CONSENT FOR RESEARCH
The Pennsylvania State University

Title of Project: Efficacy of sip^{IT} Intervention for Increasing Urine Output in Patients with Urolithiasis

Principal Investigator: David Conroy, PhD

Address: 17 Rec Hall
University Park, PA 16802

Telephone Number: 8:00 a.m. to 5:00 p.m. (717) 531-0003, extension 284233.

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 and there will be no penalty or loss of benefits to which you are entitled.

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 at least 18 years old, have had a kidney stone in the past 5 years, and have recently had a low 24-hour urine volume. This research is being done to determine if sip^{IT} tools, a drinking sensor on a smart watch, a smart water bottle, and smartphone apps can increase urine volume in patients with a history of kidney stones.

Approximately 216 people will take part in this research study at Penn State.

2. What will happen in this research study?

- **We will ask you to complete the 1st study visit.**
    - If face-to-face research visits are permitted at Penn State: Research staff will meet you at the Hershey Center for Applied Research. Research staff will explain this consent form to you and you will be asked to verbally consent to participate. We will then measure your height, weight, waist circumference, and complete a few questionnaires. This visit should take roughly 45-minutes
    - If face-to-face research visits are limited at Penn State: Research staff will schedule a remote meeting either over the phone or over zoom to explain this consent form to you. We will then ask you to verbally consent to participate in this research study. The call should take 10-15 minutes. Staff will meet you at your next regularly scheduled Penn State Urology visit to measure your height, weight, waist circumference, and complete a few questionnaires which should take no more than 15 minutes.
- **You will be randomly assigned to one of two groups.** Both groups will receive information and advice on increasing fluid intake. One group will be asked to go on with their normal activities and the other group will be given a smart watch with a drinking detection sensor, smart water bottle, and asked to download their related smartphone apps. You will be randomly assigned to receive one of

the two study treatments. This means whichever study treatment you receive will be determined purely by chance. You will have an equal chance of being placed in to either group.

- **You may be asked to use a smart watch, smart water bottle, and smartphone app for 12 months.** If you are assigned to the experimental group, you will be given a smart watch (Fitbit Sense), smart water bottle (HidrateSpark Steel), and asked to download and accept the terms of service for their related apps on your personal smartphone. Staff will assist you in setting up the technology as well as train you how to use and maintain the technology.
    - We ask that you wear the smart watch, carry the smart water bottle, and smartphone for a minimum of 12-hours per day to track your fluid intake (either automatically via the bottle or, smart watch sensor or manually via the Hidrate app) as well as, receive text message reminders. You will be able to enter your fluid intake amount through the mobile app for drinking done in an alternate way (e.g. coffee cup, water fountain, soda bottle).
    - If 8 oz of fluid is not consumed every one hour, then a notification will be delivered through text messaging on your smartphone. If the goal is met, then the notification is canceled. The default hours will be 8am-8pm, however this may be adjusted to your preference for a 12-hour awake period. The goal is to drink 96 oz. per day which is what most patients require for a urine output <2.5L daily.
- **You will be asked to complete a 24-hour urine after 1 month of participation.** A staff member will call you approximately 2-weeks before the test date and confirm your address to send the 24-hour urine collection kit. Each test will be collected using Litholink services and arrive on a Sunday. You will be asked to collect the sample on Sunday and it will be taken by FedEx the next day (Monday). You will receive an email to complete a short survey to confirm completion of the 24-hour urine. If we do not receive a response then we will call you to confirm completion.
- **You will be asked to complete a study visit and 24-hour urine after 3 months of participation.** A staff member will call you approximately 2-weeks before the test date and confirm your address to send the 24-hour urine collection kit. Each test will be collected using Litholink services and arrive on a Sunday. You will be asked to collect the sample on Sunday and it will be taken by FedEx the next day (Monday). You will receive an email to complete a short survey to confirm completion of the 24-hour urine. If we do not receive a response then we will call you to confirm completion.

  We will schedule you to visit Research Staff at the Hershey Center for Applied Research where we will measure your weight, waist circumference, and complete a few questionnaires. The visit should last roughly 45-minutes.
- **You will be asked to complete a study visit and 24-hour urine after 12 months of participation.** A staff member will call you approximately 2-weeks before the test date and confirm your address to send the 24-hour urine collection kit. Each test will be collected using Litholink services and arrive on a Sunday. You will be asked to collect the sample on Sunday and it will be taken by FedEx the next day (Monday). You will receive an email to complete a short survey to confirm completion of the 24-hour urine. If we do not receive a response then we will call you to confirm completion.

  We will schedule you to visit Research Staff at the Hershey Center for Applied Research where we will measure your weight, waist circumference, complete a few questionnaires, and complete a voice recorded end of study interview. The visit should last roughly 45-minutes.
- **We will collect information from your medical record that is relevant to urolithiasis.** Throughout the study, staff will access your medical records to collect any information that may be relevant to urolithiasis (kidney stones) Examples include: recurrence of kidney stones, stone type, treatment type, absence of exclusion criteria, and current medications.

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

- **Loss of confidentiality:** 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. The confidentiality of your electronic data created by you or by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.
- **24-hour urine tests**: You may feel embarrassed to collect 24-hour urine, however this is temporary and is expected to resolve in a short period of time.
- **Questionnaires:** There may be some mild discomfort associated with answering some of the survey questions. You have the right to refuse to answer questions that you find too uncomfortable to answer.
- **Text notifications:** You may feel self-conscious or embarrassed when receiving a notification on your phone. You may ignore messages when it is unsafe or inopportune for their receipt (for example, unsafe to receive while driving and inopportune during a work meeting).

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

4a. What are the possible benefits to you?
There is no guarantee that you will benefit from this research. The possible benefits you may experience from this research study include increasing your fluid intake and reducing the chance of kidney stones.

4b. What are the possible benefits to others?
The results of this research may guide the future treatment and prevention of kidney stones.

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

You may decide not to participate in this research study.

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

If you agree to take part, it will take you 12 months to complete this research study. You will be asked to complete three visits at the Penn State Hershey Medical Center. The first will be at the very beginning of the study, the second visit will be after 3-months, and the last visit will be at the very end of the study after 12-months. Each visit should take approximately 45 minutes.

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

7a. What happens to the information collected for the research?
This section is about your identifiable health information that will be collected for this research study as explained above.

1. We will use and disclose your information only as described in this summary and in the HMC privacy Notice.

2. If you do not want us to use your identifiable health information, you should not be in this research.

3. Your permission for the use and sharing of your identifiable health information will continue indefinitely.

4. You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address on the front of this form.

5. The PSU Institutional Review Board, the Human Subjects Protection Office and the Research Quality Assurance Office at HMC/PSU, FDA, and Office for Human Research Protections in the Department of Health and Human Services may need to read your medical and research records if they need to review this study as part of their duties.

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

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. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed.

- A list that matches your name with your code number will be kept in a locked file or password protected file in REDCap (a password-protected and encrypted electronic research data program). Research staff will use REDCap to both collect and store data.
- Your research records will be labeled with your code number and research records will be kept in locked areas of the research labs.

  For research records and specimens sent to Litholink (a CLIA-certified, state-licensed laboratory in Chicago, IL) via FedEx, you will be identified by name, address, date of birth, and code number.

  For research records sent to Fitabase API (application programming interface), you will be identified by code number.

  For research records sent to HidrateSpark, you will be identified by code number.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot disclose information that identifies you to anyone not connected with the research. This protection also prevents this information from being used or disclosed for legal proceedings, such as being accessed through a court order. The Certificate of Confidentiality however does not prevent disclosures required by law, such as information about child abuse or neglect and harm to yourself or others. Also, your information may be disclosed in accordance with any consent you provide, including for your medical treatment or use in other research. Additionally, the Certificate of Confidentiality does not prevent your information from being disclosed to the National Institute of Diabetes and Digestive and Kidney Diseases in order for it to evaluate or audit the research, or prevent disclosures required to meet FDA requirements. For additional information ask the principal investigator or a member of the study team or contact the Office for Research Protections at (814) 865-1775.

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 Office for Human Research Protections in the U. S. Department of Health and Human Services
- The research study sponsor, The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).
- The Institutional Review Board (a committee that reviews and approves research studies) and Penn State's Office for Research Protections.
- The Food and Drug Administration.

Research staff will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

7b. What will happen to my research information and/or samples after the study is completed?

We may use your research information for future research studies or may share your information with other investigators here or at other institutions for future research without your additional informed consent. Future research may be similar to this study or completely different. Before we use or share your information, we will remove any information that shows your identity.

Once the trial is completed you will have the option to receive study results and summary data if you wish.

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

8a. What will you have to pay for if you take part in this research study?

For costs of tests and procedures that are only being done for the research study:

- You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of the research and are outside the standard of care (what is normally done) for your condition.
- The research-related tests and procedures that will be provided at no cost to you include:
    - 24-hour urine tests

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

8b. What happens if you are injured as a result of taking part in this research study?

In the unlikely event you become injured as a result of your participation in this study, medical care is available. It is the policy of this institution to provide neither financial compensation nor free medical treatment for research-related injury. By signing this document, you are not waiving any rights that you have against The Pennsylvania State University for injury resulting from negligence of the University or its investigators.

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

You will receive $30.00 for completion of your 1-month 24-hour urine, $35.00 after completing your 3-month 24-hour urine and in-person visit, $40.00 after completing your 12-month 24-hour urine and in-person visit.

You will be given a bonus of $50.00 if you complete all of the study visits and 24-hour urine tests throughout the 12-month study. By completing each study visit and 24-hour urine test you will receive a total of $180.00 for your participation in this study (bonus included). If you do not complete the study for any reason, you will be paid for the visits you have completed.

You will also receive/or retain a smart watch ($249.95) and smart water bottle ($64.99) as a bonus for completing all portions of the study.

If you live more than 20 miles from the Hershey Medical Center you qualify for travel reimbursement. We will compensate you for the round trip for $0.56 per mile (up to 100 miles). All travel reimbursement will be provided by Greenphire.

You will need to provide your social security number and address to receive a check for payment. The payment will be provided by Greenphire Clincard.

This reimbursement will be issued by an external company called Greenphire, which will issue your reimbursement. You will be issued a ClinCard, which is a debit card that your funds are loaded onto and can be used at your discretion. The research team will give Greenphire some personal information about you, as described below. Greenphire will only use your personal information to process this reimbursement and will not share it with anyone for any other purpose. Details of the

debit card system are explained on an additional sheet. If you lose the card, you may be responsible for the replacement fee.

When a visit is completed, funds will be approved and loaded onto your card. The funds will be available within 2-3 business days. In order to assign a ClinCard to you and load funds onto the ClinCard, Greenphire will need your Study/Subject ID, Name, Address, and Social Security Number.

You will have the option to receive updates related to payment alerts via text message and/or email message. Standard text messaging rates will apply. In order to send you messages Greenphire will need your Mobile Phone Number and/or E-mail Address.

Payment received as compensation for participation in research is considered taxable income. If payments from Greenphire exceed $600 in any one calendar year, Greenphire will file a 1099 (Miscellaneous Income) form on behalf of Penn State.

10. Who is paying for this research study?

The institution and investigators are receiving a grant from National Institute of Health (NIH) via The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to support this research.

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.

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal: inability to complete study visits, continuing the research would be harmful, you did not follow the instructions of the study doctor, or if you become unable or unwilling to use the smart water bottle, smart watch, or smartphone app at any time during the study.

If you stop being in the research, already collected data may not be removed from the study database. If you withdraw completely from the research study, no further information will be collected, and your participation will end. You may discontinue taking part at any time without penalty or loss of benefits to which you are otherwise entitled.

During the course of the research, you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

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

Please call the Research Coordinator James Marks at (717) 531-0003, extension: 284233 or the Principal Investigator, Dr. David Conroy (814) 863-3451 if you:

- Have questions, complaints or concerns about the research, including questions about compensation.
- 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, IRB-ORP@psu.edu if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns, complaints, 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.

You may visit the Office for Research Protections' website at https://www.research.psu.edu/irb/participants for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and
- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the ORP at (814) 865-1775.

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.

INFORMED CONSENT TO TAKE PART IN RESEARCH

Tell the researcher your decision regarding whether or not to participate in the research. Please keep or print a copy of this form for your records.