Appendix H: ENRICHD Informed Consent Forms

Enhancing Recovery in Coronary Heart Disease (ENRICHD)
Patients Study

DRAFT INFORMED CONSENT

After being hospitalized for a heart attack some people are depressed or have feelings of low perceived social support. Symptoms of depression include sadness, tiredness, feeling bad, a loss of interest in usual activities and other symptoms. Low perceived social support is a feeling that you don't have someone you can count on for help doing day-to-day activities such as driving to the doctor or cooking, or just someone to talk with about your feelings.

People who have had a heart attack and who are depressed or have low perceived social support are more likely to have another heart attack than people who are not depressed or who do not have low perceived social support. But doctors do not know whether giving advice (counsel) to a person who has depression or low perceived social support will help them to lessen their chance of another heart attack or of dying from heart disease.

The doctors at this hospital have asked you to take part in a research study that will help them find out the answer to this question. This study is called the Enhancing Recovery in Coronary Heart Disease (ENRICHD) Patients Study.

Before you can decide whether or not you should agree to join this study, you should find out enough about its risks and benefits to make a good judgment. This is called informed consent.

The consent form you are reading describes the research study which the doctor will talk to you about. Once you know what the study is about, you will be asked to sign this form if you want to join. You will have a copy of this form to keep as a record.

PURPOSE OF THE ENRICHD STUDY: We hope to learn whether counseling for a person who is depressed or who has low perceived social support will not only reduce their depression and increase

their social support, but will also lower their risk of a future heart attack or of dying from heart disease. This study will help doctors find the best treatment to use in the future.

DESCRIPTION OF THE STUDY

About 3,000 patients across the country will take part in the ENRICHD study. You were selected to take part in this study because you are being treated in the hospital for a heart attack. If you agree to be in the study, we will look at your hospital records to find out if there are any medical reasons that would not allow you to enter into the study.

We will then ask you questions that will help the doctors decide whether you have depression and/or feelings of low perceived social support, and if so, how much you are having these feelings or symptoms. If you have certain symptoms, such as thoughts of suicide, you would not be eligible to enter the study.

These questions will be asked at least once while you are in the hospital and, in many cases, during an outpatient visit to your doctor or on a telephone call to you within the first three weeks after your heart attack. Once it has been decided that you may take part in the ENRICHD study, you will be chosen by chance, or randomized, to be in one of the two groups. In one group, called a usual care group, you will receive the care you would ordinarily receive from your doctor. In the other group, you will receive usual care and counseling sessions for depression or low perceived social support, or both.

In the usual care group, your primary care doctor will keep taking care of you, and will not withhold any treatment from you. This includes counseling and prescribing and following up on any drugs he or she feels you need. You will also be asked by the ENRICHD study doctors to come to the clinic for follow-up visits, and you will be contacted by telephone, as described in the "FOLLOW-UP" section below.

In the group that receives usual cardiac care and the counseling we are examining in this study, your primary care doctor will also continue to take care of you. You will also be scheduled for

counseling sessions by the ENRICHD study doctors, at no cost to you. These counseling sessions will involve from 16 to 28 individual and/or group sessions with specially trained ENRICHD study doctors or health care personnel. These sessions would start up to three weeks after your heart attack. Four to six individual sessions will first be held between you and your ENRICHD study doctor. Then you will go to the group meetings once a week for about 12 weeks. These group meetings will be with other patients in the ENRICHD study who, like you, have had a heart attack.

FOLLOW-UP

You will be contacted every six months during the ENRICHD study for either a clinic visit or telephone call to answer questions about your health. Each clinic visit will last about an hour. You will be part of the ENRICHD study until _____ (DATE).

If your depression does not improve or if it gets worse, we may talk to your primary care doctor about giving you medication for your depression. We will also talk to your primary care doctor if other symptoms of depression occur, such as thoughts of suicide. If it is thought that you would benefit from medication for depression, an ENRICHD study doctor will work with your primary care doctor to prescribe the best medication for your depression, and will follow you to see how you are doing on these medications. You will be tested for any medical conditions that would affect which medications you should take. If you are in the usual care group and your primary care doctor feels you need counseling or medications for depression, these will not be kept from you. However, they will not be paid for by the ENRICHD study.

RISKS AND DISCOMFORTS

All medical care, including the type given in studies such as this, has some risk of injury, but there are no known risks for the type of counseling involved in the ENRICHD study. You may feel nervous about sharing your feelings or experiences, but this type of counseling mostly involves problem solving and positive thinking. Patients who have had a heart attack and who were depressed or had low perceived social support have done well with counseling of this type, but the ENRICHD study does not know or promise that you will receive any benefits from this study.

If any medical conditions or severe depression occur, the ENRICHD doctors will help you find the correct treatment, but the study will not provide any money for the treatment. You may call Dr. (name of Principal Investigator, address, telephone number) or _____ (alternate) if you have questions at any time or if a problem comes up while you are taking part in the ENRICHD study.

BENEFITS

The benefits of this study to you include close follow-up of your medical care. Also, by being in this study, you may help doctors find out whether treating people with depression or low perceived social support will lower their risk of another heart attack or death, which might help patients like you in the future. Many patients like to have someone to talk to or to meet other heart patients. If you wish, results of your tests for the ENRICHD study will be given to your doctor at no cost to you.

ALTERNATIVE TREATMENT

If you choose not to join this study, you may decide to talk to your primary care doctor about the potential benefits of counseling for depression or low perceived social support. Choosing not to join this study will not change or decrease the health care you receive. You may continue with your usual health care whether you join the study or not.

CONFIDENTIALITY

All information on your medical condition and your answers to questions that are asked for the ENRICHD study will be kept confidential to the extent the law allows. Records about you will be put under a code number. In some cases, personnel from the National Heart, Lung, and Blood Institute or the Food and Drug Administration may need to see your records to verify study information, but they will not be told who you are. The results of the study may be published, but your identity will not be given and the results will be given only for groups of people, not individuals. At the end of the study, all paper forms with your name or other information that could identify you will be kept in a locked room for a period of _____ years (determined by State regulations) and then will be destroyed.

You will be asked to give your Social Security number (under Public Health Service Act 42 USC 285a) so that study staff can locate you in the future if you cannot be located by other means. Giving this information is up to you and you may still take part in the study even if you refuse to give us this information. You will not be denied any federal right, benefit or privilege by refusing to give this information.

Your name, Social Security number, Medicare number and all other publicly identifying information will be kept in computer records separate from the data collected as part of your taking part in this study. Any medical information about you will be kept in computer records for analysis with such information from all other individuals in the study, but these records will not contain your name or Social Security or Medicare number or any other publicly identifying information.

COSTS

There will be no payment to patients who take part in this study. Your ENRICHD counseling sessions and ENRICHD clinic visits will be covered by the ENRICHD study. All other treatments, procedures, and clinic visits for your heart condition are considered usual medical care and their costs are expected to be covered by your insurance carrier or you.

LIABILITY

The U.S. Department of Health and Human Services or any agency funding this study in which you are taking part will not provide compensation nor medical treatment in the event the study results in injury.

The _____(name of institution) is covered by liability insurance. If you suffer any injury from taking part in the study, compensation would be available to you only if you establish that the injury occurred through the fault of the institution, its officers or employees.

You do not give up any rights for personal injury by signing this form. For further information on your rights, please phone or write _____(name of patient ombudsman, address, telephone number).

RIGHT TO ASK QUESTIONS AND TO WITHDRAW FROM THE STUDY

The doctors listed on this consent form have offered to answer any questions you might have. You are encouraged to ask questions about the tests and results, and the physicians in charge of the project will do their best to answer these questions. You are free to decide not to take part in this study, and you can withdraw from it any time without penalty and without changing your treatment by your primary care doctors. If you do not choose to enter this study, your own doctor will decide what treatment will be given to help you recover from your heart attack.

You will be given a copy of this consent form to take home.

You are making a decision whether to join this study. Your signature below shows that you have read this consent form and agree to join in this study.

_____ _____

Signature Date

_____ _____

Signature of Study Personnel Date

Study Investigator: (Name, Address, Phone)

_____

Alternative Study Staff: (Name, Address, Phone)

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