Pilot Study of Urine Content

NCT05637840

Informed Consent Form

5/19/2023

University of Wisconsin-Madison
Consent to Participate in Research and
Authorization to Use Protected Health Information for Research

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Study Title for Participants: **Pilot Study of Urine Content**

Formal Study Title: **Longitudinal study of metabolic content of human urine**

Lead Researcher: **Joshua Coon, (608) 263-1718, 4400 Genetics-Biotechnology Center**

Institution: **Department of Biomolecular Chemistry, University of Wisconsin-Madison**

Key Information

The information in this section is to help you decide whether or not to be a part of this study. You can find more detailed information later on in this form.

Why are researchers doing this study?

We invite you to take part in a research study that will analyze urine samples to identify metabolites that have the potential to be used for medical diagnosis. We are inviting you because you have expressed interest in participating.

The purpose of this research study is to test the different components in urine and see if we can match them to food, exercise and sleep that you report. We are trying to find out if urine would allow us to predict medical problems as they are happening. We are doing this research because we think that real-time predictions from urine could provide a way to measure overall health and give insights into how diseases start and progress through time.

What will I need to do in this study?

The research team will ask you to provide urine samples for 14 days, log your food and medications, take 2 finger stick blood tests and download data from a FitBit wearable device.

Some participants will be asked to limit their sleep to 6 hours a night for 2 nights in a row. This group will be chosen by chance, like flipping a coin. Neither you nor the study team will choose if you are in this group.

We expect that you will be in this research study for 28 consecutive days.

You can find detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

What are some reasons I might – or might not – want to be in this study?

You may want to be in this study if you are:	You may NOT want to be in this study if you:
• Willing to give urine samples on a daily basis. • Are interested in learning how to us a wearable devise to track your activities. • Interested in contributing to scientific knowledge even though you won't benefit directly from the study.	• Have difficulty urinating. • Have a sleep disorder or difficulty sleeping. • May not have time to log your food and medications. • Are uncomfortable using wearable technology such as a FitBit.

Do I have to be in the study?

No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights. You can ask all the questions you want before you decide.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

How is research different from health care?

When you take part in a research study, you are helping to answer a research question. Study tests and procedures are not for your health care.

Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to the research team at Laura Van Toll at 608-262-9469 or laura.vantoll@wisc.edu.

If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

If I take part in the study, what will I do?

If you decide to participate in this research study, the researchers will ask you to:

- Complete a questionnaire of basic health information: weight, height, age, sex, ethnicity and tobacco use. You may skip any question on the questionnaire that you do not wish to answer.
- Contribute 2-3 urine samples per day for 14 consecutive days, freezing them after collection. The process is similar to a urine sample collection procedure used at your doctor's office. You will be provided with an on-site urine collection kit and packaging and postage to mail your frozen urine samples to us.
- Wear a FitBit wearable device for 28 consecutive days, starting 14 days before urine collection and continuing for 14 days of urine collection.
- Take a finger stick test for inflammation at the beginning and the end of the 28 days. The test will be provided. The test is mailed to a lab for processing.
- Log your food intake, supplements and medication use for the 14 days you are collecting urine samples. You may use the FitBit wearable device (provided), a paper journal (provided) or a combination of the above. You may also photograph the food and beverage consumed instead of journaling.
- Participants will be randomly placed into one of two groups. One group will be asked to reduce their level of sleep to 4 hours per night for 2 nights in a row. The other group will not do this.
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Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Results of tests or procedures done as part of the study
- Things you tell the researchers about your health

What happens if I say yes, but I change my mind later?

You can leave the research at any time. If you choose to leave the study, your choice will not affect your healthcare or any services you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) will last until the research study is done. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.

- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Research Coordinator, Laura Van Toll via email to laura.vantoll@wisc.edu or US mail at 4400 Genetics-Biotechnology Center, 425 Henry Mall, Madison WI, 53706.

Will being in this study help me in any way?

Being in this study will not help you directly. Your participation in the study may benefit other people in the future by helping us learn how to use information from urine to predict disease.

What are the study risks?

- There is risk of infection from the finger stick test
- There is a risk that your information could become known to someone not involved in this study. The identity of people participating in this study will not be disclosed by the study team.

What happens to the information collected for the research?

We have strict rules to protect your personal information and protected health information (PHI). We will limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. This includes University of Wisconsin and its representatives and affiliates, including those responsible for monitoring or ensuring compliance, such as the Human Research Protection Program.

We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed in this form for the purposes described in this form. Once your health information is released outside UW-Madison it may not be protected by privacy laws and might be shared with others.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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.

Will information from this study go in my medical record?

None of the information we collect for this study will go in your medical record.

Will I receive the results of research tests?
Most tests done as part of a research study are only for research and have no clear meaning for health care. In this study, you will not be informed of any test results or unexpected findings.

What else do I need to know?

Will I receive anything for participating?
We will not pay you to take part in this study or pay for any out of pocket expenses related to your participation, such as travel costs. The FitBit wearable device provided by the research team will be yours to keep at the end of the study. If you withdraw from the study early, the FitBit is yours to keep.

Permission to communicate about the study by email
We are requesting your email address so we can contact you with reminders for downloading your wearable data, send shipping labels for your completed samples or follow-up if we have questions on your samples.

Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact study coordinator, Laura Van Toll at 608-262-9469. You do not have to provide your email address to participate in this study.

How many people will be in this study?
We expect about 30 people will be in this research study.

Who is funding this study?
This research is being funded by the Morgridge Institute for Research and the Kohler Company.

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study. If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Signature of participant	Date
Printed name of participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	