**INFORMED CONSENT FORM**

**NAME OF SPONSOR COMPANY**: Turtle Health, Inc.

**PROTOCOL NUMBER AND TITLE OF STUDY**: 016 "The SELF-GYN (Sonograms Enable Looking Forward – Get Your iNformation) Extension – I Trial"

**NAME AND PHONE OF THE PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/INVESTIGATOR)**: **Dr.'s Aaron Styer, Caitlin Sacha** (Massachusetts, Florida and Vermont locations), **Annie Martini** (District of Columbia, Maryland, and Virginia locations)**, Ben Doke (**Texas**), Rebecca Gray (**Texas**), Linda Bernstein (**Texas**), and Lauren Verrilli** (Utah, Maine, and New Hampshire locations), **508-251-9269**

Thank you for participating in Turtle Heath's SELF-GYN (Sonograms Enable Looking Forward – Get Your iNformation) Extension – I Trial. This informed consent describes the test, the process, potential benefits of participating in this trial, and certain risks.

## Introduction

You are deciding if you would like to volunteer for a research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. Do not sign this form if you have any questions that have not been answered. Please call the number listed on the top of this form if you have any questions as you read this form.

The investigator is being paid by the sponsor, Turtle Health, Inc. (the company paying for this study) to conduct this research study. The investigator and staff involved with this study have a financial interest in the study sponsor. You have the right to ask the researcher about these financial interests.

## What is the purpose of the study?

The study is intended to evaluate if the Turtle Health Ultrasound Scanner works in the real world as well as it has worked in controlled trials. The Turtle Health Ultrasound Scanner allows a woman to collect ultrasound images at home, with remote coaching from a specially trained ultrasound technologist.

Ultrasound is when high frequency sound waves are used to create an image or video, and does not use radiation like an X-Ray or CT scan. Transvaginal ultrasounds are used when more detailed images are needed than can be produced with transabdominal ultrasound.

Turtle Health, the company developing home ultrasound, will likely submit this data to the United States Food and Drug Administration (FDA), as the company is seeking authorization to provide ultrasounds to women at home in the United States.

The use of the device to do these ultrasounds in an at-home setting is investigational and has not yet been approved by the FDA.

**Why is this trial happening now?**

Turtle Health conducted a previous study, the SELF-HELP study. Fifty-six women participated in that trial, and the results were published in the top gynecology journal, *Obstetrics and Gynecology*, which is also called the *Green Journal*. That study showed that at-home imaging performed very similarly to in-clinic imaging. 96% of at-home images were "clinically interpretable," compared with 98% in-clinic, which is considered similar statistically. Women considered the at-home ultrasound experience to be preferable to in-clinic.

Although the previous trial demonstrated strong performance of the technology, the FDA has asked some additional questions. They are especially interested to validate that this product works well in certain populations, for example, women who may live in rural areas and people who may have not been able to take time off work to go see a doctor recently or who find it difficult to go to an in-person clinic for other reasons. They also want to make sure that the product is used in the absolute safest manner by each and every patient – for example, that every patient applies a probe cover before use.

**How long will the study last and how many people will be in the study?**

Your participation in this study will be fully remote and consist of one fully virtual appointment, a self-administered ultrasound at-home. An experienced ultrasound technologist with special training in virtual exams will coach you through collecting some short video clips of your pelvic organs.

The home visit is usually under 30 minutes including setup, and you must be able to receive and sign for the package with the ultrasound before the visit and mail it back using the pre-paid return label.

Approximately 1000 women will be in this trial. The trial aims to recruit all the participants in about 6-12 months.

**How do the process and logistics work for this study?**

- You likely started your journey by receiving an email from your trial site, or seeing an ad on social media. From there, you likely went to turtlehealth.com to learn about the different participation options. If you have not already done so, please go to turtlehealth.com and click on "Let's get started" to learn more.
- You can then choose to participate in the ultrasound trial.
- If you are interested in participating in this trial, you will be asked to complete a brief online form to confirm your eligibility.
- If you are eligible, you will receive an email inviting you to sign this consent form electronically.
- Once a member of the clinical trial team signs it too, you will be invited to create an account on Turtle Health portal and provide additional information to schedule your virtual appointment. If you have purchased a consult, additional information will be gathered at this stage to evaluate other fertility risks, like smoking history.

- Your exam will be scheduled based on your primary method of birth control:
    - If you have an IUD, arm implant, or receive birth control shots, your exam will be scheduled at any time that is convenient for you.
    - If you use birth control pills, patches, or the vaginal ring, non-hormonal birth control options only, or are not on any form of birth control, your exam will be scheduled during days 3-10 your menstrual cycle, counting day 1 as the first day of your period.
- Before your home exam, Turtle Health will ship you an ultrasound scanner and everything else you need for the testing, including a probe cover (similar to a condom) and a spare probe cover.
- During your home exam, a specially trained ultrasound technologist will call the phone provided, and walk you through the exam at the scheduled time. You should follow the instructions, including opening the box just before the exam and setting up a comfortable, private spot in your house with a pillow nearby.
- After the exam, you should ship back the box using the pre-paid label according to the instructions provided by the trial coordinator and/or the ultrasound technologist.
- Your images will be sent to at least two independent doctors to evaluate. The doctors will be blinded, meaning they will not know to which patient the images belong.
- About 3 days after the exam, you will be asked to fill out a brief survey about your experience.
- If you opted for the ultrasound only, you will receive your image results, usually in around 2-3 weeks. If you opted for the full consult, you will receive a complete report after all the test results are in and have been reviewed by a doctor.
- Around 3 weeks after your virtual visit, we will send you a short, optional survey to check in and make sure that you have not had any unexpected side effects.

**What are the benefits of participating in this study?**

There are two potential benefits to you of participating in this study.

First, by participating in the trial you will obtain information about your uterine health, such as if any potential fibroids are seen, and Antral Follicle Count (AFC). AFC is the number of immature eggs that are seen on your ovaries. In the previous SELF-HELP trial, 96% of home-based images were of good enough quality to be interpreted, so there is a high, but not guaranteed, chance to get your AFC evaluated. AFC together with Anti-Mullerian Hormone (AMH) are two key indicators of ovarian reserve and should be interpreted together. This trial itself doesn't provide an AMH blood test.

Secondly, you will be contributing to future care options for women. This might even include yourself a few years down the line. Today, all transvaginal ultrasounds must be conducted in-person. If the FDA agrees with the data produced in this trial, in the future, such exams may be able to be conducted at home. This will help many women access clinical care that may be inconvenient or invasive today.

**Will I be paid to participate in this study?**

There is no financial compensation for participating in this trial.

**What are the costs of participating in this study?**

It will not cost you anything to participate in the study. Timely return of probe is expected as part of your participation. Should you not return the probe in a timely manner, we will permanently disable it, rendering it unusable.

**What are the risks to participating in this study?**

There are several known potential risks; there may be others that are discovered.

- Device cleanliness: Turtle Health reprocesses the ultrasound, removing dirt and bacteria according to a procedure that has been tested by an independent lab. However, if that procedure were to fail, such as due to human error, it is possible you could contract a Sexually Transmitted Disease (STI). *You should always use a probe cover which will be provided.*
- Physical discomfort or physical side effects: There is a small chance that you could experience infection, bleeding, pain, or injury to nearby organs. Please immediately reach out to the number at the top of this form if you experience any discomfort during or following the exam.
- Emotional discomfort or invasion of privacy: You will need to remove all of your clothes from your waist down for the exam.
- Data security of image transmission: Your data will be captured in Clarius Live, and then evaluated using HIPAA compliant technologies for the independent physician raters. These technologies are Ambra and a HIPAA compliant version of Google Drive. Clarius Live received FDA clearance and is routinely used with a doctor on-site to share data; it has so far met security performance indicators. Ambra and Google Drive are also routinely used for similar medical purposes. While the risk of re-identification of images, hacking, or other malicious events is low, complete confidentiality cannot be guaranteed.
- Interpretability and confidence in results: While a trial has already been published utilizing this product, this trial is bigger and includes a more diverse population, as well as more ultrasound technologists guiding the exams at home. These results should be considered experimental until the FDA has authorized this product.
- While participating in only the trial (without marketed virtual consult) doesn't include a consultation with a doctor, in case of any significant findings during the exam, Turtle Health will help you to get a confirmatory in-person scan by a physician.
- Confirming placement or presence of an IUD is outside of the scope of this study.

**What will I need to do during this research study?**

While participating in this research study, you will need to:

- Be willing and able to follow the study directions and procedures
- Tell the study staff about any side effects or problems
- Ask questions as you think of them
- Tell the investigator or the study staff if you change your mind about staying in the study

**What are the alternatives to participating in this study?**

Since this study is for research only, the only other choice would be not to be in the study.

**What if I don't want to be in the study?**

Your participation is voluntary, and it is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study, or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

The investigator, the Sponsor company, Castle Institutional Review Board (Castle IRB), or the FDA, if applicable, may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

**New Findings**

Any new findings during the course of this study that may affect your willingness to continue participation will be provided to you in a timely manner.

**Confidentiality**

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The investigator and the staff at the in-person clinic you attend
- The ultrasound technologist
- Sponsor company or research institution [including monitor(s) and auditor(s)]
- The United States Food and Drug Administration (FDA) and other regulators
- Castle Institutional Review Board (Castle IRB)

The Institutional Review Board (Castle IRB) and accrediting agencies (FDA) may inspect and copy your records. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

The Turtle Health administrative team will have access to your address in order to ship the ultrasound scanner to your home.

Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records.

The research team will know your identity and that you are in the research study. Other people at Turtle Health may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Turtle Health may need to see or receive your information for this study. Examples include government agencies, safety monitors, and companies that sponsor the study, as listed above.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Turtle Health who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the study doctor by phone or in writing. If you request by phone, you must follow-up with a written request that includes the study number and your contact information. Your site's PI's information is on page one of this consent form, and s/he may be contacted by phone at 508-251-9269.

You have the right to access the health information gathered during your participation in this study, but access to it may be temporarily denied until the study is completed.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to PI to cancel your authorization.

**In case of study related injury**

In case of injury, compensation to cover direct costs will be provided if the injury resulted from participation in the research. If care for any injury is required, you should seek urgent care if it is urgent; if it is less time sensitive, the investigator covering your geography can provide care, or can help you locate a qualified doctor closer to you.

**Not medical advice**

This test is not intended to diagnose any medical conditions, or to serve as a substitute for professional medical advice or diagnosis as it's an investigational technique not yet FDA approved. It is offered for informational purposes only.

Turtle Health encourages you to consult with a healthcare professional if you have any questions or concerns about your medical condition or results, or if your results are unexpected. Never disregard

professional medical advice or delay in seeking it because of something you have read or been told in connection with this study.

Further, please note that any information provided to you is intended to describe if you may have conditions associated with a higher risk of having difficulty conceiving a child, but does not describe your ability to have or not have children. The test is not intended to tell you anything about your current state of health, or to be used to make medical decisions, including whether or not you should take a medication, how much of a medication you should take, or determine any particular course of treatment or therapy.

**Contact information**

If you have questions, concerns, or complaints about this study, or to report a research-related injury, please contact:

**Dr. Aaron Styer**
**Dr. Caitlin Sacha** (covering Massachusetts, Florida and Vermont locations)
**Dr. Lauren Verrilli** (covering Utah, Maine, and New Hampshire locations)
**Dr. Annie Martini** (covering District of Columbia, Maryland, and Virginia locations)

**Dr. Ben Doke** (covering Texas locations)
**Dr. Rebecca Gray** (covering Texas locations)
**Dr. Linda Bernstein** (covering Texas locations)

**Telephone:** 508-251-9269

If you do not want to talk to the investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact Castle IRB. Castle IRB is a group of people that has reviewed this research study. The main goal of this review is to protect the rights and well-being of the human subjects participating in research studies.

You may contact Castle Institutional Review Board (Castle IRB) at 888-442-2472 extension 2 or irbteam@castleirb.com.

Castle has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean Castle has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

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

**Consents: to be electronically signed**

I voluntarily consent to participating in this feasibility research study. I have had all my questions answered prior to signing this informed consent document. I will receive a copy of this informed consent for my records.

I consent to have Turtle Health anonymously store my image(s) for (1) submission to FDA and other regulators and (2) research and education, including as part of an image bank to improve home scans.

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE STATEMENTS, OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE STATEMENTS, YOU SHOULD NOT SIGN THIS INFORMED CONSENT DOCUMENT.

_____

Printed Name of Adult Study Participant

_____

Signature of Adult Study Participant Date

_____

Printed Name of Person Explaining Consent Form

_____

Signature of Person Explaining Consent Form Date