TrueLoo™: Determining the Feasibility of an Electronic Bowel Movement and Urinary Event Log via In Situ Categorization of Physical Properties of Stool and Urine

Principal Investigators
Paul Cristman, Ph.D.

Sponsor
Toi Labs, Inc.

Protocol Number: TLSD-001

Version 1.1

14th November 2019

Affected Section(s)	Summary of Revisions Made	Rationale

IRB APPROVED
AS MODIFIED
Nov 14, 2019

CONSENT FOR RESEARCH STUDY PARTICIPATION

TITLE: TrueLoo™: Determining the Feasibility of an Electronic Bowel Movement and Urinary Event Log via In Situ Categorization of Physical Properties of Stool and Urine

PROTOCOL NO.: TLSD-001
WIRB® Protocol #20191822

SPONSOR: Toi Labs, Inc.

INVESTIGATOR: Paul Francis Cristman, PhD, MS, BS 1830 Harrison Street
San Francisco, California 94103
United States

STUDY-RELATED PHONE NUMBER(S): 585-576-7697
415-952-3470
415-794-3871 (24 hours)

Toi Labs, Inc. (the "Company") is collaborating with your senior living community (the "Community") to develop and improve a toilet monitoring system that will take images of excreta (waste in the toilet). The Company invites you to volunteer and take part in our research study.

This Consent, has important information about the reasons for doing this study, what we will ask you to do if you decide to be in this study, and the way we would like to use information about you if you choose to be in the study.

Purpose: The purpose of the study is to gather as many images of excreta as possible and collect some relevant health history and data to help train the Company's technology.

What will I do if I choose to be in this study? The Company will install a new toilet seat for you in your bathroom at your Community. You will continue to use your toilet as usual, with no special action required from you beyond what is involved in the regular use of the toilet. You will also have your health history taken, participate in check-ins about your health during the Study, and potentially allow some urine samples to be taken.

Study duration: Study participation will last for approximately eight months.

What are the possible risks or discomforts? To the best of our knowledge, the

in everyday life. Your participation in this study does not involve any physical or emotional risk to you. The device complies with applicable laws and safety regulations, including electrical codes and Federal Communications Commission regulations, and there are no known dangers with using the device in this study. As with all testing, however, you should take care to use caution and good judgment and the Company does not guarantee any usefulness of the device, data in any way. There is a risk of a loss of confidentiality of your personal health information.

Toilet safety rails: If your toilet has existing safety rails that interfere with the installation of the new toilet seat, the Company will provide to you at no charge a free-standing toilet safety rail (Drive Medical, Item # RTL12079, UPC # 50822383253508, https://www.drivemedical.com/us/en/products/bathroom safetv/toilet-safety/free-standing-toilet-safety-rail/p/245-1). You agree that using this safety rail is at your own risk and release the Community and the Company from any liability associated with its use.

What are the possible benefits for others or myself? There is no direct benefit from being in this research study and your individual data will not be sent back to you or made available to you. The study results may be used to help other people in the future.

Subject Payment and Costs
You will receive a $20 gift card for being in this study. There are no costs to you for participating in this study.

Ownership, use of device: The use of this device is experimental in this research study. You agree to allow the Company to remove its equipment at the Company's expense at the end of the study or if you stop participating. You should continue any current medical monitoring or treatments, if any, as directed by your healthcare provider and not rely on this experimental device to replace any medical monitoring or treatments. The Company is under no duty to provide any data back to you. THE COMPANY EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Health history, urine collection, reporting and medical records: You may be asked to provide answers to health history questions and urine samples to a trained healthcare professional engaged by the Company over the course of the study. You may be asked to keep track of your toileting activities and/or release your relevant medical records. You agree to allow the Community to share your relevant health history and records with the Company.

Privacy and release of health information and data rights: The Company

anatomy as well as toilet types, there is a small possibility that private body parts may be imaged. The Company minimizes this risk by using a privacy zone that cannot be imaged. In the event a private body part is imaged, the Company will immediately inform you, permanently destroy any images showing any body parts, and suspend your device until the privacy zone has been increased, further reducing the area being imaged. As with all research and wireless data transfer, there is a chance that confidentiality of the information we collect from you could be breached - we will take appropriate steps to minimize this risk, as discussed in more detail on our website at www.toilabs.com/household-study. To the extent that this study involves protected health information, publicity or data rights, you consent and agree that the Company may use your anonymized data for any and all purposes for all time, including but not limited to research, commercial purposes, product development and sale and selling anonymized data from the study. The data from the research may be viewed by the US Food and Drug Administration and the Institutional Review Board (IRB) overseeing the research.

What are my rights as a research participant? Participation in this study is voluntary. You can choose not to take part, and you can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled. This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research. If at any time and for any reason, you would prefer not to participate in this study, please contact the Company at the contact info below. You may withdraw from this study at any time, and you will not be penalized in any way for deciding to stop participation. If you decide to withdraw from this study, after you notify the Company, the Company will stop collecting your information. You understand that the Company cannot remove or delete information already collected from you that has been anonymized into group data even if you ask to stop participating. If information is found during the course of the study which may affect your willingness to continue as a participant, you will be informed of any such information. In the unlikely event of any injury to you related to the use of this toilet, please notify us at 415-952-3470 after you have attended to the injury.

Termination of participation: As the sponsors of this study, Toi Labs, Inc. and its representatives retain the right to terminate your participation in the study without regard to prior consent at any time, if deemed necessary. You will be notified by telephone or email.

Who can I contact if I have questions or concerns about this research study?
If you have questions, concerns or complaints about the research, think the research has harmed you, or wish to stop participating, you may contact the

Study Coordinator at trueloo@toilabs.com or 415-952-3470 at the Company. You may also call 585-576-7697 or 415-794-3871 (24 hours).

IRB APPROVED
AS MODIFIED
Nov 14, 2019

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

All regular users should sign: This study automatically collects images of excreta in your toilet at the Community. To be complete and legally effective, all regular users of the bathroom where the device is installed should sign before participating in the study. The Company provides a conspicuous notice on the toilet seat about this study.

Consent

I have read this form and the research study has been explained to me. I have been given the opportunity to ask questions and my questions have been answered. If I have additional questions, I have been told whom to contact. I understand that I release rights to data and data protection, for myself and if any, my children and household guests. I agree to participate in the research study described above and will receive a copy of this Consent form. • All subjects unable to consent are required to assent

- If assent is obtained, have the person obtaining assent document assent on the consent form

Signature of adult participant capable of consent OR adult participant's legally authorized representative Date

Printed name of participant

Printed name of participant's legally authorized representative

If consent is being provided by legally authorized representative: ❑ I have

explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.

Signature and name of person obtaining consent/assent Date 4

CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another has the right to:

(a) Be informed of the nature and purpose of the experiment.
(b) Be given an explanation of the procedures to be followed in the medical experiment and any drug or device to be used.
(c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment, if applicable.
(d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment if applicable.
(e) Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
(f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment or if complications should arise.
(g) Be given an opportunity to ask any questions concerning the experiment or other procedures involved.
(h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue in the medical experiment without prejudice.
(i) Be given a copy of a signed and dated written informed consent form when one is required.
(j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Signature of adult subject capable of consent, child subject's parent, individual authorized to consent to the child subject's general medical care, or adult subject's legally authorized representative
Date