

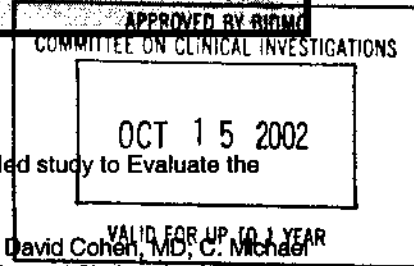
****FOR CCI USE ONLY****

Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations, New Procedures and New Forms of Therapy:

Protocol Administrator: Maura Kennedy Date: 5-30-02

Protocol Number: E-01-0335-FB Expiration Date: 10-15-02

INFORMED CONSENT



Subject's name: _____
Title of Research Protocol: (304386) A Multicenter, Randomized, Double-Blind, Placebo Controlled study to Evaluate the Efficacy and Safety of Ad5FGF-4 in Patients with Stable Angina

Principal Investigator's Name: Roger Laham, MD

Co-Investigators: Joseph Kannam, MD, Joseph P. Carrozza, MD; Lawrence Garcia, MD; David Cohen, MD; C. Michael Gibson, MD; Kalon Ho, MD; Donald Cutlip, MD; Arjuna Mannam, MD; Samuel Shubrooks, MD, David Leeman, MD, and Philip Fitzpatrick, MD Theresa Bishop, RN; Mary Trovato, RN; Paula Rooney, RN;

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INTRODUCTION:

In order to decide whether you wish to participate in this research study, you should understand enough about its risks and benefits to be able to make an informed decision. This process is known as "informed consent."

This consent form describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study. After you understand the study and if you decide to participate, you will be asked to sign this informed consent form. You will receive a copy of the signed informed consent form to keep for your records.

PURPOSE OF STUDY:

The purpose of this study is to determine whether gene therapy using Ad5FGF-4, an investigational procedure, can be safely administered, and whether such therapy can stimulate the growth of new blood vessels in the heart and benefit patients with angina pectoris. Angina pectoris is a temporary pain caused by the narrowing of the blood vessels to the heart. Ad5FGF-4 contains the FGF-4 gene that controls the growth of new blood vessels.

A gene is a piece of DNA that tells a cell how to make proteins. Gene therapy refers to a new form of therapy in which genes are introduced into cells, and the cells then produce the specific protein that the gene directs, in this case a protein known as fibroblast growth factor 4 (FGF-4). The gene is carried into the heart cells by a modified virus. This modified virus (Ad5) has been manufactured from adenovirus, a similar virus that sometimes causes the common cold. The adenovirus has been modified in such a way that it cannot reproduce in your body. The FGF-4 gene has been added to the modified adenovirus. The FGF-4 gene is being used because FGF-4 has been found to stimulate the growth of new blood vessels. In an experimental animal model in pigs that imitates human disease, it was found that therapy with Ad5FGF-4 resulted in production of FGF-4 and improved blood flow to the heart to relieve an experimentally induced condition equivalent to angina pectoris. This study is being funded by a grant from Berlex Laboratories, Inc., to Beth Israel Deaconess Medical Center.

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7SUBJECT SELECTION:

You are being asked to participate in this study because during times of stress, your heart has too little blood flow, resulting in angina pectoris and your angina is disabling and interfering with your quality of life. Your active participation in this study will last about 12 months. Approximately 450 patients will be enrolled in this trial at up to 100 centers throughout the US. Twenty to thirty patients will participate at Beth Israel Deaconess Medical Center.

APPROVED BY BIDMC
COMMITTEE ON CLINICAL INVESTIGATIONS
OCT 15 2002
VALID FOR UP TO 1 YEAR

PROCEDURE:

If you agree to participate in this study, you will undergo the following baseline evaluations and tests. The results of these tests will be used to determine whether you are eligible to enter the study.

Baseline period/baseline evaluations and tests

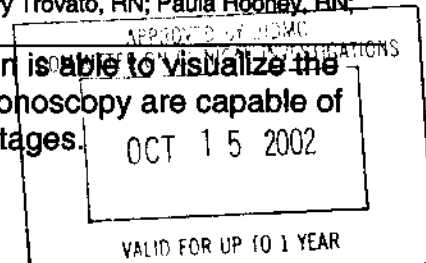
Evaluations and procedures during this period will include the following: A Medical History will be taken and a physical exam (including a rectal exam) will be performed. Females will undergo a pelvic exam, Pap smear and mammogram; however, the Pap smear and mammogram will not be completed if they have been done within the previous 12 months, and there is no suspicion of malignancy. Blood tests (2 tablespoons), urine and stool tests, electrocardiogram (ECG – a measure of your heart's electrical activity), HIV testing (you will sign a separate consent form). It is the policy of BIDMC to record the results of HIV testing in your medical record. A chest x-ray will be performed. You will have an echocardiogram (a test that uses high frequency sound waves to image the heart and surrounding tissues) if you have not had one in the last 12 months. You will have an eye exam by an ophthalmologist. You will be given a diary at this time and asked to keep track of your angina attacks and nitroglycerin consumption for six months after your treatment begins. You will be asked to complete several "Quality of Life" questionnaires, which ask, "How difficult is it to dress yourself, climb a flight of stairs". The questionnaires will take approximately 20 minutes of your time.

You will perform two or three exercise tolerance tests (ETT) on a standard treadmill to see if you can exercise for the required duration before stopping because of chest pain. At the same time you are performing the ETT, an ECG (sensors attached to wires will be attached by sticky pads to several areas on your chest, your arms and your legs) will be taken to confirm your angina. Each ETT must be conducted in the early morning, at least one day apart and no more than 7 days apart. The study staff will discuss with you any food, medication and exercise restrictions.

You may be required to undergo an examination of the inside of your bowel (large intestine) referred to as sigmoidoscopy or colonoscopy. A sigmoidoscopy examines the lower 12 inches or so of the large bowel that extends away from the rectum, which is where colon cancer most commonly occurs. If you have a family history of colon cancer in a first-degree relative (parent or sibling), then colonoscopy, in which the entire length of the colon is examined, will be required. These examinations, conducted by a qualified medical doctor, are routine. A thin flexible tube, about the

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size of your finger, is inserted into your rectum and from there, the physician is able to visualize the progress of the flexible tube into your large bowel. Sigmoidoscopy and colonoscopy are capable of detecting cancer or precancerous abnormalities of the colon at very early stages.



In-Hospital Treatment Period

As part of the protocol you will come to the hospital and undergo cardiac catheterization and coronary angiography. You will be asked to sign a separate consent form for these procedures. Cardiac catheterization is a procedure that allows access to your heart through standard methods through the femoral artery in your groin. Once a guide catheter, a long tube used to allow access to a blood vessel from outside the body, is in place in your heart, a dye will be injected into the catheter, so that the blood vessels of your heart can be seen very clearly by using a scanning machine. The results of your screening tests and angiography will be reviewed by the study doctor, and if you qualify for participation in this study, you will be randomized (like a flip of a coin) to receive either one of two doses of Ad5FGF-4 or placebo (looks like the study drug, but contains no active medication). You will have a two in three chance of receiving the Ad5FGF-4, and a one in three chance of receiving placebo. Since this is a double-blind study, neither you nor the study doctor or study staff will know which treatment you receive. Ad5FGF-4 or placebo will be injected by catheter into the coronary arteries supplying blood to your heart.

If the narrowing in your coronary arteries is such that another, more urgent treatment is necessary, you will not receive the study medication. Your doctor will discuss with you the best form of treatment for your condition.

You will be observed in the hospital overnight and have a blood test (2 tablespoons) the following morning before being discharged from the hospital. Following hospital discharge, you will return to the clinic at the following specified intervals.

Two weeks after treatment, you will return to the hospital to be examined, have blood (2 tablespoons) and urine tests, and an ECG. You will also be asked to submit your diary, and you will be given a new one.

Four weeks after treatment, you will again return to the hospital to be examined, have blood (2 tablespoons) and urine tests, an ECG, and also have a repeat exercise treadmill test. You will be asked to complete several "Quality of Life" questionnaires. The questionnaires will take approximately 20 minutes of your time. You will submit your diary and be given a new one.

Eight weeks after treatment, you will return to the hospital to be examined, have blood (2 tablespoons) and urine tests, and an ECG. You will submit your diary and be given a new one.

Twelve weeks after treatment, you will return to the hospital to be examined, have blood (2 tablespoons) and urine tests, an ECG and also have a repeat exercise treadmill test. You will be

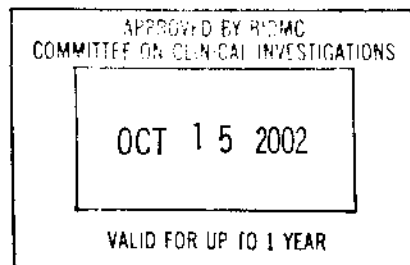
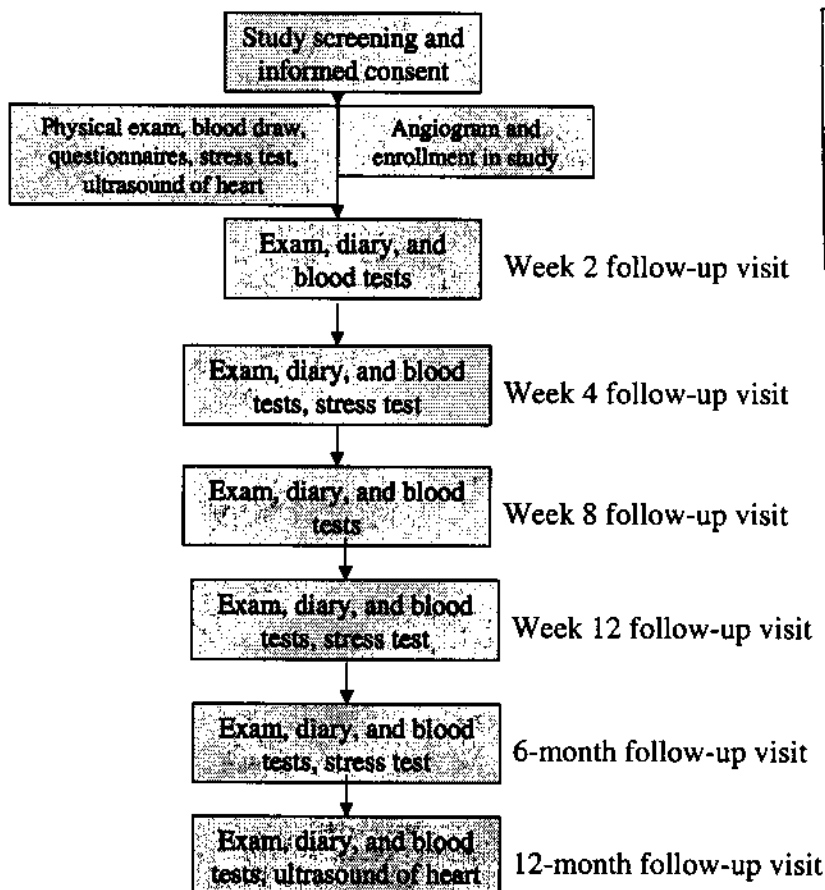
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asked to complete several "Quality of Life" questionnaires. The questionnaires will take approximately 20 minutes of your time. You will submit your diary and be given a new one.

Six months after treatment, you will return to the hospital to be examined, have blood (2 tablespoons) & urine tests, an ECG, a repeat exercise treadmill test and an eye exam. You will be asked to complete several "Quality of Life" questionnaires. The questionnaires will take approximately 20 minutes of your time. You will be asked to submit your diary.

Twelve months after treatment, you will return to the hospital to be examined, have blood (2 tablespoons) & urine tests, an ECG, and a chest X-ray. You will be asked to complete a "Quality of Life" questionnaire. The questionnaire will take approximately 5 minutes of your time.

Every six months thereafter, for a period of approximately 18-24 months you will be contacted by telephone and asked several basic questions concerning your health status. Our research nurse will continue to call you for health status updates for the duration of the entire study (up to 5 years).



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SPECIAL CONSIDERATIONS

Because gene therapy is new and long-term effects are not known, there is a need for careful evaluation. It is very important that you return for all visits. We ask that you notify us if you change your address.

RISKS AND DISCOMFORTS:

This study may involve the following risks or discomforts:

Risks associated with using an adenovirus for gene therapy in the human heart are unknown. Potential risks include:

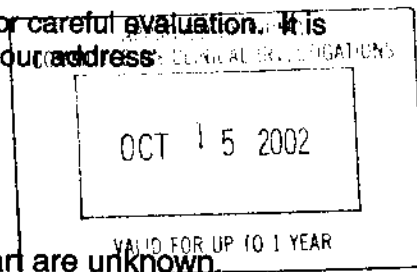
The adenovirus being used is modified so that it cannot multiply and cause infection. However, it is remotely possible that during the study the virus will acquire the ability to cause infection. It is known that the adenovirus from which this modified adenovirus was derived is typically associated with the common cold. Therefore, serious complications are unlikely.

You could have a mild allergic reaction. It is also possible, although unlikely, that your immune system, reacting to the virus, could cause inflammation to your heart. Such inflammation may lead to irregular heart beat, speeding up of arteriosclerosis (abnormal thickening and hardening of the arterial wall), or a reduction in the heart's pump function. Previous animal studies and data collected so far from two human studies have failed to show any evidence of heart inflammation from the study product.

There has been a well-publicized gene therapy study at the University of Pennsylvania (Upenn) in which a young study subject died. Although this was a gene therapy study using an adenoviral vector, there are a few major differences between our study and the study at U Penn:¹

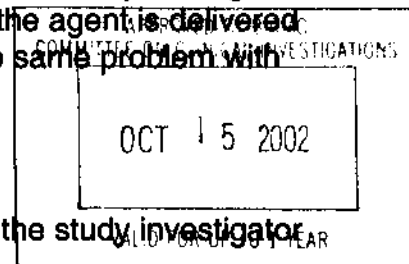
- The study at UPenn treated study participants with liver disease. Our study excludes subjects with hepatic (liver) disease.

- ¹ This study is using a first generation adenoviral vector (E1 A/B deleted Adenovirus serotype 5). At U. Penn, second generation adenoviral vectors were used (either E1/E3 deleted or E1/E4 deleted).
- The toxicity of the vector (the agent) is dose dependent and time limited. The dose given to the subject who died in the U Penn study was at least 3000 times (approximately 3800 times) greater than the highest dose to be used in the this study.
- As adenoviruses are taken up by the liver, the route of administration is very significant with regard to adenovirus induced liver problems. In the UPenn study, the gene product was injected into a branch of the hepatic (liver) artery. In the current study the product is administered intracoronary (in the coronary artery), using selective cardiac infusion catheters (directly in the artery). Data from the Phase I study showed a high first pass uptake in the myocardium with a median uptake of 87%. Of note, any spillage from the intracoronary administration goes through the pulmonary capillary bed (lung) before becoming systemic and then gets to the liver after getting diluted by the systemic blood. Also significant is the fact that subjects with hepatic (liver) disease were being studied in the UPenn trial, whereas, the current study excludes subjects with hepatic (liver) disease.
- One more difference is the transgene (gene product in the vector).



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- In the study at UPenn, the agent was delivered directly into the liver. In our study, the agent will be delivered into the coronary artery. Because of the way in which the agent is delivered (directly into the artery using cardiac infusion catheters), there is not the same problem with the agent going to the liver.
- Our study uses a different model of the agent.



*If you have any further questions regarding the UPenn study, you should ask the study investigator to discuss this with you.

Potential risks to a fetus are unknown, so women of childbearing potential are not being enrolled in this trial. If you are a woman and could become pregnant, do not enroll in this trial. If you are a man, you must agree to abstain from intercourse or use a condom for 8 weeks following treatment.

Ad5FGF-4 causes the production of a growth factor, FGF-4. It is possible that the growth factor could circulate in your blood and have effects at distant sites. Therefore, growth of blood vessels at sites outside the heart could occur. For example, if this growth is on the skin, it could result in the formation of small capillaries (hemangiomas). In the eye, abnormal blood vessel growth could interfere with vision. An ophthalmologist will check your vision and evidence for these vascular growths in the eye. We do not expect this vascular growth to occur in any other place than the heart, based on animal experiments and data from two previous human studies.

Some patients will receive placebo. You and your doctor will not know whether you receive Ad5FGF-4 or placebo. This study will involve two doses of Ad5FGF-4, a lower dose and a higher dose. Since each patient will only receive one dose of the study product, some patients will receive the low dose while others will receive the higher dose. While animal studies indicated that the beneficial effects occurred at doses that did not have any toxic reaction, there is no absolute assurance that the same will be true in patients. The doses used in animal studies were 100-1000 times greater.

Animal studies have not shown any evidence that adenovirus gene therapy can alter the DNA in your reproductive cells and have not shown any evidence of cancer production. While such side effects are therefore very unlikely, they could occur.

There is a risk that you may experience temporary, mild to moderate inflammation of your liver as a result of your receiving Ad5FGF-4. Based on prior gene therapy research studies conducted by Berlex Laboratories, it is expected that any inflammation, if it occurs, will not result in any long term ill effects.

While the growth factor FGF-4 does not cause cancer, it could stimulate the growth of already existing malignant tumors. While your doctor has examined you and performed tests to detect

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tumors, it is possible that an occult (not detected by clinical methods) tumor could be stimulated to grow faster by FGF-4.

COMMITTEE ON CLINICAL INVESTIGATIONS
OCT 5 2002

In a previous gene therapy research study sponsored by Berlex Laboratories using Ad5FGF-4, we are aware of two patients who were diagnosed with malignant tumors after receiving the gene study product. One patient with a strong family history of colon cancer was diagnosed with cancer (adenocarcinoma) of the large intestine approximately 8 months after receiving that gene study product. Upon further examination, the patient was found to have colon cancer spread to the lungs and liver and a separate kidney cancer. The patient subsequently died. It is considered unlikely that the tumor was caused by the Ad5FGF-4 but it is possible that it may have played a role in its growth. A second patient was found to have a primary brain tumor, which was detected approximately 3 months after receiving that study product. The patient subsequently died. It was also considered unlikely that the tumor was caused by the Ad5FGF-4, but it is possible that it may have played a role in its progression.

RISKS ASSOCIATED WITH OTHER PROCEDURES THAT ARE PART OF THIS STUDY

Treadmill exercise testing carries a slight risk of causing heart rhythm abnormalities, occurring in less than 1 in 10,000 patients. Should such arrhythmias occur, proper drugs and equipment are readily available for treatment.

Risks associated with sigmoidoscopy: There is minor discomfort associated with the examination. Because the instruments blow air into the rectum and the colon, you might feel pressure and slight cramping in your lower abdomen. You will feel better afterwards as the air leaves your colon. There is also a minor risk of bleeding. Major medical complications can result from the examination, such as puncture of the colon. However, such complications are very rare. All of these possible risks and discomforts will be described to you during the consent process for this procedure.

Risks associated with cardiac catheterization: The cardiac catheterization procedure involves insertion of a catheter in both an artery and a vein, passage of those catheters into the heart, injection of contrast material for x-ray, injection of the test product into the artery supplying the heart at the treatment phase, withdrawal of the cardiac catheters and continued hospitalization and observation overnight. You will be asked to sign separate consent forms for cardiac catheterization at the time of the cardiac catheterization. In general, risks associated with the catheterization procedure include damage to the artery or vein which might require surgical repair, heart rhythm abnormality which might require treatment in the catheterization laboratory, damage to the arteries within the heart which might require emergency cardiac surgery and/or other complications including death. While these complications are relatively rare, they could occur. The risk of death from cardiac catheterization is less than 1 per 1,000 patients.

Risks associated with x-rays used in the angiogram procedure: X-rays are used in the routine angiogram procedure for the cardiologist to view placement of the catheter in your coronary artery. In addition to this routine study, this research study involves additional exposure to radiation from two chest x-rays, from a mammogram (required if you are female and have not had one in the past 12

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months) and from x-rays taken after the angiogram in conjunction with the Ad5FGF-4 infusion. The amount of radiation exposure you will receive from these additional procedures is equivalent to a uniform whole body exposure of 1.2 rem. This is equivalent to one-quarter of the annual radiation exposure limit allowed for a radiation worker (such as the cardiologist performing your angiograms). The risk from radiation exposure of this magnitude is considered to be comparable to other everyday risks.

ADDITIONAL RISKS

This study involves the investigational agent Ad5FGF-4 with which we have only limited human experience. While animal tests suggest that this will be safe and effective, and no evidence of serious toxicity was found at the doses being used, it is possible that additional risks and/or discomforts which are presently unknown and unforeseen could occur.

The risks and discomforts of blood drawing from a vein include the possibility of pain or bruising at the site of the blood draw, occasional feelings of lightheadedness, and, rarely, infection at the site of the blood draw.

BENEFITS:

It is not known at the present time if Ad5FGF-4 will relieve your angina pectoris. The knowledge gained from your participation in this research study may be of benefit to other patients in the future.

ALTERNATIVE PROCEDURES:

At the time of catheterization, you may be found to have treatment options for your angina pectoris:

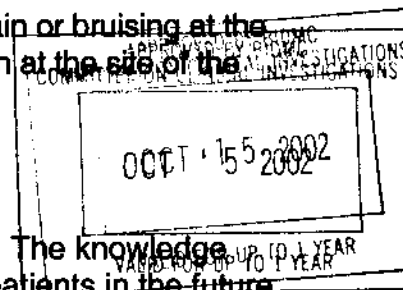
You may continue on your current medical therapy.

Depending on the extent and location of narrowing in your coronary arteries, you could undergo coronary angioplasty. Your doctor can discuss this possibility with you. Coronary angioplasty is effective in relieving angina pectoris.

Depending on the location and severity of the narrowing in your coronary arteries, you could undergo coronary artery bypass graft surgery to relieve your angina pectoris. Your doctor can discuss this possibility with you. Coronary bypass surgery is effective in relieving angina pectoris.

PARTICIPATION AND WITHDRAWAL:

Participation in this study is voluntary. You have the right to refuse to take part in this study. If you choose to participate, you have the right to withdraw at any time. Refusal to participate in the study will involve no penalty or loss of benefits to which you are entitled, and will not affect your present or future medical care at the Beth Israel Deaconess Medical Center. If a significant new finding develops during the study, which may influence your willingness to participate, you will be informed as soon as possible.

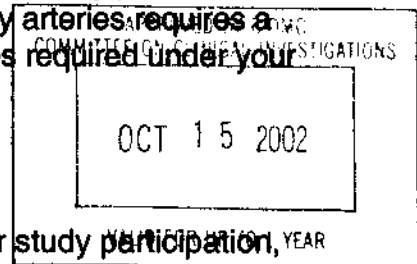


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You may also be withdrawn from this study without your permission if, in the opinion of the investigators or your physician, further participation will be detrimental to your health. In addition, the sponsor may stop the study at any time.

COST/PAYMENT:

You will not be charged for any doctor's visits, lab work, tests or procedures that are needed only for this study. This includes all laboratory tests, coronary angiography, echocardiograms, chest x-rays, and ECGs. You or your insurance company will be responsible for payment of all medical care that would normally be part of the treatment of your illness ("Standard of Care"). Mammogram and Pap smear (females) and sigmoidoscopy will be charged to your insurance if the study doctor determines it is part of your normal medical care. Cardiac catheterization and coronary angiography are study procedures and will not be billed to your insurance provider unless the narrowing in your coronary arteries requires a more urgent therapy. You will be responsible for any co-payments or deductibles required under your insurance for these Standard of Care tests and procedures.



INJURY:

If you become injured during this study and your injury is a direct result of your study participation, medical treatment will be provided at BIDMC. The costs of reasonable treatment will be paid by the sponsor, Berlex Laboratories, Inc., to the extent it is not covered by your health insurance. You will be responsible for paying deductibles or co-payments as required by your insurance. The sponsor will not be responsible for any other treatment costs for your regular medical care. No further compensation for research-related injury is available.

CONFIDENTIALITY:

Information derived from this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA), state and federal regulatory agencies, the drug manufacturer (Berlex Laboratories, Inc.), and the Committee on Clinical Investigations of the Beth Israel Deaconess Medical Center, with protection of confidentiality so far as permitted by applicable law. Information resulting from this study and from your medical record may be used for research purposes and may be published; however you will not be identified by name in such publications.

CONTACT INFORMATION:

If you have any questions about the research or experience any problems, you should contact Roger Laham, MD at (617) 667-4138.

Date Submitted to the Committee:
Revisions

September 24, 2001
March 31th, 2002

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CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page(s) of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Chairman of the Medical Center's Committee on Clinical Investigations (CCI) at (617) 667-0469.

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that I may be contacted by the Beth Israel Deaconess Medical Center's Committee on Clinical Investigations during or after my participation in this study as part of its efforts to monitor the experience of subjects in clinical investigations.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

WITNESS

STUDY SUBJECT

DATE

PARENT OR LEGAL GUARDIAN

DATE
(If subject is a minor, or subject is unable to give consent)

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

PRINT INVESTIGATOR'S NAME

SIGNATURE OF INVESTIGATOR (or designee)

DATE

