Official Title: RACE-CARS - RAndomized Cluster Evaluation of Cardiac ARrest Systems

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VERBAL INFORMED CONSENT FORM TO PARTICIPATE IN RESEARCH

RAndomized Cluster Evaluation of Cardiac ARrest Systems (**RACE-CARS)** Pro00105633

1. Verbal Consent Script for RACE-CARS study

Introduction:

Hello. My name is [interviewer's name]. I work at the Duke Clinical Research Institute and I am calling to speak with [patient name] about a study we are doing in conjunction with [name of county patient resides in]. May I please speak with [Mr./Ms. & last name]? ***(If the participant is to be noted to be a class CPC 3 or 4 on discharge per EMS records sent to DCRI please ask to speak to the patient's primary care giver/legally authorized representative.)***

If confirmed that you are speaking with subject- then move to section below. If potential subject not available move to # 2.

Study Overview:

Our group at Duke is partnering with the emergency medical care system in [name] County and others across the state on a research study to improve the care of people who have a heart arrest or heart stoppage. We are contacting people who have survived a heart arrest event, such as yourself, to assess how things are going, how you are feeling, and how well you have recovered. The name of our study is RACE-CARS. RACE-CARS stands for RAndomized Cluster Evaluation of Cardiac ARrest Systems. It is being supported by the National Heart Lung and Blood Institutes. I would like to explain the study to you and then see if you are willing to be a part of it. This explanation should take less than 5 minutes. If you are willing to talk to us about your health and recovery, the second part of the call should take about another 20 minutes or less.

May I explain the RACE-CARS study to you? [Y/N]

- ❑ Yes
- ❑ Please call back at a later time (document time and date for call back #2b)
- ❑ If the potential participant is not interested then skip to #2.

The **purpose** of the RACE CARS research study is to test whether a set of community-based programs involving the emergency medical systems, 911 operators and members of the community can improve the rate of survival with good recovery for people whose heart stops beating due to an abnormal heart rhythm. One important part of this is discharge from the hospital. We also want to assess how well people do over the following year after getting out of the hospital. We expect the study will enroll approximately 2,100 participants over a 4-year period in this program following cardiac arrest survivors across North Carolina.

If you agree to take part in this study today, I will ask you some standard general health and well-being questions. I will also get additional contact information from you today so I know how best to reach you for the second call several months from now to ask the same questions in order to see how things have changed. Your participation in this study is voluntary and you may end your participation at any time. If we cannot reach you for the second phone call, we may contact you by email or postal mail. We may also contact alternate contacts you provided at the time of consent to see how you are doing if we cannot reach you.

There are no costs for you to participate and you will not be paid for your participation in this study. If you choose not to participate, it will not affect the relationship you have with your local EMS or your healthcare providers.

Your responses to these questions will help heart investigators and doctors understand patient's experiences after a heart stoppage episode, and your responses may help improve heart arrest care for future patients.

You may choose not to be in the study, or, if you agree to be in the study you may withdraw at any time.

In the event you withdraw from the RACE-CARS before the second call, study personnel will use public records or contact the EMS agency that responded to you to determine if you are alive. Knowing this "vital status" and survival after you enroll is a very important piece of this study.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Your privacy and the confidentiality of your information are very important to us, and we will make every effort to protect both. Registry records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access.

Your name, address, phone number, and other contact information, will be shared with assigned research staff at DCRI who will be conducting the telephone interviews.

Email messages for this study are not encrypted and may not be secure means of communication. The study team will email you to send you a copy of this consent, in the event we cannot reach you, or to inform you of any study updates.

Once your protected health information has been disclosed to a third party, federal privacy laws may no longer protect it from further disclosure.

While the information and data resulting from this registry may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

De-identified data collected in this study may be used for future research.

HOW WILL MY (YOUR) PRIVACY BE PROTECTED?

Study records that identify you will be kept strictly confidential, as required by law. Regulations provide safeguards for privacy, security, and authorized access. Your records may be reviewed in order to ensure that the study meets all relevant federal or state regulations. Reviewers checking on this may include, for example, my colleagues on the research study staff of the Duke Clinical Research Institute (Duke University) and its representatives. Your information may be re-disclosed to outside reviewers at the NIH for monitoring purposes. If this happens, it may not be covered by federal patient privacy rules (HIPAA).

WHAT ARE THE RISKS OF THE STUDY?

There are no physical risks to you. Your medical care will not change because you are taking part in the study. You and your doctor will keep making all the decisions about your treatment and care.

There is a potential risk of loss of confidentiality. We will make every effort to protect your information to minimize this risk. Some of the questions we will ask you as part of this study may make you to feel

uncomfortable. You may refuse to answer any of the questions. You may stop your participation in this study at any time.

If you have any questions, you can email RACE-CARS-PRO@duke.edu or call 1-833-266-8831You can also contact this email or phone number if you decide at any time that you no longer want to be in the study.

You may also contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 if you have questions about your rights as a research subject or if you want to discuss concerns about the study, or to obtain additional information or offer input about the research.

A description of this clinical trial will be available on www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Do you have any questions about the RACE CARS program? (participant can ask questions)

Consent to Study: (If NOT interested, go to 2)

Participant: If you would like to participate in the study, please indicate "Yes."

❑ Yes, Thank you for your participation. (Review Contact information.)

Legally Authorized Representative (LAR): (If NOT interested, go to 2):

If you would like to give permission as the legal authorized representative (LAR) of _<participant name> please agree to this statement:

❑ Yes, "I am the representative of the subject and am acting on behalf of the subject. I am not aware of any factor that might create a conflicting interest for me in this role (for example, something that might bring me personal benefit). I consent to the subject's participation in this study." Thank you for your participation. (Review Contact information).

Subject's legal name: _____

LAR Full legal name:_____

Today's date and time: _____

Interviewer consenting: <insert name>_____initials:_____

**If the potential participant is unable to consent and a legally authorized representative/proxy is available to approve enter the name of the participant and name of LAR above.*

***Once verbal consent is received and documented scan and send a pdf copy of the consent to the participant.*

2. No, Do not want to participate

Thank you for your time and consideration of this study. Would you be willing to offer a reason for why you are not interested in participating?

- ❑ Not interested
- ❑ Never returned phone call (passive refusal)Too ill/poor health – patient self- report
- ❑ Privacy concerns
- ❑ No reason given
- ❑ Other text:_____