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ALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY
MONTEFIORE MEDICAL CENTER

Parental Permission and Young Adult Assent for Participation in Research

INTRODUCTION:

By signing this form you have voluntarily agreed to participate in a research study Sleep Mechanisms in Children: role of metabolism to be carried out under the supervision of:

Principal Investigator: Gabriel G. Haddad
Office Address:
Office Phone:

CONFIDENTIALITY: (Who May See Your Records)

The study research records will be kept confidential and you will not be identified in any written or verbal reports. As part of this study, the researchers will review your medical records and will keep the information confidential. All laboratory specimens and reports will be identified only by a coded number to maintain subject confidentiality. The research records will be kept in a secured area and locked in a file cabinet in the research offices of the Principal Investigator. Research personnel authorized by the Principal Investigator will have access to these records. All laboratory specimens and reports will be identified only by a coded number to maintain subject confidentiality. The research records will be kept in a secured area and locked in a file cabinet in the Albert Einstein College of Medicine Clinical Research Center (CRC). The Clinical Research Center staff, as well as research personnel authorized by the Principal Investigator will have access to these records.

Members of the research team, the sponsors of this research and other institutions who participate in this study may inspect your research records and medical records. These include: The Albert Einstein College of Medicine of Yeshiva University, Montefiore Medical Center, Jacobi Medical Center, and North Central Bronx Hospital. These include: The Albert Einstein College of Medicine, Yeshiva University, Montefiore Medical Center, Yale University and the National Institute of Health. All of these groups have been requested to maintain confidentiality.

Your records may also be inspected by the human research committee(s) of the Albert Einstein College of Medicine Committee on Clinical Investigations (CCI), and the Montefiore Medical Center Institutional Review Board (IRB).

WHOM TO CONTACT FOR QUESTIONS:

You can call the supervisor of this study, named at the beginning of this consent document in the **INTRODUCTORY PARAGRAPH,** either Dr. Hoby Hetherington, Dr. Jullie Pan or Dr. Lewis Kass for Dr. Lewis Kass:

- You have any questions related to this research project.
- You have any questions about your rights as a research participant.
- You believe you have any injury related to this study.

You may also call the Administrator of Committee on Clinical Investigations of Yeshiva University, Monday through Friday between 9 AM and 5 PM, or the IRB Manager of the Montefiore Medical Center Institutional Review Board, Monday through Friday between 9 AM and 5 PM.

STUDY SPECIFICS

1. PURPOSE:

You and approximately 47 other young adults are invited this year to participate in a study that will examine the levels of certain chemicals in the brain when you are awake and sleep and how the brain functions during sleep. We are studying how acetate and glucose (blood sugar) in the brain change or convert themselves to the chemicals glutamate and glutamine. You have been asked to participate in this study because you are a normal healthy person with no disease wand would therefore, represent who a healthy person responds.

2. PROCEDURES:

The study will involve 3 visits to the Children' Hospital/MR Center under the observation of Drs. Lewis Kass or Haddad. Visit #1 is a screening Specialty Clinic visit during which a physical exam, a history with blood tests will be performed. Visits #2 and 3 will be visits to the magnetic resonance (MR) visits. Visits and procedures are as follows:

Screening Clinic Visit (Visit #1):

Before you can be part of the study, you will come to the Specialty Pediatric Clinic (4th floor of the Children's Hospital) for a screening visit of approximately 1 hour. During this visit, the procedures of the study will be explained to you by a doctor who also will perform a physical examination and ask about your medical history. During this visit a set of blood and urine tests will be done. The amount of blood taken will be 1/2 ounce. One week later, after the results of the first screening visit have been evaluated by the study investigators, Drs. Kass, or Haddad will call you on the phone, to set up a date for the next visits as described below. There are 4 groups of adolescent children participating and you will be randomly assigned to one of these groups, as described below.

Groups of children participating (visits #2, 3):

There are 4 groups of children in this study. Two groups will be studied with an infusion into a vein containing ^{13}C-acetate and the other two groups with an infusion containing ^{13}C-glucose. Carbon 13 (^{13}C) is a stable (non-radioactive) carbon that is present in nature. The ^{13}C is part of the glucose or acetate, and we use it to study metabolism. These infusions will allow us to monitor the chemicals in your brain as we describe below. One group receiving the acetate infusion will be studied during wakefulness or sleep after a normal daily activities and the other group will be studied after sleep deprivation of one whole night. That is, you will be studied during the following day or night after you

have not slept one whole night prior to the study day or night. Similarly, each of the two groups receiving the glucose infusion will be studied in the same way as for the groups receiving acetate, that is one group will be studied after normal activities during the previous day and the other after one night without any sleep.

The studies will be done in a large magnet whether you will be studied awake or asleep. The study in the magnet will make us able to look at how your brain functions during sleep or when you are awake.

PAYMENTS TO SUBJECTS:

In order to help defray the costs you have incurred in each visit, we will compensate your family as follows: $50 for the clinic visit (screen), $100 for the sleep visit and $150 for each of the 2 NMR studies. If you finish 1-2 phases, you will be compensated for your time.

3. RISKS:

The risks of this study are minimal. Intravenous catheters used during the glucose or acetate infusion are associated with a mild pain upon insertion, and a small risk of localized bruise, hematoma and/or infection. Other than the needle stick for the local numbing (anesthesia) of the skin before the infusion is started, this is a painless procedure. Hence the risks in this whole study are minimal.

If there is a physical injury as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally.

The amount of hemoglobin in your blood will be tested prior to the study and if it is low you will be excluded from the study. The total blood loss for the study will not exceed 1.5 ounces, a volume which is safe to take and which is only a small fraction of the amount of blood taken during a normal blood donation

Glucose and acetate are naturally occurring substances in your body. Carbon 13 is an isotope of carbon, it is not radioactive and has no known harmful effects. It exists in nature and it is the form of carbon that can be measured with the magnet.

While high field (4 Tesla) magnets of the type used for this study are still considered experimental, they are well within the safe limits of magnetic field exposure as currently set by the Food and Drug Administration and are not considered to have any additional risk. The large magnet and magnetism will give us chemical information from your body. If you have a pacemaker or some type of metallic implant, you will be excluded from this study due to possible effects of magnetic fields on the pacemaker or implant. Be sure to tell us if you know or think you have a pacemaker or a metallic implant in your body. When you fill out the attached safety questionnaire make sure that there is no hazard to you from one of the devices mentioned on the form. There are no known side effects associated with these procedures. A few people become anxious when they are in the magnet. If you think or know that you feel that way, let us know.

PROTOCOLS WITH RESULTING DATA THAT HAVE THE POTENTIAL TO AFFECT SUBJECT INSURABILITY:

Some tests reveal information that may not affect a person's insurability.

4. BENEFITS:

This study offers no direct benefits to you. However, it is hoped that the results of this study will give more insight into how the brain uses glucose (sugar) and acetate in healthy individuals during wakefulness, during sleep and after people are deprived of sleep. This will not help you but will help, possibly other children.

5. ALTERNATIVES:

You may choose not to participate in this study.

COSTS TO SUBJECTS:

These studies are performed free of charge.

WITHDRAWAL:

Your participation in this study is voluntary. You may be a participant in it only if you wish, and you may withdraw from the study at any time. Your treatment by doctors and staff at the institution(s) involved in this study, now and in the future, will not be affected in any way if you refuse to participate or if you enter the program and withdraw later.

SUMMARY:

The information in this Informed Consent Document has been explained and discussed with you. You have also been given the opportunity to ask questions about this research and have your questions answered. A copy of this consent document has been given to you, whether or not you have agreed to participate in this study.

_____ _____

Signature of Participant Date

_____ _____

Signature of person obtaining consent Date

PARENTAL PERMISSION:
I voluntarily give permission for my child to participate in the research protocol.

Signature of Parent or Guardian

Date

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