COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
200 FR. 4 (2014-4)

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

Study Title: Miraculous Coma Survivor Study
Principal Investigator: David Mathew Greer, MD, MA
Funding Source: N/A

In this consent form, "you" always refers to the research subject. When this document is used as a parental permission form, the word "you" refers to "your child".

Invitation to Participate and Description of Project

You are invited to take part in a research study designed to look at the clinical and investigational data of coma survivors whose initial prognostication was estimated to be consistent with a non-recoverable neurological function and poor outcome. You have been asked to take part because you were previously diagnosed as either having a non-survivable injury or to be in a permanent coma.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures and possible benefits. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree to take part in this study, we will ask you to give us permission the to review your medical record during the hospital admission when you/your family were told that you had a non-survivable event or no chance of meaningful neurological recovery. We will mail you a medical release form, which we ask you to sign and return to us. We will send this form to the hospital at which you were treated and get the medical record for review.

The types of information to be collected include: name, age, admission diagnosis, past medical history, neurological examination, prognosis documentation, vital signs, imaging, diagnostic procedures, medications, laboratory evaluations and surgical interventions, if applicable. If we are unable to get enough information from the medical record, we may call you and ask you questions over the phone.

Lastly, we do not plan to disclose or discuss various details of your hospitalization with you individually.

Risks and Inconveniences

There are no physical risks associated with this study. However, some questions may make you uncomfortable and there is the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Benefits

Participation in this study will have no direct benefit to you. However, your participation will help us to better understanding possible difficulties in accurately predicting what is, and what is not a survivable event, and who is likely to recover from a coma or not.

Economic Considerations

There will be neither compensation nor any costs for you to participate in this study.

Confidentiality and Privacy

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as permitted by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. Patient's data will remain confidential and safeguarded through storage in password-protected computer/database. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

We understand that information obtained about you is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information such as your name, age and medical history. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace any identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to the coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. The research team will only give this coded information to others to carry out this research study. The link to the personal information will be kept until the conclusion of the study, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form until it is destroyed.

The information about your health that will be collected in this study includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this Study.
- Records about phone calls made as part of this research
- Records about your study visits
- Name, Age, admission diagnosis, past medical history
- Vital signs
- Physical and neurological exams
- Documentation of prognosis, neurosurgical interventions
- Imaging data, laboratory, x-ray, and other supplementary prognostic tools (such as somatosensory evoked potential studies, EEG reports)

Information about your health which might identify you may be used by or given to:

- Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on

human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.

- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The Principal Investigator, Dr. David M. Greer.

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staffs at the Yale School of Medicine and Yale-New Haven Hospital are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However to better protect the health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

You have the right to review and copy your health information in medical record in accordance with institutional medical records policies. This authorization to use and disclose your health information collected during participation in this study will never expire.

Voluntary Participation and Withdrawal

Participating in this study is voluntary. You are free to choose not to take part in this study. You do not waive any of your legal rights by signing this form. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as health care outside the study, the payment for your health care, and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

Withdrawing From the Study

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

The researchers may withdraw you from participating in the research if necessary (e.g. in cases where there is no documentation of poor prognosis by any physician during patient's hospital admission). Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with your health care facility.

Withdrawing Your Authorization to Use and Disclose Your Health Information

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to Dr. David M Greer at the Yale University, 15 York Street LLCI 1004, New Haven, CT 06520. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject:_____

Signature:_____

Date:_____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator Dr. David Greer at (203) 737-1057. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.