Draft: 11/19/84

INFORMED CONSENT TO PARTICIPATE IN CLINICAL INVESTIGATION

Prospective Investigation of Pulmonary Embolism Diagnoses

You are being asked to take part in a project on the helpfulness and accuracy of two tests for blood clots in the lung. These tests are the ventilation-perfusion lung scan and the pulmonary angiogram. All such projects in this hospital are subject to rules of conduct written by the Federal Government and by this hospital. These rules require your signed agreement if you wish to take part in this study.

Your physician has ordered a ventilation-perfusion lung scan to help determine whether or not you have had a pulmonary embolus. A pulmonary embolus is a blood clot which formed in the leg but broke loose and traveled to the lung. A ventilation-perfusion scan is a test of how well air moves in and out of the lungs, and how well blood flows through the lungs. These scans use low levels of radioactivity in air breathed and in intravenous infusions to look at the lungs.

The data available from this hospital and from many other institutions suggest that a completely normal ventilation-perfusion lung scan probably eliminates the possiblity of a pulmonary embolus being present. An abnormal ventilation-perfusion scan may represent a pulmonary embolus, but often does not since lung diseases such as pleurisy or pneumonia make the scan abnormal. This study is trying to determine what appearances of a ventilation-perfusion scan are uniquely characteristic of pulmonary emboli seen on a pulmonary angiogram, the final test in difficult cases.

The pulmonary angiogram involves the passage of a catheter through a vein in the leg or arm up to the heart and into the lung blood vessels. Dye is then injected into the blood vessels and multiple X rays taken to search for clots. The X ray exposure is equal to that received in having an upper and lower gastrointestinal series. There is small risk of allergic reaction to the dye or to the local anesthetic, irregular heart beats and damage to the blood vessel in the leg or arm where the catheter is inserted. Deaths in the course of pulmonary angiography have occured, but are rare. Rest in bed may be required for up to six hours after the procedure to allow the catheter insertion site to heal sufficiently to allow walking.

If you agree to take part in this study, your doctors will use a lottery procedure to decide whether or not to follow your ventilation-perfusion scan with a pulmonary angiogram for this study. If your ventilation-perfusion scan is entirely normal, you will not be asked to agree to have a pulmonary angiogram performed. If you agree to take part in this study, information will be recorded on your condition now, during your stay in the hospital, and at three month intervals for one year after you leave the hospital. Your doctors may contact you in the future to request your participation in other studies of pulmonary embolism.

No costs will be added to your care or charged to your insurance carrier as a consequence of this research.

PIOPED Informed Consent

You may refuse to take part in or withdraw from this study at any time without harming your present or future care at this hospital.

Your alternative to taking part in this study is to receive your doctor's standard treatments for pulmonary embolism. If your doctors decide you should undergo pulmonary angiography, they may request that test whether or not you participate in this study.

In this study your doctors will make note of your initials, age, sex, weight, height and other facts about you. These details will be stored in a private Data and Coordinating Center on a computer. You will not be identified personally in any reports from this study. Every effort will be made to keep your own personal medical data confidential.

Should an unforeseen physical injury occur, appropriate medical care, as determined by the hospital will be provided but no financial compensation will be offered. Should you have any questions about your rights in the study you may call either (name and phone number) or the office of Research Administration at (phone number). You will be given a copy of this form to keep if you agree to take part in this study.

****

I have read and discussed the explanation of this study with the study doctor. I have had enough time with the study doctor to discuss all of my questions and concerns. I willingly consent to be part of this study.

I agree to release of medical information by study doctors to my referring doctor.

_____ _____

Signature of Patient Date

_____ _____

Signature of Witness Date

I confirm that I have explained to this patient the nature and purpose, the possible benefits, and possible risks of the study procedures and drugs.

_____ Check if patient refuses study participation

_____ _____

Signature of Physician Date

ID No.