PUBLIC NOTIFICATION OF AN EXCEPTION TO
THE REQUIREMENTS FOR INFORMED CONSENT UNDER EMERGENCY CIRCUMSTANCES FOR A
CPR RESEARCH STUDY
IN MILWAUKEE COUNTY, WI
(Amiodarone (PN101), Lidocaine, or Neither for Out-of-Hospital Cardiac Arrest Due to
Ventricular Fibrillation or Tachycardia [ALPS 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 the most commonly used heart rhythm medications (amiodarone or lidocaine), or whether neither is beneficial when treated by the Milwaukee County Emergency Medical Services (EMS) System. The study began in March 2013 in Milwaukee County, Wisconsin using the Food and Drug Administration's (FDA) regulations allowing exception to informed consent in emergency research circumstances.

Cardiopulmonary arrest is the sudden loss of pulse and breathing. CPR is typically performed until normal heart function can be restored. In this study, one-third of the patients in cardiac arrest will receive amiodarone, one-third will receive lidocaine and one third will receive a placebo made up of salt water rather than either medication. All patients will receive all other standard treatments for cardiac arrest.

All research contains risks. Surviving cardiac arrest with damage to the brain is a potential risk for any patient. Risks will be monitored on an ongoing basis and the study stopped if they occur. Possible reactions to the study drugs are seizures, a severe drug allergy, or a slow heart beat that may require a pacemaker (a small device placed under the skin to speed up the heart beat). Potential risks for any patient undergoing 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. 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 resuscitation 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. The study team will make every effort to protect your personal health information and keep it confidential, but it is possible that an unauthorized person might see it. 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 Food and Drug Administration 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 2013. 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 those who do not wish to participate in this trial and would like to request an opt-out bracelet, 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/ROCALPS). Feedback from the community may be used to further modify the design of the study.