**Partners HealthCare System**
**Research Consent Form**

Subject Identification

**General Consent Form Template**
**Version Date: January 2019**

Protocol Title: **TestBoston: The BWH/Broad Direct-to-Patient COVID-19 Testing Study**

Principal Investigator: Ann E. Woolley, MD, MPH; Lisa A. Cosimi, MD

Site Principal Investigator:

Description of Subject Population: Adults who live in the Boston area

## 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 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.

This study is being conducted by researchers at the Broad Institute of MIT and Harvard, a nonprofit research institute, and researchers at Brigham and Women's Hospital.

# Key Information

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. Your decision won't change the medical care you get within Partners now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

## Why is this research study being done?

In this research study we want to learn more about how many adults in Massachusetts have COVID-19. We want to know how common it is to get COVID-19 but not have symptoms. We will try to learn more about how to better estimate the infection rate. We will study how to track the infection rate and how to respond if there are new outbreaks of COVID-19 in the coming months. We also want to understand whether people who get COVID-19 are less likely to get it again a second time. This study will also develop a good system for implementing at-home COVID-19 testing so that large numbers of people can be tested.

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

If you decide to join this research study, it will take you about **6 months** to complete the study. During your study participation, we will not ask you to make any study visits to Brigham and Women's Hospital.

## What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen.

We will ask you to answer a few questions which include how you have recently been feeling and your recent medical history. We will send you an at-home COVID-19 test kit with instructions and a pre-paid return packet. We will ask you to collect 2 samples: a sample from inside your nose and a sample of blood from your finger. These samples will then be shipped back to the Broad Institute in Cambridge, MA in a return packet so that we can test them to see if there is evidence of active COVID-19 virus and/or a positive antibody. After the first month, if you choose to be contacted again, we will send you a COVID-19 test kit monthly and ask you to complete a short health questionnaire for the subsequent 5 months. If you start to feel sick with COVID-19 symptoms at any time during the study, you can request an immediate test.

We will also review your medical records.

## Why might you choose to take part in this study?

While you may not directly benefit from participating in this study, others with and without COVID-19 may benefit in the future from what we learn in this study.

## Why might you choose NOT to take part in this study?

Taking part in this research study has some minimal risks that you should consider carefully.

Important risks and possible discomforts to know about include discomfort from collecting your own specimen. There may be some physical discomfort when the nasal swab or blood is collected. There is a small chance that you will develop a bruise, feel lightheaded, faint, or develop an infection at the site. There is a low risk of loss of confidentiality. We will take additional measures to protect your privacy.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

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

You do not need to participate in this study in order to be tested for COVID-19. If you are experiencing symptoms of COVID-19 or believe you have been exposed to COVID-19, you may be able to get tested at a clinic by asking your doctor to order a test for you.

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

You can call us or email the study email address info@testboston.org with any questions or concerns you may have.

If you have questions about the study, please contact the research investigators, Dr. Ann Woolley and Dr. Lisa Cosimi at 617-525-4220 during the weekdays between 9-5pm. You can also call Brigham and Women's Hospital ask for them to be paged 24/7: 617- 732-5700, pager #26276 for Dr. Woolley and pager #21519 for Dr. Cosimi.

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
- Any pressure to take part in, or to continue in the research study

## Detailed Information

## Why is this research study being done?

We are doing this research to learn more about how many adults in Massachusetts have COVID-19.

We want to understand the risk of SARS-CoV-2 (the virus that causes COVID-19) infection amongst different people who receive some medical care at Brigham and Women's Hospital and who live in the greater Boston area. We also want to understand who gets infected without developing symptoms and who is more likely to experience more serious disease. We will do this by testing your blood for antibodies against SARS-CoV-2 and testing a self-collected sample from your nose for active SARS-CoV-2 virus and by asking you questions about yourself, your risks for infection, and your symptoms. This information will be used to carry out more targeted infection control activities both during the current outbreak and in future outbreaks. It will also be used to understand how our bodies fight infection and if we can be infected more than once.

This study will develop a model for implementing at-home COVID-19 testing so that it can be used to test large numbers of people and minimize the need for people to have to come to clinics, emergency rooms, or other testing sites. We will study how to track the infection rate so that we can respond if there are new outbreaks of COVID-19 in the coming months.

## Who will take part in this research?

We are asking you to take part in this research study because you are an adult who has received medical care at Brigham and Women's Hospital within the past 12 months.

About 10,000 people who have had care at Brigham and Women's Hospital will take part in this research study.

Brigham and Women's Hospital is paying for this research to be done.

## What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

During this study:

- You will be asked to complete a short online survey about your current health.
- A sample collection kit will be delivered to your home that will allow you to collect a sample from your nose and a few blood drops from your finger. This kit will contain detailed instructions about how to do these collections.
- For sample collection from your nose, you will use an anterior nasal swab from the kit and insert the tip of the swab into one nostril. The swab does not need to be inserted far—insert just until the tip of the swab is no longer visible. You will rotate the swab in a circle around the entire inside edge of your nostril at least 3 times. Then you will repeat the process in the other nostril with the same swab and store the swab in a tube that will come with your kit.
- To collect blood from your finger, you will first clean your fingertip with a small alcohol wipe from the kit. You will then use a lancet, a small needle, to prick your finger. You will need to put a few drops of blood on a card that will also be part of the kit. Once complete, you should cover your fingertip with the bandaid from the kit.
- You will then need to package the samples according to the directions we will provide and the package will then be collected from your home and delivered to the lab at the Broad Institute where the testing will be done. Your personal contact information may be shared with a courier service.
- If you choose to continue in the study, you will receive an additional kit monthly, for the subsequent 5 months, and be asked to complete a short health questionnaire each month for the subsequent 5 months as well.
- If you start to feel sick with COVID-19 symptoms at any time during the study, you can request an additional test to be sent immediately.
- We will also review your medical records.

**Review of Medical Records from Hospital Admission or Emergency Department Visits**
Partners has an electronic system that lets your study doctors know if you are admitted to a Partners Hospital, or if you visit a Partners Hospital Emergency Department. We want to make sure the study doctors know about any possible problems or side effects you experience while you are taking part in the study.

**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 test done at the hospital labs.)

Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

## How may we use and share your samples and health for other research?

The samples and information we collect in this study may help advance other research. At the completion of this research study, we would like to store and be able to use and share your identifiable samples and health information with researchers at Brigham and Women's Hospital and the Broad Institute for other research related to COVID-19. If we share your samples and/or health information with other researchers outside of Brigham and Women's Hospital or the Broad Institute, we will label the samples and information with a code instead of your name or other directly identifying information. The key to the code connects your name or other identifiers to your sample and/or information. We will keep the code in a password protected computer.

Because these samples and/or health information are identifiable, we are asking your permission to store, use and share your samples for other research. You can still take part in this research study whether or not you give permission for the storage, use, and sharing of the samples and health information for other research.

Do you agree to let us store and use your samples and health information for other research related to COVID-19?

• YES • NO Initial _____

## Will you get the results of this research study?

Because the antibody test from the blood sample will be performed in a research laboratory (a facility in which scientific research, experiments, and measurement may be performed) and not a clinical laboratory (a laboratory where tests are usually done on clinical specimens in order to obtain information about the health of a patient), we cannot directly release results from the research antibody test to you. We will report aggregate results (your results combined with other research participants results) to the Massachusetts Department of Public Health and other key stakeholders in public health to determine what percent of study participants had a positive antibody, and to help us better understand the prevalence, or how widespread COVID-19 is.

The viral test from the nasal swab will be performed in a clinical laboratory. But because this is a research study involving at-home specimen collection that is not yet FDA-approved, we are only allowed at this time to release the result of the COVID-19 viral test to you as a research result. We ask you to contact your physician to order another test so that the specimen can be collected under a clinician's supervision and the result can be confirmed at a clinical laboratory (a process called "CLIA confirmation"). This additional step is necessary in order to return these results to you. A CLIA lab meets government-mandated requirement for quality assurance and quality control, and is certified to release results from patient test for clinical and diagnostic purposes. We would be happy to help you contact your local doctor to order the CLIA confirmation testing and return your results to you if that would be easier. The results will be returned to your doctor who can make sure you receive the proper medical care as needed.

You can choose to be on an email list to receive newsletter updates about the research we are doing. This newsletter will not announce your results or anyone else's, but it will tell you some information about what we are learning about COVID-19. We will also publish what we learn in medical journals. In the future, when research results are published, they may show that certain groups (for example, racial or ethnic groups, or men/women) have genes that are associated with increased risk of a disease. If this happens, you may learn that you are at increased risk of developing a disease or condition.

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

Important risks and possible discomforts to know about include discomfort from collecting your own specimen. There may be some physical discomfort when the nasal swab or blood is collected. However, if you have an ongoing local inflammatory process, or were overly

aggressive in execution of the anterior nasal swab, there may be other risks such as bleeding or infection. There is a small chance that you will develop a bruise, feel lightheaded, faint, or develop an infection at the site where you prick your finger to get a few blood spots.

Your privacy is very important to us and we will use many safety measures to protect your privacy. However, in spite of all of the safety measures that we will use, we cannot guarantee that your identity will never become known. The risk of this happening is currently very low. It is possible also that someone could get unauthorized access or break into the system that stores information about you. Every precaution will be taken to minimize this risk. There also may be other privacy risks that we have not foreseen.

There could be other unforeseeable risks that are currently unknown.

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

You may not benefit from taking part in this research study. You may find out that you are infected with COVID-19, but you will need to be retested by your PCP or at the clinic to confirm this result. Your participation in this study may help us learn how to help patients with and without COVID-19 in the future, and how to handle future outbreaks of COVID-19 in our community.

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

You do not need to participate in this study in order to be tested for COVID-19. If you are experiencing symptoms of COVID-19 or believe you have been exposed to COVID-19, you may be able to get tested at a clinic by asking your doctor to order a test for you.

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

Yes. Your decision about whether or not to participate in this study will not 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.

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 you do if you 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 you be paid to take part in this research study?

You will not be paid for taking part in this research study.

We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose.

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

Study funds will pay for certain study-related items and services, such as the sample collection kits and processing the samples. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. 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 you are 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 examples, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

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 beginning of this consent form.

## If you take part in this research study, how will we protect your privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

### In this study, we may collect identifiable 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 information and why they may need to do so:

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

- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable 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 identifiable 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 identifiable 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 identifiable information for any mailing or marketing list. However, once your identifiable 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 identifiable information. Your permission to use and share your identifiable information does not expire.

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 identifiable 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 identifiable 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 identifiable 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.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable 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

## Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

**Statement of Hospital Medical Interpreter**

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter Date Time (optional)

## TestBoston Version 5.0