actual coding of project tracings. Within the CEL, ECGs are periodically recirculated to detect coding deficiencies. A staff member who is identified as having inadequate performance undergoes remedial training until performance improves. Kappa statistics are calculated biannually for the physicians and laboratory supervisors.

In addition, the CC is recirculating a blinded sample of 200 baseline ECGs for Q wave interpretation. A 25% sample of ECGs that indicate Q waves during follow-up and an additional 0.5% of ECGs without Q waves are also being recirculated. This serves to document the reliability of the central diagnosis of this major BARI end point. Interreader variability of binary data will be assessed by using the Kappa statistics.

Exercise Test Acquisition

Exercise tests are performed by using a motor-driven treadmill and following the Bruce protocol[8] with no or at least one half of a warmup stage if necessary. A physician is in attendance throughout the test, and the patient and ECG tracings are carefully observed. All patients undergo a pretest evaluation, during which ongoing drug therapy and indications for stopping the exercise are ascertained.

The Mason-Likar 12-lead torso ECG is the lead set used. Four specific tracings are required: upright immediately before exercise; peak exercise; immediate postexercise; recovery period (3–5 minutes after exercise); or an ECG showing maximum postexercise change.

Exercise Test Digitization

Exercise ECGs are first examined for the presence of excess artifacts, baseline wandering, and missing leads or ECGs. Each test is reviewed by the laboratory supervisor or associate to determine the presence of exclusion codes such as left bundle branch block, left ventricular hypertrophy, etc. The maximum depth of ST segment depression, maximum height of ST elevation in a non–Q wave lead, maximum number of abnormal leads, and maximum height of ST elevation in a Q wave lead are calculated. A Q wave lead is one in which the Q wave width exceeds 0.03 seconds. This is determined from the resting ECG that undergoes Minnesota Coding. These exercise ECG data are transmitted weekly to the CC.

Quality Control of Exercise ECG Data

A 2% sample of scheduled and unscheduled exercise ECGs are submitted for reproducibility studies. The sample is enriched with 25% of all exercise tests that indicate a myocardial ischemic response. Variables to be analyzed for reproducibility include the maximum number of abnormalities in any lead group, the total number of abnormal leads, and the maximum depth of ST segment depression.

Serial Comparison

For both rest and exercise ECGs, serial comparisons are performed by using the most recent rest ECG or exercise test and the ECG or test that preceded it. Both ECGs or sets of ECGs are available to the laboratory supervisor and physician at the time of overreading. The standard Minnesota and supplemental codes are used to determine significant change in Q, ST, and T wave items.

Appendix 8
Form A

Consent for Participation in the Research Study Entitled Bypass Angioplasty Revascularization Investigation (BARI), a Randomized Trial Comparing Coronary Bypass Surgery to Coronary Angioplasty

Study Investigators: _____

Office of Human Research: _____

General Description and Purpose of Research

You are invited to participate in a trial sponsored by the National Heart, Lung, and Blood Institute which involves comparison of two treatments for patients with severe myocardial ischemia and coronary artery disease. You have coronary artery disease involving at least two of the major coronary arteries that supply blood to your heart muscle. Your doctors have determined that you are a candidate for either percutaneous transluminal coronary angioplasty (PTCA), a procedure in which a balloon catheter will be passed across the narrowing in your coronary artery to open the narrowing, or coronary artery bypass graft (CABG) surgery, an operation in which the narrowing in the coronary artery will be bypassed by using a vein from your leg or an artery from your chest. One of the potential complications of using the balloon catheter (PTCA) is that the narrowing may return at the site of dilation. This renarrowing has been found in as many as 30% of patients undergoing this procedure at various medical centers. Narrowing generally occurs within the first 6 months, and a second balloon angioplasty procedure usually can be performed. When the narrowing does not recur within the initial 6 months, it is not likely to occur in the subsequent 3–5 years.

I understand that the risks of CABG and PTCA are considered to be similar and that it is possible for death to occur in approximately 1–2% of patients undergoing these procedures. The likelihood of sustaining a heart attack (myocardial infarction) during either of these procedures is approximately 5%. During the study, 2,400 patients will be assigned by chance to either form of therapy during a period of 2 years in 14 hospitals.

If I agree to participate in the randomized clinical research study, one of these two revascularization procedures will be chosen randomly (by chance) as the method to correct the narrowings of my coronary arteries. If I am selected to receive CABG, this procedure will be carried out within 2 weeks after my coronary angiogram was made, at a time that is

mutually agreeable to me and the physicians caring for me.

If I am selected to receive PTCA, I agree to undergo a repeat heart catheterization and to have balloon angioplasty performed on one or more of the narrowings in my coronary arteries. The PTCA procedure is successfully performed in approximately 80% of patients. Should this procedure fail because of complications resulting from the procedure, I understand that it may be necessary to proceed immediately with CABG.

After the treatment, whether it is PTCA or CABG, I will be carefully followed for 5 years and will be seen, or contacted by telephone, throughout my hospital stay, at 4–12 weeks after hospital discharge, at 6 and 12 months after the procedure, and every year thereafter. An exercise test will be performed at 4–14 weeks and at 1, 3, and 5 years after the procedure to determine maximal exercise capacity; this test may provide diagnostic information concerning my state of health. I understand that certain complications may occur during or after an exercise test, such as abnormal blood pressure response, dizziness, irregular heart beat, or, very rarely, a heart attack or death. However, the risk of a complication during exercise testing is infrequent, and the risk is further decreased by the presence of appropriate medical facilities and an experienced medical team.

At 5 years, I will be admitted to the hospital for a repeat coronary angiogram. Coronary angiography defines the presence, location, and extent of coronary disease and associated heart muscle function. The test will assess the results of the PTCA or CABG. Complications from a coronary angiogram are infrequent (less than 1%) and include a blood clot where the catheter is introduced and the possibility of a stroke, heart attack, or death (less than 5%). The risk is no greater than that incurred during the initial coronary angiography.

Risks and Benefits

I understand that there are possible risks to me if I agree to participate in this study. The risks are those of the PTCA procedure, CABG, exercise tests, and coronary angiography as stated above. I understand that my doctor has recommended that I have a revascularization procedure (PTCA or CABG) and that the test procedures described above are routinely used in the assessment and follow-up of patients with coronary artery disease. With participation in this study there is a risk that I may receive the less effective of the treatments being studied. However, the potential benefits include the possibility that I may receive the more effective therapy. The best medical knowledge at this time does not permit a scientific recommendation to me as to which option is better.

Voluntary Consent, Right to Withdraw

If I agree to participate in this study, I understand that my care will in no way be compromised. My participation in this study is voluntary. My refusal to participate will involve no penalty or compromise in my medical care or loss of benefits to which I am otherwise entitled. I may discontinue participation at any time without penalty or loss of the benefits to which I am entitled.

Alternative Treatments

Possible alternatives to my participation in this study include medical therapy with standard approved drug regimens, coronary angioplasty, or coronary bypass surgery. Each of these three options is standard in the management of patients with coronary artery disease.

Investigational Sponsorship and Cost Considerations

The physician investigators listed on this form; research personnel associated with this study at _____; and the National Heart, Lung, and Blood Institute (the sponsor of the study) may inspect and copy my medical records relating to this study. The results of the study will be reported to a coordinating center selected for data analysis. Confidentiality of my medical record will be maintained by the use of a numerical or alphabetical code. In the event of any publications regarding this study, my identity will not be disclosed. I will be informed of any significant new findings developed during the course of the research which may relate to my willingness to continue in the study. These findings may also be published in the medical literature.

The choice of PTCA or CABG may affect the number of days I will be hospitalized. In general, CABG requires a longer hospitalization than PTCA does. However, PTCA may require repeat admissions in the initial year after the procedure because of recurrent narrowings, which may require a second angioplasty procedure. One of the purposes of this study is to determine whether there are differences in the total number of days of hospitalization, over the long term, depending on the initial revascularization procedure chosen. My physician has recommended that I would best be treated by having PTCA or CABG. Therefore, the costs of the PTCA and of the CABG, the direct hospital expenses, and the direct physician fees that are considered clinically indicated for my care will not be paid for by the sponsor of this study. The use of exercise studies with or without a radionuclide is considered routine clinical care in the follow-up of patients with coronary artery disease and will not be paid for by the sponsor. The cost of the coronary angiogram performed 5 years after CABG will be paid for by the sponsor of the study if this test is not required as part of usual care.

(Medical Center Title), in fulfilling its public responsibility, accepts professional liability and responsibility for physical injury if it is caused by negligence of the Center and its employees or agents. No person shall have any authority, orally or in writing, to change the terms of the foregoing. Any questions that I have concerning the research study or my partici-

pation in it, before or after my consent, will be answered by _____.

In the event I believe that I have suffered any injury as a result of participation in the research project, I am to contact _____, who will be able to refer me to an individual who will review the matter with me, identify other resources that may be available to me, and provide information concerning additional inquiries. If I am a woman, I am not pregnant, to the best of my knowledge. I am not participating in any other medical research study. I have read the above statement and have been able to express concerns which have been satisfactorily responded to by the investigator.

I believe I understand the purpose of this study, as well as the potential benefits and risks that are involved. I hereby give my informed and free consent to be a participant in this study.

_____ _____
Patient's Signature Date

_____ _____
Witness's Signature Date

I certify that I have explained to the above individual the nature, purpose, potential benefits, and possible risks associated with participating in this research study. I have answered any questions that have been raised and have witnessed the above signature. These elements of informed consent conform to the assurance given by _____ Department of Health and Human Services, to protect the rights of human subjects. I provided the patient a copy of this signed consent document.

_____
Investigator's Signature Date

Appendix 8
Form B

Patient Consent to Participate in the Bypass Angioplasty Revascularization Investigation Registry

Principal Investigator _____

Approved by Institutional Review Board _____

Date_____

Some patients at the _____ Medical Center undergoing percutaneous transluminal coronary angioplasty (PTCA) or coronary artery bypass graft (CABG) surgery are being enrolled in a Registry of scientific data as part of a national collaborative clinical study comparing the outcome of these procedures. The purpose of this Registry is to provide scientific information about the merits of PTCA compared with CABG, another procedure for restoring the flow of blood to heart muscle. You are invited to participate in this Registry. If you decide to participate, you will be interviewed each year for the next 5 years or more by mail or telephone. Should you move from your present address, a private agency may be used to determine your new home or place of work. These interviews will take approximately one-half hour of your time. The questions asked will be about your symptoms of angina or other heart problems. You will also be asked whether or not you have undergone any hospitalizations because of your heart problems or whether you have undergone a repeat PTCA or CABG or have been hospitalized for treatment of a heart attack. The questions are not considered to have psychological stress. No standard treatment will be required by your treating physicians nor will any standard treatment be withheld from you. You will receive no payment or other compensation for participating in this Registry. There may be no immediate benefit to you, but the combined information from this Registry may help your physician and other physicians in the future to better understand the effects of the treatment you have received on ischemic heart disease and its course.

I understand that, upon my request, a BARI research investigator will answer questions about the study. I may refuse to participate or discontinue participating in the study at any time without penalty or loss of benefits available to me as a patient at this medical center.

I understand that no commitment is made to provide complimentary medical care or compensation for any adverse results of my participation in this study. Further information concerning institutional policies in this regard or information about the conduct of this study or the rights of research subjects may be obtained from _____.

Confidentiality of information concerning participants will be maintained. Names of participants or material identifying participants will not be released without written permission, except as such release is required by law. Medical records related to this study may be made available to the Food and Drug Administration, as provided for in federal regulations.

_____ _____
Date Signature of Participant

_____ _____
Date Signature of BARI Investigator Obtaining Consent

Appendix 9
BARI
List of Participants
Clinical Centers

University of Alabama

Principal Investigator:	William J. Rogers, MD
PTCA Operators:	William A. Baxley, MD
	Larry S. Dean, MD
	Gary S. Roubin, MD
Surgeons:	James K. Kirklin, MD