



UNIVERSITY OF
CALGARY

FACULTY OF MEDICINE

Office of Medical Bioethics
Heritage Medical Research Building/Rm 93
Telephone: (403) 220-7990
Fax: (403) 283-8524

2000-08-14

Dr. A.R. Anton
c/o Emergency Medicine
Room C231
Foothills Hospital
Calgary, Alberta.

Dear Dr. Anton:

Re: Early Access to Defibrillation for Victims of Out-of-Hospital Cardiac Arrest (OOH-CA) – PAD Protocol

The above-named research project (dated January 26, 2000) and the consent forms have been granted ethical approval by the Conjoint Health Research Ethics Board of the Faculties of Medicine, Nursing and Kinesiology, University of Calgary, and the Affiliated Teaching Institutions. The Board conforms to the Tri-Council Guidelines and ICH Guidelines, including membership and requirements for a quorum.

You and your co-investigators are not members of the CHREB and did not participate in review or voting on this study.

Please note that this approval is subject to the following conditions:

- (1) you must obtain approval from your appropriate institution where the research project will be conducted (if applicable);
- (2) an agreement between the Sponsor and the University of Calgary governing conduct of the study must be executed on behalf of the University and Affiliated Hospitals by authorized signing officers;
- (3) a copy of the informed consent form must have been given to each research subject, if required for this study;
- (4) a Progress Report must be submitted in one year, 2001-08-14, containing the following information:
 - (i) the number of subjects recruited;
 - (ii) a description of any protocol modification;
 - (iii) any unusual and/or severe complications, adverse events or unanticipated problems involving risks to subjects or others, withdrawal of subjects from the research, or complaints about the research;
 - (iv) a summary of any recent literature, finding, or other relevant information, especially information about risks associated with the research;
 - (v) a copy of the current informed consent form;
 - (vi) the expected date of termination of this project;
- (5) a Final Report must be submitted at the termination of the project.

Please accept the Board's best wishes for success in your research.

Yours sincerely,

Ian Mitchell, MB, FRCPC
Chair, Conjoint Health Research Ethics Board

c.c. Adult Research Committee
Research Services



Emergency Medical Services

Assurance of Compliance with DHHS regulations for Protection of Human Research Subjects

Emergency Medical Services Department, hereinafter known as the institution, hereby gives assurance that it will comply with the Department of Health and Human Services (DHHS) regulations for the protection of human research subjects (45 CFR 46) as specified below.

PART 1

Ethical Principles and Institutional Policies Governing Research Involving Human Subjects

i. Applicability

Except for research exempted or waived under the DHHS regulations 45 CFR 46.101, Part 1 of this Assurance applies to all research involving human subjects, and all other activities which even in part involve such research, regardless of whether the research is otherwise subject to federal regulation, if:

- (a) the research is sponsored by this institution, or
- (b) the research is conducted by or under the direction of any employee or agent of this institution in connection with institutional responsibilities, or
- (c) the research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
- (d) the research involves the use of this institutions nonpublic information to identify or contact human research subjects or prospective subjects.



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II. Ethical Principles Governing Human Subjects Research

This institution is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report) and as specified below.

- A. This institution recognizes the principles of respect for persons, beneficence (including minimization of harms and maximization of benefits), and justice as stated in the Belmont Report and will apply these principles in all research covered by this Assurance.
- B. This institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human research subjects.

III. Policies

- A. This institution acknowledges that it and its investigations bear full responsibility for the performance of all research covered by this Assurance, including full responsibility for complying with Federal, state and local laws as they may relate to such research.
- B. This institution assures that before human subjects are involved in research, proper consideration will be given to:
 - (1) the risks to the subjects,
 - (2) the anticipated benefits to the subjects and others,
 - (3) the importance of the knowledge that may reasonably be expected to result,
 - (4) the informed consent process to be employed,
 - (5) the provisions to protect the privacy of subjects, and
 - (6) the additional safeguards for vulnerable populations.
- C. This institution recognizes the need for appropriate additional safeguards in research involving subjects who are likely to be vulnerable to coercion or undue influence such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- D. This institution encourages and promotes constructive communication among the institutional officials, research administrators, department heads, research investigators, clinical care staff, human subjects, and all other relevant parties as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.
- E. This institution will exercise appropriate administrative overview carried out at least annually to assure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.

Part 2
IRB, Institution, and Investigator Compliance with 45 CFR 46

I. Applicability

Part 2 of this Assurance applies to the following research project which is conducted or sponsored by this institution and supported by the Department of Health and Human Services (DHHS).

Project Title: *Early Access to Defibrillation for Victims of Out-of-Hospital Cardiac Arrest*

DHHS Project Number: _NO1-HC-95177

Project Principal Investigator: Andy R. Anton MD, FRCPC – Alfred Hallstrom PhD

II. Institutional Responsibilities

- A. This institution has complied and will continue to comply with the requirements of 45 CFR 46 as specified below.
- B. In accordance with the compositional and quorum requirements of 45 CFR 46.107 and 46.108, the Institutional Review Board (IRB) designated in Part 3 and in the attached roster is responsible for the initial and continuing review of this project.
- C. This institution has provided and will continue to provide both meeting space for the IRB and sufficient staff to support the IRB's review and record keeping duties.
- D. In addition to the review and approval of the IRB, this institution has reviewed and sponsors the project referenced above.

III. IRB Review

- A. The IRB shall review, and have the authority to approve, require modification in, or disapprove this research activity or proposed changes in it before human subjects may be involved.
- B. The convened IRB reviewed and approved the above project.
- C. The IRB determined, in accordance with the criteria found at 45 CFR 46.111, and where applicable, 45 CFR 46 Subparts B, C, and D, that protections for human subjects are adequate.
- D. The IRB has the authority to suspend or terminate approval of the above referenced research in accordance with 45 CFR 46.113 for (1) non-compliance with 45 CFR 46, and this Assurance document or the IRB's requirements, and (2) for elimination of unexpected serious harm to subjects.
- E. The IRB has determined that legally effective informed consent [**copy of document must be attached unless specified otherwise by OPRR**] will be obtained in a manner and method which meets the requirements of 45 CFR 46.116 and 46.117.

- F. Certification of IRB approval, at least annually shall be submitted to the DHHS awards unit that issued the award, as a condition for receipt of funds for a non-competing continuation and/or additional involvement of human subjects.
- G. Continuing reviews by the IRB shall be conducted at intervals appropriate to the degree of risk, but not less than once per year. (45 CFR 46.109 [e]). The IRB may be called into an interim review session by the Chairperson at the request of any IRB member or Institutional Official to consider any matter concerned with the rights and welfare of any subject.
- H. The IRB shall prepare and maintain adequate documentation of its activities in accordance with 45 CFR 46.115.
- I. The IRB shall report promptly to institutional officials and the Office for Protection from Research Risks (OPRR):
 - (1) any serious or continuing noncompliance by investigators with the requirements of the IRB,
 - (2) any suspension or termination of IRB approval,
 - (3) any unanticipated problems or injuries involving risks to subjects or others, and
 - (4) any changes in this research activity which are reviewed and approved by the IRB.
- J. Where appropriate, the IRB will determine that adequate additional protections are ensured to fetuses, pregnant women, prisoners, and children as required under Subparts B, C, and D of 45 CFR 46. The IRB will notify OPRR promptly when IRB membership is modified to satisfy the requirements at 45 CFR 46.304 and when the IRB fulfills its duties under 45 CFR 46.305 (c).
- K. The IRB will comply fully with the requirements of all applicable Federal policies and guidelines, including those concerning notification of sero-positivity, counseling, and confidentiality of subjects.

IV. Research Investigator Reporting Responsibilities

- A. Investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of this Assurance and 45 CFR 46.
- B. Research investigators shall report promptly to the IRB proposed changes in this research activity and the changes shall not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subjects.
- C. Research investigators shall report promptly to the IRB any unanticipated problems involving risks to subjects and others.

Part 3

Certification of IRB Approval and Institutional Endorsement

Project Title: *Early Access to Defibrillation for Victims of Out-of-Hospital Cardiac Arrest*

DHHS Project Number: NO1-HC-95177

Project Principal Investigator : Andy R. Anton, MD, FRCPC /Al Hallstrom, PhD

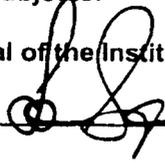
Date of IRB Approval : 2000,08,14 Date of Next Scheduled IRB Review : 2001,08,14

The officials signing below assure that the project referenced above was approved by the IRB of the date indicated and that the project will be conducted in accordance with the requirements of Part 46, Title 45 of the Code of Federal Regulations and this Assurance document. A dated roster listing the current membership of the designated IRB is attached.

As appropriate, the officials signing below further assure that for each protocol in this project for which IRB approval was not possible due to delayed onset of subject involvement, the IRB's institution will provide a copy of the IRB-approved protocol, IRB-approved consent language, and documentation of IRB certification (Optional Form 310), including the applicable Assurance number, to OPRR for approval prior to accrual of human subjects.

I. Authorized Official of the Institution Providing this Assurance

Signature



Date:

2000 October 25th

Name and Title: Tom Sampson, Chief of EMS
Institution: Emergency Medical Services Dept.
Address: P O. Box 2100 Stn M, Calgary Alberta Canada

Telephone: 403 268-2785

Fax: 403 268-4696

II. Authorized Official of the Institution with the IRB

This institution authorizes the designation of its IRB for review of the project referenced in this Assurance

Signature:



Date:

Oct 30 / 2000

Name and Title: I. Mitchell, MB, FRCPC, Director, Office of Medical Bioethics
Institution: University of Calgary
Address: Heritage Medical Research Building/Rm 93 3330 Hospital Drive N.W.
Calgary, Alberta Canada, T2N 4N1
Telephone: 403 220-7990 Fax: 403 283-8524

III. IRB Chairperson

(Must be completed in all cases [see IRB membership list])

Signature:  Date: 30 October 2000

Name and Title: Christopher J. Doig, MD, MSc, FRCPC, Chair, Conjoint Research Ethics Board
Institution: University of Calgary
Address: Heritage Medical Research Building/Rm 93 3330 Hospital Drive N.W.
Calgary, Alberta Canada, T2N 4N1

Telephone: 403 220-7990 Fax: 403 283-8524
MPA Number if applicable: _____

IV. Responsible Project Investigator at Institution Providing this Assurance

I have attached copies of all OPRR requested and IRB approved Informed Consent Documents to be used in this project unless the designated IRB operates under an OPRR-approved Multiple Project Assurance (MPA) or unless OPRR has indicated otherwise.

Signature:  Date: Oct. 25, 2000

Name: Andy R. Anton, MD, FRCPC,
Title: Medical Director Emergency Medical Services/Fire Departments
Institution: Emergency Medical Services
Address: P.O. Box 2100 Stn M, Calgary Alberta Canada

Al Hallstrom, PhD

Telephone: 403 816-4600 Fax: 403 268-3742

All parts of this Assurance are in compliance with the requirements of Part 46, Title 45, of the Code of Federal Regulations.

DHHS Approving Official

Signature: _____ Date: _____

Name:

Address: Assurance Coordinator, Division of Human Subject Protections
Office for Protection from Research Risks (OPRR), OD
NIH MSC 7507
6100 Executive Boulevard, Suite 3B01
Rockville, Maryland 20892-7507 [Courier only: 20852]
Telephone #: 301-496-7041
Fax #: 301-402-0527
E-mail address:

ASSURANCE NUMBER S- _____

An application for new or competing support for continuation in which human subjects will be involved will require a new and separate Assurance, unless the activity is exempt under section 45 CFR 46.101 (b).

SINGLE PROJECT ASSURANCE
(PLEASE RESUBMIT AS CHANGES OCCUR)
INSTITUTIONAL REVIEW BOARD (IRB) MEMBERSHIP

NAME OF INSTITUTION PROVIDING THIS ASSURANCE: The City of Calgary, Emergency Medical Services

NAME OF INSTITUTION WITH THE IRB (IF DIFFERENT FROM ABOVE): Conjoint Health Research Ethics Board

MEMBER NAME			HIGHEST DEGREES EARNED	PRIMARY SCIENTIFIC OR NONSCIENTIFIC SPECIALTY	AFFILIATION WITH INSTITUTION(S) ABOVE (YES/NO; IF YES, WHICH ONE)	A
FIRST	M	LAST				
Ian		Mitchell	MB/ChB	Paediatrics/Bioethics	Professor	Office of Med Faculty of Med 3330 Hospital Calgary, Alber T2N 4N1 Telephone: (4 FAX: (403) 28 IRB CHAIR SIGNATURE NOTE Each IRB non-scientific area institution. Please
Michael	C.	King	PhD	Psychology	Associate Professor	
Kathy		Oberle	PhD	Nursing	Assistant Professor	
*Christopher	J.	Doig	MD/MSc	Medicine/Epidemiology/ Bioethics	Assistant Professor	
J.	Chris	Levy	LLB/LLM	Law	Professor	
**T.	Douglas	Kinsella	CM/MD	Medicine/Bioethics	Professor	
James	H.	Laycraft	LLB	Law	None	
Deborah	J.	Clark	MB/ChB	Paediatrics	Associate Professor	
Sharon	J.	Berling	Diploma	Journalist	None	
Joseph	C.	Dort	MD	Surgery/Neurosciences	Associate Professor	
Gordon	H.	Fick	MD	Community Health Sciences	Professor	
Maeve		O'Beirne	MD	Family Medicine	Professor	
Julian	P.	Midgley	MD	Paediatrics	Assistant Professor	
Gilbert	A.	Schultz (NV)	MD	Biochemistry	Associate Dean (Research)	
Rhiannon	M.	Hughes	MD	Oncology	Assistant Professor	
Jeanne		Besner	PhD	Nursing/Epidemiology	CRIA	
Elijah		Dixon	MD	Surgery	Resident	
Cathy		MacKinnon	BEng	Engineering	None	
Marlene	A.	Reimer (NV)	RN, PhD	Nursing	Associate Dean	
Walter		Herzog (NV)	PhD	Kinesiology	Associate Dean	
Brian	R.	MacIntosh	PhD	Kinesiology	Adjunct Associate Professor	
Kathryn		Andruchuk	BA	Nursing	Undergraduate Student	

* DENOTES CHAIRPERSON

** DENOTES ALTERNATES (IF ANY, DENOTE MEMBER FOR WHOM ALTERNATE WILL SERVE

NV DENOTES NON-VOTING MEMBER



THE CITY OF CALGARY

**PAD STUDY (#16)
COMMUNITY VITALITY & PROTECTION**



**Volunteer Informed Consent
Emergency Medical Services Department
Public Access Defibrillation Trial**

Informed Consent to Participate in a Clinical Research Study

Investigator: Dr. A. Anton, M.D. FRCPC Emergency Phone Number: 816-4600

INVESTIGATORS' STATEMENT

PURPOSE AND BENEFITS

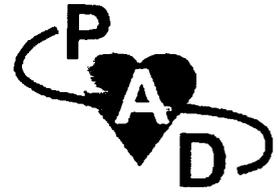
This study is a multicenter clinical research trial sponsored by the National Heart, Lung, and Blood Institute, the American Heart Association, and manufacturers of automatic heart defibrillators. The purpose of the study is to determine if treatment of cardiac (heart) arrest by non-medical, trained,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

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 personnel, their use has been extended in other circumstances, such as police, fire departments, flight attendants, and security guards. 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. They 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.

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.

PROCEDURES

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 will be determined randomly, like flipping a coin. Whether or not you receive training to use an AED, you will be taught other aspects of emergency medical care to allow you to respond to a cardiac arrest.



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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, and 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 of 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.

The study will last approximately 2 years.

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 electric shock, or even a burn. Every effort will be made to be sure that you are trained well to use an AED safely.

It is possible that there could be a legal liability associated with providing assistance in an emergency medical situation. However, the Province has adequate "Emergency Medical Aid Act" laws to protect you if you are assisting in an emergency medical situation. In addition, you will be designated as an official volunteer non-medical responder and become a part of the emergency medical system, which also provides liability coverage. Furthermore, manufacturers of AED's offer legal protection to individuals who are threatened with legal action as a result of their use of this device. No funds are available for legal proceedings or litigation through the local Principal Investigator, University, Coordinating Center, or the National Heart, Lung, and Blood Institute.



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COMMUNITY VITALITY & PROTECTION**

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.

OTHER INFORMATION

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 arrest. As in all studies which evaluate new devices, records (which may contain identifying information such as your 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.

You are free to decide not to participate in this project, and you can withdraw from it at 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.

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 the study.

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.

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SUBJECT'S STATEMENT

The study described above has been explained to me. I understand that I am free to refuse to participate and to withdraw from the study at any time without penalty or loss of benefits to which I am otherwise entitled. I voluntarily consent 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.

Signature of Subject

Date

cc: Subject
Investigator's File



CONSENT FORM

Research Project Title: Public Access Defibrillation Trial

Investigator(s): Dr. A. Anton, Emergency Medical Services/Calgary Fire Department

This consent form, a copy of which has been given to you, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

INVESTIGATORS' STATEMENT

PURPOSE AND BENEFITS

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

The location at which you suffered the medical emergency is participating in a research study to see how best to respond to sudden cardiac arrests. Normally, only medical personnel use defibrillators. Unfortunately, once 911 has been called, sometimes medical personnel do not arrive quickly enough to save a life. In this research study, all volunteers are being taught the optimal standard of care for out-of-hospital cardiac arrest, which includes recognition of cardiac arrest, calling 911, and performing cardiopulmonary resuscitation(CPR). At some locations non-medical volunteers are also being trained to use a defibrillator. The purpose of the research study is to determine whether more people survive cardiac arrest at locations where a volunteer has a defibrillator available. This study was described to the general population through the media of newspapers, radio, and television. Community involvement was sought, and community leaders and citizens agreed that this study was needed.

For most cardiac arrests, defibrillation 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.

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COMMUNITY VITALITY & PROTECTION**

Because you had a medical emergency at one of the participating study locations, you were enrolled in this study. By participating in this study, you had the opportunity to receive defibrillation 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.

If there is any benefit to you of being in the study, it has already occurred. You may receive no further benefit from being in this study. However, your continued participation in this study may benefit society if we are able to show the benefit of allowing trained non-medical personnel to use defibrillators.

PROCEDURES

Continued participation involves allowing us to collect information about your treatment, recovery, and general health after your medical emergency. We would like to review your hospital records to determine what treatment you receive in the hospital, and the extent of your recovery by the time of hospital discharge. Part of this data collection involves analyzing the cost of your hospitalization. Approval for your further participation in this study has been obtained from your personal physician.

We would also like to continue to contact you by phone after you have been discharged from the hospital every month for 3 months, then every 3 months for 2 years. During this contact we will ask you or your family members a series of questions related to your mental status, your day-to-day health status, your quality of life, and your medical care, treatments, procedures, and hospitalizations to determine the cost of your care.

The mental status survey will be completed only at the 3 month contact, evaluating your ability to remember things such as where and when you were 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 your physical health related to such things as your ability to hear, see, talk, and walk. It takes about 20 – 30 minutes to complete. It asks about your ability to perform physical activity and an assessment of how your heart problem is affecting your everyday life in relationships with family and friends. Some questions will ask you to rate your feelings of fear, discouragement, and depression. A typical question is "During the past 4 weeks how much of the time has your physical health or

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emotional problems interfered with social activities (like visiting with friends, relatives, etc.)?”.

A sample of each questionnaire is available should you want to review it.

Assessment of the cost of your medical care will be performed each month for 3 months and will simply consist of questions about whether you have been hospitalized, if you have been seen by a physician, and what tests or procedures have been performed since your last contact.

The cost and quality-of-life questionnaires will be conducted by telephone, and a family member may be asked to help determine how you are doing.

All of the treatment for your cardiac condition will be determined by your physicians, and this study will not interfere with such treatment in any way. The only treatment being evaluated is the strategy of making defibrillation available from non-medical volunteers. Because all treatments, tests, and procedures are part of your routine care and not a part of this study, this study will not pay for any part of your medical care. Any tests, procedures, or treatment determined by your doctors to be necessary for your care will require a separate consent form.

RISKS, STRESS, OR DISCOMFORT

The risks or discomfort associated with participating in this study include a small time commitment when you are asked about your health, and your quality-of-life. You could experience some psychological distress at having to remember your medical emergency and the subsequent hospitalization, or at having to consider questions which you don't ordinarily think about.

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 your heart rhythm to normal. However, you have already experienced these risks. Even if the volunteer responder had difficulty using the device, the paramedic or emergency medical technician arrived without delay for your usual medical care. Though taught to call 911 first, there was a small risk that the volunteer would delay calling 911 as he/she tried to use the defibrillator, which could make survival worse, or neurologic injury worse.

In the event that you suffer injury as a result of participating in this research, no compensation is available for any injury, adverse event, or disability which may result from this study. You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages.

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OTHER INFORMATION

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 you were successfully resuscitated. Therefore, you have already received either CPR, the electric shock, or both the electric shock and CPR.

You will not be charged for the care rendered by the trained volunteer non-medical responder at the time of your medical emergency.

Medical records will be reviewed and retained by the investigators for at least 5 years after the completion of the study, and if it forms any part of a medical or scientific report, your identity will not be disclosed.

You are free to decide not to participate in this project, and you can withdraw from it at any time without penalty and without jeopardizing your further care.

You are also free to refuse to answer any question about your health, quality of life, or medical care without penalty and without jeopardizing your further care.

Should you decide not to participate in this study, your medical records will not be reviewed further, and you will not be further contacted.

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation. If you have further questions concerning matters related to this research, please contact:

**Dr. Andy Anton, MD, FRCP(C)
(403) 268-2271**

**PAD STUDY (#16)
COMMUNITY VITALITY & PROTECTION**

If you have any questions concerning your rights as a possible participant in this research, please contact Pat Evans, Associate Director, Internal Awards, Research Services, University of Calgary at 220-3782.

Participant's Signature

Date

Investigator and/or Delegate's Signature

Date

Witness' Signature

Date

A copy of this consent form has been given to you to keep for your records and reference.



THE CITY OF CALGARY

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**Public Access Defibrillation Trial
Information Sheet**

City of Calgary Emergency Medical Services

Research Project Title: Public Access Defibrillation Trial

Investigator(s): Dr. A. Anton, Emergency Medical Services/Calgary Fire Department

PURPOSE AND BENEFITS

Your relative had a medical emergency and collapsed, and a volunteer responded to help. Your relative's heart stopped beating, and an approved medical device called a "defibrillator" may have been used to try to shock and restart the heart electrically. Unfortunately, despite the emergency medical care that your relative received, your relative was unable to survive his/her cardiac arrest.

The location at which he/she suffered the emergency is participating in a research study to see how best to respond to sudden cardiac arrests. Normally, only medical personnel use defibrillators. Unfortunately, once 911 has been called, sometimes medical personnel do not arrive quickly enough to save a life. In this research study, at some locations non-medical volunteers are being trained to use a defibrillator. The purpose of the research study is to determine whether more people survive cardiac arrest at locations where a volunteer uses a defibrillator. Although your relative may not have benefited from the study, we do not, at this time, believe that participating in the study increased the risks to your relative.

Defibrillation must be performed within a few minutes of the cardiac arrest. As a result, it was impossible to obtain your relative's consent or your consent prior to enrolling him/her in this study. Because your relative had a collapse at one of the participating study locations, he/she was enrolled in this study. This study was described to the general population through the media of newspapers, radio, and television. Community involvement was sought, and community leaders and citizens agreed that this study was 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.





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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.

If you have further questions concerning matters related to this research, please contact:

**Dr. Andy Anton, MD, FRCP(C)
(403) 268-2271**

If you have any questions concerning your rights as a possible participant in this research, please contact Pat Evans, Associate Director, Internal Awards, Research Services, University of Calgary at 220-3782.

Participant's Signature Date

Investigator and/or Delegate's Signature Date

Witness' Signature Date

A copy of this consent form has been given to you to keep for your records and reference.



SURROGATE CONSENT FORM

Research Project Title: Public Access Defibrillation Trial

Investigator(s): Dr. A. Anton, Emergency Medical Services/Calgary Fire Department

This consent form, a copy of which has been given to you, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

INVESTIGATORS' STATEMENT

PURPOSE AND BENEFITS

Your relative has had a medical emergency and has survived, though is still unable to understand what happened. Your relative collapsed, and a volunteer responded to help. If your relative lost consciousness and was unresponsive, an approved medical device called a "defibrillator" may have been used to shock and restart the heart electrically. Your relative received treatment quickly enough to save his/her life.

The location at which he/she suffered the medical emergency is participating in a research study to see how best to respond to sudden cardiac arrests. Normally, only medical personnel use defibrillators. Unfortunately, once 911 has been called, sometimes medical personnel do not arrive quickly enough to save a life. In this research study, all volunteers are being taught the optimal standard of care for out-of-hospital cardiac arrest, which includes recognition of cardiac arrest, calling 911, and performing cardiopulmonary resuscitation (CPR). At some locations non-medical volunteers are also being trained to use a defibrillator. The purpose of the research study is to determine whether more people survive cardiac arrest at locations where a volunteer has a defibrillator available. This study was described to the general population through the media of newspapers, radio, and television. Community involvement was sought, and community leaders and citizens agreed that this study was needed.

For most cardiac arrests, defibrillation must be performed within a few minutes of the victim's collapse. As a result, it was impossible to obtain your relative's consent or your consent prior to enrolling him/her in this study. At this point we are asking your consent to allow us to keep your relative in the study.



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Because your relative had a medical emergency at one of the participating study locations, he/she was enrolled in this study. All survivors or their relatives 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.

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

If there is any benefit to him/her of being in the study, it has already occurred. He/she may receive no further benefit from being in this study. However, his/her continued participation in this study may benefit society if we are able to show the benefit of allowing trained non-medical personnel to use defibrillators.

PROCEDURES

Continued participation involves allowing us to collect information about your relative's treatment, recovery, and general health after the medical emergency. We would 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 hospitalization. Approval for your relative's further participation in this study has been obtained from his/her personal physician. As soon as your relative is conscious and able to understand a discussion about this study, we will obtain permission from him/her to continue.

We would also like to continue to contact him/her by phone after he/she has been discharged from the hospital every month up for 3 months, then every 3 months for 2 years. During this contact we will ask a series of questions related to his/her mental status, day-to-day health status, quality of life, and medical care, treatments, procedures, and hospitalizations to determine the cost of care.

The mental status survey will be completed only at the 3 month contact, evaluating the 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 physical health related to such things as his/her ability to hear, see, talk, and walk. It takes about 20 – 30 minutes to complete. It asks about the ability to perform physical activity and an assessment of how his/her heart problem is affecting everyday life in relationships with family and friends. Some questions will ask him/her to rate feelings of fear, discouragement, and depression. A typical question is

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“During the past 4 weeks how much of the time has your physical health or emotional problems interfered with social activities (like visiting with friends, relatives, etc.)?”.

A sample of each questionnaire is available should you want to review it.

Assessment of the cost of medical care will be performed each month for 3 months and will simply consist of questions about whether he/she has been hospitalized or been seen by a physician and what tests or procedures have been performed since the last contact.

The cost and quality-of-life questionnaires will be conducted by telephone, and a family member may be asked to help determine how he/she is doing.

All of the treatment for your 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 strategy of making defibrillation available from non-medical volunteers. Because all treatments, tests, and procedures are 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 will require a separate consent form.

RISKS, STRESS, DISCOMFORT

The risks or discomfort associated with participating in this study include a small time commitment when he/she is asked about health, the cost of medical care, and quality-of-life. He/she could experience some psychological distress at having to remember the medical emergency and the subsequent hospitalization, or at having to consider questions which he/she doesn't ordinarily think about.

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, your 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 the volunteer would delay calling 911 as he/she tried to use the defibrillator, which could make survival worse, or neurologic injury worse.

In the event that you suffer injury as a result of participating in this research, no compensation is available for any injury, adverse event, or disability which may result from this study. You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages.

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OTHER INFORMATION

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 your relative was successfully resuscitated. Therefore, he/she has already received either the CPR, electric shock, or both the electric shock and CPR.

Your relative will not be charged for the care rendered by the trained volunteer non-medical responder at the time of the medical emergency.

Medical records will be reviewed and retained by the investigators for at least 5 years after the completion of the study, and if it forms any part of a medical or scientific report, your relative's identity will not be disclosed.

You are free to decide not to allow your relative to participate in this project, and you can withdraw him/her from it at any time without penalty and without jeopardizing further care.

You are also free to refuse to answer any question about your relative's health, quality of life, or medical care without penalty and without jeopardizing further care.

Should you decide not to allow your relative to participate in this study, his/her medical records will not be reviewed further, and he/she will not be further contacted.

In the event that you suffer injury as a result of participating in this research, you still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages".

There will be no payment to volunteers participating in this study, and patients or their insurance companies will be billed for all tests necessary for their evaluation and treatment. It is not expected that participation in this research study will result in any additional cost for treatment. No compensation is available for any injury, adverse event, or disability which may result from this study. You and your relative will be informed of any significant findings that could effect your decision to continue in the study.

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new

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information throughout your participation. If you have further questions concerning matters related to this research, please contact:

**Dr. Andy Anton, MD, FRCP(C)
(403) 268-2271**

If you have any questions concerning your rights as a possible participant in this research, please contact Pat Evans, Associate Director, Internal Awards, Research Services, University of Calgary at 220-3782.

Participant's Signature Date

Investigator and/or Delegate's Signature Date

Witness' Signature Date

A copy of this consent form has been given to you to keep for your records and reference.



SURROGATE CONSENT

Your injury or illness (or injury) made it impossible for you to participate in the informed consent process, the proxy (delegated) consent of your next of kin (legal surrogate or guardian) was obtained on your behalf. Your surrogate believed you would have wished to participate in this research if you had been able to express your own opinion at the beginning of the research.

As noted earlier, the process of informed consent must be continuous throughout a research project. This means that patients have the right to change their minds and therefore, must be given opportunities to voice any changes they might wish. In your situation, you now have the opportunity to agree or disagree with the decision made by your surrogate to enroll you in this research project.

If you agree with the decision made by your surrogate to enroll you, your signature will affirm your participation in this study. If you do not agree with the decision made by your surrogate to enroll you, you may withdraw at any time from the study.

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators, sponsors or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification for new information throughout your participation.

Please check the appropriate box(es) to indicate your decision:

I do agree with my surrogate's decision.

I do not agree with my surrogate's decision.

I wish to remain in the study.

I wish to withdraw from the study.

Patient's signature

Date

Witness' signature

Name of Witness

S:\Staff Development\Assistant to the MD\PAD\Surrogate Consent.DOC





UNIVERSITY OF
CALGARY

FACULTY OF MEDICINE

Office of Medical Bioethics
Heritage Medical Research Building/Rm 93
Telephone: (403) 220-7990
Fax: (403) 283-8524

2001-01-18

Dr. A.R. Anton
c/o Emergency Medicine
Room C231
Foothills Hospital
Calgary, Alberta.

Dear Dr. Anton:

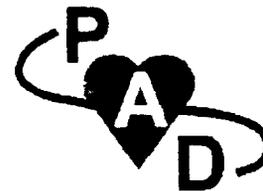
Re: **Early Access to Defibrillation for Victims of Out-of-Hospital Cardiac Arrest (OOH-CA) PAD Protocol**

I am pleased to advise you that it is permissible for you to use the submitted Notice for public forum and the press release to aid in recruitment, based on the information contained in your correspondence of January 10, 2001.

Yours sincerely,

Christopher J. Doig, MD, MSc, FRCPC
Chair, Conjoint Health Research Ethics Board

CJD/mc



City of Calgary Community Vitality and Protection

Community Consent Plan for the Calgary PAD Site

- 1) Submit ethics application to the Calgary Research Ethics Board as well as the Calgary Regional health Authority Centre for advancement of Health. This will provide an ethics review by the University of Calgary IRB/Ethics Committee as well as the Regional Health Authority which represents all hospitals in the region. These review boards all have lay representation of the community participating in the review and therefore provides a detailed review of the protocol and the risks and benefits to the community.
- 2) Obtain letters of support from community agencies such as :
 - The office of the Mayor, The City of Calgary
 - The office of the Emergency Medical Services Chief
 - The office of the Fire Chief.
- 3) Include a PAD information component on Calgary EMS Website.
- 4) Provide all tenants of commercial facilities an information sheet describing the PAD trial with a contact number for any questions or concerns.
- 5) Place an information article in the Calgary Sun and Calgary Herald to inform the community at large of the trial. The article will provide a contact number to allow questions or concerns to be addressed and access to the principal investigator and co-ordinators for consultation. Public service announcements on local television stations outlining PAD project will also be utilized.
- 6) Hold a community public forum with the principal investigator and co-ordinators available to answer questions raised by the public.
- 7) Press conference with principal investigator and co-ordinators regarding PAD trial to be arranged with local television and radio stations.





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**Calgary PAD
City of Calgary
Emergency Medical Services/Fire Departments
P.O. Box 2100, Station "M", Calgary, Alberta, Canada, T2P 2M5**

Public Access Trial

**Implementation of Community Consent and Notification Plan
to comply with regulations CFR 50.24 items 7 (I to V)**

As per the community consent plan, we feel that we have met all requirements to proceed with the PAD trial.

1. We have submitted ethics applications to the Calgary Research Ethics Board as well as the Calgary Regional Health Authority Centre for Advancement of Health.
2. We have received letters of support from the community agencies listed in the community consent plan.
3. We have included a Public Access AED component to the Calgary EMS website.
4. We have provided tenants in all commercial facilities an information sheet describing the trial. We will do this for all commercial facilities prior to starting up each facility.
5. Management organizations at all sites have been instructed to notify all tenants, residents and facility users of the study.
6. We placed a Public Notice in each of the local newspapers, the Calgary Sun and the Calgary Herald, on Tuesday January 23rd describing the PAD trial, and informing the community of the public forum.
7. A press conference was held based on the press release sent out to all media outlets within the City of Calgary. Dr. Anton and both local research coordinators attended this press conference.
8. These public notices generated media interest and two newspaper articles concerning the study were run in local papers prior to the forum. Information given included a contact name and number for the public to call with questions. In response, a call was received from a local radio station and an interview was subsequently aired. Although there were no phone calls received from the public, a television news network did interview project staff and aired a segment containing information on the study. This broadcast included a reminder of the forum and contact information for use by those unable to attend. There were no telephone inquiries received.
9. The community public forum was held on Feb 05th where Dr. Anton outlined the ethical issues regarding AED Vs a control unit and described the entire consent process. A total of 15 people came to the forum and asked numerous questions specific to AEDs as well as asking about the study locations and criteria, selection of volunteers, training provisions, randomization, and asking further for clarification concerning general health issues related to the use of CPR and AEDs. A local radio station taped the forum and conducted an interview with the Principal Investigator. A television news network filmed portions of the forum and aired a news presentation describing the meeting. No further inquiries have been received.

Respectfully Submitted,

Andy R. Anton, MD., FRCPC
Principal Investigator
PAD Trial, Calgary PAD location

Feb 7, 2001

Date





Calgary PAD City of Calgary Emergency Medical Services/Fire Departments P.O. Box 2100, Station "M", Calgary, Alberta, Canada, T2P 2M5

Public Access Trial

Principal Investigator: Dr. Andy Anton
Trial Co-ordinators: Dennis Rabel, EMT-A, CFD Stephen Yahn, EMT-P, EMS

2000 November 02

Community Consent and Notification Plan

Code of Federal Regulations Section 50.24

CFR 50.24: Exception from Informed Consent requirements for emergency research.
Items 7i-v

- 7(i) Consultation: See Items 1,2,6 of Community Consent Plan
- (ii) Public Disclosure: See Items 1, 3, 4, 5, 6, 7 of Community Consent Plan
- (iii) Public Disclosure of Trial Results. We plan on issuing a press release with the results of the trial using data obtained from the P.A.D. Central Co-ordinating Centre.
- (iv) Independent Data Monitoring Committee: A Data and Safety Monitoring Board (DSMB) has been formed to provide an independent review of the study progress, CTC and site performance, safety issues and sequential monitoring and provide recommendations to the NHLBI. The DSMB met in January 2000 and approved the protocol.
- (v) Informed consent will not be possible prior to resuscitation attempts. A clinician from the Calgary Regional Health Authority will visit the patient in the hospital to notify them of the trial and to obtain consent. From the patient or next of kin for follow-up and medical record access. The Calgary study site will document efforts made to contact the patient or family members and submit this information to the Calgary Conjoint Research and Ethics board for annual review.

