SUGGESTED DRAFT

(INSTITUTION)

CONSENT TO PARTICIPATE AS A RESEARCH SUBJECT IN THE STUDIES OF LEFT VENTRICULAR DYSFUNCTION (SOLVD)

The National Institutes of Health is conducting research Studies of Left Ventricular Dysfunction at about one hundred medical centers in the U.S., Canada and Belgium. The purpose of the study is to evaluate the effects of long-term drug administration on patients who have moderate left ventricular dysfunction or those who have overt heart failure.

I have been found to have left ventricular dysfunction; that is, my heart does not pump blood adequately. Patients with this problem are more likely to suffer from premature death than those who have normal ventricular function.

Some of the patients in this study will be found to have overt heart failure and symptoms such as leg swelling and shortness of breath. Studies have shown that treatment of heart failure usually improves these symptoms. Doctors do not agree about whether or not treatment of heart failure prolongs life. The aim of this study is to evaluate whether or not the study drug (enalapril) used routinely prolongs life in those who suffer from heart failure or left ventricular dysfunction. Regardless of the benefit I may get from the treatment of heart failure, the information gathered in this study will be very important for doctors in deciding how to treat persons who have left ventricular dysfunction.

During approximately the first three weeks of the study, I will receive for some period of time the active medication (enalapril) and during another part I will receive an inactive medication that appears to be similar (a placebo). My response during the first three weeks will determine whether or not I am continued in the study. During the remainder of the study, I will be on either enalapril or placebo.

The type of drug I will be taking during the remainder of the study is selected by chance rather than by my clinic doctor. I have an equal chance of receiving enalapril or the placebo. In order for the study to be successful, neither the clinic doctor nor I will know what drug I am taking, although should a need arise to know the identity of the drug, it can be revealed. I will be taking one pill twice a day.

Enalapril is an accepted agent for treating patients with high blood pressure. The drug can occasionally (in about 3% of cases) cause side effects which are rarely serious but can sometimes be bothersome. There is a small chance I could experience side effects such as: light-headedness, skin rash or protein in my urine, or occasionally a drop in blood pressure that may require treatment. Rarely, an altered taste in the mouth or very rarely a low white blood count or an allergic reaction may occur which may result in redness or swelling of the skin or breathing difficulty. All these side effects are thought to be reversible. If any of these events happen, my drug dosage may be reduced or discontinued.

All information being collected will be continually monitored by independent researchers associated with the Study. Additionally, a group of national experts will be reviewing the data at frequent intervals. I also understand that safety precautions have been set up to ensure that if my condition worsens my doctor may change other aspects of my treatment other than the study drug to treat my heart failure. I will always be offered any treatment that my medical condition requires and participating in this study will not affect that. Alternative options for therapy of my left ventricular dysfunction are available if I choose not to participate in this study. Additional or alternative forms of treatment for patients with left ventricular dysfunction and congestive heart failure symptoms include diuretics (water pills), digitalis, anticoagulants (blood thinners), antiarrhythmic drugs (drugs to regulate my heart's rhythm) and vasodilator drugs that include nitroglycerin tablets, hydralazine, prazosin, diltiazem, and/or nifedpine. All or some of these drugs may be given to me while I am in SOLVD and taking enalapril or placebo. Any extra tests or hospitalization required by the study will be covered and paid for by the study.

I agree to participate in the Studies of Left Ventricular Dysfunction Program which is currently scheduled to conclude in 1991.

I agree to take part in the procedures to be done at baseline visit and subsequent follow-up visits.

At these visits some or all the following will take place:

1. The information about my medical history and general well-being will be collected.

2. I will be given a brief physical examination.

3. Samples of my urine may be collected for tests. There are no risks involved in this procedure.

4. I may have blood drawn from my arm with a needle for test. I understand that the needle feels like a pin prick. Occasionally, bruising may result.

The baseline visit will take about 30 minutes.

The next visit will take place a few days after this visit, and subsequent visits are less frequent. After the first four months, I will only be required to visit the clinic every four months, unless certain special circumstances occur. Most of these visits will be considerably shorter than the first visit.

I will be given the results of all my examinations and procedures at all clinic visits and, if I give my permission, these results may also be reported to my private doctor.

I understand that my Social Security or Medicare number will be used to help the SOLVD Clinic know if I am in the hospital. I also understand that this will in no way affect my Medicare coverage. I understand that this and all information obtained as part of the study will be considered confidential and only used for research purposes. My identity and my Social Security number will be kept confidential. Please be aware that certain agencies of the Department of Health and Human Services, such as the Food and Drug Administration have the right to audit records for scientific or fiscal purposes.

For this study to be a success, it is important that I remain in communication with the study and if I lose touch with the clinic, they will try to find me to ask about my health. For this reason, I agree to tell the clinic when I move and also to provide names, addresses and phone numbers of relatives who will know my state of health. I agree to try my best to keep appointments at the clinic and to let the clinic know if I need to change appointments or when I have any problems following the instruction of the clinic staff. It is also important that I take all the tablets prescribed to me, although when necessary the dose of the tablets may be increased or decreased.

[Federal Regulations requires a clinic specific statement regarding compensation related to participation as a human research subject.]

My participation in the study is entirely voluntary and will not affect any medical care to which I am entitled. Further, I am free to refuse to take part or withdraw at any time. I have been given a copy of this form.

_____ has discussed this information with me. If I have any questions about the study, about my rights as a research subject, or about research related injury at any time in the future, I can call _____.
(Name)

_____
(Telephone number)

_____ _____
Signature of Investigator Date

_____ _____
Signature of Subject Date

_____ _____
Witness to Subject's Signature Date