TWIN SLEEP STUDY

Principal Investigator: Naomi Friedman, Ph.D.

PARTICIPANT INFORMED CONSENT FORM
September 2009

Please read the following material that explains this research study. Signing this form will indicate that you have been informed about the study and that you want to participate. We want you to understand what you are being asked to do and what risks and benefits—if any—are associated with the study. This should help you decide whether or not you want to participate in the study.

You are being asked to take part in a research project conducted by Naomi Friedman, Ph.D., a faculty research associate in the University of Colorado at Boulder's Institute for Behavioral Genetics, 447 UCB, Boulder, CO 80309-0447. Dr. Friedman can be reached at (303) 492-7362.

Project Description:

This research study is about sleep patterns and difficulties. You are being asked to be in this study because you are a twin who has participated in studies from our Colorado Twin Registry and studying twins will help us understand how genes and environment influence sleep behaviors. Your participation in this study is entirely voluntary.

Procedures:

If you agree to take part in this study, you will be asked to complete a questionnaire which is available on-line. If you prefer we will mail a paper-and-pencil copy or read it to you as a telephone interview. Examples of the questionnaire items are: "Have you ever had difficulty falling asleep?" "Are you an irritable person?" "Sometimes I wonder why I have the thoughts I do" (strongly disagree to strongly agree) and items on a "stress" questionnaire checklist such as experiencing the death of family member, financial difficulties, and health and legal problems. We may use the information about you collected during this session in conjunction with DNA samples you have previously provided, or may provide in the future, to locate genes involved in these behaviors.

Participation in the study should take about 30-45 minutes of your time.

About 2800 individuals will be invited to participate in this research study.

Risks and Benefits:

Risks. We do not foresee any significant risks associated with participation in this study. However, you might find some of the questions embarrassing. Benefits. Although it should not be considered a substitute for a clinical evaluation, some feedback on your sleep patterns and sleepiness levels will be provided.

Source of Funding:

Funding for this study will be provided by a private foundation (the Henry Ford Hospital). In the future we may request additional funding from a federal agency that requires that data be collected in a form that may be analyzed for differences between men and women and races or ethnic groups.

There is no cost to you for participation in this study.

Subject Payment:

You will be paid $20 by check for completion of the questionnaire .

Study Withdrawal:

You have the right to withdraw your consent or stop participating at any time. You have the right to refuse to answer any question(s) or refuse to participate in any procedure for any reason. Refusing to participate in this study will not result in any penalty or loss of benefits to which you are otherwise entitled.

Confidentiality:

We will make every effort to maintain the privacy of your data. All of the information you will provide will be strictly confidential. Your completed questionnaire will be identified only by a numerical code, not your name. All written materials are stored in locked file cabinets, and all computer-based materials are stored in password-protected electronic files. Your responses will not be released to anyone.

Other than the research team, only regulatory agencies such as the Office of Human Research Protections, the University of Colorado Institutional Review Board, and authorized personnel from the National Institutes of Health may see your individual data as part of routine audits.

Invitation for Questions:

If you have any questions regarding your participation in this research, you should ask the investigator before signing this form. If you should have questions or concerns during or after your participation, please contact the Study Coordinator, Sally Ann Rhea, at 303-492-2822 or the Principal Investigator, Naomi Friedman, at 303-492-7362

If you have questions regarding your rights as a participant, any concerns regarding this project or any dissatisfaction with any aspect of this study, you may report them -- confidentially, if you wish -- to the Executive Secretary, Institutional Review Board, 563 UCB, ARCE Room A15, University of Colorado at Boulder, Boulder, CO 80309, (303) 735-3702

Authorization:

I have read this paper about the study or it was read to me. I know the possible risks and benefits. I know that being in this study is voluntary. I choose to be in this study. I know that I can withdraw at any time. I have received, on the date signed, a copy of this document containing 2 pages.

Name of Participant (printed) _____ Age _____

Signature of Participant _____ Date _____
(Also initial previous page of the consent form.)

For IRB Use Only

This consent form is approved for use from _____ to _____.

_____ Panel Coordinator, Institutional Review Board
(Signature)