**RE: Canadian Resuscitation Outcomes Consortium (CanROC) Epinephrine Dose: Optimal versus Standard Evaluation Trial (CanROC EpiDOSE Trial)**

Dear Patient or Family Member:

This letter is being given to you on behalf of Emergency Medical Services. We understand that this may be coming to you at a very difficult time. Please accept our apologies for this intrusion.

**Why are you receiving this letter?**

You are being given this letter as you or your family member were recently treated by Regional Emergency Medical Services paramedics for an out-of-hospital cardiac arrest (OHCA; sudden stopping of the heart), which involved the use of standard medical procedures that are called Advanced Cardiac Life Support. At that time, you or your family member were included in a research study called EpiDOSE therefore we wish to provide you with information about the study as well as contact information should you have any questions.

**Study information**

On the following ‘Study Information Form for Patients or Family’ you will find a detailed account of the EpiDOSE trial. Should you have further questions, please do not hesitate to contact the following or visit [www.epidose.ca](http://www.epidose.ca):

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| **Principal Investigators:** | **Dr. Paul Dorian; email:** [**paul.dorian@unityhealth.to**](mailto:paul.dorian@unityhealth.to);  **phone: 416-864-5104**  **Dr. Steve Lin; email:** [**steve.lin@unityhealth.to**](mailto:steve.lin@unityhealth.to); **phone 416-864-6060 x 7873**  St. Michael’s Hospital, 30 Bond Street, Toronto, ON M5B 1W8 |
| **Site Investigator:** | **Dr. Sheldon Cheskes; email:** [**sheldon.cheskes@sunnybrook.ca**](mailto:sheldon.cheskes@sunnybrook.ca); **phone: 416-667-2200 x 0**  Sunnybrook Center for Prehospital Medicine, 77 Brown’s Line, Suite 100,  Toronto, ON M8W 3S2 |
| **Research**  **Ethics Contacts:** | **Dr. Brian J Murray (Chair); phone: 416-480-6100 x 88144**  Sunnybrook Health Sciences Centre Research Ethics Board  2075 Bayview Avenue, Toronto, ON M4N 3M5 |

In addition to enrollment in the EpiDOSE trial, there may be other cardiac related research involving you or your family member. As such, you may receive information about other research in the mail. Information about other ongoing cardiac arrest studies can be found on the EpiDOSE website ([www.epidose.ca](http://www.epidose.ca)) or you may email [epidose@unityhealth.to](mailto:epidose@unityhealth.to) to learn more.

Again, we apologize for this intrusion. We appreciate how difficult this situation may be for you and your family. No action on your part is required unless you wish to receive additional information or discuss the study further.

With kind regards,

**Dr. Sheldon Cheskes**

Medical Director

Sunnybrook Center for Prehospital Medicine

Regions of Peel and Halton

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**RE: Canadian Resuscitation Outcomes Consortium (CanROC) Epinephrine Dose: Optimal versus Standard Evaluation Trial (CanROC EpiDOSE Trial)**

**Study Information Form for Patients or Family**

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| **Study Manager:** | **Theresa Aves; email:** [**theresa.aves@unityhealth.to**](mailto:avest@smh.ca)**; phone: 416-864-6060 x 46787**  St. Michael’s Hospital, 30 Bond Street, 8-005 Bond Wing, Toronto, ON M5B 1W8 |
| **Research**  **Ethics Contacts:** | **Dr. Brian J Murray (Chair); phone: 416-480-6100 x 88144**  Sunnybrook Health Sciences Centre Research Ethics Board, 2075 Bayview Avenue, Toronto, ON M4N 3M5 |
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| **Site Coordinator:** | Please contact the Study Manager as listed above |
| **Study Webpage:** | [**www.EpiDOSE.ca**](http://www.EpiDOSE.ca) |
| **Funding Source:** | **Canadian Institutes of Health Research** |
| C**onflicts of Interest:** | **There are no conflicts of interest to report** |

The information outlined below is intended to supplement the above letter and relates to the study in which you or a member of your family was enrolled. In the unfortunate event that your family member has not survived, all references to “you” are intended to be references to your family member.

If you have any questions after you read this form, please ask the principal investigators or the study manager. The research program at St. Michael’s Hospital part of Unity Health Toronto that includes St. Michael’s, St. Joseph’s and Providence Healthcare has received funding to conduct this study from the Canadian Institutes of Health Research. The investigators involved however, do not receive any direct payment for patients enrolled into the trial. The grant pays for study operations including study related employment salaries and contract wages.

**INTRODUCTION**

The investigators in association with the Regional Emergency Medical Services (EMS) and Fire Services are conducting a research study to determine how to best treat out-of-hospital cardiac arrests (OHCAs). EMS providers treat cardiac arrest (sudden stopping of the heart) by performing cardiopulmonary resuscitation (CPR) which includes chest compressions and helping a person to breathe. By giving chest compressions during CPR, blood is circulated throughout the body to important organs. As part of Advanced Cardiac Life Support (ACLS), different drugs such as epinephrine may be administered in addition to CPR in order to increase blood flow to the heart to improve its chances of restarting.

**WHY IS THIS STUDY BEING DONE?**

Though epinephrine has been used in Advanced Cardiac Life Support for decades, there is limited proof that the current standard dose of epinephrine is effective at improving survival out of the hospital. Some research has suggested that epinephrine may even be harmful at higher doses though there is not enough good quality research to conclude this. This study is being

conducted in order evaluate the effects of two different doses of epinephrine including a low total dose and a standard total dose during treatment of out-of-hospital cardiac arrest.

*Our goal is to determine whether intravenous administration of a low total dose of epinephrine (up to 2mg) compared to a standard total dose of epinephrine (up to 6mg) will improve survival to hospital discharge following an OHCA.*

**DESCRIPTION OF THE STUDY**

It is anticipated that 3790 people across Canada (Vancouver, Ottawa and Greater Toronto Area) will be included in this study. The entire study is expected to take about 5 years to complete.

This study is a single blinded randomized controlled trial where included individuals are randomly assigned to one of two treatment groups. This means that you were assigned by chance to receive either a low total dose of epinephrine or a standard total dose of epinephrine, in addition to the usual standard of care. Neither you nor the investigators know which treatment group was assigned. This is referred to as “blinding” which is done to minimize bias in the study outcomes and maximize the validity of the results.

**WHAT WILL HAPPEN DURING THIS STUDY?**

In order to evaluate the different total doses of epinephrine during treatment for cardiac arrest, we will be analyzing data that paramedics and hospitals collect surrounding the cardiac arrest.

The information that we collect includes:

1. Basic information about you including age and sex
2. Information surrounding the cardiac arrest such as whether or not it was seen by someone, who performed CPR, how many defibrillator shocks were given and what other drugs may have been used during treatment
3. If you were brought to the hospital, information about the hospitalization such as the unit of admission and length of stay

Together with similar data from almost 4000 other patients we will learn about how a low total dose or a standard total dose of epinephrine may be beneficial for survival out of the hospital, after cardiac arrest. These data are collected from several sources including the Ambulance Call Report (ACR) that was filled out by your paramedics as well as administrative databases including the Discharge Abstract Database (DAD) and the National Ambulatory Care Reporting System Metadata (NACRS). Details of the treatment performed will be attached to the ACR and included in your clinical file in the hospital database. Data collected for the study will be stored up to 25 years.

Data from these sources are entered into a web-based data entry system (a computer program) hosted by St. Michael’s Hospital. All personal information including name, date of birth, healthcare number are removed or blocked out and replaced with a unique study number, which you have already been assigned. This information is confidential so that no one can gain specific information about you personally. Although all of your data are kept confidential, medical records such as the Ambulance Call Report may be accessed by the study staff, Sunnybook Health Sciences Center Research Ethics Board, and/or by government regulatory authorities (e.g. Health Canada). Such access will be used only for the purpose of verifying the authenticity and accuracy of the information collected for the study. The results of this study may be presented at conferences and may be published in scientific journals. Results will be published about the study population as a whole; neither your name nor your identifying information will be used.

If you choose to email us ([epidose@unityhealth.to](mailto:epidose@unityhealth.to)) with any questions once you have reviewed this letter, we ask that you limit the amount of personal health information that you share, for your safety. We also ask that you do not use email for medical emergencies. If you experience a medical emergency please call your healthcare provider or 911 or visit your nearest emergency department. Only approved members of the study team will have access to our EpiDOSE email address which is monitored daily. If at any time you wish to stop email correspondence, we ask that you inform us via emailor call 416-864-6060 x 46787.

**WHAT ARE THE RISKS OF THE STUDY**

Epinephrine is the standard drug used in cardiac arrest. Patient safety is carefully monitored and recorded for any complications of study treatments. There are no anticipated additional risks in the low dose group compared to the standard dose group. Epinephrine may cause adverse effects, including inflammation at the injection site if the drug is given into the skin, worsening of heart rhythm disturbances, or reduced circulation to certain organs such as the heart or brain though these events can occur even in the absence of epinephrine injection.

Additionally, there are common risks of using email to communicate. If you choose to correspond with us by email, please consider the following:

* Information travels electronically and is not secure in the way a phone call or regular mail would be.
* If someone sees these emails they may know that you are a participant in this study or see the health information included in the email.
* Emails may be read or saved by your internet or phone provider (i.e. Rogers, your workplace, “free internet” providers).
* Copies of an email may continue to exist, even after efforts to delete the email have been made.
* There is always a chance with any unencrypted email, however remote, that it could be intercepted or manipulated.

**WHAT ARE THE BENEFITS OF THE STUDY?**

You may or may not receive any direct benefits from being in this study. However, results from this study could further medical or scientific knowledge in the area of cardiac arrest research and help those who may suffer a cardiac arrest in the future.

**PRIVACY AND CONFIDENTIALITY**

The research team only collects information they need for this study. The study data will be collected from the ACR, DAD and NACRS databases. All persons involved in the study (the study staff) and the Data Coordinating Centre (the Applied Health Research Centre at St. Michael’s Hospital) are committed to respecting your privacy. The study staff and the Data Coordinating Centre will make every effort to keep all personal health information private and confidential in accordance with all applicable privacy legislations, including the Personal Health Information Protection Act of Ontario.

Authorized representatives of the following organizations may look at your original (identifiable) study records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines:

* Sunnybrook Health Sciences Center Research Ethics Board*,* to oversee the ethical conduct of research at this location

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/presented to the scientific community at meetings and in journals. Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

**WHAT ARE THE COSTS?**

Participation in this study will not result in any costs to you.

**PARTICIPATION AND WITHDRAWAL**

If you no longer wish to be contacted and wish to withdraw (either yourself or on behalf of your family member) you may do so by calling 416-864-6060 x 46787 and providing your full name. Withdrawing from the study will not affect the care you or your family member currently receive or will receive in the future.

Withdrawing from the study means that information about you that transpired up to the date and time withdrawal will be collected to maintain the scientific integrity of the study, but no further information will be collected unless required by government regulatory authorities (e.g. Health Canada)

**WHERE CAN I GET MORE INFORMATION?**

A description of this clinical trial is available on <http://www.ClinicalTrials.gov> (NCT03826524) and a dedicated study website: [www.epidose.ca](http://www.epidose.ca). These sites will not include any identifying information about you. Any results from this study will be summarized on both sites or published in a confidential manner. If you wish to be directly informed of the study results upon completion, please contact [epidose@unityhealth.to](mailto:epidose@unityhealth.to).

**RESEARCH ETHICS BOARD CONTACT**

If you have any questions regarding your rights as a research participant, you may contact the Sunnybrook Health Sciences Centre Research Ethics Board by phone at 416-480-6100 x 88144.

**STUDY CONTACT**

If you have any questions about this study or would like to receive a more detailed account of the research, please do not hesitate to contact:

**Dr. Paul Dorian by email at** [**paul.dorian@unityhealth.to**](mailto:paul.dorian@unityhealth.to) **or by phone at 416-864-5104 or**

**Dr. Steve Lin by email at** [**steve.lin@unityheatlh.to**](mailto:steve.lin@unityheatlh.to) **or by phone at 416-864-6060 x 7873 (lead investigators)**, Or

**Dr. Sheldon Cheskes by email at** [**sheldon.cheskes@sunnybrook.ca**](mailto:sheldon.cheskes@sunnybrook.ca) **or by phone at 416-667-2200 x 0 (local site investigator)**

**ADDITIONAL RESEARCH**

As mentioned above, in addition to enrollment in the EpiDOSE trial, there may be other cardiac related research involving you or your family member. As such, you may receive information about other research in the mail. Information about other ongoing cardiac arrest studies can also be found on the EpiDOSE website ([www.epidose.ca](http://www.epidose.ca)) or you may call 416-854-6060 x 46787 to learn more.

No action on your part is required unless you wish to receive additional information or discuss the study further.