PReventing Emerging infections through Vaccine EffectiveNess Testing—COVID (Project PREVENT II)

MANUAL OF OPERATING PROCEDURES

Co-Principal Investigators: Nicholas Mohr, MD, MS and David Talan, MD

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1.0 Key Personnel and Contact Information

Title	Contact
Co-Principal Investigator	Nicholas Mohr, MD, MS Nicholas-mohr@uiowa.edu
Co-Principal Investigator	David Talan, MD dtalan@ucla.edu
Project Statistician	Patrick Ten Eyck, PhD patrick-teneyck@uiowa.edu
Clinical Coordinating Center (CCC)	Anusha Krishnadasan, PhD, Director CCC idnet@ucla.edu Kavitha Pathmarajah, MPH kpathmarajah@dhs.lacounty.gov Eva Gonzalez egonzalez7@dhs.lacounty.gov
Data Coordinating Center (DCC)	Kari Harland, PhD, Director DCC kari-harland@uiowa.edu Kelli Wallace, MS REDCap manager kelli-wallace@uiowa.edu Tracy Young, MS Data manager tracy-young@uiowa.edu Anne Zepeski PharmD, BCPS Verifications manager anne-zepeski@uiowa.edu Eric Kontowicz, PhD Data Analyst eric-kontowicz@uiowa.edu
Olive View-UCLA ERI Contracts Administrator	Denise Tritt denisetritt@ovuclaeri.com
Project email address	EmergencyIDNet-PREVENT@uiowa.edu

Project website	http://www.prevent-project.org
Project text messages	319-519-0087

2.0 Site Contact Information

Site	Site project email	Site project telephone number
Baystate Medical Center	EM.Research@BaystateHealth.org	413-794-8680
The Brigham and Women's Hospital	prevent@bwh.harvard.edu	617-732-5638
Jackson Memorial Hospital, Miami	PREVENT@jhsmiami.org	786-658-0253
University Medical Center, New Orleans	projectprevent@lcmchealth.org	504-702-4852
University of Alabama at Birmingham	PREVENTproject@uabmc.edu	205-996-4791
University of California Los Angeles Medical Center	PREVENTProject@mednet.ucla.edu	(310) 913-9847
University of Iowa Hospitals and Clinics	EmergencyMedicine-PREVENTProject@uiowa.edu.	319-384-8578
University of Massachusetts Memorial Medical Center	PreventProject@umassmed.edu	508-421-1443
University of California, San Francisco – Fresno	projectprevent@communitymedical.org	559-499-6638
University of Chicago	PreventProject@uchicago.edu	773-834-4135
University of New Mexico	HSC-EMED-Prevent@salud.unm.edu	505-925-4725
University of Washington	ProjectPrevent@uw.edu	206-825-4645
University Health/University of Missouri – Kansas City	PREVENT@uhkc.org	816-404-5087
Thomas Jefferson University	ProjectPrevent@jefferson.edu	919-808-2702
Valleywise Medical Center	PREVENT@valleywisehealth.org	602-344-5951
Duke University	Prevent2@duke.edu	704273-5451
OHSU	serologystudyCV19@ohsu.edu	503-494-5281

University of Utah	EM.Research@hsc.utah.edu	801-581-2045
Johns Hopkins Hospital	ggladfe1@jhmi.edu	443-202-3914

3.0 List of Abbreviations

Abbreviation	Description
CCC	Clinical Coordinating Center
DCC	Data Coordinating Center
HCP	Health care personnel
IRB	Institutional Review Board
ROI	Release of Information
RT-PCR	Reverse-transcriptase polymerase chain reaction

4.0 Recruitment and Enrollment

Sites will work closely with their employee health departments and institutions to select and recruit/invite health care personnel (HCP) who were tested for COVID-19 during the period of surveillance. Specifically, we will select HCP who test positive and test negative (see Section 4.4.2) and send them an invitation by email and/or text to participate in the project.

4.1 Recruitment Plan

Recruitment methods will be site-specific depending on the capabilities and resources available at each site. Each site must submit a Recruitment Plan to the CCC for approval prior to being allowed to recruit HCP.

Potentially eligible HCP will be identified from local employee health records for recruitment in one of two ways:

1) Local employee health departments will provide the site team with a weekly list of HCP who were tested or reported outside testing for COVID with their test results. If employee health departments are able to release HCP names, but not test results, this is acceptable only if the site team is able to achieve at least a 50% response rate from tested HCP with their test result; and
2) Sites whose local employee health department prefers not to release lists of HCP tested to the site team may also work with an appointed contact (or contacts) within the employee health department to invite HCP to the project.

Note, HCP lists will be maintained at the site and will not be shared with coordinating sites or CDC. The above methods of identifying HCP for recruitment are preferred, but site teams may also use the following methods to supplement identifying potential recruits:

1) For employees who are tested outside their employer (employee health clinic or employer-sponsored testing center) – from non-employee health clinics that have tested HCPs –, or
2) From employees volunteering – through e-mails, signs posted in staff patient care areas, screensavers, and other employee-directed communication, HCP who are tested outside the health system and have their test results available for verification purposes are eligible to participate in the project (within 60 days of test).

4.1.1 Centralized prescreening recruitment strategy

In 2023, many employee health departments discontinued COVID testing and reporting requirements for HCP thus limiting recruitment at some sites that were relying solely on employee health test lists (see section 4.1). The PREVENT team set up an alternate centralized prescreening recruitment strategy for these sites that includes the distribution of home molecular (NAAT) tests to symptomatic HCP reporting negative antigen tests, to improve the ability to recruit negative controls for positive cases. It is important that HCP who express willingness to receive a NAAT test, take the test within 14 days of the start of their symptoms.

Sites will use the above described recruitment strategies (see Section 4.1) to contact as many HCP as possible at their institution on a regular basis (e.g., biweekly or monthly email blasts to all departments or department list serves, announcements in employee newsletters, posters, flyers, or in person) and present a web link to a prescreening recruitment survey which was designed in REDCap by the DCC. This prescreening recruitment REDCap, is separate from the main PREVENT II database, and asks HCP who access the link to report their test date, test type, and result. Each participating site will receive a separate site-specific link for prescreening recruitment.

HCP who indicate they had a COVID positive test or a negative PCR test in the last 60 days will provide their names and email addresses, and site coordinators can add them to their PREVENT Recruitment Log (see Section 4.2). Participants who report a negative antigen test who have symptoms will be asked for the date when their symptoms began. If it has been more than 10 days since their symptoms began, they are not eligible to receive a NAAT test and participate. If they report their symptoms began within the last 10 days, then they are asked if they would receive and take a NAAT test immediately. The REDCap will calculate a "test-by" date, which is the date 14 days after their symptoms began and which will be the date they must report their test results back by. If they are eligible and agree to participate, they will be informed that they will receive $50 compensation for their time to take the test and send the results of test back to the site team using the QR code or emailed link they receive.

If they agree to take the NAAT test, then they will input their address information. The CCC and site team will receive an email notification as soon as the participant indicates they agree and will ship a test overnight as soon as possible to ensure the participant can receive the test and take it before the "test by" date. The CCC team will be responsible for shipping the tests to participants. They will include a printout of the survey access code and QR code that links to REDCap to report their test results and upload a picture of the test. They should write the REDCap record ID of the HCP on the printout to ensure they are sending the right test to the right HCP. The CCC team will also record the kit and lot number of the test sent in REDCap.

The HCP will receive a reminder every two days by REDCap automated email. The site may also set up their own non-REDCap text reminder to send to participants as necessary to report their results after they take the NAAT test. After the HCP inputs their results using the REDCap link, the participant will receive $50 by check from the University of Iowa DCC team. The CCC and site team will receive an email notification from REDCap when the participant has uploaded their test result and the site team can add them to the PREVENT II Recruitment Log and invite them into PREVENT II when appropriate, i.e., see Section 4.4.5. If the participant takes the test and the results are indeterminant, they will be sent another test to try again one more time. They will still receive payment for participating.

The following reports will be available to the CCC and site teams to help with tracking prescreening recruitment activities.

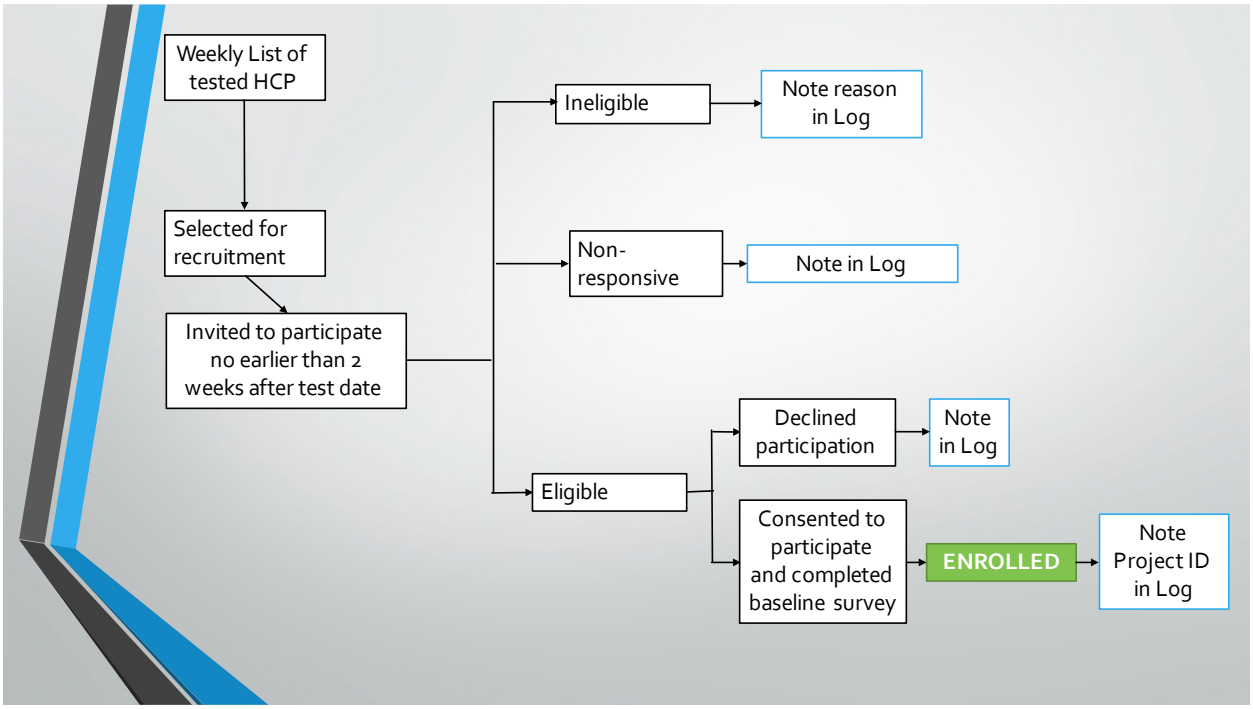
Report title	Report Explanation	Site Action

Needs NAAT mailed	Lists the name and mailing address of individuals who need an NAAT test mailed to them	Communicate with CCC to confirm individual is an HCP.
Needs PREVENT II link	The participant has a negative NAAT test result or positive antigen/NAAT result and can be added to Recruitment Log	Send PREVENT II link when appropriate (see Section 4.4.5).
NAAT testing results not received	A NAAT test has been mailed to the individual and it has been a minimum of 2 days since mailed and test results have not been sent to PREVENT team	Confirm with CCC that test was sent and contact participant to remind them to take the test.
NAAT test result date ineligible	The participant has completed the NAAT test but the date of collection is outside of the acceptable period for recruitment	Contact the participant to let them know they will not be eligible for PREVENT II due to their test being outside of range.

4.2 Site-specific Recruitment Log

Sites will be directed by the CCC when to initiate recruitment activities. These activities will be conducted by the site project team weekly throughout the surveillance period. Per their site-specific Recruitment Plan, each site team will compile a list of employees who were tested for COVID-19 weekly. The weekly list will be generated from Sunday (12:00 am) to Saturday (11:59 pm). This site-specific Recruitment Log must include a list of HCP with their names, COVID test dates, COVID test results, email addresses, and the date the HCP was added to the Recruitment Log. This list will be maintained at the site and will not be sent to PREVENT II coordinating centers or CDC. The sites should note on the Recruitment Log whether the HCP was selected for recruitment (i.e., invitation to participate in PREVENT II sent, Yes or No; see Section 4.4.2).

Figure 1. Recruitment overview



4.3 Tracking recruitment rates

In order to keep track of recruitment rates, all sites can obtain a weekly record (Sunday-Saturday) of the total number of HCP who tested at or reported their test to the site and the total number of HCP who tested positive for COVID. Since it is impossible to obtain the number of HCP who had outside testing and who did not report their results to employee health departments, we can rely on information available from employee health departments. If available, for all employees tested from the employee health department, sites are encouraged to collect additional information on age, sex, job category, and symptomatic/asymptomatic at time of testing in order to estimate possible recruitment bias.

4.4 Selection and Invitation

4.4.1 Site enrollment launch

The enrollment launch date for a particular site is the date when a site will begin selecting and inviting/recruiting HCP to enroll in the project from their Recruitment Log. Sites will be released to initiate enrollment when the following tasks/items are completed:

1) approval of the site-specific Recruitment Plan by the CCC,
2) site team testing of their Recruitment Plan to identify any initial issues,
3) site readiness call with the Project Manager,
4) site team required project trainings, including medical records abstraction training quiz completion for relevant site team members,
5) all site team members have access to main REDCap, and
6) receipt of project invitation link for HCP from the DCC.

4.4.2 Definition of cases and controls

Cases are defined as those who have a positive SARS-CoV-2 RT-PCR, SARS-CoV-2 NAAT test, or SARS-CoV-2 antigen test deployed in routine local medical or public health clinical practice. For cases, a positive test (antigen, molecular/NAAT, or PCR) performed at home is also acceptable. Controls are defined as those with a negative SARS-CoV-2 RT-PCR or SARS-CoV-2 NAAT test. Note that due to the low sensitivity of antigen tests, negative SARS-CoV-2 antigen tests alone will NOT be permitted as a single test sufficient to qualify for inclusion as a control participant, but a positive antigen is sufficient for defining a case.

At the time of selection, the site team may need to rely on HCP or employee health report of their test result and may not be able to confirm whether an HCP case or control meets the above definition. In these instances, participant eligibility will be confirmed after they are selected and invited to participate when they complete the Screening Form (see Section 4.5). After enrollment, participants may be retained even if the result of the reported test differs from the result reported to the study team from the employee health department (usually this will occur in the setting of multiple recent tests).

4.4.3 Selecting potential cases and controls/Using the Selection Macro

Depending on the numbers of cases and controls tested in a particular week, the selection macro will adjust to ensure we maintain a case to control ratio of at least 1:1 and at most 1:6:

For weeks when more cases than controls are tested (i.e., case to control ratio is greater than or equal to 2), the macro will select one case for each control. For weeks when less cases than controls are tested (i.e., the case to control ratio is less than 0.5; 1:2, 1:3, 1:4, etc.), all of those with a positive test result (cases) will be selected and a sample of up to 6 negatives for each positive will be randomly selected from all negative tests within the same week. The site team should maintain a list of duplicate testing and those who decline participation to ensure participants are not selected and invited multiple times, selection procedure is completed at least once per week, and cases and corresponding controls are selected from the same week. If there are no controls available in a particular week, then no participants should be selected and enrolled.

The DCC will send sites an algorithm to select cases and controls to invite to the project. This algorithm has been programmed into a Microsoft Excel macro, which will be used to select cases and controls each week. Sites will be expected to retain the processed Excel file, if used, to document adherence with selection procedures.

To use the Microsoft Excel Macro, update the weekly recruitment list such that all test results are recorded as 1 (positive) or 0 (negative). Split the “Name of employee” column into two columns, with the first column “Last Name” and the second column “First Name”. Open the Microsoft Excel Macro. If warning messages appear, select “yes” to trust the document, enable content, and enable editing. After doing this, from the weekly recruitment list, copy and paste the columns containing last name, first name, phone number, email address, test date, and test result into the “Entry” sheet of the Microsoft Excel Macro. Save the macro as ‘PREVENT II mmddyy-

mmddyy', where the dates match the Sunday-Saturday dates for that week. Double check the COVID test dates for each HCP to make sure that their test date is within that 7-day period.

Once all the information is in the "Entry" sheet, click "Process." If any of the columns have missing data, a warning will pop up alerting you of the number of empty cells and will ask if you wish to continue. Select "no" to verify that the required "Last Name", "First Name", and "Results" columns are filled in. If all the required columns are filled in, select "yes." Next, a summary will pop up with the total number of positive test results and the total number of negative test results entered. This pop up will inform you of the ratio for randomly selecting controls and the number of positive and negative records that were selected. Once you select "yes" the "Entry" sheet will be locked and no more data entry can occur. If you wish to proceed, select "yes." After "yes" is selected, two sheets will be created: "Final" and "Leftovers." The "Final" sheet will contain the selected cases and controls. These are the HCP to be invited. Depending on the case to control ratio for that week, the "Leftovers" Sheet may contain an additional random list of cases and/or controls.

4.4.4 Reselection of cases or controls identified after initial selection

If sites are aware of a new case or control that occurred in a week for which that they have already run their initial selection macro, and there are additional cases and/or controls ("leftovers") that still have not been invited into the project from that same week or newly identified cases or controls that were tested that week, then they can rerun the selection macro to select controls for a case or if applicable, a case for a control. It is important to save this file under a new file name that clearly indicates this is a different round of selection than the first.

4.4.5 Inviting to participate

Site teams will invite the potentially eligible HCP selected (using the methods described in Section 4.4.3) a minimum of 14 days and up to 60 days after their test date by sending them an email with an invitation letter and a site-specific link (see Appendix B). This link will be provided by the DCC and will take the invited HCP to the main PREVENT II project REDCap Screening Form (see Section 4.5.1). The e-mail invitation should also include a link for declination (that will initiate an e-mail to the local project team and allow for invited HCP to easily indicate that they are not interested). This invitation may be sent using the site team's project specific email address or through employee health communication, but it should be a separate PREVENT II project-specific invitation email (i.e., not embedded in another email intended for other HCP announcements or communication).

In most cases, sites will invite HCP to participate between 14 and 21 days after their test date. At a minimum, a site should send each HCP two e-mail invitations spread out over a week. At sites that permit telephone calls, teams are encouraged to call selected HCP to ensure that they have had the opportunity to participate. Anyone who has not responded within one week will be contacted at least two more times by a site coordinator by email, telephone, text message, or other communication mode, as permissible at each site -- a minimum of four total contact points for every invited HCP.

4.5 Screening for eligibility

All HCP who are invited to the project will receive a website link that will take them to the main Project PREVENT II REDCap Screening Form. The responses they enter into the Screening form will determine whether the HCP qualifies for the project. If they qualify, then they will be asked to provide consent to participate in PREVENT II. If they provide consent and complete the baseline survey, then they will be enrolled in the project. The REDCap Screening Form will ask HCP for their names so local project staff will be able to track which HCP completed the Screening form and which were eligible or ineligible and why. It is important for site teams to keep track of those who were invited to participate but do not complete the Screening Form, were deemed ineligible, or not enrolled and record the reason for non-enrollment if available (e.g., declined participation, ineligible and reason, admitted to hospital, unable to determine/non-responsive).

4.5.1 Screening Log

A Screening Log will be maintained at each site that includes all the HCP selected to participate in the project. The purpose of the Screening Log is to help the site team keep track of the HCP who are selected to participate in the screening process, and to identify any issues/barriers in their recruitment procedures. The site team should record for each selected HCP the dates they were sent an invitation to participate in the project. Note that in most cases, all HCP who were selected to participate should be invited to the project, but there may be cases, especially at very large hospital sites, where the project team might stagger invitations to HCP to accommodate their team's workflow. It is especially important at these sites to keep careful records of which HCP were invited and when.

Of those HCP who are sent an invitation to participate, the site team should record the following information on the log:

a) Did HCP decline participation prior to completing the Screening form? (Yes/No),
b) Did HCP complete the PREVENT II Screening Form? (Yes/No) ,
c) Was the HCP eligible? (Yes/No), and
d) If eligible, did the HCP consent to participate? (Yes/No) and if Yes, record their assigned Project ID found in REDCap.

Sites are encouraged to maintain a list of current participants, HCP judged to be ineligible (who will not be eligible in the future), and any other HCP who would not be able to participate, or who have indicated they do not want to be contacted further. If these HCP are tested again, sites should refrain from inviting them to participate. Note that if the team is aware the HCP is hospitalized, they can still be enrolled after discharge, so should not be excluded or deemed ineligible.

4.5.2 Screening Form

The site-specific invitation link will take the HCP to the REDCap screening form, which consists of questions to determine whether the HCP is eligible for participation in the project. Contact information (name) will be collected from all those screened, regardless of eligibility. This will

allow the site team to track which HCP were deemed eligible/not eligible or declined participation. Only those who meet the following inclusion/exclusion criteria based on their responses to the Screening Form will be presented with the electronic informed consent form (see Section 4.6) and given the opportunity to enroll by completing the baseline survey. After completion of the Screening Form, the participant will be automatically sent an email with a link to a survey queue, which they can use to return to their record to complete surveys or upload documents.

4.5.3 Inclusion criteria

Participants must meet all the following inclusion criteria:

1) Any HCP (employee or volunteer) in a participating health care system who was tested for COVID-19 (positive/negative RT-PCR, positive/negative molecular/NAAT test, or positive antigen test) in the past 60 days and after launching the project at a site,

2) HCP who have the potential for direct or indirect exposure to patients or infectious materials, including body substances, contaminated medical supplies, devices, and equipment, contaminated environmental surfaces, or contaminated air. These can include HCP of any job classification in any department of participating health care systems including staff physicians, resident physicians, advanced practice providers (PA/NP), nurses, patient care technicians/nursing assistants, pharmacists, social workers, respiratory therapists, physical therapists, clerks and administrative staff, security personnel, dieticians, cafeteria staff, environmental services/custodial staff, managers and administrators, research staff, and health sciences students (medical, nursing, pharmacy, dentistry, or others, as available). Employees, students, and volunteers who meet any of the criteria above are eligible, and

3) HCP who test positive for COVID-19 must have at least <u>one</u> of the following symptoms during a period from 14 days prior to their first COVID-19 test to 14 days after that test:

    a) Abdominal pain,
    b) Bruised toes or feet,
    c) Changes in ability to smell or taste,
    d) Chest pain or chest tightness,
    e) Chills,
    f) Cough,
    g) Diarrhea,
    h) Fatigue (unusual feeling of tiredness),
    i) Fever (greater than 100°F or 37.8°C),
    j) Headache,
    k) Loss of appetite,
    l) Myalgia (muscle aches),
    m) Nausea (sick to your stomach) or vomiting,
    n) Rhinorrhea (runny nose),
    o) Rigors (sudden feeling of cold with shaking),

p) Severe respiratory illness, including pneumonia,
q) Shortness of breath or difficulty breathing,
r) Sinus or nasal congestion, or
s) Sore throat.

For HCP who test negative for COVID-19, no symptoms are required for enrollment.

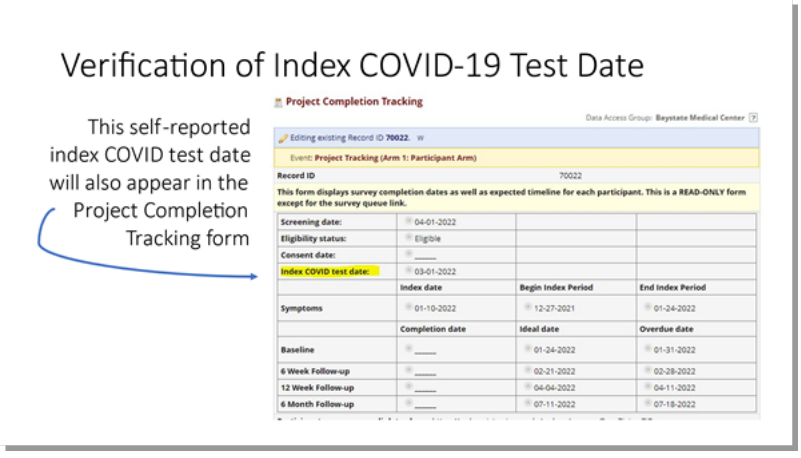
4.5.4 Exclusion criteria

Participants must not meet any of the following exclusion criteria:

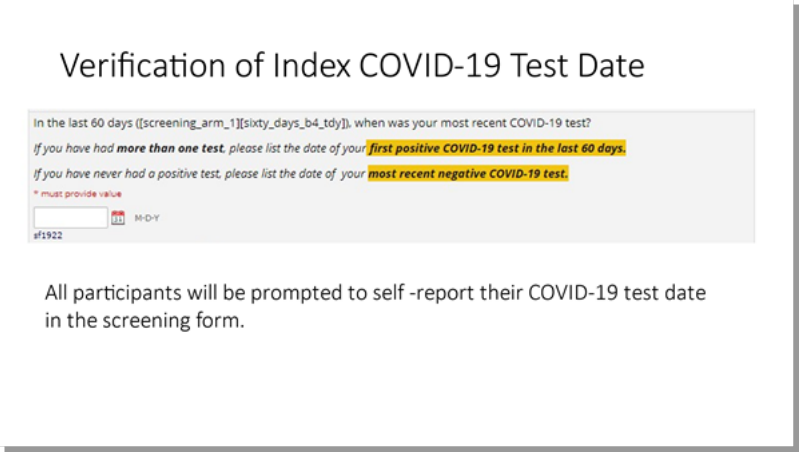
1) HCP that are unable or unwilling to confirm test results or vaccine administration using an approved method (see section 5.7);
2) Previously enrolled HCP who did not complete any follow-up surveys during a previous enrollment;
3) HCP who do not intend to be working, studying, or volunteering in the participating health care facility for at least 6 weeks after enrollment;
4) HCP who do not speak English or Spanish; and
5) HCP who work remotely from home (defined as not working at least 1 day in a healthcare facility over the last 2 weeks, as defined above).

4.5.5 Defining Index COVID test date, Index date, and Index period

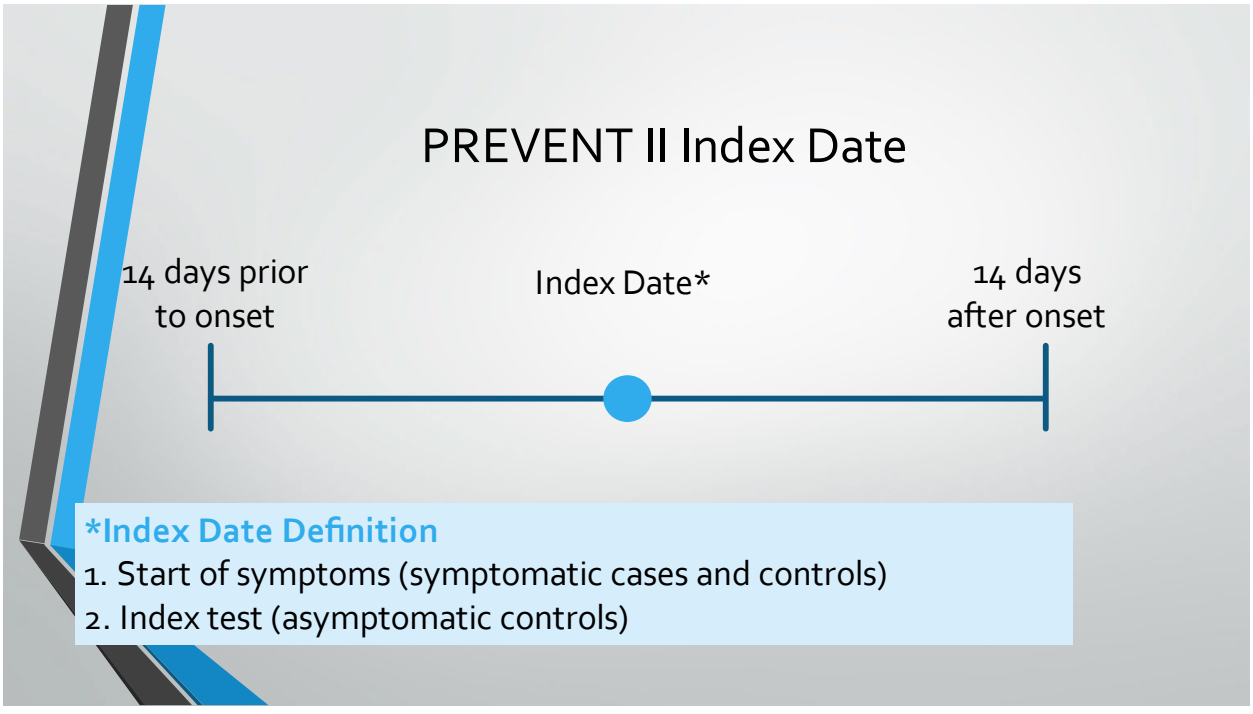
This section defines three terms - the Index COVID test date, the Index date, and the Index period that will be used as reference for participants and by site teams to define the relevant time points for reporting tests, vaccinations, health care utilization, and completing verifications. When completing the PREVENT II screening form, the HCP will be prompted to self-report their COVID-19 test date and whether or not they had symptoms in the two weeks prior and after their test. The REDCap will automatically determine the Index COVID test date, and Index Date and Index Period based on responses provided by the HCP and will be summarized on the Project Completion Tracking Form on REDCap.



The Index COVID test date is defined differently for HCP who test positive and negative. For those who test positive, it is the date of their **first positive** COVID-19 test in the last 60 days. For negatives, it is the date of their **most recent negative** COVID-19 test.



The Index Date is defined differently for HCP who report or do not report symptoms. To be eligible for PREVENT II, positives must also report symptoms in the two weeks before or after their test date (see Inclusion criteria #3 in Section 4.5.3). Negatives can be symptomatic or asymptomatic in that same period. If eligible and enrolled, the Index Date for symptomatic positives and negatives will be the date they report their symptoms started. For negatives who are asymptomatic (i.e., do not report symptoms in the two weeks prior and after their most recent COVID test), their Index Date will be their Index Test date.



Finally, the Index Period is defined as the time period two weeks before and two weeks after the Index Date. For symptomatic participants, this will be the 14 days prior to and after the onset of their symptoms. For asymptomatic participants this will be the 14 days prior to and after their Index Test date.

4.5.6 Additional notes regarding eligibility

Any HCP who participated in a COVID-19-related vaccine trial may be included, but detailed information about enrollment and allocation will be required. For this project, HCP who had prior COVID-19 infection >90 days before their COVID-19 index date (i.e., symptom start date for symptomatic HCP and test date for asymptomatic HCP) may be enrolled. HCP may be enrolled more than once if it has been at least 6 months since their previous enrollment.

Please note that project staff may participate and be enrolled in the study, but any enrolled project staff should have data verification done by another project staff member. Under no circumstances should a project team member validate his/her own records or record his/her own participation. These project staff participant enrollments should be reported to a local site PI for data integrity monitoring.

4.6 Informed consent

REDCap will automatically present the informed consent document (see Appendix C) to HCP who are eligible (i.e., meet the above inclusion/exclusion criteria) based on their responses to the Screening Form.

Informed consent must be obtained prior to obtaining eligible employee's records or survey. Informed consent will be completed electronically and maintained within the REDCap database managed centrally at the DCC. This consent form provides information regarding the following:

1) General project information,
2) PREVENT II project goals,
3) Expected participant obligations,
4) Participant compensation, and
5) Participant rights.

Eligible HCP will have the option of selecting a decision to proceed with project participation or not. In order to provide ample time to make a decision, HCP can return to the electronic consent form at a later time using the survey queue link that was emailed to them after they completed the Screening Form. If the HCP has any questions about consent, they should contact their site PI or the site team. This will be noted in the invitation letter/email to the HCP. After confirming their participation, HCP will have the option to save a PDF and print a copy of the consent document with acknowledgement of participation (see below). HCP will provide consent by selecting "Yes" to the statement, "you acknowledge that you have read the information presented, and that you agree to participate in this project."

4.6.1 Informed consent for interviews, proxy, or Spanish speakers

If an eligible HCP prefers to complete the data collection forms by telephone, the local site coordinator may collect data using a guided interview. If the project teams learn that an invited participant has died or is unable to complete participation because of their illness, they may contact the next of kin to invite a proxy interview, if permitted by local regulation.

The site coordinators will identify which employees prefer to complete the surveys via interview or proxy during recruitment activities. The site coordinator will read the consent document and if the employee is willing to participate, then they will provide verbal consent to participate. This consent will be documented by site project staff on the Verbal Consent and LAR Documentation form (in REDCap) that includes a site coordinator attestation. The site coordinator can print and send a copy of the consent document to the participant or proxy, if requested.

Some sites will be able to recruit employees who prefer to complete the surveys in Spanish. These will be conducted by scheduled interview with one of the Spanish-speaking site coordinators. After confirming eligibility, the site coordinator will use a Spanish version of the consent form to obtain verbal consent from the participant prior to conducting the surveys. The site coordinator will enter the participant's responses directly into REDCap.

4.7 Enrollment and project ID assignment

Providing informed consent and completing the baseline survey will enroll the participant in the project and REDCap will automatically assign the participant a project ID. Site teams should record the project ID on their Screening Log. The DCC will be responsible for monitoring enrollment at all sites and will communicate with sites regularly as to whether they need to make adjustments (or to stop enrolling) to ensure that enrollment is distributed appropriately across sites.

4.8 Withdrawals

Reasons for withdrawal include:

1) Participant found to be ineligible after enrollment,
2) Participant requests withdrawal.

The site coordinator should contact the DCC so that the record in REDCap for a participant is marked as withdrawn on the Project Completion Tracking form.

5.0 Data collection

5.1 REDCap access and reports

A central PREVENT II Project REDCap database will be maintained by the DCC (through the University of Iowa Institute for Clinical and Translational Sciences) and will be used at all sites for project data collection. Access to the REDCap will be enabled for the following groups: 1)

participants, 2) site investigators and project oversight staff, and 3) coordinators, project assistants, and others who are validating data elements and conducting data collection activities.

All project team members who need access to REDCap must email their name, title, institution, email address, and cell phone number to emergencyidnet-prevent@uiowa.edu to obtain access to REDCap. Note that only project team members who will be regularly accessing REDCap for project activities need access. The cell phone number must be unique to a staff member as Duo authentication is required to access REDCap. The DCC will send a request to University of Iowa IT department to obtain a HawkID. This will generate an email from University of Iowa IT department to the relevant project team members. After they set up their Hawk ID, they must login to this website: https://redcap.icts.uiowa.edu/redcap/ to access REDCap. Participants will not need login credentials.

If a project team member has questions about or an issue with a particular question in REDCap, the coordinator or the participant should record the item number that is below the answer response (e.g., *ef4242*) for that question and send an email to emergencyidnet-prevent@uiowa.edu. If a site coordinator finds an error that should be corrected in any survey, they should send an email to emergencyidnet-prevent@uiowa.edu.

The DCC has created several REDCap reports to help site teams keep track of project activities. Appendix F lists all the reports available to site teams, a detailed description of each, and what the site teams need to do for participants that are listed on the reports. Appendix G contains a list of REDCap alerts, including a description of all automatic email and text alerts, that have been programmed to assist with reminding participants to complete their surveys and upload their required documents.

5.2 Overview of data collection process

Two possible strategies for data collection are available: 1) participant self-reported data collection using the online REDCap surveys, and 2) structured interviews (performed by telephone, zoom, or in-person) with project staff and a participant or a proxy (see sections 5.2.2 and 5.2.3).

5.2.1 Participant self-reported data collection

1) After informed consent, the data system will present the survey to collect **contact information**, including the participant's cell phone, and emergency contact;
2) Next is the **baseline survey** (section 5.3.1). The participant has 14 days from screening to complete the baseline survey. For participants who are being tested and vaccinated at work and indicate their test results and vaccination information can be obtained through their occupational health department, the site team may request and upload the information into REDCap for the participant. But if the participant has their test results, vaccination records and/or other relevant medical records, they will be able to upload the information as a pdf, screenshot, or photograph themselves to the REDCap;
3) For situations in which medical record requests are indicated, REDCap will output data on site-specific medical record release forms and will automatically send these forms pre-

filled through DocuSign by e-mail to the participants. They will electronically sign the forms and these signed forms will be available in REDCap for downloading by local project staff to initiate requests for the records;

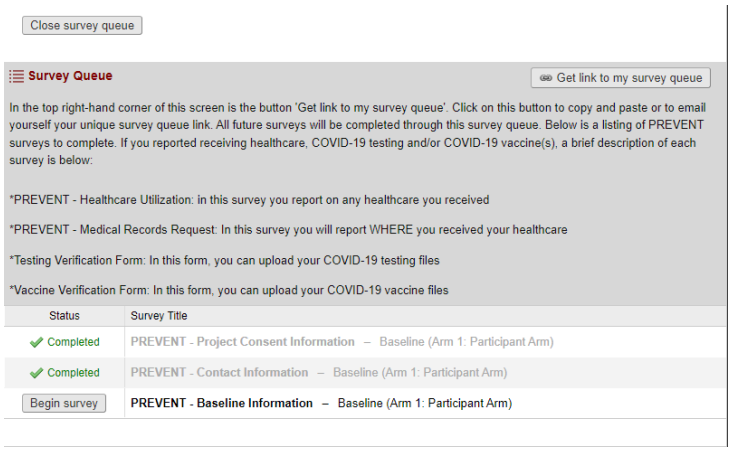
4) At six weeks, twelve weeks, and six months after the date of their initial qualifying symptom(s) or test date (index date), participants will receive a follow-up e-mail and text message from REDCap to complete a **follow-up survey** (section 5.3.3). If the participant reports health care utilization 14 days prior to onset of symptoms (if symptomatic) or test date (if asymptomatic) through 14 days after their symptoms began in the follow-up survey, then a new pre-filled DocuSign medical release form will be generated and sent to the participant for electronic signature. The site teams will ensure that these records are uploaded to the system. After the follow-up surveys are completed and any relevant medical record release forms are signed by the participant, their participation will end; and
5) Any data that requires clarification or confirmation will be resolved and documented by additional electronic or telephone communication between site project staff and participants. An emergency contact with contact information will be collected from the participant at the time of project enrollment to capture information in the event of severe illness or nonresponse.

5.2.2 Participant Interview

If HCP elect to complete an interview rather than complete surveys online, the site team will schedule an interview (telephone, video, or in-person) at a time that is convenient for both the site and the HCP.

To complete the Screening form as an interview, the site coordinator will use the unique site link provided by the DCC and read the questions to the HCP on the surveys as written. Since the provided email address from the Screening form is used for all project communication including the release of information forms sent by DocuSign, the participant email must be entered into the Screening form. If the HCP is eligible, the REDCap will auto-continue to the consent document. The site coordinator should read the consent form in its entirety to the HCP. The interviewer must complete the Verbal Consent and LAR Documentation form in REDCap. This documentation is available for both the baseline and follow-up surveys.

In order to complete a baseline or follow-up survey as an interview, the site coordinator can click on the 'Project Completion Tracking' form and click on the link next to 'Open survey queue.' The system will ask the site coordinator to log in by entering the participant's first name, last name, and birthdate which may be found on the screening form. Click on the link to 'Begin survey' listed next to the survey that needs to be completed. An example of what the survey queue will look like if a participant needs to complete the baseline survey is shown below.



The site coordinators will enter the interview data collected from the participant interview in real-time into REDCap. If the participant reports healthcare utilization during the baseline or follow-up surveys, two additional surveys will appear in the survey queue called 'Healthcare Utilization/Verification' and 'Medical Records Requests.' These surveys are repeatable and should be completed for **each** non-mental health/psychiatric healthcare visit. As described above for self-reported participant data collection, the REDCap will generate and email the participant a pre-filled medical records release form for each relevant medical record. The site coordinator should remind the participant to access the form(s) in their email and provide their electronic signature via Docusign. After the form is signed, the site coordinator should ensure that all relevant medical records (i.e., test results, vaccination, and medical visits) are uploaded to REDCap.

5.2.3 Proxy interview

A proxy interview is a method of collecting data from an individual who is not the participant. This will most commonly be performed if the participant is critically ill in the hospital (possibly related to COVID-19 or a COVID-19-like illness). If a proxy is used for an interview, the following criteria should be met:

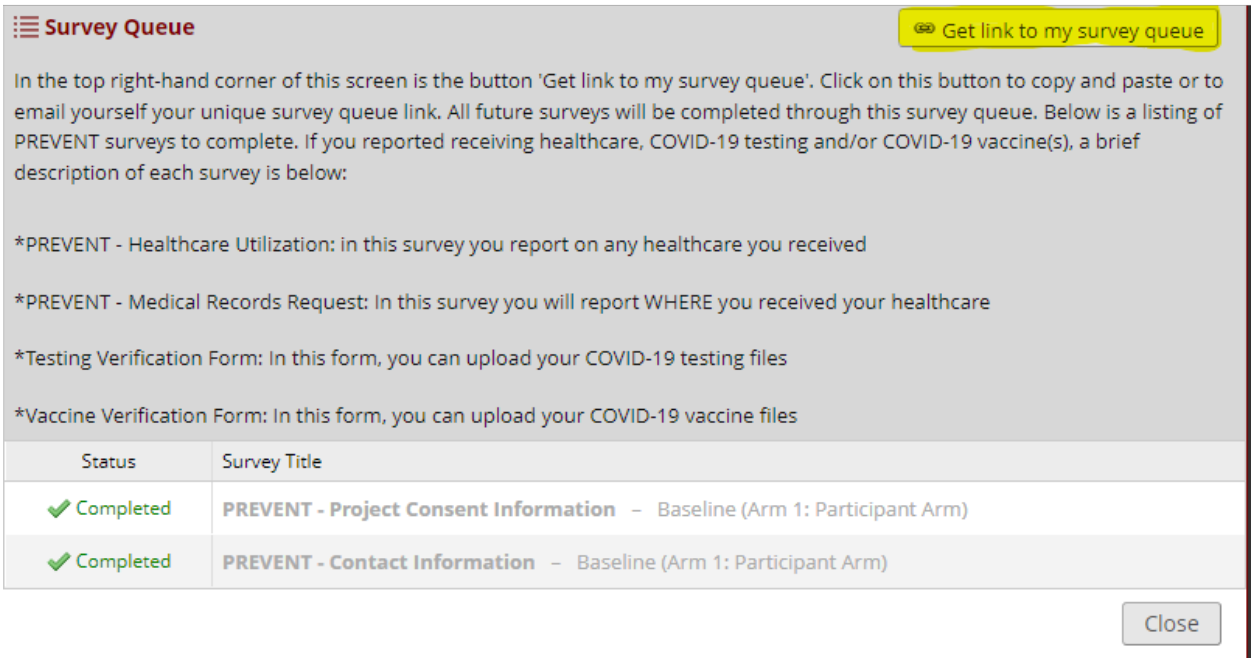
1) The employee is physically unable to participate (due to severe illness, incapacitation, or death); and
2) The proxy would meet criteria for providing consent as a legally authorized representative for a research project, according to local regulation. In most cases, this requirement will include an individual who has durable power of attorney for health care decision-making or an appropriate first-degree family member.

Under no circumstances should a proxy interview be substituted for participant data collection if the subject has the capacity to participate but chooses not to. These cases should be treated as "decline to participate."

5.3 Participant Survey details

After participants provide consent, the system automatically takes the participant to the Contact Information survey to enter in their cell phone number and emergency contact. After entering in

this information, they are taken to their own survey queue which lists the surveys they need to complete. Participants are instructed in REDCap to save their survey queue link with the following instructions, “In the top right-hand corner of this screen is the button ‘Get link to my survey queue.' Click on this button to copy and paste or to email yourself your unique survey queue link. All future surveys will be completed through this survey queue.”



If a participant decides they prefer to complete a survey at a later time, they will be able to return to the survey queue using their saved link. They will need to log into their survey queue by entering their first name, last name, and date of birth EXACTLY as it was entered on the Screening form. At the bottom of the screening survey, eligible participants are reminded of exactly what they must enter to be able to log into future surveys. If a participant forgets what they entered on the Screening form, they should contact their local site team. The local site team will be able to send the participant a link to their survey queue from their “Project Completion Tracking” form.

5.3.1 Baseline survey

The Baseline survey should take about 15-20 minutes to complete and asks participants about their:

1) illness, including why and when they were tested for COVID, and whether they sought healthcare for their illness,
2) entire vaccination history for COVID,
3) job, including PPE use, level of patient contact, and exposure to patients with COVID,
4) exposures outside of work;
5) living situation;
6) time away from and return to work;

7) medical history; and
8) demographics.

The site team should ensure that the participant completes the baseline survey as soon as possible, but no later than two weeks after screening (the baseline survey will no longer be in the survey queue after 14 days). If a participant does not want to complete the entire baseline survey at once, then they can click "Save & Return" and they will be given the option to send an email to themselves with the link to return to the survey at a later time. If a participant has not started their baseline survey they will receive a reminder to finish the survey at 1, 3, and 5 days from when it was originally available to the participant.

It is the site's responsibility to ensure the participant completes the baseline survey. The site team can track participants who still have not completed their baseline survey 7 days after it was sent by viewing the report in REDCap called 'Baseline survey overdue.' The baseline survey will no longer be available to the participant for completion in the survey queue 14 days after screening form completion.

5.3.2 Clinical Trial Follow-up

Participants who are enrolled in a vaccine clinical trial are eligible for PREVENT II if they meet all inclusion/exclusion criteria. If they do not know which trial arm they were enrolled in or whether they received a COVID vaccine at the time of enrollment, then they will be sent a monthly survey (for up to 12 months) following their enrollment into PREVENT II to ask which trial arm they were assigned to, placebo or active vaccine. Participants will be asked to upload a copy of their clinical trial assignment documentation. If they are unable to provide a copy approximately 30 days after their participation in the trial ends, the site team will ask the participant for the clinical trial staff contact information to request it from them. If the participant has a copy of their vaccination card with their unblinded vaccine information, this is also acceptable for verification purposes.

5.3.3 Follow-up surveys

Participants who are symptomatic, regardless of test result, will report the date they started having symptoms and participants who are asymptomatic controls will report their last negative test date on the Screening form. REDCap will send the participant an email and text message 6 weeks, 12 weeks, and 6 months, after this date (index date) with a link to their 6 week, 12 week, and 6 month follow-up surveys, respectively. For each survey timepoint, the participant will also get a reminder 2, 4, and 6 days after the initial email is sent if the participant has not yet completed the follow-up survey. It is the responsibility of the site to ensure that the participant completes all follow-up surveys within two weeks of the date it was sent. The surveys will expire 14 days after the initial links are sent, so they will not be accessible to the participants after that timepoint. The site team can track participants who still have not completed their follow-ups surveys 7 days after it was sent by viewing the reports in REDCap called 'Follow-up overdue', with a separate report for each follow-up. Please note that for participants enrolling between 42 and 60 days after the onset of symptoms (or a negative asymptomatic test), the 6-week survey

will be sent to the participant immediately after completion of the baseline survey (since the 6 weeks have already elapsed at the time of enrollment).

The follow-up surveys should take about 10-15 minutes to complete and asks the participant about:

1) the reasons for and results of any subsequent COVID-19 tests,
2) return to work,
3) symptoms,
4) additional vaccinations, and
5) healthcare visits.

5.4 Participant compensation

Participants will be compensated $25 for completion of the Baseline survey and an additional $25 for completion of each of the follow-up surveys, whether it is completed online or by interview. If a proxy interview is done, the proxy and the participant will each receive $25. Their compensation will be sent by check to the mailing address they provide in the Contact information (or proxy) form from the University of Iowa DCC within 3 weeks after survey completion (participants can expect to receive 4 checks if they complete 4 surveys If a participant does not complete the entire survey, they will not be compensated for that survey. A participant will be compensated for a completion of a survey, even if they do not upload necessary testing and vaccine documentation.

5. 5 Non-compliance and lost to follow-up

A participant will be considered non-compliant but will ***not*** be removed from the project if they:

1) do not complete one or more of the follow-up surveys;
2) do not allow access (i.e., do not provide consent) to release their medical records to the site team for all emergency department, urgent care, clinic or hospital visits 14 days before the onset of symptoms or index COVID-19 test date to 14 days after the onset of symptoms or index COVID-19 test date; or
3) are unable to provide appropriate documentation for their COVID-19 test result and/or their COVID-19 vaccination record.

A participant is considered lost to follow-up if they consent to participate but do not complete their baseline survey.

5.7 Medical Records Abstraction

The following medical records abstraction methods describe data capture and verification procedures. The purpose of these methods is to minimize bias and maximize the robustness of our data. This process is very important since participant response alone is insufficient for reporting the primary exposures and outcomes of interest. All site team members who will be

abstracting medical records must complete training and pass a short quiz prior to site launch and another quiz for the 2023-2024 season. Site team members will not be allowed access to REDCap until they have passed the short quiz. The initial project start up training video will be posted on the project website (www.prevent-project.org). **Only those site team members who have been approved by the DCC to abstract medical records should perform these procedures and will be referred to in this section as "abstractors."** We anticipate that the number of abstractors at each site will be limited, even if a larger number of staff are involved with recruitment and participant communication.

The abstractors will be responsible for ensuring that medical records of relevant tests, vaccinations and health care visits are obtained (from participant, extracted from EMR or employee health records, or requested from relevant hospital/clinic) and uploaded to REDCap. In addition, a verification form in REDCap which indicates that the abstractor has reviewed and validated the medical records must be completed by an abstractor for **each** COVID test record, COVID vaccination record, and health care visit record. REDCap reports and dashboards provide "to-do" lists for abstractors to track tests, vaccinations, and healthcare visits reported by participants that need to be requested and verified.

Note that all participants must have a COVID test and vaccine record (even if not vaccinated), but not all will have sought health care for their illness during their Index period (see Section 4.5.5). If a participant has not received a COVID vaccine, a vaccine verification must be completed documenting this. Also, if the participant provides all their required medical records by uploading it into REDCap themselves, the abstractors will only need to review and verify the records by completing the relevant verification forms but will not need to go through the process of requesting those records unless they are found to be incomplete.

5.7.1 Obtaining Medical Records

Each site will be responsible for creating a system to capture or request and upload medical records (including testing, vaccination, and healthcare visit utilization records) to REDCap in a timely manner. There are four ways that the site teams can obtain medical records depending on where the records are accessible and available (which will be site-dependent):

1) Participants provide records themselves (e.g., pdf, screenshot, photograph) and uploads it to the REDCap;
2) the site team receives or extracts the records from their employee health system;
3) the site team extracts the records from their EMR system; or
4) the site team requests the information from the hospital/clinic, which are typically transmitted via fax or secure email.

If a participant reports they want to upload documentation during their survey (see #1 above), they will be directed to complete the vaccine and/or testing verification form in their survey queue. If the site has established a plan to receive bulk reports from employee health regarding vaccine administration or testing (see #2 above), then each record still needs to be reviewed and verified by the abstractor. The entire report should not be uploaded into REDCap but should be kept available at the local site. If the participant sought care at the institution they are employed

at and team members have access into their local electronic medical record (EMR) system (e.g., EPIC) based on institutional policies, then team members will access the participant's records via the EMR after confirming participant completed ROI documentation (see section 5.7.1.1). If abstractors are extracting records for their own institution (see #3 above), then they need to make sure that they indicate they were "requested" on the medical record release form even if they are just accessing the EMR for the records so they don't end up on the "need to request" report.

In a situation in when records are not available from employee health for bulk download or participant did not receive testing or vaccine administration documentation, and/or their encounters for health care visits were not at the institution of employment, records will need to be requested from all facilities the participant reported encounters with. This may include other hospitals, private practice clinics, urgent care clinics, COVID testing sites, etc. (#4 above).

The abstractor will be responsible for contacting that facility to initiate the request of records.

- For hospital records (including inpatient admissions and ED visits), the medical records office at the hospital should be contacted during business hours via phone or email. The signed ROI form (see section 5.7.1.1) will need to be transmitted to the facility along with a fax number or email for documents to be sent to. Turnaround time is typically 1-3 business days.
- For clinic/private practice visits, the abstractor should contact the clinic directly and request to be transferred to appropriate contact for medical records. Send ROI forms and provide fax number or email address for records to be returned.

Note: The medical practice, clinic, or hospital website often contains contact information for requesting medical records. All documentation that contains protected health information (PHI) must be kept confidential and secure at every stage. Paper copies containing PHI will be handled and destroyed following the site's usual research policies and guidelines.

All obtained records will need to be uploaded to REDCap. See specific instructions within each section below (test results, vaccine verification, health care encounters) for guidance on uploading the documentation. Any participant who provides data through an interview will still provide access to records in the same manner, and project site staff will manage the workflow of the verification process similarly.

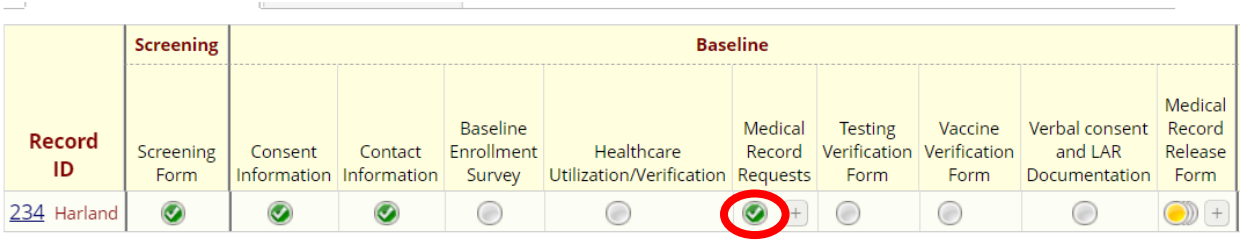
5.7.1.1 Release of Information (ROI) form and DocuSign

When a participant reports receiving COVID testing or any health care during their Index period (see Section 4.5.5) on their surveys, an electronic medical records release form will be auto-filled using the information provided by the participant. A separate release of information (ROI) form will be generated for each facility they report visiting. The forms will be pre-checked to indicate which records that should be requested. If a participant does not want to share a particular record, they will have the ability to uncheck it on the ROI form, EXCEPT for the COVID test result and COVID vaccination records, which are required for participation. These auto-filled forms will be emailed to the participant for electronic signature via DocuSign. After the participant signs these forms, it will be sent back to REDCap and uploaded into the participant's record. These signed

forms will be accessible by abstractors to download and print to request medical records, as necessary.

5.7.1.2 Manually initiating an ROI form

If a participant indicates on their survey that they will upload their own records, the ROI form process described in the previous section is **not** initiated. So, if after indicating on the survey they have the records, but then are unable to find their records (e.g., they lost their vaccination card), the abstractor will ask the participant where the records could be obtained. They will need to also manually initiate a ROI form in REDCap. To do this, the site can go to the record of the participant and click on 'Medical Record Requests.'

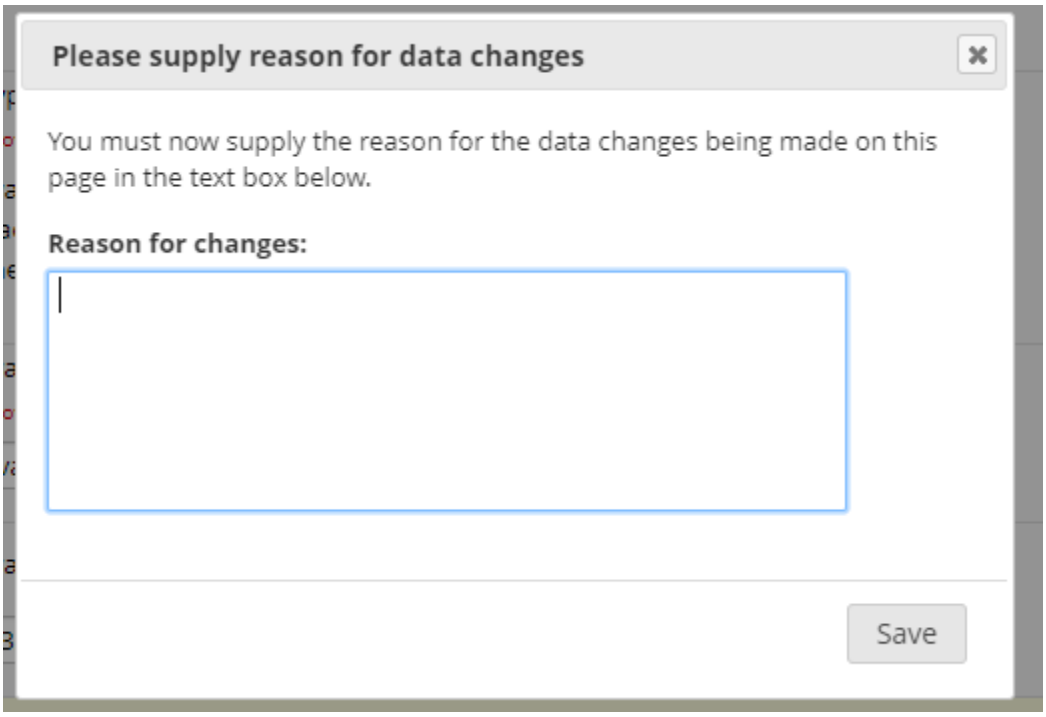


Record ID	Screening	Baseline								
	Screening Form	Consent Information	Contact Information	Baseline Enrollment Survey	Healthcare Utilization/Verification	Medical Record Requests	Testing Verification Form	Vaccine Verification Form	Verbal consent and LAR Documentation	Medical Record Release Form
234 Harland										

On the 'Medical Record Requests' form, the site must enter the name of the facility or provider, the medical information to be requested (e.g., COVID-19 test, emergency room visit), and the city and state of the facility/provider. The site should then click 'no' for further facility to request information from and then change the form to 'complete' and the DocuSign process will be initiated. The participant will receive an e-mail to allow for electronic signature, and the signed form will be deposited into REDCap.

5.7.1.3 Participant uploads incorrect or insufficient documentation

The abstractor should be checking through all the documentation that the participant uploads to ensure that the documentation contains the information required by the project (see sections 5.7.2, 5.7.3, and 5.7.4). If they find that the participant uploaded incorrect or insufficient documentation, they will record this by checking "No, inadequate documentation provided" to the question "Can this test (or record) be verified?". When they submit the form, REDCap will ask the abstractor for a reason for changing the form. The abstractor should enter "verification" as the reason.



If they have access to the participant's EMR and an ROI has been signed by the participant, the abstractor must create a new (testing, vaccination, or health care visit) verification form, upload the appropriate source documentation form mark it as verified, by checking "Yes" to the question "Can this test (or record) be verified?" If they do not have access to the participant's EMR, then they must contact the participant and ask for the corrected source documentation. The participant can upload this information from their survey queue, which will create a new verification form, which the abstractor will complete after verifying the new source documentation is correct. Alternatively, the participant can send the source documentation to the abstractor, who can create a new verification form and upload the revised documentation and complete the form.

5.7.2 COVID-19 test results abstraction

All SARS-CoV-2 or "COVID-19" RT-PCR, molecular/NAAT, or antigen testing test results during the Index period (see Section 4.5.5) should be obtained and recorded. In addition, the index COVID test must be obtained and recorded, even if outside of the index period. For all COVID tests reported, EXCEPT for tests taken and resulted at home, an abstractor must verify test results (type of test/assay, date of test, result) from at least one of the following sources:

1) medical record of the occupational health/employee health or health system (may include a dataset with a bulk reporting of COVID-19 test results),
2) medical record of the primary care physician or another testing center, or
3) participant submitted photograph of test result or official test result report (screenshot or PDF file with test result).
4)

For home tests resulted at home (i.e., not sent out to a laboratory for processing), the test result or a picture of the test kit box is not required. The participant or the abstractor will choose the test kit type which is listed on the form along with an image of the box. If the result of the home test is available, the abstractor or participant can upload the results, but it is not required. A participant's self-report of a RT-PCR test result alone will be insufficient, but a self-reported home SARS-Co-V-2 antigen or molecular/NAAT test is sufficient.

An abstractor will verify and attest to each result in REDCap by completing a Testing Verification Form (see Section 6.1). All participants should have a Testing Verification Form completed and verified for their index COVID test. If the participant uploaded their own documentation, a Verification Form is automatically created in REDCap. The abstractor will be able to edit this Verification form that the participant initiated to document their verification. When submitting this information, REDCap will display a pop-up asking the abstractor to supply the reason for the change to the form. The abstractor should type "verification" for the reason (see figure in 5.7.1.3). If medical records are obtained, then source documents will be uploaded into REDCap and a determination will be recorded (along with the identifier of the person making the determination) that the test meets the requirements of the project.

If data are obtained from an employer or clinic through a bulk download process for which verification of methods have already been performed, then the project team attestation will meet the requirements verification. Multiple documents may be provided for multiple tests, and all tests performed within the Index period will be recorded. Each individual test requires completion of a separate verification form. If no source documents are provided by the participant, the abstractor MUST complete the information above the 'site verification' header.

If the participant received a COVID-19 test outside the Index period, they do not need to provide documentation unless the index COVID test is outside the Index period. The abstractor does not need to verify this testing record and should mark the question on the Testing Verification form 'Was this record able to be verified?' as 'No, out of date range.'

For participants who had their specimen tested at a laboratory (i.e., not resulted at home) and have source documents that provide verification, those documents must include the following:

1) an official result from a health care provider, employee health clinic, or testing center;
2) the date of the test;
3) identifying information about the organization or agency reporting the test;
4) the type of assay performed (e.g., RT-PCR). If the type of assay cannot be confirmed, the issuer may be contacted by project personnel to confirm the type of assay; and
5) the definitive test result. Samples that are positive for COVID-19 may be reported as "Positive," "Present," "Detected" or "+." Any other result should be confirmed with the DCC or the issuing provider.

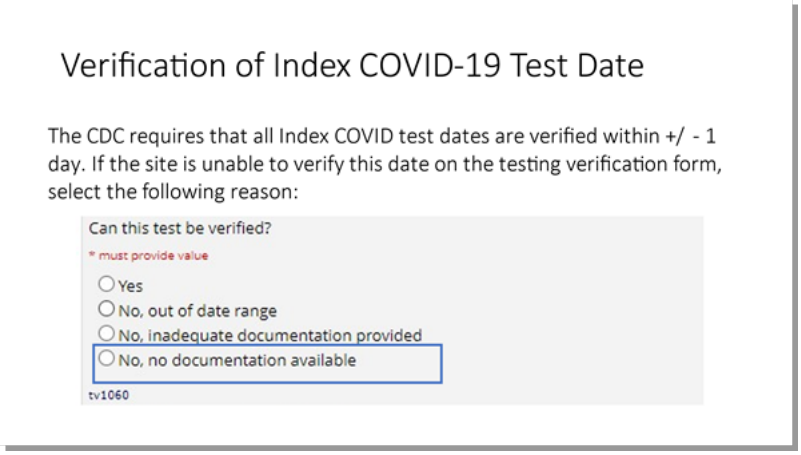
It is preferable that the test result have a definitive identifier that links the test result with the project participant's name, but it is not required (for example, if the participant takes a screenshot of their test result on their MyChart app on their phone). For rapid antigen tests or molecular tests that are resulted at home, the participant will be prompted to identify the at-home test that was used. If the participant indicates they took a different test than what was provided in REDCap, the site team will ensure the test has received emergency use authorization from the FDA prior to verification: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas.

If a participant reports they want to upload their own test records during their survey, they will be directed to complete the testing verification form in the survey queue. If the participant

uploaded their own documentation, a Verification Form is automatically created. The abstractor will be able to edit this Verification form that the participant initiated to document whether they uploaded the appropriate documentation. When submitting this information, REDCap will display a pop-up asking the abstractor to supply the reason for the change to the form. The abstractor should type "verification" for the reason (see figure in 5.7.1.3).

If the test records that the participant uploaded does not include the required information, then the abstractor should record on the Test Verification Form that the records were unable to be verified due to inadequate documentation provided (i.e., select "No, inadequate documentation provided") and ask the participant for new documentation. When the new complete and appropriate source documentation is uploaded, it will create a new Testing Verification Form, that the abstractor can record as verified. If the site team discovers the participant took a test (e.g., through medical record review), but the participant did not report the test on their survey, the abstractor will need to create a Testing Verification Form and fill it out in its entirety, including obtaining records of the test.

All participants must have a testing verification form completed for the testing date reported on their Screening form (Index covid test). If the site is unable to verify the testing date on the screening form, the testing verification form should be marked as unable to be verified (i.e., select "No, no documentation available").



5.7.3 Vaccine data abstraction

All COVID-19 vaccinations (all doses) received before their index COVID test will be recorded. Vaccines received after their index COVID test and reported on the 12 week and 6 month surveys will be collected from the participant by self-report, but are not required to be verified. For vaccines received prior to the index COVID test, the abstractor will verify vaccine data (i.e., date, product, manufacturer, lot number, number of doses) from at least one of the following sources (a participant's self-report of vaccine information alone will be insufficient):

1) medical record of the occupational health/employee health or health system (bulk reporting from employee health clinical will be sufficient for source verification),
2) medical record of the primary care physician or other vaccination center, or
3) state or federal vaccine registry (state Immunization Information System, Vaccine Administration Management System, or other vaccination registry).

An abstractor from each site will verify each vaccine record and attest to that verification within REDCap by completing a Vaccine Verification Form (see Section 6.2). All participants should have a Vaccine Verification Form completed for the COVID vaccine, whether or not they indicated they received COVID vaccine (see 5.7.3.1). If there are multiple vaccinations recorded on a single source document, then the abstractor does not need to upload the same source document into each vaccine verification form if it is available on the first form. If medical records are obtained, then source documents will be uploaded into REDCap and a determination will be recorded (along with the identifier of the person making the determination) that the vaccination record meets the requirements of the project. If data are obtained from an employer or clinic through a bulk download process for which verification of methods have already been performed, then the abstractor attestation will meet the requirements for verification.

If the participant received a COVID-19 vaccine after their index COVID test, then they do not need to provide documentation. The abstractor does not need to verify this health record and should mark the question on the Vaccine verification form 'Was this record able to be verified?' as "No, out of date range." If the abstractor is unable to obtain the vaccine documentation, then they should mark the response "No, no documentation available."

For participants with source documents that provide verification, the document must include the following:

1) a definitive identifier that links it with the project participant (e.g., name),
2) the date of administration of the vaccine(s), and
3) the manufacturer or product name of the vaccine administered.

If a participant was vaccinated as part of a clinical trial, a letter with trial arm allocation can be used to provide source document verification. The lot number should be recorded if known, but is not required. If the lot number is unknown, please enter '9999'.

If the vaccine records that the participant uploaded do not include the required information, then the abstractor should note on the Vaccine Verification Form that the records was unable to be verified because inadequate documentation was provided (select "No, inadequate documentation provided") and ask the participant for new documentation. In addition, the abstractor can cross check missing information with bulk data sources (e.g., employee health bulk download or state registry). When the new complete and appropriate source documentation is uploaded, it will create a new Vaccine Verification Form, that the abstractor can note as verified.

If a participant reports more vaccines in their baseline survey than you are able to verify through the means above, then please create a vaccine verification form and click 'no, no documentation available' and add the vaccine verification date.

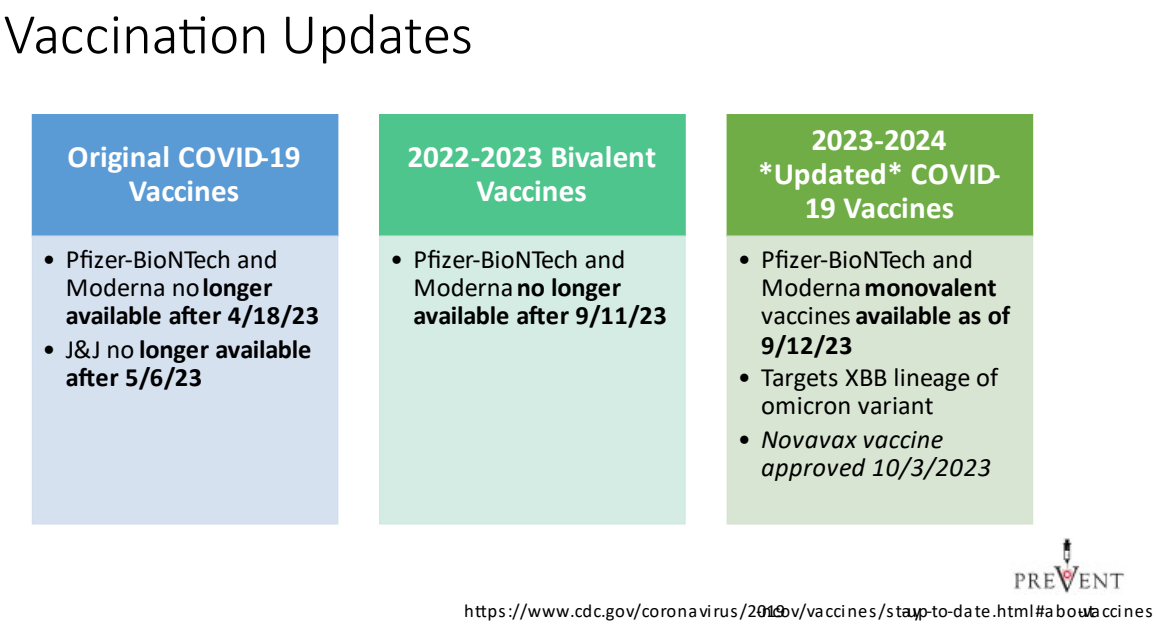
Section 5.7.3.1 Verification of COVID non-vaccination

To ensure that no COVID vaccine administrations are misreported, all sites must set up a plan to verify responses from participants who indicate they <u>did not</u> get a COVID vaccine. This plan will

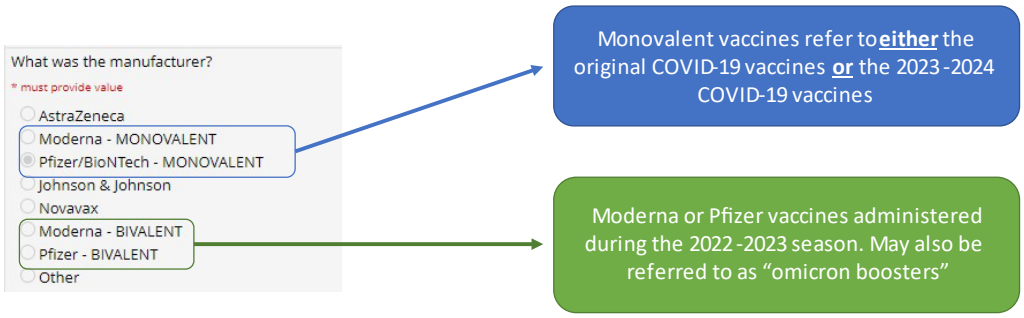
most likely involve searching the site's local employee health records and/or state vaccine registries to verify that all participants who reported they did not get a COVID vaccine during their participation in the project, did not actually receive one.

To record that non-vaccination was verified, the abstractor should create a new verification form. For the question "What is this participants vaccination status?" they should check "No vaccine" and record the source of data used for verification. Every participant who responds that no vaccine has been administered will need to have this verification completed by project staff.

Section 5.7.3.2 Additional guidance to report 2023-2024 vaccines and valency



Changes to forms - Vaccine Verification



Rules have been created in REDCap to prompt abstractors if vaccines are selected during time periods when they were not available

PREVENT

5.7.4 Healthcare visit records abstraction

If a participant has received health care during their Index period (see Section 4.5.5), then the following medical records should be obtained and recorded:

1) inpatient or observation hospital admission (i.e., stayed overnight in the hospital in an inpatient room or assigned to admit team) at an acute care hospital will be included, but skilled nursing care, rehabilitation, mental health/psychiatric admissions, long-term acute care hospital admissions, or other post-acute admissions will not be included;
2) ED, urgent care, or other unscheduled clinic visits (including an evaluation in employee health, but visits for any mental health/psychiatric cause will not be included); and
3) unscheduled non-emergency episodic outpatient care visit (urgent care, walk-in clinic, etc. except for any mental health/psychiatric cause); and
4) outpatient clinic appointment (only in relation to current or recent symptoms infection).

The following components of the health care record are already requested, if they are available, in the pre-filled ROI form sent to participants for electronic signature via DocuSign:

1) clinic notes;
2) emergency department (ED) visit record;
3) hospital admission notes (H&P, progress notes, consultation notes, procedure notes, discharge summary, vitals flowsheets, medication administration record);
4) radiology reports (X-ray, CT, MRI, VQ scan, ultrasound; Note: copies of the actual images are not needed);
5) lab results/reports (including microbiology and cultures);
6) vitals signs;

7) vaccination records;
8) medication lists; and
9) problem list (patient summary list).

An abstractor will upload these source documents into REDCap and will abstract the record using the Healthcare Utilization/Verification Form (see Section 6.3) in REDCap. These source documents must be uploaded as a single document in REDCap for each visit. This form is built as both a survey to be completed by the participant and a corresponding verification form to be completed by the site team. After the participant completes the survey, the abstractor can open the form from the participant dashboard and click on "edit survey" at the top of the survey. Sites are responsible for completing all components below the "Site Verification Form" Header.

Please note that a visit for testing only (with no corresponding clinical evaluation) or telehealth appointments do not need to be reported as a health care visit. If a participant reports a healthcare encounter that should be excluded, then the site team will indicate on the survey form the encounter does not need to be reviewed, e.g., "No, out of date range". If a participant is admitted to the hospital during their Index period (see section 4.5.5), then the entire hospitalization will be abstracted even if discharge occurs after their Index period. Site coordinators will need to create a new health care utilization form for any emergency department visits associated with a hospital admission and abstract that information on a separate HCU form. For participants requiring inpatient or outpatient COVID-19 treatment, severity of illness will be confirmed through the participant medical record.

If the healthcare is utilized outside the date range, then the abstractor should mark the question 'Does the health care visit reported by the participant meet requirements for an encounter that needs to be verified?" as 'No, out of date range.' If the abstractor is unable to obtain the required documentation for the visit, then they should mark "No, no documentation available."

5.7.5 REDCap reports to track medical record abstraction

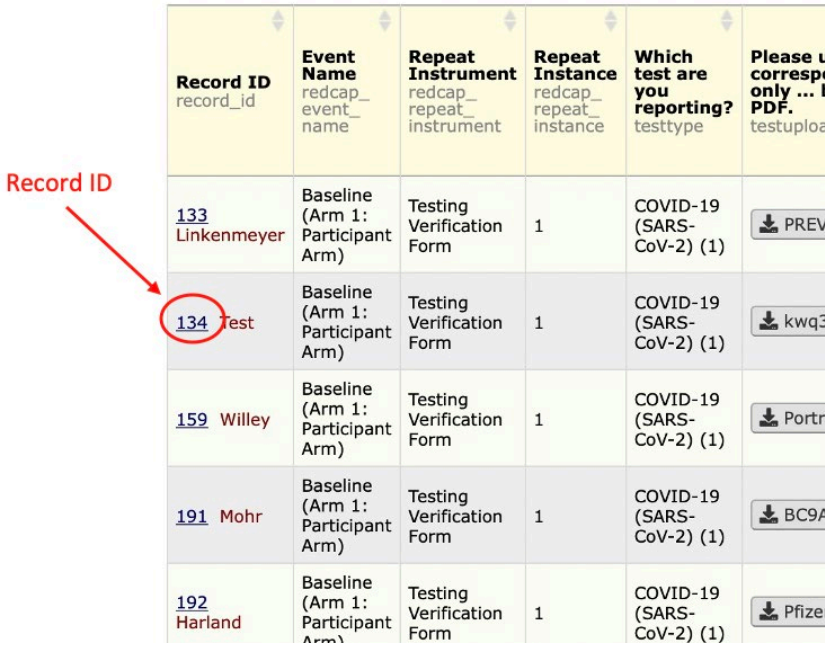
The following REDCap reports (Appendix F) are available to abstractors to ensure medical record abstraction is completed:

1) Medical release request needs completed by participant
   - The participant reported that the site would need to obtain their testing, vaccine or healthcare documentation but no medical release request was initiated by participant for a DocuSign ROI to be sent. Participant must be contacted to complete the medical record request survey.
2) Medical records to request
   - Signed ROI received from DocuSign but no documentation of chart request
3) Medical records requested but not received
   - Medical records requested but not received within 7 days
4) Medical records abstractions to complete
   - Medical records have been received but have yet to be abstracted
5) Vaccine verifications to complete
   - COVID-19 vaccine documentation uploaded by participant but not yet abstracted

6) Testing verification to complete
   - COVID-19 testing documentation uploaded by participant but not yet abstracted

5.7.6 Communication with DCC during abstraction

If team members who are abstracting medical records have questions or concerns while performing the review and abstraction, then the abstractor should record the item number (e.g., *ef4242*) for that question and survey record id (e.g. 134) and send an email to emergencyidnet-prevent@uiowa.edu. A DCC team member will respond via email or phone call to address the concern within 2 business days. The item number can be found under the question on the survey and in the left-hand column of the table with instructions for each survey question. The record ID is found on the report page in the left-hand column.



Record ID record_id	Event Name redcap_event_name	Repeat Instrument redcap_repeat_instrument	Repeat Instance redcap_repeat_instance	Which test are you reporting? testtype	Please u corresp only ... PDF. testuploa
133 Linkenmeyer	Baseline (Arm 1: Participant Arm)	Testing Verification Form	1	COVID-19 (SARS-CoV-2) (1)	PREV
134 Test	Baseline (Arm 1: Participant Arm)	Testing Verification Form	1	COVID-19 (SARS-CoV-2) (1)	kwq3
159 Willey	Baseline (Arm 1: Participant Arm)	Testing Verification Form	1	COVID-19 (SARS-CoV-2) (1)	Portr
191 Mohr	Baseline (Arm 1: Participant Arm)	Testing Verification Form	1	COVID-19 (SARS-CoV-2) (1)	BC9A
192 Harland	Baseline (Arm 1: Participant Arm)	Testing Verification Form	1	COVID-19 (SARS-CoV-2) (1)	Pfize

If the DCC needs to contact abstractors or specific reviewers regarding concerns or questions, an email will be sent to the abstractor followed by a phone call if there has not been a response within 2 business days.

6.0 REDCap form-specific instructions

6.1 Test record verification

Specific instructions for testing verification form (to be done by abstractors) are detailed in the table below. All COVID tests obtained during the Index period must be verified.

ALPHANUMERIC IDENTIFIER	DATA FIELD OR QUESTION	INSTRUCTIONS FOR DATA COLLECTOR
GENERAL INFORMATION		

tv3695_eip16	Type of test being reported?	**Required.** Select appropriate response. Reminder: a separate form must be filled out for **each** test obtained.
tv4729	Obtain medical records and upload test results.	**Required.** Confirm medical records release form was completed by the participant for the facility where test was done, if necessary. Determine if proof of test result is already available via bulk reporting by employee health or if the records need to be requested from a specific facility. If records are available via bulk reporting, screenshot the participant's information to upload (instead of uploading the entire document). If records need to be requested, follow process outlined in section 5.7.1 of the manual of procedures. Obtain copy of all testing records during the Index period. Upload a copy of the test record (pdf or photo) into REDCap by clicking on the link and selecting the appropriate file. **Only upload one document per form.** *Multiple documents may be provided for multiple tests, and all tests performed within the 14-day period after the index test will be recorded, however each test requires a separate form.* *For cases, the index test is the first positive result.* *For controls, the index test is the most recent negative result.*
tv1605	Record reviewer, name and affiliation	**Required.** Free text. Record your (the reviewer's) HawkID used to log into REDCap
tv1849_eip16	Date of sample collection	**Required.** Enter in MM/DD/YYYY format.
tv1060	Verification of test	**Required.** Select the appropriate response. If data are obtained from an employer or clinic through a bulk download process for which verification of methods have already been performed, then the project team attestation will meet the requirements for verification. For participants who receive lab testing with source documents that provide verification, those requirements include **ALL** of the following:

		1) must be provided as an official result from a health care provider, employee health clinic, or testing center 2) must include a definitive identifier that links it with the project participant unless it a screenshot from their smartphone MyChart app or equivalent 3) must show the date of the test 4) must confirm identifying information about the organization or agency reporting the test 5) must show the type of assay performed (e.g., RT-PCR). If the type of assay cannot be confirmed, the issuer may be contacted by project personnel to confirm the type of assay 6) must definitively report the test result. Samples that are positive for COVID-19 may be reported as "Positive," "Present," or "+." Any other result should be confirmed with the DCC or the issuing provider.
COVID-19 or SARS-CoV-2 TEST		
tv1839_eip16	COVID test, specimen type	Select the appropriate response if information is available.
tv3312_eip16	COVID test type	**Required.** Select the appropriate response.
tv1294_eip16	[if PCR] Test type specifics	Select appropriate response from dropdown if information is available. Select "other" if the PCR test manufacturer is not listed or is unknown. You will enter the information manually on the next question.
tv3087	[if PCR] Test type listed as other	Free text the PCR manufacturer if information available or enter "unknown".
tv3024_eip16	[if Antigen] Test type specifics	**Required.** Select appropriate response from dropdown if information is available. Select "other" if the antigen manufacturer is not listed or is unknown. You will enter the information manually on the next question.
tv4785	[if antigen] Test type listed as other	Free text the antigen manufacturer if information available or enter "unknown." The site team should make sure the test type is listed on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

tv4907_eip16	COVID test results	**Required.** Select the appropriate response. When reporting results, • Samples that are positive for COVID-19 may be reported as "Positive," "Present," or "+." • select "pending" if a test result is reported as pending in the medical chart • select "unknown" if the test result is not available and not noted as pending in the medical chart, • select "indeterminate" if a test result is reported as "indeterminate" or "invalid" in the medical chart. Note: pending or unknown results will require follow up and this form will not be complete. For pending results, updated records will need to be requested. **For home antigen/molecular tests,** the participant will be asked to select a picture of the test they used and report the result. The participant does have the ability to upload their test result as well. The site team should make sure the image matches a test listed on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas
FORM COMPLETION		
		Select from the following responses: • "incomplete" if there are pending results or any responses were left blank • "complete" if test results were verified and there are no pending results or if all responses were completed with test results but you were unable to verify the results based on the above criteria

6.2 Vaccine verification form

All vaccines including booster doses received prior to Index date (see Section 4.5.5) should be verified. Complete a separate form for each vaccine dose, i.e., if three doses of vaccine received, three forms need to be completed. As long as one instance has the required documentation (i.e., a copy of the vaccine card uploaded) it does not have to be uploaded into each instance but this is preferred.

ALPHANUMERIC IDENTIFIER	DATA FIELD OR QUESTION	INSTRUCTIONS FOR DATA COLLECTOR
GENERAL INFORMATION		
vv4897_eipvaxform	Vaccine type being reported	**Required.** Select appropriate response *Note: this form needs to be completed separately for each vaccine administered and each separate dose.*
vv2257	Upload vaccine record documentation	**Required.** Confirm medical release forms have been completed by participant. Please request records to confirm each vaccine, and all other vaccines in the records from health care providers. At a **minimum**, each individual should have the following sources queried: 1. Employee health/occupational health clinic 2. Institutional vaccination records 3. State vaccine administration system/registry/VAMS 4. Any self-identified health care providers, clinics, or hospitals that the participant recalls providing vaccination 5. Any self-identified health care providers, clinics, or hospitals that provided care during the study period If you are unable to find record of the vaccine in the occupational health system or vaccine registry, you will need to request medical records from the facility where the vaccine was administered. See section 5.7.1 for specific instructions on requesting medical records. Please upload a copy of vaccine records in PDF or photo form to REDCap by clicking on the upload link. **Only upload one document per form.** Each vaccine dose and each separate vaccine administered requires completion of a separate form.
vv2490	Record reviewer, name and affiliation	**Required.** Free text. Record your (the reviewer's) HawkID used to log into REDCap
vv4979	Date of vaccine administration	**Required.** Enter in MM/DD/YYYY formatting

		Note: Only provide date for vaccines doses the participant has received. Do not include information on future planned doses which have not yet been administered.
vv4406	Source of vaccine verification	**Required.** Select appropriate response.
vv3772	Confirmation of verification of vaccine.	**Required.** Select the appropriate response. • data are obtained from an employer or clinic through a bulk download process for which verification of methods have already been performed (the project team attestation will meet the requirements for verification.) • For participants with source documents that provide verification, those documents **must include all of the following:** 1) identifying information about the organization or agency that administered the vaccine (i.e., a health care provider, employee health clinic, clinical trials office, or vaccination center) a. If a participant was vaccinated as part of a clinical trial, a letter with trial arm allocation can be used to provide source document verification; 2) a definitive identifier that links it with the project participant; 3) the date of administration of the vaccine(s); 4) the manufacturer or product name of the vaccine administered and a lot number. These elements are required for COVID-19 vaccination.
INFORMATION re: SARS-CoV-2 VACCINE		
vv3662	COVID vaccine manufacturer	**Required.** Select appropriate response. If the vaccine manufacturer is unknown, select other
vv2613	COVID vaccine manufacturer, other or unknown	**Required.** Provide the name of the COVID vaccine manufacturer. If unknown, please indicate by typing "unknown"
vv3723	COVID vaccine lot number	Provide lot number if available. If lot number unavailable, enter 9999
FORM COMPLETION		
	Vaccine verification form complete?	Select from the following responses: • "incomplete" if there are pending results or any responses were left blank

		• "complete" if test results were verified and there are no pending results or if all responses were completed with test results but unable to verify the results based on the above criteria

6.3 Medical Records/Health Care Visit Record Verification

All health care utilization received during the Index period must be verified. Please complete a different form for every health care encounter. This includes creating a separate form for an emergency department visit resulting in a hospital admission. Encounters for testing alone only need to be verified on the testing form.

ALPHANUMERIC IDENTIFIER	DATA FIELD OR QUESTION	INSTRUCTIONS FOR DATA COLLECTOR
GENERAL INFORMATION		
mv2274	Record reviewer, name and affiliation	**Required.** Free text. Record your (the reviewer's) HawkID used to log into REDCap
mv4473	Medical records regarding health care visits	Required for participants who sought outpatient care or required COVID-19 treatment. Request the medical records from every qualified visit which includes: 1) Any acute inpatient or observation hospital admission (for any cause) within Index period. Comprehensive medical records for all hospital admissions should be included (including but not limited to admission note/H&P, daily provider and nursing progress notes, procedure notes, consult notes, discharge summary, vital sign summaries, lab and imaging results, and medication administration record), even if discharge did not occur end of Index period. 2) Emergency department visit (for any cause) within Index period 3) Unscheduled non-emergency episodic outpatient care visit (urgent care, walk-in clinic, etc.) within Index period 4) Any scheduled outpatient clinic appointment (only in relation to COVID-19 infection) within Index period 5) Any employee health/occupational health clinic visits within Index period Encounters to exclude: • admissions to skilled nursing facility (SNF), rehabilitation, long-term acute care hospital

		admissions (L-TACH), or other post-acute admissions • visits or admissions related to psychiatric care • telehealth visits Please upload a copy of all medical records to REDCap (see section 5.7.4 for comprehensive list of records to be included, if available). These may be uploaded in PDF or photo form and may be uploaded as one or multiple files. **Note: a separate form needs to be filled out for each health care encounter. If a participant is admitted to the hospital from the ED, the ED visit and admission should be considered separate encounters with separate survey forms completed for each.**
mv3193	Type of health care encounter	**Required.** Select appropriate response. Regarding hospital admission, select "yes" if the participant was hospitalized at in the relevant date range.
mv2012_eipmed17b	Encounter date	**Required.** Admission date for hospital admissions or visit date for outpatient visits. Enter in MM/DD/YYYY formatting **Note: Please complete a different form for every health care encounter**
mv3859	Visit verification	**Required.** Select the appropriate response. • data are obtained from an employer or clinic through a bulk download process for which verification of methods have already been performed (the project team attestation will meet the requirements for verification.) • medical records have been obtained that include all of the following: 1. must be provided as an official record from a health care provider, employee health clinic, or hospital 2. must include a definitive identifier that links it with the project participant 3. must show the date of the visit or admission

		4. must include a provider note. If records are from a hospital admission, it must include an H&P Patient provided report is not sufficient to verify visit.
mv3911	Steroid/antiviral	**Required.** -If the indication is COVID-19 then code as 'Yes' -if the indication is known and NOT COVID-19 then code as 'No' -if the indication is unknown, then code as 'unknown' Below are examples of antivirals, monoclonal antibody treatments, or corticosteroids used for COVID-19 treatment • Antivirals: Paxlovid™ (nirmatrelivir/ritonavir), Lagevrio™ (molunpiravir), Veklury® (remdesivir) • Corticosteroids: dexamethasone, prednisone, methylprednisolone
mv1871_eip37	Documentation of underlying medical conditions	**Required.** Select all that apply. Refer to the "problem list" or "diagnoses" list in the medical chart. For hospitalized patients, can also refer to the admission or discharge note. List only underlying medical conditions in this section, do not note new diagnoses here. Note that "history" is sometimes abbreviated as "PMH", "PMHx", "hx", or "h/o" Use the following examples as needed: • select asthma if there is documented "childhood asthma" or "history of asthma" • allergic rhinitis may be documented as seasonal allergies • Chronic Obstructive Pulmonary Disease (COPD) includes emphysema and chronic bronchitis • "other chronic lung disease" includes reported lung diseases other than asthma or COPD. Examples include cystic fibrosis, bronchiectasis, pulmonary sarcoidosis or pulmonary hypertension. • Hypertension is abbreviated as "HTN"

		• coronary artery disease (CAD) includes documentation of heart attack, myocardial infarction (MI), and STEMI. History of coronary stent placement (PCI) or coronary artery bypass graft (CABG) surgery would also be indicative of a history of CAD. • For "other heart condition" note any cardiac diagnoses other than hypertension or coronary artery disease. Examples include arrythmia (such as atrial fibrillation (afib)), supraventricular tachycardia (SVT), sick sinus syndrome, tachy-brady syndrome, heart block, congestive heart failure (also documented as CHF, HFpEF and HFrEF), congenital heart disease, valve abnormality, pacemaker, history of non-coronary heart surgery (i.e., previous ablation) • Stroke is also documented as cerebral vascular accident or CVA. Stroke includes cerebral infarct/ischemic stroke and hemorrhagic stroke/intracerebral hemorrhage (ICH). Do not include transient ischemic attack (TIA) as a stroke • Diabetes Mellitus, type 1 may also be documented as "T1DM" • Diabetes Mellitus, type 2 may also be documented as "T2DM" • Select "diabetes mellitus, unspecified" if the type is not clearly identified! • Chronic kidney disease may be abbreviated as CKD or end stage renal disease or ESRD • Dialysis includes hemodialysis (HD) and peritoneal dialysis (PD). • Examples of autoimmune or rheumatologic diseases include celiac disease, rheumatoid arthritis, psoriasis/psoriatic arthritis, multiple sclerosis, systemic lupus erythematosus (lupus or SLE), inflammatory bowel disease (IBD), Crohn's disease, ulcerative colitis, Hashimoto's thyroiditis, antibody deficiencies (e.g., X-linked agammaglobulinemia and common variable immunodeficiency, selective IgA deficiency and IgG subclass deficiency), severe combined immunodeficiency (SCID

		disease), DiGeorge syndrome, Chediak-Higashi syndrome, Leukocyte Adhesion Deficiency (LAD), myeloperoxidase deficiency, HIV/AIDS, asplenia, chronic renal disease, history of organ transplantation, active malignant neoplasm. • Select "other immune suppressing condition" if patient is taking any of the immune suppressing medications listed in Appendix E, Table 1 • "active cancer" is defined as solid organ or hematologic (leukemias, lymphomas) cancer diagnosed or treated (chemotherapy, radiation, surgery) within the previous 12 months, recurrent, regionally advanced or metastatic cancer, or hematological cancer that is not in complete remission. Appendix E, Table 2 lists chemotherapy drugs. • Deep vein thrombosis is abbreviated "DVT" and pulmonary embolism is abbreviated "PE" • Chronic liver disease includes alcoholic liver disease, fatty liver disease, steatohepatitis, cirrhosis, hepatitis, hepatocellular carcinoma (HCC), nonalcoholic fatty liver disease (NAFLD), nonalcoholic steatohepatitis (NASH), primary biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC), autoimmune hepatitis (AIH) and Budd-Chiari syndrome • Depression or other mood disorder includes major depression disorder (MDD), seasonal affective disorder (SAD), adjustment disorder, bipolar disorder (which includes mania and hypomania), dysthymia, cyclothymic disorder, premenstrual dysphoric disorder (PDD) • Anxiety, obsessive-compulsive and trauma-related disorders includes generalized anxiety disorder (GAD), panic disorder, social anxiety disorder, phobias, obsessive-compulsive disorder, body dysmorphic disorder, hoarding disorder, trichotillomania, excoriation, post-traumatic stress disorder (PTSD), acute stress disorder, adjustment disorder

		• Sleep disorders includes insomnia, narcolepsy, obstructive sleep apnea (OSA), central sleep apnea, sleep-related hypoventilation, circadian rhythm sleep-wake disorders, parasomnias (such as REM sleep disorders, nightmare disorder, restless leg syndrome, unspecified insomnia, hypersomnolence or sleep-wake disorder) • Cognitive disorders includes the following diagnoses within neurodevelopmental disorders (such as intellectual disability, intellectual developmental disorder, autism spectrum disorder, attention deficit/hyperactivity disorder (ADHD/ADD), specific learning disorder (i.e., math, reading)) and neurocognitive disorders (such as delirium, mild neurocognitive disorder, major neurocognitive disorder, mild cognitive impairment, memory loss, dementia, cognitive impairment associated with a medical condition) • Movement disorders includes Huntington's disease, Parkinson's disease or parkinsonism, tardive dyskinesia, essential tremor, dystonia and ataxia, Tourette's disorder, tic disorder • Select alcohol abuse if there is documentation in the medical record of any of the following terms: "alcohol abuse," "alcoholic," "alcoholism," "alcohol dependence," "alcohol addiction," "alcohol misuse disorder" or "alcohol withdrawal." Note: alcohol can be abbreviated as 'ETOH' in the medical record. If a history of alcohol abuse is noted in the chart, without specifying whether the condition still exists, record as current alcohol abuse.
mv1368	Fever	**Required.** Select the appropriate response. Fever is defined as temperature greater than 100.0°F or 37.8°C. Only include documented fever during the visit.
mv4377	Highest temperature	**Required.** Free text – enter in the highest documented fever. It may be documented as Tmax. Report temperature in Celsius (C).

INFORMATION PERTAINING TO HOSPITAL ADMISSIONS:		
mv4377_eipmed17c	Discharge date (or date of death)	**Required.** Format as MM/DD/YYYY. Please provide the date participant was discharged from the hospital (or date of death if death occurred during hospital admission).
mv1447_eipmed17d	Was participant transferred from another hospital?	**Required.** Select "yes" if the participant initially presented to a different hospital and was transferred. This includes ED to ED, ED to inpatient, and inpatient to inpatient transfers. This may be listed in an H&P note as "presenting from outside hospital" or "from OSH." This does not include patients who were sent to the ED from a clinic visit. (However, note that both the clinic visit and ED visit need forms completed for verification.) **Note: this form needs to be completed for both hospital encounters.** **Reminder, ED visit and inpatient admission should be considered separate encounters, so a separate form needs to be completed for each.**
mv2819_eipmed17f	Hospital admission date	**Required.** Format as MM/DD/YYYY. Please provide the date participant was transferred from their originally admitting hospital and admitted to second hospital.
ICU admission?		
mv1618_eipmed18	Did participant require ICU admission?	**Required.** Select appropriate response. May be listed in chart as admission to critical care unit (CCU) or intensive care unit (ICU). Select yes if patient was admitted to any type of ICU, including but not limited to any of the following: MICU, SICU, CVICU, SNICU, TICU.
mv4380_eipmed18a	ICU admission date	**Required.** Format as MM/DD/YYYY. If the participant had multiple ICU visits during this hospital stay, please only report the dates for the first ICU stay.
mv3582_eipmed18b	ICU discharge date	**Required.** Format as MM/DD/YYYY. This is date patient was discharged from ICU to a lower level of care (i.e., step down unit, inpatient floor, palliative floor, etc.) or the date of death if patient died in the ICU. This information will likely

		be found in the progress note plans or a flowsheet on patient location/room number. If the participant had multiple ICU visits during this hospital stay, please only report the dates for the first ICU stay.
Vitals during **first 24 hours** of hospital admission		
mv1874_eipmed19a	Respiratory rate >30	**Required.** Select yes if a respiratory rate greater than 30 breaths per minute was documented in the first 24 hours of hospital admission. • Respiratory rate is also documented as "RR" or there may be a number followed by "breaths per minute" or "bpm" or "br/min" This will likely be located in the physical exam section of the admission note, physical exam section of progress note, nursing progress notes or in vitals flowsheets.
mv1874_eipmed19b	Heart rate >125	**Required.** Select yes if a heart rate greater than 125 beats per minute was documented in the first 24 hours of hospital admission. • Heart rate is also documented as "HR" and pulse. "bpm" is used to reference beats per minutes This will likely be located in the physical exam section of the admission note, physical exam section of progress note, nursing progress notes, in vitals flowsheets, and on an electrocardiogram (identified as rate)
mv1874_eipmed19c	Oxygen saturation <93% on room air or requirement of supplemental oxygen to maintain saturation >93%	**Required.** Select yes if an oxygen saturation of less than 93% was documented or if participant required supplemental oxygen to maintain saturation greater than 93% in the first 24 hours of hospital admission. • Oxygen saturation may be documented as "pulse ox" or SpO2. • If supplemental oxygen is required, it may say "O2 via…" then a route such as nasal cannula (NC), nonrebreather (NRB), BVM (bag valve mask) or mechanical ventilation. This will likely be located in the physical exam section of the admission note, physical exam section of progress note, nursing progress notes, or in vitals flowsheets.
Evidence of respiratory failure **at any point** during the hospital admission		

mv2784_eipmed20a	New BiPap/CPAP use?	**Required.** Select appropriate response. Do not include night-time continuous positive airway pressure (CPAP) that was previously prescribed at home for non-COVID indications. This is often prescribed for patient with sleep apnea. Previously prescribed CPAP may be documented in the chart as "obstructive sleep apnea (OSA) on CPAP".
mv2784_eipmed20b	Was high flow nasal cannula (HFNC) used?	**Required.** Select yes if there is documentation of use of high flow nasal cannula (HFNC) which includes Vapotherm and Optiflow. **Note**: the chart should specify if patient was on high flow nasal cannula versus the much more common nasal cannula. If HFNC is used, there is likely documentation of a FiO2 percentage and volume >8L.
mv2784_eipmed20c	Was participant intubated?	**Required.** Select yes if there is documentation of patient needing intubation, endotracheal tube (ETT), definitive airway, mechanical ventilation. This information should be listed in the plan part of a daily progress note under the respiratory section or in a respiratory therapy progress note. There may also be documentation of ventilator settings (such as PEEP, PIP, tidal volume) in the vitals flowsheets which is an indication a participant was intubated. Additionally, there should be a procedure note for all patients who are intubated. This may be a separate document or may be listed in the procedure section of an ED note or ICU H&P. If patient was intubated prior to their arrival to the hospital (i.e., by EMS or transferring hospital), the ED and/or ICU H&P should indicate patient was intubated on arrival.
mv2784_eipmed20d	Did participant require ECMO/ECLS?	**Required.** Select yes if patient was placed on extracorporeal life support (ECLS) or extracorporeal membrane oxygenation (ECMO) or other documentation of being placed on heart and lung bypass.
Other evidence of severe infection **at any point** during hospital admission		
mv3787_eipmed21	Was vasopressor therapy initiated?	**Required.** Select yes if patient was placed on vasopressor therapy which includes dobutamine, dopamine,

		epinephrine/adrenaline, milrinone, phenylephrine, norepinephrine/levophed, or vasopressin. Documentation of these medications can be found in the medication administration record (MAR)
mv2871_eipmed22	Development of acute neurologic dysfunction?	**Required.** Select all that apply. • hemorrhagic stroke or intracerebral hemorrhage is abbreviated ICH • cerebral infarction/ischemic stroke may be documented as CVA • Guillain-Barre syndrome is often abbreviated as GBS. • only include new diagnosis of peripheral neuropathy These diagnoses can be found in the plan part of the progress notes (list of problems being addressed during the hospital admission) and/or on the discharge problem list. Select "no signs of acute neurologic dysfunction" if • the participant is noted not to have any new neurologic diagnoses in the discharge summary or progress notes • participant has a history of a neurologic condition (such as past stroke or past Guillain-Barre Syndrome) but no newly diagnosed neurologic conditions during their hospitalization for COVID-19 or COVID-19-like illness
mv2757_eipmed23	Outcome of hospital admission	**Required.** Select "dead" if patient died during hospital admission.
Chest imaging obtained		
mv2247_eipmed30	Was chest imaging obtained?	**Required.** Select yes if patient had a chest x-ray (CXR), chest CT (CTPE, CTA chest) or chest MRI performed.
mv1355_eipmed30a	Result of chest imaging	**Required if chest imaging performed.** Select yes if there were abnormal acute findings on chest imaging. This information is found on the "impression" or "findings" section of radiology reports.
mv3520_eipmed30b	Abnormal results on chest imaging	**Required for abnormal chest imaging.** Review the imaging report and select all that apply. Pneumothorax may be abbreviated PTX and pulmonary embolism may be abbreviated as PE.

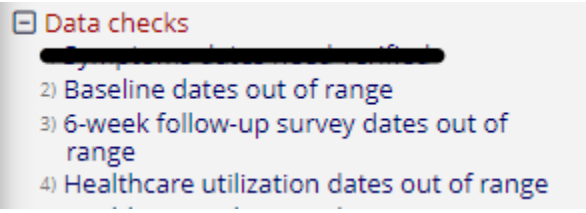
Discharge diagnoses		
mv2752_eipmed31	New diagnoses present at discharge	**Required.** Select new diagnoses that were not present on hospital admission. Select yes even if the issue resolved during hospital admission. • Acute kidney injury is documented as AKI. New dialysis may be documented as continuous renal replacement therapy (CRRT) • if patient was intubated, select yes for acute respiratory failure

7.0 Quality Assurance

The CCC and DCC will be monitoring recruitment activities and data collection throughout the project period to ensure high recruitment rates and complete, accurate, and timely data collection and reporting.

The DCC set up several REDCap Reports (see Appendix F) for site teams to track participant survey completion and other project task activities, including completion of verifications and medical records release form completion. Any element of the protocol is considered 'overdue' if it has been 7 days since the survey or medical release was sent to the participant or for uploads 7 days since the participant completed the survey. These reports have also been built as dashboards within REDCap.

The DCC has also set up methods to identify data that is out of range for testing or health care utilization, i.e., if a participant reports testing or healthcare utilization outside of 14 days before to 14 days after the index date, these data will appear in the following REDCap reports:



It is the site team's responsibility to follow-up with participants to ensure the dates entered by the participant are correct and updated if necessary.

Finally, the DCC will send out queries (every two weeks or monthly) to sites listing all outstanding data verifications, inconsistent data to check, and other project tasks.

7.1 Recruitment and screening log completion

It is essential for sites to keep a careful Recruitment List and Screening Log throughout the entire project. Prior to study launch, each site should test their process of recording this information to ensure that the information is obtainable and organized appropriately. The CCC may request de-identified copies of the Recruitment List or Screening Logs from sites especially at the early stages of recruitment to track and identify any errors or issues.

7.2 Tracking recruitment rates

It is essential for sites to set up a process to determine the recruitment rates and test this process prior to launch. If the site recruitment rates are less than 50% after the first two weeks of inviting participants, the site team will meet with the CCC to discuss strategies to increase their rates.

7.3 Medical records collection and verification

7.3.1 Abstractor training

All site team members who will be abstracting medical records must complete training and be approved to abstract prior to site launch. Initial project training will initially occur via an all-site meeting and the video will be posted at www.prevent-project.org. After the training session, team members will complete a short quiz to ensure competence. This short quiz will include a mock patient file and will include test results, vaccine information and records from a health care encounter. The abstractor will be given approximately one week to complete the test and submit their answers to the DCC. If the abstractor does not pass the quiz, then they will receive individual feedback on the incorrect answers and will be provided with a second mock file and quiz. If the second quiz is not passed, then the data abstractor will not be approved, and the site will need to select a replacement who will undergo the same training and testing. Sites will not be released to do medical record abstraction until at least one team member has passed training. The training will be recorded, and a video will be posted on the project website (www.project-prevent.org) for team members to review as needed.

Site teams will need to obtain and verify test results, vaccine results, and healthcare visit records per the procedures detailed in Section 5.7. A member of the DCC team will randomly select multiple records per site each week to verify the information recorded is correct. If there are discrepancies, then the DCC team member will contact the abstractor to discuss. The DCC will also track the collection and verification of this information regularly, and if a site is missing large amounts of information or is not collecting information in a timely manner, they will contact the site team to discuss further. It is the responsibility of the site teams to contact the DCC immediately for any issues or barriers encountered with obtaining and verifying this information and for assistance with troubleshooting.

7.3.2 Abstractor retraining for 2023-2024 season

All site abstractors will be asked to take another training quiz in fall of 2023 to ensure continued understanding of verification procedures and of any new procedures adopted since the launch of the project. There will not be a formal retraining, but the revised MOP Version 5.0 will be

distributed to site prior to quiz administration. All sites must have all site abstractors pass the quiz by October 31, 2023. If the abstractor does not pass the quiz, they will be notified by email that they must wait at least 24 hours before taking retaking the quiz. The abstractor must pass the quiz for REDCap access.

Appendix A. PREVENT flyer/poster examples


Have you been tested for COVID-19 in the last 60 days?
COVID-19 Ag
C
T
S
If you are interested in participating in a CDC COVID surveillance study, scan the QR code or go to www.prevent-project.org
• Voluntary & Confidential
• $100 for completion of four online surveys over 6 months
• OVMC employees only
Scan To Be Contacted
PREVENT
For more information visit www.Prevent-project.org
or contact the research team at x73115 or email at OV-ProjectPrevent@dhs.lacounty.gov

Appendix B. PREVENT II Project Invitation E-mail example

Subject Heading: CDC- funded surveillance Project PREVENT Invitation
<Institutional Letterhead>

Dear <Institution> Employee,

The <Institution> is partnering with the Centers for Disease Control and Prevention (CDC) to conduct Project PREVENT. **Project PREVENT (PReventing Emerging Infections Through Vaccine EffectiveNess Testing) is evaluating the effectiveness of COVID-19 vaccines and its impact on health care providers. You were recently tested for COVID-19 and may be able to participate in this important project.**

Your participation in this project is voluntary and choosing to participate or not participate will not impact your employment or standing with <Institution>. If you are interested in learning more about the project, please click on the following link: <Link to local REDCap>
The link will take you to a screening page to see if you meet the criteria to participate in this project. If you meet the screening criteria then you will be invited into the project and asked to complete four online surveys. **You will be paid $25 by the PREVENT Project Team after completing each of the four surveys for a total of $100.** The checks will be mailed to you by the project coordinating center.

You will not be given any vaccines or other medications as part of this project. Being vaccinated is not a requirement for participating. No information about you has been given to the project team.

The initial results from this project which currently includes over 10,000 U.S. health care workers have been published in the New England Journal of Medicine (NEJM Link)

For more information, please visit w ww.prevent-project.org.

If you have any questions about the project, please contact the <Institution> project team members at <Insert contact info of site team>

Sincerely,

<Site PI>

Appendix C. Informed Consent document

Preventing Emerging Infections through Vaccine Effectiveness Testing
(Project PREVENT II)
Informed Consent

You are being asked to participate in this project, called PREVENT II, because you work in a medical center or health system and you were recently tested for COVID-19. With support from the Centers for Disease Control and Prevention (CDC), investigators at the David Geffen School of Medicine at UCLA and the University of Iowa College of Medicine are conducting surveillance at this and other U.S. hospitals to measure the effectiveness of SARS-CoV-2 vaccine boosters in preventing COVID-19 and reducing the severity and duration of illness among health care workers. We are also measuring how COVID-19 impacts returning to work activities, how long SARS-CoV-2 vaccines protect against infection and long term symptoms. You may participate whether or not you have received the COVID-19 vaccine, and you will not receive any vaccination as part of this project.

If you choose to participate, you will complete an initial survey with questions about you, why you were tested, your job, COVID-19 exposure, symptoms, and medical care. You will then complete follow-up surveys at approximately 4 weeks, 12 weeks, and 6 months from now with questions about your illness and your recovery (3 follow-up surveys in total). To compensate you for your time, you will receive $25 for each survey completed ($100 total for completing all surveys). You will receive a check after each completed survey. The first survey will take about 20 minutes to complete and each follow-up survey will take about 10-15 minutes to complete. Some participants will complete their project activities using computerized surveys, and others will complete project activities through interviews. We will also ask you or your employee health/occupational health clinic and any other health care providers you visited to provide documentation of the following:

1. Results of any recent COVID-19 testing;
2. SARS-CoV-2 Vaccination records (vaccine administration will be confirmed with employee health/occupational health records or vaccine registries regardless of vaccine status); and
3. Medical records for care related to your current/recent illness. We will use medical records, hospitalizations, emergency department visits or unscheduled walk-in/urgent care clinic visits, and illness-related clinic visits to help us know how sick you became after your COVID-19 testing.

Your data will be protected. It will be maintained in a secure database that is only accessible to the project team. After we have completed data analysis, we will remove your personal identifying information from all project documents. Only de-identified data will be shared with the Centers for Disease Control and Prevention. None of your responses will be shared with your employer. The results of this project will be published, but your name or any other personal identifying information will not appear in any reports, databases, or publications. Your participation is completely voluntary and there is no penalty for declining to participate.

Are you willing to participate in this study?

- Yes
- No

Appendix D. List of Forms

Form	Completed by	Completed when
Screening Form	Recruited employee	At least two weeks after test result
Consent Form	Participant	Immediately prior to enrollment
Contact Information	Participant	Enrollment
Baseline Survey	Participant	Enrollment through 2 weeks
Healthcare Utilization Form	Participant	Baseline and six week Follow-up Survey
Monthly check in for Clinical Trial Participants	Participants who are enrolled in a vaccine clinical trial	Monthly
Medical Record Request Form	Participant	Baseline and six week Follow-up Survey
6-week follow-up Survey	Participant	6 weeks after index symptoms or test date
12-week follow-up survey	Participant	12 weeks after index symptoms or test date
6-month follow-up survey	Participant	6 months after index symptoms or test date
Testing Verification Form	Participant/Site coordinator	TBD by DCC
Vaccine Verification Form	Participant/Site coordinator	TBD by DCC
Medical Record Verification Form	Participant/Site coordinator	TBD by DCC
LAR Documentation	Site coordinator	If proxy interview requested by participant at enrollment
Weekly Facility Form	Site coordinator	Weekly throughout recruitment

Appendix E. List of common chemotherapeutics and other immunosuppressant medications

Table 1. Common immunosuppressants

Immunosuppressants should include systemic formulations only (medications given by the following routes: oral (PO), intramuscular (IM), intravenous (IV)). For the purposes of this study, topical immunosuppressants should not be documented as they are not expected to cause clinically significant immunosuppression.

GENERIC NAME	TRADE NAME
5-FLUOROURACIL (5-FU, FLUOROURACIL)	EFUDEX, FLUOROPLEX, CARAC, ADRUCIL
6-MERCAPTOPURINE (6-MP, MERCAPTOURINE)	PURINETHOL
ACTINOMYCIN-D (DACTINOMYCIN)	COSMEGEN
ADALIMUMAB	HUMIRA
AFATINIB	GIOTRIF
ALDESLEUKIN (INTERLEUKIN-2)	PROLEUKIN
ALEMTUZUMAB	CAMPATH
ALTRETAMINE	HEXALEN
ANTI-THYMOCYTE GLOBULIN	THYMOGLOBULIN, ATG, ATGAM
ARSENIC TRIOXIDE	TRISENOX, ARSENOX
ASPARAGINASE	ERWINAZE, CRISANTASPASE, ASPARAGINASE MEDAC, CIDEROLASE, ONCASPAR, SPECTRILA
ATEZOLIZUMAB	TECENTRIQ
AXITINIB	INLYTA
AZACITIDINE	MYLOSAR, VIDAZA
BASILIXIMAB	SIMULECT
BENDAMUSTINE	TREANDA, BENDEKA
BEVACIZUMAB	AVASTIN
BEXAROTENE	TARGRETIN
BLEOMYCIN	BLEO 15K
BORTEZOMIB	VELCADE
BOSUTINIB	BOSULIF
BRENTUXIMAB VEDOTIN	ADCETRIS
BUSULFLAN	BUSULFLEX
CABAZITAXEL	JEVTANA
CAPECITABINE	XELODA
CARBOPLATIN	PARAPLAT, PARAPLATIN
CARFILZOMIB	KYPROLIS
CARMUSTINE	BICNU, GLIADEL WAFER
CERTOLIZUMAB	CIMZIA

CETUXIMAB	ERBITUX
CHLORAMBUCIL	LEUKERAN
CISPLATIN	PLATINOL, CDDP
CLOFARABINE	CLOLAR
CRIZOTINIB	XALKORI
CYCLOPHOSPHAMIDE	CLAFEN, CYTOXAN, NEOSAR
CYCLOSPORINE	NEORAL, SANDIMMUNE, GENGRAF, RESTASIS
CYTARABINE	CYTOSAR-U, TARABINE PFS
DACARBAZINE (IMIDAZOLE CARBOXAMIDE)	DTIC-DOME, DTIC, DIC
DACLIZUMAB	ZENAPAX
DACTINOMYCIN (ACTINOMYCIN)	COSMEGEN
DASATINIB	SPRYCEL
DAUNORUBICIN	CERUBIDINE, RUBIDOMYCIN
DECITABINE	DACOGEN
DENOSUMAB	XGEVA
DOCETAXEL	TAXOTERE
DOXORUBICIN	ADRIAMYCIN, DOXIL, DOX-SL, EVACET, LIPODOX, RUBEX
EPIRUBICIN	ELLENCE
ERIBULIN	HALAVEN
ETANERCEPT	ENBREL
ETOPOSIDE	TOPOSAR, VEPESID, ETOPOPHOS
EVEROLIMUS	AFINITOR
FLOXURIDINE	FUDR
FLUDARABINE	FLUDARA
FLUOROURACIL	ADRUCIL, FLUOROPLEX, CARAC. EFUDEX
GEFITINIB	IRESSA
GEMCITABINE	GEMZAR
GEMTUZUMAB OZOGAMICIN	MYLOTARG
HYDROXYCHLOROQUINE	PLAQUENIL
HYDROXYUREA	HYDREA, DROXIA
IBRITUMOMAB	ZEVALIN
IDARUBICIN	IDAMYCIN
IDELALISIB	
IFOSFAMIDE	CYFOS, IFEX
IMATINIB	GLEEVEC
IMIQUIMOD	ALDARA
INFLIXIMAB	REMICADE
INTERFERON ALFA	INTRON A, WELLFERON
IPILIMUMAB	YERVOY

IRINOTECAN	CAMPTOSAR, ONIVYDE
IXABEPILONE	IXEMPRA
LAPATINIB	TYKERB
LENALIDOMIDE	REVLIMID
LEUSTATIN	CLADRIBINE
LOMUSTINE	CEENU, CCNU, GLEOSTINE
MECHLORETHAMINE	MUSTARGEN, VALCHLOR
MELPHALAN	ALKERAN, EVOMELA
METHOTREXATE	ABITREXATE, RHEUMATREX, TREXALL, OTREXUP, RASUVO, FOLEX, MEXATE, MEXATE-AQ
MITOMYCIN	MITOSOL
MITOXANTRONE	NOVANTRONE
MUROMONAB-CD2	ORTHOCLONE OKT3
MYCOPHENOLIC ACID (MYCOPHENOLATE)	CELLCEPT, MMF, MYFORTIC
NELARABINE	ARRANON
NIVOLUMAB	OPDIVO
_OBLIMERSEN	GENASENSE
OFATUMUMAB	ARZERRA
OLAPARIB	LYNPARZA
OMACETAXINE MEPESUCCINATE	SYNRIBO
OXALIPLATIN	ELOXATIN
PACLITAXEL	TAXOL, ABRAXANE
PANITUMUMAB	VECTIBIX
PAZOPANIB HYDROCHLORIDE	VOTRIENT
PEGASPARGASE	ONCASPAR
PEGINTERFERON ALFA-2B	PEGINTRON, SYLATRON
PEMBROLIZUMAB	KEYTRUDA
PEMETREXED	ALIMTA
PERTUZUMAB	PERJETA
PRALATREXATE	FOLOTYN
PROCARBAZINE	MATULANE
REGORAFENIB	STIVARGA
RITUXIMAB	RITUXAN
ROMIDEPSIN	ISTODAX
RUXOLITINIB	JAKAFI
SIPULEUCEL-T	PROVENGE
SIROLIMUS	RAPAMYCIN, RAPAMUNE
SORAFENIB	NEXAVAR
STREPTOZOCIN	ZANOSAR

TACROLIMUS	PROGRAF, PROTOPIC, ASTAGRAF XL, AND ENVARSUS XR
TEMOZOLOMIDE	METHAZOLASTONE, TEMODAR
TEMSIROLIMUS	TORISEL
TENIPOSIDE	VUMON
THIOTEPA	THIOPLEX, TEPADINA
TOCILIZUMAB	ACTEMRA
TOPOTECAN	HYCAMTIN
TRASTUZUMAB	HERCEPTIN
TRASTUZUMAB EMTANSINE	KADCYLA OR T-DM1
VALRUBICIN	VALSTAR
VANDETANIB	CAPRELSA
VEMURAFENIB	ZELBORAF
VINBLASTINE	VELBAN, VELSAR
VINCRISTINE	VINCASAR, MARQIBO
VINORELBINE	NAVELBINE
VISMODEGIB	ERIVEDGE
VORINOSTAT	ZOLINZA

Table 2: Common chemotherapy drug regimens

Acronyms	Drug Names
5-FU/LV	Fluorouracil, Leucovorin
5-FU/LV + BV	Fluorouracil, Leucovorin, Bevacizumab
ABVD	Doxorubicin, (Adriamycin), Bleomycin, Vinblastine, Dacarbazine
ABVE-PC	Doxorubicin, (Adriamycin), Bleomycin, Vincristine, Etoposide, Prednisone, Cyclophosphamide
AC	Doxorubicin, (Adriamycin), Cyclophosphamide
AC-T	Doxorubicin (Adriamycin), Cytoxan, Taxol
ADE	Cytarabine, Daunorubicin Hydrochloride, Etoposide
BEACOPP	Cyclophosphamide, Doxorubicin, Etoposide, Procarbazine, Prednisone, Bleomycin, Vincristine
BEP	Bleomycin, Etoposide, Cisplatin
CAF	Cyclophosphamide, Doxorubicin, Fluorouracil (5FU)
CAPOX	Capecitabine, Oxaliplatin
CF	Cisplatin, Fluorouacil
CHOP	Cyclophosphamide, Doxorubicin, Prednisone, Vincristine
CHOP+R	Cyclophosphamide, Doxorubicin , Prednisone , Rituximab , Vincristine
CMF	Cyclophosphamide, Methotrexate, 5-Fluorouracil
CVP	Cyclophosphamide, Vincristine, Prednisone
DHAP	Cisplatin, Cytarabine , Dexamethasone
DI	Doxorubicin, Ifosfamide
DVD	Dexamethasone, Doxorubicin, Vincristine
EPOCH	Etoposide, Prednisone, Vincristine, Cyclophosphamide, Doxorubicin
FEC	Fluorouracil (5FU), Epirubicin, Cyclophosphamide

FOLFIRI	Fololinic acid, Fluorouracil (5FU), Irinotecan
FOLFOX	Fluorouracil, Leucovorin, Oxaliplatin
FOLFOX4+BV	Fluorouracil, Leucovorin, Oxaliplatin , Bevacizumab
FU-LV	Fluorouracil, Leucovorin
GC	Carboplatin , Gemcitabine
GEMOX	Gemcitabine , Oxaliplatin
ICE	Ifosfamide, Carboplatin, Etoposide, Mesna
MOPP	Mechlorethamine, Vincristine, Matulane, Prednisone
MTX/6-MP	Mercaptopurine , Methotrexate
MTX/6-MP/VP	Mercaptopurine , Methotrexate , Prednisone , Vincristine
MTX-CDDP/Adr	Cisplatin , Doxorubicin , Leucovorin , Methotrexate
PCB	Bevacizumab , Carboplatin , Paclitaxel
R-CHOP	Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, Prednisone
R-CVP	Rituximab, Cyclophosphamide, Vincristine, Prednisone
RICE	Carboplatin , Etoposide , Ifosfamide , Rituximab
Stanford V	Cyclophosphamide, Doxorubicin, Vinblastine, Vincristine, Bleomycin, Etoposide, Prednisone
VAMP	Vincrstine, Doxorubicin, Methotrexate, Prednisolone
VIP	Etoposide, Vinblastine, Ifosfamide, Cisplatin, Mesna
XELOX	Capecitabine, Oxaliplatin

Appendix F. PREVENT REDCap Reports

Report #	Report	Report Description	Frequency	Site Action
Participant follow-up required				
1	Consented participant contact information	The participant's contact information	As needed	Sites can access this information as needed to contact consented participants.
2	Eligible but not completed consent	The participant screened eligible but has not completed the consent	Daily	Contact potential participant. If the participant has met your site protocol for follow-up and you have been unsuccessful in contacting them, their final status on the Project Completion Tracking form should be updated to 'Refused'
3	Consented but baseline not complete	The participant has consented but has not completed the baseline	Daily	Contact potential participant per your site protocol
4	Baseline survey overdue	The participant has not completed the baseline within 7 days of consenting	Weekly	These participants should have previously been contacted as part of the protocol for the report 'consented but baseline not completed'. If the participant has met your site protocol for follow-up and you have been unsuccessful in contacting them, their final status on the Project Completion Tracking form should be updated to 'Lost to follow-up'

Report #	Report	Report Description	Frequency	Site Action
5	Baseline test upload overdue	The participant has not uploaded their test results after completing the baseline survey	Daily	Contact potential participant if it has been 2 days since they completed their survey
6	Baseline test upload overdue—contact info	The participant has not uploaded their test results after completing the baseline survey (contact info)	Daily	Contact potential participant if it has been 2 days since they completed their survey
7	Baseline vaccine upload overdue	The participant has not uploaded their vaccine documentation after completing the baseline survey	Daily	Contact potential participant if it has been 2 days since they completed their survey
8	Baseline vaccine upload overdue—contact info	The participant has not uploaded their vaccine documentation after completing the baseline survey (contact info)	Daily	Contact potential participant if it has been 2 days since they completed their survey
9	6-week follow-up survey due	The participant is due to complete their follow-up survey as it has been 6 weeks since the start of symptoms	Daily	Contact potential participant
10	6-week follow-up survey overdue	The participant has not completed the 6-week follow-up within 7 days of being eligible for survey	Daily	These participants should have previously been contacted before the last report. If the participant has met your site protocol for follow-up and you have been unsuccessful in contacting them, their final status on the Project Completion Tracking form should be updated to 'Lost to follow-up'
11	6-week follow-up test upload overdue	The participant has not uploaded their test results within 7 days of completing the 6-week follow-up survey	Daily	Contact participant
12	6-week follow-up test upload overdue—contact info	The participant has not uploaded their test results within 7 days of completing	Daily	Contact participant

Report #	Report	Report Description	Frequency	Site Action
		the 6-week follow-up survey (contact info)		
13	12-week follow-up survey due	The participant is due to complete their follow-up survey as it has been 12 weeks since the start of symptoms	Daily	Contact participant
14	12-week follow-up survey overdue	The participant has not completed the 12-week follow-up within 7 days of being eligible for survey. Contact information is provided in this report.	Daily	Contact participant
15	6-month follow-up survey due	The participant is due to complete their follow-up survey as it has been 6 months since the start of symptoms	Daily	Contact participant
16	6-month follow-up survey overdue	The participant has not completed the 6-month follow-up within 7 days of being eligible for survey Contact information is provided in this report.	Daily	Contact participant
	Medical release request needs completed by participant	The participant reported the site needs to acquire documentation for testing, vaccines or healthcare but a medical record release survey was not created	Daily	Contact participant to go back into their survey queue and complete the medical release request survey
17	Medical record release not complete	The participant has not completed the DocuSign ROI	Weekly	Contact participant about signing ROI if it has been more than 7 days since it was sent.
18	Medical record release not complete—contact info	The participant has not completed the DocuSign ROI (contact info)	Weekly	Contact participant about signing ROI if it has been more than 7 days since it was sent.
19	Medical record release overdue	The participant was sent a DocuSign ROI greater than 7 days ago	Daily	Contact participant

Report #	Report	Report Description	Frequency	Site Action
20	Medical record release overdue—contact info	The participant was sent a DocuSign ROI greater than 7 days ago (contact info)	Daily	Contact participant
21	Clinical trials participant with unknown vaccine status	A listing of PREVENT participants who are/were in a clinical trial but do not currently know their vaccination status	Weekly	This is just an FYI for sites to review weekly to see that clinical trial participants are completing their forms
22	COVID symptoms more than two weeks before COVID test	Participants who reported their symptoms began more than 14 days prior to getting tested for COVID	Daily	Contact potential participant. Update sf1463 on Project Tracking Completion tracking form on participant dashboard to document date verification. After completing sf1463, instructions are given to sites on how to proceed.
23	Completed Participants	Participants who have completed all surveys (Baseline and 3 follow-up surveys) and all required verifications are completed	NA	NA
24	Participant Project Tracking	Tracking of the participants progress throughout the project (this report only shows data for participants who have had the project tracking completion form clicked on in REDCap so only partial information is given)	NA	NA
25	Participant needs to complete HCU survey	Participant reported healthcare utilization on their baseline survey but did not complete the HCU survey at baseline	Daily	Reach out to participant asking them to go back into their survey queue and complete the healthcare utilization survey.
Medical Record Abstraction				

Report #	Report	Report Description	Frequency	Site Action
1	Medical records to request	Participant has completed ROI but medical records need to be requested	Weekly	Request medical record from healthcare facility/institution
2	Medical records requested but not received	Participants medical records were requested 7 days prior and have not been received from outside healthcare facility	Weekly	Follow-up with HCP at outside health care facility on ROI to received medical record information
3	Medical record abstractions to complete	The participant reported healthcare utilization and their medical record has been received but the healthcare utilization verification form has not been completed	Weekly	Complete healthcare utilization verification form
4	Medical record abstractions completed	Participant healthcare utilization medical record abstraction is complete		NONE—a listing for site review
5	Healthcare utilization survey completed	Participant healthcare utilization survey has been completed		NONE—a listing for site review
6	Vaccine verifications complete	Site verification of all vaccines have been completed		NONE-a listing for site review
Verifications				
1	Vaccine verifications to complete	The participant uploaded vaccine verification information, but the site verification of this information has not been completed	Weekly	Complete vaccine verification form NOTE: • If the site is responsible for obtaining this information, the participant will only show up in this report after vaccination information has been uploaded into the form in vv2257.

Report #	Report	Report Description	Frequency	Site Action
				• Verifications of COVID-19 non-vaccination will not appear in this report • If participant information is not sufficient for documentation, mark the verification form as 'no' for if the vaccine was able to be verified and then contact participant for correct information
2	Testing verification to complete	The participant uploaded testing verification information, but the site verification of this information has not been completed	Weekly	Complete testing verification form NOTE: If the site is responsible for obtaining this information, the participant will only show up in this report after testing information has been uploaded into the form in tv4729.
3	Healthcare utilizations to verify	The participant reported healthcare utilization and healthcare utilization form needs to be completed	Weekly	Complete the site abstraction portion of the healthcare utilization form
4	# of COVID tests reported at baseline	Participant reported total number of COVID tests at baseline (includes dates of test/s)	As needed	NONE-for sites to know the number of COVID test verification forms the DCC is expecting to be completed for a participant.

Report #	Report	Report Description	Frequency	Site Action
Participant Progress Tracking—This section of reports is for sites to be able to track in real time the recruitment and completion totals. No actions are required from these reports unless you believe the information to be inaccurate—if so, please reach out to the DCC.				
1	Screening report-Total	Participants who have successfully completed screening	NA	NA
2	COVID-19 Positive Testing status (self-reported) (sites)	Participant self-reported COVID-19 positive on the screening survey and completed the baseline survey	NA	NA
3	Screening report-Eligible	Participants who have screened eligible	NA	NA
4	Screening report-Ineligible	Participants who have screened ineligible	NA	NA
5	Screening report-Refused screening	Participants who refused screening	NA	NA
6	Consented	Participants who have consented	NA	NA
7	Screened eligible but refused consent	Participants who screened eligible but refused at consent	NA	NA
8	Baseline complete	Participants who have completed the baseline survey	NA	NA
9	Follow-up survey: eligible for survey	Participants who are eligible to complete their follow-up survey as it has been 6 weeks since the onset of symptoms.	NA	NA
10	6-week follow-up survey complete	Participants who have completed the 6-week follow-up survey	NA	NA
11	12-week follow-up survey complete	Participants who have completed the 12-week follow-up survey	NA	NA
12	6-month follow-up survey complete	Participants who have completed the 6-month follow-up survey	NA	NA
13	Baseline and follow-up survey complete	Participants who have completed the baseline and follow-up surveys	NA	NA
14	Lost to follow-up	Participants who have consented to the project but have not completed it within	NA	NA

Report #	Report	Report Description	Frequency	Site Action
		60 days of testing OR have been coded as lost to follow-up in the Project Tracking Completion form		
15	COVID-19 Negative Testing status (self-reported) (sites)	Participant self-reported COVID-19 negative on the screening survey and completed the baseline survey	NA	NA
16	COVID-19 Vaccination received (self-reported) (sites)	COVID-19 vaccination received as reported by participants on the baseline survey	NA	NA
17	COVID-19 Vaccination not received (self-reported) (sites)	COVID-19 vaccination not received or unknown as reported by participants on the baseline survey	NA	NA
18	Participant final status	For participants with a final status (e.g., ineligible, refused, withdrawn, complete, etc.)	NA	NA
19	Completed participants	Participants who have completed all surveys (Baseline and 3 follow-up surveys)	NA	NA

Appendix G. PREVENT Automated alerts and notifications

Baseline Not Complete: Email
This alert is sent when the baseline enrollment survey has been started but is not complete and when the contact form has been completed but the baseline enrollment survey has not been started. It is scheduled to send the following day at 8:30am. If the survey remains incomplete, the reminder will send every 2 days for a total of 3 times.

Survey Queue Link: Email
This alert sends as soon as the participant has completed the screening form. The alert contains the participant's survey queue link for future use. It will only send one time.

File Upload Link: Email
This alert is sent immediately when a participant indicates on the baseline or follow-up survey that they will upload test/vaccine verification documents at a later time. Alert contains the survey queue link and will only send once.

Follow-up: Email
This alert is scheduled to send at 8:30am CST 42 days after the date symptoms started. This email contains the link to the follow-up survey. If the survey remains incomplete, the reminder will send every 2 days for a total of 3 times.

Follow-up: Text
This text alert will send at 8:30am CST 42 days after the date symptoms started. The text includes the link to the follow-up survey. It will only send one time.

Follow-up Not complete: Email
This alert is sent when the follow-up survey has been started but not completed. It is scheduled to send the following day at 8:30am CST. If the survey remains incomplete, the reminder will send every 2 days for a total of 3 times.

Clinical Trial Check-in: Email
When a participant indicates that they have participated in a vaccine clinical trial and do not know which arm they were in (placebo vs active vaccine), they will be asked to complete an update every 30 days until they have been informed of their assignment. For the participants that meet this criteria, this alert will send every 30 days at 8:30am CST (for a maximum of 12 months) until they indicate that they know their clinical trial assignment. The email will include the link to the appropriate monthly check in. If the survey remains incomplete, the reminder will send every 2 days for a total of 3 times.

Clinical Trial Check-in: Text
When a participant indicates that they have participated in a vaccine clinical trial and do not know which arm they were in (placebo vs active vaccine), they will be asked to complete an update every 30 days until they have been informed of their assignment. For the participants that meet this criterion, this text will send at 8:30am CST every 30 days (for a maximum of 12

months) until they indicate that they know their clinical trial assignment. The text will include the link to the appropriate

Completion of survey: Email

After completion of each survey, participants will receive a confirmation email that they have completed the survey.