

# Partners HealthCare System Research Consent Form

General Template - Drug Clinical Trial  
Version Date: August 2016

Subject Identification

Protocol Title: A randomized, single center, double-blind, parallel-group, placebo-controlled study assessing the effect of CSP01 on chronic idiopathic constipation and irritable bowel syndrome with constipation

Principal Investigator: Kyle Staller, MD, MPH

Site Principal Investigator:

Description of Subject Population: Adults 22 to 70 years old with symptoms of Chronic Idiopathic Constipation or Irritable bowel syndrome with constipation

## About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called “subjects.” This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as “Partners.”

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

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

## Why is this research study being done?

This study is being done to study the effectiveness of the hydrogel capsule, CSP01, compared to the active control (carboxymethylcellulose) and placebo (non-medicine sugar pill), to relieve

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constipation among subjects with chronic idiopathic constipation (CIC) or with irritable bowel syndrome with constipation (IBS-C). CSP01 capsules are taken prior to a meal with water. The term “study device” will be used in statements collectively regarding either CSP01, the active control (carboxymethylcellulose or CMC) or placebo (non-medicine sugar pill).

You are being asked to be a subject in this research study because you have been diagnosed with Chronic Idiopathic Constipation or with irritable bowel syndrome with constipation (IBS-C). Constipation is a common gastrointestinal motility disorder that is often chronic, negatively affects patients' daily lives. Constipation occurs when bowel movements become difficult or less frequent. The normal length of time between bowel movements ranges widely from person to person. Some people have bowel movements three times a day; others, only one or two times a week. By acting as a bulking agent CSP01 may contribute to constipation relief.

Subjects who meet the Rome IV criteria for Chronic Idiopathic Constipation or with IBS-C, who meet the inclusion criteria, will be offered participation in this study.

CSP01 is not approved by the U.S. Food and Drug Administration (FDA). This means that CSP01 can only be used in research studies.

All subjects will also be asked to take two SmartPill Tests. The SmartPill Test is approved by the U.S. Food and Drug Administration (FDA) to measure transit time in the GI tract. This procedure uses the SmartPill capsule, a receiver, and computer software. The SmartPill capsule is pill-shaped and about an inch long and ½ inch wide, or about the size of a vitamin pill. The receiver unit is about the size of a paperback book. The receiver gets signals from the capsule and stores the signals on a computer chip. The capsule detects the level of acidity, temperature, and pressures in your stomach and intestines and sends the information by radio wave signals to the receiver.

This is a pilot study. Pilot studies are done on a small group of subjects to learn if a larger study would be useful.

This study aims to recruit 53 total subjects to be enrolled here at Massachusetts General Hospital (MGH).

Gelesis Inc., the company that makes CSP01 is paying for this study to be done.

## How long will I take part in this research study?

This study will take up to 8 weeks to complete. During this time, we will ask you to make a total of 5 study visits to MGH. We will also call you at least 3 times during the study.

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## What will happen in this research study?

### Screening Visit (Study Visit 1: Day -28 to -15)

This visit will take about 2 hours.

At the Screening Visit, we will do some tests and procedures to see if you qualify to take part in this research study. The study doctor will review the results of these tests and procedures. If you don't qualify, the study doctor will tell you why.

At this visit, we will:

- Do a physical examination, including vital signs (blood pressure, pulse, heart rate).
- Ask you about your demographic information (age, gender, weight, height).
- Ask you about your medical history and what medications you are taking.
- Draw blood samples for:
  - Routine lab tests
  - Pregnancy test for females who are able to become pregnant. Pregnant women can't take part in this research study.
- Ask you for a urine sample for drug screening.

### Run-in period ( Days -14 to 0)

If you are eligible to participate in the study following the Screening Visit, we will ask that you stop taking any anti-constipation aids.

When you stop using any anti-constipation aids, this is called a "washout period." The washout period will allow you to resume your normal constipation. Without your regular medications, your constipation may get worse. If this happens, please call the study doctor at the number provided in this consent form.

### ***Prohibited Medications***

Certain medications are NOT allowed during this study unless you have been on a stable dose of these medications for at least 3 months. These are medications that may affect the bowel mobility, and cannot be taken during the study:

- Laxatives
- Prokinetic medications (i.e. Domperidone, Reglan, Erythromycin, Octreotide)
- Anti-depressant medications (i.e. TCA's such as Amitriptyline, Nortriptyline, or SSRI's such as Lexapro, Prozac, Zoloft)

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- Medications for treatment of Parkinson's disease (i.e. Dopamine Agonists such as L-DOPA)
- Opiates (i.e. Hydrocodone, Oxycodone)
- Calcium-channel blockers (i.e. Verapamil, Nifedipine, Amlodipine)
- Aluminum/Magnesium hydroxides (i.e. Maalox)

Please note that chronic use of non-steroidal anti-inflammatory drugs (NSAIDs), such as Excedrin, Motrin, Advil, Aleve, etc., is also contraindicated for this study, meaning we suggest that they should not be used throughout the study; however, chronic use is defined as taking full dose NSAIDs on a regular basis (three times a week) for a long term duration (at least six months).

Because you will be asked to stop taking some of your medications for your condition, your stomach or constipation symptoms may get worse. The study staff will talk with you and ask you how you feel on the day you start the tests.

We will also ask you to complete a daily diary regarding your bowel movements and straining, as well as evaluation of abdominal pain and recording of any medication taken, if applicable.

## ***Preparation for Study Visit 2***

The nurse or coordinator will call you after 6 days of run-in to evaluate your well-being. They will also confirm applicable medications have been stopped prior to visit 2 and ask you do to the following:

- not eat anything starting at 10:00pm the night before visit 2
- not drink alcohol for 1 day before coming to the study office or for 3 days after
- not use any form of tobacco 8 hours before coming to the office or for 8 hours after the office visit

When you arrive at the study site, we will ask you to use the bathroom to empty your bladder. If you are a woman who can become pregnant, you will have a urine pregnancy test. We will ask you where you are in your menstrual cycle. Pregnant women cannot take part in this study.

## **Smartpill Baseline Visit (Study Visit 2: Day -7)**

This study visit should take about 2 hours to complete and will take place 7 days after Visit 1.

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After 7 days you will be asked to visit MGH for a meeting with your study doctor. We will again confirm that you qualify for the study based on the diary you completed and a constipation symptoms questionnaire. If the study doctor determines that you fit the criteria, we will:

- Explain the testing procedure to you, and answer any questions you may have
- Have you ingest the SmartBar, a standardized meal used to accurately measure gastric emptying time (similar to a granola bar). Please note, while low in gluten, the SmartBar is not gluten-free. (If you have a known food allergy/dietary restriction, you may be given the standard egg beater meal as a substitute). You will be asked to complete the meal in 10 minutes, while we prepare the SmartPill capsule for ingestion.
- After finishing the standardized meal, we will have you swallow the SmartPill capsule with water (about 1/3 cup).
- Ask you about your constipation symptoms and ask you to complete a questionnaire
- Fill out a questionnaire about your quality of life, such as your ability to do daily activities

Once the capsule has been swallowed, we will give you the SmartPill receiver, which you will need to clip on your belt-loop or wear around your neck with a lanyard for the duration of 7 full days.

During the initial 8 hours after capsule ingestion, you will be permitted to sit, stand or walk, however, you will not be allowed to sleep because sleep can affect how things move through your digestive system.

## ***After Visit 2***

You will be asked not to eat anything for eight hours after ingesting the SmartPill capsules. We will give you a bottle of Ensure® (a meal replacement drink) that you will drink 8 hours after you swallow the SmartPill capsule. One hour after you drink the Ensure® meal, you may resume your normal meal intake.

We will also go over instructions with you about how to complete your daily patient diary, and also schedule a follow up visit for when you will be returning the receiver and diary. We will also answer any questions you may have and provide you with any information that we feel would be useful to you.

After the visit, you will need to keep the receiver with you at all times during the study period. You should keep the receiver as close as possible to you (no more than 5 feet from you whenever you are unable to keep it on your belt or on the lanyard around your neck). This includes when you go to sleep or take a shower/bath, that you place the receiver on your nightstand or

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countertop, so that it remains as close as possible to you at all times. The receiver is not waterproof.

You will also be asked not to do any strenuous activities such as sit-ups, abdominal crunches, and prolonged aerobic activity (greater than 15 minutes), for the duration of the SmartPill Test, which means for at least 5 days, depending on when you are asked to return the SmartPill receiver.

During the testing period, we ask that you not drink any alcohol; however, you may use tobacco 8 hours after ingesting the capsule.

We also ask that you do not use any stomach or intestine medicines until after you have completed the study unless the study doctor tells you to take the medicines. Medicines you should not use during the monitoring period include laxatives or anti-diarrhea medicine.

## *Study Diary*

During this study visit, we will also provide instruction on how to fill out your daily patient diary. We will ask you to press the “Event” button on the receiver and record any of the following events:

- When you have a bowel movement
- When you have a meal
- When you go to sleep
- When you wake up

We will ask you to write down the date and time of each event. We ask that you use the time written on the receiver for the time you will record in the diary.

We will also ask that after each bowel movement, you wait for 5 minutes, before flushing the toilet, so that we will know if the SmartPill was evacuated in your stool. After waiting 5 minutes, it is okay to flush the toilet, even with the SmartPill present.

If you do not have any documented bowel movement for 5 consecutive days, and you are in need of a rescue treatment, we ask that you please contact us immediately. At this time, we will recommend the following treatment, as applicable, in the following order:

1. Glycerin suppository
2. Enema
3. Laxadin/bisacodyl tablets (three tablets at 5mg each)

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Administration of the rescue treatment will be at the discretion of the investigator based on his/her assessment of your symptoms; administration of rescue will be monitored and recorded.

## **Treatment Visit 1 (Study Visit 3: Day 0)**

This study visit should take about 1 hour to complete and will take place 7 days after Visit 2.

During this study visit, we will:

- Collect the SmartPill Receiver
- Review your study diary
- Discuss the results of your SmartPill test
- Assign you to a study group
- Dispense study capsules
- Instruct you on how to take the study device
- Ask you about your constipation symptoms and ask you to complete a questionnaire
- Fill out a questionnaire about your quality of life, such as your ability to do daily activities
- Instruct you on how to complete the daily diary

If the SmartPill capsule has not left your body through your stool, we will prescribe you erythromycin liquid suspension (an antibiotic). You will take the erythromycin before meals and at bedtime for the next 7-9 days in order to facilitate capsule expulsion from your stomach.

## ***Assignment to Study Group***

If you are eligible to continue in the study, you will be assigned by chance (like a coin toss) to either the CSP01 group, active control (carboxymethylcellulose) group, or placebo group (non-medicine sugar pill).

You and the study doctor cannot choose your study group. You will have an equal chance of being assigned to the CSP01 group, active control-group, or placebo group. You and the study doctor will not know which group you are in, but he can find out, if necessary.

## ***Taking the Study Device***

For the next 3 weeks, you will be instructed to ingest three capsules, twice daily, for a total of 6 capsules a day. You will ingest the first 3 capsules before breakfast and the second 3 capsules before dinner (with 16oz or 500mL of water). We ask that during the duration of the study you refrain from making any major lifestyle changes such as starting a new diet or changing your exercise pattern.

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## ***Study Diary***

During the treatment period, you will be instructed to complete a simple web-based daily diary. Everyday, a link to that day's entry will be emailed to you. This diary will ask you to record the number and time of bowel movements, document complete/incomplete evacuation, and answer questions about straining, abdominal discomfort, bloating, constipation severity and overall relief.

## ***Preparation for Study Visit 4***

The nurse or coordinator will call you after 6 days of treatment (day 13 of the study) to evaluate your well-being. They will also confirm applicable medications have been stopped prior to study visit 4 and ask you to do the following:

- not eat anything starting at 10:00pm the night before study visit 4
- not drink alcohol for 1 day before coming to the study office or for 3 days after
- not use any form of tobacco 8 hours before coming to the office 8 hours after the office visit

When you arrive at the study site, we will ask you to use the bathroom to empty your bladder. If you are a woman who can become pregnant, you will have a urine pregnancy test. We will ask you where you are in your menstrual cycle. Pregnant women cannot take part in this study.

## **Treatment Visit 2 – SmartPill Visit (Study Visit 4 – Day 15)**

This study visit should take about 2 hours to complete and will take place 15 days after Visit 3.

At this visit, you will go through the same SmartPill study as you did for Study Visit 2. You will also:

- Respond to questions about your constipation symptoms and complete a questionnaire
- Fill out a questionnaire about your quality of life, such as your ability to do daily activities

The instructions for this visit are the same as outlined above in Study Visit 2.

If you do not have any documented bowel movement for 5 consecutive days, and you are in need of a rescue treatment, we ask that you please contact us immediately. At this time, we will recommend the following treatment, as applicable, in the following order:

1. Glycerin suppository
2. Enema
3. Laxadin/bisacodyl tablets (three tablets at 5mg each)



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Administration of the rescue treatment will be at the discretion of the investigator based on his/her assessment of your symptoms; administration of rescue will be monitored and recorded.

## **Treatment Visit 3 (Study Visit 5 – Day 22)**

This study visit should take about 1 hour to complete and will take place 7 days after Study Visit 4.

During this study visit, we will:

- Collect the SmartPill Receiver
- Review your study diary
- Discuss the results of your SmartPill test
- Ask you about your constipation symptoms and ask you to complete a questionnaire
- Fill out a questionnaire about your quality of life, such as your ability to do daily activities

If the SmartPill capsule has not left your body through your stool, we will prescribe you erythromycin liquid suspension (an antibiotic). You will take the erythromycin before meals and at bedtime for the next 7-9 days in order to facilitate capsule expulsion from your stomach.

## **Follow Up Period (Days 23 to 30)**

After 29 days, although study treatment will be stopped, we will continue to evaluate you for an additional week with no treatment, where you will be asked keep to completing the daily diary regarding your bowel movements.

## **End of Study Phone Call (Day 31 (+3 days))**

After the follow up period, on Day 28, the study coordinator will call you to evaluate your well being.

During this phone call, we will:

- Ask you to list any medications that were taken during the week follow up period where you received no treatment.

## ***Taking Medications During the Study***

If you use any medications in addition to the study device during the study, you must report this to the study team, so that it can be documented for the study.

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## Stopping the Study Early

You can choose to stop taking part in this study at any time. If you decide to stop taking part in the study for any reason, you will be asked to return any unused capsules, if you still have any.

Additionally, the study doctor or the Sponsor may have to take you out of the study without your permission. This might happen because:

- The study doctor thinks it is best for your health that you no longer be in the study.
- You do not comply with the study protocol.
- You experience a serious side effect or any medical condition that, in the opinion of the study doctor, warrants discontinuation from the study for your safety.
- You become pregnant.
- You did not follow the study doctor's instructions.
- The study doctor stops taking part in the study.
- The Sponsor decides to terminate the study.
- You do not consent to continue in the study after being told of changes in the research that may affect you.
- You developed a medical disease, after the Screening Visits, which may affect the function and interpretation of study results.

If you are removed from the study as a result of a serious side effect, we will ask that you make one last visit to the clinic—so that we can perform a final physical examination. If you are removed due to a serious side effect, we will continue to follow up with you until the side effect has resolved.

## Study Information Included in Your Electronic Medical Record

A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs).

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

### Risks from CSP01 and Active Control (CMC)

Both carboxymethylcellulose (CMC) and citric acid (a component of the capsule) are food products which have multiple studies indicating their safety. Based on experiences with

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carboxymethylcellulose, which is more than 99% of CSP01 and existing data from related products we would not expect any serious effects following the administration of CSP01. Most likely, the side effects associated with overconsumption of CSP01 would include gastrointestinal symptoms (e.g., nausea, vomiting, flatulence, bloating, abdominal pain, constipation, and diarrhea). Individuals experiencing these symptoms should inform the study doctor, but it is not necessarily a reason for study discontinuation.

## **Risks to an Embryo, Fetus, or Breastfeeding Infant**

The effect of CSP01 on an embryo or fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown. Out of an abundance of caution, the use of CSP01 should be restricted for certain people who are:

- Pregnant
- Trying to become pregnant
- Breastfeeding

If you are a menopausal woman and have not had a period for the past 12 months or more, you will not need to have a pregnancy test. Also, if you have had any well-documented method of surgical sterilization, you will not need to have a pregnancy test. Methods of surgical sterilization include having had a hysterectomy (removal of the uterus with or without the ovaries), bilateral oophorectomy (removal of both ovaries), a tubal ligation (having your tubes tied), or transvaginal occlusion (plugging the opening of the tubes with a coil). All other female subjects must have a negative pregnancy test before taking the study device.

If you are a female who is sexually active and able to become pregnant, you must agree to use one of the birth control methods listed below. You must use birth control for the entire duration of the study.

Acceptable birth control methods for use in this study, when used consistently and correctly, are:

- Implants (i.e. Implanon, Nexplanon)
- Injectables (i.e. Depo-Provera)
- Combined Oral Contraceptives
- Intrauterine Devices (IUD's) (i.e. Mirena, ParaGard)
- Sexual Abstinence

## **Risks from the SmartPill Capsule Test**

There is a small chance that the capsule will not pass from your stomach or intestines. If we cannot verify that you have passed the capsule, you will have an abdominal X-ray. If the X-ray shows that the capsule is still inside you, or if you report symptoms that suggest the capsule is stuck, we will work to get you medical care to remove the capsule.

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If you do not pass the capsule within 5 to 7 days and test data indicate the capsule has moved from your stomach, the study doctor may decide to give you a laxative to help move the capsule through your gastrointestinal tract. If the capsule is still in your intestines after treatment, you may be referred to a doctor who specializes in intestinal tract disorders. The doctor may order an abdominal x ray to confirm capsule location and will discuss with you using stronger medicines to help the capsule move, or the possibility of endoscopy, colonoscopy or surgery to remove the capsule.

From previous experiences with the SmartPill, about 4 out of 1000 people have side effects from the capsule. This drops to about 1 in 1000 people if laxatives are used. However, there remains a very slight chance that the capsule could lodge in your intestine. If the device becomes lodged and does not pass, it may need to be endoscopically or surgically removed.

Other rare side effects seen in studies of the SmartPill capsule included, but are not limited to:

- Nausea
- Vomiting
- Aspiration (breathing into the lungs) of the capsule or test meal
- Abdominal pain
- Diarrhea or constipation.

If the capsule is still in your stomach you will be prescribed erythromycin liquid suspension, a drug to help move the capsule out of the stomach. Risks of erythromycin include:

- Nausea or vomiting
- Abdominal pain
- Diarrhea
- Abnormal liver function

As with any drug, you may have an allergic reaction to erythromycin. Allergic reactions can be mild or serious, and can even result in death in some cases. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. If you think you are having an allergic reaction, call the study doctor right away. If you are having trouble breathing, call 911 immediately.

### ***Risks for Subjects with Other Monitoring Equipment***

The smartpill capsule and monitoring equipment could keep other medical devices such as pacemakers from working properly. It is important that you NOT take part in the study if you use any other implanted or externally worn medical device such as, but not limited to, a pacemaker, infusion pump, or insulin pump.

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## ***Risks of MRI following SmartPill Swallow***

It is important that you do not undergo any MRI (magnetic resonance imaging) scans during the study until the study doctor has confirmed that the SmartPill capsule has passed from your body. Having an MRI while the capsule is inside you could damage your stomach or intestines. If you are advised to have an MRI while participating in this study, call the study doctor.

## ***Risks of X-rays***

As a result of your participation in this study you may be exposed to radiation from up to two abdominal X-rays. Please note that this radiation is not necessary for your medical care and is for research purposes only.

The total amount of radiation exposure you will get from taking part in this study is equal up to a whole body exposure of about 1 milliSievert (mSv). A mSv is a unit of radiation dose. This amount of radiation is about the same as you would normally get in about four months from natural background sources from the earth and the sky.

Scientists disagree on whether radiation doses at these low levels are harmful. A possible effect that could occur at doses used in this study is a slight increase in the risk of developing cancer later in life. If you are pregnant or breast feeding, you may not be able to participate in this research study.

## **Risks of Placebo Group**

A placebo (non-active) device may be one of the study devices you receive during the study. If you receive a placebo (non-active) device, your condition may go untreated and may worsen as a result.

## **Risks of Washout Period, Stopping Medications**

During the treatment period, you will be asked to stop taking any medications that alter bowel mobility. During this period, your symptoms may get worse. If this happens, please tell the study doctor, immediately.

## **Unforeseeable Risks**

There may be other risks of SmartPill Tests, and CSP01 that are currently unknown. You might have side effects or discomforts that are not listed in this form. New ones could happen to you, including worsening of your symptoms. The study doctor will examine and question you carefully throughout this study. Tell the study doctor or study staff right away if you have any problems.

## **Other Risks**

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Filling out the questionnaires could cause you to feel uncomfortable or upset. Please tell the study doctor or study staff if you feel uncomfortable or upset while filling out a questionnaire.

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

Given the early evidence of this novel capsule's ability to absorb water in the stomach and small intestine and release it in the colon, it is hypothesized that it may be of benefit in patients with chronic idiopathic constipation. Potential benefits may include a decrease in self-reported abdominal discomfort, straining, bloating, and constipation severity, as well as improved quality of life and symptom severity using validated measures.

There is no guarantee that your condition will improve as a result of your participation in this study. It may stay the same or worsen. This is a research study and CSP01 is not available for prescription by your doctor for your constipation after the end of the study. However, the information learned from this study may help other people with this disease in the future.

## What other treatments or procedures are available for my condition?

You do not have to participate in this study to receive treatment for your condition. In most cases dietary and lifestyle changes will help relieve symptoms. Also recommended are:

- Increased fluid consumption
- Increased fibers consumption
- Consumption of psyllium
- Consumption of bran
- A treatment with laxatives or enemas may be recommended for a limited time

The study doctor will discuss study alternatives with you and their risks and benefits.

## Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

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Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

## What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

## Will I be paid to take part in this research study?

We will pay you \$200.00 if you complete this study. If you do not complete the entire study, you may still be paid for a portion of your time.

We will pay you \$25.00 for each of the following completed:

- The initial screening visit
- Completion of the 2 week run-in period
- Visit 2
- Visit 3
- Completion of treatment period leading up to visit 4
- Visit 4
- Visit 5
- Follow up

We will also reimburse up to \$160.00 for travel costs of the visits / weeks of treatment listed above.

## What will I have to pay for if I take part in this research study?

The study device will be provided to you at no cost. The Sponsor will cover the cost of all study visits and procedures and tests that are done as part of this study.

You and/or your insurance will be responsible for the costs of the regular treatment for your condition. These would be done even if you were not in this study. The costs for these procedures will be billed to your insurance in the usual way. If you are uninsured, you will be

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billed for them. You will be responsible for any costs your insurance does not cover. You will not be responsible for the procedures that are part of the research.

If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

## What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

The Sponsor will pay for medical treatment for any injury that is not paid for by your health insurer if the injury is a direct result of your taking part in the study. The Sponsor has no plans to offer you any other payments or other type of compensation.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

## If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Kyle Staller, MD, MPH is the person in charge of this research study. You can call him at 617-724-6038 Mondays-Fridays from 9 a.m. to 5p.m. You can also page Dr. Staller 24 hours a day, 7 days a week by dialing 617-726-2000 and asking for pager # 18702.



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If you have questions about the scheduling of appointments or study visits, call the clinical research coordinator, at 617-724-0480 Mondays-Fridays from 9 a.m. to 5 p.m.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

## If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as “health information.” In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

### In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

### Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.

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- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

## Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

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If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

## Informed Consent and Authorization

### Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

### Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

\_\_\_\_\_  
Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time (optional)

### Signature of Study Doctor or Person Obtaining Consent:

#### Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

\_\_\_\_\_  
Study Doctor or Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time (optional)

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