Sleep Optimization to Improve Glycemic Control in Adults with Type 1 Diabetes

Informed Consent Form

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University of Illinois at Chicago (UIC) and/or
University of Illinois Hospital & Health Sciences System (UI Health)
Research Information and Consent for Participation in Biomedical Research
Sleep Optimization to Improve Glycemic Control in
Adults with Type 1 Diabetes

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Sponsor: Funded by the National Institutes of Health

About this research study
You are being asked to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

Taking part in this study is voluntary
Your participation in this research study is voluntary. You may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with the University of Illinois Hospital and Health Sciences System (UI Health) and/or University of Illinois at Chicago (UIC).

This consent form will give you information about the research study to help you decide whether you want to participate. Please read this form and ask any questions you have before agreeing to be in the study.

You are being asked to participate in this research study because you are an adult with type 1 diabetes who reports sleeping less than 6.5 hours per night on average OR a variable sleep schedule.

Up to 300 subjects will be enrolled in this research study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

WHY IS THIS	This research is being done to better understand how to improve

STUDY BEING DONE?	sleep for individuals with type I diabetes. The purpose of this study is to evaluate the outcomes of a sleep intervention compared to a healthy living intervention.
WHAT WILL I BE ASKED TO DO DURING THE STUDY?	After obtaining your consent on this electronic consent form, we will send you a link to complete questionnaires (about your health, diabetes care, mood and stress levels) online. Then we will mail study materials and supplies including written and video instructions to your home. Then we will schedule an initial meeting (Week 0 – screening) for orientation to the study procedures and to collect baseline information. All meetings will be conducted remotely by videoconference (on a mobile device or computer). We do require that you confirm that you have a private location for the meetings Week 0: During the first remote visit we will meet for approximately one hour to review the study procedures and teach you how to obtain the baseline measures: 1.) First we will ask you to test a urine sample for pregnancy (women- one time). If the pregnancy test is positive, you will not be able to participate in the study. 2.) We will ask you to measure your waist circumference (one time) and report the results. 3.) Next we will teach you how to collect a fingerstick of blood to measure your hemoglobin A1c (A1C). 4.) place and care for a continuous glucose monitor (CGM) and sleep watch (actiwatch) that you will wear for one week. 5.) and complete a paper and pencil sleep log for the same week. After one week, we will ask you to remove the CGM and actiwatch and return the supplies in a postage paid package. We will also ask you to provide your most recent estimated glomerular filtration rate (eGFR) and height and weight from your health care provider. A1C provides an average of your blood glucose over 2-3 months, and the estimated glomerular filtration rate provides a measure of how quickly your kidneys filter substances in your blood. Once we receive the supplies, we will review the sleep data, A1C, eGFR and questionnaire results. We will then determine if you qualify to participate in the study. If the pregnancy test is positive, the estimated glomerular filtration rate is too low, the A1c is 10% or more, the mood score indicates you might be depressed or the sleep watch shows that you are sleeping more than 6.5 hours on average per week OR your sleep schedule is very consistent (less than 1 hour variation from day-to-day), you will not be able to participate in the study. We will know the results within two weeks. <u>Weeks 1-12:</u>

	Study participants will be randomly (like the flip of a coin) divided into one of two groups. Group A (Sleep Optimization group) will receive a Fitbit, bedtime text message reminders, weekly lessons and coaching from a sleep coach. Specifically, the first week (week 1) you will be provided a Fitbit and asked to download the Fitbit app to your smartphone and participate in a brief training session. Weeks 1-12, You will receive 8 telephone or video calls from a sleep coach (Weeks 1-4, 6,8,10,12) at a time that is convenient for you. These calls will last about 10 minutes and provide coaching related to your sleep goals. You will receive lessons (same weeks as calls) and progress reports delivered by email that can be viewed on your mobile device or computer. Every evening, you will receive a reminder text message, 30 minutes before your usual bedtime. These text messages can be turned off during weeks 7-12. You will be able to keep the Fitbit after the study is completed. Group B (Healthy Living group) will receive 8 telephone or video calls from a coach (Weeks 1-4, 6,8,10,12) at a time that is convenient for you. These calls will last about 10 minutes. You will also receive 8 emails (same weeks) with information related to healthy living. You will receive a Fitbit to keep at the end of the study but will not use it during the study. <u>Assessments (Data collection at weeks 6, 12 and 24):</u> Study materials will be sent to your home and we will schedule a videoconference meeting to collect similar information as at the beginning of the study: 1.) you will be asked to complete questionnaires (we will send an email link), and 2.) collect a fingerstick of blood for A1C, 3.) place and wear a CGM and 4.) actiwatch for one week, 5.) fill out the paper sleep log for one week. After one week of wearing the CGM and actiwatch you will return the supplies in the postage-paid package provided. This program will not change your usual diabetes care. Any questions you may have regarding your diabetes care should be directed to your diabetes physician.
HOW MUCH TIME WILL I SPEND ON THE STUDY?	The total length of the study is 25 weeks. There will be 4 visits by videoconference for data collection (weeks 0, 6, 12 and 24). Each visit will last one hour. The 8 lessons delivered by email take

	approximately 10 minutes to read. The 8 coaching calls (last approximately 10 minutes per week).
ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?	Being in this study may not help you directly. We hope that your participation in the study may benefit other people in the future by helping us learn more about improving sleep in people with type 1 diabetes.
WHAT ARE THE MAIN RISKS OF THE STUDY?	1.There are minor risks associated with your participation in this study. The likely risks and discomforts expected in this study are discomfort, irritation, or bleeding at the fingerstick site and insertion site (for CGM). You may experience skin irritation from wearing the wristband activity monitor (Actiwatch and/or Fitbit). 2.Some of the questions we ask may make you feel uncomfortable answering them. If you don't wish to answer a question you may skip it and go to the next question. 3.The less likely risks and discomforts expected in this study are: • Infection at the fingerstick site or insertion site (for CGM). The risk for this problem is very rare and is minimized by following standardized procedures by trained study personnel. • Loss of confidentiality. We will utilize standard procedures to protect your identity. We will monitor for these potential effects throughout the study. For details and a list of risks you should know about, please see the "What Are the Potential Risks and Discomforts of the Study" section below.
DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?	You may choose not to participate in this study. If you suspect you have a sleep disorder you can contact your physician to discuss and referral for a sleep study or clinical sleep evaluation.
QUESTIONS ABOUT THE STUDY?	For questions, concerns, or complaints about the study, please contact Pamela Martyn-Nemeth 312-996-7903 or email at pmartyn@uic.edu. If you have a research related injury, you should immediately contact Pamela Martyn-Nemeth at 708-204-6313. If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects

	(OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu. If you have questions or concerns regarding your privacy rights under HIPAA, you should contact the University of Illinois HIPAA Privacy Office at (844) 341-2201 or hipaa@uillinois.edu.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research. Please also feel free to ask the study team questions at any time.

Who May Participate in the Study?

Working age adults 18-65 years of age with type 1 diabetes for one year or more and typically sleep less than 6.5 hours a night or have a variable sleep schedule (bedtimes vary an hour or more from day-to-day) may be eligible to participate.

What Procedures are Involved?

This research will be performed at your home and all meetings will be conducted remotely by phone call/videoconference on a mobile device or computer (your preference). We will review the study procedures and instruct you how to use the study materials.

- → *At the first visit (week 0) the following procedures will be done: you will collect urine for pregnancy (if applicable), measure your waist size, provide eGFR and height and weight from your health care provider, complete questionnaires, apply a continuous glucose monitor (CGM) and actiwatch to wear and complete a sleep log for one week, and complete fingerstick blood sampling to obtain a measure of A1C. A postage-paid envelope will be provided to return the materials in one week.*
- → *Once the actiwatch is received and analyzed and blood values and questionnaire results have returned, you will be contacted to inform you of your eligibility to participate in the study. Those who are not eligible will receive their blood, CGM and actiwatch results and be thanked for their time. Those that are eligible will be randomized (like the flip of a coin) to participate in the sleep group or healthy living group.*
- → *Weeks 1-12 – study participants will be contacted by their coach for their study group and will be provided instructions which include: a schedule of the lessons, an email lesson and coaching call during 8 of the 12 weeks.*
- → *Those in the sleep group will receive a Fitbit in the mail and will be instructed on how to use it. Those in the healthy living group will receive a Fitbit at the end of the study.*
- → *Blood samples, questionnaires, CGM and actiwatch data collection will be repeated at weeks 6, 12 and 24.*
- → *There are 4 data collection videoconference meetings in total with each visit lasting one hour.*

During this study, Dr. Pamela Martyn-Nemeth and her research team will collect information about you for the purposes of this research.

Screening information that we will obtain before scheduling a study visit to determine preliminary eligibility:

- Demographic and health information that includes your: name, home address, email address, telephone number, age, sex, how long you have had diabetes, whether you have had a severe hypoglycemic episode in the past 6 months, other health conditions besides diabetes, allergies, pregnancy or planning pregnancy, rotating shift or night work, medications used, usual sleep patterns and sleep difficulties, height and weight.

Information that we collect from you over the entire study includes:

- Asking you to complete questionnaires that assess your sleep quality and factors that can influence your sleep such as caffeine use, menopause (in women), mood, stress, fatigue levels and quality of life.
- Other questionnaires will ask you about your usual diabetes self-care, experiences with hypoglycemia (low blood glucose) and fear of hypoglycemia and dietary information because sleep can influence diabetes self-care and food intake
- During the weeks that you wear the actiwatch, we will collect information on your sleep duration and timing that is an important factor we want to know about in this study
- During the 4 weeks that you wear the CGM, we will collect information on your interstitial (tissues under your skin) glucose levels because sleep may influence glucose levels
- Most recent eGFR from your health care provider for baseline kidney function; also pregnancy test (as applicable) and A1C to confirm eligibility.
- A1C will be measured 3 times during the study to determine if there are any changes over time.
- Audio recordings/video recordings of the coaching calls will be made for the purpose of assuring consistency of delivery of the intervention among the research personnel. These recordings will be coded to protect your identity. Only authorized key research personnel will listen to the recordings and the recordings will be destroyed at the end of the study.
- For those in the sleep group, Fitbit data will be collected and your coach will review it with you during coaching calls for the purpose of helping you to meet your sleep goals.

Will I receive the results (including any psychological, health, and/or biospecimen results) from the study?

We may learn things about you from this study which could be important to your health or treatment. If this happens, this information will be shared with you. Your fingerstick blood sample results, actiwatch sleep patterns and CGM glucose patterns will be shared with you at the

end of the study. You may need to meet with experts to help you learn more about your study results. The study will not cover the costs of any follow-up actions.

What are the potential risks and discomforts of the study?

Side effects, risks, and/or discomforts from participation in this study include:

- Discomfort, irritation, or bleeding at the fingerstick site and insertion site (for CGM). This discomfort usually subsides within a few minutes.

- You may experience skin irritation from wearing the wristband activity monitor (Actiwatch and/or Fitbit). This occurs rarely but can be minimized by adjusting the placement of the band or adjusting the tightness. The monitors can also be moved to the opposite wrist.

- Some of the questions we ask may make you feel uncomfortable answering them. If you don't wish to answer a question you may skip it and go to the next question.

- Infection at the fingerstick site or insertion site (for CGM). The risk for this problem is very rare and is minimized by following standardized procedures that you will be instructed on by trained study personnel.

- Loss of confidentiality. The risk for this problem is very low. We will utilize standard procedures to protect your identity. None of your data will be associated with your name and all of the data is stored very securely.

- Loss of privacy. The risk for this problem is very low. We will utilize private and secure locations to collect data at all times and will ask you to be in a private location during study meetings.

- We do not recommend participation in more than one study at a time. If you are participating in another study, please inform us.

- There may be risks from the study that are not known at this time.

What about privacy and confidentiality?

Efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. In general, information about you, or provided by you, during the research study, will not be disclosed to others without your written permission. However, laws and university rules might require us to tell certain people about you. For example, study information which identifies you and the consent form signed by you may be looked at and/or copied for quality assurance and data analysis include:

- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- Government Regulatory Agencies, such as the Office for Human Research Protections (OHRP).
- The National Institutes of Health.

A possible risk of the study is that your participation in the study or information about you and your health might become known to individuals outside the study. Your personal information, research data will be coded and stored in a password protected secure university server to prevent access by unauthorized personnel.

Your individual data will be stripped of all direct identifiers or destroyed after the final analysis of the research data.

To help us protect you and the information, documents, and biospecimens we will be collecting from you, this research has been given a Certificate of Confidentiality by the National Institutes of Health (NIH). This Certificate means that researchers cannot be forced, even by courts or the police, to disclose information, documents, and biospecimens that may identify you. However, your information and biospecimens may be given to personnel of the United States Government to audit or evaluate projects that are federally funded or to meet the requirements of the Food and Drug Administration (FDA). The Certificate does not stop you or a family member from disclosing, or agreeing in writing to allow researchers to disclose, information, documents, and biospecimens about you, including your participation in this research. For example, if you would like an employer or insurer to know something about you that is documented in this research, you can write and sign a statement telling the researchers it is okay to give your employer or insurance company information.

Even if the research has a Certificate, the research or any member of the study staff must report (even if it is without your consent) evidence of harm to self or others, including actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult. In addition, if the research shows that you have a reportable communicable disease (for example, tuberculosis [TB] or HIV/AIDS), the researchers may report this to the appropriate authorities.

When the results of the study are published or discussed in conferences, no one will know that you were in the study. During the study, audiotape recordings/video recordings will be collected for the purpose of assuring consistency of the study procedures. Your identity will be protected by eliminating any identifying information about you. The audiotapes will be destroyed at the conclusion of the study.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What if I am injured as a result of my participation?

If you get ill or injured from being in the study, UIC will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Pamela Martyn-Nemeth, PhD at 312-996-7903.

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proven that your injury or illness is directly caused by the negligence of UIC.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

What are the costs for participating in this research study?
There are no costs to you for participating in this research study.

Will I be reimbursed for any of my expenses or paid for my participation in this research study?
You will receive $50 in cash at week 12 and $50 in cash at week 24 for your participation in the research (Total $100).

Will I be told about new information that may affect my decision to participate?
During the course of the study, you will be informed of any significant new research findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

Can I withdraw or be removed from the study?

If you decide to participate, you have the right to withdraw your consent and leave the study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent if they believe it is in your best interests.

If you choose to no longer be in the study and you do not want any of your future information to be used, you must inform the researchers in writing at the address on the first page. The researchers may use your information that was collected prior to your written notice.

Will health information about you be created, used or shared with others during this study?

State and federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect your health information. This section of this form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information in this research study. By signing this form you are authorizing Dr. Pamela Martyn-Nemeth and her research team to create, get, use, store, and share protected health information that identifies you for the purposes of this research.

The health information includes all information created and/or collected during the research as described within this consent form and/or any health information in your medical record that is needed for the research and that specifically includes: :

- Personal identifiers (your name, address, phone number, date of birth)
- Medical diagnosis

During the conduct of the research, the researchers may use or share your health information:

- With each other and with other researchers involved with the study.
- With law enforcement or other agencies, when required by law.
- With the sponsor/funding agency of the research, the National Institutes of Health
- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- United States Government Regulatory Agencies, including but not limited to the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA).

If all information that identifies you is removed from the research data, the remaining information is no longer subject to the limits of this Authorization or to the HIPAA privacy laws. Therefore, the de-identified information may be used and released by the researchers (as permitted by law) for other purposes, such as other research projects.

How will your health information be protected?
The researchers and National Institutes of Health agree to protect your health information and will only share this information as described within this research consent/authorization form.

When your health information is given to people outside of the research study, those agencies that receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it. They may also share your information with others without your permission, unless permitted by laws that they have to follow.

Your Authorization for release of health information for this research study expires at the end of this study but can be canceled sooner if you decide to withdraw your permission.

You may change your mind and cancel this Authorization at any time. To cancel this Authorization, you must write to: Dr. Pamela Martyn-Nemeth, 845 S. Damen Ave, Room 720, Chicago, IL 60612

If you cancel this Authorization, you may no longer be allowed to take part in the research study. Even if you cancel this Authorization, the researchers may still use and disclose health information they have already obtained as necessary to maintain the integrity and reliability of the research and to report any adverse (bad) effects that may have happened to you.

Right to Refuse to Sign this Authorization
You do not have to sign this Consent/Authorization. However, because your health information is required for research participation, you cannot be in this research study if you do not sign this form. If you decide not to sign this Consent/Authorization form, it will only mean you cannot take part in this research. Not signing this form will not affect your non-research related treatment, payment or enrollment in any health plans or your eligibility for other medical benefits.

What if I am a UIC student?
You may choose not to participate or to stop your participation in this research at any time. This will not affect your class standing or grades at UIC. The investigator may also end your participation in the research. If this happens, your class standing or grades will not be affected. You will not be offered or receive any special consideration if you participate in this research.

What if I am a UIC or UI Health employee?
Your participation in this research is in no way a part of your university duties, and your refusal to participate will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment at UIC or UI Health. You will not be offered or receive any special consideration if you participate in this research.

Remember:
Your participation in this research study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Future contact:
I agree to allow the researchers to contact me about future research

☐ I agree --Initials _____.
☐ I DO NOT agree -Initials _____.

Audio recordings/video recordings
I agree to allow the researchers to record (audio/video) the entire intervention sessions during the study period.

☐ I agree --Initials _____.
☐ I DO NOT agree -Initials _____.

Signature of Subject

I have read the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research study. I will be given a copy of this form.

If you have not already received a copy of the Notice of Privacy Practices, you should ask for one.

Your signature below indicates that you are providing both consent to participate in the research study and authorization for the researcher to use and share your health information for the research.

_____ _____
Signature Date

_____
Printed Name

_____ _____
Signature of Person Obtaining Consent Date (must be same as subject's)

_____
Printed Name of Person Obtaining Consent