PUBLIC NOTIFICATION OF AN EXCEPTION TO
THE REQUIREMENTS FOR INFORMED CONSENT UNDER EMERGENCY CIRCUMSTANCES FOR A
CPR RESEARCH STUDY
IN MILWAUKEE COUNTY, WI
(Trial of Continuous Compressions Versus Standard CPR in Patients with Out-of-Hospital Cardiac Arrest [CCC Trial])

This announcement serves as public notification of a cardiopulmonary resuscitation (CPR) research study comparing survival and quality of life in adult patients with cardiac arrest resuscitated using continuous chest compressions versus standard CPR treated by the Milwaukee County Emergency Medical Services (EMS) System. The study began in March 2012 in Milwaukee County, Wisconsin using the Food and Drug Administration's (FDA) regulations allowing exception to informed consent in emergency research circumstances.

Cardiac arrest is the sudden loss of pulse and breathing. CPR is typically performed until normal heart function can be restored. The purpose of the study is to compare survival to hospital discharge and quality of life after continuous chest compressions versus standard CPR with interrupted chest compressions. Successful resuscitation in humans experiencing cardiac arrest is associated with greater blood flow during CPR. Continuous chest compressions may provide better blood flow compared with standard CPR.

All research contains risks. Surviving cardiac arrest with damage to the brain is a potential risk for any patient undergoing any method of CPR. 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. Other potential risks for any patient undergoing any method of CPR include fluid build-up in the lungs, low blood pressure following successful resuscitation, airway bleeding, pneumonia, bacteria in the blood stream, bleeding in the brain, stroke, seizures, bleeding requiring transfusion or surgical intervention, repeat cardiac arrest, rib fractures, sternal fractures, or internal organ injuries. These potential risks are not expected to be different with continuous chest compressions compared with standard CPR. However, these potential risks will be monitored on an ongoing basis and the study stopped if it occurs. Every precaution will be taken to assure personal safety.

The information that is obtained from this study may be useful scientifically and possibly helpful to others. The benefit that may reasonably be expected from participating in this study is improved effectiveness of CPR and an increased chance for survival, but these potential benefits are not guaranteed. There are no financial risks or benefits for study participation. For this study, there are no appropriate alternative procedures that are known to be advantageous during cardiac arrest. All information obtained from this study that can be identified to an individual person will remain absolutely confidential. The scientific or medical information not identifiable with a patient resulting from the study will be presented at meetings and published so that the information can be useful to others.

The FDA has implemented regulations allowing an exception to informed consent under emergency research circumstances where acquiring written informed consent is impossible and there is reasonable scientific evidence to suggest a possible benefit from a new intervention. FDA regulations require public notification to inform the community that a research project will be done that may impact members of the local population. In accordance with FDA regulations, this notification was initially made prior to the initiation of the study in March 2012, Public notification will also occur after the study is completed, which is anticipated in December 2015.

This study meets the FDA guidelines for exception to informed consent under emergency circumstances because informed consent cannot be obtained from a victim of sudden cardiac arrest. Interested parties with questions or concerns or requiring information on obtaining opt-out bracelets are encouraged to contact the principal investigator, Dr. Tom P. Aufderheide, either by phone (414-805-6493), mail (Department of Emergency Medicine, 9200 W. Wisconsin Ave., Froedtert Hospital East, PV1, Milwaukee, Wisconsin 53226 or email (taufderh@mcw.edu), or visit the web site at (www.mcw.edu/ROCCCC). Feedback from the community may be used to further modify the design of the study.