INFORMED CONSENT TO PARTICIPATE IN ABIOCOR™ IMPLANTABLE REPLACEMENT HEART INITIAL CLINICAL TRIAL

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<Institution name, address, and telephone number>

Sponsor:
ABIOMED, Inc.
Cherry Hill Drive
Danvers, MA 01923

Patient Consent Form

The Use of the AbioCor™ Implantable Replacement Heart in Patients with End-Stage Heart Failure

<Principal Investigators' names, addresses, and telephone numbers>

Introduction
The Department of Surgery, *INSTITUTION NAME*, is involved in an FDA-approved clinical trial. A clinical trial is a research study. The purpose of this study is to determine whether the implantation of an experimental device called the AbioCor™ Implantable Replacement Heart is an effective therapy for human patients with life-threatening end-stage heart failure. I understand that I am being considered for participation in this research study. Up to 15 patients will be involved in this initial study.

This form is intended to assist me in coming to an informed decision about whether to participate in the study.

Purpose of the Study
This study will determine the safety and potential effectiveness of the AbioCor Implantable Replacement Heart for patients, such as myself, who have life-threatening end-stage heart failure and have no other available options that have a fair chance of extending my life.

Why I am Being Considered as a Candidate for the Study
I understand that I have a heart condition that is considered end-stage and that patients with a condition such as mine typically die within a relatively short period of time. I also understand that, in the judgment of my physicians, there are no currently available medical or surgical alternatives that would have a reasonable chance of extending my life.

Other Factors Affecting My Eligibility for the Study
I understand that I may not participate in this study if I am currently in another clinical trial or research study of any kind. I agree that I will tell my doctor if I am in any other such trial or study.

[*Applicable to female patients only:*] I understand and agree that if I am a woman of childbearing age and could be or become pregnant, I will undergo a pregnancy test prior to enrollment in the study. I understand that a confirmed positive pregnancy test will exclude me from the study.

This Study Is Experimental
I understand that implantation of the AbioCor Implantable Replacement Heart is an experimental surgery which is undergoing initial evaluation in patients such as myself. I understand that if I am implanted with an AbioCor Implantable Replacement Heart, I may be the very first human patient, or one of the first human patients, to undergo such surgery.

This Study Involves Complex Surgery and Permanent Replacement of the Natural Heart
I understand that the implantation of the AbioCor Implantable Replacement Heart will involve the removal of the two main pumping chambers of my heart (right and left ventricles). The pumping unit of the AbioCor device is placed in my chest in the space where my heart's ventricles were and is intended to take over the pumping function of the ventricles. I understand that it will never be possible to put my natural heart back in my chest.

I understand that the implantation of the AbioCor Implantable Replacement Heart is major open heart surgery that is done under general anesthesia. To perform the surgery, an incision is made in the middle of my chest over my sternum (breastbone), extending into my upper abdomen. It will be necessary to use the heart-lung machine, as in other

types of heart surgery, to support my circulation during the implantation of the AbioCor Implantable Replacement Heart.

I understand that the implantation of the AbioCor Implantable Replacement Heart also requires placement inside my body of an internal controller, an internal battery and a transcutaneous energy transmission (TET) coil. The TET coil is designed to allow for transfer of energy across the skin to power the heart. The internal battery can power the AbioCor device for brief periods of time. The internal controller helps regulate the function of the AbioCor device.

System Testing

In preparation for this clinical trial, two types of tests have been conducted on the AbioCor device to evaluate its safety and reliability. The reliability and durability of the system have been bench-tested in the manufacturer's laboratory. Certain biologic interactions have been evaluated in animals in which the native heart ventricles were replaced by the AbioCor device.

Ongoing laboratory ("bench") testing is being conducted with [*] systems of the current design. As of June 2001, [the average run time exceeded one year, with a range of *]. I understand that I have the right to ask for updates of this information.

Animal testing for 30 days has been conducted to reveal the biological compatibility of the system as an implant. [*] animal studies with the AbioCor achieved the intended 30 days of implantation. Two major safety issues are tested in animals, one being the degree of thromboembolic complications and the other being the level of heat generation by the system. Although animal results cannot be directly translated to what may occur in human, no major thromboembolic complications were encountered in these 14 studies. There is no guarantee that problems of thromboembolic nature would not occur in human implants. Heat generation and its effect on the surrounding tissue has not caused tissue damage in our animal studies unless the AbioCor is running at its upper limits continuously.

I understand that the performance of the AbioCor may differ between bench and animal testing and when implanted in a human, that performance may vary from device to device and that there can be no guarantee that the device will perform effectively in me for any minimum period of time.

Implantation with the AbioCor Device Involves Potential Risks

I understand that significant risks are associated with implantation of the AbioCor Implantable Replacement Heart. I understand that a complete listing of all risks would not be practical. I understand that a list of the risks considered to be most significant and the range of possible adverse effects have been provided to me.

I understand that the risks to me can be loosely classified into two general categories: first, risks related to the performance and the implantation of the AbioCor device; and second, risks if I do not observe the instructions, warnings or limitations of activity that are communicated to me.

The major risks in this study may involve stroke leading to brain and/or organ damage, loss of mental function, and death.

A. Risks Related to Operation and Implantation of the AbioCor Device

1. Surgery. The implantation of the AbioCor will involve use of the heart-lung machine, general anesthesia, a variety of medications, opening of sections of my body, the removal of the majority of my heart, and the implantation of the AbioCor. This procedure is experimental and may have unforeseen complications.

2. Device Failure. Once my natural heart is removed and I am taken off the heart-lung machine, my life will depend on the performance of the AbioCor device. This experimental device is subject to failure at any time from a variety of possible causes. Device failure could be sudden and catastrophic. If this happens, there is no assurance that medical intervention will be immediately available or that, if available, it will be capable of saving my life.

   The AbioCor Implantable Replacement Heart is a complex system, and failure of the device could result from a wide variety of causes. For example, a valve might stick. Or the AbioCor pump might develop a leak. A leak could allow blood to enter the inside of the pump, damaging the pump mechanism, or might allow silicone hydraulic fluid to enter my body or my bloodstream. Electronic components, batteries or alarms in the system may fail.

3. Blood Clotting and Thromboembolism. Blood clots and thromboembolism may occur within the pump and may interfere with the functioning of the pump and its valves. If such blood clots travel to other parts of the body, they could become lodged in blood vessels and impair blood circulation to vital organs. This could cause me to have a stroke.

   I understand that anticoagulation medications (blood thinners) will be used to minimize the risk of blood clotting. These medications themselves involve certain risks, by making it more difficult to control bleeding. I understand that I must rely on the judgment of my physicians to find a proper balance in the use of such medications.

4. Bleeding. In any surgical procedure, there may be unusual and excessive bleeding from both surgical causes (cut vessels or incomplete sewing together of vessels) and coagulation disorders (the blood does not clot normally). In an implantation, it is also necessary to attach the natural blood vessels, such as veins and arteries, to the artificial device being implanted. The point at which a blood vessel is attached to the artificial device can be weak or vulnerable, and if the attachment fails, uncontrolled internal bleeding can occur.

5. Infections. Localized infections can occur, as well as infections that spread through my body. These may include infections of the blood stream

(bacteremia or septicemia), infection of the chest cavity (mediastinitis), lung infections (pneumonia or lung abscess), and "pocket" infection or abscess in the area of the implanted AbioCor controller, battery pack, TET coil, cables, or the pump. Infection can compromise my quality of life and lead to other medical complications.

6. Injury to Soft Tissue. The AbioCor system includes a pair of transcutaneous energy transmission (TET) coils. One is on the outside of my body and one is implanted under the skin. Together, these recharge the AbioCor's internal implanted battery pack and provide the energy for the AbioCor to pump blood through my body. The heat produced by the AbioCor's energy-transmission coil might injure the tissues that surround it. This may cause liquid or white blood cells to accumulate leading to swelling. Because of these accumulations, the TET could deliver less power to the AbioCor. It might then become necessary to replace the implanted coil, relocating it to a different part of my body. It could also become necessary to use a special power cable that would go through the skin. This could lead to a significant risk of infection where the cable passes through the skin.

   It is also possible that implanted components of the AbioCor could push on or injure my esophagus (the tube through which food one swallows goes to the stomach), or on a section of my bowels.

7. Discomfort or Pain. Even after a successful recovery from the pain associated with cardiovascular surgery, I may experience discomfort or pain due to the fact that parts of the AbioCor system (battery, controller, cables) have been implanted in the muscle layers of my abdomen, or, in the case of the pump, in my thoracic cavity. This may occur at any time, but especially with certain movements such as bending over. When eating, I may feel "full" earlier than usual, or my appetite may be affected.

8. Impaired Breathing. The nerves that enable the diaphragm muscle to move air into my lungs could be injured during the operation. If this happens, it may be necessary to support my breathing permanently with a mechanical ventilator (respirator).

9. Kidney Failure. Partial or total loss of the kidneys' ability to make urine may occur. Sometimes kidney failure is reversible and function is recovered over a period of days to weeks. Sometimes partial loss of kidney function can be managed through the use of medications or temporary dialysis (artificial kidney). Permanent and complete loss of kidney function may result in the need to consider dialysis or kidney transplantation, an option which may not be open to someone in my condition.

10. Decreased Red Blood Cells (anemia). Some patients who have received other heart pumps for more than a few months have developed low blood cell counts (anemia). People with anemia may feel tired or short of breath. It is

conceivable that low blood counts might occur with the AbioCor Implantable Replacement Heart. If they do, my treatment may require blood transfusions or other therapies such as medications to correct anemia.

11. Liver Failure. Partial or total loss of the liver's ability to perform its functions in your body's metabolism may occur. Sometimes liver failure is reversible and function is recovered over a period of days to weeks. Sometimes partial loss of liver function can be managed through the use of medications or temporary filtration of the blood. Permanent or complete loss of liver function may result in the need to consider liver transplantation, which may not be an option to someone in my condition.

12. Closing the Chest. Every effort will be made ahead of time to determine that the AbioCor will fit into my body, by using x-ray images and other measurements. Despite these efforts, it might be impossible to bring my breast bone back together normally. If this happens, a piece of plastic may be used to allow my chest cavity to be closed and complete the surgery.

13. Difficulty of Replacing Failed or Failing Components. If an implanted component of the AbioCor device fails, replacement of such a component is not easy, and would require additional surgery. I understand that it may not be possible to deal with a component failure promptly enough to prevent death or severe and permanent physiological and neurological damage. It cannot be known in advance whether it will be impossible to replace an AbioCor component, due to scar tissue that may have formed or other complicating factors that may arise. I understand that I may be unable to receive a replacement AbioCor pump or a donor heart transplant. As a result, my life expectancy may be limited by the durability of the AbioCor.

14. Need for Periodic Surgical Replacement of Components. I also understand that, even if my implantation is successful, some parts of the AbioCor system will need periodic replacement and that future surgeries would be required. For example, the battery pack implanted under the skin is intended to last for about one year under limited use conditions. Surgery is required to have a new battery pack implanted. If this becomes necessary, I will review information related to the surgery. Then I will decide whether to sign a separate consent form. If I decline such subsequent surgery, I will jeopardize the continued operation of the AbioCor. It is important, though, that before I decide about participating in this study I am aware that continuing on AbioCor support would involve more surgeries later on.

B. Risks Related to My Own Conduct

1. Attention to Charging Batteries and Obeying Warnings. The AbioCor device is powered by rechargeable batteries. There will be a battery pack on the inside of my body and a battery pack on the outside of my body. The AbioCor automatically provides messages and warnings about the amount of power

remaining in the batteries and about other system functions. For the AbioCor to continue to pump blood to keep me alive, it is essential that I and those who are taking care of me promptly respond to these messages and warnings. The batteries must not become completely discharged. If the batteries are allowed to run out of power or if messages requiring action are ignored, I understand that I will die.

2. Continuous Running of System at Upper Limits. The AbioCor produces heat, the levels of which increase based on the level of my physical exertion. I understand that if the AbioCor is continually run at its upper limits it may produce levels of heat that may cause damage to surrounding tissue. I understand that continually running the AbioCor at its upper limits is not recommended for the AbioCor system or for me.

3. Bathing and Swimming. I understand that the way in which the AbioCor adjusts its output to my body's needs and level of exertion relies on accurate pressure measurements that it performs automatically. Submerging my body under water may cause the pressure measurements to be inaccurate and the AbioCor might malfunction. This could lead to serious injury or death. Bathing is allowed but swimming is not.

4. Limitations on Travel. If I receive an AbioCor device implant, it is possible that at some point I will be able to leave the hospital after I have healed from my surgery. For safety, I will be required to remain within limited travel time from the hospital. There will be special precautions on air travel.

5. Limitations on Employment. Although the AbioCor device is designed to enable implant recipients, after recovery, to perform routine daily activities including light work, it is possible that I may not be able to return to regular employment if I wish to do so.

6. Limitations on Pregnancy and Childbearing. I understand that no testing has been performed to evaluate the functioning of implanted AbioCor components under the conditions of pregnancy, with regard to blood flow to the tissues in the mother's body or with regard to the blood flow to a fetus. If I am a pre-menopausal woman and I receive the AbioCor device, I should take appropriate measures, even after a successful implantation, to insure through a medically acceptable form of contraception that I do not become pregnant while on support with the AbioCor device. If I find or suspect that I am pregnant, I will immediately inform INVESTIGATOR NAME. Although I would continue to be seen by my surgeon and cardiologist, I understand that I may have to face a decision whether to terminate the pregnancy.

There May Be Unknown or Unforeseeable Risks Associated with Implantation

I understand that because this is a new and experimental surgical operation, complications could occur which were previously unknown or currently unforeseeable.

These complications could result in death, or in permanent physical or mental disability, including the possibility of stroke, paralysis and loss of brain function.

I acknowledge that no guarantees have been made to me concerning the results of my surgery or the results of the implantation of the AbioCor Implantable Replacement Heart and that there may be other risks that are presently unknown. I understand that the favorable or unfavorable outcome in other clinical trial participants with the AbioCor is no indication that I will encounter the same outcome.

Potential Benefits

I understand that there may be benefits for me in undergoing implantation with the AbioCor Implantable Replacement Heart. I understand that because this treatment is highly experimental, such potential benefits are uncertain and have not been proven to exist. I also understand that, if any benefits result, they may be of very limited duration.

I have been told that the following benefits are hoped for, but are neither certain nor predictable:

1. The AbioCor Implantable Replacement Heart may increase my life expectancy significantly compared to conventional non-experimental medical therapy. AbioCor implantation may prolong the life of a patient such as myself whose natural heart has irreversibly failed (both ventricles), who has not responded to available medicines to make the heart contract more forcefully, who otherwise would die unless the natural heart is promptly replaced, and who is unable to receive a heart transplant at the time that the AbioCor is implanted.

2. The AbioCor Implantable Replacement Heart may offer a lower risk of infection compared to blood pumping devices that are outside the body or that have connections that go through the surface of the skin.

3. My quality of life during the time I am supported by the AbioCor Implantable Replacement Heart may be significantly better than the quality of life I would enjoy were I to receive conventional medical therapy.

I understand that standard therapy for people with severe heart failure is continued treatment with medications or consideration for heart transplantation. I understand that currently I am not a candidate for heart transplantation. I also understand that because my heart failure is so advanced, continued treatment with medical therapy is associated with a high risk of death in the relatively near future.

Agreeing to Participate in the Study Does Not Mean That I Will Necessarily Receive an Implant

I understand that signing this consent form does not give me any right to receive an implant with the AbioCor device, and that the ultimate decision to perform or not to perform an implant depends on other factors. I understand that this decision may be

affected by medical, regulatory, or device-related and anatomic considerations, such as potential misfit of the device in my body.

I may be in the Study for the Remainder of My Life

I understand that I will be enrolled with this study as long as I have the AbioCor Implantable Replacement Heart. This means that, if my implant is successful, I will likely be in the study for the remainder of my life. It is possible that after two months of implantation with the AbioCor device my medical condition may have changed sufficiently so that I may be eligible for transplantation. The investigator may offer me the choice of transplantation of a human donor heart, if such a heart is available and it is possible and appropriate to perform such surgery at that time. If cardiac transplantation is performed, I will remain in the study for an additional month after the transplant primarily for data monitoring purposes.

I understand that if I withdraw from the study or fail to see my doctor for monitoring and assessment of the AbioCor Implantable Replacement Heart, I could die.

I understand that I will have to undergo repeat blood tests, questionnaires about quality of life, and standard exercise tests at regular intervals after my surgery. I understand that an exercise test is one measure that is used to assess my overall health and heart function.

I understand that, because the implantation of the AbioCor Implantable Replacement Heart is a major heart surgery, I will be an inpatient at *INSTITUTION NAME* for this treatment and that I could remain in the hospital for a prolonged period of time or possibly for the rest of my life. During my treatment, if I recover and am well enough, I may be able to go out of the hospital "on pass" for short periods of time. If I am well enough after two months of recovery from surgery, it is possible that I may be moved out of the hospital to a place that is more like home, such as the *HALF-WAY HOUSE FACILITY NAME*. There can be no assurance that this will happen.

Participating in the Study May Result in Loss of Privacy

I understand that by participating in this study, my family and I may become targets of media attention, which could result in a significant loss of privacy. I understand that the hospital has offered counsel regarding methods for mitigating loss of privacy, such as making home telephone numbers unlisted, but that considerable loss of privacy is still to be expected.

My Medical Information Will Be Kept Confidential, With Certain Limited Exceptions

I understand that, if I decide to participate in this study, all medical information relating to my participation will be kept confidential at *INSTITUTION NAME*. However, I agree that such information may be provided as necessary or upon request to the *INSTITUTION NAME* Institutional Review Board, to members of the study staff, to the clinical trial sponsor, ABIOMED, Inc., which manufactures the AbioCor device, and/or to regulatory authorities, including the FDA. I hereby give my permission for the release of my records and/or medical bill(s) to these groups. I also understand and agree that

information about my treatment or condition may be presented or published provided that my identity is not disclosed in connection with such information dissemination.

I understand that, subject to the permissions given herein, my anonymity and the confidentiality of my medical information will be protected to the extent required by law and professional standards of confidentiality, but recognize that absolute confidentiality cannot be guaranteed.

Responsibility for Costs Relating to Participation in the Study
[* .] I will not be personally responsible for such costs in the event that third party payment is not obtained.

Desirability of Health Care Proxy, "Living Will," and/or a Durable Power of Attorney; Right to Consult Attorney
I have been advised that, because medical circumstances could arise that would make it impossible or impractical for me to be consulted about medical decisions affecting me, or to conduct my own affairs, it might be useful to me prior to implantation, to have executed (i) a power of attorney or health care proxy regarding my medical management, (ii) a so-called "living will," and/or (iii) a durable power of attorney with respect to conduct of my financial and personal affairs.

Consent to Explantation in the Event of Death
It is important to the scientific purpose of this study to understand the cause or causes of death. For that reason, I hereby agree and consent that, if I should die after being implanted with the AbioCor device, any implanted component of the device may be explanted, and may be returned to its manufacturer for analysis and study.

My Rights to Obtain Other Information; Contact Persons
If I have any further questions, I may call Dr. _____, or one of their assistants at the telephone numbers listed above. I understand that I may also seek advice from any non-hospital related person that I may choose. I may also contact the hospital's Institutional Review Board at *TELEPHONE NUMBER* to discuss in confidence any questions about my rights as a research subject with a member of that committee. I understand that the Institutional Review Board, which is an independent committee composed of faculty and staff at _____ as well as lay members of the community not connected with the institution, has reviewed this study.

If I or My Family Have Complaints
I understand that if I or my family feel I have been injured or harmed in any way by participation in this study, we should contact my physician or the chairperson of the hospital's Institutional Review Board, *IRB CHAIRPERSON NAME* at *TELEPHONE NUMBER*.

I understand that *INSTITUTION NAME* does not voluntarily provide compensation to a person who is injured while participating in a research study (such as lost wages, inconvenience of discomfort). This does not waive my rights in the event of negligence.

I understand that *PRINCIPAL INVESTIGATOR NAME* and/or his associates are available and willing to answer any questions I may have about the study and about my rights, and I may contact *PRINCIPAL INVESTIGATOR NAME* in the event of a study-related injury. The phone number is *TELEPHONE NUMBER*.

Consent and Voluntary Participation *[patient should be asked separately and orally whether patient subscribes to these statements]*

I fully understand that participation in this experimental study is voluntary and that I may decline to participate. I understand that not participating in this research study will not influence the quality or choice of my subsequent medical treatment.

I understand that, even if I sign this consent and am selected for implantation with the AbioCor device, I am free at any time to decline to proceed with the implantation, without any penalty or loss of benefits to which I am otherwise entitled.

I also understand that I may discontinue participation in the study at any point without incurring any penalty or losing any benefits to which I may otherwise be entitled. However, once I have been implanted with the AbioCor, a decision to withdraw from the study may jeopardize my survival.

I am over eighteen years of age and am of sound mind.

I have been given the opportunity to ask additional questions. I have had any such questions answered to my satisfaction and in a language that I understood.

I understand that I will be informed of any new findings that develop during the course of the research, which may be related to my willingness to continue to participate in this study.

I am signing this consent form of my own free will.

Having read (or had read to me), and having understood all of the above, I do hereby voluntarily consent to participate in this study.

Consent

_____ _____
Signature of Subject Date Signed

The patient is unable to sign because_____

_____ _____
Signature of Witness Date Signed

_____ _____
Signature of Person Explaining the Consent Form Date Signed

_____ _____
Signature of Investigator Date Signed

List of Investigators Phone Numbers

_____ _____

Consent by Proxy

{to be used when patient is incapable of giving informed consent and consent is being given by a legally-authorized proxy}

I represent that I am duly authorized by law, or by power of attorney, health care proxy, or other legally-effective document, to consent on behalf of _____ to his/her participation in this study. I have read and understood the consent form, and hereby voluntarily consent to _____'s participation in the study under the conditions described above.

_____ _____
Signature of Proxy Date Signed

_____ _____
Signature of Witness Date Signed

_____ _____
Signature of Legal Representative Date Signed

_____ _____
Signature of Person Explaining the Consent Form Date Signed

_____ _____
Signature of Investigator Date Signed

List of Investigators Phone Numbers

_____ _____