INFORMATION for PARENTS/GUARDIANS of POTENTIAL PARTICIPANTS

Name of Study:	A Multinational, Multicenter, Masked, Randomized, Parallel Group, Controlled Study to Assess the Safety and Efficacy of Lucinactant for Inhalation versus nCPAP Alone in Preterm Neonates 26 to 32 Weeks Gestational Age with Respiratory Distress Syndrome
Study Number:	03-CL-1702
Study Sponsor:	Windtree Therapeutics, Inc. 2600 Kelly Road, Suite 100 Warrington, PA 18976
Study Doctor (Investigator):	[Investigator Name] [Site Address] [Office Hours Tel] [Out of Hours Tel]
Institutional Review Board or Ethics Committee	[IRB/EC Name] [IRB/EC Address] [Office Hours Tel] [Out of Hours Tel]

Why are you receiving this information?

You are being asked to consider whether you would like your baby to participate in a clinical research study. The following information describes the study and your baby's role as a possible participant. You, as a parent or legal guardian, have the right to know all the details about this research. When you understand these details, including all the possible risks, hazards, or benefits, you may then decide whether your baby should participate in this study. This consent form will help you understand this study and help you decide whether to give your consent to allow your baby to participate in this research study. Please read this information carefully and do not hesitate to ask the study doctor any questions you may have. This informed consent does not replace any other informed consents you may have signed.

Your baby has been asked to take part because your baby was born approximately 8 to 14 weeks before your baby's due date (your baby is at a gestational age between 26 and 32^{+6} weeks). Also, your baby is receiving supplemental oxygen and breathing support by nasal continuous positive airway pressure (or some other type of non-invasive support), because your baby has suspected respiratory distress syndrome and surfactant deficiency.

What is the purpose of this clinical research study?

Babies born before 36 weeks gestational age often develop breathing problems. One of the reasons for this is that their lungs are not fully able to make a substance called surfactant, which is a natural liquid that coats the surface of our lungs. Our bodies normally make surfactant to help our lungs work properly. Babies who are born early and who have too little surfactant may develop a lung problem called respiratory distress syndrome, or RDS. Babies with RDS often need to be treated with oxygen and/or a breathing machine. If a baby needs a lot of support to help the baby breathe, the baby's doctor may place a tube into the baby's windpipe. This tube can be connected to a breathing machine and also can be used to treat the baby with surfactant by delivering the surfactant as a liquid to the lungs.

If a baby is breathing but needs a little support, then he or she may receive supplemental oxygen through a pair of short tubes called nasal prongs. The nasal prongs fit into the baby's nostrils. There are different types of support that use nasal prongs. One type is continuous positive airway pressure (CPAP). When this type is used with nasal prongs, it is called nasal continuous positive airway pressure (nCPAP). Babies who do not have a tube placed in their windpipe and instead receive nCPAP support do not get surfactant unless they develop more severe breathing problems.

Even if a baby starts with supplemental oxygen and nCPAP for breathing support, they are at risk for developing more severe breathing problems and may require a tube in the baby's windpipe and connecting that tube to a breathing machine. If this happens, the baby may also receive surfactant directly into the lungs through the tube in the windpipe.

Right now, the only way to give surfactant to a baby is when there is a tube in the baby's windpipe. Windtree Therapeutics has made a synthetic (man-made) surfactant that can be delivered using a new device as an aerosol, or mist, that does not require a tube in the baby's windpipe. The man-made surfactant is called lucinactant and the new device is named the Aerosol Delivery System (ADS). The mist, delivered by the ADS, is an investigational "drug-device" combination, known as Aerosurf, that is not yet approved for general use and can be used only in a research study. Windtree Therapeutics is developing Aerosurf, also known as "lucinactant for inhalation," to be able to give surfactant to babies without having to place a tube in the baby's windpipe.

The purpose of this study is to evaluate the safety and tolerability of lucinactant, delivered as an aerosol using the investigational ADS device, in babies with RDS who are being treated with supplemental oxygen and nCPAP.

Lucinactant, in the form of a liquid, has been approved by the United States Food and Drug Administration (FDA). The purpose of this experimental study is to evaluate the safety and effectiveness of lucinactant for inhalation, in babies being supported with supplemental oxygen and nCPAP.

What makes this different from the usual treatment?

Usually when babies require surfactant to help them breathe, the doctor places either a breathing tube or other small tube into the windpipe and puts the liquid surfactant directly into the lungs through the tube. In this study, the baby will receive lucinactant, a surfactant, as an aerosol, through the nasal prongs. The amount of surfactant delivered to the baby will be less than what is typically delivered as a liquid through a tube in the windpipe.

Lucinactant and the ADS have been used together in three other studies including approximately 200 preterm babies treated with lucinactant for inhalation who also have RDS.

How long will your baby be in the trial?

The duration of the study treatment will be approximately 1-2 days. Your baby will continue to have their health information collected while he or she is in the hospital, until he or she reaches 36 weeks gestational age, or until 28 days of life (whichever is later). After that, the study doctor or a member of the site medical team will contact you around your baby's 6-month corrected age to ask you about how your baby is doing. Also around your baby's 1-year corrected age, the site research team will request that you visit the study site again so the study doctor can perform a brief physical and a developmental exam. "Corrected age" means that the baby's age is calculated from when the baby was expected to be born (a gestational age of 40 weeks). For example, if your baby was born at 30 weeks gestational age, then the 6-month corrected age would be 6 months plus 10 weeks from the baby's date of birth.

What are the treatments and how are they assigned?

If your baby meets the requirements for the study and you provide your consent, and your baby is one of the first 2 to be enrolled at the site, your baby will receive "open-label" lucinactant for inhalation. After the first 2 babies are enrolled, your baby will be randomly chosen to receive either lucinactant for inhalation (study drug) along with nCPAP or nCPAP alone. The use of nCPAP alone is considered "standard of care." Thus, your baby will receive standard of care alone or standard of care plus the investigational treatment. Your baby will also get the usual care and treatment given to all babies who are born before 36 weeks gestational age. All babies will be monitored with a

transcutaneous carbon dioxide monitor for three days, which is a slightly-heated sensor that measures carbon dioxide, or CO_2, which is one indicator of how well your baby is breathing. The carbon dioxide is measured through the skin so that it is not necessary to take blood from the baby to measure his/her carbon dioxide.

If your baby is chosen to receive study drug, your baby will receive the lucinactant as a mist, or aerosol. The amount of aerosolized lucinactant your baby will receive will depend the number of treatments your baby receives.

- Group 1 – lucinactant for inhalation (160 mg total phospholipids [TPL]/kg) for 100 minutes in conjunction with nCPAP (up to 65 babies)
- Group 2 (Control Group) – continuous nCPAP alone (up to 65 babies)

If your baby continues to have trouble breathing after receiving lucinactant for inhalation, your baby may receive additional doses of lucinactant that are half as much as the first dose. Babies can receive up to 3 additional doses within 36 hours of the first dose.

Whether your baby gets nCPAP with lucinactant for inhalation or nCPAP alone depends on a computer random-generator system. This system will choose the treatment for babies by chance (like the flip of a coin). There is a 1 in 2 chance that your baby will receive lucinactant for inhalation. If you have a multiple birth and your site has 2 ADS devices, your babies will be randomized separately, so they may be in different study groups.

Except for the first 2 babies at each site, this is a masked (double-blind) study. This means neither you, your baby's doctor, nor the study doctor will know whether your baby has received nCPAP with lucinactant for inhalation or nCPAP alone. Specific health care staff who have been educated and trained to use both the drug and the ADS will be assigned to prepare and give your baby's treatment. The care your baby receives will not be affected by whether he or she receives aerosolized lucinactant.

What if I decide to allow my baby to participate?

If you decide to allow your baby to participate in this study, you will be required to sign this Informed Consent Form. Medical records of the mother (related to your baby's birth) will be reviewed, and your baby's medical records will be reviewed.

Your baby will have a physical exam and a chest x-ray done to see if he or she qualifies to be in the study. In order for your baby to be considered for this study, he or she must be supported by supplemental oxygen and nCPAP for at least 15 minutes.

The following procedures will be conducted if your baby qualifies for the study.

1) Lucinactant, a surfactant, is made into a mist, or aerosol, by the ADS
2) If your baby is assigned to receive lucinactant, your baby will receive aerosolized lucinactant through nasal prongs placed in your baby's nostrils. The nasal prongs and the nCPAP machine used are commercially available and indicated for use in infants.
3) A tube, called an orogastric or nasogastric tube, will be placed through your baby's mouth or nose and into his/her stomach to prevent too much air from accumulating in the stomach. This is often done for babies receiving nCPAP.
4) Before, during, and after each treatment of study drug, your baby's vital signs, blood oxygen and carbon dioxide levels, and nCPAP settings will be checked and documented. These assessments are part of the routine hospital care of babies born early.
5) One blood sample (about a quarter of a teaspoon) will be taken to calibrate the transcutaneous monitor that records your baby's carbon dioxide levels. This sample will be taken from a catheter if the catheter is already in a blood vessel. If there is no catheter or the catheter cannot be used to draw blood, the blood sample will be drawn from a vein by temporarily placing a needle into the vein, or by collecting the blood from a pinprick in the heel. Once calibrated, your baby's carbon dioxide level will be monitored using the transcutaneous monitor and not by taking and testing the baby's blood.
6) Your baby will be monitored and his or her vital signs, blood oxygen levels, and nCPAP settings will be checked and documented while in the hospital up to 36 weeks gestational age or 28 days of life (whichever is later).
7) One additional chest x-ray may be done for the study if your child requires intubation (breathing tube placement) or if your baby is having increased respiratory problems.
8) When your baby reaches 36 weeks gestational age (or 28 days of life), or is discharged or transferred from the hospital (whichever comes first), your baby will have a brief physical exam.
9) At 6-months corrected age, someone from the study team will contact you to ask you about if your baby has been in the hospital and if your baby has needed help with breathing. You will also be asked about medications that your baby has taken.
10) At 1-year corrected age, your baby will be seen by the study team. A brief physical exam and developmental exam will be done during that visit. The study team will also ask you if your baby has been in the hospital and if your baby has needed help with breathing and about

medications that your baby has taken.

What will happen at the end of the study?

At the end of the study, or after you decide to withdraw your baby from the study, the study doctor (or appointed delegate) may seek to establish your baby's long-term health status for a period of not more than 16 months, by accessing your baby's hospital records, or publicly available sources such as national registries, newspaper obituaries and social networking websites. Attempts may also be made to contact you or your relatives to ascertain this information. If you do not want this information about you to be collected, you may record your objection with your study doctor at any time.

What are the potential risks and discomforts?

Babies who are born preterm are at risk for complications related to preterm birth. The degree of risk is different for every baby and depends on many factors. These risks are present whether your baby participates in this study or not. Your baby's doctor or the study doctor can talk to you about these risks.

Babies who have RDS and who require breathing support are at risk for developing more severe breathing problems that may require placing a tube in their windpipe and connecting that tube to a breathing machine. If this happens, your baby's doctor may also decide to give your baby surfactant directly in your baby's lungs through the tube in the windpipe. This risk is present whether your baby participates in this study or not. Your baby's doctor or the study doctor can talk to you about these risks.

Lucinactant for inhalation is an investigational drug-device combination that is being tested in humans. This means there may be unknown risks to your baby. It also means it is not known whether this drug will be of any benefit to your baby or make your baby's problem worse. In previous studies in babies born as early as 26 weeks gestation, lucinactant, given as a liquid into a tube in the baby's windpipe, did not increase the risk of babies developing complications or dying.

Previous research in babies has shown that when lucinactant is delivered as a liquid through a tube in the baby's windpipe, side effects commonly reported (10 or more people out of 100) or less likely reported (between 1 and 9 people out of 100) include the following:

Commonly reported (10 or more people out of 100):

- Oxyhemoglobin desaturation (a decrease in the oxygen level in the blood for a short

period of time),
- Apnea (stopping breathing for a few seconds), and
- Bradycardia (a slowing of the heart).

Less likely reported (between 1 and 9 people out of 100; less than 10%):
- Gagging, which might occur when the surfactant first goes into the large airways of the lung,
- Vomiting when drug is given, and
- Pallor (a lack of color in your baby's skin).

These side effects are generally seen with most of the surfactants currently used for respiratory diseases. These events may require your baby's doctor and/or the study doctor to stop giving the study drug. Treatment may be stopped at any time if it is in your baby's best interest. Delivering lucinactant as a mist may decrease the side effects described above, although this is not known for sure now.

Some of the lucinactant aerosol will not reach the baby's lungs. It is possible that none of the lucinactant aerosol will reach the lungs. It is possible that your baby may not tolerate the delivery of the lucinactant mist and may develop some of the side effects listed above. Your baby will be monitored during the delivery of the lucinactant mist, and if your baby is not tolerating the treatment, the study doctor will stop the investigational treatment.

It is possible that the lucinactant mist may partially or totally clog the inside of the nasal prongs. Your baby will be monitored during the delivery of the lucinactant mist and the caretakers will check the prongs during the delivery of the aerosolized lucinactant.

To generate the mist, lucinactant is heated as it passes through the ADS. The device has been designed to generate a mist with a temperature that is safe for your baby, and there are automatic controls to check the mist temperature and to stop the treatment if the temperature is too hot or too cool. However, if the temperature safety controls of the device fail, it is possible that the mist might be too hot for your baby.

A transcutaneous monitor will be placed on your baby prior to receiving the study drug and for at least 72 hours after. Such a monitor is frequently used for preterm infants to measure carbon dioxide levels. The use of this monitor may cause some temporary irritation on the skin of your baby and, rarely, can produce a burn. The skin irritation, if it happens, will go away soon after the monitor is removed.

All babies enrolled in this study are required to be on nCPAP. This is a standard of care for babies who have respiratory distress. The nCPAP devices used in this research study are commercially available and indicated for use in infants. The risks of nCPAP are minor, and include the following:

- Excess air in the stomach,
- Redness or irritation of the nose from the nasal prongs used to provide nCPAP,
- Congestion or runny nose, and
- Pneumothorax.

As part of the study, a tube will be placed temporarily into the stomach, through either the mouth (orogastric) or nose (nasogastric). Orogastric and nasogastric tubes are generally very safe. However, even if it is placed gently, this tube can irritate the nose, mouth, or stomach and cause some (usually minor) bleeding. If placed in the nose, it may cause some nasal stuffiness and occasionally a nasal infection.

Obtaining blood samples from babies born early is part of usual care. Obtaining blood samples is done using sterile materials and established techniques. Possible side effects from blood drawing include the following:

- irritation of the vein, such as redness or swelling,
- pain,
- bruising or bleeding at the blood draw site, and
- a slight possibility of infection.

Your baby will be closely watched by his or her doctor and health care staff during the study. From the time of enrollment to the end of the study, all babies enrolled will be monitored for all possible side effects, and especially for signs that the baby's breathing problem is getting worse. The performance of the investigational ADS device will also be monitored. This information and the baby's safety will be closely followed by the study doctors. An independent safety committee (also known as a Data Monitoring Committee) will also oversee this study safety. This committee is comprised of doctors who are specialists in this field and are not employed by the Sponsor. This committee will advise the Sponsor about the safety of study subjects and will also evaluate the ongoing scientific strength of the study.

What are the advantages and disadvantages of participation in the study?

As with any investigational product, there is no guarantee this treatment will help all or any of the babies in the study. New information about the benefits and safety of aerosolized lucinactant

will be obtained from your baby's participation in this study. This new information may benefit other babies in the future if aerosolized lucinactant is shown to be safe and effective in babies with respiratory distress syndrome who require supplemental oxygen and nCPAP.

Are there any alternative treatments?

If you do not wish your baby to take part in the research, your baby will be provided with the established standard treatment available at this center. Babies diagnosed with respiratory distress syndrome usually receive nCPAP and sometimes receive liquid surfactant through a tube placed in the windpipe. Your study doctor will discuss these treatments with you, as well as the associated risks and benefits.

Will you be informed if new information becomes available during the study?

The study doctor will inform you in a timely manner of any new information learned during the study that may affect your willingness to continue your baby's participation.

Who can you contact with further questions?

You may ask questions about this consent form or the study at any time (before or during the course of the study). If you have additional questions, or your baby experiences a research-related injury, contact the study doctor using the details provided in the table on the first page of this information sheet.

If you have a complaint or question about your baby's rights as a research subject, you may contact the institutional review board or ethics committee using the details provided in the table on the first page of this information sheet. This is a group of scientific and non-scientific individuals who review research studies with the safety and welfare of research subjects in mind.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US Law. This website will not include information that can identify you or your baby. At most, the website will include a summary of the results. You can search this website at any time. This website only shows data in English, but you can request information from the study staff at any time and have access to data that are publicly available.

What happens if you change your mind?

You and your baby's participation in this study is voluntary. You do not have to allow your baby to take part, and you may discontinue your baby's involvement at any time without penalty or loss

of benefits to which you or your baby are otherwise entitled. Refusing to allow your baby to participate will not affect your treatment or your baby's treatment or your rights at this center in any way. If you enroll your baby in this study and then later withdraw your baby from this study, any information obtained while your baby was enrolled in the study may be used to evaluate the safety and tolerability of aerosolized lucinactant.

If you decide to leave the study before your baby has completed the study, tell the study doctor and follow their instructions. It may be helpful if you could explain your reasons.

In addition, the study doctor or the Sponsor may withdraw your baby from the study for his or her own safety, even if you wish your baby to continue to participate. For example:

- If your baby needs additional medication
- If your baby experiences a study-related injury
- If you or the study site do not follow the study rules

If your baby's participation in the study is stopped early, you may be asked to allow end of study procedures (such as a final medical examination and laboratory tests) to be completed on your baby, for your baby's own safety.

[TEXT FOR THE UNITED STATES]

Are there any costs if I decide to participate?

Study drugs will be made available to your baby at no charge and you will not be required to pay for any study procedures. You or your insurance company may be billed for any standard medical care that is not required for the research study.

Is there a payment if I decide to participate?

You will not receive payment for participating in this study, but the study drugs will be made available to you at no charge and you will not be required to pay for any study procedures.

Will I receive compensation if my baby is injured because of the study?

If your baby is injured because of his or her participation in this study, treatment for the injury will be made available through [name of physician] and [institution]. Windtree Therapeutics, Inc. will pay the costs of this treatment not paid by your medical insurance. No other payment is available from the Sponsor or the study doctor in the event of injury. You are not waiving any legal rights by signing this form, accepting medical care, or accepting payment for medical expenses.

Will the personnel involved in the study receive any payment?

The [institution] receives payment from Windtree Therapeutics, Inc. who is the Sponsor of this study.

What will happen to my baby's data?

- For sites located in California, the HIPAA authorization must be separate from the ICF (at the end of the ICF document) with a separate signature and 14-point font under California's medical privacy laws.

This research study may be performed only by collecting and using your baby's medical information. Your baby's study records will be kept as confidential as possible. Only a number will be used to identify your baby. You or your baby will not be personally identified in any reports or publications that may result from this research study.

Because of the research goals of this study, however, your study records cannot be kept completely confidential. The study personnel, Windtree Therapeutics, Inc. and its agents will need to review the medical information collected from your baby for use in this study to accurately record information for this study. In addition, to review the study findings, the U.S. Food and Drug Administration (FDA) and other regulatory agencies may review your baby's medical records. The following sections provide a specific description of how your baby's information will be used and disclosed if you consent for your baby to participate in this research study. By signing this consent form, you are authorizing such access. If you do not sign this form to authorize access, your baby will not be able to participate in this research study.

The medical information that will be collected from you and your baby if your baby participates in the study includes:

- Information obtained from procedures to determine your baby's eligibility to participate in the study, including a routine medical history, physical exam, x-rays, and blood and breathing tests.
- Information that is created or collected from your baby during your baby's participation in the study, including the results of the tests included in the previous bullet point and any other procedures performed during the study.
- Information contained in your baby's underlying medical records related to your baby's medical history and treatment.

The above information may identify you and/or your baby by name, address, telephone number, social security number, health plan number, study number, date of birth, dates relating to various medical procedures, and/or other identifying information.

If you sign this form and allow your baby to participate in the study, the study personnel will be authorized to use the information described above to carry out the purposes of the research study. The study personnel will also be authorized to disclose the relevant information described above to the following parties involved in the research study:

- Windtree Therapeutics, Inc. or other agents designated by Windtree Therapeutics, Inc. to collect or review study data for verification of study procedures and/or adverse event reporting.
- The Institutional Review Board (IRB) that oversees the research study at your site.
- Government regulatory agencies including the FDA.

Once your baby's information is disclosed to Windtree Therapeutics, Inc., its agents, the IRB, or government agencies as described above, there is a potential that your baby's medical information will be re-disclosed and will no longer be protected by U.S. federal privacy regulations.

The study data may be transferred to other countries for processing, including countries not covered by data protection legislation. The laws of your state may provide further protection.

While the study is in progress, your access to your baby's study records will be temporarily suspended. You will be able to access your baby's information when the research study is completed. You have the right to see and copy the medical information collected from your baby during the study for as long as that information is maintained by the study personnel and other entities subject to federal privacy regulation.

- Edit the expiration date in the 2nd sentence of this paragraph if a specific date of expiration is required by state law (e.g., CA, MN, IL)

Study data, including your coded medical information, may be used and shared for pharmaceutical research purposes related to this study. This authorization has no expiration date. In signing this form, you authorize the use and disclosure of your baby's information for purposes of the study at any time in the future.

You may withdraw your authorization at any time by sending a written request to [insert name of responsible study personnel] at [insert address]. If you withdraw your authorization, data collected prior to your withdrawal may still be processed along with other data collected as part of the study.

Normally, no new information will be collected for the study database unless you specifically authorize that. However, the law does require that any side effects your baby may suffer are documented and reported. To complete the study findings, your baby's long-term health status may also be obtained from public sources.

[TEXT FOR POLAND]

Are there any costs if you decide to participate?

You will not receive payment for allowing your baby to participate in this study, but study treatments will be made available to you and your baby at no charge and you will not be required to pay for any study procedures.

Who is funding this research?

Windtree Therapeutics, Inc. (a United States biotechnology company), will be organizing and funding this study. Windtree Therapeutics Inc. will pay your baby's study doctor and the study site to cover their costs of conducting this study. If applicable, your study doctor will disclose to you any financial links or other interests that he/she may have to the Sponsor.

Am I insured when I or my baby participates in the study?

If your baby is injured because of his or her participation in this study, you will be entitled to receive compensation in accordance with Polish legal regulations. Your baby's study doctor will explain how you can obtain a copy of these guidelines.

How will my confidentiality be respected, and the privacy of my personal information maintained?

You have the right to control the use and disclosure of your personal information and your baby's personal information. Basic personal information will be recorded, including your and your baby's name, contact details, gender, height, weight, and racial origin (to be used only for clinical purposes), as well as information on your and your baby's medical history and clinical data. The following people may also access these records:

- Study monitors and auditors, who may work for Windtree Therapeutics, Inc. or its authorized representatives, who check that the study is being performed correctly and that

the information collected about you and your baby is accurate;
- The Ethics Committee that approved this study and ensures that your baby's rights and well-being are safeguarded;
- National and international regulatory authorities involved in keeping research safe for participants. All personnel accessing your and your baby's records are required to respect your and your baby's confidentiality at all times.

To ensure privacy, your and your baby's name and other identifying information will not be attached to records or samples released for research purposes. Instead, your baby will only be identified by a code. Only the study doctor and authorized personnel at the site will be able to connect this code to your and your baby's name, by a list that will be kept securely by the study site for 20 years. The baby's coded data will be entered into a computer database and processed by Windtree Therapeutics, Inc. to allow the results of this study to be analyzed and reported. If the results of the study are published, your and your baby's identities will remain confidential. A list of companies to whom your coded information is transferred is available from Windtree Therapeutics, Inc. via your study doctor.

Under the General Data Protection Regulation (GDPR), your study site and Windtree Therapeutics, Inc. shall be jointly responsible as 'controllers' for ensuring that your information is safeguarded. **Windtree Therapeutics, Inc. has appointed Clinical Consulting as its data privacy officer in your country to fulfill its obligations under this law.** You have the right to access, through your baby's study doctor, all the information collected about you and your baby and, if applicable, ask for corrections. To protect the scientific integrity of the study, the treatment your baby received in this study needs to remain unknown (masked) until the study data is analyzed. Recipients of your baby's information may be in countries that do not have data protection safeguards and rights. However, Windtree Therapeutics, Inc. and its authorized representatives, and regulatory authorities, shall seek to maintain confidentiality within the limits of local laws in these countries.

If you should withdraw your baby from the study, data collected prior to your withdrawal may still be processed along with other data collected as part of the study. Normally, no new information will be collected for the study database unless you specifically consent to that. However, the law does require that any side effects your baby may suffer are documented and reported. To complete the study findings, your baby's long-term health status may also be recorded (unless you object). You have the right to require that any previously retained samples are destroyed.

What will happen to your baby's data?

This clinical study may only be performed by collecting and using your baby's medical information. Data protection laws give you the right to control the use of your personal information. Therefore, by signing this form you specifically authorize your baby's information to be checked, transferred and processed as follows:

- The authorized representatives of Windtree Therapeutics, Inc., the Ethics Committee, and regulatory authorities' inspectors may review your baby's medical information by direct access to your baby's medical records.
- Study data, including your baby's coded medical information, may be used and shared for legitimate study and scientific purposes, including, if you do not object, for future use in medical or pharmaceutical research.
- Study data may be transferred to other countries for processing, including countries not covered by the data protection legislation.

Has the study received medical or ethical approval?

This research study has been approved by and received the positive opinion from both Ethics Committee and Polish Ministry of Health.

Statement of Consent

- I have read and understand the statements in this informed consent form
- I have had the opportunity to ask questions and I am satisfied with the explanations provided
- I voluntarily agree to allow my baby to take part in this study
- I understand that I and/or my legal representative will receive a copy of this signed and dated written consent form

[Add for US:]

- I additionally consent to the use of my baby's coded medical information for future medical or pharmaceutical research

_____

Subject Printed Name

_____	_____	_____
Parent or Legal Guardian Printed Name	Signature	Date

_____	_____	_____
Witness (if applicable) Printed Name	Signature	Date

- I have presented the study and answered the subject's questions
- I will give the subject/legal representative a copy of this signed and dated Informed Consent

_____	_____	_____
Presenter (Investigator/Delegate) Name	Signature	Date