

COPE Consortium IRB Tool Kit

We have compiled a document to assist you as you are trying to get approval for use of the COVID-19 Symptom Study app at your institution. These documents are templates to help you as you work towards getting IRB approval, but please acknowledge that local requirements might be different from our Partners IRB. Please also understand that our ability to change documents within the app are limited, which include our terms of use, consent forms, and privacy policy. Our questionnaire was designed to be brief, but comprehensive and adaptable to rapid developments associated with COVID-19. We understand you may have individual research questions of interest. We are happy to take suggestions (e-mail predict@mg.harvard.edu) but we may not be able to accommodate all requests.

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Notification of IRB Review

Protocol #: 2020P000909

Date: March 29, 2020

To: Chan, Andrew, MD, MPH MGH
Partners > MGH > Medical Services > Clinical & Translational
Epidemiology Unit

From: Partners Human Research
399 Revolution Drive, Suite 710
Somerville, MA 02145

Title of Protocol: COVID-19 Real-time Symptoms Epidemiology Tracker--CORSET Study 1

Version/Number: 1

Version Date: 3/23/2020

IRB Amendment #: 1

IRB Review Type: Expedited

IRB Approval Date: 03/29/2020

Approval/Activation Date: 03/29/2020

Next Review: Institutional Review

IRB Expiration Date: 03/27/2021

This project has been reviewed and approved by the **PHS IRB**. During the review of this project, the IRB specifically considered (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of subjects; (iii) the procedures for obtaining and documenting informed consent; (iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data.

Please note that if an IRB member had a conflict of interest with regard to the review of this project, consistent with IRB policies and procedures, the member was required to recuse him/herself and, if applicable, leave the room during the discussion and vote on this project except to provide information requested by the IRB.

The following documents were reviewed and approved by the IRB:

Consent Form
Protocol Summary
Protocol Summary
Consent Form Instrument/Questionnaire
Instrument/Questionnaire



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GENERAL REVIEW COMMENTS

(1) Amendment notes: "Detailed data will be shared after we arrange appropriate secure data transfer with ancillary sites." **Please note a Data Use Agreement will need to be executed for each ancillary site before data sharing. IRB approval is not contingent on this, but you are reminded of this requirement with this approval.**

(2) Please be reminded that all recruitment materials must be approved by the IRB. If external organizations plan to send recruitment materials to their members, please use previously approved advertisements or submit new advertisements via future IRB amendment.

As Principal Investigator, you are responsible for ensuring that this project is conducted in compliance with all applicable federal, state and local laws and regulations, institutional policies, and requirements of the IRB, which include, but are not limited to, the following:

1. Submission of any and all proposed changes to this project (e.g., protocol, recruitment materials, consent form, status of the study, etc.) to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB as an unanticipated problem.
2. Submission of a continuing review submission or institutional status report as required by the IRB and/or institution to continue the research, and submission of a final report when the project has been closed or completed.
3. Submission of any and all unanticipated problems, including adverse event(s) in accordance with the IRB's policy on reporting unanticipated problems including adverse events.
4. Obtaining informed consent from subjects or their legally authorized representative prior to initiation of research procedures when and as required by the IRB and, when applicable, documenting informed consent current IRB approved consent form(s) with the IRB-approval stamp in the document footer.
5. Informing all investigators and study staff listed on the project of changes and unanticipated problems, including adverse events, involving risks to subjects or others.
6. When investigator financial disclosure forms are required, submitting updated financial disclosure forms for yourself and for informing all site responsible investigators, co-investigators and any other members of the study staff identified by you as being responsible for the design, conduct, or reporting of this research study of their obligation to submit updated Investigator Financial Disclosure Forms for this protocol to the IRB if
(a) they have acquired new financial interests related to the study and/or (b) any of their previously reported financial interests related to the study have changed.

IMPORTANT REMINDER: THE IRB HAS THE AUTHORITY TO TERMINATE PROJECTS THAT ARE NOT IN COMPLIANCE WITH THESE REQUIREMENTS.

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Questions related to this project may be directed to **Line Papin | Tel: 857-282 - 1908 |**
Email: lpapin@partners.org

cc:

**Andrew Chan, MD, MPH, Principal Investigator, Clinical & Translational Epidemiology
Unit, Medical Services**

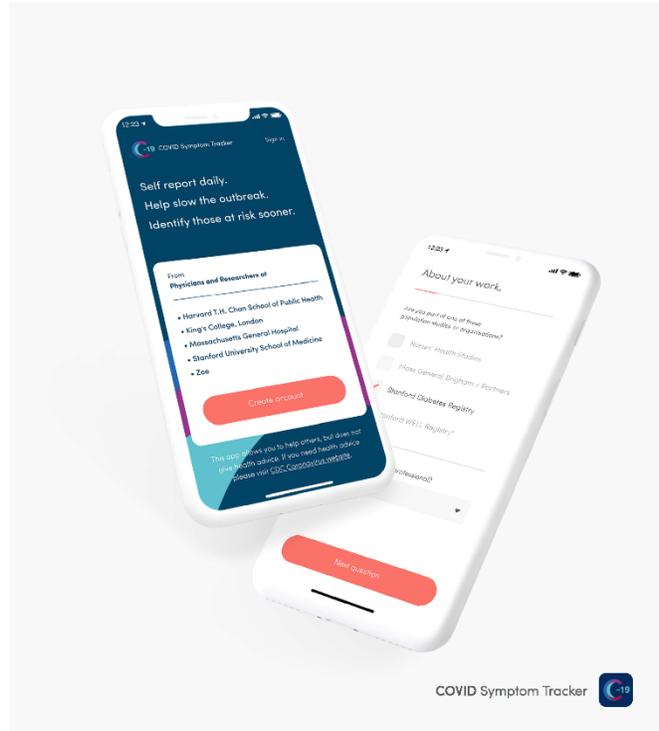
Marina Magicheva-Gupta, Research Coordinator/Manager, Other

COVID-19 Symptom Tracker App Screenshots

Take 1-minute to self-report daily, even if you are well. Help our scientists identify:

- How fast the virus is spreading in your area
- High-risk areas in the UK
- Who is most at risk, by better understanding symptoms linked to underlying health conditions

Designed by doctors and scientists at King's College London, Guy's and St Thomas' Hospitals in partnership with ZOE.



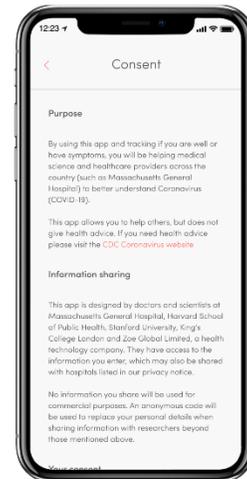
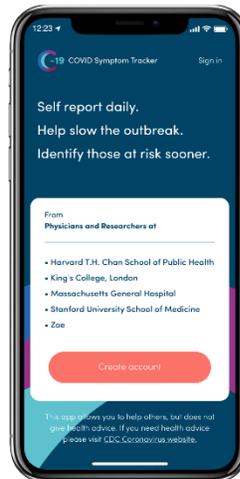
By taking 1-min daily to self-report your symptoms, even if you are healthy, you help slow the outbreak and identify those at risk sooner by:

(a) helping us to understand quicker the spreading zones to predict faster future spreading

(b) help us identify sooner those at risk by connecting progression of symptoms with people's profiles, and in some cases their long-term health data

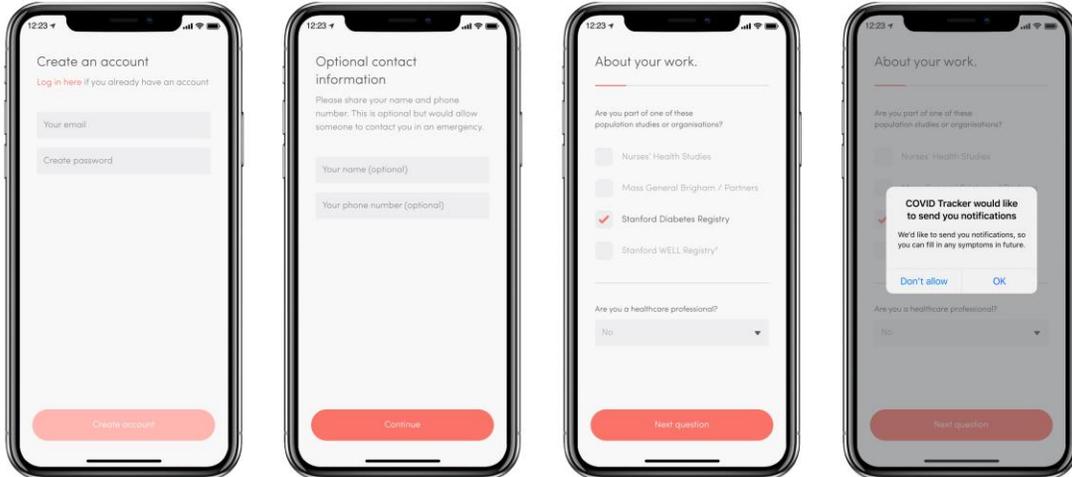
On first use, the app records location, age, core health risk factors (diabetes, lung disease, immunosuppressants, etc).

Then each time they use it, they identify whether they are healthy, and if sick what symptoms they have, and update as these change. They can also indicate if they are self-quarantining or going to hospital. If they go to hospital they can share the level of intervention.

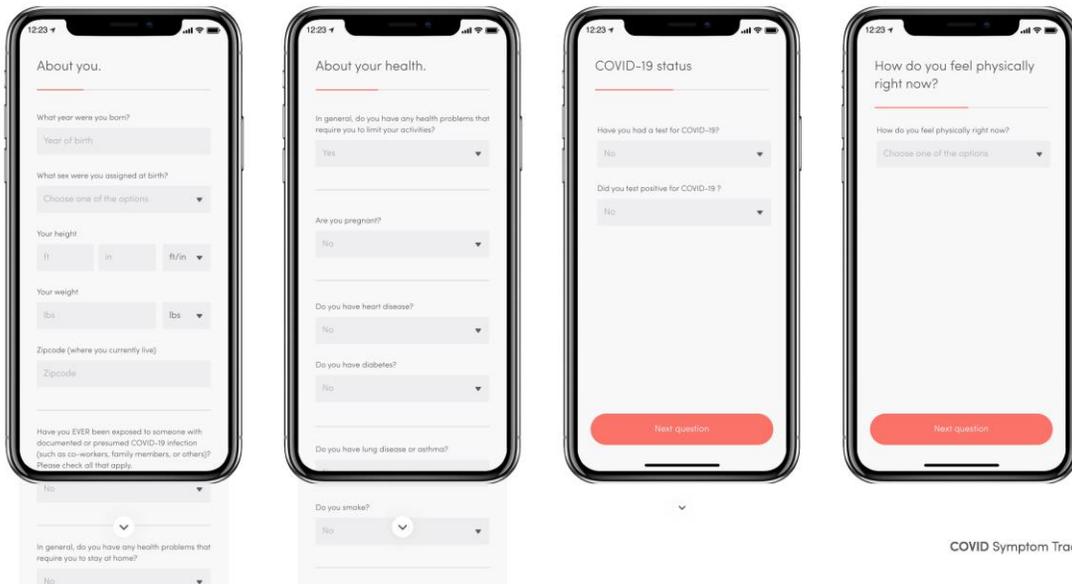


*Will be replaced with IRB consent text

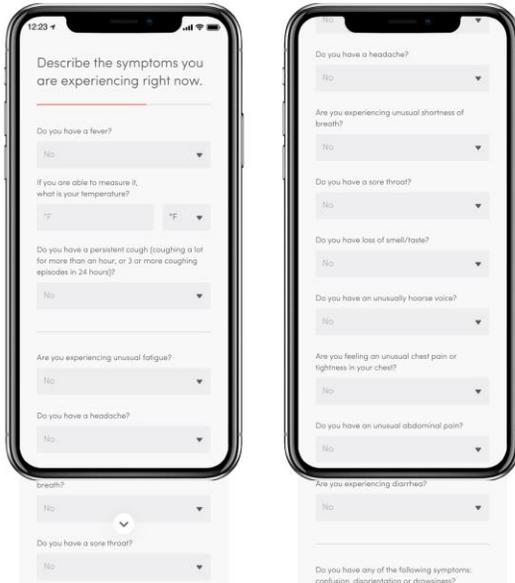
Initial information gathered



Initial information gathered

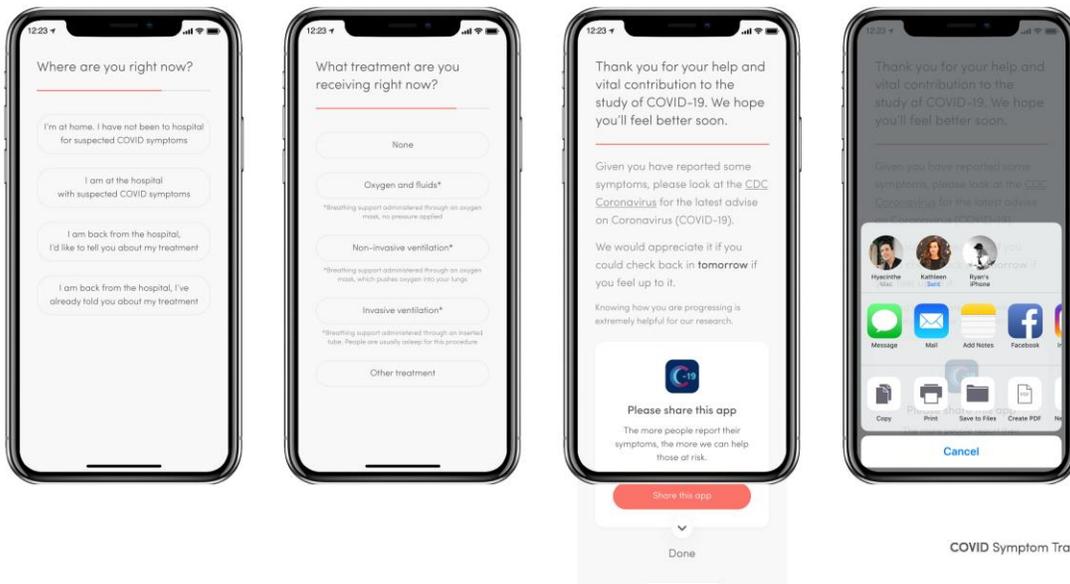


Daily questions



COVID Symptom Tracker 

When users are experiencing symptoms, we collect more data



COVID Symptom Tracker 

**PARTNERS HUMAN RESEARCH COMMITTEE
PROTOCOL SUMMARY**

Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

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Sites Relying on this IRB:

American Cancer Society / Cancer Prevention Study 3
Alpa Patel, PhD
Sr Scientific Director, Epidemiology Research
alpa.patel@cancer.org
404-329-7726

Harvard T.H. Chan School of Public Health / Health Professionals Follow-Up Study
Walter C. Willett, MD, DrPH

PROTOCOL TITLE

COVID-19 Real-time Symptom Epidemiology Tracker (CORSET), NCT04331509

Version Date: 1/12/2021

SPECIFIC AIMS

To identify risk factors for incidence and outcomes related to COVID-19 across the spectrum of disease presentation and severity to provide a resolution snapshot on the current pandemic as well as develop an infrastructure within infected populations for long-term follow-up and molecular studies to prevent the next global outbreak.

BACKGROUND AND SIGNIFICANCE

In December 2019, a series of pneumonia cases of unknown cause emerged in Wuhan, Hubei, China. Deep sequencing analysis from lower respiratory tract samples indicated a novel coronavirus, which was named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (previously known as 2019-nCoV). Despite efforts to contain the outbreak, the infection soon spread to over 180 countries and was declared a pandemic by the World Health Organization on 11 March 2020.

COVID-19 infection causes a spectrum of respiratory illness that includes symptoms of dry cough and fever which can progress to dyspnea and severe respiratory distress syndromes. Symptoms can be slowly progressive to acute in onset. More recently, non-respiratory symptoms, including malaise, fatigue, and gastrointestinal distress (e.g. diarrhea, abdominal pain) have been appreciated and can precede respiratory symptoms. Moreover, it is increasingly clear that individuals may harbor infection without clinical symptoms, which has made containment of the virus a significant challenge. To date, our hospitals are also seeing unprecedented numbers of patients presenting with clinical symptoms potentially consistent with COVID-19. However, after those patients interact with our providers, they are often sent home without a method of follow-up and check-in about symptoms. Thus, there is a high unmet need for methods to prospectively collect high-quality, real-time data from patients in the community using a rapidly adaptable data-capture platform for COVID-19 infection that encompasses the spectrum of symptom onset, diagnosis, treatment, vaccination, and clinical outcomes.

Because of their background and work environments, health care workers (HCW) have heightened awareness of the onset of potential COVID-19 symptoms and greater access to testing and care, thereby offering unique insights into the trajectory of symptom onset, diagnosis, treatment, and clinical outcomes. HCW are also at high personal risk of infection, leading to subsequent community spread. Limited availability of adequate personal protective equipment (PPE) has raised concern about their vulnerability to infection, work stress, and absenteeism, which further strains our response to the crisis. Thus, there is an urgent need to prospectively collect high-quality, real-time, data from HCW using a rapidly adaptable data-capture platform for COVID-19 infection that encompasses the spectrum of symptom onset, diagnosis, treatment, vaccination, and clinical outcomes. Further, there is an imperative for more accurate estimates of disease incidence; identification of characteristics for risk stratification to improve guidelines for testing, quarantine, treatment, and hospitalization; and assessment of PPE effectiveness in reducing infection, stress, and absenteeism. Such data are critical for not only protecting our healthcare workforce but to optimally allocate resources for the general population.

To address these urgent priorities, we have established a partnership with physicians and epidemiologists at King's College London (KCL) and Guy's and St. Thomas' Hospital London

and software engineers at Zoe Global Ltd, a health data science company focused on developing mobile phone apps to generate high-dimensional datasets for predictive machine learning approaches. We will survey populations of patients and HCW in real-time and rapidly advance our understanding of COVID-19 at population scale. Together, we are launching COVID-19 Symptom Tracker, a “symptom tracking app” that has been built for both Apple and Android platforms and is currently approved in their UK app stores and in submission to their US app stores. The app is supported through emergency funds provide by the UK National Health Service National Institute for Healthcare Research and the Wellcome Trust. On first use, the app records location, age, and core health risk factors. With continued use, participants can provide daily updates on symptoms, health care visits, and COVID testing results. They can also indicate if they are self-quarantining or seeking health care. If they seek healthcare, they can share the level of intervention and related outcomes. Healthcare workers will be asked specific questions about intensity of patient exposure, use of PPE, and stress/anxiety. The use of an app will facilitate prospective collection of data related to COVID-19 and capture the dynamic nature of exposure, onset of symptoms, history of vaccination, disease trajectory, and clinical outcomes currently observed. In addition, participants will receive a one-time COVID Diet Quality and Habits Questionnaire, a supplemental questionnaire that collects additional data on changes in diet, alcohol consumption, the use of supplements and physical activity.

Our overall goal is to identify risk factors for incidence and outcomes related to COVID-19 across the spectrum of disease presentation and severity to provide a resolution snapshot on the current pandemic as well as develop an infrastructure within infected populations for long-term follow-up and molecular studies to prevent the next global outbreak.

There is an urgent need to deploy this app in real time to maximize the collection of information as the COVID-19 pandemic accelerates and is likely to peak in the coming weeks.

RESEARCH DESIGN AND METHODS

We will recruit individuals who want to track their COVID-19 symptoms and especially nurses, advanced practice providers, physicians, and other health care workers (HCW) within Mass General Brigham in collaboration with Incident Command leadership and the office of the Chief Information Officer through advertisements, including the Partners Broadcast email system, linkage to Rally for Research pages in the COVID Pass cleared for work app, and direct emails from the relevant nursing and physician organizations at each Partners Hospital. We also will recruit participants enrolled in the Growing Up Today Study (GUTS), HCW enrolled in the Nurses’ Health Study (NHS), Nurses’ Health Study II (NHS II), Nurses’ Health Study III (NHS III) which are based at Brigham and Women’s Hospital as well as HCW in the Health Professionals Follow-up Study (HPFS) which is based at Harvard T.H. Chan School of Public Health and the Cancer Prevention Study 3 which is hosted by the American Cancer Society. Although we recognize that members of the NHS, NHS II, NHS III and HPFS may not be active HCW, we will still include them to provide comparative data among a population without sustained occupational exposure to potential COVID-19.

We will also encourage “CoV-risk” patients to enroll in the app as a means to provide clinical information, data on symptoms, and clinical outcomes for linkage with data collected through

other protocols (Partners 2020P000804). These participants will be told about this study by individual study staff after patients have been enrolled on their study.

Participants will be provided an option in the app to “opt-in” to learning about additional sub-studies in the future related to them being an app user. The question that will be asked is “Are you interested in being contacted to learn about additional studies related to COVID-19 or use of this app?” It will be added as a separate question within the app at the end of the questionnaire set. These individuals will be contacted/recruited according to sub-study IRB protocols as appropriate.

The app is also now being offered in Spanish.

Inclusion Criteria

- Adults at least 18 years of age

Exclusion Criteria

- None.

Enrollment will be ongoing with initial target of 2,000,000 participants.

Briefly describe study procedures. Include any local site restrictions, for example, “Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study.” Describe study endpoints.

This research study entails collecting questionnaire data via a mobile app from study participants. All study participants will be adults over the age of 18 years. The mobile application is designed on the same digital backbone as that used for the PREDICT app (see Partners IRB 2018P002078)

Eligible participants will be directed to enroll through the COVID symptom tracker app through an email invitation, Rally for Research with Partners, or for “CoV at risk” patients, through participation in an existing protocol (Partners 2020P000804). The first step within the app is to provide informed consent (See “Informed Consent Process” document). The consent is also now being offered in Spanish. Within the app, at the time of enrollment, each participant will provide their email address, and basic demographic information including age, sex, and zip code, and basic information on health status. App users will be able to update their location (zip code) if traveling/relocating to another area. They will be asked if they are an employee of Mass General Brigham or a member of the NHS, NHS II, NHS III, HPFS or GUTS cohort, or are being followed at Mass General Brigham. If they are an employee of Mass General Brigham or a member of the NHS, NHS II, NHS III, HPFS, CPS3 cohorts, they will have the option to provide their employee number or study ID number to facilitate downstream linkage. If an app user participates in multiple research studies, they can select all studies they are a part of. Participants who previously could not identify with multiple studies, are now able to update their profile.

They will also be provided the option to provide their name. They will also be asked if they are a health professional, if so what type, and if they are currently in direct patient care roles.

At baseline, participants will be asked to provide basic demographic and health data and information on their baseline health status. They will then be asked to report if they have been tested for COVID-19 and if so, the results, as well as if they have been well over the last 24 hours. They will also be asked about symptoms. If they test positive or exhibit symptoms, they will be directed to additional questions regarding quarantine and treatment. They will also be queried about their use of PPE and work-related stress and anxiety. The app will track symptoms on a daily basis through July 1, 2021 based on best estimates of the duration of the current COVID-19 response crisis. However, this protocol may be terminated early if investigators deem that that crisis has receded, and a critical mass of participants are no longer logging data. Similarly, the protocol may be extended if the crisis persists beyond July 1, 2021.

Participants will also receive a one-time COVID Diet Quality and Habits Questionnaire, a supplemental questionnaire that collects additional data on changes in diet, alcohol consumption, the use of supplements and physical activity. This questionnaire will be administered through the app and the users will have the option of skipping this questionnaire if they don't want to complete it. On average it should take about 15 minutes to complete the questionnaire.

We will execute a data usage agreement (Partner Agreement #2020A004627) with Zoe. In brief, data will be returned by Zoe Ltd to Mass General Brigham for data analysis. Within the Mass General Brigham population, we will associate the data collected in the app with internal Mass General Brigham employee databases or with data collected in other protocols (e.g. Partners 2020P000804). Within the NHS, NHS II, NHS III, HPFS, GUTS, or CPS3 population, we will link data by name, zip code, or cohort ID with our cohort databases for further analysis. Zoe will strip the database of names, cohort/employee IDs, or email for use in any aggregate analyses of COVID-19 incidence with other academic centers that have contributed data. Zoe will not share any name, age, IDs, or emails with any other entities other than the Mass General Brigham PIs. No other data currently maintained in the Mass General Brigham population or in the NHS, NHS II, NHS III, HPFS or GUTS will be shared with Zoe without additional human subjects approval or data usage agreements.

Deidentified data collected externally by other investigators related to COVID-19 may be shared with investigators on this protocol for aggregate data analyses related to the objectives designed here. Data will be made available according to individual data use agreements.

Dr. Christina Astley of Boston Children's hospital will be assisting the team with analyzing data from the app.

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

Participation in the study only requires participants to fill a questionnaire. It therefore does not change the standard of care for any past, present or future conditions.

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

This research only includes observational surveys.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

The risk of collecting questionnaire data is negligible. This study does not change the standard-of-care received by patients. Any email communication with prospective participants will be done using encryption, i.e. the "Send Secure" function.

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

Participants will provide their health information to COVID Symptom Tracker based on an agreed upon Consent page, as well as agreeing to the Privacy Policy and Terms and Conditions outlined in the app. This study has been designed to minimize participant burden while allowing for robust and repeated data collection necessary to obtain to adequate data to assess the dynamic and brief trajectory between symptom onset, COVID-19 diagnosis, vaccination, and PPE utilization. All data entered by participants is voluntary and participants can discontinue data entry at any time. They may also contact us or Zoe Global directly to have their data removed from the database. No additional personal health information provided to Mass General Brigham or through their participation in all Harvard Nurses' Health studies, HPFS, and GUTS or other protocols will be provided to Zoe.

EXPECTED BENEFITS

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, "It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

There is no specific individual health benefit expected as a direct result of participating in this study. However, participants will provide vital data that will help the general public in improving our understanding of the clinical symptoms and trajectory to illness associated with COVID-19. This may inform models related to disease incidence and patterns of spread that are critical to optimize resource allocation for testing, treatment, and utilization of PPE.

EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

Subjects must be over the age of 18. Because COVID-19 is not prevalent among children, they are being excluded from the study. No other special classes of subjects will be excluded.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

Non-English speakers will not be recruited as the application is currently only available in English.

REQUIREMENT PROCEDURES

Mass General Brigham healthcare workers will be invited to enroll through a process to be determined by the Incident Command Crisis committee and Partners Chief Information Officer, which may include direct email through the Partners Broadcast system, Rally for Research with Partners, as well as direct email via the nursing and physician leadership after obtaining the necessary approvals through institutional processes.

In COVID Pass, after completing daily attestations, the app will provide a link to Rally pages for ongoing COVID studies that may be of interest to HCW. Our Rally page will be among these studies. Participants will need to voluntarily navigate to the Rally page (e.g. they are not automatically redirected) by clicking on a link for learning more about potential studies like ours or direct links to our study. We anticipate that our study may recruit people through this feature for as long as the COVID pass is in use and allows use of this feature, per Institutional Leadership recommendations. HCW who are interested in joining our study will go to the Rally page and register interest as is standard for Rally use. Registered individuals will be contacted with the IRB-approved HCW specific email (see attachments).

NHS, NHS II, NHS III, HPFS and GUTS participants will be contacted by email by the Principal Investigators of each cohort: Meir Stampfer (NHS), Walter Willett and Heather Eliassen (NHS II), Jorge Chavarro (NHS III), Jaime Hart (GUTS) and Walter Willett (HPFS).

CPS3 participants will be recruited by email by Alpa Patel.

“CoV at risk” patients will be told about this study as a part of their participation in additional protocols (e.g. 2020P000804). Use of the app as a part of other study protocols will be included in the specific trial protocols and will point to this IRB protocol to cover use of the app. These participants will sign consent per this protocol when using the app covering data collection and sharing of their data back with other study investigators. Regulations at Partners in the Respiratory Illness Clinics (RIC) have recently been put in place which do not allow for the use

of paper on the clinical floors. As a result, CoV at risk studies that are using electronic consent will include a link to the app in that consent communication to ensure their participants are able to gain access to the app. In addition, they will hang laminated download instructions in RIC clinics that are able to be disinfected. After agreeing to participate in the CoV at risk studies, research nurses will point out these visual instruction cards for participants to use their phones to scan a QR code pointing them to the respective app store for download.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

None.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Recruitment-Of-Research-Subjects.pdf>

Guidelines for Advertisements for Recruiting Subjects

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Guidelines-for-Advertisements.pdf>

Remuneration for Research Subjects

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Remuneration-for-Research-Subjects.pdf>

CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators' own patients, describe how the potential for coercion will be avoided.

Participants will be directed to enroll in the COVID Symptom Tracker app through an invitation email or messaging to be developed in conjunction with the Incident Command Crisis management team at Mass General Brigham hospitals. Within the app will be an informed consent page with an attestation signing link. This process is described in detail in the attached "Informed Consent Process" document.

In brief, participants will consent on the app to provide responses to questions about symptoms, diagnosis of COVID-19, clinical outcomes, use of PPE.

Participants can withdraw their consent at any time during the course of the study without any reason by no longer providing data to the app or emailing study staff to remove them from the study.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:

<https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb>

For guidance, refer to the following Partners policy:

Informed Consent of Research Subjects:

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Informed-Consent-of-Research-Subjects.pdf>

DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

We do not anticipate safety issues. The principal investigator, in collaboration with data managers at Zoe and Kings College will monitor data quality and integrity, review subject enrollment, and address any subject-related issues that might arise.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor

and the Partners' IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners' IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

There will be no DSMB for this study as it is an observational study.

MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

The principal investigator will be reviewing each subject's data periodically throughout the duration of the study for quality, validity and integrity assurance and for adherence to the IRB approved protocol.

Additionally, interim and final data and safety monitoring reports performed twice a year by the principal investigator will include the following:

- Changes to protocol including
 - o Amendments to the protocol
 - o Investigator/key personnel changes
 - o Changes to the consent document and communications to participants regarding changes
- Monitoring the progress of the study
- Narrative summary of interim or final data analyses
- Protocol adherence
- Recruitment and retention summaries
 - o Enrollment numbers
 - o Withdrawals (provide summary of reason(s) for withdrawal)
 - o Dropouts (provide summary of reason(s) for dropouts)

PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

The privacy of all subjects will be protected and confidentiality maintained. Any email communication with patients will be done using encryption, i.e. the "Send Secure" function. Participants will be discouraged from communicating about medical issues by non-

secure email. The privacy of data is outlined in the “Informed Consent Process”, “Privacy Policy”, and “Terms and Conditions” appendices.

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

Study data will be kept on Zoe Global Ltd servers. Data will be collected using the same mobile app platform as used for the PREDICT-US study (Partners Protocol 2018P002078) which has previously been reviewed and approved by RISO. Data will be stored and transmitted back to Partners in an identical fashion as described in this protocol (using secure Partners Enterprise Dropbox). We will only analyze or store data on previously approved FAS/Odyssey or Channing Division of Network Medicine research clusters that are approved for storage and analysis of Human data, adequately protected using government and HIPAA standards for two-factor authentication and encryption.

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

Data will be stored on servers at Zoe Global Ltd in England. Participants may withdraw their consent at any time by emailing leavecovidtracking@joinzoe.com

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

Questionnaire data from the mobile app will be collected by our collaborators in England, Zoe Global Ltd and transferred to MGH via the MGH Enterprise Dropbox as described in the detailed protocol.

Deidentified data related to COVID-19 exposures, outcomes, symptoms, disease trajectory collected by external collaborators as they align with the objectives of this protocol may be shared with investigators on this protocol. These data will be completely stripped of identifying information and data use will be outlined in individual executed data use agreements.

PARTNERS HUMAN RESEARCH COMMITTEE DETAILED PROTOCOL

Title

CCOVID-19 RReal-time SSymptom EEpidemiology TTracker (CORSET)

NCT04331509

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1 Background & Rationale

In December 2019, a series of pneumonia cases of unknown cause emerged in Wuhan, Hubei, China¹. Deep sequencing analysis from lower respiratory tract samples indicated a novel coronavirus, which was named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (previously known as 2019-nCoV)². Despite efforts to contain the outbreak, the infection soon spread to over 180 countries and was declared a pandemic by the World Health Organization on 11 March 2020³.

COVID-19 infection causes a spectrum of respiratory illness that includes symptoms of dry cough and fever which can progress to dyspnea and severe respiratory distress syndromes^{4–6}. Symptoms can be slowly progressive to acute in onset. More recently, non-respiratory symptoms, including malaise, fatigue, and gastrointestinal distress (e.g. diarrhea, abdominal pain) have been appreciated and can precede respiratory symptoms^{7,8}. Moreover, it is increasingly clear that individuals may harbor infection without clinical symptoms⁹, which has made containment of the virus a significant challenge. To date, our hospitals are also seeing unprecedented numbers of patients presenting with clinical symptoms potentially consistent with COVID-19. However, after those patients interact with our providers, they are often sent home without a method of follow-up and check-in about symptoms. Thus, there is a high unmet need for methods to prospectively collect high-quality, real-time data from patients in the community using a rapidly adaptable data-capture platform for COVID-19 infection that encompasses the spectrum of symptom onset, diagnosis, treatment, vaccination, and clinical outcomes

Because of their background and work environments, health care workers (HCW) have heightened awareness of the onset of potential COVID-19 symptoms and greater access to testing and care, thereby offering unique insights into the trajectory of symptom onset, diagnosis, treatment, and clinical outcomes. HCW are also at high personal risk of infection, leading to subsequent community spread. Limited availability of adequate personal protective equipment (PPE) has raised concern about their vulnerability to infection, work stress, and absenteeism, which further strains our response to the crisis. Thus, there is an urgent need to prospectively collect high-quality, real-time, data from HCW using a rapidly adaptable data-capture platform for COVID-19 infection that encompasses the spectrum of symptom onset, diagnosis, treatment, vaccination and clinical outcomes. Further, there is an imperative for more accurate estimates of disease incidence; identification of characteristics for risk stratification to improve guidelines for testing, quarantine, treatment, vaccination, and hospitalization; and assessment of PPE effectiveness in reducing infection, stress, and absenteeism. Such data are critical for not only protecting our healthcare workforce but to optimally allocate resources for the general population.

To address these urgent priorities, we have established a partnership with physicians and epidemiologists at King's College London (KCL) and Guy's and St. Thomas' Hospital London and software engineers at Zoe Global Ltd, a health data science company focused on developing

mobile phone apps to generate high-dimensional datasets for predictive machine learning approaches. We will survey populations of patients and HCW in real-time and rapidly advance our understanding of COVID-19 at population scale. Together, we are launching COVID-19 Symptom Study App, a “symptom tracking app” that has been built for both Apple and Android platforms and is currently approved in their UK app stores and in submission to their US app stores. To differentiate this study using the app from other apps that “track” individual locations for contact tracing, the app and the study are also referred to as the COVID Symptom Study. The app is supported through emergency funds provide by the UK National Health Service National Institute for Healthcare Research and the Wellcome Trust. On first use, the app records location, age, and core health risk factors. With continued use, participants can provide daily updates on symptoms, health care visits, and COVID testing results. They can also indicate if they are self-quarantining or seeking health care. If they seek healthcare, they can share the level of intervention and related outcomes. Healthcare workers will be asked specific questions about intensity of patient exposure, use of PPE, and stress/anxiety. The use of an app will facilitate prospective collection of data related to COVID-19 and capture the dynamic nature of exposure, onset of symptoms, disease trajectory, and clinical outcomes currently observed. In addition, participants will receive a one-time COVID Diet Quality and Habits Questionnaire, a supplemental questionnaire that collects additional data on changes in diet, alcohol consumption, the use of supplements and physical activity. It is our intention to perform pooled data analyses using data collected from this study, and de-identified data from other sources that collect complementary data for COVID-related exposures, onset of symptoms, disease trajectory, and clinical outcomes (e.g. HowWeFeel; covidnearyou.org). This secondary use of data by investigators will be detailed through individual data use agreements via the COPE Consortium, but broadly will be used to address the objectives presented here.

Our overall goal is to identify risk factors for incidence and outcomes related to COVID-19 across the spectrum of disease presentation and severity to provide a resolution snapshot on the current pandemic as well as develop an infrastructure within infected populations for long-term follow-up and molecular studies to prevent the next global outbreak.

There is an urgent need to deploy this app in real time to maximize the collection of information as the COVID-19 pandemic accelerates and is likely to peak in the coming weeks.

2 Study Aim and Objectives

Overview: The proposed study will contact health care professionals working at Mass General Brigham (Partners Healthcare) or participants enrolled in the Harvard Nurses’ Health Study, Harvard Nurses’ Health Study II, Harvard Nurses’ Health Study III (NHSII/NHSIII), Growing Up Today Study (GUTS), Health Professionals Follow-up Study (HPFS), American Cancer Society Cancer Prevention Study 3 cohorts and direct them to use “COVID-19 Symptom Tracker,” a novel app for mobile devices designed to specifically capture self-reported information regarding symptoms associated with COVID-19 and use of PPE during the current COVID-19 pandemic. In addition, we will enroll individuals in other cohorts who may use this protocol as a

cede protocol to recruit their participants to the research study by seeking formal approval of recruitment materials. We will also use this app to track patients who are enrolled in additional protocols across Mass General Brigham who under investigation for COVID-19 (“CoV-Risk.”), including Partners IRB Protocol: 2020P000804 or individuals in the general public who enroll in this app on their own. This app is a joint development between Zoe Global Ltd and a team of physicians and epidemiologists at King’s College London, Guys and St. Thomas’ Hospital London, MGH, BWH, and the Harvard T.H. Chan School of Public Health. These data will be collected by Zoe Global Ltd and returned to the PI and co-investigators.

Specific objectives include:

1. Collect real-time data on COVID-19 symptoms from general public individuals and healthcare workers (HCW) during the 2020 pandemic using mobile digital technology. These data will allow for the construction of more accurate models of disease incidence and outcomes which can inform risk stratification for testing, algorithms for management (i.e. quarantine and hospitalization), and allocation of PPE. These data will also be used to understand the role of PPE in preventing infection and alleviating work-related stress and absenteeism.
2. Link real-time data on COVID-19 symptoms with ongoing collection of data on lifestyle, diet, health conditions, vaccination, and psychosocial stress among HCW enrolled in the Nurses’ Health Study II that have been extensively phenotyped over the last 30 years and genetically profiled to examine the role of these factors in COVID-19 disease, chronic complications, and psychosocial stress.
3. Collect real-time data on COVID-19 symptoms from patient or external cohorts that are being enrolled who are being investigated for COVID-19 (“CoV Risk”). These data will allow us to link the presentation of symptoms with clinical course, including likelihood of testing positive for COVID-19, development of new symptoms, vaccination, and clinical outcomes. These data can be linked with other clinical data or biospecimens that are being collected in other protocols (e.g. Partners 2020P000804). These data may be linked back to parent cohorts according to other Data Use Agreements.
4. Use deidentified data collected from other external or internal sources to pool with our collected data to perform proposed analyses. This will include data collected by other investigators using similarly designed tools and made available to investigators on this protocol according to other Data Use Agreements as they pertain to the analyses outlined in this detailed protocol.

3 Subject Selection

3.1 Study population

We will recruit individuals who wish to have their COVID-19 symptoms tracked. This will include nurses, advanced practice providers, physicians, and other health care workers (HCW) within Mass General Brigham via appropriate channels through consultation with the office of the Chief Information Officer and Incident Command leadership. The app is also being offered in Spanish.

Possible methods may include direct emails or advertisements, including through the Partners Broadcast email system from the relevant nursing and physician organizations at each Partners Hospital. We also will recruit participants/HCW enrolled in the Growing Up Today Study (GUTS), the Nurses' Health Study (NHS), Nurses' Health Study II (NHS II) or Nurses' Health Study III (NHS III) which are based at Brigham and Women's Hospital as well as the Health Professionals Follow-up Study (HPFS) which is based at Harvard T.H. Chan School of Public Health. We will additionally enroll individuals from other prospective cohorts. For some cohorts that are not based at Partners, the investigators may submit, through a cede protocol, recruitment materials for their cohorts to recruit participants to use the COVID symptoms tracker app and allow us to collect data on their cohorts.

NHS was established in 1976 and recruited 121,700 female nurses. The original focus of the study was on contraceptive methods, smoking, cancer, and heart disease, but has expanded over time to include research on many other lifestyle factors, behaviors, personal characteristics, and more than 30 diseases.

NHS II was begun in 1989 with the recruitment of 116,430 female nurses from across the US who have completed follow-up questionnaires every other year. Participants have provided a variety of biological specimens over the course of follow-up and participated in digital phenotyping studies.

GUTS recruited children of Nurses' Health Study II participants. The first phase of the study began in 1996 during which 16,882 girls & boys between the ages of 9 & 14 were enrolled into the study. The second phase of GUTS (GUTS2) was rolled out in 2004, with the enrollment of an additional 10,923 children between the ages of 10 & 17. This is a cross-generational study allowing for exploration of the relation between early life exposures and health in adulthood.

NHS III cohort is an expansion of the NHS II that began enrolling female RNs, LPNs, and nursing students in 2010. In 2015, eligibility was expanded to include male nurses. More than 45,000 female and male nurses and nursing students currently participate.

HPFS is a male study designed to complement the female NHS. It began in 1986 and enlisted 51,529 men in health professions to participate in the study. The purpose of the study is to

evaluate a series of hypotheses about men's health relating nutritional factors to the incidence of serious illnesses, such as cancer, heart disease, and other vascular diseases.

The American Cancer Society would like to enroll participants in their Cancer Prevention Study 3 (CPS3). In December 2013, the American Cancer Society completed the initial recruitment of its newest study, Cancer Prevention Study-3, with over 304,000 participants. The American Cancer Society's Epidemiology Research Program invited men and women between the ages of 30 and 65 years who had no personal history of cancer to join this historic research study. The ultimate goal was to enroll at least 300,000 adults from various racial and ethnic backgrounds from across the United States and Puerto Rico.

Although we recognize that members of the NHS, NHS II, NHS III and HPFS may not be active HCW, we will still include them to provide comparative data among a population without sustained occupational exposure to potential COVID-19.

We will also encourage "CoV-risk" patients to enroll in the app as a means to provide clinical information, data on symptoms, vaccination, and clinical outcomes for linkage with data collected through other protocols (Partners 2020P000804). Other protocols enrolling CoV-risk patients may add use of the app to their own IRB protocols and point to this protocol to cover data collection using the app. These studies may directly inform participants about this tool.

As the crisis continues, we may develop additional sub-studies that users of the app may be interested in participating in. We will provide an opt-in checkbox (defaults to opted out) to allow app users to denote whether they are interested in learning about additional studies being performed by the research team. The question that will be asked is "Are you interested in being contacted to learn about additional studies related to COVID-19 or use of this app?" It will be added as a separate question within the app at the end of the questionnaire set. Individuals who record their interest may be contacted directly with recruitment materials in the future for research studies (submitted as independent IRB protocols) related to their being a user of the app.

3.2 Inclusion criteria

Participants are eligible for inclusion if they are:

- Adults at least 18 years of age.

3.3 Exclusion criteria

None.

4 Subject Enrollment

4.1. Procedures for Recruitment/Eligibility Screening

Mass General Brigham participants will be invited to enroll through channels that are developed through collaboration with the Chief Information Officer and Incident Command leadership. This may include:

- direct email through the Partners Broadcast system;
- Rally for Research with Partners, an online platform that supports collaboration between the public and the research community;
- Direct links to the Rally Page for HCW in the COVID Pass employee symptom clearance app in use by MGB/Partners employees before entering work.
- direct email through the nursing and physician leadership after obtaining the necessary approvals through institutional processes.

Examples of digital communication, Rally with Partners communication, and physical letter communication templates have been attached.

In COVID Pass, after completing daily attestations, the app will provide a link to Rally pages for ongoing COVID studies that may be of interest to HCW. Our Rally page will be among these studies. Participants will need to voluntarily navigate to the Rally page (e.g. they are not automatically redirected) by clicking on a link for learning more about potential studies like ours or direct links to our study. We anticipate that our study may recruit people through this feature for as long as the COVID pass is in use and allows use of this feature, per Institutional Leadership recommendations. HCW who are interested in joining our study will go to the Rally page and register interest as is standard for Rally use. Registered individuals will be contacted with the IRB-approved HCW specific email (see attachments).

NHS, NHS II, NHS III, HPFS and GUTS participants will be contacted by email by the Principal Investigators of each cohort: Meir Stampfer (NHS), Walter Willett and Heather Eliassen (NHS II), Jorge Chavarro (NHS III), Jaime Hart (GUTS) and Walter Willett (HPFS). See attached example recruitment and reminder letter templates. The individual cohort name and appropriate PI name will be replaced in each case for each cohort.

CPS3 participants will be recruited by email (see attached email letter) by the Principal Investigator of CPS3, Alpa Patel, and be instructed to go through the standard research consent process and disclose their affiliation with CPS3.

“CoV at risk” patients will be told about this study as a part of their participation in additional protocols (e.g. 2020P000804). These other studies will be modified as necessary to include discussion of the application for collection of symptom data as appropriate and integrate this into their workflows/recruitment materials.

Members of the general public or other cohorts may also be recruited to the study. Specific recruitment approaches from other studies will either occur through amendment in local IRB protocols or through cede review to this protocol. Participants in other studies that are recruited in real-time by study coordinators/research nurses may also be told about the app

They will introduce the possibility of participating in this study as another optional study to consider after individuals consent to their protocol

As a part of evolving regulations in the Respiratory Illness Clinics (RIC) at Mass General Brigham, paper products are not allowed in the RIC to limit transmission of COVID-19. Therefore, we cannot provide instruction sheets to these participants for them to take and download the app later. Leadership in the RIC have recommended that we place a laminated 8-1/2x11" sign that is capable of being disinfected in rooms where research nurses are consenting CoV at risk patients to protocols intending to use the app (see "RIC Instruction Sheet"). Once they agree to participate in these other studies, Research Nurses will point out these signs with instructions of how to download the app. Research nurse staffing has also pointed out that there is a concern that some participants may not have a phone on them. In the absence of being able to hand out a paper card with take-home instructions, the research staff of other studies may provide a direct download link for the app in email communications with their participants. The exact language for this will be included in other IRB protocols as a part of their approved email communication language.

Rally for Research is also public facing and may recruit members of the public who see this app. Any person's use of the app and subsequent data collection and ultimate consent to participate in this study will be captured via the app consent process. Anyone may voluntarily associate themselves with other research studies at MGH or other institutions in the app (like all Nurses' Health Studies/HPFS/GUTS participants do). In addition, it is possible that individuals participating in these other studies, may find our study on their own and will be given the option to self-associate with other existing studies at Mass General Brigham.

This data will be treated as Personal Identifying Information and will not be shared between studies, but investigators wishing to abstract data on their study participants will be allowed access to this information to link participants back, after approval by their own IRB to collect this data (secondary use of already collected data).

4.2 Procedures for Obtaining Informed Consent

Within the app will be an informed consent page and option to digitally record consent. The consent is also being offered in Spanish. The process for and Informed Consent text is fully described in the attachment "Informed Consent Process" In brief, participants will consent on the app prior to providing responses to questions about symptoms, diagnosis of COVID-19, clinical outcomes, use of PPE. These consents will be initially collected and recorded by Zoe Global Ltd and copies provided to MGH. All participants, regardless of recruitment source, will go through this informed consent process which has been approved by the PHRC IRB.

4.3. Procedures for participation termination or withdrawal

Participants can withdraw their consent at any time during the course of the study without any reason by no longer providing data to the app.

5 Study Procedures

5.1 Recruitment and baseline enrollment

Participants will be directed to enroll through the COVID symptom tracker / COVID symptom study app, as described. Within the app, at the time of enrollment after signing informed consent within the document, each participant will provide their email address, and basic demographic information including age, sex, and zip code, and basic information on health status. They will be asked if they are an employee of Mass General Brigham or a member of the NHS, NHS II, NHS III, HPFS or GUTS cohort, or are being followed at Mass General Brigham, or other research study. If an app user participates in multiple research studies, they can select all studies they are a part of. Participants who previously could not identify with multiple studies, are now able to update their profile. If they are an employee of Mass General Brigham or a member of the NHS, NHS II, NHS III, HPFS, or CPS3 cohorts, they will have the option to provide their employee number or study ID number to facilitate downstream linkage. They will also be provided the option to provide their name. They will also be asked if they are a health professional, if so what type, and if they are currently in direct patient care roles.

5.2. Symptom tracker

At baseline, participants will be asked to provide basic demographic and health data and information on their baseline health status. They will then be asked to report if they have been tested for COVID-19 and if so, the results, as well as if they have been well over the last 24 hours. They will also be asked about symptoms. If they test positive or exhibit symptoms, they will be directed to additional questions regarding quarantine and treatment. They will also be queried about their use of PPE and work-related stress and anxiety. App users will be able to update their location (zip code) if traveling/relocating to another area. The app will track symptoms on a daily basis through July 1, 2021 based on best estimates of the duration of the current COVID-19 response crisis. However, this protocol may be terminated early if investigators deem that that crisis has receded, and a critical mass of participants are no longer logging data. Similarly, the protocol may be extended if the crisis persists beyond July 1, 2021.

Participants will also receive a one-time COVID Diet Quality and Habits Questionnaire, a supplemental questionnaire that collects additional data on changes in diet, alcohol consumption, the use of supplements and physical activity. This questionnaire will be administered through the app and the users will have the option of skipping this questionnaire if they don't want to complete it. On average it should take about 15 minutes to complete the questionnaire.

This app is built on the digital backbone of Zoe's PREDICT app, previously reviewed and approved by Partners RISO as a part of Partners IRB Protocol 2018P002078.

5.3. Data return

We will execute a data usage agreement with Zoe (submitted in parallel as the initial IRB application as Partners 2020A004627). In brief, data will be captured by Zoe Ltd and returned to Mass General Brigham for data analysis using secure Partners Enterprise Dropbox. This will include deidentified data for all users in the COVID Symptom Study as well as identified data as outlined below. This process for data sharing with Zoe Global Ltd was reviewed and approved previously by Partners RISO office as a part of Partners IRB Protocol 2018P002078. Within the Mass General Brigham population, we will associate the data collected in the app with internal Mass General Brigham employee databases or with data collected in other protocols (e.g. Partners 2020P000804). Within the NHS, NHS II, NHS III, HPFS, and GUTS population. Principal Investigators will link COVID-19 data by name, zip code, or cohort ID with their cohort databases for further analysis. After transfer to the MGH teams, Zoe will strip the database of names, cohort/employee IDs, or email for use in any aggregate analyses of COVID-19 incidence with other academic centers that have contributed data. Zoe will not share any name, age, IDs, or emails with any other entities other than the Mass General Brigham PIs. No other data currently maintained in the Mass General Brigham population or in the NHS, NHS II, NHS III, HPFS, GUTS or CPS3 will be shared with Zoe without additional human subjects approval or data usage agreements. Data returned to MGH will only additionally be stored and analyzed within Partners approved platforms for human subjects research data including the Channing Division of Network Medicine and Harvard FAS/Odyssey computing clusters that comply with federal, HIPAA, and Partners regulations related to protection of human data, including but not limited to encryption and two-factor authentication. Access to these systems is granted on a per user basis. Accounts are frequently reviewed for access need. Access to data is granted on an as needed basis per the P.I. permission. Channing Servers reside inside the Partners Needham Datacenter as do all Channing Data Storage devices with the exception of the data archive which is located at Simches MGH Datacenter for distancing purposes.

Data on HPFS and CPS3 participants will be handled as all participants data is and stored on Zoe Global Ltd servers until transfer to MGH as described above. Data will be shared with the Harvard T.H. Chan School of Public Health or the American Cancer Society only once Data Use Sharing agreements are in place and only according to these agreements for linkage back with their CPS3 datasets. Exported data will only include personal identifiers for members who disclosed they were a part of the CPS3 cohort.

Deidentified data relevant to the proposed analyses that have been collected by external investigators (e.g. those not included as investigators on this protocol) related to COVID-19 exposures, outcomes, symptoms, vaccination, and disease trajectory/clinical outcomes may be shared with CORSET investigators via additional data use agreements. This protocol will cover the secondary use of that data as it pertains to COVID-related analyses.

Deidentified data collected by CORSET, including data collected by the COVID Symptom Tracker / COVID Symptom Study app may be included in public databases in the future according to federal requirements related to funding sources.

6 Statistical Analysis

Given the urgent nature of the COVID-19 pandemic, there are not available numbers regarding the potential number of eligible participants within the Mass General Brigham. We estimate contacting approximately 10,000 NHS, 51,000 NHS II, 30,500 NHS III, 20,000 GUTS, 20,000 HPFS participants. “CoV at risk” protocols are currently open to enrollment. External site enrollment has no specific target, but is expected to exceed 50,000 people.

Statistical analyses will be based on traditional methods examining exposures to outcome.

Dr. Christina Astley of Boston Children’s hospital will be assisting the team with analyzing data from the app.

7 Risks and Discomforts

Participants will provide their health information to COVID Symptom Tracker / COVID Symptom Study app based on consent provided in the Terms and Conditions outlined in the app (attached). This study has been designed to minimize participant burden while allowing for robust and repeated data collection necessary to obtain to adequate data to assess the dynamic and brief trajectory between symptom onset, COVID-19 diagnosis, and PPE utilization. All data entered by participants is voluntary and participants can discontinue data entry at any time. They may also contact us to have their data removed from the database. No additional personal health information provided to Mass General Brigham or through their participation in the GUTS, HPFS and all Harvard Nurses’ Health studies, or other protocols will be provided to Zoe.

8 Potential Benefits

There is no specific individual health benefit expected as a direct result of participating in this study. However, participants will provide vital data that will help the general public in improving our understanding of the clinical symptoms and trajectory to illness associated with COVID-19. This may inform models related to disease incidence and patterns of spread that are critical to optimize resource allocation for testing, treatment, and utilization of PPE.

9 Monitoring and Quality Assurance

We do not anticipate safety issues. The principal investigator, in collaboration with data managers at Zoe and Kings College will monitor data quality and integrity, review subject enrollment, and address any subject-related issues that might arise.

10 References

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11 Signatures

Principal Investigator:

Date:

Print name: Andrew T. Chan, MD, MPH

COVID Symptom Study App Questionnaire v.7

Q (single-select): I am in an existing research study or trial, and I want my data to be shared with investigators on that study.

1. Yes, I am
2. No, I am not

Q (text entry): Your email

Q (text entry): Your name

Q (text entry): Phone number

If "Yes, I am" show:

Q (multi-select): Is your study one of the following?

- a. Harvard Nurses' Health Studies
- b. Harvard Growing Up Today Study
- c. Harvard Health Professionals Follow-Up Study
- d. Mass General/ Brigham
- e. Stanford Nutrition Studies Group
- f. Multiethnic Cohort Study
- g. PREDICT 2
- h. American Cancer Society Cancer Prevention Study-3
- i. UCSD/COH California Teachers Study
- j. The Sister Study
- k. The Agricultural Health Study (AHS)
- l. The GuLF Study
- m. ASPREE-XT
- n. Black Women's Health Study
- o. ColoCare study
- p. PROMISE/PCROWD study
- q. PREDETERMINE study
- r. NIEHS Environmental Polymorphisms Study
- s. Chasing COVID-CUNY ISPH
- t. CovidNearYou/FluNearYou
- u. Partners Biobank
- v. Mass Eye and Ear Infirmary
- w. MD Anderson D3CODE Study
- x. Hispanic Colorectal Cancer Study
- y. Colon Cancer Family Registry
- z. Louisiana State University
- aa. COVID SIREN
- bb. NorthShore Genomic Health Initiative
- cc. C19 Human Genomics Study
- dd. ORIGINS
- ee. School reopening

Q (text entry): If not, add the names of your studies.

Q (text entry): If you know it, what is the name of your contact at the study (investigator, physician, study coordinator, etc.)?

Q (text entry): If you know it, what university or hospital runs this study?

Q (text entry): What is the NCT number (if you know it)?

Q (select one): Are you a healthcare worker (including hospital, elderly care, or in the community):

1. No
2. Yes, I currently interact with patients
3. Yes, but I do not currently interact with patients

Q (select one): Do you care for multiple people in the community, with direct contact with your patients?

1. No
2. Yes

If "Yes, I currently interact with patients" show:

Q (multi-select): Since the COVID-19 epidemic began, have you physically worked in?

- a. Hospital inpatient
- b. Hospital outpatient
- c. Clinic outside a hospital
- d. Nursing home/ elderly care or group care facility
- e. Home health
- f. School clinic
- g. Other health care facility

Q (select one): Have you EVER interacted in person with patients with documented or suspected COVID-19 infection?

1. Yes, documented COVID-19 cases only
2. Yes, suspected COVID-19 cases only
3. Yes, both documented and suspected COVID-19 cases
4. Not that I know of

Q (select one): Since the COVID-19 epidemic began, have you used person protective equipment (PPE) at work?

1. Always
2. Sometimes
3. Never

If "Always" show:

Q (select one): Choose one of the options

1. I have had all the PPE I need for work
2. I had to reuse PPE because of shortage

If "Sometimes" show:

Q (select one): Choose one of the options

1. I haven't always needed to use PPE, but have had enough when I did
2. I would have used PPE all the time, but I haven't had enough
3. I've had to reuse PPE because of shortage

If "Never" show:

Q (select one): Choose one of the options

1. I haven't needed PPE
2. I needed PPE, but it was not available

Q (text entry): What year were you born?

Q (select one): What sex were you assigned at birth?

1. Male
2. Female
3. Intersex
4. Prefer not to say

Q (select one): What gender do you most identify with?

1. Male
2. Female
3. Intersex
4. Prefer not to say
5. Other, please specify

If "Other, please specify" show:

Q (text entry): Please specify as you wish

Q (multi-select): What is your race?

- a. American Indian or Alaska Native
- b. Asian
- c. Black or African- American
- d. Native Hawaiian or other Pacific Islander
- e. White
- f. Other, please specify
- g. Prefer not to say

If "Other, please specify" show:

Q (text entry): Please specify your race

Q (select one): What is your ethnicity?

1. Hispanic or Latino or Spanish origin
2. Not Hispanic or Latino, or Spanish origin
3. Prefer not to say

Q (text entry): Your height?

Q (text entry): Your weight?

Q (text entry): Your zipcode?

Q (multi-select): Have you EVER been exposed to someone with documented or suspected COVID-19 infection (such as co-workers, family members, or others)? Please check all that apply.

- a. Yes, documented COVID-19 cases only
- b. Yes, suspected COVID-19 case only
- c. Yes, both documented and suspected COVID-19 cases
- d. Not that I know of

Q (select one): In general, do you have any health problems that require you to stay at home?

1. No
2. Yes

Q (select one): Do you need someone to help you on a regular basis?

1. No
2. Yes

Q (select one): If you need help, can you count on someone close to you?

1. No
2. Yes

Q (select one): Do you regularly use a cane, walker or wheelchair to get about?

1. No
2. Yes

Q (select one): In general, do you have any health problems that require you to limit your activities?

1. No
2. Yes

If answered "female" previously show:

Q (select one): Are you currently having periods?

1. I've never had periods
2. I'm currently having periods
3. I've stopped having periods
4. I'm pregnant
5. I'm not currently having periods
6. Prefer not to say
7. Other

If currently having periods,

Q (select one): Do you periods usually occur?

1. regularly every 3-6 weeks
2. Regularly, but less often than every 6 weeks
3. At irregular intervals

If I've stopped having periods

Q (text response): At what age did your periods stop?

If pregnant,

Q (text response): How many weeks pregnant are you?

Q (select one): Are you taking any of the following forms of hormone treatment?

1. No
2. Combined oral contraceptive pill
3. Progesterone only pill
4. Mirena or other hormone coil
5. Depot injection or implant
6. Hormone replacement therapy
7. Estrogen hormone therapy for gender transitioning
8. Testosterone hormone therapy
9. Prefer not to say
10. Other

Q (select one): Do you have heart disease?

1. No
2. Yes

Q (select one): Do you have diabetes?

1. No
2. Yes

Q (select one): Do you have hayfever (seasonal allergies)?

1. No
2. Yes

Q (select one): Do you have eczema?

1. No
2. Yes

Q (select one): Do you have asthma?

1. No
2. Yes

Q (select one): Do you have lung disease?

1. No
2. Yes

Q (select one): Do you smoke?

1. Never
2. Not currently
3. Yes

If "Not currently " show:

Q (text entry): How many years since you last smoked?

Q (select one): Do you have kidney disease?

1. No
2. Yes

Q (select one): Are you living with cancer?

1. No
2. Yes

If "Yes" show:

Q (text entry): What type of cancer do you have?

Q (select one): Are you on chemotherapy or immunotherapy for cancer?

1. No
2. Yes

Q (select one): Do you regularly take immunosuppressant medications (including steroids, methotrexate, biologic agents)?

1. No
2. Yes

Q (select one): Do you regularly take aspirin (baby aspirin or standard dose)?

1. No
2. Yes

Q (select one): Do you regularly take “NSAIDs” like ibuprofen, nurofen, diclofenac, naproxen?

1. No
2. Yes

Q (select one): Are you regularly taking any blood pressure medications?

1. No
2. Yes

If "Yes" show:

Q (select one): Are you regularly taking any blood pressure medications ending in “-pril”, such as enalapril, lisinopril, captopril, ramipril?

1. No
2. Yes

Q (select one): Are you regularly taking blood pressure medications ending in “-sartan”, such as losartan, valsartan, irbesartan?

1. No
2. Yes

Q (multi-select): Have you been taking any vitamins or other supplements regularly for more than 3 months? Regularly means more than 3 times a week on average. Select all that apply. We are exploring the possible effects of vitamin supplements on COVID infection.

- a. No
- b. Vitamin C
- c. Vitamin D
- d. Omega-3 or Fish Oil
- e. Zinc
- f. Garlic
- g. Probiotics
- h. Multi-vitamins and minerals
- i. Other, please specify
- j. Prefer not to say

If "Other" show:

Q (text entry): Please specify the vitamins or supplements.

Q (select one): If you know it, what is your blood group?

1. A
2. B
3. AB
4. O
5. I don't know my blood group for certain
6. Prefer not to say

The following questions on weight, nutrition, and exercise are to help us understand whether COVID may be impacting our health in these areas and how significant these effects are. These questions are all optional. Since March when COVID became prevalent:

Q (select one): How has your weight changed?

1. Increased
2. Decreased
3. Stayed the same
4. Prefer not to say

If "Increased" or "Decreased" show:

Q (text entry): By how much (an estimate is fine)?

Q (select one): How has your diet changed in your opinion?

1. It has become healthier
2. It has become more unhealthy
3. It has stayed the same
4. Prefer not to say

Q (select one): How has your snacking changed?

1. I am snacking more
2. I am snacking less
3. My snacking levels are the same
4. Prefer not to say

Q (select one): How has your alcohol consumption changed?

1. I am drinking more alcohol
2. I am drinking less alcohol
3. I don't drink alcohol
4. My alcohol consumption is the same
5. Prefer not to say

Q (select one): Have your physical activity levels changed?

1. Yes, increased
2. Yes, decreased
3. No change, has remained the same
4. Prefer not to say

Q: New COVID studies and how you can help. Are you interested in being contacted to learn about additional studies related to COVID-19 or use of this app?

Q (select one): Have you felt unwell in the month before you started reporting on this app?

1. No
2. Yes

If "Yes" show:

Q (multi-select): Did you have any of the following symptoms?

- k. Loss of smell/taste
- l. Unusual shortness of breath
- m. Unusual fatigue
- n. Fever
- o. Skipped meals
- p. Persistent cough
- q. Diarrhea
- r. Unusual chest pain or tightness in your chest
- s. Hoarse voice
- t. Abdominal pain

u. Confusion, disorientation, drowsiness

Q (text entry): How many days ago did your symptoms start?

Q (select one): Are you still experiencing symptoms?

1. No
2. Yes

If "Yes" show:

Q (select one): How have your symptoms changed over the last few days?

1. Much better
2. A little better
3. The same
4. A little worse
5. Much worse

Q (select one): Do you think you have already had COVID-19, but were not tested?

1. No
2. Yes

If "Yes" show:

Q (select one): Did you have the classic symptoms (high fever and persistent cough) for several days?

1. No
2. Yes

This information can help us understand the impact of social distancing and face masks on infection rates. These questions are completely optional.

Q (select one): How much have you been isolating over the last week?

Q (text response): In the last week how many times have you been outside, with little interaction with people outside your household (e.g. exercise)?

Q (text response): In the last week, how many times have you visited somewhere with lots of people (e.g. groceries, public transport, work)?

Q (text response): In the last week how many times have you visited a healthcare setting, including your work (e.g. hospital, clinic, dentist, pharmacy)?

Q (select one): In the last week, did you wear a face mask when outside the house?

1. Never
2. Sometimes
3. Most of the time
4. Always
5. Not applicable

If "Sometimes", "Most of the Time", or "Always" show:

Q (multi-select): What kind of face mask do you use? Check all that apply.

- a. Cloth or scarf
- b. Surgical mask
- c. N95/FFP respirator
- d. Not sure/ prefer not to say
- e. Other, please specify:

If “Other”, long text entry appears

COVID & Diet

We would like to ask you some on-off diet and lifestyle questions to help researchers understand how diet can impact the likelihood and severity of getting COVID.

They also want to understand how the pandemic has impacted our diet and lifestyle habits. It will take 10-15 minutes to complete.

- a. Yes, let's do it
- b. No, but ask me later
- c. Skip and don't ask me again.

If “Yes, let's do it”, please refer to COVID Diet Questionnaire.

Q (select one): If you have ever had a COVID-19 test, please add below. You can edit these at any time in the future.

1. Add new test
2. I have never had a COVID test

If adding a test,

Q (select one): Do you know the date of your test?

1. No
2. Yes

If no,

Q (select one): Between which two dates do you think you had your test?

Select dates on a calendar

If yes

Q. When was your test?

Q (select one): How was this test performed?

1. A swab of my nose or throat
2. I spat in a cup/ tube
3. A finger-prick blood test
4. A blood test, done using a needle
- 5.. Other, please specify

If “A swab of my nose or throat”:

Q (select one): Did a trained worker swab you?

1. Yes
2. No
3. Unsure

If other, please indicate how the test was performed.

Q (select one): Where was your test performed?

1. At home
2. Hospital (not drive-through)
3. Work (excluding hospital or GP)

4. Local health department
5. Store or pharmacy clinic
6. Other, please specify

If other, please specify the test location

Q (select one): What are the results of this test?

1. Negative
2. Positive
3. Not clear/ failed
4. Waiting for results

Tell us if you have ever had at least one dose of a COVID-19 vaccine. We can't record COVID-19 vaccines taken as part of a trial yet. If this how you received your vaccination, please don't add it for now.

Q. (select one)

1. Add vaccine
2. I haven't had a vaccine

If "add vaccine", go to section "tell us about your vaccine"

Q. When was your injection? Enter date

Q: Have you had a second dose yet?

1. No
2. Yes

If yes, show:

Q. When was your injection? Enter date.

Confirm either one or two doses→ click "this information is correct" button.

Q. Are you experiencing any symptoms near the injections site?

Check all that apply:

1. Pain
2. Redness
3. Swelling
4. Swollen glands in the armpit
5. Warmth
6. Itch
7. Tenderness
8. Other

If other, describe your symptoms in the free text box

If, selected "I have not had a vaccine"

Q. Would you accept a COVID-19 vaccine if offered? (select one):

1. Yes
2. No
3. I don't know

If "No",

Q. Please tell us why (check all that apply):

1. I took part on a vaccine trial
2. Religious reasons
3. Personal belief/philosophical reasons
4. Pregnancy/breastfeeding
5. Illness/medication
6. Concerned about long term side effects
7. Concerned about adverse reaction
8. Do not know enough about it
9. Do not think it will work
10. Do not think it will be available to me
11. Do not think it is necessary
12. Prefer not to say
13. Other

If other, describe your symptoms in the free text box

If "I don't know"

Q. Please tell us why (check all that apply):

1. I took part on a vaccine trial
2. Religious reasons
3. Personal belief/philosophical reasons
4. Pregnancy/breastfeeding
5. Illness/medication
6. Concerned about long term side effects
7. Concerned about adverse reaction
8. Do not know enough about it
9. Do not think it will work
10. Do not think it will be available to me
11. Do not think it is necessary
12. Prefer not to say
13. Other

If other, describe your symptoms in the free text box

Q (select one): How do you feel physically right now?

1. I feel physically normal
2. I'm not feeling quite right

If "I'm not feeling quite right" show:

Q (select one): Do you have a fever or feel too hot?

1. No
2. Yes

Q (select one): Do you feel chills or shivers (feel too cold)?

1. No
2. Yes

Q (number entry): If you are able to measure it, what is your temperature?

Q (select one): Do you have a persistent cough (coughing a lot for more than an hour, or 3 or more coughing episodes in 24 hours)?

1. No
2. Yes

Q (select one): Are you experiencing unusual fatigue?

1. No
2. Mild fatigue
3. Severe fatigue - I struggle to get out of bed

Q (select one): Do you have a headache?

1. No
2. Yes

If yes,

Q (select one): How often are you experiencing headaches?

1. All of the day
2. Most of the day
3. Some of the day

Q (select one): Have you felt nausea or experiencing vomiting?

1. No
2. Yes

Q (select one): Are you experiencing dizziness or light-headedness?

1. No
2. Yes

Q (select one): Are you experiencing unusual shortness of breath or have trouble breathing?

1. No
2. Yes. Mild symptoms - slight shortness of breath during ordinary activity.
3. Yes. Significant symptoms - breathing is comfortable only at rest.
4. Yes. Severe symptoms - breathing is difficult even at rest.

Q (select one): Do you have a sore or painful throat?

1. No
2. Yes

Q (select one): Do you have loss of smell/taste?

1. No
2. Yes

Q (select one): Do you have an unusually hoarse voice?

1. No
2. Yes

Q (select one): Are you feeling unusual chest pain or tightness in your chest?

1. No
2. Yes

Q (select one): Do you have unusual abdominal pain or stomach ache?

1. No
2. Yes

Q (select one): Are you experiencing diarrhea?

- 1.No
- 2.Yes

If yes, Q (select one): How many loose stools in the last 24 hours?

1. 1-2
2. 3-4
3. 5+

Q (select one): Do you have unusual strong muscle pains or aches?

1. No
2. Yes

Q (select one): Have you had raised, red, itchy, welts on the skin or sudden swelling of the face or lips?

1. No
2. Yes

Q (select one): Have you had any red/purple sores or blisters on your feet, including your toes?

1. No
2. Yes

Q (select one): Do you have any of the following symptoms: confusion, disorientation, or drowsiness?

1. No
2. Yes

Q (select one): Do your eyes have any unusual eye-soreness or discomfort (e.g. light sensitivity, excessive tears, or pink/red eye)?

1. No
2. Yes

Q (select one): Have you been skipping meals?

1. No
2. Yes

Q (long text entry): Any there other important symptoms you want to share with us?

Q (select one): Where are you right now?

1. I'm at home. I have not been to the clinic or hospital for suspected COVID symptoms
2. I am at the clinic or hospital with suspected COVID symptoms
3. I am back from the clinic or hospital, I'd like to tell you about my treatment
4. I am back from the clinic or hospital, I've already told you about my treatment

If "I am in the hospital with suspected COVID symptoms" OR "I am back from the hospital, I'd like to tell you about my treatment" show:

Q (select one): What treatment are you (did you) receiving right now?

1. None
2. Oxygen and fluids* (*Breathing support through an oxygen mask, no pressure applied)
3. Non-invasive ventilation* (*Breathing support through an oxygen mask, which pushes oxygen into your lungs)
4. Invasive ventilation* (*Breathing support through an inserted tube. People are usually asleep for this procedure)
5. Other

If "Other" show:

Q (text): What medical treatment are you receiving?

Additional daily questions for healthcare workers, who currently treats patients shown on repeat use.

Q (select one): In the last day, have you interacted with any patients in person?

1. No
2. Yes

If yes,

Q (select one): In the last day, did you treat patients in person with documented or presumed COVID-19 infection? Please check all that apply.

1. Yes, documented COVID-19 cases only
2. Yes, suspected COVID-19 cases only
3. Yes, both documented and suspected COVID-19 cases
4. Not that I know of

Q (select one): In the last day, did you use personal protective equipment (PPE) at work? *Depending on your specific work requirements, PPE might include gloves, masks, face shields, etc.

1. Always
2. Sometimes
3. Never

If "Always" show:

Q (select one): Choose one of the options:

1. I had all the PPE I need for work
2. I had to reuse PPE because of a shortage

If "Sometimes" show:

Q (select one): Choose one of the options:

1. I haven't always needed to use PPE all the time, but had enough when I did
2. I would have used PPE all the time, but I haven't had enough
3. I've had to reuse PPE because of a shortage

If "Never" show:

Q (select one): Choose one of the options:

1. I haven't needed PPE
2. I needed PPE, but it was not available

Additional question about participation in future research studies

Q. (select one): Are you interested in being contacted to learn about additional studies related to COVID-19 or use of this app?

1. Yes
2. No

DATE

Dear Colleague,

The coronavirus (COVID-19) pandemic is precipitating a chain of events that is unprecedented in our lifetime. As dedicated healthcare workers, sharing your experiences during this pandemic can help inform the impact the disease is having on healthcare workers across the world. As you may have read or heard, it has been challenging to track rates of infection. We would like to invite you to help address this challenge by taking 1-3 minutes/day to log your daily health status on a new COVID Symptom Tracker that we have developed in collaboration with King's College and Zoe Global Ltd, a health data science company. After initially downloading an app providing some basic descriptive facts, the daily task is simply to note if you are feeling well or experiencing any symptoms. If you are still active in patient care, you'll be asked about your contact with patients and use of personal protective equipment such as gowns, gloves, and face shields (PPE). That's all.

Please note that this app is NOT a replacement for the Partners COVID Pass employee self-monitoring system that is currently required before you arrive for work. This COVID symptom tracker is a completely optional data collection tool that you will use in addition to the Partners COVID Pass.

This project will offer real time data into the hidden iceberg of potential cases of COVID-19 in our health care communities and the full course of exposure, diagnosis, treatment and recovery. This information can be turned around rapidly to be used to guide public health planning around testing, quarantine, treatment, and recovery, which may have an immediate impact on our clinical response to this fast-moving pandemic.

We will not be providing additional personal information to our partners. However, they may use aggregated de-identified information along with data collected from others for studies such as mapping disease incidence. They will return your data to us so that we can link it with additional data we have already collected on our work force or may collect in the future. You may be asked to provide your Partners ID (username) so that we can do this. Together, these will provide a unique opportunity to learn about the how COVID-19 impacts our work and well-being.

We know this is a very stressful and busy time, and we do not want to compound circumstances. However, we hope that you will be willing to join us in this unique opportunity to contribute to our health care community's response to this unprecedented threat to our colleagues and greater communities. For this research, we are interested in information from everyone, whether you are or are not currently working directly with patients.

If you are interested in participating, please follow these instructions to download the app. Your friends and family, even if they are not health professionals, can also download the app and participate. The more people that use the app, the more helpful it will be!

We thank you for your continued dedication to helping us understand and fight this pandemic.

Sincerely yours,
Andrew T. Chan, MD, MPH
Principal Investigator

Bruce Walker, MD
Co-Investigator

DATE

Dear Colleague,

The coronavirus (COVID-19) pandemic is precipitating a chain of events that is unprecedented in our lifetime. As dedicated participants in the Nurses' Health Study II, sharing your experiences during this pandemic can help inform the impact the disease is having on current and former nurses. As you may have read or heard, it has been challenging to track rates of infection. We would like to invite you to help address this challenge by taking 1-3 minutes/day to log your daily health status on a new COVID-19 symptom tracker that we have developed in collaboration with physicians and epidemiologists at King's College London and software engineers at Zoe Global Ltd, a health data science company. After initially downloading an app on your Apple or Android phone and providing some basic descriptive facts, the daily task is simply to note if you are feeling well or experiencing any symptoms. If you are still active in patient care, you'll be asked about your use of gowns, gloves, and face shields. That's all.

This project will offer real time data into the hidden iceberg of potential cases of COVID-19 in our communities and the full course of exposure, diagnosis, treatment and recovery. This information can be turned around rapidly to be used to guide public health planning around testing, quarantine, treatment, and recovery, which may have an immediate impact on our clinical response to this fast-moving pandemic.

We will not be providing any of your previously collected personal information to our partners. However, they may use aggregated de-identified information along with data collected from others for studies such as mapping disease incidence. They will return your data to us so that we can link it with the information on diet and lifestyle you have already provided over the years. In the coming days, we may also contact you to join an optional web-based study to collect more detailed information about your experiences during the pandemic. Together, these will provide a unique opportunity to learn about the role of lifestyle, diet, and other factors on COVID-19 disease.

We know this is a very stressful and busy time, and we do not want to compound circumstances. However, we hope that you will be willing to join us in this unique opportunity to contribute to our health care community's response to this unprecedented threat to our health professional colleagues and greater communities. For this research, we are interested in information from everyone, **whether you are or are not currently working in the medical field.**

If you are interested in participating, please follow these instructions to download the app. Your friends and family, even if they are not health professionals, can also download the app and participate. The more people that use the app, the more helpful it will be!

We thank you for your continued dedication to the Nurses' Health Studies.

Sincerely yours,
A. Heather Eliassen, ScD
Principal Investigator

Walter C. Willett, MD ScD
Principal Investigator

Terms of Use

Effective date: March 25, 2020

Welcome to the COVID-19 Symptom Tracker, provided by Zoe Global Limited (together with its affiliates, “Zoe,” “us,” “we”). Please read on to learn the rules and restrictions that govern your use of our website(s), products, services and applications (the “Services”). By using this app and tracking if you are well or have symptoms, you will be helping medical science and healthcare providers across the country (such as Massachusetts General Hospital) to better understand Coronavirus (COVID-19). The Services are not intended for commercial purposes. If you have any questions, comments, or concerns regarding these terms or the Services, please contact us at:

For queries please email covidtrackingquestionsus@joinzoe.com and to leave leavecovidtracking@joinzoe.com

Address: Zoe Global Limited, 164 Westminster Bridge Road, London SE1 7RW, United Kingdom

These Terms of Use (the “Terms”) are a binding contract between you and us. Your use of the Services in any way means that you agree to all of these Terms, and these Terms will remain in effect while you use the Services. These Terms include the provisions in this document as well as those in our Privacy Policy [\[INSERT LINK TO PRIVACY POLICY\]](#).

Please read these Terms carefully. They cover important information about Services provided to you. **These Terms include information about future changes to these Terms, limitations of liability, a class action waiver and resolution of disputes by arbitration instead of in court. PLEASE NOTE THAT YOUR USE OF AND ACCESS TO OUR SERVICES ARE SUBJECT TO THE FOLLOWING TERMS; IF YOU DO NOT AGREE TO ALL OF THE FOLLOWING, YOU MAY NOT USE OR ACCESS THE SERVICES IN ANY MANNER.**

ARBITRATION NOTICE AND CLASS ACTION WAIVER: EXCEPT FOR CERTAIN TYPES OF DISPUTES DESCRIBED IN THE ARBITRATION AGREEMENT SECTION BELOW, YOU AGREE THAT DISPUTES BETWEEN YOU AND US WILL BE RESOLVED BY BINDING, INDIVIDUAL ARBITRATION AND YOU WAIVE YOUR RIGHT TO PARTICIPATE IN A CLASS ACTION LAWSUIT OR CLASS-WIDE ARBITRATION.

Will these Terms ever change?

We are constantly trying to improve our Services, so these Terms may need to change along with our Services. We reserve the right to change the Terms at any time, but if we do, we will place a notice on our site located at <https://covid.joinzoe.com/us>, post a notice within the app, send you an email, and/or notify you by some other means.

If you don’t agree with the new Terms, you are free to reject them; unfortunately, that means you will no longer be able to use the Services. If you use the Services in any way after a change to the Terms is effective, that means you agree to all of the changes.

Except for changes by us as described here, no other amendment or modification of these Terms will be effective unless in writing and signed by both you and us.

What about my privacy?

Zoe takes the privacy of its users very seriously. For the current Zoe Privacy Policy, please click [here](#).

What are the basics of using Zoe?

You may be required to sign up for an account using your email. You represent and warrant that you are an individual of legal age to form a binding contract (or if not, you’ve received your parent’s or guardian’s permission to use the Services and have gotten your parent or guardian to agree to these Terms on your behalf). If you’re agreeing to these Terms on behalf of an organization or entity, you represent and warrant that you are authorized to agree to these Terms on that organization’s or entity’s behalf and bind them to these Terms (in which case, the references to “you” and “your” in these Terms, except for in this sentence, refer to that organization or entity).

You will only use the Services for your own internal, personal, non-commercial use, and not on behalf of or for the benefit of any third party, and only in a manner that complies with all laws that apply to you. If your use of the Services is prohibited by applicable laws, then you aren't authorized to use the Services. We can't and won't be responsible for your using the Services in a way that breaks the law.

No Medical Advice; Not for Emergencies

Zoe does not offer medical advice or diagnoses, or engage in the practice of medicine. Our Services are not intended to be a substitute for professional medical advice, diagnosis, or treatment and are offered for informational and communicative purposes only. The Services are not intended to be, and must not be taken to be, the practice of medicine, nursing, pharmacy or other healthcare advice by Zoe.

The Services are not meant to diagnose or treat any conditions – only your medical professional can determine the right course of treatment for you and determine what is safe, appropriate and effective based on your needs. Reliance on any information provided by Zoe or in connection with the Services is solely at your own risk. You are solely responsible for any decisions or actions you take based on the information and materials available through the Services.

Healthcare providers and patients should always obtain applicable diagnostic information from appropriate trusted sources. Healthcare providers should never withhold professional medical advice or delay in providing it because of something they have read in connection with our Services.

THE SERVICES SHOULD NEVER BE USED AS A SUBSTITUTE FOR EMERGENCY CARE. IF YOU HAVE A MEDICAL OR MENTAL HEALTH EMERGENCY, ARE THINKING ABOUT SUICIDE OR TAKING ACTIONS THAT MAY CAUSE HARM TO YOU OR TO OTHERS, YOU SHOULD SEEK EMERGENCY TREATMENT AT THE NEAREST EMERGENCY ROOM OR DIAL 911.

Not a Medical Device

The Services are not medical devices and are not intended to be used as medical devices. Furthermore, the Services are neither regulated nor approved by the U.S. Food and Drug Administration, and are not designed to detect or prevent causes of any medical condition. The Services are not a substitute for medical care or adult supervision. You acknowledge, understand and agree that your use of the Services is entirely at your own risk.

Are there restrictions in how I can use the Services?

You represent, warrant, and agree that you will not contribute any content or otherwise use the Services or interact with the Services in a manner that:

- (a) infringes or violates the intellectual property rights or any other rights of anyone else (including Zoe);
- (b) violates any law or regulation, including, without limitation, any applicable export control laws, privacy laws or any other purpose not reasonably intended by Zoe;
- (c) is dangerous, harmful, fraudulent, deceptive, threatening, harassing, defamatory, obscene, or otherwise objectionable;
- (d) attempts, in any manner, to obtain the password, account, or other security information from any other user;
- (e) violates the security of any computer network, or cracks any passwords or security encryption codes;
- (f) runs Maillist, Listserv, any form of auto-responder or "spam" on the Services, or any processes that run or are activated while you are not logged into the Services, or that otherwise interfere with the proper working of the Services (including by placing an unreasonable load on the Services' infrastructure);
- (g) "crawls," "scrapes," or "spiders" any page, data, or portion of or relating to the Services (through use of manual or automated means);
- (h) copies or stores any significant portion of the Services; or

- (i) decompiles, reverse engineers, or otherwise attempts to obtain the source code or underlying ideas or information of or relating to the Services.

A violation of any of the foregoing is grounds for termination of your right to use or access the Services. Subject to these Terms, we grant each user of the Services a worldwide, non-exclusive, non-sublicensable and non-transferable license to use the Services. You understand that Zoe owns the Services. You won't modify, publish, transmit, participate in the transfer or sale of, reproduce (except as expressly provided in this Section), create derivative works based on, or otherwise exploit any of the Services.

Will Zoe ever change the Services?

We're always trying to improve our Services, so they may change over time. We may suspend or discontinue any part of the Services, or we may introduce new features or impose limits on certain features or restrict access to parts or all of the Services.

What if I want to stop using the Services?

You're free to do that at any time; please refer to our Privacy Policy, as well as the licenses above, to understand how we treat information you provide to us after you have stopped using our Services.

Zoe is also free to terminate (or suspend access to) your use of the Services for any reason in our discretion, including your breach of these Terms. Zoe has the sole right to decide whether you are in violation of any of the restrictions set forth in these Terms.

Account termination may result in destruction of any content associated with your account, so keep that in mind before you decide to terminate your account.

Provisions that, by their nature, should survive termination of these Terms shall survive termination. By way of example, all of the following will survive termination: any obligation you have to pay us or indemnify us, any limitations on our liability, any terms regarding ownership or intellectual property rights, and terms regarding disputes between us, including without limitation the arbitration agreement.

Mobile Applications

You acknowledge and agree that the availability of our mobile application is dependent on the third party stores from which you download the application, e.g., the App Store from Apple or the Android app market from Google (each an "App Store"). Each App Store may have its own terms and conditions to which you must agree before downloading mobile applications from such store, including the specific terms relating to Apple App Store set forth below. You agree to comply with, and your license to use our application is conditioned upon your compliance with, such App Store terms and conditions. To the extent such other terms and conditions from such App Store are less restrictive than, or otherwise conflict with, the terms and conditions of these Terms of Use, the more restrictive or conflicting terms and conditions in these Terms of Use apply.

I use the Zoe App available via the Apple App Store – should I know anything about that?

These Terms apply to your use of all the Services, including our iOS applications (the "Application") available via the Apple, Inc. ("Apple") App Store, but the following additional terms also apply to the Application:

- (a) Both you and Zoe acknowledge that the Terms are concluded between you and Zoe only, and not with Apple, and that Apple is not responsible for the Application;
- (b) The Application is licensed to you on a limited, non-exclusive, non-transferrable, non-sublicensable basis, solely to be used in connection with the Services for your private,

- personal, non-commercial use, subject to all the terms and conditions of these Terms as they are applicable to the Services;
- (c) You will only use the Application in connection with an Apple device that you own or control;
 - (d) You acknowledge and agree that Apple has no obligation whatsoever to furnish any maintenance and support services with respect to the Application;
 - (e) In the event of any failure of the Application to conform to any applicable warranty, including those implied by law, you may notify Apple of such failure; upon notification, Apple's sole warranty obligation to you will be to refund to you the purchase price, if any, of the Application;
 - (f) You acknowledge and agree that Zoe, and not Apple, is responsible for addressing any claims you or any third party may have in relation to the Application;
 - (g) You acknowledge and agree that, in the event of any third-party claim that the Application or your possession and use of the Application infringes that third party's intellectual property rights, Zoe, and not Apple, will be responsible for the investigation, defense, settlement and discharge of any such infringement claim;
 - (h) You represent and warrant that you are not located in a country subject to a U.S. Government embargo, or that has been designated by the U.S. Government as a "terrorist supporting" country, and that you are not listed on any U.S. Government list of prohibited or restricted parties;
 - (i) Both you and Zoe acknowledge and agree that, in your use of the Application, you will comply with any applicable third-party terms of agreement which may affect or be affected by such use; and
 - (j) Both you and Zoe acknowledge and agree that Apple and Apple's subsidiaries are third-party beneficiaries of these Terms, and that upon your acceptance of these Terms, Apple will have the right (and will be deemed to have accepted the right) to enforce these Terms against you as the third-party beneficiary hereof.

What else do I need to know?

Warranty Disclaimer. Zoe and its licensors, suppliers, partners, parent, subsidiaries or affiliated entities, and each of their respective officers, directors, members, employees, consultants, contract employees, representatives and agents, and each of their respective successors and assigns (Zoe and all such parties together, the "Zoe Parties") make no representations or warranties concerning the Services, and the Zoe Parties will not be responsible or liable for the accuracy, copyright compliance, legality, or decency of material contained in or accessed through the Services or any claims, actions, suits procedures, costs, expenses, damages or liabilities arising out of use of, or in any way related to your participation in, the Services. THE SERVICES ARE PROVIDED BY ZOE (AND ITS LICENSORS AND SUPPLIERS) ON AN "AS-IS" BASIS, WITHOUT WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR THAT USE OF THE SERVICES WILL BE UNINTERRUPTED OR ERROR-FREE. SOME STATES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, SO THE ABOVE LIMITATIONS MAY NOT APPLY TO YOU.

Limitation of Liability. TO THE FULLEST EXTENT ALLOWED BY APPLICABLE LAW, UNDER NO CIRCUMSTANCES AND UNDER NO LEGAL THEORY (INCLUDING, WITHOUT LIMITATION, TORT, CONTRACT, STRICT LIABILITY, OR OTHERWISE) SHALL ANY OF THE ZOE PARTIES BE LIABLE TO YOU OR TO ANY OTHER PERSON FOR (A) ANY INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING DAMAGES FOR LOST PROFITS, BUSINESS INTERRUPTION, LOSS OF DATA, LOSS OF GOODWILL, WORK STOPPAGE, ACCURACY OF RESULTS, OR COMPUTER FAILURE OR MALFUNCTION, (B) ANY SUBSTITUTE GOODS, SERVICES OR TECHNOLOGY, (C) ANY AMOUNT, IN THE AGGREGATE, IN EXCESS OF ONE-HUNDRED (\$100) DOLLARS OR (D) ANY MATTER BEYOND OUR REASONABLE CONTROL. SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL OR CERTAIN OTHER DAMAGES, SO THE ABOVE LIMITATION AND EXCLUSIONS MAY NOT APPLY TO YOU.

Indemnity. You agree to indemnify and hold the Zoe Parties harmless from and against any and all claims, liabilities, damages (actual and consequential), losses and expenses (including attorneys' fees) arising from or in any way related to any claims relating to (a) your use of the Services (including any actions taken by a third party using your account), and (b) your violation of these Terms. In the event of such a claim, suit, or action ("Claim"), we will attempt to provide notice of the Claim to the contact information we have for your account (provided that failure to deliver such notice shall not eliminate or reduce your indemnification obligations hereunder).

Assignment. You may not assign, delegate or transfer these Terms or your rights or obligations hereunder, or your Services account, in any way (by operation of law or otherwise) without Zoe's prior written consent. We may transfer, assign, or delegate these Terms and our rights and obligations without consent.

Choice of Law. These Terms are governed by and will be construed under the Federal Arbitration Act, applicable federal law, and the laws of the State of Massachusetts, without regard to the conflicts of laws provisions thereof.

Arbitration Agreement. Please read the following ARBITRATION AGREEMENT carefully because it requires you to arbitrate certain disputes and claims with Zoe and limits the manner in which you can seek relief from Zoe. Both you and Zoe acknowledge and agree that for the purposes of any dispute arising out of or relating to the subject matter of these Terms, Zoe's officers, directors, employees and independent contractors ("Personnel") are third-party beneficiaries of these Terms, and that upon your acceptance of these Terms, Personnel will have the right (and will be deemed to have accepted the right) to enforce these Terms against you as the third-party beneficiary hereof.

(a) Arbitration Rules; Applicability of Arbitration Agreement. The parties shall use their best efforts to settle any dispute, claim, question, or disagreement arising out of or relating to the subject matter of these Terms directly through good-faith negotiations, which shall be a precondition to either party initiating arbitration. If such negotiations do not resolve the dispute, it shall be finally settled by binding arbitration in Boston, Massachusetts. The arbitration will proceed in the English language, in accordance with the JAMS Streamlined Arbitration Rules and Procedures (the "Rules") then in effect, by one commercial arbitrator with substantial experience in resolving intellectual property and commercial contract disputes. The arbitrator shall be selected from the appropriate list of JAMS arbitrators in accordance with such Rules. Judgment upon the award rendered by such arbitrator may be entered in any court of competent jurisdiction.

(b) Costs of Arbitration. The Rules will govern payment of all arbitration fees. Zoe will pay all arbitration fees for claims less than seventy-five thousand (\$75,000) dollars. Zoe will not seek its attorneys' fees and costs in arbitration unless the arbitrator determines that your claim is frivolous.

(c) Small Claims Court; Infringement. Either you or Zoe may assert claims, if they qualify, in small claims court in Boston, Massachusetts or any United States county where you live or work. Furthermore, notwithstanding the foregoing obligation to arbitrate disputes, each party shall have the right to pursue injunctive or other equitable relief at any time, from any court of competent jurisdiction, to prevent the

actual or threatened infringement, misappropriation or violation of a party's copyrights, trademarks, trade secrets, patents or other intellectual property rights.

(d) *Waiver of Jury Trial.* YOU AND ZOE WAIVE ANY CONSTITUTIONAL AND STATUTORY RIGHTS TO GO TO COURT AND HAVE A TRIAL IN FRONT OF A JUDGE OR JURY. You and Zoe are instead choosing to have claims and disputes resolved by arbitration. Arbitration procedures are typically more limited, more efficient, and less costly than rules applicable in court and are subject to very limited review by a court. In any litigation between you and Zoe over whether to vacate or enforce an arbitration award, YOU AND ZOE WAIVE ALL RIGHTS TO A JURY TRIAL, and elect instead to have the dispute be resolved by a judge.

(e) *Waiver of Class or Consolidated Actions.* ALL CLAIMS AND DISPUTES WITHIN THE SCOPE OF THIS ARBITRATION AGREEMENT MUST BE ARBITRATED OR LITIGATED ON AN INDIVIDUAL BASIS AND NOT ON A CLASS BASIS. CLAIMS OF MORE THAN ONE CUSTOMER OR USER CANNOT BE ARBITRATED OR LITIGATED JOINTLY OR CONSOLIDATED WITH THOSE OF ANY OTHER CUSTOMER OR USER. If however, this waiver of class or consolidated actions is deemed invalid or unenforceable, neither you nor Zoe is entitled to arbitration; instead all claims and disputes will be resolved in a court as set forth in (g) below.

(f) *Opt-out.* You have the right to opt out of the provisions of this Section by sending written notice of your decision to opt out to the following address: Zoe Global, 192 South Street, Suite 100, Boston, MA 02111, postmarked within thirty (30) days of first accepting these Terms. You must include (i) your name and residence address, (ii) the email address and/or telephone number associated with your account, and (iii) a clear statement that you want to opt out of these Terms' arbitration agreement.

(g) *Exclusive Venue.* If you send the opt-out notice in (f), and/or in any circumstances where the foregoing arbitration agreement permits either you or Zoe to litigate any dispute arising out of or relating to the subject matter of these Terms in court, then the foregoing arbitration agreement will not apply to either party, and both you and Zoe agree that any judicial proceeding (other than small claims actions) will be brought in the state or federal courts located in, respectively, Boston, Massachusetts, or the federal district in which that county falls.

(h) *Severability.* If the prohibition against class actions and other claims brought on behalf of third parties contained above is found to be unenforceable, then all of the preceding language in this Arbitration Agreement section will be null and void. This arbitration agreement will survive the termination of your relationship with Zoe.

Miscellaneous. You will be responsible for paying, withholding, filing, and reporting all taxes, duties, and other governmental assessments associated with your activity in connection with the Services, provided that the Zoe may, in its sole discretion, do any of the foregoing on your behalf or for itself as it sees fit. The failure of either you or us to exercise, in any way, any right herein shall not be deemed a waiver of any further rights hereunder. If any provision of these Terms are found to be unenforceable or invalid, that provision will be limited or eliminated, to the minimum extent necessary, so that these Terms shall otherwise remain in full force and effect and enforceable. You and Zoe agree that these Terms are the complete and exclusive statement of the mutual understanding between you and Zoe, and that these Terms supersede and cancel all previous written and oral agreements, communications and other understandings relating to the subject matter of these Terms. You hereby acknowledge and agree that you are not an employee, agent, partner, or joint venture of Zoe, and you do not have any authority of any kind to bind Zoe in any respect whatsoever.

Except as expressly set forth in the sections above regarding the Apple Application and the arbitration agreement, you and Zoe agree there are no third-party beneficiaries intended under these Terms.

COVID-19 Symptom Tracker App Privacy Policy

Effective Date: March 25, 2020

At Zoe Global Limited (together with its affiliates, “Zoe,” “we,” “us”) we take your privacy seriously. Please read the following to learn how we treat your personal information. By using or accessing the COVID-19 Symptom Tracker app and associated website covid.joinzoe.com (together, the “Services”) in any manner, you acknowledge that you accept the practices and policies outlined in this Privacy Policy, and you hereby consent that we will collect, use, and share your information in the following ways.

Remember that your use of our Services is at all times subject to our Terms of Use [[INSERT LINK](#)], which incorporates this Privacy Policy. Any terms we use in this Policy without defining them have the definitions given to them in the Terms of Use.

What this Privacy Policy Covers

This Privacy Policy covers how we treat Personal Data that we gather when you access or use our Services. “Personal Data” means any information that identifies or relates to a particular individual and also includes information referred to as “personally identifiable information” or “personal information” under applicable data privacy laws, rules, or regulations. This Privacy Policy does not cover the practices of companies we don’t own or control or people we don’t manage.

Sources of Personal Data

We collect Personal Data about you from:

- You:
 - when you provide such information directly to us, and
 - when Personal Data about you is automatically collected in connection with your use of our Services.
- Our subsidiaries and affiliates (together, “Affiliates”), when they provide us with Personal Data about you.
- On our COVID-19 Tracker website <https://covid.joinzoe.com/> we collect Personal Data through cookies and similar technologies such as pixel tags, web beacons, clear GIFs, and JavaScript (collectively, “Cookies”) to enable our servers to recognize your web browser and tell us how and when you visit and use our website, to analyze trends, learn about our user base and operate and improve our website. Cookies are small pieces of data— usually text files – placed on your computer, tablet, phone, or similar device when you use that device to visit our Services. We may also supplement the information we collect from you with information received from third parties, including third parties that have placed their own Cookies on your device(s). For example, Google, Inc. (“Google”) uses cookies in connection with its Google Analytics services. Google’s ability to use and share information collected by Google Analytics about your visits to the Services is subject to the Google Analytics Terms of Use and the Google Privacy Policy. You have

the option to opt-out of Google's use of cookies by visiting the Google advertising opt-out page at www.google.com/privacy_ads.html or the Google Analytics Opt-out Browser Add-on at <https://tools.google.com/dlpage/gaoptout/>. Please note that because of our use of Cookies, the website does not support "Do Not Track" requests sent from a browser at this time. For more information about our use of cookies, please see our Cookie Policy [INSERT LINK TO <https://joinzoe.com/static/websiteprivacypolicy.pdf>]

Personal Data We Collect

We collect and process of the following types of Personal Data about you:

Personal Identifiers:

We collect personal identifiers from you and your device such as your name (optional), email address (optional), phone number (optional), a user name and password, IP address, device ID, location (including postcode or zip code) and other identifiers including your year of birth. Note that providing your name and phone number is optional. We also collect your IP address and other geolocation identifiers, including your postcode or zip code. (All of the foregoing, "Personal Identifiers.")

We process Personal Identifiers for the purposes of providing you the Services and developing, improving, promoting and running the Services. For example, we use your personal identifiers to allow you to create and customize your account. We may ask for your feedback on the app and we may conduct other surveys (which are of course voluntary). We may also send you information about new versions of the app or similar apps we may have in the future. Every marketing email sent by us will include a link you can click to opt-out from receiving such emails.

Health data and other protected classification characteristics:

Through our Service, you may choose to submit health related information about yourself, such as your sex at birth, your age, your height, weight and information about your health, pre-existing conditions and symptoms (including your body temperature). You may also submit your COVID-19 test status and details of any treatment. (All of the foregoing, "Health Data and Other Protected Classifications")

We process Health Data and Other Protected Classifications for the following purposes:

- To better understand symptoms of COVID-19
- To track the spread of COVID-19
- To advance scientific research into the links between patient's health and their response to infection by COVID-19
- To provide you with the Services
- In the future we may use this data to help healthcare providers such as hospitals support sick individuals

Personal Data of Children

As noted in the Terms of Use, we do not knowingly collect or solicit Personal Data from children under 18; if you are a child under 18, please do not attempt to register for or otherwise use the Services or send us any Personal Data. If we learn we have collected Personal Data from a child under 18, we will delete that information as quickly as possible. If you believe that a child under 18 may have provided us Personal Data, please contact us at dpo@joinzoe.com.

Sharing of Personal Data

Third party processors: We use third parties to process some of your Personal Data on our behalf, for example security and fraud prevention providers, hosting and other technology and communications providers, analytics providers, and staff augmentation and contract personnel. When we allow them access to your data, we do not permit them to use it for their own purposes. We have in place with each processor a contract that requires them only to process the data on our instructions and to take proper care in using it.

These processors include:

- Amazon Web Services
- Google Cloud Platform
- SurveyMonkey
- Segment
- Google Analytics
- Mixpanel
- Google G Suite
- MailChimp
- Mailgun
- Intercom
- Sentry
- Google Firebase
- SwiftyBeaver

Research Partners and Other Third Parties:

Research Partners: The purpose of our Services is to understand and prevent the spread of COVID-19. In order to do this, we share data with people doing health research, for example, people working in:

- Hospitals
- Clinics
- Universities
- Health charities
- Other research institutions

For example, doctors and scientists at Massachusetts General Hospital, Harvard School of Public Health, Stanford University, and King's College London will have access to your Personal Data for the foregoing purpose. Below is a list of institutions with whom we share your Personal Data. (Please note that this list is provided as an example only, and we may add institutions to this list.) Data shared with research partners other than hospitals and teaching institutions will be de-identified.

Institutions we share data with include (without limitation):

Harvard University
Stanford University
Massachusetts General Hospital
Tufts University
Berkeley University
King's College London
Guys & St Thomas' Hospitals
UK National Health Service
Nottingham University
University of Trento
Lund University

Transfer: We may restructure how we provide the Services, and as part of that, your Personal Data may be transferred to one of our affiliates or to a not-for-profit organization.

Data Security and Retention

We seek to protect your Personal Data from unauthorized access, use and disclosure using appropriate physical, technical, organizational and administrative security measures based on the type of Personal Data and how we are processing that data. You should also help protect your data by appropriately selecting and protecting your password and/or other sign-on mechanism; limiting access to your device; and signing off after you have finished accessing your account. Although we work to protect the security of your account and other data that we hold in our records, please be aware that no method of transmitting data over the Internet or storing data is completely secure. We cannot guarantee the complete security of any data you share with us, and except as expressly required by law, we are not responsible for the theft, destruction, loss or inadvertent disclosure of your information or content.

We retain Personal Data about you for as long as you have an open account with us or as otherwise necessary to provide you with our Services. In some cases we retain Personal Data for longer, if doing so is necessary to comply with our legal obligations, resolve disputes or collect fees owed, or is otherwise permitted or required by applicable law, rule or regulation. We may further retain information in an anonymous or aggregated form where that information would not identify you personally. We keep your contact information for 6 years after the last communication with us, or the last use of the app, for liability purposes, then we delete it.

Your rights

California Resident Rights

If you are a California resident, you have the rights outlined in this section under the California Consumer Privacy Act (“CCPA”). Please see the “Exercising Your Rights” section below for instructions regarding how to exercise these rights. If there are any conflicts between this section and any other provision of this Privacy Policy and you are a California resident, the portion that is more protective of Personal Data shall control to the extent of such conflict. If you have any questions about this section or whether any of the following applies to you, please contact us at dpo@joinzoe.com

Access

You have the right to request certain information about our collection and use of your Personal Data over the past 12 months. We will provide you with the following information:

- The categories of Personal Data that we have collected about you.
- The categories of sources from which that Personal Data was collected.
- The business or commercial purpose for collecting or selling your Personal Data.
- The categories of third parties with whom we have shared your Personal Data.
- The specific pieces of Personal Data that we have collected about you.

If we have disclosed your Personal Data for a business purpose over the past 12 months, we will identify the categories of Personal Data shared with each category of third party recipient.

If we have sold your Personal Data over the past 12 months, we will identify the categories of Personal Data purchased by each category of third party recipient.

Deletion

You have the right to request that we delete the Personal Data that we have collected from you. Under the CCPA, this right is subject to certain exceptions: for example, we may need to retain your Personal Data to provide you with the Services or complete a transaction or other action you have requested. If your deletion request is subject to one of these exceptions, we may deny your deletion request.

Exercising Your Rights

To exercise the rights described above, you must send us a request that (1) provides sufficient information to allow us to verify that you are the person about whom we have collected Personal Data, and (2) describes your request in sufficient detail to allow us to understand, evaluate, and respond to it. Each request that meets both of these criteria will be considered a “Valid Request.” We may not respond to requests that do not meet these criteria. We will only use Personal Data provided in a Valid Request to verify you and complete your request. You do not need an account to submit a Valid Request.

We will work to respond to your Valid Request within 45 days of receipt. We will not charge you a fee for making a Valid Request unless your Valid Request(s) is excessive, repetitive, or manifestly unfounded. If we determine that your Valid Request warrants a fee, we will notify you of the fee and explain that decision before completing your request.

You may submit a Valid Request using the following methods:

- Emailing us at: dpo@joinzoe.com

Personal Data Sales

We do not sell your Personal Data.

We Will Not Discriminate Against You for Exercising Your Rights Under the CCPA

We will not discriminate against you for exercising your rights under the CCPA.

Other State Law Privacy Rights

California Resident Rights

Under California Civil Code Sections 1798.83-1798.84, California residents are entitled to contact us to prevent disclosure of Personal Data to third parties for such third parties' direct marketing purposes; in order to submit such a request, please contact us at dpo@joinzoe.com.

Your browser may offer you a "Do Not Track" option, which allows you to signal to operators of websites and web applications and services that you do not wish such operators to track certain of your online activities over time and across different websites. Our Services do not support DO Not Track requests at this time. To find out more about "Do Not Track," you can visit www.allaboutdnt.com.

Nevada Resident Rights

If you are a resident of Nevada, you have the right to opt-out of the sale of certain Personal Data to third parties who intend to license or sell that Personal Data. You can exercise this right by contacting us at dpo@joinzoe.com with the subject line "Nevada Do Not Sell Request" and providing us with your name. Please note that we do not currently sell your Personal Data as sales are defined in Nevada Revised Statutes Chapter 603A.

European Union Data Subject Rights

EU Residents

If you are a resident of the European Union ("EU"), United Kingdom, Lichtenstein, Norway, or Iceland, you may have additional rights under the EU General Data Protection Regulation (the "GDPR") with respect to your Personal Data, as outlined below.

For this section, we use the terms “Personal Data” and “processing” as they are defined in the GDPR, but “Personal Data” generally means information that can be used to individually identify a person, and “processing” generally covers actions that can be performed in connection with data such as collection, use, storage and disclosure. Zoe Global Limited will be the controller of your Personal Data processed in connection with the Services.

If there are any conflicts between this this section and any other provision of this Privacy Policy, the policy or portion that is more protective of Personal Data shall control to the extent of such conflict. If you have any questions about this section or whether any of the following applies to you, please contact us at dpo@joinzoe.com.

Personal Data Use and Processing Grounds

We will only process your Personal Data if we have a lawful basis for doing so. Lawful bases for processing include consent and our “legitimate interests” or the legitimate interest of others, as further described below.

Legitimate Interests: Our legal basis for processing your Personal Identifiers is our legitimate interest in providing you the Services and developing, improving, marketing and running the Services. Other examples of legitimate interests include provision of support, protection from fraud or security threats, compliance with legal obligations and completion of corporate transactions.

Consent: In some cases, we process Personal Data based on the consent you expressly grant to us at the time we collect such data. When we process Personal Data based on your consent, it will be expressly indicated to you at the point and time of collection. Specifically, we process the category of Health Data and Other Protected Classifications based on your consent. Because of the tight regulatory requirements placed on us, we need your consent to process data about your health, which means that if you do not consent (or withdraw your consent), we cannot allow you to use the app. This is not meant unkindly, we are simply not able to provide you with the service without your consent.

If you wish us to stop processing Health Data and Other Protected Classifications, you may withdraw your consent at any time by emailing us at leavecovidtrackingus@joinzoe.com. When you withdraw your consent, we will delete all Health Data and Other Protected Classifications we hold about you.

Other Processing Grounds: From time to time we may also need to process Personal Data to comply with a legal obligation, if it is necessary to protect the vital interests of you or other data subjects, or if it is necessary for a task carried out in the public interest.

EU Data Subject Rights

Under the [GDPR](#) you have a number of important rights with respect to your Personal Data, including those set forth below. For more information about these rights, or to submit a request, please email us at dpo@joinzoe.com. Please note that in some circumstances, we may not be

able to fully comply with your request, such as if it is frivolous or extremely impractical, if it jeopardizes the rights of others, or if it is not required by law, but in those circumstances, we will still respond to notify you of such a decision. In some cases, we may also need to you to provide us with additional information, which may include Personal Data, if necessary to verify your identity and the nature of your request.

- **Access:** You can request more information about the Personal Data we hold about you and request a copy of such Personal Data. You can also access certain of your Personal Data by logging on to your account.
- **Rectification:** If you believe that any Personal Data we are holding about you is incorrect or incomplete, you can request that we correct or supplement such data. You can also correct some of this information directly by logging on to your account.
- **Erasure:** You can request that we erase some or all of your Personal Data from our systems.
- **Withdrawal of Consent:** If we are processing your Personal Data based on your consent (as indicated at the time of collection of such data), you have the right to withdraw your consent at any time. Please note, however, that if you exercise this right, you may have to then provide express consent on a case-by-case basis for the use or disclosure of certain of your Personal Data, if such use or disclosure is necessary to enable you to utilize some or all of our Services.
- **Portability:** You can ask for a copy of your Personal Data in a machine-readable format. You can also request that we transmit the data to another controller where technically feasible.
- **Objection:** You can contact us to let us know that you object to the further use or disclosure of your Personal Data for certain purposes, such as for direct marketing purposes.
- **Restriction of Processing:** You can ask us to restrict further processing of your Personal Data.

For further information on each of those rights, including the circumstances in which they apply, see the [Guidance from the United Kingdom Information Commissioner's Office \(ICO\) on individuals rights under the General Data Protection Regulation](#).

If you would like to exercise any of those rights, please email, call or write to our data protection officer using the contact details given below.

The [General Data Protection Regulation](#) also gives you the right to lodge a complaint with a supervisory authority, in particular in the European Union (or European Economic Area) state where you work, normally live or where any alleged infringement of data protection laws occurred. The supervisory authority in the UK is the Information Commissioner who may be contacted at <https://ico.org.uk/make-a-complaint/your-personal-information-concerns/> or telephone: +44 0303 123 1113.

Transfers of Personal Data

The Services are hosted and operated in the United Kingdom and in the United States (“U.S.”) through Zoe Global Limited and its service providers and the third parties with whom we share information (see the **Sharing of Personal Data** section above), and laws in the U.S. may differ from the laws where you reside. By using the Services, you acknowledge and agree that any Personal Data about you, regardless of whether provided by you or obtained from a third party, is being provided to Zoe Global Limited and third parties (as disclosed in this Privacy Policy) in the U.S. and will be hosted on U.S. servers, and you authorize Zoe to transfer, store and process your information to and in the U.S., and possibly other countries.

Changes to this Privacy Policy

We’re constantly trying to improve our Services, so we may need to change this Privacy Policy from time to time as well, but we will alert you to changes by placing a notice in the app or on our website, by sending you an email, and/or by some other means. Please note that if you’ve opted not to receive legal notice emails from us (or you haven’t provided us with your email address), those legal notices will still govern your use of the Services, and you are still responsible for reading and understanding them. If you use the Services after any changes to the Privacy Policy have been posted, that means you agree to all of the changes. Use of information we collect is subject to the Privacy Policy in effect at the time such information is collected.

About us

Our address is: Zoe Global Limited, 164 Westminster Bridge Road, London SE1 7RW, United Kingdom

Data Protection Officer: dpo@joinzoe.com

CONSENT PROCESS:

This document outlines a 4-step process for obtaining informed consent from research participants.

- 1) Upon opening the app for the first-time prospective users are provided the general population consent document. The first line reads:**

If you are a participant of any ongoing research studies at Brigham and Women’s Hospital (e.g. the Nurses’ Health Study), Massachusetts General Hospital (e.g. COVID-19 related studies), or other medical center, [click here \[link to RESEARCH STUDY/HEALTHCARE WORKER INFORMED CONSENT\]](#)

- 2) Participants will be linked to the following Research Study/Healthcare Worker Informed Consent Page in the app. The Privacy Policy Page and Terms and Conditions referred to within the consent page are embedded within the application are attached as appendices to the protocol.**

RESEARCH STUDY INFORMED CONSENT

About this consent form

Please read this form carefully. It tells you important information about a research study.

If you have any questions about the research or about this form, please ask. Taking part in this research study is up to you.

Why is this research study being done?

We are doing this research to determine health and lifestyle factors related to the symptoms and outcomes associated with the Coronavirus (COVID-19). By using this app that consists of a series of questions meant to collect data on whether you are well or have symptoms, you will be helping medical science and healthcare providers across the country to better understand this disease. This app is designed to be a tool for data collection and to help medical professionals and researchers understand this disease. It does not give health advice. The Centers for Disease Control and Prevention has publicly-accessible information related to COVID-19 that can be found at: <https://www.cdc.gov/coronavirus/2019-ncov/index.html>

How long will I take part in this research study?

Your use of this mobile application is completely voluntary. You can use it as little or as much as you would like and can stop using it at any time. We find that answering the series of questions takes a matter of minutes (no more than 10 minutes on average).

What will happen in this research study?

We will ask you a series of questions related to your occupation, your possible affiliation with certain ongoing studies or research centers, basic personal characteristics (gender/age), your health status, any medications you are using, how you are feeling, what symptoms you might be experiencing, and what, if any, treatments you've received either in outpatient or in-hospital settings. We will also ask you about what the outcome of any of those treatments. All questions are optional and you need not answer any questions you are uncomfortable answering.

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

We don't expect you to experience any risks or possible discomforts associated with being in this study. Some people may not feel comfortable answering some of the questions asked, but no question is required to be answered. While necessary security precautions have been taken, there is a minor risk as there is with all digital data that information shared with us may be inadvertently accessed by others not identified in this consent form.

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

There are no direct benefits to you for taking part in this study. Your participation may contribute more widely, with all the other participants to the advancement of research into the COVID virus.

Can I still get medical care within hospitals affiliated with the research in this study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within affiliated hospitals 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.

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.

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. You may withdraw your consent at any time by emailing leavecovidtracking@joinzoe.com

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

No payments will be made for participation in this voluntary research study.

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

Voluntary participation in this research study will come at no-cost to you.

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

Zoe Global Ltd. Staff is supporting and responsible for this study. Any questions may be sent to covidtrackingquestions@joinzoe.com

You may also contact local U.S. based study staff at predict@mgh.harvard.edu.

If you were directed to this app because of your participation in another research study, you should contact the applicable study contact or Institutional Review Board that is associated with each study. If the study is affiliated with Mass General Brigham Health / Partners Healthcare, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

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 will collect health information about:

- your health status and condition related to COVID-19
- any medications you are using
- how you are feeling
- what symptoms you might be experiencing
- what, if any, treatments you’ve received either in outpatient or in-hospital settings
- the outcome of any of those treatments

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

For complete details of the data we collect, who may see, use, and share your data and the reasons for doing so, please see the [Privacy Policy](#) [Link to privacy policy page]. In brief, the privacy plan details that we may share your data with the researchers involved with this study, the sponsor of the study, and 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, in addition to other individuals. If you denote that you are a part of an ongoing research study, we may ask you what the name or trial identifier (e.g. ClinicalTrials.gov NCT#) of that research study is, who your treating physician is, or who at that site we might contact regarding your participation in this survey. By participating in this survey and disclosing your participation in those studies, you give us permission to contact the study’s investigators, research site, and/or treating physician to let them know you have participated. You also provide us permission to provide information directly to those entities including your personal identification information and your answers to this survey.

Some people or groups who get your health information might not have the 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. 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. We will not contact you without your permission and will not use or share your information for any mailing or marketing list.

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.

We may link data collected as a part of this app with additional data collected through your participation in other research studies you have consented to at the following institutions: Massachusetts General Hospital, Brigham and Women’s Hospital, Mass General Brigham Hospitals (formerly Partners Healthcare), or other partnering research institutions. Deidentified data, meaning that it any information that can identify you as an individual has been removed, may be included in public databases in the future.

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 cannot 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 us in writing by emailing leavecovidtracking@joinzoe.com

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.

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

By clicking below, you consent to our using the personal information we collect through your use of this app in the way we have described.

We adhere to the General Data Protection Regulation ‘GDPR’. For more information about how we use and share personal information about you, please see our privacy notice

<https://www.notion.so/joinzoe/Covid-privacy-notice-8d2d36b7c3e04e0ea6d017801be7b54c>

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.

Digital 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.

In addition, you acknowledge that you have read and understand the Privacy Policy and Terms of Use. The privacy policy describes what data is collected, how it is stored, secured, and shared, and with whom, and what your rights are to that data. The terms state that that the application is not meant to give medical advice, not meant for emergencies and describes, this is not a medical device, and limitations of liability and data sharing plans.

- I consent to the processing of my personal data (including without limitation data I provide relating to my health) as set forth in this consent and in the Privacy Policy [LINK].
- I have read and accept Zoe Global's Terms of Use [LINK] and Privacy Policy. [LINK]

"I agree" Button

- 3) In the event that an appropriate individual does not link to the RESEARCH STUDY/HEALTHCARE WORKER Informed Consent page, they will only be able to continue if they sign the general public consent which appears as below:

GENERAL PUBLIC CONSENT

If you are a healthcare worker or a member of any ongoing research studies at Brigham and Women's Hospital (e.g. the Nurses Health Study), Massachusetts General Hospital (e.g. COVID-19 related studies), or other academic medical center, [click here](#)

Purpose

By using this app and tracking if you are well or have symptoms, you will be helping medical science and healthcare providers across the country (such as Massachusetts General Hospital) to better understand Coronavirus (COVID-19).

This app allows you to help others, but does not give health advice. If you need health advice please visit the CDC Coronavirus website <https://www.cdc.gov/coronavirus/2019-ncov/index.html>

Information sharing

This app is designed by doctors and scientists at Massachusetts General Hospital, Harvard School of Public Health, Stanford University, King's College London and Zoe Global Limited, a health technology

company. They have access to the information you enter, which may also be shared with hospitals listed in our privacy notice.

No information you share will be used for commercial purposes. An anonymous code will be used to replace your personal details when sharing information with researchers beyond those mentioned above.

Your consent

By checking the box below, you consent to our using the personal information we collect through your use of this app in the way we have described.

For more information about how we use and share personal information about you, please see our privacy policy.

[URL XXX](#)

You may withdraw your consent at any time by emailing leavecovidtrackingus@joinzoe.com

Any questions may be sent to covidtrackingquestionsus@joinzoe.com

- I consent to the processing of my personal data (including without limitation data I provide relating to my health) as set forth in this consent and in the Privacy Policy [LINK].
- I have read and accept Zoe Global's Terms of Use [LINK] and Privacy Policy. [LINK]

"Sign Up" button

- 4) After providing either consent, the individual will be provided with a page asking them if they are a member of any ongoing research studies or healthcare workers at specific hospitals, including Mass General Brigham affiliated hospitals. If they reach this page through the standard consent and check any of these boxes and they have not filled out the RESEARCH STUDY/HEALTHCARE WORKER Informed Consent page, they will be redirected back to the RESEARCH STUDY/HEALTHCARE WORKER Informed Consent page for completion before answering any health-related questions.