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

Apwopo fòmilè konsantman sa a

Tanpri li fòmilè sa a avèk anpil atansyon. Li ba w enfòmasyon enpòtan apwopo yon etid rechèch. Yon manm ekip rechèch nou a pral pale avèk ou tou sou patisipasyon w nan etid rechèch sa a. Yo rele moun ki aksepte patisipe nan etid rechèch yo \"sijè\". Nou pral itilize tèm sa a nan tout fòmilè konsantman sa a.

Sistèm Partners HealthCare gen ladan lopital, founisè swen sante, ak chèchè Partners yo. Nan rès la fòmilè konsantman sa a, nou rele sistèm Partners lan tou senpleman “Partners.”

Si w deside patisipe nan etid rechèch sa a, ou dwe siyen fòmilè sa a pou montre ou vle patisipe ladan. Nou pral ba w yon kopi fòmilè sa a ki siyen pou w konsève.

Moun k ap dirije etid sa a se chèchè nan Broad Institute of MIT and Harvard, yon enstiti rechèch ki pa pou fè pwofi, epi chèchè nan Brigham and Women's Hospital.

Enfòmasyon kle

Patisipasyon nan etid rechèch sa a se nan men w li ye. Ou kapab deside pou w pa patisipe. Si w deside patisipe kounye a, ou ka chanje lide epi w abandone pita. Desizyon ou p ap chanje swen medikal ou jwenn nan Partners kounye a oswa pi devan.

Enfòmasyon kle sa yo se pou ede w deside si wi ou non ou dwe patisipe nan etid rechèch sa a. Nou mete plis detay sou rechèch la nan seksyon enfòmasyon detaye ki apre enfòmasyon kle yo.

Poukisa y ap fè etid rechèch sa a?

Nan etid rechèch sa a nou vle aprann plis sou kantite granmoun nan Massachusetts ki gen COVID-19. Nou vle konnen nan ki pwen li komen pou trape COVID-19 san w pa gen okenn sentòm. Nou pral eseye aprann plis fason pou fè yon meyè estimasyon to enfeksyon an. Nou pral etidye fason pou suiv pousantaj enfeksyon yo ak fason pou reyaji si gen nouvo epidemi COVID-19 nan mwa k ap vini yo. Nou vle konprann tou si moun ki trape COVID-19 gen mwens chans pou yo genyen li ankò yon dezyèm fwa. Etid sa a ap devlope tou yon bon sistèm pou mete an plas tès pou COVID-19 nan kay dekwa pou yo kapab teste yon gwo kantite moun.

Ki kantite tan ou pral patisipe nan etid rechèch sa a?

[HT] 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.

Kisa ki pral rive si w patisipe nan etid rechèch sa a?

Si w deside antre nan etid rechèch sa a, bagay annapre la yo pral rive.

[HT] 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.

[HT] We will also review your medical records.

Poukisa ou ta ka chwazi pou w patisipe nan etid sa a?

Byenke ou gendwa pa benefisye direkteman nan patisipasyon w nan etid sa a, lòt moun ki gen COVID-19 ak moun ki pa genyen l ka benefisye alavni nan sa nou aprann nan etid sa a.

Poukisa ou ta ka chwazi pou w PA patisipe nan etid sa a?

Patisipasyon nan etid rechèch sa a gen kèk risk minim ou ta dwe konsidere ak anpil atansyon.

[HT] 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.

[HT] 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?"

Ki lòt tretman oswa pwosedi ki disponib pou pwoblèm ou an?

Ou pa oblije patisipe nan etid sa a pou w fè tès pou COVID-19. Si w gen sentòm COVID-19 oswa ou kwè ou te ekspoze nan COVID-19, ou ka anmezi pou fè tès nan yon klinik si w mande doktè k ap suiv ou a preskri yon tès pou ou.

Si w gen kesyon oswa enkyetid apwopo etid rechèch sa a, kimoun ou kapab rele?

Ou kapab rele nou oswa voye yon imèl bay adrès imèl etid la info@testboston.org pou nenpòt enkyetid oswa kesyon ou ta renmen poze.

Si w gen kesyon sou etid la, tanpri kontakte chèchè rechèch la, Doktè Ann Woolley ak Doktè Lisa Cosimi nan 617-525-4220 pandan jou lasemèn yo ant 9-5 pm. Ou ka rele Brigham and Women's Hospital tou, lajounen kou lannuit, pou w mande lopital la rele yo nan pedjè: 617-732-5700, pedjè #26276 pou Doktè Woolley ak pedjè #21519 pou Doktè Cosimi.

Si w vle pale ak yon moun ki pa patisipe dirèkteman nan etid rechèch sa a, tanpri kontakte biwo Partners Human Research Committee. Ou kapab rele yo nan 857-282-1900.

Ou kapab pale avèk yo osijè:

- Dwa ou genyen antanke sijè nan yon rechèch
- Enkyetid ou yo konsènan rechèch la
- Yon plent konsènan rechèch la
- Nenpòt presyon pou w patisipe ladan, oswa pou w kontinye patisipe nan etid rechèch la

Enfòmasyon detaye

Poukisa y ap fè etid rechèch sa a?

N ap fè etid rechèch sa a pou n aprann plis sou kantite granmoun nan Massachusetts ki gen COVID-19.

[HT] 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.

Etid sa a pral devlope yon modèl pou mete an plas tès pou COVID-19 lakay pou li kapab itilize pou teste yon gwo kantite moun epi pou diminye nesesite pou moun vini nan klinik, sèvis dijans, oswa lòt sant pou tès. Nou pral etidye fason pou suiv pousantaj enfeksyon yo dekwa pou nou ka reyaji si gen nouvo epidemi COVID-19 nan mwa k ap vini yo.

Kimoun ki pral patisipe nan rechèch sa a?

Nou mande ou pou patisipe nan etid rechèch sa a paske ou se yon granmoun ki te resevwa swen medikal nan Brigham and Women's Hospital nan 12 mwa ki sot pase yo.

Apeprè 10 000 moun ki te resevwa swen nan Brigham and Women's Hospital pral patisipe nan etid rechèch sa a.

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

Kisa ki pral rive nan etid rechèch sa a?

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

[HT] During this study:

- Yo pral mande pou w reponn yon sondaj kout sou entènèt sou sante w aktyèlman.
- Yo pral livre lakay ou yon kit pou kòlèk echantiyon ki pral pèmèt ou pran yon echantiyon nan nen w ak kèk gout san nan dwèt ou. Kit sa a ap gen ladan machasuiv detaye sou fason pou fè kòlèk sa yo.
- Pou kòlèk echantiyon nan nen w, ou pral sèvi ak yon aplikatè nazal anteryè nan kit la epi foure pwent aplikatè a nan yon twou nen w. Ou pa bezwen foure aplikatè a lwen—annik foure li jiskaske pwent aplikatè a pa vizib ankò. Ou pral vire aplikatè a nan yon mouvman an sèk toutotou anndan rebò twou nen w omwen 3 fwa. Apre sa, ou pral refè pwosesis la nan lòt twou nen an avèk menm aplikatè a epi estoke aplikatè a nan yon tib ki pral vini avèk kit ou a.
- Pou pran san an nan dwèt ou, ou pral toudabò netwaye pwent dwèt ou avèk yon ti tanpon alkòl ki nan kit la. Apre sa, ou pral sèvi ak yon lansèt, yon ti zegui, pou pike dwèt ou a. Ou pral gen pou w mete kèk gout san sou yon kat ki pral fè pati kit la tou. On fwa ou fini, ou dwe kouvri pwent dwèt ou a ak pansman ki nan kit la.
- [HT] 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.
- Si w chwazi pou w kontinye nan etid la, ou pral resevwa yon kit anplis chak mwa, pandan 5 mwa annapre yo, epi yo pral mande pou w ranpli yon kesyonè kout sou sante w chak mwa pandan 5 mwa annapre yo tou.
- [HT] 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.
- [HT] We will also review your medical records.

[HT] Review of Medical Records from Hospital Admission or Emergency Department Visits

[HT] 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.

[HT] Study Information Included in Your Electronic Medical Record

[HT] 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.)

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

Kijan nou ka itilize ak pataje echantiyon ak enfòmasyon sou sante w pou lòt rechèch?

Echantiyon ak enfòmasyon nou pran nan etid sa a ka ede fè lòt rechèch yo avanse. Nan fen etid rechèch sa a, nou ta renmen konsève epi kapab itilize ak pataje echantiyon ak enfòmasyon sou sante ki ka idantifye w avèk chèchè nan Brigham and Women's Hospital ak Broad Institute pou lòt rechèch anrapò ak COVID-19. Si nou pataje echantiyon ak/oswa enfòmasyon sou sante w avèk lòt chèchè deyò Brigham and Women's Hospital ak Broad Institute, nou pral make echantiyon yo ak enfòmasyon yo avèk yon kòd olye non w oswa lòt enfòmasyon ki idantifye w dirèkteman. Kle pou kòd la konekte non w oswa lòt enfòmasyon idantifikasyon avèk echantiyon w ak/oswa enfòmasyon ou yo. Nou pral konsève kòd la nan yon konpitè ki pwoteje ak modpas.

Piske yo ka idantifye echantiyon ak/oswa enfòmasyon sou sante sa yo, n ap mande otorizasyon w pou n estoke, itilize ak pataje echantiyon ou yo pou lòt rechèch. Ou ka patisipe nan etid rechèch sa a kanmenm kit wi ou non ou bay otorizasyon pou estoke, itilize, epi pataje echantiyon yo ak enfòmasyon medikal yo pou lòt rechèch.

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

• Wi • Non Paraf _____

Èske w ap jwenn rezilta etid rechèch sa a?

[HT] 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.

[HT] 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.

[HT] 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.

Ki risk ak malèz ki posib nan patisipasyon nan etid rechèch sa a?

[HT] 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.

Nou bay vi prive w anpil enpòtans epi nou pral itilize anpil mezi sekirite pou n pwoteje vi prive w. Sepandan, malgre tout mezi sekirite nou pral pran yo, nou pa kapab garanti yo p ap janm vin konnen idantite w. Risk pou sa rive se risk ki trè fèb aktyèlman. Li posib tou pou yon moun ka jwenn aksè san otorizasyon oswa antre nan sistèm ki estoke enfòmasyon ki konsène w. Nou pral pran tout prekosyon pou diminye risk sa a nèt. Ka gen lòt risk pou vi prive tou ke nou pa te prevwa.

Ta ka gen lòt risk nou pa ka prevwa ki enkoni aktyèlman.

Ki avantaj ki posib nan patisipasyon nan etid rechèch sa a?

[HT] 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.

Ki lòt tretman oswa pwosedi ki disponib pou pwoblèm ou an?

Ou pa oblije patisipe nan etid sa a pou w fè tès pou COVID-19. Si w gen sentòm COVID-19 oswa ou kwè ou te ekspoze nan COVID-19, ou ka anmezi pou fè tès nan yon klinik si w mande doktè k ap suiv ou a preskri yon tès pou ou.

Èske w ka resevwa swen medikal nan Partners kanmenm si w pa patisipe nan etid rechèch sa a, oswa si w sispann patisipe?

[HT] 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.

N ap fè w konnen sa si nou aprann nouvo enfòmasyon ki ta ka fè ou chanje lide konsènan patipasyon nan etid rechèch sa a.

Kisa w dwe fè si w vle sispann patisipe nan etid la?

Si w patisipe nan etid rechèch sa a, epi w vle abandone, ou dwe di nou sa. Nou pral asire ou sispann etid la san danje. Nou pral pale avèk ou tou sou swen suivi, si sa nesesè.

Epitou, li posib nou pral oblije mande pou w abandone etid la anvan w fini li. Si sa rive, n ap fè w konnen poukisa. Nou pral ede tou pou fè aranjman lòt swen pou ou, si sa nesesè.

Èske yo pral peye w pou patisipe nan etid rechèch sa a?

Nou p ap peye w pou patisipasyon w nan etid rechèch sa a.

Nou gendwa itilize echantiyon ak enfòmasyon ou yo pou n kreye yon nouvo pwodui oswa yon tès medikal pou n vann. Esponnsò a, lopital la, ak chèchè yo ka benefisye si sa rive. Pa gen okenn plan pou n peye w si yo itilize echantiyon oswa enfòmasyon ou yo pou objektif sa a.

Kisa w pral gen pou w peye si w patisipe nan etid rechèch sa a?

[HT] 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.

Kisa ki rive si w pran chòk akòz patisipasyon w nan etid rechèch sa a?

[HT] 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.

[HT] 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.

[HT] 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.

Si w patisipe nan etid rechèch sa a, kijan nou pral pwoteje vi prive w?

[HT] 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."

[HT] In this study, we may collect identifiable information about you from:

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

[HT] Who may see, use, and share your identifiable information and why they may need to do so:

- [HT] Partners researchers and staff involved in this study
- [HT] The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- [HT] Other researchers and medical centers that are part of this study
- [HT] The Partners ethics board or an ethics board outside Partners that oversees the research
- [HT] A group that oversees the data (study information) and safety of this study

- [HT] 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)
- [HT] People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- [HT] 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
- [HT] 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)
- [HT] Other:

[HT] 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.

[HT] 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.

[HT] 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.

Dwa sou vi prive w

Ou gen dwa pou **pa** siyen fòmilè sa a ki pèmèt nou itilize ak pataje enfòmasyon ki idantifye w pou rechèch; men, si w pa siyen li, ou pa kapab patisipe nan etid rechèch sa a.

Ou gen dwa pou w anile otorizasyon ou ban nou pou n itilize oswa kominike enfòmasyon ki ka idantifye w pou etid rechèch sa a. Si w vle anile otorizasyon ou an, ou dwe enfòme moun ki responsab etid rechèch sa a alekri. On fwa ou retire otorizasyon ou an, ou pa kapab kontinye patisipe nan etid la.

Si w anile otorizasyon ou an, nou p ap kapab reprann enfòmasyon nou te deja itilize oswa kominike bay lòt moun, epi yo gendwa kontinye itilize enfòmasyon sa yo pou sèten objektif, pa egzanp pou respekte lalwa oswa pou konsève fyabilite etid la.

Ou gen dwa pou w gade ak pou jwenn yon kopi enfòmasyon ki ka idantifye w ke yo itilize oswa kominike pou tretman oswa pou peman. Pou mande enfòmasyon sa yo, tanpri kontakte moun ki responsab etid rechèch sa a. Ou ka jwenn enfòmasyon sa yo apre rechèch la fini sèlman.

Konsantman eklere ak otorizasyon

Deklarasyon moun k ap bay konsantman eklere ak otorizasyon

- Mwen te li fòmilè konsantman sa a.
- Yo eksplike ban mwen etid rechèch sa a, ansanm ak risk epi avantaj ki posib (si genyen), lòt tretman oswa pwosedi ki posib, ak lòt bagay enpòtan konsènan etid la.
- Mwen te gen okazyon pou m poze kesyon.
- Mwen konprann enfòmasyon yo ban m yo.

Siyati sijè a:

Mwen bay konsantman m pou m patisipe nan etid rechèch sa a epi mwen aksepte pou otorize yo itilize ak pataje enfòmasyon sou sante m jan sa dekri anwo a.

Subject Date Time (optional)

Doktè etid la oswa moun ki resevwa konsantman an:

Deklarasyon doktè etid la oswa moun ki resevwa konsantman an

- Mwen eksplike rechèch la pou sijè etid la.
- Mwen reponn tout kesyon konsènan etid rechèch sa a nan meyè fason mwen kapab.

Study Doctor or Person Obtaining Consent Date

Konsantman sijè ki pa pale anglè avèk itilizasyon "fòmilè kout" la ekri nan lang sijè a pale a

Deklarasyon entèprèt medikal lopital la

Antanke moun ki konprann ni anglè ni lang sijè a pale a, mwen te entèprete, nan lang sijè a, prezantasyon ke chèchè a fè pou fòmilè konsantman anglè a. Yo te bay sijè a okasyon pou l poze kesyon.

Hospital Medical Interpreter Date Time (optional)

TestBoston Vèsyon 5.0