Study Title:
Feasibility of Using sipIT Tools to Increase Compliance With Fluid Consumption Guidelines in Urolithiasis -Prone Subjects

NCT Number: 03787615

Date of Consent: November 12, 2018

CONSENT FOR RESEARCH

The Pennsylvania State University

Title of Project: *Feasibility of Using sip^{IT} Tools to Increase Compliance with Fluid Consumption Guidelines in Urolithiasis-Prone Subjects*

Principal Investigator: *David E. Conroy, Ph.D.*

Address: *17 Recreation Building*

Telephone Number: *814-865-7935*

Subject's Printed Name: _____

We are asking you to be in a research study. This form gives you information about the research.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you.

Please ask questions about anything that is unclear to you and take your time to make your choice.

1. Why is this research study being done?

We are asking you to be in this research because you are age 18 or older, own an iPhone, and have a history of urolithiasis (kidney stones).

This research is being done to find out if we can use sensors, smart water bottles and mobile apps to increase fluid consumption.

Approximately 30 people will take part in this research study.

2. What will happen in this research study?

- This study involves three lab visits over the course of three months.
- Over the course of the three months, you will be asked to wear your FitBit watch, use an H_2O Pal water bottle and record your fluid consumption using mobile apps.
- You will be asked to respond to text notifications on your watch or iPhone if the measurement tools do not detect a drinking event within 30 minutes. These notifications will not be sent during "do not disturb" or self-reported sleep times.
- In this first lab visit, you will have your height and weight measured, complete questionnaires, receive your FitBit watch and H_2O Pal water bottle, have the sip^{IT} and Fitbit apps loaded on to your iPhone and receive training on use of these tools. You are free to skip any question that you feel uncomfortable answering.
- During the second lab visit, you will have your weight measured, complete questionnaires, participate in an informal interview discussing your experience with the sip^{IT} tools thus far, and receive compensation earned for the participation to date. This second lab visit will happen approximately 1 month after your first lab visit.

- During the third lab visit, you will you will have your weight measured, complete questionnaires and participate in an informal interview discussing your overall experience with the sip^{IT} tools. This third lab visit will happen approximately 3 months after your first lab visit.
- At the third lab visit, you will return the FitBit watch and receive your final compensation.
- You may be contacted at a later time to participate in a follow up study, if you are interested.

3. What are the risks and possible discomforts from being in this research study?

There may be a risk of feeling self-conscious or embarrassed when receiving text notifications on your FitBit watch or iPhone. There may be some mild discomfort associated with answering some of the interview or questionnaires. You have the right to refuse to answer questions that you find too uncomfortable. There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. Code numbers rather than names will be used on all research records and the information linking these codes to participants' identity will be kept separate from research records. The confidentiality of your electronic data created by this lab visit will be maintained to the degree permitted by the technology used. Despite our best efforts, absolute confidentiality cannot be guaranteed.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to you?

Increased compliance with fluid intake guidelines.

4b. What are the possible benefits to others?

This research can benefit others by informing future interventions that can use the sip^{IT} tools to help individuals increase compliance with fluid consumption guidelines.

5. What other options are available instead of being in this research study?

You may decide not to participate in this research.

6. How long will you take part in this research study?

If you agree to take part, you will participate in the study for 3 months. This includes 3 lab visits that can range from 1-2 hours each.

7. How will your privacy and confidentiality be protected if you decide to take part in this research study?

Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information.

- A list that matches your name with your code number will be kept in a locked file in the locked office of the research project manager (18A Recreation Building).
- Your research records will be labeled with your code number and stored electronically in a secure, cloud-based storage site created by our development team and approved by Penn State which is password and identity protected.

- Your study records to the point of withdraw must remain with the study records and cannot be removed.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

We will do our best to keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may find out about your participation in this research study. For example, the following people/groups may check and copy records about this research.

- The US Food and Drug Administration (FDA)
- The research study sponsor, the National Institutes of Health
- The Office for Human Research Protections in the U. S. Department of Health and Human Services
- The Institutional Review Board (a committee that reviews and approves research studies) and
- The Office for Research Protections.

Some of these records could contain information that personally identifies you. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order. One exception is if you agree that we can give out research information with your name on it. Other exceptions are information about child abuse or neglect and harm to yourself or others.

A description of this clinical trial will be available on http://clinicaltrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

8. What are the costs of taking part in this research study?

You will be responsible for your transportation to/from the lab visits.

9. Will you be paid or receive credit to take part in this research study?

You will receive $20 at your second lab visit as compensation for completing all study procedures up to that point. You will receive an additional $50 and will get to keep your H_2O Pal water bottle at your third lab visit as compensation for completing all remaining all study procedures and returning the FitBit watch to the lab.

10. Who is paying for this research study?

The project described was supported by the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant UL1TR002014 to the Penn State Clinical and Translational Science Institute.

11. What are your rights if you take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.
- If you decide to leave the research study before the 3 month period, ***you will not receive compensation at the end for your time spent completing the study materials, although you may still receive compensation for returning the study devices***.
- If you decide to leave the research, ***contact the study team so that the investigator can arrange to pick up the study FitBit watch.***

12. If you have questions or concerns about this research study, whom should you call?

Please call the Project Manager, Deborah Reese (814) 865-7935 if you:

- Have questions, complaints or concerns about the research.

Please call the head of the research study (principal investigator), Dr. David Conroy at 814-865-3451 if you:

- Believe you may have been harmed by being in the research study.

You may also contact the Office for Research Protections at (814) 865-1775, ORProtections@psu.edu if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns or general questions about the research.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

INFORMED CONSENT TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative and have answered any questions he/she has about the research.

_____

_____	_____	_____
Signature of Person Who Explained this Research	Date	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and agree to allow your information to be used and shared as described above.

_____	_____	_____
Signature of Subject	Date	Printed Name