HRP-591 - Protocol for Human Subject Research

Protocol Title:

Provide the full title of the study as listed in item 1 on the "Basic Information" page in CATS IRB (http://irb.psu.edu).

Feasibility of Using sip^{IT} Tools to Increase Compliance with Fluid Consumption Guidelines in Urolithiasis –Prone Subjects

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Version Date:

Provide the date of this submission. This date must be updated each time the submission is provided to the IRB office with revisions.

10/30/2018

Clinicaltrials.gov Registration #:

Provide the registration number for this study, if applicable.

Not applicable

Important Instructions for Using This Protocol Template:

1. Add this completed protocol template to your study in CATS IRB (http://irb.psu.edu) on the "Basic Information" page, item 7.
2. This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to determine whether a study meets all applicable criteria for approval.
3. **Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.**
4. **For research being conducted at Penn State Hershey or by Penn State Hershey researchers only, delete the instructional boxes from the final version of the protocol prior to upload to CATS IRB (http://irb.psu.edu). For all other research, do not delete the instructional boxes from the final version of the protocol.**
5. When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the Study Submission Guide available in the Help Center in CATS IRB (http://irb.psu.edu) for using track changes.

If you need help…	
University Park and other campuses: Office for Research Protections Human Research Protection Program The 330 Building, Suite 205 University Park, PA 16802-7014 Phone: 814-865-1775 Fax: 814-863-8699 Email: irb-orp@psu.edu	**College of Medicine and Hershey Medical Center:** Human Subjects Protection Office 90 Hope Drive, Mail Code A115, P.O. Box 855 Hershey, PA 17033 (Physical Office Location: Academic Support Building Room 1140) Phone: 717-531-5687 Fax number: 717-531-3937 Email: irb-hspo@psu.edu

Table of Contents

1.0 Objectives

1.1 Study Objectives

Describe the purpose, specific aims or objectives. State the hypotheses to be tested.

The purpose of this study is to examine the feasibility of using sip^{IT} tools (i.e., wrist-worn sensors, smart water bottles, mobile applications) to increase compliance with physician-recommended fluid consumption guidelines in participants with a history of urolithiasis. The study aims to: 1) deliver notifications regarding fluid consumption to the FitBit Versa and the participant's smartphone based on the participant's assessed fluid intake, and 2) determine the acceptability of using the sip^{IT} tools to increase fluid consumption. It is hypothesized that receiving notifications regarding fluid consumption will lead to an increased compliance in attaining fluid consumption guidelines. Further, it is hypothesized that the frequency of notifications will diminish across the study duration.

1.2 Primary Study Endpoints

State the primary endpoints to be measured in the study. Clinical trials typically have a primary objective or endpoint. Additional objectives and endpoints are secondary. The endpoints (or outcomes), determined for each study subject, are the quantitative measurements required by the objectives. Measuring the selected endpoints is the goal of a trial (examples: response rate and survival).

The objective is to determine the acceptability of the sip^{IT} tools for participants with a history of urolithiasis who seek to increase fluid intake as recommended by physician guidelines.

1.3 Secondary Study Endpoints

State the secondary endpoints to be measured in the study.

1) Assess the usability of sip^{IT} tools and the burden upon participants.
2) Characterize changes in the frequency of fluid intake reminder notifications over three months.

2.0 Background

2.1 Scientific Background and Gaps

Describe the scientific background and gaps in current knowledge.

Complying with fluid consumption guidelines provides a variety of health benefits. Patients with a history of urolithiasis are a segment of the population that can benefit from meeting physician-recommended fluid consumption guidelines. Preliminary studies with this population have revealed patient interest in using various technologies (i.e., wrist-worn sensors, smart water bottles, mobile applications) to increase their fluid consumption but we are not aware of any that combine multiple technologies. Our long-term goal is to examine if just-in-time reminder notifications to drink following periods when patients have not been drinking will increase compliance among those with a history of urolithiasis. To prepare for that study, we seek to evaluate the feasibility and acceptability of the sip^{IT} tools in this study.

2.2 Previous Data

Describe any relevant preliminary data.

This study is part three of a set of studies aimed at determining the feasibility of using technology to increase compliance with fluid consumption guidelines. Preliminary data included 1) a focus group of

participants with a history of urolithiasis and 2) a lab study to examine the feasibility of using wrist-worn sensors to detect non-alcoholic drinking events. Data from the focus group revealed that participants are interested in using a variety of technologies (e.g., wrist-worn sensors, smart water bottles, mobile applications) to assist with increasing fluid consumption. Data from the lab study revealed that using wrist-worn inertial sensors to detect drinking events is feasible. Based on data from the lab study, an algorithm was developed to detect these drinking events and has been implemented in a consumer smartwatch consumer smartwatch app for just-in-time drinking detection.

2.3 Study Rationale

Provide the scientific rationale for the research.

Certain populations, such as those with a history of urolithiasis, can benefit from complying with fluid consumption guidelines. For those patients, complying with fluid consumption guidelines is often the first line of defense in preventing a recurrence of stone episodes. Focus groups with participants with a history of urolithiasis revealed that there is an interest in using wrist-worn sensors and mobile applications to improve compliance. Further, wrist-worn sensors can be used to detect drinking events. The use of wrist-worn sensors (i.e., FitBit Versa), an H_2OPal connected water bottle and fluid consumption monitoring mobile applications – collectively referred to as the sip^{IT} tools – can be used to engage participants over time and support compliance with physician-recommended fluid consumption guidelines. Participants with a history of urolithiasis present an important population to target with these tools given their unique need for complying with fluid consumption guidelines.

3.0 Inclusion and Exclusion Criteria

Create a numbered list below in sections 3.1 and 3.2 of criteria subjects must meet to be eligible for study enrollment (e.g., age, gender, diagnosis, etc.). Indicate specifically whether you will include any of the following vulnerable populations: (You may not include members of these populations as subjects in your research unless you indicate this in your inclusion criteria.) Review the corresponding checklists to ensure that you have provided the necessary information.

- **Adults unable to consent**
  - Review "CHECKLIST: Cognitively Impaired Adults (HRP-417)" to ensure that you have provided sufficient information. HRP-417 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).
- **Individuals who are not yet adults (infants, children, teenagers)**
  - If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children"), review the "CHECKLIST: Children (HRP-416)" to ensure that you have provided sufficient information. HRP-416 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).
- **Pregnant women**
  - Review "CHECKLIST: Pregnant Women (HRP-412)" to ensure that you have provided sufficient information. HRP-412 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).
- **Prisoners**
  - Review "CHECKLIST: Prisoners (HRP-415)" to ensure that you have provided sufficient information. HRP-415 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).
- **Neonates of uncertain viability or non-viable neonates**
  - Review "CHECKLIST: Neonates (HRP-413)" or "CHECKLIST: Neonates of Uncertain Viability (HRP-414)" to ensure that you have provide sufficient information. HRP-413 and HRP-414 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

3.1 Inclusion Criteria

List the criteria that define who will be included in your study.

(a) Age 18 years or older
(b) Fluent in spoken and written English, and capable of providing informed consent
(c) Own an iPhone (version 6 or higher)
(d) History of urolithiasis, and
(e) Willingness to complete all study procedures: completing questionnaires, participating in semi-structured interviews, tracking fluid consumption, wearing a FitBit Versa and receiving notifications on the FitBit and their smartphone for a three-month period

3.2 Exclusion Criteria

List the criteria that define who will be excluded in your study.

(a) Any medical condition that interferes with regular fluid consumption

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

Insert subject withdrawal criteria (e.g., safety reasons, failure of subject to adhere to protocol requirements, subject consent withdrawal, disease progression, etc.).

Participants may withdraw their consent for participating at any time to remove themselves from the study. Participants may also be removed from the study for failure to adhere to protocol requirements.

3.3.2 Follow-up for withdrawn subjects

Describe when and how to withdraw subjects from the study; the type and timing of the data to be collected for withdrawal of subjects; whether and how subjects are to be replaced; the follow-up for subjects withdrawn from investigational treatment.

The researcher can withdraw a participant if they fail to wear the study-provided smartwatch for a period of 7 days. Non-wear will be determined by monitoring heart rate data from the smartwatch. Participants who are withdrawn will be replaced.

4.0 Recruitment Methods

4.1 Identification of subjects

Describe the methods that will be used to identify potential subjects or the source of the subjects. If not recruiting subjects directly (e.g., database query for eligible records or samples) state what will be queried, how and by whom.
StudyFinder: If you intend to use StudyFinder (http://studyfinder.psu.edu) for recruitment purposes, please indicate this in section 4.1 along with any other methods for identifying subjects. Note that information provided in this protocol should be consistent with information provided on the StudyFinder page in your CATS IRB study.

For Penn State Hershey submissions using Enterprise Information Management (EIM) for recruitment, attach your EIM Design Specification form on the Basic Information page in CATS IRB (http://irb.psu.edu). See HRP-103 Investigator Manual, "What is appropriate for study recruitment?" for additional information.

Participants will be recruited from the State College area as well as Penn State Health Hershey Medical Center. Methods of recruitment in State College will include fliers, StudyFinder, HHD listserv, television advertisements, and newspaper advertisements. Methods of recruitment from Hershey Medical Center will include contacting patients from the Urology Clinic who have previously consented to be contacted for future studies involving fluid consumption guidelines (from IRB 5926).

4.2 Recruitment process

Describe how, where and when potential subjects will be recruited (e.g., approaching or providing information to potential subjects for participation in this research study).

Potential participants may receive an email or telephone call from a researcher if they expressed interest in being contacted about future studies. Potential participants may see a flier on Penn State's campus, in downtown State College, or may see advertisements on television, StudyFinder, in local newspapers, or through the HHD listserv. Interested participants will contact the study team via phone or email, to arrange an appointment to verbally go through the screening process.

4.3 Recruitment materials

List the materials that will be used to recruit subjects. Add recruitment documents to your study in CATS IRB (http://irb.psu.edu) on the "Consent Forms and Recruitment Materials" page. For advertisements, upload the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.

StudyFinder: If you intend to use StudyFinder (http://studyfinder.psu.edu) for recruitment purposes, you do not need to upload a separate recruitment document for information placed on the StudyFinder site to your study in CATS IRB. Necessary information will be captured on the StudyFinder page in your CATS IRB study.

Attached is a flier that will be posted as well as the text for the video and newspaper advertisements. Additionally, the email that will be sent the HHD listserv is attached. A study information flier that will be sent to interested participants is also attached.

4.4 Eligibility/screening of subjects

If potential subjects will be asked eligibility questions before obtaining informed consent, describe the process. Add the script documents and a list of the eligibility questions that will be used to your study in CATS IRB (http://irb.psu.edu) on the "Consent Forms and Recruitment Materials" page.

StudyFinder: If you intend to use StudyFinder (http://studyfinder.psu.edu) for recruitment purposes, any scripts (phone, email, or other) used when contacting StudyFinder participants as well as any eligibility screening questions must be added to your study in CATS IRB (http://irb.psu.edu) on the "Consent Forms and Recruitment Materials" page.

Prospective participants who contact the lab will be sent a study information flier. Shortly thereafter, the researcher will call the participant to conduct a telephone screening to verify eligibility using the screening questionnaire attached. Participants that qualify for the study will be given information regarding requirements of the study and asked verbally if they choose to participate. If they agree, they will be scheduled for a training session. If the participant declines participation or is ineligible for the study, they will be thanked for their time and interest.

5.0 Consent Process and Documentation

Refer to "SOP: Informed Consent Process for Research (HRP-090)", for information about the process of obtaining informed consent from subjects. HRP-090 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

5.1 Consent Process

5.1.1 Obtaining Informed Consent

5.1.1.1 Timing and Location of Consent

Describe where and when the consent process will take place.

Written informed consent will take place prior to the field study during the first lab visit. These visits will be held in the Motivation Lab (17 Rec Hall) on Penn State University's campus.

5.1.1.2 Coercion or Undue Influence during Consent

Describe the steps that will be taken to minimize the possibility of coercion or undue influence in the consent process.

The researcher will distribute two copies of the consent form to each prospective participant and provide them with ample time to read the document. The researcher will briefly review its contents, emphasize that participation is voluntary and answer any questions or address any concerns that arise. Afterwards, prospective participants will have the option to leave if they do not wish to participate. Interested individuals will be asked to sign the consent form if they wish to participate in the study. Compensation provided is an equitable amount meant to offset the time and inconvenience of participation in the study as well as to serve as an incentive. The compensation is not excessive to coerce subject participation.

5.1.2 Waiver or alteration of the informed consent requirement

If you are requesting a waiver or alteration of consent (consent will not be obtained, required information will not be disclosed, or the research involves deception), describe the rationale for the request in this section. If the alteration is because of deception or incomplete disclosure, explain whether and how subjects will be debriefed. Add any debriefing materials or document(s) to your study in CATS IRB (http://irb.psu.edu) on the "Supporting Documents" page. NOTE: Review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure you have provided sufficient information for the IRB to make these determinations. HRP-410 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Not applicable

5.2 Consent Documentation

5.2.1 Written Documentation of Consent

Refer to "SOP: Written Documentation of Consent (HRP-091)" for information about the process to document the informed consent process in writing. HRP-091 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

If you will document consent in writing, describe how consent of the subject will be documented in writing. Add the consent document(s) to your study in CATS IRB (http://irb.psu.edu) on the "Consent Forms and Recruitment Materials" page. Links to Penn State's consent templates are available in the same location where they are uploaded and their use is required.

The person responsible for obtaining written consent will verify that the consent form is in language that is understandable to the subject. The name of the subject and the person obtaining consent will be printed on the document. The subject and the person obtaining consent will personally sign and date two copies of the consent forms. Participants will be provided a copy of the consent document and one will be retained by the researcher.

5.2.2 Waiver of Documentation of Consent (Implied consent, Verbal consent, etc.)

If you will obtain consent (verbal or implied), but not document consent in writing, describe how consent will be obtained. Add the consent script(s) and/or information sheet(s) to your study in CATS IRB (http://irb.psu.edu) on the "Consent Forms and Recruitment Materials" page. Links to Penn State's consent templates are available in the same location where they are uploaded and their use is required. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information. HRP-411 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.

The written script of the information will be presented orally (verbal consent) prior to the commencement of the screening process and all written information contains the required and appropriate elements of consent (see attached verbal consent for screening document). The waiver of consent is requested as the research presents no more than minimal risk of harm to subjects. The research involves no procedures for which written consent is normally required outside of the research context.

5.3 Consent – Other Considerations

5.3.1 Non-English Speaking Subjects

Indicate what language(s) other than English are understood by prospective subjects or representatives.

If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

Indicate whether the consent process will be documented in writing with the long form of the consent documentation or with the short form of the consent documentation. Review the "SOP: Written Documentation of Consent (HRP-091)" and the "Investigator Manual (HRP-103)" to ensure that you have provided sufficient information. HRP-091 and HRP-103 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Not applicable

5.3.2 Cognitively Impaired Adults

Refer to "CHECKLIST: Cognitively Impaired Adults (HRP-417)" for information about research involving cognitively impaired adults as subjects. HRP-417 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

5.3.2.1 Capability of Providing Consent

Describe the process to determine whether an individual is capable of consent.

Not applicable

5.3.2.2 Adults Unable To Consent

Describe whether and how informed consent will be obtained from the legally authorized representative. Describe who will be allowed to provide informed consent. Describe the process used to determine these individual's authority to consent to research.

For research conducted in the state, review "SOP: Legally Authorized Representatives, Children and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "legally authorized representative". HRP-013 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." HRP-013 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Not applicable

5.3.2.3 Assent of Adults Unable to Consent

Describe the process for assent of the subjects. Indicate whether assent will be required of all, some or none of the subjects. If some, indicate which subjects will be required to assent and which will not.

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

Not applicable

5.3.3 Subjects who are not yet adults (infants, children, teenagers)

5.3.3.1 Parental Permission

Describe whether and how parental permission will be obtained. If permission will be obtained from individuals other than parents, describe who will be allowed to provide permission. Describe the process used to determine these individual's authority to consent to each child's general medical care.

For research conducted in the state, review "SOP: Legally Authorized Representatives, Children and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children". HRP-013 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." HRP-013 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Not applicable

5.3.3.2 Assent of subjects who are not yet adults

Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. When assent of children is obtained describe whether and how it will be documented.

Not applicable

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

This section is about the access, use or disclosure of Protected Health Information (PHI). PHI is individually identifiable health information (i.e., health information containing one or more 18 identifiers) that is transmitted or maintained in any form or medium by a Covered Entity or its Business Associate. A Covered Entity is a health plan, a health care clearinghouse or health care provider who transmits health information in electronic form. See the "Investigator Manual (HRP-103)" for a list of the 18 identifiers. HRP-103 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

If requesting a waiver/alteration of HIPAA authorization, complete sections 6.2 and 6.3 in addition to section 6.1. The Privacy Rule permits waivers (or alterations) of authorization if the research meets certain conditions. Include only information that will be accessed with the waiver/alteration.

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

☒ Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study. *[Mark all parts of sections 6.2 and 6.3 as not applicable]*

☐ **Authorization will be obtained and documented as part of the consent process.** *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*

☐ **Partial waiver is requested for recruitment purposes only (Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Full waiver is requested for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained).** *[Complete all parts of sections 6.2 and 6.3]*

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2.1.1 Plan to protect PHI from improper use or disclosure

Include the following statement as written – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver of authorization. If the section is not applicable, remove the statement and indicate as not applicable.

Not applicable

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include when and how identifiers will be destroyed. If identifiers will be retained, provide the legal, health or research justification for retaining the identifiers.

Not applicable

6.2.2 Explanation for why the research could not practicably be conducted without access to and use of PHI

Provide an explanation for why the research could not practicably be conducted without access to and use of PHI.

Not applicable

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Provide an explanation for why the research could not practicably be conducted without the waiver or alternation of authorization.

Not applicable

6.3 Waiver or alteration of authorization statements of agreement

By submitting this study for review with a waiver of authorization, you agree to the following statement – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a

waiver or alteration of authorization. If the section is not applicable, remove the statement and indicate as not applicable.

Not applicable

7.0 Study Design and Procedures

7.1 Study Design

Describe and explain the study design.

Participants will be asked to fill out baseline questionnaires and height and weight will be measured at the beginning of the study. Additional questionnaire completion and interviews will take place at one month and three months. Participants will wear a Fitbit Versa smartwatch and use an H_2OPal water bottle (and install their associated mobile apps on the participant's personal smartphone) to track their fluid consumption over the entire three month study. If one of the measurement tools (i.e., self-monitoring in the H2OPal app, the H2OPal water bottle, the sip^{IT} watch app) does not detect a drinking event within 30 minutes, a text message prompting fluid consumption will be sent to the participant's smartphone and smartwatch. If one of the measurement tools detects drinking, no notification will be delivered.

7.2 Study Procedures

Provide a description of all research procedures being performed and when they are being performed (broken out by visit, if applicable), including procedures being performed to monitor subjects for safety or minimize risks. Include any long-term follow-up procedures and data collection, if applicable.

Describe where or how you will be obtaining information about subjects (e.g., medical records, school records, surveys, interview questions, focus group topics, audio or video recordings, data collection forms, and collection of specimens through invasive or non-invasive procedures to include the amount to be collected and how often). Add any data collection instruments that will be seen by subjects to your study in CATS IRB (http://irb.psu.edu) in the "Supporting Documents" page.

7.2.1 Visit 1 (Training session)

Provide a description as defined above and format accordingly.

1. After providing informed consent, participants will have their height and weight measured, and complete baseline questionnaires.
2. The research assistant will provide the participant with a Fitbit Versa smartwatch and H_2OPal water bottle.
3. The research assistant will load the sip^{IT}, H_2OPal, and Fitbit apps on the participant's phone.
4. The research assistant will provide training on using the sip^{IT} tools to the participants and help the participant to set "do not disturb" times on weekdays and weekends. This visit will last approximately one hour.

7.2.2 Days 1-30 (Study enrollment)

Provide a description as defined above and format accordingly.

1. Participants will wear a Fitbit Versa smartwatch, use an H2OPal water bottle, and utilize the smartphone apps for each of these devices to track their fluid consumption.
2. Participants will receive a text message prompting fluid consumption if the measurement tools do not detect a drinking event within 30 minutes. Participants are

asked to confirm message receipt by swiping the notification. If participants are unable to answer the message (for example, they are driving and cannot safely answer the phone) we ask that you respond to the message when you are able to. The messages will not be sent during the participant's self-reported "do not disturb" times.

7.2.3 Visit 2 (One month follow up visit)

Provide a description as defined above and format accordingly.

1. Participants will return to the lab for a one-hour visit to complete questionnaires and follow up interview questions.
2. Participants will receive payment for their participation in the first month of the study.

7.2.4 Days 31-90 (Study enrollment)

1. Participants will wear a Fitbit Versa smartwatch, use an H2OPal water bottle, and utilize the smartphone apps for each of these devices to track their fluid consumption.
2. Participants will receive a text message prompting fluid consumption if the measurement tools do not detect a drinking event within 30 minutes. Participants are asked to respond to these messages by touching the "response" key on their phones. If participants are unable to answer the message (for example, they are driving and cannot safely answer the phone) we ask that you respond to the message when you are able to. The messages will not be sent during the participant's self-reported sleep times

7.2.5. Visit 3 (Three months after initial visit)

Provide a description as defined above and format accordingly.

1. Participants will return to the lab for a 1.5-hour visit to complete questionnaires and a semi-structured interview, and return the Fitbit Versa smartwatch.
2. Participants will receive payment and the H2OPal water bottle as compensation for their participation.

7.3 Duration of Participation

Describe the duration of an individual subject's participation in the study.

Participation will last for approximately 3 months.

7.4 Test Article(s) (Study Drug(s) and/or Study Device(s))

7.4.1 Description

Provide a brief description of all test articles (drugs (including any foods and dietary supplements), devices and/or biologics used in the research including the purpose of their use and their approval status with the Food and Drug Administration (FDA). Include information about the form of the drug product (e.g., tablets, capsules, liquid).

The Fitbit Versa worn on the nondominant wrist will be utilized to monitor the drinking motion of the participant and the H2O Pal devices will be utilized to record the amount of water consumed. The custom app developed for our laboratory by West Arete receives the outputs from the water bottle and the Fitbit Versa and determines if a drinking event has occurred within the past 30 minutes. The server log records the time of the drinking event, the heart rate (to assure wear of the device) and the activity data. If a drinking event has occurred within 30 minutes, the participant is not contacted. If no drinking event has occurred within 30 minutes a

reminder notification is delivered to the participant. The server logs the notification and the response from the participant.

7.4.2 Treatment Regimen

Describe dose, route of administration and treatment duration. Include information about dose adjustments.

The devices will be utilized for a period of three months.

7.4.3 Method for Assigning Subject to Treatment Groups

Describe the randomization process and how the associated treatment assignment will be made.

Not applicable.

7.4.4 Subject Compliance Monitoring

Insert the procedures for monitoring subject compliance.

The database will be monitored daily for the participant's response to the sent messages and for heartrate measured by the Fitbit Versa. Any participant that has not responded to any sent messages or has not recorded a heartbeat over a three-day period will be contacted by a study team member. The research team will assure that no safety or study issues have occurred and that the participant wishes to continue with the study procedures.

7.4.5 Blinding of the Test Article

Describe how the test article is blinded.

Not applicable.

7.4.6 Receiving, Storage, Dispensing and Return

7.4.6.1 Receipt of Test Article

Describe how the test article will be obtained and from what source. Describe how the study test article will be packaged along with amounts (e.g., number of tablets/capsules or volume of liquid) and labeling. If drug kits are used, describe all the contents of the kit and associated labeling.

The Fitbit Versa and the H2O Pal will be purchased from their commercial manufacturers.

7.4.6.2 Storage

Describe the plans to store, handle the test article so they will be used only on subjects and only by authorized investigators. Describe storage temperature requirements and how temperature will be monitored and recorded.

Not applicable.

7.4.6.3 Preparation and Dispensing

Describe how the test article will be assigned to each subject and dispensed. Describe the steps necessary to prepare the test article. Include where the test

article preparation will be done and by whom. Fully describe how the study treatment is to be administered and by whom.

The H2O Pal and Fitbit Versa will be linked with the participant's smartphone via apps. The devices will be prepared and linked during Visit 1 (training session) for the participant by the research study team.

7.4.6.4 Return or Destruction of the Test Article

Describe the procedures for final reconciliation of the test article supply at the end of the study and whether the test article is to be shipped back to a source or destroyed on site.

The participant will keep the H2O Pal water bottle upon study completion. The participant will be asked to return their Fitbit Versa at Visit 3, upon completion of the study.

7.4.6.5 Prior and Concomitant Therapy

Describe what prior and/or concomitant medical therapy will be collected. Describe which concomitant medicines/therapies are permitted during the study. Describe which concomitant medicines are not permitted during the study.

Not applicable.

8.0 Subject Numbers and Statistical Plan

8.1 Number of Subjects

Indicate the total number of subjects to be accrued.

If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

We plan to enroll 30 participants.

8.2 Sample size determination

If applicable, provide a justification of the sample size outlined in section 8.1 – to include reflections on, or calculations of, the power of the study.

The above sample size is based on resource constraints for a feasibility study. Only descriptive statistics will be calculated; therefore, a power analysis was not conducted.

8.3 Statistical methods

Describe the statistical methods (or non-statistical methods of analysis) that will be employed.

Descriptive statistics will be employed to assess feasibility of using sip^{IT} tools for increasing fluid consumption guidelines as well as to assess participant acceptability of using the sip^{IT} tools.

9.0 Confidentiality, Privacy and Data Management

For research being conducted at Penn State Hershey or by Penn State Hershey researchers only, the research data security and integrity plan is submitted using "HRP-598 – Research Data Plan Review Form Application Supplement", which is available in the Library in CATS IRB (http://irb.psu.edu). Refer to Penn State College of Medicine IRB's "Standard Operating Procedure Addendum: Security and Integrity of Human Research Data", which is available on the IRB's website. **In order to avoid redundancy, for this section state "See the Research Data Plan Review Form" in section 9.0 if you are conducting Penn State Hershey research and move on to section 10.**

For all other research, in the sections below, describe the steps that will be taken to secure the data during storage, use and transmission.

9.1 Confidentiality

9.1.1 Identifiers associated with data and/or specimens

List the identifiers that will be included or associated with the data and/or specimens in any way (e.g., names, addresses, telephone/fax numbers, email addresses, dates (date of birth, admission/discharge dates, etc.), medical record numbers, social security numbers, health plan beneficiary numbers, etc.).

If no identifiers will be included or associated with the data in any way, whether directly or indirectly, please indicate this instead.

Participants will be provided with an email address created by lab staff that will be used to link data and preserve confidentiality. Identifiable information (the names, email addresses and phone numbers of the participants) will be indirectly associated with the data via the master code list.

9.1.1.1 Use of Codes, Master List

If identifiers will be associated with the data and/or specimens (as indicated in section 9.1.1 above), describe whether a master record or list containing a code (i.e., code number, pseudonyms) will be used to separate the data collected from identifiable information, where that master code list will be stored, who will have access to the master code list, and when it will be destroyed.

If identifiers are included or associated with the data as described in section 9.1.1 above, but no master record or list containing a code will be used, it will be assumed by the IRB that the investigator plans to directly link the identifiers with the data.

Alphanumeric codes matching the lab-generated email accounts will be used to identify participants (e.g., PSUsipIT_01). A master list containing the alphanumeric codes will be used to separate the data collected from identifiable information (the names, email addresses and phone numbers of the participants). This list that matches the names and contact information along with the code numbers will be stored in the locked file cabinet of the locked office of the research project manager (18A Rec Hall). Only the study team members responsible for consent will have access to that list. The list will be destroyed after return of study information to interested participants upon study completion.

9.1.2 Storage of Data and/or Specimens

Describe where, how and for how long the data (hardcopy (paper) and/or electronic data) and/or specimens will be stored. NOTE: Data can include paper files, data on the internet or websites, computer files, audio/video files, photographs, etc. and should be considered in the responses. Refer to the "Investigator Manual (HRP-103)" for information about how long research records must be stored following the completion of the research prior to completing this section. HRP-103 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Please review Penn State's Data Categorization Project for detailed information regarding the appropriate and allowable storage of research data collected according to Penn State Policy AD71. Although the IRB can impose greater confidentiality/security requirements (particularly for sensitive data), the IRB cannot approve storage of research data in any way or using any service that is not permissible by Penn State Policy AD71.

Paper consent forms and contact information sheets will be stored in a locked file cabinet of the locked office of the research project manager (18 A Recreation Building) for a period of three years after the end of the study.

De-identified data will be stored on a fileshare server developed by our software development team, West Arete. De-identified data is stored in a relational database and encrypted during transmission. The data is stored in servers which are virtual machines hosted at a major provider, dedicated solely to our application on a network that is shared with other unrelated hosts, and is protected by a host-based firewall with "default closed" policy. The security practices that are applied to the servers include antivirus protection, host-based intrusion detection, uptime monitoring, strong authentication (private key with strong password) logins, and the operating system security updates are monitored and applied nightly. Logs are monitored daily and there are encrypted off-site backups. The de-identified data will be stored indefinitely.

This study will be issued a Certificate of Confidentiality. Researchers will not disclose or provide any identifiable information without the subject's prior consent or where permitted according to NIH's Policy on Issuing Certificates of Confidentiality.

9.1.3 Access to Data and/or Specimens

Identify who will have access to the data and/or specimens. This information should not conflict with information provided in section 9.1.1.1 regarding who has access to identifiable information, if applicable.

Approved research team members who have completed CITI Training for Human Subjects Research will have access to de-identified sensor data, questionnaire responses and semi-structured interview responses. Our vendors (Fitabase and West Arete) will have access to de-identified data from the smartphone and mobile apps.

9.1.4 Transferring Data and/or Specimens

If the data and/or specimens will be transferred to and/or from outside collaborators, identify the collaborator to whom the data and/or specimens will be transferred and how the data and/or specimens will be transferred. This information should not conflict with information provided in section 9.1.1.1 regarding who has access to identifiable information, if applicable.

West Arete developed a server that the data will be stored on. West Arete will share the data stored on the server with the research team (i.e., David Conroy, Deborah Brunke-Reese, Ashley Sanders, Josh Cermak, and Necole Streeper).

The researchers do not plan to release identifiable information collected in the study. However, if researchers consider releasing identifiable information in the future, the individual or institution receiving the identifiable information will be made aware they are also subject to the requirements of subsection 301 (d) of the Public Health Service Act.

9.2 Subject Privacy

This section must address subject privacy and NOT data confidentiality.

Indicate how the research team is permitted to access any sources of information about the subjects.

Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact with or to whom they provide personal information.

Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

During the consent process, the researcher will emphasize that participants can decline to answer any questions they find intrusive or do any actions they are not comfortable with.

10.0 Data and Safety Monitoring Plan

This section is required when research involves more than Minimal Risk to subjects. As defined in "SOP: Definitions (HRP-001)", available in the Library in CATS IRB (http://irb.psu.edu), Minimal Risk is defined as the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners, Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. **Please complete the sections below if the research involves more than minimal risk to subjects OR indicate as not applicable.**

10.1 Periodic evaluation of data

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Not applicable

10.2 Data that are reviewed

Describe the data that are reviewed, including safety data, untoward events, and efficacy data.

Not applicable

10.3 Method of collection of safety information

Describe the method by which the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls and with subjects).

Not applicable

10.4 Frequency of data collection

Describe the frequency of data collection, including when safety data collection starts.

Not applicable

10.5 Individuals reviewing the data

Identify the individuals who will review the data. The plan might include establishing a data and safety monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

Not applicable

10.6 Frequency of review of cumulative data

Describe the frequency or periodicity of review of cumulative data.

Not applicable

10.7 Statistical tests

Describe the statistical tests for analyzing the safety data to determine whether harms are occurring.

Not applicable

10.8 Suspension of research

Describe any conditions that trigger an immediate suspension of research.

Not applicable

11.0 Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. For each potential risk, describe the probability, magnitude, duration, and reversibility. Consider all types of risk including physical, psychological, social, legal, and economic risks. If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable. If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant. If applicable, describe risks to others who are not subjects.

Please keep in mind that loss of confidentiality is a potential risk when conducting human subject research and should be addressed as such.

Participation in this research involves no foreseeable substantial physical risks. There may be some mild discomfort associated with answering some of the baseline questionnaires or interview questions. Participants will be instructed that they have the right to refuse to answer questions that they find too uncomfortable. There are potential risks include of feeling self-conscious or embarrassed when receiving a notification on their phone or Fitbit. Participants will be instructed to ignore messages that are received when it is unsafe or inopportune for their receipt (for example, unsafe to receive while driving and inopportune during a work meeting). The participants will be asked to respond to them as soon as they are safely capable of doing so. Participation in this study does involve the unlikely risk of breach of confidentiality. In order to avoid this risk, any information obtained from this research will be kept as confidential as possible. All data captured from devices is encrypted and transmitted and stored using secure protocols. Alphanumeric codes rather than names

will be used on all research records and data. The confidentiality of electronic data will be maintained to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

12.0 Potential Benefits to Subjects and Others

12.1 Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research. If there is no direct benefit to subjects, indicate as such. Compensation is not considered a benefit. Compensation should be addressed in section 14.0.

The potential benefit to participants is that the notification messages could remind them to drink more fluids and help them reach their fluid consumption guidelines.

12.2 Potential Benefits to Others

Include benefits to society or others.

This study may aid in the development of future interventions with the sip^{IT} tools, to promote fluid consumption that increases usability and decreases user burden. These interventions could be targeted towards any population that could benefit from increasing their fluid consumption.

13.0 Sharing Results with Subjects

Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared.

Results (individual subject and/or overall study) can be shared with participants upon request. Results will not be shared with others. The code list linking the identifiable contact information with the participant will be used to identify the participant and share their individual results. The list linking the codes and the identifiable information will be destroyed upon completion of the return of the results.

14.0 Subject Stipend (Compensation) and/or Travel Reimbursements

Describe the amount and timing of any subject stipend/payment or travel reimbursement here. If there is no subject stipend/payment or travel reimbursement, indicate as not applicable.

If course credit or extra credit is offered to subjects, describe the amount of credit and the available alternatives. Alternatives should be equal in time and effort to the amount of course or extra credit offered.

If an existing, approved student subject pool will be used to enroll subjects, please indicate as such and indicate that course credit will be given and alternatives will be offered as per the approved subject pool procedures.

Parking fees will be paid for the participants at the training session and follow up visits. Participants will receive $20 cash at the end of the first month as compensation for completing all study procedures up to that point. Participants will then receive $50 cash and will get to keep their H_2O pal (value ~$100) at the end of 3 month study as compensation for their continued completion of study procedures and for the return of the FitBit Versa watch. The total compensation that participants will receive is $70 and the water bottle (valued at $100) at the end of the study.

15.0 Economic Burden to Subjects

15.1 Costs

Describe any costs that subjects may be responsible for because of participation in the research.

Participants will be responsible for their own transportation.

15.2 Compensation for research-related injury

If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

If there is no sponsor agreement that addresses compensation for medical care for research subjects with a research-related injury, include the following text as written - DO NOT ALTER OR DELETE:
It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

For sponsored research studies with a research agreement with the sponsor that addresses compensation for medical care for research-related injuries, include the following text as written - DO NOT ALTER OR DELETE:
It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Such charges may be paid by the study sponsor as outlined in the research agreement and explained in the consent form.

Not applicable

16.0 Resources Available

16.1 Facilities and locations

Identify and describe the facilities, sites and locations where recruitment and study procedures will be performed.

If research will be conducted outside the United States, describe site-specific regulations or customs affecting the research, and describe the process for obtaining local ethical review. Also, describe the principal investigator's experience conducting research at these locations and familiarity with local culture.

The Motivation Lab, 17 Recreation Building, on the Penn State University Park campus, will be the site of the study procedures of obtaining written consent, study training, baseline questionnaire and interview collection, and follow up appointments.

16.2 Feasibility of recruiting the required number of subjects

Indicate the number of potential subjects to which the study team has access. Indicate the percentage of those potential subjects needed for recruitment.

Urolithiasis prevalence is ~1 in 11 Americans and according to the US Census Bureau approximately 433,563 people live in Centre County and Dauphin County PA. We seek to recruit 30 participants or ~0.075% of this pool.

16.3 PI Time devoted to conducting the research

Describe how the PI will ensure that a sufficient amount of time will be devoted to conducting and completing the research. Please consider outside responsibilities as well as other on-going research for which the PI is responsible.

The PI has 5% of his time protected by the Department of Kinesiology for the purpose of performing this research study. Sufficient study personnel and resources exist to facilitate the completion of the study when he must be absent.

16.4 Availability of medical or psychological resources

Describe the availability of medical or psychological resources that subject might need as a result of their participation in the study, if applicable.

Not applicable

16.5 Process for informing Study Team

Describe the training plans to ensure members of the research team are informed about the protocol and their duties, if applicable.

The investigator and research team members involved in the study have completed their required Collaborative IRB Training Initiative (CITI) in the protection of Human Research Subjects. Study staff delegated to conduct specific study procedures will be trained on these procedures individually or in a group format by the PI.

17.0 Other Approvals

17.1 Other Approvals from External Entities

Describe any approvals that will be obtained prior to commencing the research (e.g., from cooperating institutions, community leaders, schools, external sites, funding agencies).

Not applicable.

17.2 Internal PSU Committee Approvals

Check all that apply:

☐ Anatomic Pathology – Hershey only – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of HRP-902 - Human Tissue For Research Form on the "Supporting Documents" page in CATS IRB. This form is available in the CATS IRB Library.

☐ Animal Care and Use – All campuses – Human research involves animals and humans or the use of human tissues in animals

☐ Biosafety – All campuses – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).

☐ Clinical Laboratories – Hershey only – Collection, processing and/or storage of extra tubes of body fluid specimens for research purposes by the Clinical Laboratories; and/or use of body fluids that had been collected for clinical purposes, but are no longer needed for clinical use. Upload a copy of HRP-901 - Human Body Fluids for Research Form on the "Supporting Documents" page in CATS IRB. This form is available in the CATS IRB Library.

☐ Clinical Research Center (CRC) Advisory Committee – All campuses – Research involves the use of CRC services in any way.

☐ Conflict of Interest Review – All campuses – Research has one or more of study team members indicated as having a financial interest.

☐ Radiation Safety – Hershey only – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload a copy of HRP-903 - Radiation Review Form on the "Supporting Documents" page in CATS IRB. This form is available in the CATS IRB Library.

☐ IND/IDE Audit – All campuses – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.

☐ Scientific Review – Hershey only – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. NOTE: Review by the Penn State Hershey Cancer Institute Scientific Review Committee is required if the study involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website at: http://www.pennstatehershey.org/web/irb/home/resources/investigator

18.0 Multi-Site Research

If this is a multi-site study (i.e., the study will be conducted at other institutions each with its own principal investigator) and you are the lead investigator, describe the processes to ensure communication among sites in the sections below.

18.1 Communication Plans

Describe the plan for regular communication between the overall study director and the other sites to ensure that all sites have the most current version of the protocol, consent document, etc. Describe the process to ensure all modifications have been communicated to sites. Describe the process to ensure that all required approvals have been obtained at each site (including approval by the site's IRB of record). Describe the process for communication of problems with the research, interim results and closure of the study.

Not applicable

18.2 Data Submission and Security Plan

Describe the process and schedule for data submission and provide the data security plan for data collected from other sites. Describe the process to ensure all engaged participating sites will safeguard data as required by local information security policies.

Not applicable

18.3 Subject Enrollment

Describe the procedures for coordination of subject enrollment and randomization for the overall project.

Not applicable

18.4 Reporting of Adverse Events and New Information

Describe how adverse events and other information will be reported from the clinical sites to the overall study director. Provide the timeframe for this reporting.

Not applicable

18.5 Audit and Monitoring Plans

Describe the process to ensure all local site investigators conduct the study appropriately. Describe any on-site auditing and monitoring plans for the study.

Not applicable

19.0 Adverse Event Reporting

19.1 Adverse Event Definitions

For drug studies, incorporate the following definitions into the below responses, as written:	
Adverse event	Any untoward medical occurrence associated with the use of the drug in humans, whether or not considered drug related
Adverse reaction	Any adverse event caused by a drug
Suspected adverse reaction	Any adverse event for which there is a reasonable possibility that the drug caused the adverse event. Suspected adverse reaction implies a lesser degree of certainty about causality than "adverse reaction". • *Reasonable possibility.* For the purpose of IND safety reporting, "reasonable possibility" means there is evidence to suggest a causal relationship between the drug and the adverse event.
Serious adverse event or Serious suspected adverse reaction	Serious adverse event or Serious suspected adverse reaction: An adverse event or suspected adverse reaction that in the view of either the investigator or sponsor, it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.
Life-threatening adverse event or life-threatening suspected adverse reaction	An adverse event or suspected adverse reaction is considered "life-threatening" if, in the view of either the Investigator (i.e., the study site principal investigator) or Sponsor, its occurrence places the patient or research subject at immediate risk of death. It does not include an adverse event or suspected adverse reaction that had it occurred in a more severe form, might have caused death.

Unexpected adverse event or Unexpected suspected adverse reaction.	An adverse event or suspected adverse reaction is considered "unexpected" if it is not listed in the investigator brochure, general investigational plan, clinical protocol, or elsewhere in the current IND application; or is not listed at the specificity or severity that has been previously observed and/or specified.

For device studies, incorporate the following definitions into the below responses, as written:	
Unanticipated adverse device effect	Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or IDE application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

Unanticipated adverse device effect: Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or IDE application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

19.2 Recording of Adverse Events

Address the frequency and process for eliciting adverse event information from research subject, e.g., "Research subjects will be routinely questioned about adverse events at study visits."

In the response, incorporate the following as written:
All adverse events (serious or non-serious) and abnormal test findings observed or reported to study team believed to be associated with the study drug(s) or device(s) will be followed until the event (or its sequelae) or the abnormal test finding resolves or stabilizes at a level acceptable to the investigator.

An abnormal test finding will be classified as an adverse event if one or more of the following criteria are met:

- The test finding is accompanied by clinical symptoms
- The test finding necessitates additional diagnostic evaluation(s) or medical/surgical intervention; including significant additional concomitant drug treatment or other therapy **NOTE:** Simply repeating a test finding, in the absence of any of the other listed criteria, does not constitute an adverse event.
- The test finding leads to a change in study drug dosing or discontinuation of subject participation in the clinical research study
- The test finding is considered an adverse event by the investigator.

Research subjects will be routinely questioned about adverse events at the one and three month study visits. All adverse events (serious or non-serious) and abnormal test findings observed or reported to study team believed to be associated with the study drug(s) or device(s) will be followed until the event (or its sequelae) or the abnormal test finding resolves or stabilizes at a level acceptable to the investigator.

An abnormal test finding will be classified as an adverse event if one or more of the following criteria are met:

- The test finding is accompanied by clinical symptoms

- The test finding necessitates additional diagnostic evaluation(s) or medical/surgical intervention; including significant additional concomitant drug treatment or other therapy

NOTE: Simply repeating a test finding, in the absence of any of the other listed criteria, does not constitute an adverse event.

- The test finding leads to a change in study drug dosing or discontinuation of subject participation in the clinical research study
- The test finding is considered an adverse event by the investigator.

19.3 Causality and Severity Assessments

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

The investigator will promptly review documented adverse events and abnormal test findings to determine 1) if the abnormal test finding should be classified as an adverse event; 2) if there is a reasonable possibility that the adverse event was caused by the study drug(s) or device(s); and 3) if the adverse event meets the criteria for a serious adverse event.

If the investigator's final determination of causality is "unknown and of questionable relationship to the study drug(s) or device(s)", the adverse event will be classified as associated with the use of the study drug(s) or device(s) for reporting purposes. If the investigator's final determination of causality is "unknown but not related to the study drug(s) or device(s)", this determination and the rationale for the determination will be documented in the respective subject's case history.

19.4 Reporting of Adverse Reactions and Unanticipated Problems to the FDA

19.4.1 Written IND/IDE Safety Reports

For a drug study under an IND, incorporate the following from 21 CFR 312.32 as written – DO NOT ALTER OR DELETE:

The Sponsor-Investigator will submit a written IND Safety Report (i.e., completed FDA Form 3500A) to the responsible new drug review division of the FDA for any observed or volunteered adverse event that is determined to be a serious and unexpected, suspected adverse reaction. Each IND Safety Report will be prominently labeled, "IND Safety Report", and a copy will be provided to all participating investigators (if applicable) and sub-investigators.

Written IND Safety Reports will be submitted to the FDA as soon as possible and, in no event, later than 15 calendar days following the Sponsor-Investigator's receipt of the respective adverse event information and determination that it meets the respective criteria for reporting.

For each written IND Safety Report, the Sponsor-Investigator will identify all previously submitted IND Safety Reports that addressed a similar suspected adverse reaction experience and will provide an analysis of the significance of newly reported, suspected adverse reaction in light of the previous, similar report(s) or any other relevant information.

Relevant follow-up information to an IND Safety Report will be submitted to the applicable review division of the FDA as soon as the information is available and will be identified as such (i.e., "Follow-up IND Safety Report").

If the results of the Sponsor-Investigator's follow-up investigation show that an adverse event that was initially determined to not require a written IND Safety Report does, in fact, meet the requirements for reporting; the Sponsor-Investigator will submit a written IND Safety Report as soon as possible, but in no event later than 15 calendar days, after the determination was made.

For a device study under an IDE, incorporate the following from 21 CFR 812.150 as written – DO NOT ALTER OR DELETE:
The Sponsor-Investigator will submit a completed FDA Form 3500Ato the FDA's Center for Devices and Radiological Health for any observed or volunteered adverse effect that is determined to be an unanticipated adverse device effect. A copy of this completed form will be provided to all participating sub-investigators.

The completed FDA Form 3500Awill be submitted to the FDA as soon as possible and, in no event, later than 10 working days after the Sponsor-Investigator first receives notice of the adverse effect.

If the results of the Sponsor-Investigator's follow-up evaluation show that an adverse effect that was initially determined to not constitute an unanticipated adverse device effect does, in fact, meet the requirements for reporting; the Sponsor-Investigator will submit a completed FDA Form 3500Aas soon as possible, but in no event later than 10 working days, after the determination was made.

For each submitted FDA Form 3500A, the Sponsor-Investigator will identify all previously submitted reports that that addressed a similar adverse effect experience and will provide an analysis of the significance of newly reported adverse effect in light of the previous, similar report(s).

Subsequent to the initial submission of a completed FDA Form 3500A, the Sponsor-Investigator will submit additional information concerning the reported adverse effect as requested by the FDA.

The sipIT tools utilized for this study are classified as a "daily activity assistant devices", 510(k) exempt, so testing of their effectiveness are IDE exempt.

19.4.2 Telephoned IND Safety Reports – Fatal or Life-threatening Suspected Adverse Reactions

For a drug study under an IND, incorporate the following from 21 CFR 312.32 into the response, as written:
In addition to the subsequent submission of a written IND Safety Report (i.e., completed FDA Form 3500A), the Sponsor-Investigator will notify the responsible review division of the FDA by telephone or facsimile transmission of any unexpected, fatal or life-threatening suspected adverse reaction.

The telephone or facsimile transmission of applicable IND Safety Reports will be made as soon as possible but in no event later than 7 calendar days after the Sponsor-Investigator's receipt of the respective adverse event information and determination that it meets the respective criteria for reporting.

Not applicable.

19.5 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be

(1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

19.6 Unblinding Procedures

Describe the procedures for unblinding study therapy on a subject, including documentation of this in the subject's source document. Include example(s) here why someone might unblind a study. In most cases, the unblinding will be part of managing a serious adverse reaction and will be reported with the serious adverse event. However, in cases where unblinding was not associated with a serious adverse event, such actions should be reported in a timely manner.

Not applicable.

19.7 Stopping Rules

In studies with a primary safety endpoint or studies with high risk to study subjects, provide the rules that define the circumstances and procedures for interrupting or stopping the study. If an independent Data and Safety Monitoring (DSMB) or Committee (DSMC) is set up for the study, the same stopping rules should be incorporated into the safety analysis plan as well.

Not applicable.

20.0 Study Monitoring, Auditing and Inspecting

20.1 Study Monitoring Plan

20.1.1 Quality Assurance and Quality Control

Include this section if FDA regulations apply to this study (see "WORKSHEET: Drugs (HRP-306)" and "WORKSHEET: Devices (HRP-307)". HRP-306 and HRP-307 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Describe how you will ensure that this study is conducted and that the data are generated, documented (recorded) and reported in compliance with this protocol, with institutional and IRB policies, with Good Clinical Practice guidelines and any other applicable regulatory requirements.

Indicate who is responsible for monitoring the conduct of the study and specify how often the study will be monitored.

For single-site studies with low risk, it may be appropriate for the principal investigator to monitor the study.

For multi-center studies or single site studies involving significant risk, an independent monitor may be required (e.g., monitoring by the staff of the PSU quality assurance program office(s) or by a clinical research organization).

All study team members have all been trained in the Conduct of Human Research and Good Clinical Practice. Study procedures will be performed as documented in the standard operational procedure manual. Study tasks for each study team member will be outlined on the study staff responsibilities checklist. The team members responsible for performance of the procedures will be trained in their conduct and the appropriate documentation of those procedures by the principle investigator. Documentation of procedural records will be reviewed weekly by the research project manager and monitored monthly by the principle investigator.

20.1.2 Safety Monitoring

Include this section if FDA regulations apply to this study (see "WORKSHEET: Drugs (HRP-306)" and "WORKSHEET: Devices (HRP-307)". HRP-306 and HRP-307 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Indicate the process for identifying, recording and reporting adverse events.

Specify roles for adverse event recording and monitoring. Indicate each staff member's role in the adverse event reporting process. Include the following if applicable:

The **Principal Investigator** will confirm that all adverse events (AE) are correctly entered into the AE case report forms by the coordinator; be available to answer any questions that the coordinators may have concerning AEs; and will notify the IRB, FDA, sponsor and/or DSMB of all applicable AEs as appropriate. All assessments of AEs will be made by a licensed medical professional who is an investigator on the research.

The **Research Coordinator** will complete the appropriate report form and logs; assist the PI to prepare reports and notify the IRB, FDA and/or DSMB of all Unanticipated Problems/SAE's.

The **Monitor** will confirm that the AEs are correctly entered into the case report forms. The Monitor will also confirm that the adverse events are consistent with the source documents and are reported to the appropriate regulatory bodies as required.

Not applicable.

21.0 Future Undetermined Research: Data and Specimen Banking

If this study is collecting identifiable data and/or specimens that will be banked for future undetermined research, please describe this process in the sections below. This information should not conflict with information provided in section 9.1.1 regarding whether or not data and/or specimens will be associated with identifiers (directly or indirectly).

21.1 Data and/or specimens being stored

Identify what data and/or specimens will be stored and the data associated with each specimen.

Not applicable

21.2 Location of storage

Identify the location where the data and/or specimens will be stored.

Not applicable

21.3 Duration of storage

Identify how long the data and/or specimens will be stored.

Not applicable

21.4 Access to data and/or specimens

Identify who will have access to the data and/or specimens.

Not applicable

21.5 Procedures to release data or specimens

Describe the procedures to release the data and/or specimens, including: the process to request a release, approvals required for release, who can obtain data and/or specimens, and the data to be provided with the specimens.

Not applicable

21.6 Process for returning results

Describe the process for returning results about the use of the data and/or specimens.

Not applicable

22.0 References

List relevant references in the literature which highlight methods, controversies, and study outcomes.

Amft, O., Bannach, D., Pirkl, G., Kreil, M., Lukowicz, P. 2010. Towards wearable sensing-based assessment of fluid intake. In Pervasive Computing and Communications Workshops (PERCOM Workshops), 2010 8th IEEE International Conference on. IEEE, 298–303.

Amft, O., TrösterG. 2009. On-Body Sensing Solutions for Automatic Dietary Monitoring. IEEE pervasive computing 8, 2 (April 2009).

Bae, S., Ferreira, D., Suffoletto, B., Puyana, JC., Kurtz, R., Chung, T., Dey, AK. 2017. Detecting Drinking Episodes in Young Adults Using Smartphone-based Sensors. Proceedings of the ACM on Interactive, Mobile, Wearable and Ubiquitous Technologies 1, 2 (2017), 5.

Conroy DE, Dubansky A, Remillard J, Murray R, Pellegrini CA, Phillips SM, Streeper NM. 2017. Using Behavior Change Techniques to Guide Selections of Mobile Applications to Promote Fluid Consumption. Urology 99:33-37.

Streeper, NE., Dubnansky, A., Sanders, A., Lehman, K., Conroy, DE. 2018 Improving Fluid Intake Behavior Among Patients with Kidney Stones: A focus Group to Understand Patients' Experiences and Acceptability of Sensors. Urology 199:416.