CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY TITLE: COGWell: COGnitive outcomes and WELLness in survivors of critical illness

PRINCIPAL INVESTIGATOR (Study Doctor): Dr. M. Elizabeth Wilcox
Toronto Western Hospital
Telephone: 416-603-5800 ext. XXXX

24-HOUR PHONE NUMBER: Toronto Western Hospital ICU
Telephone: 416-603-XXXX
(Ask for the attending physician on call)

This consent is directed to the patient, but, in the event that the patient is unable to give consent on his/her behalf, a next-of-kin or legal representative may provide consent on the patient’s behalf.

INTRODUCTION
You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary. Regardless of your decision, you will continue to receive the best care possible at the University Health Network.

BACKGROUND/PURPOSE
You are being asked to take part in this study because you have an acute illness that required mechanical ventilation in the intensive care unit (ICU). There is currently little information available on the long-term outcomes after ICU. Up to 9 out of 10 patients may experience problems with their memory and attention, and in approximately half of patients these problems can last for years. Two important questions are 1) whether or not we can predict which patients will have memory or attention problem years later and 2) are there things that can be done to minimize the effect of critical illness on memory and attention?

STUDY DESIGN
The purpose of this study is to learn what the one-year memory, attention and concentration, and day-to-day function (ability to balance check book, make a shopping list, etc.) is in patients who have been on a mechanical ventilator for at least 3 days. We also want to see how sleep quality and different blood changes may affect one-year performance on these tests. Lastly, this study wants to see if a routine test to measure brain activity can predict who will have memory, attention and concentration, and day-to-day function at one-year follow-up.
While in the ICU, you have received standard care as required by your diagnosis and clinical symptoms. Taking part in the study does not involve changes in the care that you will be receiving while at the University Health Network. If you choose to take part, a set of tests will be done in addition to those routinely done during your hospital stay.

The Apolipoprotein E (APOE) blood test is a test for genetic risk factors for Alzheimer’s disease. The sample will be taken to check for the relationship between APOE and sleep disruption and memory, attention, and concentration in survivors of critical illness. This sample will be collected while you are still in hospital and sent to the Hospital for Sick Children, Toronto, ON for analysis. Another blood sample will be tested to see how the activity of the immune system changes over time after critical illness. This sample will be stored at the University Health Network and then tested at the University of Toronto. The results of these tests will not be available to study participants. The blood samples will be destroyed after the testing is done.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
About 150 patients will be taking part in this study. Of those 150 patients, around 100 will be at the University Health Network.

PROCEDURES
Study visits:
Within the first week after discharge from the ICU, if you are able, you will be asked to:
- Provide a 10-20 ml blood sample for two blood tests: the APOE and biomarkers.
- Wear a wristwatch-like device (actigraph) for 10-days to measure continuously your movement to assess amount and quality of your sleep.
- Stickers will be put on your head to monitor your brain activity during the day or early evening (approximately 1 hour).
- Complete questionnaires that will ask about quality of sleep in the ICU and memory, attention and concentration after ICU discharge. These questionnaires will take approximately 20 minutes to complete.
- A family member or a close friend will be asked to complete a questionnaire describing how your memory, attention and concentration were prior to being admitted to the hospital. This will take approximately 10 minutes to complete.

You will be seen in clinic at the University Health Network at 6- and 12-months after your discharge from the ICU. You will be contacted 2-3 weeks before your follow-up appointment to confirm availability. As part of these visits, you will be asked to:
- Provide a 10-20 ml blood sample for biomarkers.
- Wear an actigraph for 10 days, after which time you will return it to the study centre by pre-paid courier.
- Wear stickers on your head to monitor your brain activity for approximately 1 hour.
- Complete questionnaires that will assess your quality of sleep, memory, attention, and concentration, and mood. These will take approximately 10 minutes each to complete.
The entire follow-up appointment should take approximately 2 hours. If preferred, you can have your memory testing done over the phone and the mood questionnaire could be completed at home and mailed. This would decrease your follow-up appointment to less than 90 minutes.

**VOLUNTARY PARTICIPATION**
The study participant’s participation in this study is voluntary. You can choose not to be in the study or you may leave the study at any time without affecting your medical care. Throughout the study, you will be advised of any new information that might affect your decision to remain in the study.

**WITHDRAWAL FROM STUDY**
If you decide to leave the study, the information that was collected before you leave the study will still be used in order to help answer the research question. No new information will be collected without your permission.

**RISKS**
This study has risks. Some of these risks we know about. There is also a possibility of risks that we do not know about and have not been seen in study participants to date. Please call the study doctor if you have any side effects even if you do not think it has anything to do with this study. The risks we know of are:

- **Blood tests:** To reduce and/or minimize any discomfort you may experience, whenever possible, we will take a blood sample while blood is being drawn as part of your standard clinical care. Blood will be taken from either a tube already inserted into your artery or if you do not have this, we will have to take it from a needle inserted into your vein. If the sample is taken using a needle you may experience discomfort or pain, and there may be a small amount of bleeding. You may experience a slight discomfort, bruising, bleeding, swelling or redness at the place of the needle puncture site. There is also a slight chance of infection at the place where the needle punctures your skin.

- **The measures of brain activity:** During the test to see what happens in the brain, the technician may encourage the patient to do things that stimulate the brain such as deep breathing or flashing lights. As a result, you may feel dizziness or lightheadedness. It is uncommon and will resolve in minutes. Mild irritation can rarely be experienced from the preparation of the skin and cream used to attach the electrodes to the scalp for recordings. This is typically very mild and resolves within hours to days. The glue used to attach electrodes has a bad smell and may cause headaches, irritation of the eyes, rarely a skin reaction. Again, these reactions are usually mild and resolve quickly.

**BENEFITS**
You may receive no direct benefits from being in this study. However, results from this study may further medical and/or scientific knowledge.
ALTERNATIVES TO BEING IN THE STUDY
If you do not take part in the study, you will be followed up as per clinical care usual schedule.

CONFIDENTIALITY
If you agree to join this study, the study doctor and his/her team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could identify you and includes your:

- Name,
- Address,
- Date of birth,
- Postal code,
- New or existing medical records that includes types, dates and results of medical tests or procedures.

Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital. This is for clinical safety purposes.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study is following proper laws and guidelines:

- Representatives of the University Health Network (UHN) including the UHN Research Ethics Board

All information obtained during the study will be held in strict confidence. The study participant will be identified with a study number only. No names or identifying information will be used in any publication or presentations. No information identifying you will be transferred outside the investigators in this study or this hospital.

COSTS
You will not have to pay for any of the procedures involved with this study. You will be given 25$ to cover parking for each of the two visits that you make to the hospital for the study.

RIGHTS AS A PARTICIPANT
If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

CONFLICT OF INTEREST
Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

**QUESTIONS ABOUT THE STUDY**
If the study participant suffers any side effects or other injuries during the study, or if you have any general questions about the study, please call the doctor in charge of this study, Dr. Elizabeth Wilcox at (416) XXX-XXXX. You may also contact the Medical/Surgical ICU study coordinator at Toronto Western Hospital, Medical/Surgical ICU) at (416) XXX-XXXX or at (416) the Toronto General Hospital at (416) XXX-XXXX, at any time.

If you have any questions about the study participant’s rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (REB) or the Research Ethics office number at (416) 581-XXXX. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.
Study Title: **COGWELL: COGnitive Outcomes and WELLness in Survivors of Critical Illness**

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study.

______________________________        __________________        __________________
Print Study Participant’s Name        Signature        Date

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions.

______________________________        __________________        __________________
Name of participant        Signature        Date
(print)

______________________________        __________________        __________________
Substitute decision-maker        Signature        Date
(print)

______________________________        __________________        __________________
Name of Person obtaining consent        Signature        Date
(print)