

07 Milwaukee



Institutions Research Committee

I.R.C. APPROVAL

**AMENDMENT I
Full Committee Review**

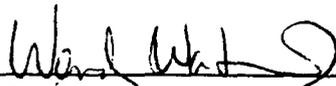
TO: Tom Aufderheide, M.D.
Emergency Medicine
FMLH-East

PLEASE BE ADVISED THAT FULL BOARD APPROVAL WAS GRANTED BY THE INSTITUTIONS RESEARCH COMMITTEE (IRC) ON BEHALF OF FROEDTERT MEMORIAL LUTHERAN HOSPITAL FOR THE ABOVE REFERENCED AMENDMENT EFFECTIVE AS OF THE DATE INDICATED BELOW.

**Public Access Defibrillation Phase 1 (PAD-1) Trial IRC#98-140
HRRC#231-98**

NOTE: Any changes in the protocol and informed consent and any severe untoward reactions, or death, must be reported in writing immediately to the Institutions Research Committee.

Federal regulations require that if any advertising is involved in the initiation of this protocol, prior approval must be obtained from the Institutions Research Committee.



Wendy Watson, M.D., Co-Chairperson
David Bresnahan, M.D., Co-Chairperson
Institutions Research Committee
Date Signed: 4-10-00

3 17.00

MEDICAL COLLEGE OF WISCONSIN
STATEMENT OF VOLUNTEER INFORMED CONSENT FOR TARGETED NON-TRADITIONAL
RESPONDERS IN A CLINICAL STUDY

INTRODUCTION: I, _____, hereby agree to participate in the investigation titled "The Public Access Defibrillation Phase I (PAD-I) Trial." I understand that while the program will be under the supervision of Tom P. Aufderheide, MD, other professional persons may be designated to assist or act for him.

PURPOSE: The purpose of the study is to determine if treatment of cardiac arrest (sudden stoppage of the heart due to an abnormal rhythm) by non-medical, trained, lay volunteer responders with automated external defibrillators (AEDs) will result in improved survival for victims of cardiac arrest. Automated external defibrillators (AEDs) have been used in hospitals, emergency rooms, and ambulances for many years. These devices are usually used by trained medical personnel such as paramedics. New technology has led to improvements in AEDs. These new devices are small and easy to use. AEDs have been carefully tested and, with training, are easy to safely operate. We now want to see if laypersons can effectively use AEDs if they are trained to do so and to see if AED use within the first few minutes following collapse from cardiac arrest results in improved survival for cardiac arrest victims.

PROCEDURES: I will attend and take part in a four-hour local training session initially, will review emergency action steps monthly, and receive a refresher training session (approximately two hours each) at three months. How often I am retrained thereafter will be determined randomly (50-50 chance, similar to flipping a coin). I will be retrained at 6 months, 9 months, 12 months or 15 months. I will also be tested at the end of the study to determine my skill retention. After completing my training and, when the study begins, I will be expected to respond to any incident in which someone in my immediate location (e.g., home, office, etc.) appears to experience cardiac arrest. My response to these incidents will involve recognizing the emergency; accessing the Emergency Medical Services system by calling 911; providing cardiopulmonary resuscitation (CPR); and, if I am trained in doing so, providing defibrillation using an automated external defibrillator (AED). An AED is a computerized medical device designed to shock the heart of a victim in cardiac arrest.

After responding to an emergency situation, I will be contacted by a study nurse, who will ask me a series of questions designed to assess exactly what took place and what effect my participation has had on me. These interviews will take approximately 15 to 20 minutes.

The experimental aspect of this study is to train, equip, and authorize laypersons such as myself to operate and use an automated external defibrillators (AED) within the first few minutes following victim collapse from cardiac arrest. It is unknown whether this approach can be effectively implemented and whether it results in improved survival from cardiac arrest.

My participation in the project will be to satisfactorily complete the initial and ongoing training sessions described above; respond to any incident in which someone in my

immediate location appears to experience cardiac arrest; and perform the sequence of actions for which I will be trained, including recognizing emergencies, accessing the Emergency Medical Services system by calling 911, providing cardiopulmonary resuscitation (CPR), and, if I am trained, using the AED. After responding to an emergency medical situation, I will also be contacted by a study nurse or physician and participate in a 15- to 20-minute interview in which I will be asked a series of questions designed to assess exactly what took place and what effect my participation has had on me.

I wish to limit my participation as a subject in the investigation as follows (if none, compared to description of participation above, write "NONE"): _____

RISKS: I have been informed of the discomforts and risks which I may reasonably expect as part of the study. These include a commitment of approximately 16 to 20 hours of my time. This time will be distributed across the three years of the study. My time will be required for initial training, monthly review of emergency action steps, and refresher training sessions; providing assistance to people experiencing cardiac arrest; and participating in follow-up interviews after I provide assistance to people experiencing cardiac arrest. I understand that I may encounter a person needing my assistance once during the course of this study, but I understand it might occur more than once.

I may experience some psychological distress as a result of providing assistance in an emergency medical situation. If I experience such distress, I may speak with the interviewer about my feelings or I may ask to speak to a physician participating in the study. Also, it is unlikely but possible that I may suffer physical injury by performing the emergency actions I will be trained to perform, including cardiopulmonary resuscitation (CPR) or using an AED in a way that is inconsistent with the training I will receive. Every effort will be made to assure that I am trained to use the AED safely. In the unlikely event that I have a physical and/or mental injury resulting from my participation in this study, medical treatment will be available at a local hospital. Fees for such treatment will be billed to me or my medical insurance.

It is possible there may be a legal liability associated with providing assistance in an emergency medical situation. However, I understand that the State of Wisconsin has a "Good Samaritan" law that protects individuals who assist by performing CPR in emergency medical situations. Wisconsin legislature has recently passed a law to also provide immunity to those operating an AED.

I understand that there may be some unknown or unanticipated discomforts or risks in addition to those specified above because some of the procedures are relatively new and are attempts to advance medical knowledge, but that every precaution will be taken to assure my personal safety and to minimize discomforts.

BENEFITS: I understand that the information which is obtained may be useful scientifically and possibly helpful to others. The benefit to me which may reasonably be expected from participating in this study is receiving training in how to help and possibly save a victim of cardiac arrest by recognizing an emergency, accessing the Emergency Medical Services

system by calling 911, performing cardiopulmonary resuscitation (CPR), and possibly being trained in the use of an automated external defibrillator (AED), but I understand that this is not guaranteed.

FINANCIAL RISKS: I understand that some third party payers (insurance companies, HMOs, etc.) may not pay for hospitalization, treatments, or procedures which are determined to be experimental. I agree that all costs not paid by my insurance will be my own financial responsibility.

ALTERNATIVE PROCEDURES: I understand that the only appropriate alternative procedure which might be advantageous for me is to not participate in the study.

ANSWER INQUIRIES: Dr./Ms./Mr. _____ has explained the above matters to me, and I understand that explanation. (S)he has offered to answer my questions concerning the procedures involved in this study.

CONFIDENTIALITY: I have been promised that any information obtained from this investigation that can be identified with me will remain confidential or will be disclosed only with my permission. However, I am in agreement that scientific data or medical information not identifiable with me resulting from the study may be presented at meetings and published so that the information can be useful to others.

I hereby authorize the United States Food and Drug Administration (FDA), the Coordinating Center for this study at the University of Washington, and the Principal Investigator, Tom P. Aufderheide, MD, and his research team to have access to my records concerning this research study.

NO PREJUDICE: I have been informed that my decision about whether or not to participate will not prejudice my present or future relationship with the Medical College of Wisconsin or the staffs of these institutions; nor will it influence the quantity or quality of care which is otherwise available to me. If I participate, I understand that I am free to withdraw at any time without prejudice, and that withdrawal would not in any way affect the nature of the care or treatment otherwise available to me. I understand that I may contact the Chairman of the Human Research Review Committee of the Medical College of Wisconsin at (414)456-8505 for further information related to the research and my rights as a subject.

COMPENSATION FOR INJURIES: I agree to take the risks listed above. If unexpected injuries which are not discussed in the paragraph entitled "Risks" occur, physician faculty of the Medical College of Wisconsin will provide me humanitarian emergency care without charging me a physician's fee for such treatment. Such free care does not mean that negligence has occurred; compensation may or may not be payable. I understand that I may contact the Chairman of the Human Research Review Committee of the Medical College of Wisconsin at (414)456-8505 for further information on the provision of medical care without charge under the terms of this paragraph.

FURTHER INFORMATION: If I have further questions concerning this project at any time, I understand that I am free to ask them of Tom P. Aufderheide, MD, by calling (414)805-6452, who will be available to answer them.

Signature of Subject or Authorized Representative

Date

Signature of Witness

Date

I have defined and fully explained the study as described herein to the subject.

TYPE OR PRINT: _____
Name of Principal Investigator or Authorized Representative

TYPE OR PRINT: _____
Position Title

Signature

Date

MEDICAL COLLEGE OF WISCONSIN
STATEMENT OF VOLUNTEER CONSENT FOR CLINICAL STUDY

(When the word "I" is used in the consent form, it will be understood to mean "I/my child.")

INTRODUCTION: I, _____, hereby agree to participate in the investigation titled "The Public Access Defibrillation Phase I (PAD-I) Trial." I understand that while the program will be under the supervision of Tom P. Aufderheide, MD, other professional persons may be designated to assist or act for him.

PURPOSE: The purpose of the study is to determine if treatment of cardiac arrest (sudden stoppage of the heart due to an abnormal rhythm) by non-medical, trained, lay volunteer responders with automated external defibrillators (AEDs) will result in improved survival for victims of cardiac arrest. AEDs are small, easy to use, medical devices that shock the heart by placing pads on the skin of the chest to treat people who have cardiac arrest within the first few minutes following collapse. AEDs have been used by trained medical personnel such as paramedics. New technology has led to improvements in AEDs. These new devices are small and easy to use. AEDs have been carefully tested and, with training, are easy to safely operate. We now want to see if laypersons can effectively use AEDs if they are trained to do so, and to see if AED use within the first few minutes following collapse from cardiac arrest results in improved survival for cardiac arrest victims.

PROCEDURES: If I have sudden cardiac arrest at a participating study site in Milwaukee, I will be randomized (a 50-50 chance, similar to "flipping a coin") to receive one of two treatments: 1) a trained lay responder will recognize my emergency; call 911; perform cardiopulmonary resuscitation (CPR); and shock my heart with an AED, if appropriate. Further treatment will be provided by paramedics responding to the 911 call; or 2) a trained lay responder will recognize my emergency; call 911; and perform CPR. My heart will be shocked, if appropriate, and further treatment provided by paramedics responding to the 911 call.

The experimental aspect of this study is to equip and train laypersons such as shop foremen, merchants, bank tellers, and security guards with automated external defibrillators for use within the first few minutes following collapse from cardiac arrest.

My participation in the project will be to be randomized (a 50-50 chance, similar to "flipping a coin") and receive one of the two treatments listed above within the first few minutes following collapse from cardiac arrest. I will also have the outcome from my resuscitation efforts (including efforts at the scene, paramedic records, and hospital records) documented and scientifically reviewed. If I survive cardiac arrest, someone from the research team will interview me or a member of my family during or after hospitalization. This interview will be conducted in person or by telephone and will require about 10 to 15 minutes of my time. Myself or a family member will be asked questions to determine what activities I am able to perform.

I wish to limit my participation as a subject in the investigation as follows (if none, compared to description of participation above, write "NONE"): _____

RISKS: I have been informed of the discomforts and risks which I may reasonably expect as part of the study. These include lack of benefit of the emergency treatment provided by trained lay responders or paramedics; imperfect performance of emergency actions implemented by trained lay responders, including recognizing the emergency, calling 911, performing CPR, and using the AED; failure of the AED device; or lack of benefit of the AED device. Surviving cardiac arrest with damage to the brain is a potential risk for any victim of cardiac arrest. It is possible that survivors in one group may have more damage to the brain. This will be monitored on an ongoing basis and the study stopped if it occurs.

I understand that there may be some unknown or unanticipated discomforts or risks in addition to those specified above because some of the procedures are relatively new and are attempts to advance medical knowledge, but that every precaution will be taken to assure my personal safety and to minimize discomforts.

BENEFITS: I understand that the information which is obtained may be useful scientifically and possibly helpful to others. The benefit to me which may reasonably be expected from participating in this study is a possibly increased chance of survival, but I understand that this is not guaranteed.

FINANCIAL RISKS: I understand that some third party payers (insurance companies, HMOs, etc.) may not pay for hospitalization, treatments, or procedures which are determined to be experimental. I agree that all costs not paid by my insurance will be my own financial responsibility.

ALTERNATIVE PROCEDURES: I understand that there are no appropriate alternative procedures which might be advantageous for me.

ANSWER INQUIRIES: Dr./Ms./Mr. _____ has explained the above matters to me, and I understand that explanation. (S)he has offered to answer my questions concerning the procedures involved in this study.

CONFIDENTIALITY: I have been promised that any information obtained from this investigation that can be identified with me will remain confidential or will be disclosed only with my permission. However, I am in agreement that scientific data or medical information not identifiable with me resulting from the study may be presented at meetings and published so that the information can be useful to others.

I hereby authorize the United States Food and Drug Administration (FDA), the Coordinating Center for this study at the University of Washington, and the Principal Investigator, Tom P. Aufderheide, MD, and his research team to have access to my records concerning this research study.

NO PREJUDICE: I have been informed that my decision about whether or not to participate will not prejudice my present or future relationship with the Medical College of Wisconsin or the staffs of these institutions; nor will it influence the quantity or quality of care which is otherwise available to me. If I participate, I understand that I am free to withdraw at any time without prejudice, and that withdrawal would not in any way affect the nature of the care or treatment otherwise available to me. I understand that I may contact the Chairman of the Human Research Review Committee of the Medical College of Wisconsin at (414)456-8505 for further information related to the research and my rights as a subject.

COMPENSATION FOR INJURIES: I agree to take the risks listed above. If unexpected injuries which are not discussed in the paragraph entitled "Risks" occur, physician faculty of the Medical College of Wisconsin will provide me humanitarian emergency care without charging me a physician's fee for such treatment. Such free care does not mean that negligence has occurred; compensation may or may not be payable. I understand that I may contact the Chairman of the Human Research Review Committee of the Medical College of Wisconsin at (414)456-8505 for further information on the provision of medical care without charge under the terms of this paragraph.

FURTHER INFORMATION: If I have further questions concerning this project at any time, I understand that I am free to ask them of Tom P. Aufderheide, MD, by calling (414)257-6060, who will be available to answer them.

Signature of Subject or Authorized Representative _____ Date _____

Signature of Witness _____ Date _____

I have defined and fully explained the study as described herein to the subject.

TYPE OR PRINT: _____
Name of Principal Investigator or Authorized Representative

TYPE OR PRINT: _____
Position Title

Signature _____ Date _____

ASSENT OF MINOR: In my opinion, the child has not reached the age of assent.

Signature of Principal Investigator _____ Date _____

The above has been explained to me, and I agree to participate.

Signature of Minor _____ Date _____

MEDICAL COLLEGE OF WISCONSIN
STATEMENT OF VOLUNTEER CONSENT FOR CLINICAL STUDY
AFTER WAIVED CONSENT

(When the word “I” is used in the consent form, it will be understood to mean “I/my child.”)

INTRODUCTION: I, _____, hereby agree to participate in the investigation titled “The Public Access Defibrillation Phase I (PAD-I) Trial.” I understand that while the program will be under the supervision of Tom P. Aufderheide, MD, other professional persons may be designated to assist or act for him.

PURPOSE: The purpose of the study is to determine if treatment of cardiac arrest (sudden stoppage of the heart due to an abnormal rhythm) by non-medical, trained, lay volunteer responders with automated external defibrillators (AEDs) will result in improved survival for victims of cardiac arrest. AEDs are small, easy to use, medical devices that shock the heart by placing pads on the skin of the chest to treat people who have cardiac arrest within the first few minutes following collapse. AEDs have been used in hospitals, emergency rooms, and ambulances for many years. These devices are usually used by trained medical personnel such as paramedics. New technology has led to improvements in AEDs. These new devices are small and easy to use. AEDs have been carefully tested and, with training, are easy to safely operate. We now want to see if laypersons can effectively use AEDs if they are trained to do so, and to see if AED use within the first few minutes following collapse from cardiac arrest results in improved survival for cardiac arrest victims.

PROCEDURES: I had a sudden cardiac arrest at a participating study site in Milwaukee. I was randomized (a 50-50 chance, similar to “flipping a coin”) to receive one of two treatments: 1) a trained lay responder recognized my emergency; called 911; performed cardiopulmonary resuscitation (CPR); and shocked my heart with an AED, if it was appropriate. Further treatment was provided by paramedics that responded to the 911 call; or 2) a trained lay responder recognized my emergency; called 911; and performed CPR. My heart was shocked, if appropriate, and further treatment was provided by the paramedics that responded to the 911 call.

Defibrillation must be performed within a few minutes of the cardiac arrest. As a result, it was impossible to obtain my consent or my next-of-kin’s consent prior to enrolling me in this study. At this point I am being asked for my consent to continue participating in the study.

Continued participation involves allowing the research team to collect information about my treatment, recovery, and general health after my cardiac arrest. The research team would also like to review my hospital records to determine what treatment I received in the hospital, and the extent of my recovery by the time of hospital discharge. Part of this data collection involves analyzing the cost of my hospitalization.

I agree to allow a member of the research team to contact me every month after my hospital discharge for 3 months, then every 3 months for 2 years. During this contact either I or a family member will be asked a series of questions related to my mental status, my day-to-

day health status, my quality of life, and my medical/care/treatments/procedures/hospitalizations to determine the cost of my care.

The mental status survey will be completed only at the 3 month contact, evaluating my ability to remember things such as where and when I was born, simple subtraction and recalling words. It takes about 20 minutes to complete.

The health status survey will be completed at 3 months and every 3 months during the follow-up contact evaluating my physical health related to such things as my ability to hear, see, talk, and walk. It takes 20-30 minutes to complete. It asks about my ability to perform physical activity and an assessment of how my heart problem is affecting my everyday life in relationships with family and friends. Some questions will ask me to rate my feeling of fear, discouragement, and depression.

Assesment of the cost of my medical care will be performed each month for 3 months and will simply consist of questions about whether I have been hospitalized and what tests or procedures have been performed since my last contact.

The cost and quality-of-life questionnaires can be conducted either in person or by telephone, and a family member may be asked to help determine how I am doing.

All of the treatment for my cardiac condition will be determined by my physicians, and this study will not interfere with such treatment in any way. The only treatment being evaluated is the defibrillation.

I wish to limit my participation as a subject in the investigation as follows (if none, compared to description of participation above, write "NONE"): _____

RISKS: : I have been informed of the discomforts and risks which I may reasonably expect as part of the study. These include lack of benefit of the emergency treatment provided by trained lay responders or paramedics; imperfect performance of emergency actions implemented by trained lay responders, including recognizing the emergency, calling 911, performing CPR, and using the AED; failure of the AED device; or lack of benefit of the AED device. Though taught to call 911 first, there was a small risk that the volunteer may have delayed calling 911 as he/she tried to use the defibrillator, which could make the chance of survival or neurologic injury worse. Surviving cardiac arrest with damage to the brain is a potential risk for any victim of cardiac arrest. It is possible that survivors in one group may have more damage to the brain. This will be monitored on an ongoing basis and the study stopped if it occurs.

The risks or discomfort associated with continued participation in this study include a small time commitment when I am asked about my health, the cost of my medical care, and my quality-of-life. I could experience some psychological distress at having to remember my cardiac arrest and the subsequent hospitalization, or at having to consider questions which I do not ordinarily think about.

I understand that there may be some unknown or unanticipated discomforts or risks in addition to those specified above because some of the procedures are relatively new and are attempts to advance medical knowledge, but that every precaution will be taken to assure my personal safety and to minimize discomforts.

BENEFITS: I understand that the information which is obtained may be useful scientifically and possibly helpful to others. The benefit to me which may reasonably be expected from participating in this study is a possibly increased chance of survival, but I understand that this is not guaranteed.

FINANCIAL RISKS: I understand that some third party payers (insurance companies, HMOs, etc.) may not pay for hospitalization, treatments, or procedures which are determined to be experimental. I agree that all costs not paid by my insurance will be my own financial responsibility.

ALTERNATIVE PROCEDURES: I understand that there are no appropriate alternative procedures which might be advantageous for me.

ANSWER INQUIRIES: Dr./Ms./Mr. _____ has explained the above matters to me, and I understand that explanation. (S)he has offered to answer my questions concerning the procedures involved in this study.

CONFIDENTIALITY: I have been promised that any information obtained from this investigation that can be identified with me will remain confidential or will be disclosed only with my permission. However, I am in agreement that scientific data or medical information not identifiable with me resulting from the study may be presented at meetings and published so that the information can be useful to others.

I hereby authorize the United States Food and Drug Administration (FDA), the Coordinating Center for this study at the University of Washington, and the Principal Investigator, Tom P. Aufderheide, MD, and his research team to have access to my records concerning this research study.

NO PREJUDICE: I have been informed that my decision about whether or not to participate will not prejudice my present or future relationship with the Medical College of Wisconsin or the staffs of these institutions; nor will it influence the quantity or quality of care which is otherwise available to me. If I participate, I understand that I am free to withdraw at any time without prejudice, and that withdrawal would not in any way affect the nature of the care or treatment otherwise available to me. I understand that I may contact the Chairman of the Human Research Review Committee of the Medical College of Wisconsin at (414)456-8505 for further information related to the research and my rights as a subject.

COMPENSATION FOR INJURIES: I agree to take the risks listed above. If unexpected injuries which are not discussed in the paragraph entitled "Risks" occur, physician faculty of the Medical College of Wisconsin will provide me humanitarian emergency care without charging me a physician's fee for such treatment. Such free care does not mean that negligence has occurred; compensation may or may not be payable. I understand that I

MEDICAL COLLEGE OF WISCONSIN
STATEMENT OF VOLUNTEER INFORMED CONSENT
FOR CLINICAL STUDY FOR FAMILY OF CARDIAC ARREST VICTIMS

INTRODUCTION: I, _____, hereby agree to allow my family member _____ to participate in the investigation titled “The Public Access Defibrillation Phase I (PAD-I) Trial.” I understand that while the program will be under the supervision of Tom P. Aufderheide, MD, other professional persons may be designated to assist or act for him.

PURPOSE: The purpose of the study is to determine if treatment of cardiac arrest (sudden stoppage of the heart due to an abnormal rhythm) by non-medical, trained, lay volunteer responders with automated external defibrillators (AEDs) will result in improved survival for victims of cardiac arrest. AEDs are small, easy to use, medical devices that shock the heart by placing pads on the skin of the chest to treat people who have cardiac arrest within the first few minutes following collapse. AEDs have been used in hospitals, emergency rooms, and ambulances for many years. These devices are usually used by trained medical personnel such as paramedics. New technology has led to improvements in AEDs. These new devices are small and easy to use. AEDs have been carefully tested and, with training, are easy to safely operate. We now want to see if laypersons can effectively use AEDs if they are trained to do so, and to see if AED use within the first few minutes following collapse from cardiac arrest results in improved survival for cardiac arrest victims.

My relative had a cardiac arrest at a participating study site in Milwaukee. (S)he was randomized (50-50 chance, similar to flipping a coin) to receive one of two treatments: 1) a trained lay responder recognized his/her emergency; called 911; performed cardiopulmonary resuscitation (CPR); and shocked his/her heart with an AED, if it was appropriate. Further treatment was provided by paramedics that responded to the 911 call; or 2) a trained lay responder recognized his/her emergency; called 911; and performed CPR. My relative's heart was shocked, if appropriate, and further treatment was provided by the paramedics that responded to the 911 call.

Defibrillation must be performed within a few minutes of the cardiac arrest. As a result, it was impossible to obtain my consent or my relative's consent prior to enrolling him/her in this study. At this point I am being asked for my consent to allow the continued participation of my relative in the study.

Continued participation involves allowing the research team to collect information about his/her treatment, recovery, and general health after the cardiac arrest. The research team would also like to review his/her hospital records to determine what treatment he/she received in the hospital and the extent of recovery by the time of hospital discharge. Part of this data collection involves analyzing the cost of his/her hospitalization.

I agree to allow a member of the research team to contact my relative every month after his/her hospital discharge for 3 months, then every 3 months for 2 years. During this contact either I or the patient will be asked a series of questions related to the patient's

mental status, day-to-day health status, quality of life, and medical/care/treatments/procedures/ hospitalizations to determine the cost of his/her care.

The mental status survey will be completed only at the 3-month contact, evaluating the patient's ability to remember things such as where and when he/she was born, simple subtraction and recalling words. It takes about 20 minutes to complete.

The health status survey will be completed at 3 months and every 3 months during the follow-up contact evaluating the patient's physical health related to such things as his/her ability to hear, see, talk, and walk. It takes 20-30 minutes to complete. It asks about his/her ability to perform physical activity and an assessment of how his/her heart problem is affecting his/her everyday life in relationships with family and friends. Some questions will ask me to rate his/her feeling of fear, discouragement, and depression.

Assessment of the cost of his/her medical care will be performed each month for 3 months and will simply consist of questions about whether the patients has been hospitalized and what tests or procedures have been performed since the last contact.

The cost and quality-of-life questionnaires can be conducted either in person or by telephone, and I may be asked to help determine how the patient is doing.

All of the treatment for my relative's cardiac condition will be determined by his/her physicians, and this study will not interfere with such treatment in any way. The only treatment being evaluated is the defibrillation.

I wish to limit my relative's participation as a subject in the investigation as follows (if none, compared to description of participation above, write "NONE"): _____

RISKS: I have been informed of the discomforts and risks which my relative may reasonably expect as part of the study. These include lack of benefit of the emergency treatment provided by trained lay responders or paramedics; imperfect performance of emergency actions implemented by trained lay responders, including recognizing the emergency, calling 911, performing CPR, and using the AED; failure of the AED device; or lack of benefit of the AED device. Though taught to call 911 first, there was a small risk that the volunteer may have delayed calling 911 as he/she tried to use the defibrillator, which could make the chance of survival or neurologic injury worse. Surviving cardiac arrest with damage to the brain is a potential risk for any victim of cardiac arrest. It is possible that survivors in one group may have more damage to the brain. This will be monitored on an ongoing basis and the study stopped if it occurs.

The risks or discomfort associated with continued participation in this study include a small time commitment when your relative is asked about his/her health, the cost of his/her medical care, and his/her quality-of-life. My relative could experience some psychological distress at having to remember the cardiac arrest and the subsequent hospitalization, or at having to consider questions which he/she does not ordinarily think about.

I understand that there may be some unknown or unanticipated discomforts or risks in addition to those specified above because some of the procedures are relatively new and are attempts to advance medical knowledge, but that every precaution will be taken to assure my relative's personal safety and to minimize discomforts.

BENEFITS: I understand that the information which is obtained may be useful scientifically and possibly helpful to others. The benefit to my relative which may reasonably be expected from participating in this study is a possibly increased chance of survival, but I understand that this is not guaranteed.

FINANCIAL RISKS: I understand that some third party payers (insurance companies, HMOs, etc.) may not pay for hospitalization, treatments, or procedures which are determined to be experimental. I agree that all costs not paid by my insurance will be my relative's financial responsibility.

ALTERNATIVE PROCEDURES: I understand that there are no appropriate alternative procedures which might be advantageous for my relative.

ANSWER INQUIRIES: Dr./Ms./Mr. _____ has explained the above matters to me, and I understand that explanation. (S)he has offered to answer my questions concerning the procedures involved in this study.

CONFIDENTIALITY: I have been promised that any information obtained from this investigation that can be identified with my relative will remain confidential or will be disclosed only with my, or my relative's permission. However, I am in agreement that scientific data or medical information not identifiable with my relative resulting from the study may be presented at meetings and published so that the information can be useful to others.

I hereby authorize the United States Food and Drug Administration (FDA), the Coordinating Center for this study at the University of Washington, and the Principal Investigator, Tom P. Aufderheide, MD, and his research team to have access to my relative's records concerning this research study.

NO PREJUDICE: I have been informed that my decision about whether or not to allow my relative to participate will not prejudice his/her present or future relationship with the Medical College of Wisconsin or the staffs of these institutions; nor will it influence the quantity or quality of care which is otherwise available to him/her. If my relative participates, I understand that he/she is free to withdraw at any time without prejudice, and that withdrawal would not in any way affect the nature of the care or treatment otherwise available to him/her. I understand that I may contact the Chairman of the Human Research Review Committee of the Medical College of Wisconsin at (414)456-8505 for further information related to the research and my relative's rights as a subject.

COMPENSATION FOR INJURIES: I agree to have my relative take the risks listed above. If unexpected injuries which are not discussed in the paragraph entitled "Risks" occur, physician faculty of the Medical College of Wisconsin will provide me humanitarian

emergency care without charging my relative a physician's fee for such treatment. Such free care does not mean that negligence has occurred; compensation may or may not be payable. I understand that I may contact the Chairman of the Human Research Review Committee of the Medical College of Wisconsin at (414)456-8505 for further information on the provision of medical care without charge under the terms of this paragraph.

FURTHER INFORMATION: If I have further questions concerning this project at any time, I understand that I am free to ask them of Tom P. Aufderheide, MD, by calling (414)805-6452, who will be available to answer them.

Signature of Subject or Authorized Representative
Relationship: _____

Date

Signature of Witness

Date

I have defined and fully explained the study as described herein to the subject.

TYPE OR PRINT: _____
Name of Principal Investigator or Authorized Representative

TYPE OR PRINT: _____
Position Title

Signature

Date

ASSENT OF MINOR: In my opinion, the child has not reached the age of assent.

Signature of Principal Investigator

Date

The above has been explained to me, and I agree to participate.

Signature of Minor

Date

MEDICAL COLLEGE OF WISCONSIN
STATEMENT OF VOLUNTEER CONSENT FOR CLINICAL STUDY
AFTER FAMILY CONSENT

(When the word “I” is used in the consent form, it will be understood to mean “I/my child.”)

INTRODUCTION: I, _____, hereby agree to participate in the investigation titled “The Public Access Defibrillation Phase I (PAD-I) Trial.” I understand that while the program will be under the supervision of Tom P. Aufderheide, MD, other professional persons may be designated to assist or act for him.

PURPOSE: The purpose of the study is to determine if treatment of cardiac arrest (sudden stoppage of the heart due to an abnormal rhythm) by non-medical, trained, lay volunteer responders with automated external defibrillators (AEDs) will result in improved survival for victims of cardiac arrest. AEDs are small, easy to use, medical devices that shock the heart by placing pads on the skin of the chest to treat people who have cardiac arrest within the first few minutes following collapse. AEDs have been used in hospitals, emergency rooms, and ambulances for many years. These devices are usually used by trained medical personnel such as paramedics. New technology has led to improvements in AEDs. These new devices are small and easy to use. AEDs have been carefully tested and, with training, are easy to safely operate. We now want to see if laypersons can effectively use AEDs if they are trained to do so, and to see if AED use within the first few minutes following collapse from cardiac arrest results in improved survival for cardiac arrest victims.

PROCEDURES: I had a sudden cardiac arrest at a participating study site in Milwaukee. I was randomized (a 50-50 chance, similar to “flipping a coin”) to receive one of two treatments: 1) a trained lay responder recognized my emergency; called 911; performed cardiopulmonary resuscitation (CPR); and shocked my heart with an AED, if it was appropriate. Further treatment was provided by paramedics that responded to the 911 call; or 2) a trained lay responder recognized my emergency; called 911; and performed CPR. My heart was shocked, if appropriate, and further treatment was provided by the paramedics that responded to the 911 call.

Defibrillation must be performed within a few minutes of the cardiac arrest. As a result, it was impossible to obtain my consent or my next-of-kin's consent prior to enrolling me in this study. At this point I am being asked for my consent to continue participating in the study.

Continued participation involves allowing the research team to collect information about my treatment, recovery, and general health after my cardiac arrest. The research team would also like to review my hospital records to determine what treatment I received in the hospital and the extent of my recovery by the time of hospital discharge. Part of this data collection involves analyzing the cost of my hospitalization.

I agree to allow a member of the research team to contact me every month after my hospital discharge for 3 months, then every 3 months for 2 years. During this contact either I or a family member will be asked a series of questions related to my mental status, my day-to-

day health status, my quality of life, and my medical/care/treatments/procedures/hospitalizations to determine the cost of my care.

The mental status survey will be completed only at the 3-month contact, evaluating my ability to remember things such as where and when I was born, simple subtraction and recalling words. It takes about 20 minutes to complete.

The health status survey will be completed at 3 months and every 3 months during the follow-up contact evaluating my physical health related to such things as my ability to hear, see, talk, and walk. It takes 20-30 minutes to complete. It asks about my ability to perform physical activity and an assessment of how my heart problem is affecting my everyday life in relationships with family and friends. Some questions will ask me to rate my feeling of fear, discouragement, and depression.

Assessment of the cost of my medical care will be performed each month for 3 months and will simply consist of questions about whether I have been hospitalized and what tests or procedures have been performed since my last contact.

The cost and quality-of-life questionnaires can be conducted either in person or by telephone, and a family member may be asked to help determine how I am doing.

All of the treatment for my cardiac condition will be determined by my physicians, and this study will not interfere with such treatment in any way. The only treatment being evaluated is the defibrillation.

I wish to limit my participation as a subject in the investigation as follows (if none, compared to description of participation above, write "NONE"): _____

RISKS: I have been informed of the discomforts and risks which I may reasonably expect as part of the study. These include lack of benefit of the emergency treatment provided by trained lay responders or paramedics; imperfect performance of emergency actions implemented by trained lay responders, including recognizing the emergency, calling 911, performing CPR, and using the AED; failure of the AED device; or lack of benefit of the AED device. Though taught to call 911 first, there was a small risk that the volunteer may have delayed calling 911 as he/she tried to use the defibrillator, which could make the chance of survival or neurologic injury worse. Surviving cardiac arrest with damage to the brain is a potential risk for any victim of cardiac arrest. It is possible that survivors in one group may have more damage to the brain. This will be monitored on an ongoing basis and the study stopped if it occurs.

The risks or discomfort associated with continued participation in this study include a small time commitment when I am asked about my health, the cost of my medical care, and my quality-of-life. I could experience some psychological distress at having to remember my cardiac arrest and the subsequent hospitalization, or at having to consider questions which I do not ordinarily think about.

I understand that there may be some unknown or unanticipated discomforts or risks in addition to those specified above because some of the procedures are relatively new and are attempts to advance medical knowledge, but that every precaution will be taken to assure my personal safety and to minimize discomforts.

BENEFITS: I understand that the information which is obtained may be useful scientifically and possibly helpful to others. The benefit to me which may reasonably be expected from participating in this study is a possibly increased chance of survival, but I understand that this is not guaranteed.

FINANCIAL RISKS: I understand that some third party payers (insurance companies, HMOs, etc.) may not pay for hospitalization, treatments, or procedures which are determined to be experimental. I agree that all costs not paid by my insurance will be my own financial responsibility.

ALTERNATIVE PROCEDURES: I understand that there are no appropriate alternative procedures which might be advantageous for me.

ANSWER INQUIRIES: Dr./Ms./Mr. _____ has explained the above matters to me, and I understand that explanation. (S)he has offered to answer my questions concerning the procedures involved in this study.

CONFIDENTIALITY: I have been promised that any information obtained from this investigation that can be identified with me will remain confidential or will be disclosed only with my permission. However, I am in agreement that scientific data or medical information not identifiable with me resulting from the study may be presented at meetings and published so that the information can be useful to others.

I hereby authorize the United States Food and Drug Administration (FDA), the Coordinating Center for this study at the University of Washington, and the Principal Investigator, Tom P. Aufderheide, MD, and his research team to have access to my records concerning this research study.

NO PREJUDICE: I have been informed that my decision about whether or not to participate will not prejudice my present or future relationship with the Medical College of Wisconsin or the staffs of these institutions; nor will it influence the quantity or quality of care which is otherwise available to me. If I participate, I understand that I am free to withdraw at any time without prejudice, and that withdrawal would not in any way affect the nature of the care or treatment otherwise available to me. I understand that I may contact the Chairman of the Human Research Review Committee of the Medical College of Wisconsin at (414)456-8505 for further information related to the research and my rights as a subject.

COMPENSATION FOR INJURIES: I agree to take the risks listed above. If unexpected injuries which are not discussed in the paragraph entitled "Risks" occur, physician faculty of the Medical College of Wisconsin will provide me humanitarian emergency care without charging me a physician's fee for such treatment. Such free care does not mean that negligence has occurred; compensation may or may not be payable. I understand that I

may contact the Chairman of the Human Research Review Committee of the Medical College of Wisconsin at (414)456-8505 for further information on the provision of medical care without charge under the terms of this paragraph.

FURTHER INFORMATION: If I have further questions concerning this project at any time, I understand that I am free to ask them of Tom P. Aufderheide, MD, by calling (414)805-6452, who will be available to answer them.

Signature of Subject or Authorized Representative

Date

Signature of Witness

Date

I have defined and fully explained the study as described herein to the subject.

TYPE OR PRINT: _____

Name of Principal Investigator or Authorized Representative

TYPE OR PRINT: _____

Position Title

Signature

Date

ASSENT OF MINOR: In my opinion, the child has not reached the age of assent.

Signature of Principal Investigator

Date

The above has been explained to me, and I agree to participate.

Signature of Minor

Date

especially helpful to the study. Device manufacturers and the American Heart Association may be useful to the Intervention Subcommittee.

Third parties will not have access to primary results prior to the public (except within 48 hours prior thereto) or access to more of the dataset than is the basis for reports that have been published or to which other qualified members of the scientific community have access, with the exception that device-specific information (the study is not powered to evaluate the 3 devices comparatively but may provide useful device-specific information), will be provided to the appropriate manufacturer on an ongoing basis. This is in the interests of the study in that, if this information leads to improvements in the device during the course of the study, it may also help to increase the likelihood of a positive result.

Waiver of Informed Consent Under Emergency Research Circumstances

Introduction

Informed consent is impossible to obtain from patients in cardiac arrest. This protocol therefore qualifies for consideration of waiver of informed consent under emergency research circumstances. The Food and Drug Administration has recently issued its final ruling on waiver of informed consent. The principal investigator has discussed these issues at length with Michelle Biros, MS, MD, an emergency medicine physician who interacted extensively with the United States Congress and the Food and Drug Administration during development of the waiver of informed consent process. A copy of Dr. Biros' emergency medicine communication titled "Update: Application of the FDA's Final Rule on informed consent and waiver of informed consent under emergency research circumstances" is located in Appendix 7. As described in this document, the most important safeguards built into the Final Rule are the requirements for community consultation, public notification, and subsequent notification of patient enrollment.

Community consultation

Community consultation involves the identification of a surrogate community that represents the population from which potential research candidates would be drawn. This community must be actively informed of the research activity and understand the nature of the research project, its goals and objectives, and the protocols involved. The community must have the opportunity to ask questions and raise concerns about the project itself. Although the community has no veto powers, the Institutions Research Committee must carefully consider the needs and the consensus of the community in which the research will be conducted.

The reader should be aware that the Principal Investigator, Tom P. Aufderheide, MD, is currently involved with this community consultation process with a different study titled "Comparison of standard CPR versus standard CPR plus an inspiratory impedance threshold valve (Resuscitator Valve™) in patients with out-of-hospital cardiac arrest" (HRRC #39-98; IRC #98-20) and is working closely with the Chair of the Human Research Review Committee, Dr. Kevin Murray, the members of the Human Research Review Committee, Arthur Derse, MD, JD, Associate Clinical Professor of Emergency Medicine and member of the

Bioethics Department at the Medical College of Wisconsin, and Robert M. Nelson, MD, PhD, Associate Professor of Pediatrics and Bioethics. Dr. Aufderheide will proceed in an identical fashion to initiate and implement community consultation for this proposed protocol with approval contingent upon successful completion of the community consultation process approved by Dr. Kevin Murray and the Human Research Review Committee.

Public notification

The Final Rule requires informing the community that a research project will be done that may impact members of the local population. This notification must be made prior to the initiation of the project and also must occur after the project is completed. The reader should be aware that the Principal Investigator, Dr. Tom Aufderheide, is currently engaged in developing a public notification process for a different study previously mentioned (HRRRC #39-98; IRC #98-20) in conjunction with the Human Research Review Committee at the Medical College of Wisconsin and Ms. Toranj Marphetia and Mr. Richard Katschke in the Public Affairs Department at the Medical College of Wisconsin. Dr. Aufderheide intends to develop a similar public notification process in conjunction with the Human Research Review Committee and Public Affairs Department of the Medical College of Wisconsin, including a media plan approved by Kevin Murray, MD, and the HRRRC at MCW.

Subsequent notification of patient enrollment

According to the FDA's Final Rule, all patients who are enrolled in studies must subsequently be notified that such enrollment occurred. If the patient is unable to comprehend this, the surrogates or legally authorized representatives must be informed. If a study patient dies as a consequence of their serious illness, the investigator is required to inform the patient's representative of the study enrollment.

The principal investigator has discussed this issue at length with Dr. Michelle Biros. Dr. Biros informed study investigators that retrospective written informed consent from patients or family members was not the intent of the FDA's Final Rule. Instead, either 1) "notification" to the patient or family member(s) that research had been performed or 2) documentation that a concerted effort to contact family members had occurred. Since survival to hospital discharge following cardiac arrest is only approximately 15%, investigators anticipate the majority of their efforts regarding subsequent notification of patient enrollment to be contacting family members. To meet these requirements, investigators propose that the PAD-I research nurse will attempt to personally interview any patient who achieves consciousness and is capable of comprehending and discussing these issues in order to inform them of the ongoing study and to address their concerns. Alternatively, the research nurse will attempt to identify and contact the patient's relatives by phone. It is anticipated that this can be accomplished by contacting the intensive care unit nurse who is caring for the patient following admission or by determining the patient's home telephone number using information from the paramedic run report and the Milwaukee telephone directory. If the patient does not have a telephone and no relatives can be identified, the research nurse will

send a letter to the patient's home address. In addition, the research nurse will contact the Medical Examiner to determine next of kin and identify the patient's relatives in that fashion.

It is proposed that the research nurse will either 1) document successful notification of the patient or family or 2) document no response from two letters sent or 3) document no response following three telephone calls.

Institutions Research Committee and Human Research Review Committee Involvement in the Waiver of Informed Consent Process

As indicated, Dr. Aufderheide is currently involved with a waiver of informed consent process for a separate protocol. It is understood that the Food and Drug Administration has not defined community consultation, public notification, or subsequent notification of patient enrollment. Accordingly, the investigators will actively participate in this process with the Human Research Review Committee at the Medical College of Wisconsin regarding these issues to protect human subject rights and optimally comply with the FDA's Final Rule. Study investigators recognize that the final approval to proceed with this investigation is dependent on the outcome of community consultation, public notification, and review of this process by the Human Research Review Committee.

Schedule of Community Consultation and Community Notification

Community consultation

Dr. Aufderheide will meet with the Chair of the Human Research Review Committee at the Medical College of Wisconsin, Kevin J. Murray, MD, and Arthur R. Derse, MD, JD, Associate Clinical Professor of Emergency Medicine and member of the Bioethics Department at the Medical College of Wisconsin, and Robert M. Nelson, MD, PhD, Associate Professor of Pediatrics and Bioethics. During that meeting, what the community consultation will consist of will be determined. In a non-related, previous study, this group of individuals determined that community consultation should consist of a 1-1/2-hour meeting involving both invited participants and participants who would attend because of public notification. For the present study, invited participants could include: 1) survivors of cardiac arrest (including children between the ages of 8-17 and adults); 2) family members of survivors and non-survivors of cardiac arrest; 3) patients with risk factors for coronary artery disease; 4) community leaders; 5) representatives of community organizations; and 6) the general public. Minutes of this meeting will be transcribed. The members of this meeting will also attend the community consultation and determine if acceptable consultation has occurred. If not, another community consultation would be scheduled. Dr. Aufderheide will determine patient demographics for cardiac arrest in Milwaukee County, including race, gender, age, and geographic location.

Community consultation agenda will include a 20-minute presentation by Dr. Aufderheide, followed by a 1- to 1-1/2-hour discussion (community consultation). The content for the community consultation may include 1) background information on cardiac arrest; 2) current lack of effective treatment

for cardiac arrest; 3) profile of the typical cardiac arrest patient in Milwaukee County; 4) description of the protocol; 5) rationale for the experimental intervention; 6) what randomization means; 7) potential risks of the study; 8) potential benefits of the study; 9) differences between research and treatment; 10) why waiver of consent is needed for this study as opposed to other studies; and 11) the ethical constructs of waiver of consent.

To initiate selection of community organizations and individuals to invite to the community consultation meeting, Dr. Aufderheide will consult with organizations such as the Wisconsin American Heart Association, the Milwaukee Black Health Coalition, the Milwaukee County Paramedic Training Center, the Milwaukee EMS Research Committee, the Milwaukee Department on Aging, Village Adult Services, pediatric organizations, hospital administrators, and practicing cardiologists in the Milwaukee area. An initial list of organizations to invite will be developed through consultations with these organizations. Each organization invited will then be asked to suggest additional organizations to invite. Cardiac arrest survivors, family members of cardiac arrest survivors, and family members of non-survivors of cardiac arrest will be contacted by physician referral. A location for the community consultation meeting, outside the Medical College of Wisconsin (such as the Italian Community Center), will be selected because of a relatively central location and extensive history of outreach to the community.

Dr. Aufderheide will target approximately 150 survivors of cardiac arrest, family members of survivors of cardiac arrest, family members of non-survivors of cardiac arrest, and individuals with risk factors for coronary artery disease to be invited. Individuals and organizations will be specifically selected to match, as closely as possible, patient demographics, including race, age, gender, and geographic location. Individuals participating in the community consultation, then, will consist of a wide range of experts and laypersons within the Milwaukee community that represents stakeholders in the issue of cardiac arrest and will have substantially different backgrounds and interest in this issue. The Human Research Review Committee at the Medical College of Wisconsin will receive intermittent notification of the specifics of this ongoing process.

In addition, representatives from the following organizations represent a sample of possible organizations to participate in the community consultation:

1. American Red Cross	29. Healthwatch / Community Advocates
2. Visiting Nurse Association	30. Family Services of Milwaukee
3. Milwaukee Chapter of the Black Nurses' Association	31. Village Adult Services
4. Black Health Coalition	32. Acting Commissioner of Health (Seth Foldy, MD)
5. La Guadalupe Senior Center	33. AARP (Louis Toth, District Coordinator)
6. Department on Aging	34. MCW Faculty Physicians and Clinics
7. Paramedic Training Center	35. Rev. Benjamin Nabors
8. Milwaukee County Health Care Programs	36. Latino Health Organization
9. Medical Society of Milwaukee County	37. Wisconsin Health and Hospital Association
10. Milwaukee Academy of Medicine	38. Sinai Samaritan Medical Center
11. American Heart Association	39. Salvation Army Clinic
12. Hmong American Women's Association	40. St. Mary's Hospital
13. Hmong Christian Community United Methodist Church	41. Milwaukee Health Department
14. Sixteenth Street Community Health Center	42. Milwaukee Women's Center
15. American Diabetes Association	43. Department of Human Services
16. American Lung Association	44. SET Ministry
17. Southeast Asian Consulting Services	45. St. Michael's Hospital
18. St. Anthony's Church	46. Ronald J. Pirralo, MD, MHSA (Milwaukee County EMS Medical Director)
19. Milwaukee Jewish Home	47. Jonathan M. Rubin, MD (Milwaukee County EMS Associate Medical Director)
20. Sethi Medical Services	48. Joseph C. Darin, MD (Wisconsin State EMS Director)
21. Shafi Medical Center, SC	49. Maureen Cassidy (Vice-President of Public Advocacy, American Heart Association)
22. UW-M Silver Spring Clinic	50. Tom Brophy (Milwaukee Hospital Association)
23. Harambee Urgent Care	51. K&R Medical, Inc.
24. Johnson Primary Care Clinic	52. Alonzo Walker, MD (Representative from Cream City Medical Society)
25. Rainbow Community Health Center	53. Blia Kong, RN, MSN
26. Isaac Cogg's Health Center	54. Pat Zapp (Director, Diabetes Control Program)
27. Healthcare for the Homeless	55. St. Francis Hospital
28. St. Ben's Clinic	56. St. Joseph's Hospital

Public notification

Dr. Aufderheide will work with the Medical College of Wisconsin's Public Affairs Department for initial notification of the community consultation meeting, public notification at the onset of the study, and post-study public notification. Planning and development of this process will begin following conditional approval by the Human Research Review Committee at the Medical College of Wisconsin.

A representative from the Medical College of Wisconsin's Public Affairs Department will attend the community consultation meeting to benefit from suggestions from community participants regarding the most effective methods for notifying their community. Dr. Aufderheide will continue to work with a representative from the Medical College of Wisconsin's Public Affairs Department to develop and implement public notification following completion of community consultation. Dr. Aufderheide intends to work with Ms. Toranj Marphetia and Mr. Richard Katschke at the Public Affairs Department and intends to use all available metromedia, including cable TV, radio, TV, print (news, daily and weekly), medical reporters from the *Milwaukee Journal Sentinel*, local news bulletins and flyers, interviews with Dr. Aufderheide on public radio, talk shows, cable TV calendar boards, and 24 community newspapers targeting Blacks, Hispanics, and the elderly. The content of the public notification message will be derived in conjunction with the Human Research Review Committee at the Medical College of Wisconsin; Kevin J. Murray, MD, Chair of the Human Research Review Committee at the Medical College of Wisconsin; Arthur R. Derse, MD, JD, Associate Clinical Professor of Emergency Medicine and member of the Bioethics Department at the Medical College of Wisconsin; and Robert M. Nelson, MD, PhD, Associate Professor of Pediatrics and Bioethics. Content of public disclosure prior to the onset of the study will include risks, benefits, and purpose of the research. Content of public disclosure following termination of this study will include results once they become available.

Timeline for community consultation and public notification

The process of community consultation and public notification will occur as outlined above. An exact timeline has not yet been derived. The process will be initiated following conditional approval of this proposal by the Human Research Review Committee at the Medical College of Wisconsin and will be successfully completed (as determined by the Human Research Review Committee at the Medical College of Wisconsin) prior to initiating the study.

Written Informed Consent

The FDA's Final Rule indicates that wherever informed consent is possible, it should be obtained within the therapeutic time window of the test agent. If circumstances do not permit prospective informed consent, then the protocol may proceed with the waiver of informed consent provided it meets the specific criteria described.

Cardiac arrest victims

By this study's definition and criteria for patient entry, it always will be impossible to acquire prospective informed consent for victims of cardiac arrest. Nonetheless, the principal investigator has included a sample of the "Medical College of Wisconsin Statement of Volunteer Consent for Clinical Study" with this protocol, including the phrase that "When the word 'I' is used in the consent form, it will be understood to mean 'I/my child'," applying to the unlikely event a child eight years of age or greater but less than 18 years of age would suffer cardiac arrest and be entered in the study as well as adult victims (18 years of age or greater) of cardiac arrest. This sample consent is located in Appendix 8. If the individual survives the OOH-CA, informed consent after waived consent will be obtained. This sample consent is located in Appendix 9. In the event that the individual survives the OOH-CA but is still unable to give consent, family informed consent will be obtained. This sample consent is located in Appendix 10.

Targeted non-traditional responders

Targeted non-traditional first responders will be adults (18 years of age or greater) who agree to participate in the training and implementation of the Public Access Defibrillation Phase I (PAD-I) Trial. Half will be randomized to receive the following education: 1) recognizing emergencies, accessing 911, and performing cardiopulmonary resuscitation or 2) recognizing emergencies, accessing 911, performing CPR, and using an AED. Prospective informed consent will be acquired for all targeted non-traditional responders. The informed consent is located in Appendix 12.

Identification of drugs or procedures which may place subjects at risk, the nature of the risks, and the precautions which will be taken

Cardiac Arrest Victims

The lack of benefit of appropriately applied resuscitative efforts by trained lay responders or paramedics, including lack of benefit of use of the AED or defibrillation, is a standard risk for any victim of cardiac arrest undergoing resuscitative efforts.

Milwaukee County paramedics are some of the best trained and capable paramedics in the United States, and survival rates following cardiac arrest are some of the highest in the country. Nonetheless, the outcome from cardiac arrest still remains dismal. Under optimal circumstances (paramedic-witnessed ventricular fibrillation), the survival rate is only 24% (3 of 4 witnessed VF patients die). Overall survival rate in our community (including non-witnessed arrests and cardiac arrest rhythms that usually do not respond to resuscitative efforts) is 9%. It is likely that the study outcome data will reflect similar instances of failure by cardiac arrest victims to respond to resuscitative efforts. It is hoped that cardiac arrest outcome will be improved at both control and intervention sites by implementing the procedures previously outlined.