National Emphysema Treatment Trial (NETT)
Consent for Pulmonary Rehabilitation

Instructions: This consent statement is to be signed and dated by the patient in the presence of a certified study staff member (not necessarily the study physician who also signs the statement), after determination of eligibility to enroll in the pulmonary rehabilitation program and prior to the beginning of the initial pulmonary rehabilitation program visit, after the patient has read the statement and has had a chance to ask any questions about its content.

1. Introduction
   The National Emphysema Treatment Trial (NETT) is a clinical trial. A clinical trial is a research study to compare alternative treatments or test new ones. Such research is done when there is no clear evidence showing that one treatment is better than another. Persons asked to take part in a clinical trial must give consent to participate in that research. The consent must be based on an understanding of the nature and risks of the treatments. Doctors and other study personnel must provide the information needed for people to understand the study and agree to take part in it.

2. The National Emphysema Treatment Trial (NETT)
   The purpose of the NETT is to compare two treatments for emphysema:

   (1) Usual medical treatment with medicines, oxygen, and a program of exercise and education about emphysema and ways to manage it. We shall call this "medical treatment".

   (2) Usual medical treatment with medicines, oxygen, and a program of exercise and education plus lung volume reduction surgery.

We do not know which treatment is better. That is, we do not know whether one treatment is more likely to reduce shortness of breath, improve the ability to walk a distance, increase general enjoyment of life, or prolong life.

The NETT is funded by the National Heart, Lung, and Blood Institute and the Health Care Financing Administration, the Government agency that oversees Medicare. Nineteen clinical centers across the United States will participate in the NETT. About 2,500 patients with emphysema will be enrolled over several years. The trial is expected to continue until about the fall of the year 2002. Followup for a patient will probably not last longer than 4½ years.

You agreed previously to be screened for the NETT. You have finished and passed the screening tests. We are now inviting you to enroll in a program of exercise and education about emphysema and ways to manage it. This program also involves treatment with medicines and oxygen as needed, exercise, individual counseling, and group sessions. This program is called pulmonary rehabilitation.

The purpose of the rehabilitation is to try to improve your physical condition and breathing. The NETT staff will give you exercises to do to increase your strength and endurance. They will slowly increase the amount of exercise you do over time. You will also learn about your disease, breathing techniques, your medications, proper eating habits, and ways to relax. In the first week, you may be at the NETT clinic every day. After that, the
program may take place at the NETT clinic or near your home.

After you have completed six to ten weeks of the rehabilitation program, NETT doctors will again check your condition. If you meet the goals set by the rehabilitation program and the tests show that you are healthy enough to have lung surgery, we will ask whether you want to consent to "treatment randomization". If you give your consent, your treatment will be decided by chance. In a process much like flipping a coin, you will be assigned to one of two treatments:

(1) Continued medical treatment and more rehabilitation, or  
(2) Lung volume reduction surgery followed by continued medical treatment and more rehabilitation.

You will have an equal chance of assignment to either of these two treatment groups. Neither you nor your physician can choose which treatment you will receive.

After treatment randomization, you will have eight more weeks of rehabilitation. If you are assigned to medical treatment, you will start the eight weeks of rehabilitation immediately. If you are assigned to have lung surgery, the operation should be done within two weeks, and the eight weeks of rehabilitation will begin after the surgery. The surgery consists of removing a portion of your diseased lungs as determined by the surgeon. This is done because many patients with emphysema have "stretched out" lungs. It is thought, but not known, that removing the most damaged parts of the lungs may reduce shortness of breath. One of two possible surgery methods to reduce the lung volume will be used. In clinics that use both procedures, the type of surgery will be chosen by a process similar to flipping a coin. In this clinic, we are using ___________method.

After treatment randomization, regardless of what treatment you receive, we will want you to come for regular visits for the duration of the study. Your medical treatment for emphysema will be reviewed during these visits and recommendations will be made to your personal physician. We want to see you twice a year for one year and once a year after that. Each visit will take one to two days and may require you to stay overnight near the clinic if you live far away. The NETT clinic will also contact you by phone or in writing between visits.

If you withdraw from the rehabilitation program, or if we do not think that surgery is safe for you when we evaluate you after six to ten weeks in the rehabilitation program, you may not continue treatment within the NETT. We will provide your personal physician with results of your tests.

You do not have to consent now to have your treatment assigned by the chance process. We will not know if you are eligible for this until six to ten weeks from now. You may want to discuss this decision with your family, doctor, or friends while you are participating in the rehabilitation program. However, if you know now that you do not want your treatment assigned by chance, you should not continue with the NETT.

3. Risks and Discomforts

The exercise sessions may be tiring. They will require a lot of effort and your full cooperation. On rare occasions, exercise can lead to collapse, injury, or a heart attack. An exercise course is part of most rehabilitation programs and therefore is part of usual care. It
is not an extra risk from being in this study.

The medicines that your doctor may prescribe have side effects. These side effects depend on the nature and dose of the drug and on your health. Medicines used may include drugs to open the airways to the lungs. Known side effects of these drugs (called bronchodilators) include irritation or dryness of the tongue and mouth, mild shakiness, rapid heart beat, and nausea. Most side effects can be controlled by reducing the dose of the medicine. These risks are part of usual medical care and are not extra risks from being in the study.

After six to ten weeks in the rehabilitation program, you will undergo various lung function and exercise tests, and some blood tests. Lung function tests may be tiring and hard to perform. We will check your heart by recording its electrical activity during exercise.

Blood tests require taking blood from veins and arteries. The needle puncture may be painful for a short while and cause bruising. An arterial puncture may cause more bleeding than a vein puncture. When blood is collected, about a tablespoon will be removed each time.

We will also ask you to fill out questionnaires about your quality of life and state of mind. You do not have to answer questions that you find embarrassing. However, your answers are important to the study, and all your answers will remain confidential. We will also collect information from you and from your insurance company about all medical services which you receive during your participation in the NETT.

You are not to smoke any tobacco products while in the study. We will ask you to report your smoking, and we will test your blood from time to time for evidence of smoking. If you smoke, we will not enroll you in the NETT.

Lung volume reduction surgery can be done by opening the chest wall or through small slits at the sides of your chest. The lung volume reduction surgery is a major operation. This surgery has some major risks related to the anaesthesia and the surgical trauma. Patients will have discomfort after the surgery, and recovery may take several weeks. Some patients may take longer to get well, and some may never fully recover to the lifestyle they had before the surgery. The lung volume reduction surgery may also shorten your life or cause death.

We do not know all of the risks of lung volume reduction surgery. It may not be effective, or the effects may not last. It can make breathing more difficult, and it may not improve the quality of your life. We will discuss the risks of lung volume reduction surgery with you later, in more detail, if you qualify for treatment randomization.

If you are waiting for a lung transplant and you agree in the future to treatment randomization, we may ask you to change your listing for lung transplant to inactive. However, you may refuse to do this and still participate in the NETT. While your listing is inactive you will not be offered a lung transplant. You will keep the waiting time you have collected so far, but you will not collect any more waiting time.

We may contact you after the conclusion of the study to find out the impact of your illness on the quality of your life.
4. Benefits

In this study you will benefit from the best known medical treatment for emphysema. A lung expert will review your treatment on a regular schedule and make recommendations to your personal physician. The rehabilitation program may help you cope better with your disease and improve your physical condition. We do not know whether lung surgery is effective. If during, or at the end of the study, we find that patients assigned to lung volume reduction surgery do better, we will offer lung surgery to patients who are suitable for surgery and who have not had it. In addition, you may help doctors learn how best to care for emphysema patients like you in the future. We hope to find out which emphysema patients benefit most from each treatment. Results from this trial will not cure their emphysema, but may improve their life. To protect your safety during the trial, a panel of experts outside the trial will monitor it. This panel will look at the data regularly and report any safety concerns. You will be informed in a timely fashion about any change in the risk to benefit balance of the two treatment options in the NETT.

5. Access to Medical Care

You are not obligated to enroll in the NETT. Emphysema can be treated with medicines and oxygen alone, involving less discomfort, risk, and personal effort than participation in the NETT requires. Though the information we will gain from you is important, you do not have to remain in the study. If you do not enroll, or if you withdraw from the NETT, you may continue to receive care at this institution. However, as presently designed, the NETT surgeons can only offer and perform this surgery on patients who enroll in the NETT. If you want to receive surgery outside of the NETT, we will refer you to another surgeon. In this case, the main NETT pulmonary physician will also have to refer you to another pulmonary physician for treatment.

6. Alternatives to Participation in the NETT

You can refuse to enroll in the NETT and continue with your current care. You may receive medical treatment without enrolling in this study. You may be able to receive rehabilitation if your insurance covers this type of service. Other treatments for your disease include supportive care only or oxygen therapy. Your symptoms can be treated as they appear. You can have lung volume reduction surgery elsewhere or with other doctors, outside of the NETT and unpaid by Medicare. You could also receive a lung transplant, depending on your overall health and the severity of your disease.

7. Confidentiality

Information gathered from you is personal and confidential. We are collecting data for the purpose of this study and will keep the data at the NETT clinic and at the NETT Coordinating Center in Baltimore, Maryland and any subcontracted data center as determined by the NETT Coordinating Center. Personal identifiers will be kept in a secure location. We will keep your records confidential to the extent possible within the limits of the law and human error. However, authorized people from the National Heart, Lung, and Blood Institute and from the NETT Coordinating Center may inspect individual records if needed. If the findings from this study are published, no information will be included which would reveal your identity.

8. Research Related Injuries

If you are injured or disabled because of participation in the NETT, you can be treated at this institution. The costs for such treatment will be covered by ___________. However, ___________ (specify institution) and the Federal Government do not have any program to provide
compensation to you or to your family if you are disabled, experience other bad effects which are not the fault of investigators, or die during the study.

9. Costs

Medicare will help cover the costs of tests, exams by NETT doctors, and the rehabilitation program after you have paid any deductible and coinsurance amounts that Medicare requires. You will have to pay the costs of traveling to the NETT clinic. You will also have to pay any lodging costs during the rehabilitation program or during followup visits.

If you continue to take part in the NETT, Medicare will help cover costs of treatment and followup directly related to the study. As before, you will need to pay any deductible and coinsurance amounts that Medicare requires. All regulations regarding Medicare coverage apply as indicated in the Medicare guidelines. You will be responsible for costs of travel and lodging. You will need to pay for medicines, including inhalers and other drugs. Medicare will pay for lung volume reduction surgery only for patients assigned to have this surgery in this trial.

10. Consent

You should be sure to have all your questions answered before you agree to take part in the rehabilitation program. The principal investigator, Dr. ___________, and the clinic staff are available at (specify phone number) to answer any questions you may have about the study, now or later. If you believe that you are not being treated fairly or have been injured by taking part in the study, you may contact the person named above or (specify IRB office) at (specify phone number). The principal investigator or clinic staff will help you obtain medical care for such an injury.

If you are willing to participate in the pulmonary rehabilitation program, please indicate so by signing below. You are entitled to receive a signed copy of this consent statement.

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Note: Study physician must sign in the presence of the patient and staff member and on the day on which the consent was signed by the patient.