INFORMED CONSENT FORM

Title of Research Study:	An Open-Label Extension Study of UT-15C in Subjects with Pulmonary Arterial Hypertension - A Long-Term Follow-Up to Protocol TDE-PH-310
Protocol Number:	TDE-PH-311
Principal Investigator:	_____ Phone: _____
Sub-Investigator:	_____
Sponsor:	United Therapeutics Corporation
Research Site/Hospital:	_____

Before agreeing to participate in this research study, it is important that you read the following information describing the purpose, procedures, benefits, risks, discomforts, and precautions of the study. Please take time to read the following information carefully and discuss it with friends and family if you wish.

This consent form may contain words that you do not understand. You will need to ask your doctor or the study staff to explain any words or information that you do not clearly understand. Your doctor should answer your questions before you sign this consent form. Once you sign this form you will be given a copy.

INTRODUCTION

You are being asked to be in this research study because you recently completed the TDE-PH-310 study. If you did not participate, participated and did not complete the TDE-PH-310 study, you cannot participate in this study.

You are being asked to be in a research study because your doctors have informed you that you have pulmonary arterial hypertension (PAH). This means that your blood vessels going from the right side of the heart to the lungs (pulmonary arteries) have higher than normal pressure. This puts strain on your heart. This strain causes the heart to pump less blood into the lungs. This will result in symptoms like shortness of breath, tiredness, and swelling in the feet and stomach. Over time, these symptoms can get worse because the heart cannot pump enough blood into the lungs.

This research study is under the direction of <name>, who is the "principal investigator," also known as the "study doctor." As the study doctor, <name> will make sure that this study is done properly and that your rights and safety as a participant in this study are protected. <Name> will carry out the day-to-day activities of the research study using his/her <his/her> best medical judgment.

United Therapeutics Corporation, a drug company, is the "sponsor" of this research study and is responsible for the development and broad oversight of the study.

PURPOSE

The purpose of this research study is to assess how an investigational drug works to treat PAH. An investigational drug is one that has not yet been approved for use by the Food and Drug Administration (FDA) or has not yet been approved for treatment of PAH. The drug in this research study is called UT-15C (treprostinil diethanolamine also known as treprostinil diolamine). UT-15C (brand name Orenitram) was approved by the United States Food and Drug Administration (FDA) in December 2013 for the treatment of PAH. UT-15C will be provided in different strength tablets that are taken by mouth three times in a day. UT-15C is a sustained release tablet. This means study drug is released slowly over an extended period of time. This study will evaluate the long-term safety of UT-15C and the effects of continued therapy on your ability to exercise.

Before this study, UT-15C has been given to over 1800 subjects. In this study, up to 850 subjects may participate.

PROCEDURES

Once you complete the TDE-PH-310 study, you and your doctor will be told whether you were receiving UT-15C (active drug) or placebo (sugar pill). If you were receiving UT-15C, you will continue receiving UT-15C while participating in this open-label study. If you were receiving placebo, you will stop taking placebo and start taking UT-15C during this open-label study.

TREATMENT PHASE

If you choose to participate in this study, your doctor will use the procedures done at the last visit in the TDE-PH-310 study to determine if you can enter in this open-label study. The final visit in TDE-PH-310 (Study Termination Visit) will also be the Baseline Visit for this open-label study. If you meet all study entry conditions for the open-label study, the dose of study drug you receive from your doctor will depend on whether you were on placebo or UT-15C in TDE-PH-310 study.

If you were on placebo in the TDE-PH-310 study, you will be given the first dose of UT-15C in the hospital or clinic. The first dose will be 0.125 mg. You will be asked to take the study drug with food. If you were on UT-15C in the TDE-PH-310 study, you will start with the same dose that you were taking at the Study Termination Visit in the TDE-PH-310 study. You will be given a supply of study drug before leaving the clinic. Study drug should be taken three times a day. The study drug should always be taken approximately every 6-8 hours during the day about 10 minutes after consuming food and should not be split, crushed, or chewed.

After the Baseline visit you will be required to visit the hospital, or clinic, on at least two separate occasions over the first 12 week period. After the first 12 weeks, you will be required to visit the hospital, or clinic, once every 12 weeks until you discontinue from the study or the study ends.

Throughout this study, you will be asked to report any difficulties or side effects you experience, and whether or not you feel they are related to or caused by the study drug. It is very important for you to discuss any illnesses, difficulties or side effects you may have during the study with your doctor. If your condition worsens, your doctor will then decide if you should come in to the hospital or clinic to change your dose of study drug or to change your treatment. Any changes in your dose of study drug will be made by the doctor responsible for this study and it is important to contact the site staff prior to making any change to your dose of study drug. Your doctor may remove you from the study to consider other treatments.

Optional Whole Genome Sequencing: You are being asked to participate in an optional portion of this study which involves additional blood samples for pharmacogenomic research.

Pharmacogenomic research is an important way to try to understand the role of genetics in human disease and how genes impact the effectiveness of drugs. There are many differences, or variations, in genes from one person to another that may affect a person's chances of suffering from a particular disease. These differences in genes can also change the way a person responds to a particular drug. We would like to learn more about PAH and the response to treatment by measuring different types of genetic material (ie, deoxyribonucleic acid [DNA]) found in your blood that is associated with PAH and/or your response to treatment. The aim is to find out if there are genetic markers which may help predict how well treatment with oral treprostinil works. Better understanding of these differences today can help doctors in the future more accurately determine which treatments are best for their patients and which treatments are least likely to cause side effects.

Blood samples will be analysed by a method called genetic sequencing. Genetic sequencing is a type of testing that enables researchers to analyze a person's genetic code, also known as the genome. Genetic sequencing will be performed by a company hired by the Sponsor.

If you choose to participate, you will be asked to give 1 additional blood sample (about 2 teaspoons [10 mL]) for the genetic sequencing. Blood will be drawn from a vein using a needle. Your blood sample, together with certain information about you obtained from your participation in the study, will be provided to a company hired by the Sponsor to conduct genetic sequencing and additional research. Neither you nor your physician will receive any genetic sequence information from your participation in this research. The information resulting from the analysis will be used anonymously, meaning that your identity will not be revealed. The research done with your blood sample may be used by the Sponsor to develop new therapies or diagnostic tests in the future. If the sponsor or any of its affiliates make a profitable product from the development of new therapies or diagnostic tests, there is no plan to share any of the profits with you.

You do not have to agree to this optional testing in order to be in this study. It is important that before you make a decision to participate, you read the rest of this form. You should ask as many questions as you need to understand what will happen to you if you decide to participate. You will have an opportunity to note your decision to participate in the whole genome sequencing separately at the end of this form.

REGULAR TELEPHONE CONTACT

You will be contacted each week by one of the study staff members by telephone weekly during the first 12 weeks of the study. After the first 12 weeks, you will be contacted by one of the study staff members by telephone at least once a month. During the telephone calls, you will be asked if you took the study drug as directed, if your symptoms of PAH are improved, the same, or worse, and if you have experienced any illness or side effects. You will be asked to provide information about the medications you are currently taking, including over the counter and herbal medications. Based on your answers, your doctor will determine if the dose of your study drug should be changed.

Additional procedures will be done during your scheduled clinic visits. They include:

Weeks 6 and 12 Visits

- Vital signs (blood pressure, heart rate, breathing rate, and weight) will be recorded
- Ranking of the severity of your PAH on a scale (WHO functional class)
- Review of any illnesses or side effects that you may have experienced
- Six-minute walk test (to measure the distance you can walk in 6 minutes). After the six-minute walk test, you will be asked to rate your shortness of breath (by using the Borg dyspnea score to rate your shortness of breath during the six-minute walk test ranging from 0-nothing at all to 10-very, very heavy shortness of breath)
- If you are a woman capable of giving birth, you will also have a urine pregnancy test
- Blood (about 3-4 teaspoons, or 15-20 milliliters) will be collected for routine laboratory tests (Only done at the Week 12 Visit)
- If necessary, your study drug dose will be adjusted
- You will be asked to return all study drug, including empty bottles, to the clinic so the site staff can determine if you have been taking the study drug as directed. You will be given a new supply of study drug
- Review of all the medications that you are taking

Follow-Up Visits after Week 12 (Once every 12 weeks)

- Vital signs (blood pressure, heart rate, breathing rate, and weight) will be recorded
- Ranking of the severity of your PAH on a scale (WHO functional class)
- Review of any illnesses or side effects that you may have experienced
- Six-minute walk test (to measure the distance you can walk in 6 minutes). After the six-minute walk test, you will be asked to rate your shortness of breath (by using the Borg dyspnea score to rate your shortness of breath during the six-minute walk test ranging from 0-nothing at all to 10-very, very heavy shortness of breath)
- If you are a woman capable of giving birth, you will also have a urine pregnancy test
- Blood (about 3-4 teaspoons, or 15-20 milliliters) will be collected for routine laboratory tests. This will be done at the first follow up visit and at every other visit afterwards
- At the third follow up visit, additional blood test will be done to see how your heart is working by measuring the level of a PAH blood marker (NT-proBNP)

- If necessary, your study drug dose will be adjusted
- At each of these visits, you will be asked to return all study drug, including empty bottles, to the clinic so the site staff can determine if you have been taking the study drug as directed. You will be given a new supply of study drug
- Review of all the medications that you are taking
- Collection of a single blood sample (about 2 teaspoons [10 mL]) for evaluation of pharmacogenomics (optional)*

** Sample to be collected at a Follow-up Visit when routine clinical laboratory samples are collected.*

Study Termination Visit

- Vital signs (blood pressure, heart rate, breathing rate, and weight) will be recorded
- Physical examination
- Ranking of the severity of your PAH on a scale (WHO functional class)
- Review of any illnesses or side effects that you may have experienced
- Six-minute walk test (to measure the distance you can walk in 6 minutes). After the six-minute walk test, you will be asked to rate your shortness of breath (by using the Borg dyspnea score to rate your shortness of breath during the six-minute walk test ranging from 0-nothing at all to 10-very, very heavy shortness of breath)
- If you are a woman capable of giving birth, you will also have a urine pregnancy test
- Blood (about 3-4 teaspoons, or 15-20 milliliters) and urine will be collected for routine laboratory tests
- Used and unused study drug will be counted
- Review of all the medications that you are taking
- Collection of blood sample (about 2 teaspoons [10 mL]) for evaluation of pharmacogenomics (optional) *

** If you discontinue prior to your next Follow-up Visit, the pharmacogenomic sample will be collected at the Study Termination Visit.*

Once you complete the study, the study staff will contact you approximately 30 days after the study termination visit to evaluate your overall health status.

WOMEN OF CHILDBEARING POTENTIAL

Women who can have children and who want to enter this study must have a negative pregnancy test before beginning the study and must use two acceptable methods of birth control during the study. Being a part of this study while pregnant or breastfeeding may expose the unborn or nursing infant to known and unknown risks. Therefore, pregnant and nursing women cannot enroll in the study. The effects of UT-15C on a fetus are not fully known. It is very important that you do not become pregnant during this study.

In an animal study, some undesirable effects were seen in the development of rabbit fetuses after the pregnant animals received high doses of study drug.

If you are a woman who can have children, you must agree to either avoid sexual intercourse (abstinence) when it is in line with your preferred and usual lifestyle or use two different forms of effective contraception from the time you sign informed consent until 30 days after the last dose of study drug. Medically acceptable, effective, birth control methods include: (1) approved hormonal contraceptives, such as birth control pills (2) barrier methods (such as a condom or diaphragm) used with a spermicide, (3) an intrauterine device (IUD), (4) partner(s) with a vasectomy. If you have previously undergone surgical sterilization such as tubal ligation or hysterectomy, then you will not need to practice these methods of contraception. If you are a woman of childbearing potential, a urine pregnancy test will be conducted at each study visit.

You should not take part in this study if you plan to become pregnant from the time you sign this consent form until 30 days after the last dose of study drug.

If you do become pregnant while participating in this study, you must notify your study doctor. Your doctor will slowly decrease your dose until you are no longer taking study drug. You will have to withdraw from active participation in the study. The site staff will continue to contact you until the outcome of the pregnancy is known. Possible outcomes include normal birth, miscarriage, or elective abortion.

MEN

The effects of UT-15C on a fetus are not fully known. You should not take part in this study if your partner plans to become pregnant during your participation in the study. You will need to use a condom during the entire length of the study, and for 2 days after taking the last dose of UT-15C. Even if your partner is pregnant at the beginning of the study, you must still use a condom. This is because some UT-15C could be in your semen and may reach the fetus.

In an animal study, some undesirable effects were seen in the development of rabbit fetuses after the pregnant animals received high doses of study drug.

RISKS AND DISCOMFORTS

Risks of UT-15C

There may be serious risks involved with being in this study. The risks may be with the UT-15C itself, the combination of UT-15C with the other drug(s) you take for PAH, and/or the scheduled procedures. These may include serious side effects of UT-15C, not all of which are known. The side effects that have been observed in patients most often so far include, but are not limited to, headache, nausea, diarrhea, facial flushing, vomiting, jaw pain, pain in extremity, dizziness and hypokalemia . If these side effects develop, the dose of the drug may need to be reduced until the side effects go away. Do not take UT-15C with alcohol as release of treprostinil from the tablet may occur at a faster rate than intended which could cause undesirable effects.

Bleeding is a rare side effect that could occur because of the way that the study drug (treprostinil) acts in the body. Bleeding has been reported in patients taking the study drug

especially when taken with other medications that can also cause bleeding. When it happens, bleeding is usually minor such as a nose bleed or bleeding from the skin after an injury or blood draw. However, there is a risk of bleeding being more severe, with some patients experiencing bleeding in the stomach and intestines.

Studies were conducted to determine whether diethanolamine (a part of UT-15C) by itself (without treprostinil or any other drug) causes cancer. Two years of topical administration (applying the medication on the skin) of diethanolamine to mice produced an increased incidence (compared to mice that did not receive diethanolamine) of malignant liver tumors in male and females, as well as an increased incidence of malignant kidney tumors in males. However, in rats, topical administration of diethanolamine for 2 years was not associated with the development of any cancers. The relevance of the mouse tumor findings to humans is not clear.

An additional study was conducted to find out whether UT-15C causes cancer. Six months of oral administration of treprostinil diethanolamine (UT-15C) to mice did not increase rates of death or occurrence of tumors or cancer in mice.

Care should be taken to avoid missing doses of study drug. If you miss two or more doses of your study drug in a row, you should contact your study doctor immediately to get information about how to restart your medication. You may need to restart at a lower dose. Also, stopping the study drug suddenly may cause worsening of your PAH symptoms, such as shortness of breath, dizziness, or chest pain, which could also be life threatening. You must swallow the tablets whole and never split, crush, or chew them. Splitting, crushing, or chewing them may cause an unexpected rapid release of drug into your body. This may result in undesirable effects such as flushing, nausea or fainting. There is also the remote possibility that an individual tablet may release drug more rapidly than it normally should. This may bring about undesired effects as described above. The tablet shell does not dissolve. In subjects with diverticulosis or other blind-end pouches in the gut, tablets can lodge in these pouches.

Other risks of study procedures include the following:

Risks of the Six-Minute Walk Test

The risks associated with the six-minute walk test may include the possibility of fatigue, fainting, muscle soreness, strain or injury.

Risks of Blood Draws

You may experience slight bruising or pain on your arm where blood samples are taken. There is also the slight risk of infection, light-headedness, and/or fainting.

Risks of Genetic Sequencing

There are known and possible risks of whole genome sequencing which may include the loss of privacy and confidentiality and the risk of discrimination. There also may be other privacy risks that we have not foreseen.

> Loss of Privacy and Confidentiality: Even without your name or other identifiers being associated with your genome sequence data, there is a potential risk that someone will

identify you from your genetic information or learn something about you by looking at your genetic information. This risk may increase in the future as technologies advance and as more researchers study your genetic information. These risks may also affect members of your family because, although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them.

Discrimination Risks: Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others. A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers (those with over 15 employees) to discriminate against you based on your genetic information. GINA does not, however, protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Additional Risks

You will be informed as additional information is discovered about how the study drug may affect the risk and/or your willingness to continue to participate in this study. Your study doctor will inform you of all known risks; however, there may be physical, mental or genetic adverse effects that are not yet known.

You understand that your study doctor, sponsor (or its designee), the FDA, institutional review boards, or other regulatory agencies have the right to withdraw you from this research study or stop the research study based on any information, not just medical information, at any time and without your agreement. If you are removed from this research study or if the study is discontinued, the study drug will no longer be provided to you and the study doctor will advise you of other available treatments that may be of benefit.

BENEFITS

There is no guarantee that you will receive any benefit from this study. There is the possibility that being in this open-label study may temporarily improve your symptoms of PAH. Another benefit may be the satisfaction you receive knowing that by participating in this open-label study, other patients with PAH may benefit from the overall results.

ALTERNATIVE THERAPY

Currently, the only medicine(s) approved for the treatment of PAH in the United States are the following:

- Phosphodiesterase-5 inhibitors (PDE-5 inhibitors) (i.e., sildenafil and tadalafil)
- Endothelin receptor antagonists (ERA) (i.e., bosentan, ambrisentan, and macitentan)
- Prostacyclins and Prostacyclin Analogues:

  - Epoprostenol sodium
  - Subcutaneous (SC), intravenous (IV) treprostinil sodium
  - Inhaled treprostinil sodium
  - Inhaled iloprost
  - Selexipag
- Soluble guanylate cyclase stimulator (i.e., riociguat)

Oral vasodilators (medications used to dilate blood vessels), oxygen, blood thinner medications, diuretics or "water pills," and digoxin (medication to help your heart pump) may also be used to treat your PAH. Lung transplantation and atrial septostomy may also be a possibility. You should discuss these alternatives with your doctor when deciding whether to participate in this study. Your doctor should tell you the risks and benefits of the alternative treatments.

Also, your study doctor will inform you if there are other studies of new medications that may be a good fit for you. You should discuss these with your study doctor before deciding whether to participate in this study.

CONFIDENTIALITY

Every reasonable effort will be made to keep your medical and study related records confidential. This Informed Consent and another document called an "Authorization to Use and Disclose Protected Health Information" will determine how your health information is used and disclosed. The study sponsor and its employees or agents may use or release information from this study. Information may be given to the United States Food and Drug Administration (FDA) or regulatory agencies in other countries where the study drug may be considered for approval. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

Once you meet all study entry conditions, your records will be identified with your initials and the subject number you were previously assigned during participation in the TDE-PH-310 study. The information gathered from your participation in this study will not be shared with anyone not listed in this informed consent or as permitted by the "Authorization to Use and Disclose Protected Health Information" that you signed, unless required by law. Medical records including electronic medical records that identify you and the Informed Consent Form that you sign will be looked at and/or copied for research or regulatory purposes by the study sponsor, its employees or agents. Your medical records and Informed Consent Form may be looked at and/or copied for research or regulatory purposes by the US FDA, the US Department of Health and Human Services agencies, or regulatory agencies in other countries and <name of IRB/EC>.

Although you may be identified on study specific tests (e.g., pulmonary function tests, six minute walk test, physical examination, ECGs, echocardiograms, right heart catheterization reports, and laboratory results) that may be sent away for review outside of your study doctor's office or hospital, the sponsor, its employees or agents will take reasonable actions to protect the health information that identifies you. Also, health information obtained in this study that identifies you will be securely retained for a period of up to 25 years after this study ends.

The scientific results from this study may be presented at meetings or published in an article. You will not be identified in any presentation or published report.

In order to participate in this study, you will need to sign both this Informed Consent Form and the "Authorization to Use and Disclose Protected Health Information." You do not have to sign these documents if you do not agree with the uses and disclosures of your records and data described above. By signing this Informed Consent Form, you agree to participate in this study and give permission to the sponsor, its employees or agents to make, receive, save and/or send out information about your health. By signing this consent form, you are not giving up any legal rights.

BIOLOGICAL SAMPLES

Biological samples including blood and urine will be collected from you during this study. These samples will be identified using your initials, gender, and clinical study subject number and will not have any of your identifying information (i.e., name, date of birth, etc.). Only the sponsor and its employees or agents will have access to these samples and to your identifying information. The recipient of the samples will not be able to link the samples to you.

Your blood and urine samples will be collected and analyzed for the following:

- Routine laboratory tests
- To assess how your heart is working by measuring the level of a PAH blood marker (NT-proBNP)
- Pregnancy test
- Optional pharmacogenomic sequencing

Any blood and urine samples obtained for this purpose become the exclusive property of the study sponsor. The sponsor may retain, preserve or dispose of these samples and may use these samples for research that may result in commercial applications. The study sponsor will own the results of research conducted using your samples collected as part of this study.

<All deviations from the text in the previous paragraph must be approved by the UT legal department>.

RIGHT TO WITHDRAW

Participation in this study is voluntary. You do not have to participate in this research—it is your decision. You are free to withdraw your consent at any time. Your withdrawal, or refusal to participate, will not affect your current or future medical care in any way. If you wish to stop taking part in this study, it is important that you inform your study doctor who will explain to you the best way for you to end your participation. If you withdraw from the study, you must return all study medication and supplies to your study doctor.

During the course of the study, you will be told of any significant new findings that may affect your willingness to continue participating in the study.

Your participation in this study may be stopped with or without your consent at any time for any reason, including:

- You did not follow the instructions provided by your study doctor
- You become pregnant
- You experience a severe side-effect
- Your study doctor feels it is best to withdraw you from the study
- United Therapeutics Corporation decides to stop the study

COSTS/COMPENSATION

If you choose to participate in this study, the investigational drug will be provided at no charge to you. UT-15C will be provided free of charge only during the course of the study. The study sponsor will pay for procedures that are performed specifically for the study. Medical expenses for tests and medical procedures that would normally be performed to treat patients with PAH will be billed as normally done by the clinic or hospital (e.g., billed to your insurance company).

There is no direct payment for participating in this study. Some payment may be provided for travel related expenses required for study participation (e.g., parking fees).

Participating in research may result in an injury, as explained above. If you suffer an injury directly related to your participation in this research study, this institution will provide any necessary emergency care and will help you obtain medical treatment for the specific injury. The institution will also provide referrals to other health care facilities, as appropriate.

In the event that you suffer a research-related injury, your medical expenses will be your responsibility or that of your third-party payer, although you are not prevented from seeking to collect payment for injury related to malpractice, fault, or blame on the part of those involved in the research.

< Please note that the previous paragraph is a verbatim example from an FDA guidance document on appropriate language in informed consent documents. Some institutions may have their own statement on injury compensation that they would prefer to use. ***All deviations from the standard text in the previous paragraph must be approved by the UT legal department.*** *>*

CONTACTS FOR QUESTIONS OR PROBLEMS

All of my questions have been answered to my satisfaction. I understand that the <Institutional Review Board/Ethics Committee> has reviewed and approved this research study. The IRB / EC consists of a group of people established to make sure that the rights of human subjects that participate in medical research are protected.

If I have further questions about:

- This research study, I should contact:

  Investigator name
  Telephone number
  E-mail address: <*email address*>

- Research subjects' rights, I should contact:

  Name of IRB/EC representative
  Institutional Review Board/Ethics Committee
  Address
  Telephone number
  E-mail address: <*email address*>

- A study-related injury, I should contact the following person for information on compensation/treatment of a study-related injury:

  Name of Investigator
  Telephone number
  E-mail address: <*email address*>

In addition to the required study procedures, I have decided the following in regard to the optional study procedure.

Optional Whole Genome Sequencing

I agree to participate in the optional whole genome sequencing in addition to the required study procedures. I agree that the blood sample collected as a part of this optional testing can be used for the purposes provided for in this Informed Consent Form. I give up any property rights I may have to the sample collected for this optional research, and any genomic sequencing information or other data derived research using the sample. I understand that I do not have to participate in this optional blood collection in order to participate in this study.

_____ *(initials) Yes, I will participate in the OPTIONAL whole genome sequencing.*

_____ *(initials) No, I will not participate in the OPTIONAL whole genome sequencing.*

I have carefully read or have had read to me this consent form. I understand the purpose and nature of this research study, the potential risks involved and alternative treatments.

All of my concerns and questions about this research study have been answered to my satisfaction. I have been given a copy of this consent form.

By voluntarily signing this document, I am saying that I understand the information in the form, assume any potential risks associated with this study, and confirm that I voluntarily agree to take part in this study. I understand that this consent document is not an agreement between myself and the study sponsor.

By consenting to participate in this research, I give up any property rights I may have to bodily fluids collected during this research.

Print Name of Subject	Signature of Subject	Date
Print Name of Investigator (or designee obtaining consent)	Signature of Investigator (or designee obtaining consent)	Date
Print Name of Witness (If applicable)	Signature of Witness (If applicable)	Date

An impartial witness is required to be present during the entire informed consent process if a subject is unable to read, or if a legally acceptable representative is unable to read. The person administering the consent cannot sign as a witness. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to and appropriately understood by the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative.

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

I agree to permit <name of hospital/clinical site>, my doctors and my other health care providers (together "Providers") to use and disclose (release) health information about me as described below.

1. The health information that may be used and disclosed includes:
   - All information collected for purposes of carrying out the TDE-PH-311 as described in the Informed Consent Form; and
   - Health information in my medical records that is relevant to the Study.

2. The Providers may:
   - Use and share my health information among themselves and with the study sponsor (and its agents and contractors) to carry out research activities under the Study; and
   - Disclose my health information to representatives of government agencies, review boards, and other persons who watch over the safety, effectiveness and conduct of research.

3. Sponsor (and its agents and contractors) may use and share my health information as permitted by the Informed Consent Form.

4. Once my health information has been disclosed, federal privacy laws may no longer protect it from further disclosure.

5. Please note that you do not have to sign this Authorization, but if you do not, you may not participate in the Study.

6. You may change your mind and revoke (take back) this Authorization at any time and for any reason. To revoke this Authorization, you must write to *<site specific contact information>*. However, if you revoke this Authorization, you will not be allowed to continue taking part in the Study. Also, even if you revoke this Authorization, your Providers and sponsor (and its agents and contractors) may continue to use and disclose the information they have already collected to protect the integrity of the research or as permitted by the Informed Consent Form.

7. This Authorization does not have an expiration (ending) date.

8. You will be given a copy of this Authorization after you have signed it.

_____	_____
Signature of participant or participant's legal guardian	Date
_____	_____
Printed name of participant	Printed name of legal representative (if applicable)
Representative's Relationship to participant:	_____