Informed Consent Form

INFORMATION for PARENTS/GUARDIANS of PARTICIPANTS

NAME OF STUDY:	**A Multinational, Multicenter, Masked, Randomized, Controlled Study to Assess the Safety and Efficacy of Lucinactant for Inhalation in Preterm Neonates 26 to 32 Weeks Gestational Age with Respiratory Distress Syndrome**
STUDY NUMBER:	03-CL-1202
STUDY SPONSOR:	Discovery Laboratories, Inc. 2600 Kelly Road, Suite 100 Warrington, PA 18976
STUDY DOCTOR (INVESTIGATOR):	[Investigator Name] [Site Address] [Office Hours Tel] [Out of Hours Tel]
[ETHICS COMMITTEE (EC) or INVESTIGATIONAL REVIEW BOARD (IRB):]	[EC/IRB Name] [EC/IRB Address] [Office Hours Tel] [Out of Hours Tel]

Why are you receiving this information?
Your baby is eligible to participate in a research study. 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 of the possible risks, hazards, or benefits involved, you may then decide whether or not your baby should participate in this study. This consent form will help you understand this study. It will also help you decide whether to give or withhold your consent to allow your baby's participation in this research study. This informed consent does not replace any other informed consents you may have signed.

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. Please read this information carefully and do not hesitate to ask the study doctor any questions to ensure that you are able to make an informed decision as to whether you would like your baby to participate.

You have been asked to take part because your baby was born approximately 8 to 14 weeks before your baby's due date. Also, your baby is at a gestational age between 26 and 32 weeks and is receiving supplemental oxygen and breathing support by nasal continuous positive airway pressure (nCPAP). This is because your baby has suspected respiratory distress syndrome (RDS) 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 liquid that coats the surface of our lungs. Surfactants are natural chemicals in our lungs. Our bodies normally make surfactant in our lungs to help them 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. This tube can also 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 and continuous positive airway pressure (CPAP) through a pair of short tubes called nasal prongs. The nasal prongs fit into the baby's nostrils. This type of support 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.

Babies with RDS who need supplemental oxygen and nCPAP for breathing support are at risk for developing more severe breathing problems and may require placing 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. In some babies, the amount of supplemental oxygen decreases through the first day after birth. In other babies, the amount of supplemental oxygen needed may stay the same, or the baby may need increasing amounts of supplemental oxygen. The more supplemental oxygen the baby needs, the higher the risk that the baby will need a tube placed in the windpipe and be connected to a breathing machine.

Aerosolized lucinactant is a synthetic (man-made) surfactant that is made by Discovery Laboratories, Inc. They have also designed a new device known as an Aerosurf Delivery System (ADS). This device heats the surfactant as it passes through a small tube called a capillary. As the liquid passes through the capillary, it becomes a fine mist, or aerosol. The ADS is an investigational device and is currently not approved for use to aerosolize medications. Aerosolized lucinactant delivered as a mist, or aerosol, using the ADS is an investigational drug-device combination that is not approved for general use and can be used only in this research study. This investigational drug-device combination is being developed in order to be able to give surfactant to babies with RDS who need supplemental oxygen and nCPAP for breathing support without having to place a tube in the baby's windpipe.

The purpose of this study, which involves research of an investigational drug-device combination, is to evaluate the safety and tolerability of two different doses of an aerosolized surfactant (lucinactant mist, or aerosol) delivered 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). Lucinactant is delivered through a tube in the baby's windpipe for the prevention of RDS in premature babies at severe risk for RDS. The Sponsor no longer makes the liquid form of lucinactant. The experimental portion of this study is the use of lucinactant as a mist or aerosol in combination with the aerosol delivery system, in babies being supported with supplemental oxygen and nCPAP.

It is expected that approximately 240 babies will be enrolled in this study.

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 surfactant directly into the lungs through the tube. In this study, the baby will receive lucinactant, a surfactant, as a mist, or 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.

Aerosolized lucinactant delivered as a mist, or aerosol, and the ADS are currently being used together in two other studies in babies of a different gestational age who also have RDS.

How long will your baby be in the trial?
The duration of the study intervention will be approximately 2-3 days. Your baby will continue to have their health information collected while he or she is in the hospital, until he or she reaches approximately 36 weeks gestational age. After that, the study doctor or a member of the site research 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. The 6 month and 1 year corrected-age means approximately6 months and 1 year after the baby was due to be born, not when they were born

What procedures are involved?
If your baby requires more than a small amount of supplemental oxygen and is receiving nCPAP, your baby will be randomly chosen to receive either continued nCPAP with lucinactant for inhalation (study drug) or continued nCPAP alone. Your baby will also get the usual treatment and care given to all babies who are born before 36 weeks gestational age at this hospital. All babies will be monitored with a transcutaneous carbon dioxide monitor, which is a heated sensor that measures carbon dioxide, or CO_2, which is an indicator of how well the baby is breathing. The carbon dioxide is measured through the skin so that it is not necessary to keep taking blood from the baby to measure his/her carbon dioxide.

If your baby is chosen to receive study drug, your baby will receive one of two doses of the aerosolized lucinactant as a mist, or aerosol. The amount of aerosolized lucinactant your baby will receive will depend on which dose group your baby is assigned to.

- Group 1 – aerosolized lucinactant (40 mg total phospholipids [TPL]/kg) for 25 minutes in conjunction with nCPAP (80 babies)
- Group 2 – aerosolized lucinactant (80 mg TPL/kg) for 50 minutes in conjunction with nCPAP (80 babies)
- Group 3 (Control Group) – continuous nCPAP alone (80 babies)

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.

If your baby continues to experience difficulty breathing in the first 24 hours after receiving lucinactant for inhalation, your baby may receive up to two additional doses of lucinactant that are equal to the first dose.

Whether your baby gets nCPAP with lucinactant for inhalation or continuous nCPAP alone depends on a computer numbering system. This system chooses subjects by chance (like the flip of a coin). There is a 2 in 3 chance that your baby will receive lucinactant for inhalation. If you have twins, your babies will be randomized separately, so they may be in different study groups.

Regardless of whether the baby gets nCPAP with lucinactant for inhalation or continuous nCPAP alone, if your baby develops more severe breathing problems, your baby's doctor may place a tube in your baby's windpipe and connect that tube to a breathing machine and may also give your baby liquid surfactant directly in your baby's lungs through the tube in the windpipe. All babies enrolled in this research study will receive all routine

care and procedures regardless of whether the baby gets nCPAP with lucinactant for inhalation or continuous nCPAP alone.

An independent safety review committee will review the study data at two times during the study. All active completed assessments and procedures through 72 hours for enrolled patients will be reviewed. Enrollment will continue throughout each review unless the committee recommends otherwise.

This is a masked study. This means neither you will not know whether your baby receives continuous nCPAP with lucinactant for inhalation (study drug) or continuous nCPAP alone. Alsoyour baby's doctor or your study doctor may not know whether your baby receives continuous nCPAP with lucinactant for inhalation (study drug) or continuous 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.

If you decide to allow your baby to participate in this study, you will be required to sign this Informed Consent Form. Your medical records (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 30 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 his/her dose of aerosolized lucinactant as a mist, or aerosol, through nasal prongs placed in your baby's nostril for the nCPAP. The nasal prongs and the CPAP machine used will both be devices that 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 CPAP alone.
4) Before, during, and after each dose of study drug, your baby's vital signs, blood oxygen level, and nCPAP settings will be checked and documented. These assessments are part of the routine hospital care of babies born early.
5) Two blood samples will be taken: one blood sample to calibrate the transcutaneous monitor that records your baby's carbon dioxide levels and one blood sample to measure sodium, chloride, potassium, and carbon dioxide levels. These samples will be taken from a catheter if the catheter is already in a blood vessel. A catheter is a device that is inserted into a blood vessel for a temporary period of time, that is used to help doctors, nurses, and other medical staff have access to draw blood more easily. If there is no catheter in a blood vessel, 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. The total amount of blood taken will be less than a quarter of a teaspoon, and your baby's carbon dioxide level will continue to 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 and up to 36 weeks gestational age.
7) The number of stools in the first 24 hours following treatment group assignment will be recorded.
8) 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.

9) When your baby reaches 36 weeks gestational age, or is discharged or transferred from the hospital (whichever comes first), your baby will have a brief physical exam.
10) 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.
11) At 1-year corrected age, your baby will be seen by the study team. A 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. You will also be asked about the medications that your baby has taken.

What will happen at the end of the study?
After the study drug is stopped, your study doctor will decide what continued medical treatment your baby should receive. The care your baby receives will not be affected by whether he or she receives study drug.

Following the end of the study, or after you have withdrawn your baby from the study before its conclusion if you decide to do so, your 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 different complications related to preterm birth. The degree of risk is different for every baby and depends on several 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 supplemental oxygen and nCPAP for 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; between 10% and 55%):

- 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 used currently for respiratory diseases. These events may require your baby's doctor and/or the study doctor to stop giving the study drug. Your baby's doctor and/or the study doctor will stop treatment at any time if it is in your baby's best interest.

Lucinactant, a surfactant, will be given after it has been made into a mist, or aerosol, using the ADS, an investigational device which has been specifically made to produce a lucinactant mist that contains very small particles of lucinactant. Delivering lucinactant as a mist may decrease the side effects described above, although this is not known for sure at this time.

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 delivery of the lucinactant mist, your baby's 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. Although the device has been designed to generate a mist with a temperature that is safe for your baby, if the temperature safety controls of the device fail, it is possible that the mist might be too hot for your baby.

The lucinactant mist carries a significant amount of fluid, and there is a potential risk that your baby would get too much fluid as a result of the investigational treatment. A blood sample will be taken to measure the sodium, chloride, potassium, and carbon dioxide levels to check to see if your baby received too much fluid.

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, and
- Congestion or runny nose.
- Pneumothorax

Your baby's breathing problem may get worse over time, regardless of whether your baby receives nCPAP plus lucinactant for inhalation or continuous nCPAP alone. If your baby's doctor decides that your baby needs more help breathing, your baby's doctor may decide to place a tube in your baby's windpipe and connect that tube to a breathing machine. Your baby's doctor may also decide give your baby liquid surfactant directly in your baby's lungs through the tube in the windpipe. This surfactant may be different from the lucinactant used in this study.

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 and effective. 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, and
- bruising or bleeding at the blood draw site.

There is also 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 will be closely followed by the Sponsor's doctors. They will review the safety of the babies taking part in this study on an ongoing basis. An independent Safety Review Committee (also known as a Data Monitoring Committee) will also oversee this study and review this information. This committee is comprised of doctors who are not employed by the Sponsor. This committee will advise the Sponsor about the safety of current and future study subjects. They 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.

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 [Ethics Committee (EC) or Institutional Review Board (IRB)] 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 Web site will not include information that can identify you/your baby. At most, the Web site will include a

summary of the results. You can search this Web site at any time. This web site 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?

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 at this center in any way. You and your baby will still have all the benefits that you would otherwise have at this center. You may withdraw your baby from participating in the research at any time that you wish without either you or your baby losing any of your rights as a patient here. Neither your treatment nor your baby's treatment at this center will be affected 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 instructions. It may be helpful if you could explain your reasons. You may receive standard treatment and no prejudice will be shown towards you for medical care or participation in future research.

In addition, the study doctor or the 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 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.

The remaining ICF content varies based on region-specific legislation & practices (see Text Conventions).

- *The Master ICF must include & adapt the sections for ALL regions to be involved in the study.*
- *Country/Site-Specific ICFs must delete information not relating to their region.*

EMEA:

Are there any costs if you decide to participate?

You will not receive payment for allowing your baby to participate in this study, but the study drugs 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?

Discovery Laboratories, Inc. (a biotechnology company), will be organizing and funding this study. Discovery Laboratories, Inc. will pay your baby's study doctor and/or 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.

Are you insured when you participate in the study?

If your baby is injured because of his orher participation in this study, you will be entitled to receive compensation in accordance with [national] legislation. Your baby's study doctor will explain how you can obtain a copy of these guidelines.

How will your confidentiality be respected and the privacy of your 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 collected about your baby's participation in the study. The following people may also access these records:

- Study monitors and auditors, who may work for Discovery Laboratories, 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 Ethical 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 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 "[insert retention period]" years. Your baby's date of birth may also be recorded to help identify your baby's study record. Your baby's coded data will be forwarded to Discovery Laboratories, Inc. and its service providers for activities related to the study e.g. laboratory analysis. It will be transferred into a computer database and processed to allow the results of this study to be analyzed and reported or published. 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 Discovery Laboratories, Inc. via your study doctor.

- ** Delete sentence in **bold** unless PPD is contracted as privacy representative. This wording should be incorporated in the country-specific ICFs for the relevant EU countries in the studies where PPD has this role. The list of studies where we are contracted, or about to be contracted in a study as representative is available at http://intranet.ppdi.com/policies_procedures/Data_Privacy_Rep_Service.htm If you are unsure, check with study PM which EU countries PPD acts in this role.*
- *If PPD is not appointed, please make sure that the non-EU based Client Company is aware of the data protection law requirements of 1) appointing a privacy representative in each Member State and 2) mentioning its identity in the ICF. If Client Company has not appointed any privacy representative and/or doesn't want to mention it in the ICF, this point can be omitted. Client Company is liable.*

Under data protection law [identification of national law] your study site and [Client Company legal entity name] shall be jointly responsible as 'controllers' for ensuring that your information is safeguarded. Discovery Laboratories, Inc. ***has appointed [PPD local company name] as its 'representative' 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. But, in order 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. [Client Company] and its authorized representatives, and regulatory authorities, shall anyway 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.

- *For signature page*

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 Discovery Laboratories, 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?
The Ethics Committee has given this study a positive opinion.

NORTH AMERICA:
Are there any costs if you decide to participate?
The 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 you 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 you receive compensation if your baby is injured as a result 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]. The Sponsor 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 Discovery Laboratories, Inc. who is the Sponsor of this study.

- *The next section is applicable to the United States ONLY. Remove this section if customizing ICF for Canada.*

What will happen to your baby's data?

- *Ensure statement regarding identifying information is correct for each study*
- *Please note: If sites are 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. See CA template.*

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 Sponsor of this study is Discovery Laboratories, Inc.

The study personnel, the Sponsor and its agents and PPD will need to review the medical information collected from your baby for use in this study in order to accurately record information for this study. In addition, in order 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:

- Discovery Laboratories, Inc., PPD or other agents designated by Discovery Laboratories, Inc. to collect or review study data for verification of study procedures and/or adverse event reporting.

- The Institutional Review Board (IRB) or Independent Ethics Committee (IEC) that oversees the research study at your site.
- Government regulatory agencies including the FDA.

Once your baby's information is disclosed to the study Sponsors, its agents, the IRB/IEC 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. In addition to disclosures to the entities identified above, PPD may further electronically disclose your coded health information to others involved in the research study, such as:

- To laboratories or offsite testing facilities for clinical tests required by study protocols.
- To approved offsite storage facilities or cloud service providers to meet study record retention and storage requirements.
- To Discovery Laboratories, Inc., who will direct the research study.
- To other third parties contracted by PPD and/or Discovery Laboratories, Inc., to provide services related to study.

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 in the course of 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.

- *The next section is applicable to the Canada ONLY. Remove this section if customizing ICF for United States.*

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

You have the right to control the use and disclosure of your and your baby's personal information. Basic personal information will be recorded, including your baby's name, contact details, gender, height, weight and racial origin, as well as information on your baby's medical history, and clinical data collected about your baby's participation in the study. Your baby's confidentiality will be respected and no information that discloses you or your baby's identity will be published without consent unless required by law. However, your baby's records may be given to and inspected by the following people:

- Study monitors and auditors, who may work for Discovery Laboratories, Inc., or its authorized representatives, who check that the study is being performed correctly and that the information collected about you is accurate;
- Ethical committee that approved this study and ensures that your rights and well-being are safeguarded;
- Health Canada/Public Health Agency of Canada senior officials, and the REB members, for the purpose of monitoring the study.

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 will be able to connect this code to your baby's name. Your baby's coded data will be forwarded to Discovery Laboratories, Inc., and its service providers for activities related to the study (e.g. laboratory analysis). It will be transferred into a computer database and processed to allow the results of this study to be analyzed and reported or published. If the results of the study are published, your and your baby's identity will remain confidential.

Under federal data protection law, The Personal Information Protection and Electronic Documents Act (PIPEDA) and regional specific regulations, your study site shall be responsible for ensuring that your information is safeguarded. You have the right to access, through your study doctor, all the information collected about you and your baby and, if applicable, ask for corrections. But, in order to protect the scientific integrity of the study, the treatment your baby received in this study needs to remain unknown (i.e., masked) until the study data is analyzed. Recipients of your information may be in countries that do not have data protection safeguards and rights. Discovery Laboratories, Inc., and its authorized representatives, and regulatory authorities, shall anyway seek to maintain confidentiality within the limits of local laws.

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.

- *The next section is applicable to the Canada ONLY. Remove text if customizing ICF for United States.*

- *For signature page*

What will happen to your baby's data?

This clinical study may only be performed by collecting and using your baby's medical information. Therefore, by signing this form you specifically authorize your baby's relevant information to be checked, transferred and processed as follows:

- The authorized representatives of Discovery Laboratories, 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 and all specified study-related documents, including your baby's coded medical information, will be stored for a minimum of 25 years and may be used and shared for legitimate study and scientific purposes during this time.

LATIN AMERICA:

Are there any costs if you decide to participate?

The study drugwill be made available to your baby at no charge and you will not be required to pay for any study procedures. You may be billed for any standard medical care that is not required for the study.

Is there a payment if you decide to participate?
You will not be paid to participate in this study.

Will you receive compensation if your baby is injured as a result of the study?
If your baby is injured because of your participation in this study, treatment for the injury will be made available through your study doctor and this institution. The Sponsor will pay the costs of this treatment [as well as the indemnification to which you would be legally entitled if you require it]. 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 or accepting medical care.

How will your confidentiality be respected and the privacy of your personal information maintained?
- *Data Protection is defined by national law; please refer to the ICF Country Specific Guidelines document for details. In the case of any discrepancy, national laws supersede the standard template text*

Basic personal information will be recorded including your and your baby's name, contact details, gender, height, weight and racial origin, as well as information on your baby's medical history, and clinical data collected about your baby's participation in the study. The following people may also access these records:
- Study monitors and auditors, who may work for Discovery Laboratories, Inc., or its authorized representatives, who check that the study is being performed correctly and that the information collected about you is accurate;
- Ethical committee that approved this study and ensures that your rights and well-being are safeguarded;
- National and international regulatory authorities involved in keeping research safe for participants.

All personnel accessing your records are required to respect your confidentiality at all times.

To ensure privacy, 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 will be able to connect this code to your baby's name. Your baby's coded data will be forwarded to Discovery Laboratories, Inc., and its service providers for activities related to the study e.g. laboratory analysis. It will be transferred into a computer database and processed to allow the results of this study to be analyzed and reported or published. If the results of the study are published, your identity will remain confidential.

- **Delete this paragraph if country does not have specific data protection legislation. For details, please refer to: http://intranet.ppdi.com/policies_procedures/PrivMain_RC3_Data_Privacy_Laws_Per_Region.htm*

Under data protection law [identification of national law] your study site shall be responsible for ensuring that your and your baby's named personal information is safeguarded. You have the right to access, through your study doctor, all the information collected about your baby and, if applicable, ask for corrections. But, in order 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 information may be in countries that do not have data protection safeguards and rights. Discovery Laboratories, Inc., *and its authorized representatives, and regulatory authorities, shall anyway seek to maintain confidentiality within the limits of local laws.*

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.

- *For signature page*

What will happen to your data?

This clinical study may only be performed by collecting and using your baby's medical 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 Discovery Laboratories, Inc., the Ethics Committee and regulatory authorities' inspectors may review your medical information by direct access to your medical records.
- Study data, including your baby's 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.

Informed Consent Form

Statement of Consent

- *Statements and signatures required may be adapted according to study population &/or local requirements*
- 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

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Subject
Printed Name Signature Date

The next signature line is applicable to the U.S. ONLY. Subjects should be made aware of this option when obtaining consent.

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

Subject
Printed Name Signature Date

Parent or Legal Guardian (if subject is a minor)
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

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Presenter (Investigator/Delegate)
Printed Name Signature Date