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NYU Langone Health

Research Subject Informed Consent Form

Title of Study: Goal-Directed Cardiopulmonary Resuscitation In Cardiac Arrest Using A Novel Physiological Target: A Pilot Mechanistic Randomized Control Trial
s20-00354

Principal Investigator: Sam Parnia, MD, PhD
[redacted]

Emergency Contact: [redacted]

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

If you are the legally authorized representative for someone without the capacity to consent for themselves, “you” and “your” throughout this document refer to this person.

If you have already recovered from cardiac arrest and have the ability to provide informed consent, this form describes what has already taken place. We are now asking for your permission to continue to use the study information we collected. If you do not agree, this information will be discarded.

2. What is the purpose of this study?

The purpose of this study is to examine the effects of two cardiopulmonary resuscitation (CPR) feedback systems in patients undergoing cardiac arrest (when the heart stops beating). These CPR feedback systems will guide clinicians to administer enhance resuscitation efforts which may include compressions during CPR within a target depth and rate recommended by the American Heart Association or other treatment options available at NYU Langone Health. During cardiac arrest, the amount of oxygen delivered to vital organs and the brain significantly decreases and this causes a chain of events that may lead to death or contribute to ongoing brain injury. Ongoing brain injury can potentially lead to severe loss of functional abilities where patients become disabled to the degree that they are unable to care for themselves or remain in a persistent comatose state. By evaluating the effects of Physiological (by using

two non-invasive devices: cerebral oximeter and end tidal carbon dioxide) Feedback CPR and Non-Physiological (Audiovisual) Feedback CPR as predictors of oxygen delivery during CPR, we are trying to improve brain function and overall survival in people who have experienced a cardiac arrest.

In this study, we plan to administer the following types of CPR:

1. Physiological-Feedback CPR: Patients will receive current CPR standard of care plus the use of a cerebral oximeter and end tidal carbon dioxide devices as predictors of oxygen delivery to the body during CPR. This information will be used to guide the way CPR is performed.

2. Non-Physiological (Audiovisual) Feedback CPR (control group): Patients will receive current CPR standard of care plus the use of audio-visual cues as a predictor of oxygen delivery to the body during CPR.

We will also evaluate the effect of these two systems in reducing brain injury by measuring blood indicators of inflammation and brain injury at different time periods of your hospital stay. We will also conduct a test to evaluate how participants brains are working at hospital discharge.

You are being approached because you or have experienced a cardiac arrest at a hospital setting.

3. How long will I be in the study? How many other people will be in the study?

The duration of your participation will be a maximum of 30 days.

About 150 participants are expected to take part in this study.

4. What will I be asked to do in the study?

If you agree to take part, you will be randomized (assigned by chance, like flipping a coin) to one of two treatment groups:

- Physiological-Feedback CPR (study intervention)
- Non-Physiological (Audiovisual) Feedback CPR (control group)

If you (or your LAR) agree to continue your participation in the study, we will collect your medical history and treatment during your hospital stay.

You received one of the two treatments during your cardiac arrest. You will not know whether you received CPR plus the study intervention or CPR standard of care alone. You may have received post-cardiac arrest management, which will include targeted temperature management (treatment to achieve and maintain a specific body temperature), ventilator management and blood sugar and electrolyte monitoring.

Blood is routinely collected from patients during and following cardiac arrest as part of the standard of care. As part of this study, we will attempt to collect additional vials of 10 mL of blood (equivalent to 2.03 teaspoons) from you at 5 time points in order to test for of inflammation and tissue damage markers: a) at baseline (during the cardiac arrest) +6 hours, b) 24 and c) 48 d)72 and e)96 hours after the cardiac arrest. Usually, research blood draws will not require additional needle sticks because you may already have your blood drawn during these times as part of routine care.

After you recover from the cardiac arrest, a clinician or a member of our research team will approach you to evaluate your neurological function (how your brain is working). This assessment will be done before you are discharged from the hospital. We hope to repeat this test again at 30 days following your cardiac arrest. This 30-day assessment can be done in person or over the phone.

5. What are the possible risks or discomforts?

You will receive CPR as part of your standard medical care. You will experience the risks of CPR regardless of your participation in the study. We do not anticipate a difference in risks between the two study groups.

Risks of blood draw includes temporary pain and bruising where the needle enters the skin, and sometimes, fainting and/or infection. It is possible that there could be future risks that are not known at this time.

The majority of people who have been unconscious as a result of cardiac arrest do not remember the event. Those who do have memories have described them as being very pleasant. However, we anticipate that it is possible some people may find it uncomfortable to talk about their experiences; if at any point you feel uncomfortable and/or wish to not talk about your experience, we will discontinue the interview. If you wish to take part in this study and find it difficult to talk about your experiences, we can refer you to an independent counselor.

There is a small possibility of breach of confidentially associated with this study. However, we have taken steps to avoid this by assigning participants a unique study identification numbers to protect their identities. We will also store all data in a secure database to prevent a breach in confidentiality. There may be additional risks, which are currently unforeseeable.

6. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

There may or may not be direct benefit to you from participation in this study. Receiving Physiological-Feedback CPR or Non-Physiological (Audiovisual) Feedback CPR during after the cardiac arrest may reduce brain injury and improve survival and survivor´s quality of life. The information that is gained from this study may lead to improvements in medical practices, which may help future patients experiencing cardiac arrest.

8. Will I be paid for being in this study?

You will not be paid for you participation in this study.

9. Will I have to pay for anything?

There is no cost to you for participating in this study. All study-related procedures such as brain monitoring, administration of the interventions, and study-related blood collection, will be paid for by the Department of Medicine at NYU Langone Health and National Institute of Health. You and/or your health insurance may be billed for the costs of medical care provided during this study if these expenses would have happened even if you were not in the study.

10. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator’s name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

11. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped, or your participation ended at any time by your physician, the study sponsor (NIH), or the Food and Drug Administration (FDA) without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor (NIH), the principal investigator, the Food and Drug Administration (FDA) or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

12. How will you protect my confidentiality?

Your medical information is protected health information, or “PHI”, and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality

To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or

local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).
The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

13. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- Governmental agencies responsible for research oversight (e.g., NIH, the Food and Drug Administration or FDA).
- The study sponsor: NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Other study sites involved in the research

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?

Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

14. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is [redacted] The NYU School of Medicine's IRB is made up of doctors, nurses, non-scientists, and people from the community.

15. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at [redacted]

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site 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.

16. Optional storage of leftover blood samples for future research:

We would also like to store and use your leftover blood samples from this study for analysis in future research conducted by NYULMC or its research partners. After the study is completed, the de-identified, archived samples will be stored at the Dr. Segal's Lab, under the direction of Dr. Leopoldo Segal, for use by other researchers including those outside of the study.

These samples could be used for research into the causes of cardiac arrest and post cardiac arrest syndrome, and their complications. The samples will be stored for up to 10 years for future use. Dr. Segal's Lab will be provided with a code-link that will allow linking the biological specimens with your medical data, although your identity will remain anonymous. Only the PI will have access to the key that links your identity to your code number. No genetic testing will be done or genetic information assessed.

You may withdraw or take back your permission to use and share banked blood samples at any time during the time the study is still ongoing. If you withdraw your permission during the study, we will not be able to take back information that has already been generated from your samples or used or shared with others. However, your samples will be destroyed so that they are not used for any additional research. Once the study is completed, the code-link that identifies you will be destroyed, so withdrawal is not possible after this point. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form.

Identifiers will be removed from your identifiable data and specimens. After such removal the data and specimens may be used for future research studies or shared with other researchers and we will not request additional informed consent from you to use these data and specimens as we have noted here.

Indicate your decision by writing your initials next to one of the two choices below. You may still participate in this study even if you do not give us this additional permission.

_____ YES: I give my permission to store my leftover blood samples for future research as described above.

_____ NO: I do NOT permit my leftover samples to be stored for future research as described above.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

For subjects unable to give consent, the consent for study participation and authorization to collect and use protected health information is given by the following authorized subject representative:

Name of Authorized Subject Representative (Print)	Signature of Authorized Subject Representative	Date

Select the category that best describes the above Authorized Subject Representative:

- ☐ Court-appointed guardian
- ☐ Health care proxy
- ☐ Durable power of attorney
- ☐ Family member/next of kin; for this category describe relationship below:

Witness to Consent of Non-English Speaking Subjects Using the "Short Form" in Subject's Spoken Language

Statement of Witness

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name of Witness (Print)	Signature of Witness	Date

Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

- ☐ Subject making his/her own "X" above in the subject signature line
- ☐ Subject showed approval for participation in another way; describe:

Name of Witness (Print)	Signature of Witness	Date