

**Participant Information Sheet and Informed Consent Form
and Authorization to Use and Disclose Health Information
(Version 2.0, 10 January 2012)**

Study Title: A Phase 2 Randomized, Observer-Blind, Dose-Ranging Study to Evaluate the Immunogenicity and Safety of Quadrivalent Seasonal Virus-Like Particle (VLP) Influenza Vaccine (recombinant) in Healthy Young (18-64) Adults.

Sponsor: Novavax, Inc.
9920 Belward Campus Drive
Rockville, Maryland 20850 USA

Principal Investigator: A/PROFESSOR STEPHEN HALL

Daytime Telephone Number: 9509 6166

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WHAT IS CONSENT AND WHAT IS THE PURPOSE OF THIS FORM?

You are being invited to participate in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You may not receive any direct benefit from being in the study, and there may also be risks related to being in the study. The study doctor thinks that you may meet the qualifications of the study. The purpose of this Participant Information Sheet and Informed Consent Form is to provide you with information about the research study.

Consent means agreeing to take part in a research study. Your decision to take part in this clinical study is voluntary, which means you can choose whether or not you want to be in the study. If you choose to be in the study and then change your mind, you are free to leave the study at any time without giving a reason. If you refuse to join the study, or decide to leave the study before it is finished, this will not change your future care or your relationship with your study doctor. Being in this research study does not replace your regular medical care. Also, your participation in this study may be stopped at any time for any reason by the study doctor or the Sponsor without your consent.

To help you decide whether or not you want to be part of this research study, the purpose, procedures, possible benefits and risks of the study are described in this form so that you can

make an informed decision. This form also explains how your medical information will be used and who may see it.

Please read this form carefully and don't hesitate to ask questions about the information. This form may contain words that you do not understand. The study doctor or study staff will answer any questions you may have about this form or about the study. You can also discuss the study with family, friends, or your personal physician or other healthcare professionals.

After reading this information, if you would like to take part, you will be asked to sign the attached Participant Informed Consent Form. You will be given a copy of this form to take home and keep for your records. Please keep your copy in case you want to read it again.

The Sponsor of this study is a company named Novavax, Inc. (called Novavax in this form). This means that Novavax planned the study, made some of the vaccines to be tested, will collect and analyse the information gained in the study, and will pay for the study. The study will be supervised by the study doctor who is named on the first page as the "Principal Investigator." The study doctor and study centre will be paid for conducting the study.

Please note, participation in this study does not replace your normal Influenza ('flu) vaccination regimen for 2012; please inform the study doctor and study staff if you plan to receive the standard 'flu vaccination in 2012 so this can be fully documented in your records.

Please sign this document only if you believe that:

- You have completely understood the purpose of the study AND
- The study procedures are clear to you AND
- The study doctor or study staff have answered all of your questions AND
- You agree to participate in the study AND
- You are aware of your rights as a participant in this clinical trial.

Once you have decided to take part in the study and are assigned to a study group, you may contact the study doctor or study staff at any time with any additional questions or concerns you may have.

WHY IS THIS STUDY BEING DONE?

What is Influenza?

Influenza is commonly known as the "flu." The influenza virus is a germ that causes the flu. The flu is an illness that may include fever, headaches, muscle aches, cough, runny nose, sore throat, tiredness, and other symptoms. The illness usually lasts about 1 to 2 weeks. Influenza virus may also cause other illnesses, such as pneumonia (an infection in the lungs) and can even lead to death. These things most often occur in people with other illnesses and in people older than 65 years of age, but can happen in anyone. Each year, flu is responsible for many hospitalisations

and about half a million deaths around the world. There are drugs available to treat the flu, but they usually only work only if given soon after the illness starts.

There are three to four main types or strains of influenza germs that cause the flu. These germs change their make-up slightly each year. Because the germs can change, vaccines are made each year against the different influenza germs to prevent the flu. Currently, most influenza vaccines that are approved for use in humans are made in chicken eggs, which is a slow process. Sometimes there is not enough of the egg-made influenza vaccine for every one that should be vaccinated. Scientists are therefore searching for new ways to produce the influenza vaccine.

What is the Influenza VLP Vaccine that is being tested?

The Influenza VLP Vaccine is an experimental vaccine against the flu that is not produced in chicken eggs. VLP vaccines are made in insect cells that have been grown in the laboratory for many years. This type of insect cell has been carefully tested; no germs that could cause disease in humans have ever been found in these cells. VLP stands for “virus-like particle.” Under a powerful microscope, an influenza VLP looks very much like the actual flu virus. The VLP contains the proteins that form the outer shell of the influenza virus, but it does not have the genes that would be needed to make a virus able to cause the flu illness. Since the VLP Vaccine is not approved by any government agency for routine use in people, it is called an “experimental” vaccine.

If the Influenza VLP Vaccine contains proteins from three types of influenza germs it is called NovaFlu™. If the Influenza VLP Vaccine contains proteins from four types of influenza germs, it is called NovaFlu-Q™.

How do the NovaFlu™ and NovaFlu-Q™ vaccines work?

The NovaFlu™ or NovaFlu-Q™ vaccine is given as a single injection (or shot) in the muscle of your upper arm. Your body will treat the vaccine as a flu germ and make an immune response against it by producing protective blood proteins called “antibodies.” The amount of antibodies that your body makes in response to the vaccine can be measured by a blood test. Although it has not yet been proven, it is believed that the antibodies made by your body after vaccination with the NovaFlu™ or NovaFlu-Q™ vaccine will prevent flu illness and symptoms caused by the flu germs.

What is the purpose of this research study?

The purpose of this study is to learn about the safety (how well your body tolerates the vaccine) of the NovaFlu™ and NovaFlu-Q™ vaccines, and what dose of vaccine will give the best antibody levels in healthy people 18-64 years of age. The study will test three different dose levels of the NovaFlu-Q™ vaccine and one dose level of the NovaFlu™ vaccine.

The safety and antibody levels in people who get NovaFlu™ and NovaFlu-Q™ vaccines will be compared with results obtained in people who receive a typical egg-based influenza vaccine called TIV in this study. The TIV in this study is an egg-based vaccine licensed in the United States. The TIV is not licensed in Australia. It is the dominant TIV vaccine in the US market. More details about the TIV follow page 9.

HOW WILL THE STUDY BE DONE?

Who is eligible, and how many people will be in the study?

This study is for adults 18-64 years old. People who are generally healthy and have not had serious reactions to flu vaccines in the past may be eligible. The study doctor will decide if you are qualified to participate after talking to you and examining you. About 500 people will be included in this study.

How will the study treatments be assigned?

If you agree to join the study and are eligible, you will be assigned to a treatment group. A treatment group is a group of people who receive one particular vaccine or vaccine dose. A computer will assign you randomly (by chance) to your treatment group. You will stay in this group for the whole study. The computer will consider your age and whether you have had a flu vaccine in the past, so that the ages and past flu vaccine experience of people in the different treatment groups are about the same.

100 patients will be placed in 5 different treatment groups. The first three treatment groups will include three different dose levels of NovaFlu-Q™, the fourth treatment group will include one dose level of NovaFlu™, and the fifth group will include a standard dose of TIV. You will have a roughly equal chance of getting one of the five treatment groups.

This is called an “observer-blind” study. This means that only the study centre staff members who operate the computer and give you the injection will know which treatment group you are assigned to. Neither you nor the study doctor or other people working at the study centre will know this information until the study ends. The information will be available if needed to deal with a medical emergency.

How long will I be in the study, and what will I have to do?

You will be in this study for about 7 months. During the study you will be asked to do the following:

- Agree with the study visit schedule, come to your scheduled visits, and complete the procedures,
- Tell the study centre staff in advance if you will have any problem keeping an appointment at the study centre, so that another can be scheduled,
- Follow the instructions of the study doctor and study staff,
- Complete the diary given to you by the study staff for 7 days following the vaccination,
- Inform your study doctor of any new health problems or concerns you may have as soon as possible,
- If you are a woman and able to have children (you continue to have periods and you have not had any surgery to prevent you from having children), you must have a negative pregnancy test before vaccination. You must agree to not become pregnant during the study. You must use an effective form of birth control for the length of the study starting from the time that you sign this form. Acceptable forms of birth control are methods with a low failure rate

when used correctly such as abstinence, hormonal contraceptives (oral contraceptive pills, injections, implants), double-barrier contraceptives (condom worn by male partner, as well as female partner utilizing one of the contraceptive methods described), and intrauterine devices (IUDs).

If you are using a hormonal contraceptive, you must have been using this method long enough for it to be effective. Ask the study doctor if you are not sure. Also, some drugs such as certain antibiotics may make contraceptives less effective. Please tell the study doctor of other medications you are taking.

The study doctor may remove you from the study at any time to protect your health or if you fail to carry out your responsibilities. He/she may do this with or without your agreement.

What about other medicines?

You must not have taken any experimental medicine or vaccine within 45 days before the date of the study vaccination. You may not take any other experimental medicine or vaccine while you are in the study. You may continue your regular medicines. You are allowed to receive routine vaccinations after completing the Day 21 visit. The study doctor will record all medications you take, any changes in your medicines, and any medical procedures while you are in the study.

WHAT ARE THE STUDY PROCEDURES?

This study will include three (3) clinic visits and three (3) telephone contact visits. The amount of time you will spend at each visit is as follows:

- Day 0: This clinic visit will be approximately 2 hours (hrs).
- Day 21: This clinic visit will be approximately 30 minutes (mins) to 1hr.
- Day 180: This clinic visit will be approximately 30 mins.
- Telephone Contact (Days 3, 7, and 90): These calls will be very brief, approximately 10 to 20 mins, but can be longer if you want to discuss any health concerns, or have any questions regarding the study.

- You will be given the study vaccine.
 - The vaccination site on the upper arm will be swabbed with alcohol, allowed to dry, and then injected with the study vaccine.
- You will wait in the clinic for 30 minutes after injection to detect any immediate reactions to the study vaccine, and have your vital signs taken before release from the clinic. *You should inform the study doctor or another member of the site staff immediately if you do not feel well or notice any symptoms; whether or not you think they are due to the injection.*
- You will be given a diary and a digital thermometer.
 - You will use the diary to make a record of certain symptoms described in the diary, and any other changes in your health or medications, and any doctor or hospital visits for treatment of a medical condition daily through the first 7 days of the study.
 - You will use the thermometer to take your temperature at least once daily through the first 7 days of the study.
 - Your study doctor or another member of the study team will teach you how to use the diary and the thermometer.
- You will tell the clinic staff the best time to call you for the Day 3 and Day 7 telephone contact visits before you are released from the clinic.

Study Visit - Day 3 and Day 7 (Telephone Follow-Up)

You will be contacted by the clinic staff by telephone on Days 3 and 7 for a review of information you have recorded in your diary. You should report any new health problems or medical procedures since the last visit, and any new and/or changed medications you are taking.

If you report a medical problem that is severe based on the definitions in the diary, you will be asked to return to the clinic so it can be checked by the study doctor.

Study Visit - Day 21 (Follow-Up)

You will return to the clinic with your diary on Day 21 (3 weeks following vaccination) for the following procedures:

- Your vital signs will be checked.
- About 30mL or 1½ tablespoons of blood will be drawn from your arm vein to measure your levels of specific antibodies against flu germs and to repeat your blood counts and tests of kidney and liver function and blood cell counts.
- A urine pregnancy test will be done for all women who are able to have children.
If you have a positive pregnancy test, you will be followed to determine the outcome of your pregnancy, but will not have any other study-related procedures performed.
- Your diary will be collected and reviewed with you. You will be asked about any new health problems or medical procedures that have occurred since the last visit, and any new and/or changed, medications.
- A Day 90 telephone follow-up visit will be scheduled.

Study Visit - Day 90 (Telephone Follow-Up)

You will be contacted by the clinic staff by telephone on or about Day 90 (about 3 months following vaccination) for a review and discussion of any new health problems or medical procedures that have occurred since the last visit, and any new and/or changed, medications.

A Day 180 clinic visit will be scheduled.

Study Visit - Day 180 (Follow-Up and Study Completion)

You will return to the clinic on or about Day 180 (about 6 months following your vaccination) for the following procedures:

- About 20mL or 1 tablespoon of blood will be drawn from your arm to measure your levels of specific antibodies against flu germs.
- Any new health problems or medical procedures that have occurred since the last visit, and any new and/or changed medications will be reviewed and recorded.

Your participation in the study will be complete after this visit.

Additional clinic visits to monitor medical problems

You may be asked to return to the clinic for weekly visits (or more often) if you have any new health problems or symptoms, or abnormal results in your blood counts or tests of liver and kidney function that are discovered when your blood is retested at Day 21. At these visits, you may have about 10mL or 2 teaspoons of blood drawn for a repeat test.

Reporting symptoms, side effects, or injuries

If you experience any symptoms or new health problems that are of concern to you, or if you suffer an injury during the study, it is important that you notify your study doctor - whether or not you believe that these conditions are related to the vaccination that you were given. You do not need to wait for a study visit to do this. If you are hospitalised, or believe you are pregnant, you should notify the study doctor immediately. Contact information for your study doctor is provided on page 13.

What if I cannot, or do not want to, complete the study?

If you (or your study doctor) decide you should withdraw from the study, you will be asked to return to the clinic to have the following study completion procedures performed:

- If before Day 21 visit, collection of blood (about 20mL or 1 tablespoon) to repeat your blood counts and laboratory tests of kidney and liver function.
- Review of the reason for your withdrawal, any new medications or procedures, and any new health problems or medical procedures since the last visit.

WHAT RISKS OR SIDE EFFECTS CAN I EXPECT?

NovaFlu™ and NovaFlu-Q™ Vaccines:

This will be the sixth study in human beings to evaluate an influenza VLP vaccine. Based on what we currently know about the NovaFlu™ vaccine, the most likely symptoms you might experience after receiving an influenza VLP vaccine include:

- Tenderness and/or pain (in 5 to 6 out of 10 persons) at the place where the shot was given; as well as swelling and/or redness (in about 2 out of 10 persons),
- Muscle aches, headache, tiredness (each in about 3 to 4 out of 10 persons); fever, chills, joint aches, cough, nausea/vomiting, diarrhoea, and red eyes (each in 1 to 2 out of 10 persons).

Less common symptoms that have been reported by 3 to 10 out of 100 persons getting influenza VLP vaccines include:

- Bruising where the shot is given,
- Chest tightness, sore throat, difficulty breathing, hoarseness, wheezing, eyelid swelling, facial swelling, and difficulty swallowing.

Most of these symptoms have been mild and have gone away without treatment. They have been similar to reactions reported by persons getting TIV vaccination, or getting other vaccines. As with any new medication or vaccine that has been given to limited numbers of people, NovaFlu™ or NovaFlu-Q™ may have side effects which are not yet known.

TIV:

The TIV is a US licensed product called Fluzone®, which is manufactured by Sanofi Pasteur. The safety of this vaccine has been studied in many people by the maker of the vaccine. The most common symptoms, reported in 10% or more (1 out of 10, or more) individuals that received an injection, have been tenderness, pain, swelling and arm stiffness where the shot is given, and headache and joint pain. Most of these events were mild in nature and were gone in 3 days.

Allergies:

Like any vaccine or medicine, NovaFlu™, NovaFlu-Q™ or TIV may cause an allergic reaction. Allergic reactions can be mild (such as an itchy rash) or severe (such as severe difficulty breathing, or collapse of the circulatory system with low blood pressure). Severe allergic reactions require emergency treatment and could cause lasting disability or death. Most severe reactions occur quickly after exposure to the drug or vaccine, and can be treated effectively. This is why you will stay in the clinic for 30 minutes following the vaccine as a precaution. There are trained medical personnel available at the study site to treat you in the event of an allergic reaction.

The study doctor will ask you if you have an allergy to egg proteins and if you do, you will not be able to participate in this study. This is for your own safety, so please ensure that you inform the study doctor during your screening visit if you have any allergy to egg or egg products.

Blood Drawing:

We will use a needle to take blood samples from a vein in your arm during the study. The risks of blood drawing may include pain, bleeding or bruising at the place where the needle goes in, fainting, and very rarely infection.

The study staff will take blood samples from you up to three (3) times. A total of 80mL of blood (about 4 tablespoons) will be taken from you over the course of the study. For comparison, about 450mL of blood (a little less than 2 cups) is usually taken during a blood donation.

Pregnancy:

The risks of using the NovaFlu™ or NovaFlu-Q™ vaccines or TIV during pregnancy are not known, and it is possible that these products could cause harm to an embryo or foetus (or unborn baby). The safety of these vaccines during breastfeeding is also not known. Women who plan to become pregnant during the study or are breastfeeding should not participate in this study.

If female, you must confirm to the investigator that, to the best of your knowledge, you are not pregnant now, and that you do not intend to become pregnant during the study.

You must use an accepted form of contraception and if currently lactating, you should not breast feed your baby while on this study and for 3 months after the last dose of study drug has been taken.

If female and you suspect that you have become pregnant during the study, you must notify your study doctor immediately. You will not be able to continue participation in the study if you become pregnant. In the event you do become pregnant, the Sponsor will request that you sign a separate consent form to allow monitoring of your pregnancy and the birth and the health of your child up to 6 months of age.

If male it is recommended that a condom be worn for all sexual relations as the study medication may:

- (1) Affect your sperm risking the potential for an abnormal child being born, or
- (2) Cause harm to your partner through the absorption of the study drug from the seminal fluid.

The effect the drug has on your fertility may not be known.

Further, you must agree that if your partner becomes pregnant while you are on the study, you will advise the study doctor who will then provide you with an authorisation form to present to your partner. If she is in agreement, that authorisation will function as consent to approve the study doctor's access to medical information to allow monitoring of the pregnancy, and the birth and the health of the child up to 6 months of age.

New findings:

Your study doctor will be told about any new, important safety information that is learned during the study and that could change your willingness to continue taking part in the study. The study doctor will be responsible for providing this information to you. You may contact the study doctor at any time during or after the study to find out if any new information has become available.

WHAT BENEFITS CAN I EXPECT?

Taking part in this study may have no direct health benefit for you. NovaFlu™ and NovaFlu-Q™ vaccines are experimental. They may not protect against the flu. In addition, the flu virus strains in the vaccines may not match the 2012 influenza vaccine used in Australia. Information collected during the study will increase knowledge about this new experimental influenza vaccine, and may be useful for the prevention of flu in the future.

WHAT ARE THE COSTS OF THE STUDY TO ME?

There will be no costs to you to take part in this study. The study vaccine is given at no charge. All clinic visits, examinations, blood tests, and procedures performed for the study's research purposes will be done at no charge to you.

WILL I BE PAID FOR BEING IN THE STUDY?

For this study, the payment for participants who complete the entire study will be \$400.

Participant payment is for your time, inconvenience and any minor discomfort you may have. Your travel expenses and parking costs have been factored into this payment.

If you choose to withdraw your consent to participate in the study, then the level of payment you will receive will be on a pro-rata basis. (i.e.: you will receive a partial payment). You should also be aware that your study payment may be reduced or forfeited if you do not comply with any of the restrictions specified in this Participant Information Document. You will receive partial payment if you are withdrawn from the study due to non-medical reasons.

You will receive full payment if you are withdrawn from the study because of medical reasons or adverse events related to the study.

ARE THERE ALTERNATIVES TO BEING IN THE STUDY?

This study is for research purposes only, and is not intended to treat or prevent any illness. Your alternative is to not take part in the study.

WILL I BE COMPENSATED IF I AM INJURED DURING THE STUDY?

If you are injured as a result of your participation in this trial you have a legal right to seek compensation.

Sponsors of clinical trials in Australia have agreed that the guidelines developed by their industry body, Medicines Australia, will govern the way in which compensation claims from injured participants are managed by sponsors. Although Novavax is an American company and thus not a member of Medicines Australia, it has agreed to abide by these guidelines to the extent they are determined to apply. These guidelines are available for your inspection at:

<http://www.medicinesaustralia.com.au/files/2010/09/Clinical-Trials-Compensation-Guidelines.pdf>

However, as guidelines, they do NOT in any way dictate the pathway you should follow to seek compensation. The sponsor is obliged to follow these guidelines.

It is the recommendation of the independent ethics committee responsible for the review of this trial that you seek independent legal advice before taking any steps towards compensation for injury.

WHAT WILL HAPPEN TO THE INFORMATION COLLECTED ABOUT ME?

If you decide to take part in this study, you agree to allow collection of information about your health and your response to the study vaccines. This permission continues at least until the study is over, and does not end at any specific time. If you withdraw your consent to participate after the start of the study, no further information will be collected from the time of your withdrawal. However, any information obtained from you up to the time at which you withdraw consent cannot be deleted.

Your personal information will be kept confidential. Information kept at the study centre will be kept under lock and key. When information is transferred from the study centre to the Sponsor, Novavax, participants will be identified by participant identification numbers only. Your personal information may be reviewed at the study site by authorised representatives of regulatory agencies that regulate medicines or vaccines, the responsible Ethics Committee and persons representing Novavax to check that the study is being carried out correctly. All those persons are required to maintain the privacy of each participant. Unless required by law, no-one else will have access to any confidential information that identifies you by name or address, or in another way.

Coded information (in which you are identified only by a number) that is collected during this study may be used in several ways:

- Information about all participants who participate in the study will be stored on computers at the Sponsor or by companies working for the Sponsor. This information will be combined and analysed to learn about the safety of the study vaccines and how they affect the immune system; and also to plan future studies.
- The results of this study may be published or shared on the internet with other scientists, doctors, or persons representing other companies.
- The results of this study may be shared with government agencies that regulate medicines or vaccines - but your identity will never be revealed if this is done.

No matter which of the above is done, your identity will never be revealed.

WHAT WILL HAPPEN TO MY BLOOD SAMPLES?

Your blood samples will be coded (by having your name replaced by a number) at the study centre and sent to Novavax, or special laboratories working for Novavax, for testing. If you withdraw consent to participate after the start of the study, all samples collected from you up to that time will be stored and used for testing. By agreeing to take part in this study, you agree that your samples may be used in the following ways:

- To determine whether changes occur in your liver or kidney function, or blood cell counts, and
- To measure your body's immune system response to the study vaccine.

Samples may be stored frozen by Novavax or companies working for Novavax for up to 25 years. Your stored samples may be used, alone or mixed with other samples, for several other purposes. If your samples are used in any of these ways, information linking the samples to you personally will be permanently destroyed. These purposes may include:

- Ensuring that the tests used for this study remain of high quality and produce results that are reliable,
- Developing new or improved tests related to influenza ("flu") viruses, or VLP flu vaccines, or
- Developing new or improved tests related to other infections or vaccines.

Your blood samples will NOT be used to test for HIV infection (AIDS virus infection) or to study your genetic make-up.

WHO DO I CONTACT FOR QUESTIONS, PROBLEMS, OR INFORMATION?

If at any time before, during, or after the study, you have any questions about this study, please contact the study doctor or a member of the study staff at:

Study Doctor: A/Professor Stephen Hall – 9509 6166

Study Staff: Gail Grant – 9509 6166

The Bellberry Human Research Ethics Committee has reviewed this study in accordance with the National Statement on Ethical Conduct in Human Research (2007). Should you wish to discuss the study or view a copy of the Complaint Procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Committee Chair, Bellberry Human Research Ethics Committee on 08 8361 3222.

WILL MY REGULAR DOCTOR KNOW ABOUT IT IF I AM IN THE STUDY?

Yes, if you provide us with the contact details of your general practitioner, we will notify them of your participation in this study.

Participant Informed Consent Form

Study Title: A Phase 2 Randomized, Observer-Blind, Dose-Ranging Study to Evaluate the Immunogenicity and Safety of Quadrivalent Seasonal Virus-Like Particle (VLP) Influenza Vaccine (recombinant) in Healthy Young (18-64) Adults

Sponsor Protocol No: NVX 778.S205

Principal Investigator: A/Professor Stephen Hall

I have read this form, and I have been able to ask questions about this study. The study doctor or study staff has talked with me about this study. They have answered all my questions to my satisfaction. I voluntarily agree to be in this study.

I have been told that no information regarding my medical history will be divulged to unauthorised third parties and the results of any tests involving me will not be published so as to reveal my identity.

I understand that access may be required to my medical records for the purpose of this study as well as for quality assurance, auditing and in the event of a serious adverse event.

I give permission for my doctors, other health professionals, hospitals or laboratories outside Emeritus Research, to release information to the staff of Emeritus Research concerning my medical condition/disease and treatment that is needed for this project. I understand that such information will remain confidential.

I understand that I am free to withdraw from the study at any stage without prejudice to future treatment. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.

I consent to my general practitioner being notified of my participation in this study and of any clinically relevant information noted by the trial doctor in the conduct of the trial.

By signing this form, I have not given up any of my legal rights as a study participant. I will get a signed copy of this consent form for my records.

Printed Name of Participant

Signature

Date

I confirm that the information provided was given in language that was understandable to the participant.

**Printed Name of Investigator
Explaining the Consent Form**

**Signature of Investigator
Explaining the Consent Form**

Date