



**HUMAN
SUBJECTS
RESEARCH
COMMITTEE**

Frederick Langendorf, M.D.
Chairman

Karen Heim-Duthoy, Pharm.D.
Vice Chair

914 South Eighth Street
900 HFA Building
Minneapolis, Minnesota 55404
612-347-8528, Fax: 612-347-7627

August 9, 2000

To: Jennifer Peterson, MPH, JD
Emergency Medicine
Hennepin County Medical Center

Your research project entitled, "*Public Access Defibrillation Trial-Early Access to Defibrillation for Victims of Out-of-Hospital Cardiac Arrest (OOH-CA)*", and its corresponding informed consent document were reviewed at the July 24, 2000 meeting of the Human Subjects Research Committee. At that meeting, approval of your project was deferred until changes were made to the informed consent document. **You have completed the community consultation and public notification portion and have now provided the IRB Office with the appropriately revised materials (revised consents dated 08/01/00).**

Your project is **approved** and you may proceed with this study. This project has been assigned **HSR #2000-821**. Please use this number in all future correspondence.

Surveillance for this project will require reporting **semi-annually**. Reporting forms will be sent to you before the report is due. It is mandatory that you complete and return these surveillance forms by the indicated date. Annual reapproval will be required for continuation of this project.

Please be informed that the Human Subjects Research Committee is in compliance with requirements in Title 45 Code of Federal Regulations Part 46, effective August 19, 1991.

Also be informed that any future proposed changes in this protocol, or any changes that may alter the risk to the subjects, must be reported to the Chairman of the Human Subjects Research Committee.

Sincerely,

Karen Heim-Duthoy, PharmD
Vice Chair
Human Subjects Research Committee

cc: Brian Mahoney, MD
Melissa Cohen

Post-It® Fax Note	7671	Date	8/9/00	# of pages	1
To	J. Peterson	From	K. Heim-Duthoy		
Co/Dept.		Co.			
Phone #		Phone #	347-3567		
Fax #	904-4241	Fax #			

- Hennepin County Medical Center - 701 Park Avenue, Minneapolis, MN 55415
- Minneapolis Medical Research Foundation - 914 South Eighth Street, 900 HFA Building, Minneapolis, MN 55404
- and Hennepin Faculty Associates - 914 South Eighth Street, 600 HFA Building, Minneapolis, MN 55404

Consent for Clinical Investigation
Conducted with Patients

Pt. Name:

180-03913 (11/90)

**Volunteer Informed Consent
Public Access Defibrillation Trial**

My signature on page 4 means three things:

- I understand all the statements in these pages.
- I agree to be a subject in the study.
- I have received a copy of these pages.

About The Study:

The following people are doing a research study:

Brian Mahoney, M.D., Principle Investigator, Emergency Department, Hennepin County Medical Center (612) 347-5683

Rachel Knudson Ballard, R.N., Study Coordinator, Hennepin County Medical Center

This study is a multicenter clinical research trial sponsored by the National Heart, Lung, and Blood Institute, the the American Heart Association, and manufacturers of automatic heart defibrillators. The purpose of the study is to determine if treatment of cardiac (heart) arrest by defibrillators. The purpose of the study is to determine if treatment of cardiac (heart) arrest by non-medical, trained, lay volunteer responders such as you will result in improved survival for victims of cardiac arrest.

The purpose of this study is to test whether non-medical people like yourself can successfully use a cardiac defibrillator to treat a victim of cardiac arrest. Cardiac arrest occurs when the heart stops beating, resulting in loss of consciousness and collapse. The optimal standard of care for pre-hospital cardiac arrest includes immediate bystander cardiopulmonary resuscitation (CPR) and earliest possible defibrillation (electric shock across the chest). For many years, only people highly trained in cardiac care could recognize and treat this heart rhythm problem. However, recently automated external defibrillators (AED's) have been developed which require minimal training for successful use. Though these devices are still used primarily by medical departments, flight attendants and security gaurds. The technology allows these devices to perform almost completely automatically. Once attached to a cardiac arrest victim, it analyzes the heart rhythm and if needed, recommends a shock be given. These "smart" defibrillators are small and easy to use. These have been tested extensively and are safe. However, early defibrillation by layperson rescuers is not proven to be effective to increase the survival of the cardiac arrest victim.

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The potential benefits of this study to you would be the satisfaction in knowing that you can respond in a helpful way to a cardiac arrest. You will be trained in the optimal standard of care for cardiac emergencies. In some circumstances, your participation may actually save someone's life. The training you receive may be useful in other emergency circumstances. It is possible that you may receive no direct benefit from this study, although the knowledge gained for society in general will be useful.

My Being In The Study:

By participating in this study, you will receive training to recognize a cardiac arrest, to call 911 (or other access to the local emergency medical services), and to perform cardiopulmonary resuscitation (CPR). Furthermore, you may be instructed in the use of an AED and have one available to use in your building or work area should anyone in the immediate area have a cardiac arrest. Whether and/or when your building or work area will have an AED available de determined randomly, like flipping a coin. Whether or not you receive training to use an AED, you will be taught other aspects if emergency medical care to allow you to respond to a cardiac arrest.

You are being asked to enroll in this study as a volunteer because you have expressed an interest in being trained to provide emergency care to a person having a cardiac arrest. After completing your first training session, you will be expected to be willing to respond to any event in your immediate area in which a person seems to be experiencing a cardiac arrest. You will be trained to call 911 first, to provide CPR, and possibly to provide defibrillation using an AED.

Initial screening of volunteers will include some basic information about you, including your name and address. You'll be trained at the outset of the study, a class lasting about 4 hours, and retraining will occur at 3 months. How often you are retrained thereafter will be determined randomly, like flipping a coin. Some volunteers will be retrained at 6 months, some at 9 months, some at 12 months, and some at 15 months. This training involves classroom lecture and demonstration, video tape demonstration, and "hands-on" practice of CPR to a manikin. At some units, "mock episodes" or practice "dry runs" will be staged to test and refresh skills of the volunteers. Furthermore, some volunteers will periodically receive instructions (and "hands-on" practice) in the use f the AED. All volunteers will be tested at the end of the study to determine their skill retention.

Each time you respond to a possible episode of cardiac arrest, you will be interviewed (debriefed) to record what happened during the event, as well as to understand your emotional responses to this event. The debriefing interview will take approximately 20 minutes. The AED records all events, including a voice channel, for later review of the sequence of actions and the outcome of the resuscitation procedure. This study will last approximately 2 years.

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Risks, Stress, Discomfort, or Inconvenience of Participation:

The major risk or inconvenience associated with your participation in this study is the commitment of time to be trained and to be periodically retrained. Each training session takes approximately 2 to 4 hours. Time will also be required for you to respond to a person possibly experiencing a cardiac arrest and in participating in the follow-up debriefing interview after you have provided assistance to someone. We estimate that the average person will see no more than one cardiac arrest during the 2 years of this study, but it could happen more frequently, or it might not happen at all.

Quickly responding to an emergency could cause you to suffer an injury (for example, from a fall, from performing CPR, etc.) and there is always a remote possibility of device malfunction that could cause injury. You could experience some psychological distress as a result of the training or as a result of having to respond to a person in distress. It is also remotely possible that you could suffer an injury if you were to use the AED in a way that is inconsistent with the training you will have received in its use. Incorrect application could cause you to receive an electrical shock, or even a burn. Every effort will be made to be sure that you are trained well to use an AED safely.

When assisting a person with their medical emergency I am acting as a private citizen. At no time am I acting as an agent of Hennepin County or my current employer. It is not likely there would ever be a legal claim associated with providing assistance in an emergency medical situation. However, in the event of a claim, as a volunteer, I am protected by the State of Minnesota "Good Samaritan" law if I am assisting in an emergency medical situation. The Good Samaritan law specifically protects persons giving care (CPR) or using an AED. Furthermore, manufacturers of AED, offers certain legal protection to individuals who are threatened with legal action with the use of this device.

In the event of an adverse effect or complication which results from the study, treatment will be available immediately from the specialists listed on this form. However, all physician, hospital and laboratory bills will be charged to you and/or your insurance company. If you think that an adverse event has occurred, call one of the investigators at the top of this form.

What will happen to the findings of the study: Confidentiality:

Records will be reviewed and retained by the investigators for at least 5 years, after the completion of the study. If it forms any part of the medical or scientific report, your identity will not be disclosed. The information gathered for this study will be used to try to determine better treatment for patients with cardiac arrests. As in all studies which evaluate new devices, records (which may contain identifying information such as your

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name and social security number) might be reviewed by the United States Food and Drug Administration, the National Heart, Lung, and Blood Institute, and the manufacturers of the AED. You are encouraged to ask questions about this study, and the investigator in charge of the project will do his/her best to answer these questions.

Alternatives:

You are free to decide not to participate in this project, and you can withdraw from it any time without penalty and without jeopardizing any future relationships with the emergency medical care system. You are free to refuse to answer any questions regarding your participation in this study.

The alternatives to your participation in this study are for you not to participate. You are under no duty to participate. If you decide not to enter this study, other volunteers will be sought.

Payment:

There will be no payment to volunteers participating in this study, but it is not expected that participation in this research study will result in cost to you, other than for the time required for your training. No compensation is available for any injury, adverse event, or disability which may result from your participation in this study. You will be informed of any significant findings that could effect your decision to continue in this study.

Whom to contact:

If at any time I have any questions about this study, I can call Dr. Brian Mahoney or Rachel Knudson Ballard, R.N. (612-347-5638) who will answer my questions to the best of their ability. If I have general questions about my rights as a research participant or any research related issues, I may contact the Chairman of the Hennepin County Medical Center Human Subjects Research Committee at 612-347-8528.

You will be given a copy of this consent form to take home.

Your decision to participate or not to participate will not effect any current or future relationship with any of the institutions or people identified with this study.

Signature of Volunteer: _____ Date: _____

Signature of Investigator: _____ Date: _____

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**Patient Informed Consent After Waived Consent
Public Access Defibrillation Trial**

My signature on page 4 means three things:

- I understand all the statements in these pages.
- I agree to be a subject in the study.
- I have received a copy of these pages.

About The Study:

The following people are doing a research study:

Brian Mahoney, M.D., Principle Investigator, Emergency Department, Hennepin County Medical Center (612) 347-5683

Rachel Knudson Ballard, R.N., Study Coordinator, Hennepin County Medical Center

I have had a medical emergency and have recovered. I collapsed, and a volunteer responded to help me. If I lost consciousness and were unresponsive, an approved medical device called a "defibrillator" may have been used to shock and restart your heart electrically. I received treatment quickly enough to save your life.

The location at which I had my medical emergency is participating in a nationwide research study to examine the best way to help people who have experienced a medical emergency involving the heart. Volunteers at these sites agreed to participate in this study and are trained by qualified medical personnel to use (CPR) or the automatic external defibrillator (a device that delivers a small electrical shock to the heart) to assist your relative. I should be aware that the person who helped me with CPR and/or use of an AED did so as a private citizen and at no time was acting as an employee or agent of Hennepin County Medical Center.

The purpose of this research study is to determine whether more people survive cardiac arrest at locations where a defibrillator is available and can be used effectively by trained non-medical personnel. For most heart related emergencies defibrillation (a small electric shock given to the heart) or CPR must be performed within a few minutes after the person collapses. The automatic external defibrillator that may have been used on me is usually only operated by trained medical personnel. Unfortunately, once 911 has been called, sometimes medical personnel cannot arrive quickly enough to save a life. Therefore, one of the trained volunteers participating in this study used CPR or the automatic external defibrillator to assist me during my medical emergency.

All the volunteers participating in this study are trained by experienced medical personnel, how to recognize a person that is experiencing an emergency involving their

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RESEARCH
INVESTIGATION

HENNEPIN COUNTY MEDICAL CENTER

Consent for Clinical Investigation
Conducted with Patients

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heart. They are all trained on how to use the autonomic external defibrillator or to perform cardiopulmonary resuscitation (CPR) and to call 911. This study was described to the general population through the media, newspapers, radio and television. This proposal was brought to the community and community leaders and citizens agreed this study is needed.

For most cardiac arrests, automatic external defibrillation (AED) or CPR must be performed within a few minutes of the victim's collapse. As a result, it was impossible to obtain your consent or your next-of-kin's consent prior to enrolling you in this study. At this point we are asking your consent to continue participating in the study.

Because I had a medical emergency at one of the participating study locations, I was enrolled in this study. By participating in this study, I had the opportunity to receive the defibrillation or CPR earlier than it might have been delivered by emergency medical personnel, if it was needed. All survivors are being asked if they are willing to allow physician investigators to monitor their recovery and general health for a period of time up to two years.

My being in the study:

If I continue in the study, information will be collected about my treatment, recovery and general health. After the medical emergency my hospital records will be reviewed to determine what treatment has been delivered, the cost of my hospital stay, and the extent of my recovery.

After I have been discharged from the hospital I will be contacted by phone every month for three months, then every three months for two years. During the phone interview I will answer questions about my health, mental status; quality of life and medical care (hospitalizations and procedures). Assessment of my medical costs will also be evaluated. A sample of each questionnaire is available for me. The questionnaires take approximately thirty minutes to complete.

All of the treatment for my cardiac condition will be determined by my physician, and this study will not interfere with such treatment in any way. The only treatment being evaluated in this study is the strategy of making defibrillation available from non-medical volunteers.

Risks:

The risks associated with the use of the automatic defibrillator by trained, authorized but non-medical users include some risk that the device might not restore the heart rhythm to normal. However, I have already experienced these risks. Even if the volunteer responder had difficulty using the device, the paramedic or emergency medical technician

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arrived without delay for usual medical care. Though taught to call 911 first, there was a small risk that a volunteer would delay calling 911 as he/she tried to use the defibrillator, which could make survival worse, or neurologic injury worse.

Continuing in this study involves the inconvenience of a small time commitment for me when completing the questionnaires. I may experience some psychological distress at having to remember the medical emergency and the hospitalization, or having to answer questions I don't ordinarily think about.

Medical treatment and costs related to the study:

In the event of a physical injury or complication which results from this study, treatment will be available immediately from the specialists listed on the first page of this form. However, all physician, hospital, and laboratory bills will be charged to me and/or my insurance company. If I believe something went wrong while the volunteer was assisting me I need to contact one of the investigators at the top of this form.

All of the treatment I receive for my heart condition will be determined by my physician and this study will not interfere with that treatment in any way. Because all treatments, tests and procedures are part of routine care and are not part of this study, this study will not pay for any part of your medical care. Any tests, procedures, or treatments determined by my doctors to be necessary for my care will require a separate consent form.

Benefits of this study:

If there is any benefit to me being in the study, it has already occurred. The benefits I have already received have occurred as a result of receiving CPR or the automatic external defibrillator. I will not receive any payment for participation in this study. The potential benefits for my participation is that we may discover a safe way to deliver emergency medical assistance in the community for people experiencing heart emergencies.

What will happen to the findings of the study: confidentiality:

Information from this study, including my name and any other confidential information, will be given to the study personnel, listed on the first page of this form. All studies which involve the evaluation of a device, medical records (which may contain identifying information, such as my relatives name and social security number) might be reviewed by the United States Food and Drug Administration, the National Heart, Lung and Blood Institute, or the manufacturers of the defibrillators. This information may also be made available to the Human Subjects Research Committee at the Hennepin County Medical Center. Confidential information will not be released for any other reason. The

CLINICAL
INVESTIGATION

HENNEPIN COUN. / MEDICAL CENTER

Consent for Clinical Investigation
Conducted with Patients

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findings may be used for scientific papers, but my name will not be revealed. However, the study personnel will keep my name and address so that they may contact me for the follow up information needed for this study.

Alternative Treatments:

There are no alternative treatments to emergency CPR and/or the electric shock to treat the victim of cardiac arrest. This treatment has already been given, and I have been successfully resuscitated.

Therefore, I have already received CPR, electric shock or both the electric shock and CPR. If I do not wish to participate in the study, then I can withdraw at anytime without penalty. I am also free to refuse to answer any question about my health, quality of life, or medical care without penalty and without jeopardizing further care. Should I choose not to participate in this study, my medical records will not be reviewed further, and I will not be contacted.

Whom to contact:

If at any time I have any questions about this study, I can call Dr. Brian Mahoney or Rachel Knudson Ballard, R.N. (612-347-5638) who will answer my questions to the best of their ability. If I have general questions about my rights as a research participant or any research related issues, I may contact the Chairman of the Hennepin County Medical Center Human Subjects Research Committee at 612-347-8528.

Knowing all of this, I voluntarily agree to participate in this study. I understand that I may refuse to participate or withdraw from the study at any time without penalty or loss of benefits to which I am otherwise entitled. I have had the opportunity to ask questions. I understand that further questions I may have about the research or the subjects' rights will be answered by one of the investigators listed above. I agree to allow access to my medical records, to permit my name and phone number to be transmitted to the Central Coordinating Center and agree to allow them to call me for follow-up data. By signing this form, I'm not giving up any of my legal rights.

I have received a copy of this consent form.

Subject's Signature

Date:

Subject's Printed Name

Date

Subject's Signature

Date:

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**Patient Informed Consent After Family Consent
Public Access Defibrillation Trial**

My signature on page 4 means three things:

- I understand all the statements in these pages.
- I agree to be a subject in the study.
- I have received a copy of these pages.

About The Study:

The following people are doing a research study:

Brian Mahoney, M.D., Principle Investigator, Emergency Department, Hennepin County Medical Center (612) 347-5683

Rachel Knudson Ballard, R.N., Study Coordinator, Hennepin County Medical Center

I have had a medical emergency and have recovered. I collapsed, and a volunteer responded to help me. If I lost consciousness and were unresponsive, an approved medical device called a "defibrillator" may have been used to shock and restart my heart electrically. I received treatment quickly enough to save my life.

The location at which I had my medical emergency is participating in a nationwide research study to examine the best way to help people who have experienced a medical emergency involving the heart. Volunteers at these sites agreed to participate in this study and are trained by qualified medical personnel to use (CPR) or the automatic external defibrillator (a device that delivers a small electrical shock to the heart) to assist me with my medical emergency. I should be aware that the person who helped me with CPR and/or use of an AED did so as a private citizen and at no time was acting as an employee or agent of Hennepin County Medical Center.

The purpose of this research study is to determine whether more people survive cardiac arrest at locations where a defibrillator and CPR is available and can be used effectively by trained non-medical personnel. For most heart related emergencies defibrillation (a small electric shock given to the heart) or CPR must be performed within a few minutes after the person collapses. The automatic external defibrillator that may have been used on me is usually only operated by trained medical personnel. Unfortunately, once 911 has been called, sometimes medical personnel cannot arrive quickly enough to save a life. Therefore, one of the trained volunteers participating in this study used CPR or the automatic external defibrillator to assist me during my medical emergency.

All the volunteers participating in this study are trained by experienced medical personnel, how to recognize a person that is experiencing an emergency involving their heart. They are all trained on how to use the automatic external defibrillator or to perform cardiopulmonary resuscitation (CPR) and to call 911. This study was described

CONSENT FOR CLINICAL INVESTIGATION

HENNEPIN COUNTY MEDICAL CENTER

Consent for Clinical Investigation
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to the general population through the media, newspapers, radio and television. This proposal was brought to the community and community leaders and citizens agreed this study is needed.

For most cardiac arrests, automatic external defibrillation (AED) or CPR must be performed within a few minutes of the victim's collapse. As a result, it was impossible to obtain your consent or your next-of-kin's consent prior to enrolling you in this study. During the first few days of your hospitalization, your family gave consent for us to follow your progress. At this point we are asking your consent to continue participating in the study.

Because I had a medical emergency at one of the participating study locations, I was enrolled in this study. By participating in this study, I had the opportunity to receive the defibrillation or CPR earlier than it might have been delivered by emergency medical personnel, if it was needed. All survivors are being asked if they are willing to allow physician investigators to monitor their recovery and general health for a period of time up to two years.

My being in the study:

If I continue in the study, information will be collected about my treatment, recovery and general health. After the medical emergency my hospital records will be reviewed to determine what treatment has been delivered, the cost of my hospital stay, and the extent of my recovery.

After I have been discharged from the hospital I will be contacted by phone every month for three months, then every three months for two years. During the phone interview I will answer questions about my health, mental status; quality of life and medical care (hospitalizations and procedures). Assessment of my medical costs will also be evaluated. A sample of each questionnaire is available for me. The questionnaires take approximately thirty minutes to complete.

All of the treatment for my cardiac condition will be determined by my physician, and this study will not interfere with such treatment in any way. The only treatment being evaluated in this study is the strategy of making defibrillation available from non-medical volunteers.

Risks:

The risks associated with the use of the automatic defibrillator by trained, authorized but non-medical users include some risk that the device might not restore the heart rhythm to normal. However, I have already experienced these risks. Even if the volunteer responder had difficulty using the device or CPR, the paramedic or emergency medical

CONSENT FOR CLINICAL INVESTIGATION

HENNEPIN COUNTY MEDICAL CENTER

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technician arrived without delay for usual medical care. Though taught to call 911 first, there was a small risk that a volunteer would delay calling 911 as he/she tried to use the defibrillator, which could make survival worse, or neurologic injury worse.

Continuing in the study involves the inconvenience of a small time commitment for me when completing the questionnaires. I may experience some psychological distress at having to remember the medical emergency and the hospitalization, or having to answer questions I don't ordinarily think about.

Medical treatment and costs related to the study:

In the event of a physical injury or complication which results from this study, treatment will be available immediately from the specialists listed on the first page of this form. However, all physician, hospital, and laboratory bills will be charged to me and/or my insurance company. If I believe something went wrong while the volunteer was assisting me I need to contact one of the investigators at the top of this form.

All of the treatment I receive for my heart condition will be determined by my physician and this study will not interfere with that treatment in any way. Because all treatments, tests and procedures are part of routine care and are not part of this study, this study will not pay for any part of your medical care. Any tests, procedures, or treatments determined by my doctors to be necessary for my care will require a separate consent form.

Benefits of this study:

There is no direct benefit to me by continuing in this study. The benefits I have already received have occurred as a result of receiving CPR or the automatic external defibrillator. I will not receive any payment for participation in this study. The potential benefits for my participation is that we may discover a safe way to deliver emergency medical assistance in the community for people experiencing heart emergencies.

What will happen to the findings of the study: confidentiality:

Information from this study, including my name and any other confidential information, will be given to the study personnel, listed on the first page of this form. All studies which involve the evaluation of a device, medical records (which may contain identifying information, such as my relatives name and social security number) might be reviewed by the United States Food and Drug Administration, the National Heart, Lung and Blood Institute, or the manufacturers of the defibrillators. This information may also be made available to the Human Subjects Research Committee at the Hennepin County Medical Center. Confidential information will not be released for any other reason. The findings may be used for scientific papers, but my name will not be revealed. However,

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HENNEPIN COUNTY MEDICAL CENTER

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the study personnel will keep my name and address so that they may contact me for the follow up information needed for this study.

Alternative Treatments:

There are no alternative treatments to emergency CPR and/or the electric shock to treat the victim of cardiac arrest. This treatment has already been given, and I have been successfully resuscitated.

Therefore, I have already received CPR, electric shock or both the electric shock and CPR. If I do not wish to participate in the study, then I can withdraw at anytime without penalty. I am also free to refuse to answer any question about my health, quality of life, or medical care without penalty and without jeopardizing further care. Should I choose not to participate in this study, my medical records will not be reviewed further, and I will not be contacted.

Whom to contact:

If at any time I have any questions about this study, I can call Dr. Brian Mahoney or Rachel Knudson Ballard, R.N. (612-347-5638) who will answer my questions to the best of their ability. If I have general questions about my rights as a research participant or any research related issues, I may contact the Chairman of the Hennepin County Medical Center Human Subjects Research Committee at 612-347-8528.

Knowing all of this, I voluntarily agree to participate in this study. I understand that I may refuse to participate or withdraw from the study at any time without penalty or loss of benefits to which I am otherwise entitled. I have had the opportunity to ask questions. I understand that further questions I may have about the research or the subjects' rights will be answered by one of the investigators listed above. I agree to allow access to my medical records, to permit my name and phone number to be transmitted to the Central Coordinating Center and agree to allow them to call me for follow-up data. By signing this form, I'm not giving up any of my legal rights.

I have received a copy of this consent form.

Subject's Signature

Date:

Subjects Printed Name

Date

Signature of Physician

Date

CONSENT FOR CLINICAL INVESTIGATION

HENNEPIN COUNTY MEDICAL CENTER

Consent for Clinical Investigation
Conducted with Patients

Pt. Med. c. #:

Pt. Name:

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All the volunteers participating in this study are trained by experienced medical personnel, how to recognize a person that is experiencing an emergency involving their heart. They are all trained on how to use the autonomic external defibrillator or to perform cardiopulmonary resuscitation (CPR) and to call 911. This study was described to the general population through the media, newspapers, radio and television. This proposal was brought to the community and community leaders and citizens agreed this study is needed.

My relative being in the study:

If my relative continues in the study, information will be collected about my relatives treatment, recovery and general health. After the medical emergency my relatives hospital records will be reviewed to determine what treatment has been delivered, the cost of their hospital stay, and the extent of their recovery. As soon as my relative is conscious and able to understand a discussion about this study, we will obtain his/her permission.

After my relative has been discharged from the hospital he/she will be contacted by phone every month for three months, then every three months for two years. During the phone interview my relative will answer questions about his/her health, mental status; quality of life and medical care (hospitalizations and procedures). Assessment of my relatives costs will also be evaluated. A sample of each questionnaire is available for me. The questionnaires take approximately thirty minutes to complete.

All of the treatment for my relative's cardiac condition will be determined by his/her physician, and this study will not interfere with such treatment in any way. The only treatment being evaluated in this study is the strategy of making defibrillation available from non-medical volunteers.

Risks:

The risks associated with the use of the automatic defibrillator by trained, authorized but non-medical users include some risk that the device might not restore the heart rhythm to normal. However, my relative has already experienced these risks. Even if the volunteer responder had difficulty using the device, the paramedic or emergency medical technician arrived without delay for usual medical care. Though taught to call 911 first, there was a small risk that a volunteer would delay calling 911 as he/she tried to use the defibrillator, which could make survival worse, or neurologic injury worse.

Continuing in the study involves a small time commitment for my relative when he/she completes the questionnaires. My relative may experience some psychological distress at having to remember the medical emergency and the hospitalization, or having to answer questions he/she doesn't ordinarily think about.

Medical treatment and costs related to the study:

In the event of a physical injury or complication which results from this study, treatment will be available immediately from the specialists listed on the first page of this form. However, all physician, hospital, and laboratory bills will be charged to my relative and/or his/her insurance

CONSENT FOR CLINICAL INVESTIGATION

HENNEPIN COUNTY MEDICAL CENTER

Consent for Clinical Investigation
Conducted with Patients

Pt. Med. Rec. #:

Pt. Name:

APPROVED AUG 09 2000

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company. If I believe something went wrong while the volunteer was assisting my relative I need to contact one of the investigators at the top of this form.

All of the treatment for my relatives heart condition will be determined by his/her physician and this study will not interfere with that treatment in any way. Because all treatments, tests and procedures are part of routine care and are not part of this study, this study will not pay for any part of my medical care. Any tests, procedures, or treatment determined by my relatives doctors to be necessary for my relative's care will require a separate consent form.

Benefits of this study:

There is no direct benefit to my relative for continuing in this study. The benefits my relative have already received have occurred as a result of receiving CPR or the automatic external defibrillator. My relative will not receive any payment for participation in this study. The potential benefits for my relative's participation is that we may discover a safe way to deliver emergency medical assistance in the community for people experiencing heart emergencies.

What will happen to the findings of the study: confidentiality:

Information from this study, including my name and any other confidential information, will be given to the study personnel, listed on the first page of this form. All studies which involve the evaluation of a device, medical records (which may contain identifying information, such as my relatives name and social security number) might be reviewed by the United States Food and Drug Administration, the National Heart, Lung and Blood Institute, or the manufacturers of the defibrillators. This information may also be made available to the Human Subjects Research Committee at the Hennepin County Medical Center. Confidential information will not be released for any other reason. The findings may be used for scientific papers, but my relative's name will not be revealed. However, the study personnel will keep my relatives name and address so that they may contact my relative for the follow up information needed for this study.

Alternative Treatments:

There are no alternative treatments to emergency CPR and/or the electric shock to treat the victim of cardiac arrest. This treatment has already been given, and my relative was successfully resuscitated.

Therefore, he/she has already received CPR, electric shock or both the electric shock and CPR. If I do not believe my relative would like to participate in the study, then I can withdraw him/her at anytime without penalty. I am also free to refuse to answer any question about my relatives health, quality of life , or medical care without penalty and without jeopardizing further care. Should I not allow my relative to participate in this study, his/her medical records will not be reviewed further, and my relative will not be contacted.

Whom to contact:

If at any time I have any questions about this study, I can call Dr. Brian Mahoney or Rachel Knudson Ballard, R.N. (612-347-5638) who will answer my questions to the best of their ability.

CLINICAL INVESTIGATION FOR CONSENT

HENNEPIN COUNT MEDICAL CENTER

Consent for Clinical Investigation
Conducted with Patients

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If I have general questions about my rights as a research participant or any research related issues, I may contact the Chairman of the Hennepin County Medical Center Human Subjects Research Committee at 612-347-8528.

The study described above has been explained to me. I understand that I am free to refuse to allow my relative to participate and withdraw from the study at any time without penalty or loss of benefits to which I am otherwise entitled. I voluntarily consent to allow my relative to participate in this study. I have had the opportunity to ask questions. I understand that further questions I may have about the research or the subjects' rights will be answered by one of the investigators listed above. I agree to allow access to my relative's medical records, to permit my relative's name and phone number to be transmitted to the Central Coordinating Center and agree to allow them to call my relative for follow-up data. By signing this form, I'm not giving up any of my relatives legal rights.

I have received a copy of this consent form.

Subjects Printed Name

Signature of Patient Representative Date Relationship

Signature of Physician Date

FOR CLINICAL INVESTIGATION

HENNEPIN COUNTY MEDICAL CENTER

Consent for Clinical Investigation
Conducted with Patients

Pt. Med. #:

Pt. Name:

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**Family Informed Consent Form
Public Access Defibrillation Trial**

My signature on page 4 means three things:

- I understand all the statements in these pages.
- I agree to be a subject in the study.
- I have received a copy of these pages.

About The Study:

The following people are doing a research study:

- Brian Mahoney, M.D., Principle Investigator, Emergency Department, Hennepin County Medical Center (612) 347-5683
- Rachel Knudson Ballard, R.N., Study Coordinator, Hennepin County Medical Center

I am being asked to allow my relative to participate in a research study. My relative has had a medical emergency and has survived, although they are unable to understand what has happened. My relative collapsed and lost consciousness and could not respond to volunteers who came to his/her aid. The volunteer who assisted my relative with his/her medical emergency may have used a medical device known as an automatic external defibrillator (AED), which delivers a safe amount of shock to restart the heart electrically, and/or used cardiopulmonary resuscitation (CPR).

The location at which my relative had their medical emergency is participating in a nationwide research study to examine the best way to help people who have experienced a medical emergency involving the heart. Volunteers at these sites agreed to participate in this study and are trained by qualified medical personnel to use (CPR) or the automatic external defibrillator (a device that delivers a small electrical shock to the heart) to assist your relative. You should be aware that the person who helped your relative with CPR and/or use of an AED did so as a private citizen and at no time was acting as an employee or agent of Hennepin County Medical Center.

The purpose of this research study is to determine whether more people survive cardiac arrest at locations where a defibrillator is available and can be used effectively by trained non-medical personnel. For most heart related emergencies defibrillation (a small electric shock given to the heart) or CPR must be performed within a few minutes after the person collapses. The automatic external defibrillator that was used on my relative is usually only operated by trained medical personnel. Unfortunately, once 911 has been called, sometimes medical personnel cannot arrive quickly enough to save a life. Therefore, one of the trained volunteers participating in this study used CPR or the automatic external defibrillator to assist my relative.

Therefore, because my relative had a medical emergency involving their heart at one of the participating study locations, he/she was enrolled in the study. Because the automatic external defibrillator must be used within a few minutes after the victim collapses we could not ask your permission to allow your relative to participate in this study. At this point we are asking you to give consent to allow your relative to keep participating in this study.

CONSENT FOR CLINICAL INVESTIGATION

Public Access Defibrillation Trial Information Sheet

PURPOSE AND BENEFITS

Your relative has had a medical emergency and collapsed and a volunteer responded to help. Your relative's heart stopped beating. The volunteer who assisted your relative with his/her medical emergency used a medical device known as an automatic external defibrillator (AED), which delivers a safe amount of shock to restart the heart electrically, and/or used cardiopulmonary resuscitation (CPR). Unfortunately, despite the emergency medical care that your relative received, your relative was unable to survive his/her cardiac arrest.

The location at which your relative had their medical emergency is participating in a nationwide research study to examine the best way to help people who have experienced a medical emergency involving the heart. Volunteers at these sites agreed to participate in this study and are trained by qualified medical personnel to use (CPR) or the automatic external defibrillator (a device that delivers a small electrical shock to the heart) to assist your relative. You should be aware that the person who helped your relative with CPR and/or use of an AED did so as a private citizen and at no time was acting as an employee or agent of Hennepin County Medical Center.

The purpose of this research study is to determine whether more people survive cardiac arrest at locations where a defibrillator and CPR is available and can be used effectively by trained non-medical personnel. For most heart related emergencies defibrillation (a small electric shock given to the heart) or CPR must be performed within a few minutes after the person collapses. The automatic external defibrillator that may have been used on my relative is usually only operated by trained medical personnel. Unfortunately, once 911 has been called, sometimes medical personnel cannot arrive quickly enough to save a life. Therefore, one of the trained volunteers participating in this study used CPR or the automatic external defibrillator to assist your relative.

Because your relative had a medical emergency involving their heart at one of the participating study locations, he/she was enrolled in the study. Because the automatic external defibrillator must be used within a few minutes after the victim collapses we could not ask your permission to allow your relative to participate in this study.

All the volunteers participating in this study are trained by experienced medical personnel, how to recognize a person that is experiencing an emergency involving their heart. They are all trained on how to use the automatic external defibrillator or to perform cardiopulmonary resuscitation (CPR) and to call 911. This study was described to the general population through the media, newspapers, radio and television. This proposal was brought to the community and community leaders and citizens agreed this study is needed.

By participating in this study, your relative may have had the opportunity to receive the defibrillation even earlier than it might have been delivered by emergency medical personnel.

PROCEDURES:

After the initial emergency medical care delivered at the scene of the cardiac arrest, all of the treatment for your relative's cardiac condition was determined by his/her physicians, and this study did not interfere with such treatment in any way. The only treatment being evaluated was the initial emergency treatment. Because all treatments, tests, and procedures were part of routine care and not a part of this study, this study will not pay for any part of his/her medical care. Any tests, procedures, or treatment determined by his/her doctors to be necessary for his/her care was performed as appropriate. Your relative will not be charged for the care rendered by the trained volunteer non-medical responder at the time of the emergency.

RISKS, STRESS, DISCOMFORT:

The risks associated with the provision of emergency medical care by trained, non-medical personnel (which might include the use of the automatic defibrillator) include the risk that the treatment will be unsuccessful. Even if the volunteer responder had difficulty delivering medical care, the paramedic or emergency medical technician arrived without delay for usual medical care. Although trained to call 911 first, there was a small risk that the volunteer would delay calling 911 as he/she tried to provide care, which could make survival worse, or neurologic injury worse.

OTHER INFORMATION

There are no alternative treatments to the electric shock to restore the normal heart rhythm. If it was needed, this treatment was given promptly.

Even with this advanced emergency medical care, your relative did not survive. We are sorry for your loss.

MINNEAPOLIS PAD TRIAL SITE
PUBLIC RESPONSE TO COMMUNITY CONSULTATION AND NOTIFICATION

1. The Hennepin County Community Health Services Advisory Committee agreed to serve as a community consent group. The committee had no negative feedback and no one called Dr. Mahoney or the Human Research Subjects line with questions or comments.
2. Star Tribune newspaper article response: no negative feedback. One inquiry was made in response to this article regarding whether Dr. Mahoney would be a medical director for a small firm that was looking to purchase an AED for their building, but they did not want to participate in the study.
3. Some people have spontaneously called to be a unit, but there were barriers to their participation (e.g., not in our service area, private homes)
4. Our PR department is currently working on the advertisement in the Minneapolis STAR TRIBUNE
5. Press releases went out to HCMC's employee newsletter, MMRF newsletter and a Senior Residents' newsletter. To date, we have received no negative feedback. We have received numerous calls in response to these newsletters about how they could participate in the study, or how they could get an AED for their Yacht Club, neighborhood, etc.

PAD Study: Plan for Community Notification and Consultation

Community Notification

Purpose: Advising people of study and informing them who to call with any questions

Timeline: After Community Consultation and approval from IRB but before study begins

Advertisement in the following:

StarTribune -

Press release to media

Note that there is no guarantee of coverage

Information sessions:

At all residential and business units

Post Study – a press release will be done after the completion of the study with the results

Community Consultation

HC Community Services Advisory Committee - June 14th meeting 11:30 –1:30 PM

Attached please find the Hennepin County CHSAC mission, Operational Procedures which includes their Powers and Duties and their current membership.

This committee is representative of Hennepin County and is made up of consumers, health care providers and other public policy makers.

Note that IRB approval will be requested after results of community consultation above.

Once IRB Approval has been obtained, meetings with study units (resident and business units) will begin. There will be one informational meeting at each residential and business unit. There will be posters placed at all units informing persons of the study. After informational sessions have been held, agreements with units for participation will be signed assuming the unit has chosen to participate.