will only get the code number.
- Because all information and samples will be coded, it will not be possible to share any test results with you or your child’s doctors. In addition, many genetic tests are experimental, and the meaning of the test results is not known.

What is an Electronic Medical Record?
Insert site specific language regarding use of EMR in research. Site note: Must indicate what information about research study will be contained within local EMR

What if new information becomes available about the study?
During this study, we may find out more information that could be important to you 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.

Are there benefits to my child from being in this study?
We expect no direct benefit to most children who take part in this study. We expect the results of this study to contribute to the care of all children with severe respiratory distress, to future studies examining the best treatments for critically ill children and to the education of pediatric doctors and nurses. Society in general and children receiving care in the Pediatric Intensive Care Unit in the future may benefit from this study.

What if I do not want my child to participate in this study?
If you do not wish your child to take part in this research study they do not have to. You child will receive the routine medical treatment available at hospital name, which may include stomach positioning, and usual or high frequency breathing machines. Their medical treatment at hospital name will not be affected now or in the future.
Will my child be paid for participating in this study?
You will receive a $50 ClinCard (this is a special debit card for clinical research) in the mail from the University of Pennsylvania for your time and effort after completing all follow up surveys.

The blood samples and other information stored as part of this study could lead to discoveries or inventions in the future that may be of value to Children’s Hospital of Philadelphia (CHOP) or to other organizations. We will not know whose samples are used for these discoveries. You or your child will not receive any money or other compensation that may come from products that are developed from research samples.

What happens if I move or change phone numbers?
We ask you to contact Dr. Curley’s research team if you move, have a new phone number or a new email address.

If we lose contact with you during the study for any reason (your phone number changes; your physical or email address changes; you are not responding to our attempts to contact you about your continued participation; etc.), we will attempt to find you or contact you in the following ways:

• The alternate contact’s phone number(s) you provided will be called, but if you are not the person who answers, we will not say the title of the study or the fact that you are/were participating in a study (in a HIPAA compliant manner to protect your privacy).

• We may contact the children’s hospital where your child first participated to see if you have returned and provided new contact information.

• A letter will be sent to the address(es) you provided to us, the return address will say the University of Pennsylvania, via certified mail requesting that you call us.

• If none of these attempts work, we may search a secure, private database for updated phone number or mailing address.

May we contact you in the future for other research studies?
We may keep your contact information to contact you in the future and tell you about other studies in which you or your child might be eligible to participate.

Will it cost me anything to allow my child to be in this study?
There will be no cost to you or your insurance company 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 to your usual payment method.

What happens if my child is injured from being in the study?
*Insert specific hospital injury/compensation language.*

If you think your child has been injured from taking part in this research study, tell the Dr. Curley as soon as possible. Dr. Curley’s phone number is listed on page one.

Can my child leave the study before it ends?
Your child is free to leave the study at any time. Your child’s future care will not be affected at hospital name if you end their participation.

When is the study over?
This study is expected to end after all participants have completed all follow up surveys, and all information has been collected. This study may also be stopped at any time by your child’s doctor, the study sponsor, or the Principal Investigator without your consent because:

- The Principal Investigator feels it is necessary for your child’s health or safety. You will be informed if such a decision is made and the reason for this decision.
- Your child has not followed study instructions.
- The sponsor, the study Principal Investigator, or the University of Pennsylvania Institutional Review Board has decided to stop the study.

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

The following information will be collected:

- Name, address, telephone number, date of birth
- Medical Record Number
- Social media profile name
- Medical history
- Current medications and therapies
- Information from the medical record related to exams and tests

**Why is my child’s personal information being used?**

Your child’s personal information will be used by the research team to contact you or your child during the study. Your child’s personal information and results of medical tests and procedures are used to:

- Do the research
- Oversee the research
- To see if the research was done right
- To evaluate and manage research functions

**How will personal information collected about me or my child be protected?**

Your child’s personal information from medical records and results of testing will be reviewed by the study team at hospital name. 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 child’s name and other personal information will not be used.

At study enrollment, your child will receive a randomly generated 7-digit identification number. Your child’s name will not be used on any study related document. This study ID number will be used to protect your child’s confidentiality when collecting and maintaining all study related materials. All study records will be maintained in locked offices at hospital name and only the care team will access them. The University of Pennsylvania will have access to these records for monitoring and audit purposes.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or blood samples that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or blood samples protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by
federal regulations protecting research subjects. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

A description of this clinical trial will be available at http://www.clinicaltrials.gov, as required by United States law. This website will not include information that can identify you or your child. At most, this website will include a summary of the study results. You can search this website at any time.

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:
- Dr. (insert local investigator) for the study and their study care team
- Authorized personnel at hospital name, including offices that support research
- Dr. Martha Curley and her study research team at the University of Pennsylvania

Who, outside of the hospital name, might receive my child’s information?
- The following research centers and their study team taking part in this study:
  - University Hospitals (UH) Rainbow Babies & Children’s Hospital
  - University Medical Center Groningen in The Netherlands
  - Children’s Hospital of Philadelphia
  - Boston Children’s Hospital
- The National Institutes of Health and organizations supporting them

Oversight organizations
- The University of Pennsylvania Institutional Review Board
- The study Data and Safety Monitoring Board
- Local Institutional Review Board

Once your child’s personal health information is disclosed to others outside hospital name, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study care team will tell you if anyone is added to the list above during your child’s participation. Any new additions will keep your child’s information private.

How long may the hospital name 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. The hospital name may not share 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 take away your permission to use and share your child’s health information and blood specimens at any time. You do this by sending a letter to Dr. Curley.

What if I decide not to give permission to use and give out my child’s health information?
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 child’s rights as a research subject?**

If you have questions, concerns or complaints regarding your child’s participation in this research study or if you have any questions about your child’s rights as a research subject, you should speak with the Principal Investigators listed on the first page of this form.

If a member of the study 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 any questions, concerns or complaints by calling (215) 898-2614.
By signing this document, you are permitting the hospital name to use and share personal health information collected about your child for research purposes as described above and you are allowing your child to take part in this research study. You will receive a copy of this consent document.

If you are unable to sign this form in person, the study team at SITE NAME will explain this study to you over the phone.

Permission for your child’s participation may be obtained over the phone. This form will be shared with you electronically. You will sign and return this form electronically. Please save or print a copy of this form.

My child has tested positive for the COVID-19 virus:

___ I consent to the data collection related to my child’s COVID-19 status and treatment

___ I do not consent to the data collection related to my child’s COVID-19 status and treatment

Name of Subject (Please Print)

Name of Parent/Legal Guardian (Please Print) 

Signature of Parent/Legal Guardian 

Date

Name of Person Obtaining Consent (Please Print)

Signature of POC 

Date

My child’s blood specimen(s) may be collected and saved for future study.

_____ I consent to have my child’s blood specimen(s) saved for future research studies.

_____ I do not consent to have my child’s blood specimen(s) saved for future research studies.

The assent of __________________________ (name of child) was waived due to:

Age (under 8 yrs.) - circle:  YES  NO
If yes, specify age: ___________

Medical state - circle:  YES  NO
If yes, specify reason:

_____________________________________________