CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

Title: Development and Validation of the Cerebral Performance Categories-Extended (CPC-E)

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Why is this research being done?
We are conducting a research study to help us understand how individuals function after cardiac arrest. We have revised a scale to include new questions and we are interested in learning if this revised scale is easy to use and thorough. For example, the new scale asks questions about your/family member’s mood, energy level, and activity level. We plan to use this information to
learn more about how people function after cardiac arrest. This information may help us improve care after cardiac arrest.

**Who is being asked to take part in this study?**
We are asking you/your family member to participate in this research because you/your family member are/is at least 18 years old and have had a cardiac arrest. We will ask a total of 50 adults to take part in this study.

**What are the procedures of this study?**
If you/your family member agree to participate, a member of our research team will come to your/family member’s hospital room. At this visit, you/family member will be asked a series of questions about your/family member’s attention, memory, level of alertness, and level of activity. The visit in the hospital is expected to take approximately 15 minutes to complete. You/your family member will also be contacted by phone 1 week after hospital discharge. During this phone call, you/your family member will be asked a series of questions about your/family member’s level of activity, mood, energy, and work status. The phone call is expected to take 10 minutes.

**What are the possible risks and discomforts of this study?**
The risks associated with this research study are minimal. There are no invasive procedures or medications included in this study. The risks associated with this study include the potential for a breach of confidentiality, and the possibility that you/your family member will become frustrated.

**Who will know about my/family member’s participation in this research study?**
Any information about you/your family member obtained from this research will be kept as confidential (private) as possible. All records related to your/family member’s involvement in this research study will be stored in a locked file cabinet. Your/family member’s information will be labeled with a linking code, and your/family member’s identity will be stored in a separate location.

**Will I/my family member benefit from taking part in this study?**
There are no direct benefits to you/your family member for participating in this study. We hope to learn if this revised tool will be useful to clinicians who treat patients after cardiac arrest.

**How much will I/family member be paid if I/family member complete/s this study?**
There is no payment for taking part in this study.

**Will anyone know that I am/family member is taking part in this study?**
All records related to your/family member’s involvement in this study are kept strictly confidential (private) and any data that includes your/family member’s identity will be stored in locked files. Your/family member’s identity will not be revealed in any description or publications of this research.

It is possible that authorized representatives from the University of Pittsburgh Research Conduct
and Compliance Office (including the University of Pittsburgh IRB) may review your/family member’s data for the purpose of monitoring the conduct of this study.

If you choose to be in this research study (or if you choose to enroll your family member in this research study), the researchers will get personal information about you/your family member. This information may include past and present medical records related to the cardiac arrest care and information obtained during this research, such as your/family member’s responses on the questionnaires. Federal regulations give you/your family member certain rights related to your/his/her health information. These include the right to know who will be able to get the information and why they may be able to get it. The researchers involved in this research study must get your/family member’s authorization (permission) to use any health information that might identify you/your family member.

For how long will the researchers be permitted to use and disclose identifiable information related to my/family member’s participation in this research study? The researchers may continue to use and disclose, for the purposes described above, identifiable information related to your/family member taking part in this research study for a minimum of 7 years after the final reporting or publication of the study.

Is my/family member’s participation in this research voluntary? Yes, your/family member’s participation in this research study is completely voluntary. You/family member may refuse to take part in it, or you/family member may stop participating at any time, even after signing this form. Your/family member’s decision will not affect your/his/her relationship with UPMC or the University of Pittsburgh. Whether or not you/family member provide your consent to take part in this study will have no effect on your current or future relationship with UPMC or the University of Pittsburgh. Neither you/your family member, nor the insurance provider, will be charged for the costs of any of the procedures performed for the purpose of this research study.

May I/family member withdraw, at a future date, my/his/her consent for participation in this research study? You/your family member may withdraw, at any time, your/his/her consent to take part in this research study, to include the use and disclosure of your/his/her identifiable information for the purposes described above. Any identifiable research information recorded for, or resulting from, your/his/her participation in this research study prior to the date that you/family member formally withdrew your/his/her consent may continue to be used and disclosed by the investigators for the purposes described above. If you/your family member withdraws participation from the study, your/family member’s current and future care will not be affected.

If you/your family member decide you/he/she no longer wish to participate after you have signed the consent form, you/your family member should contact Dr. Rittenberger or his research colleagues (412-647-3078). Your/family member’s decision to withdraw from this study will have no effect on your/his/her current or future relationship with the University of Pittsburgh.

How can I get more information about this study?
If you or your family member would like additional information, you/he/she may contact the Research Office at 412-692-5551. Questions about your/family member’s rights as a research participant can be answered by the Human Subject Protection Advocate at the University of Pittsburgh IRB Office- 866-212-2668.

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VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of the study, and that such future questions will be answered by a qualified individual or by the investigator listed on the first page of this consent document. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in this research study, and I am giving permission to use my health information for the purposes described above. A copy of this consent form will be given to me.

_________________________________________  _________________________
Participant’s Signature      Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions of the individual(s) have about the study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component but this protocol was begun until after this consent form was signed.
<table>
<thead>
<tr>
<th>Printed Name of Person Obtaining Consent</th>
<th>Role in Research Study</th>
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<td>Signature of Person Obtaining Consent</td>
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PROXY CONSENT

Participant’s Name (Print) ___________________________ Date _____________

The above-named individual is unable to provide direct consent for study participation because ____________________________________________________________________________________________________________

Therefore, by signing this form, I give my consent for his/her participation in this research study.

Representative’s Name (Print) ___________________________ Representative’s Relationship to Participant ___________________________

Representative’s Signature ___________________________ Date _____________

Witness Signature ___________________________ Date _____________

VOLUNTARY ASSENT:
This research has been explained to me, and I agree to participate.

Participant’s Signature ___________________________ Date _____________

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent ___________________________ Role in Research Study ____________

Signature of Person Obtaining Consent ___________________________ Date _____________

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I understand that I am currently participating in a research study. I further understand that consent for my participation in this research study was initially obtained from my authorized representative as a result of my inability to provide direct consent at the time that this initial consent was requested. I have now recovered to the point where it is felt that I am able to provide direct consent for continued participation in this research study.

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. By signing this form I agree to participate in this research study.

VOLUNTARY ASSENT:

Patient provides voluntary assent to participate in the study.

_____ YES     _____ NO     Date: __________________

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after the participant provided assent.

___________________________________  ________________________
Printed Name of Person Obtaining Consent  Role in Research Study

__________________________________  _________________________
Signature of Person Obtaining Consent  Date