All Site Call: DCC REDCap Training

September 29, 2022

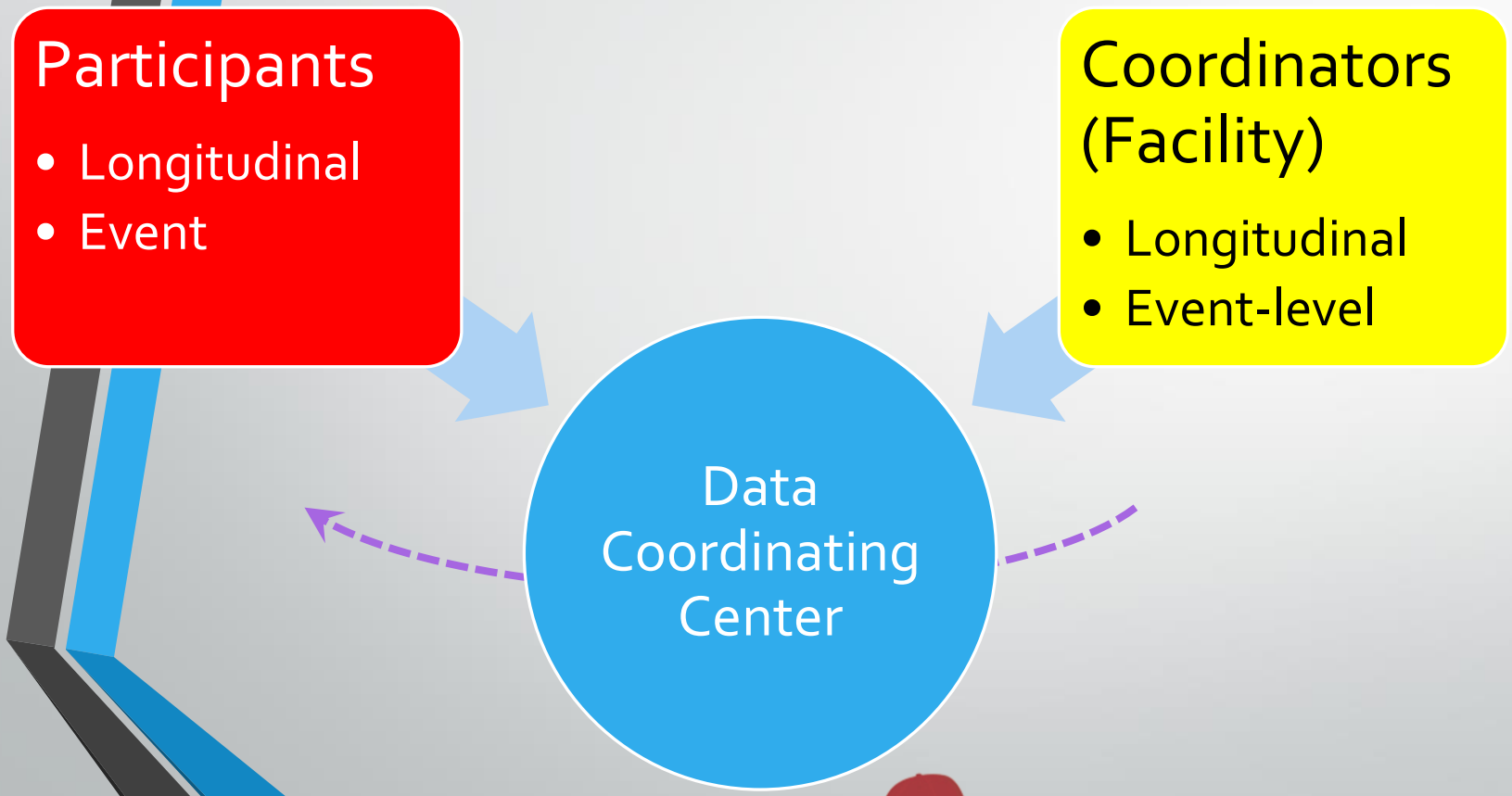
11am PT/2pm ET

Please mute when not speaking!

Objectives

- Data overview for PREVENT
- Participant forms & follow-up
- Site forms
- Queries

Data Overview



Role of Local Project Coordinator

- Enter facility-level longitudinal data
- Invite participants
- Track participant form completion
  - Baseline & Follow-up Surveys
  - Uploading of event (test and vaccine) data
- Complete verification of event data (vaccine, testing and healthcare utilization)

REDCap
Research Electronic Data Capture

PREVENT

Data collection

Participant

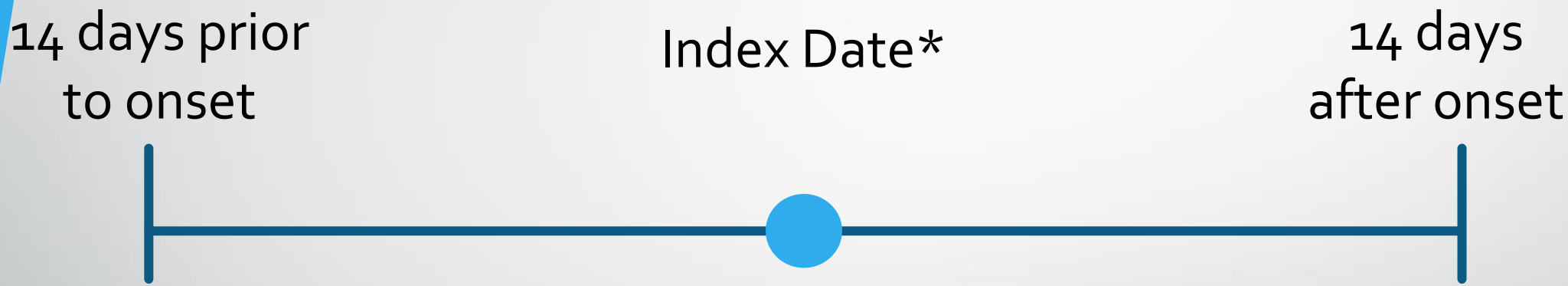
- Baseline Survey
  - -Participant is considered enrolled at baseline completion
- Follow-up Surveys
  - - 6 weeks, 12 weeks and 6 months after index date
  - - email and text reminders
- Compensation by check **from University of Iowa** $25/survey
- Can be done by interview or proxy

Site Team

- Weekly facility form
- Test results verification
- Vaccination results verification
- Health care utilization/medical records verification

PREVENT

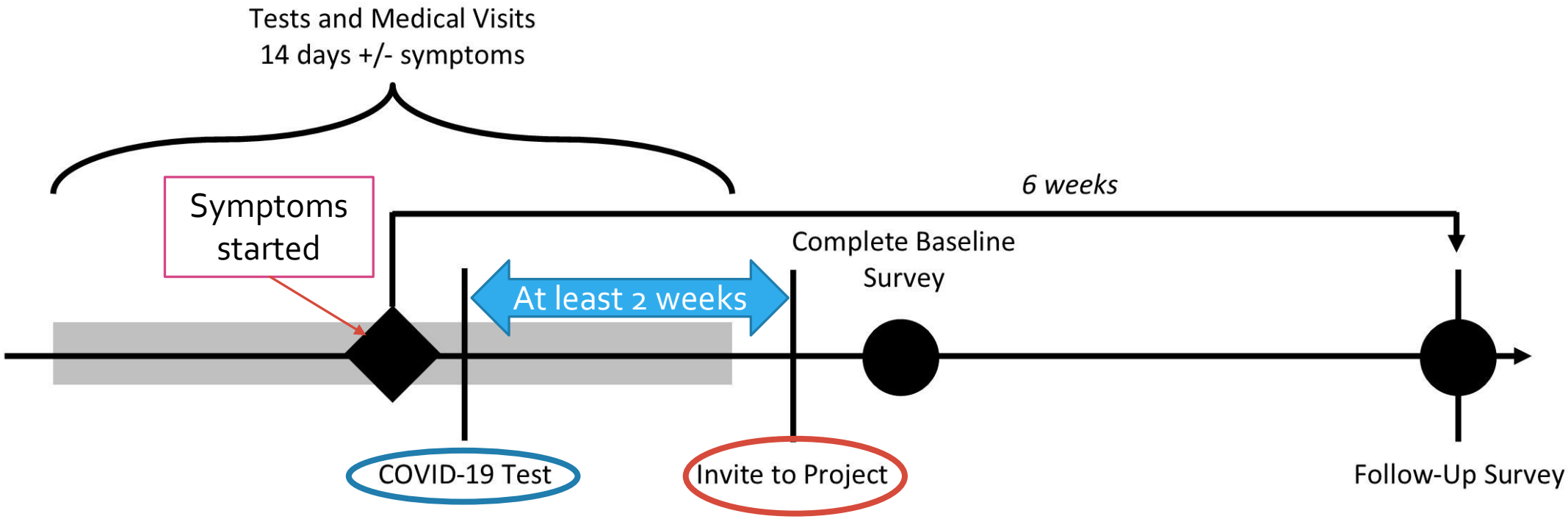
PREVENT II Index Date



***Index Date Definition**

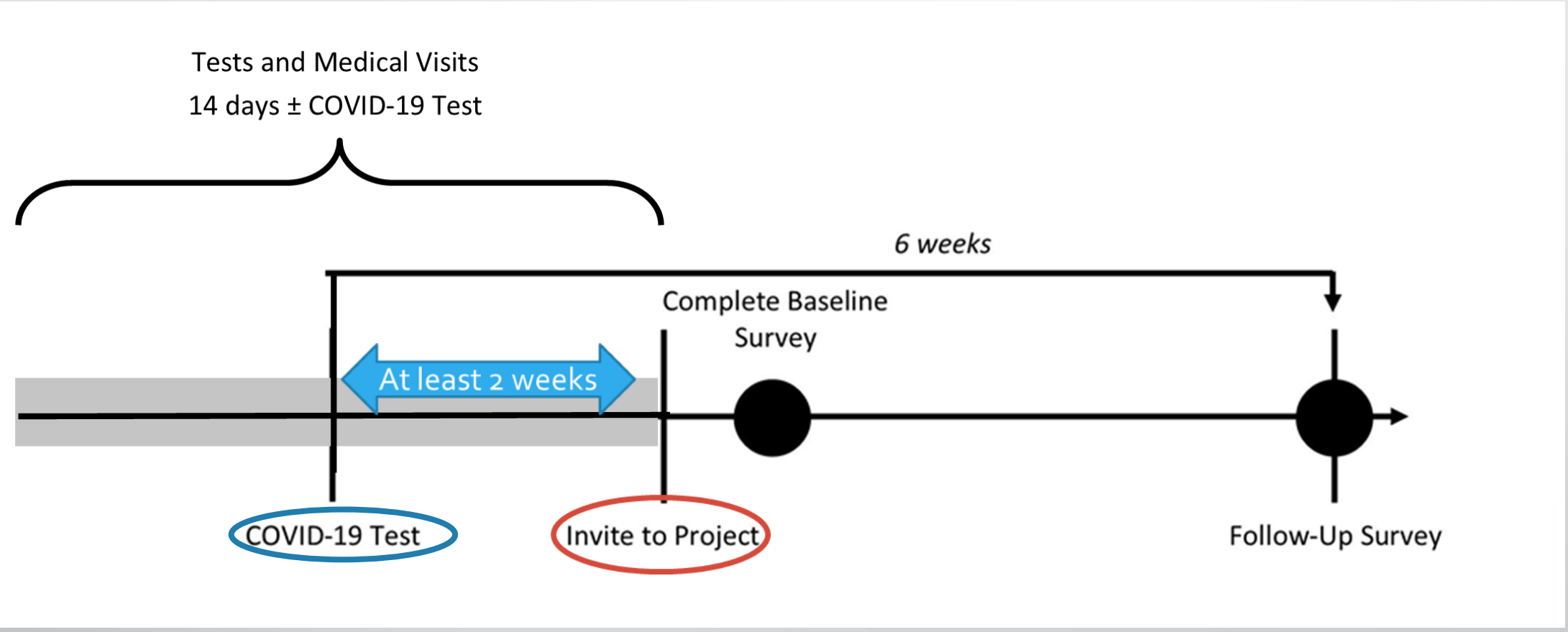
1. Start of symptoms (symptomatic cases and controls)
2. Index test (asymptomatic controls)

Data collection timeline-symptomatic



12-week and 6-surveys sent based on symptom start date

Data collection timeline-asymptomatic



12-week and 6-surveys sent based on COVID Index test date

PREVENT

PREVENT Survey Queue

- All surveys live within the project survey queue
- For a participant to enter the queue they must enter the first name, last name and date of birth as they entered it on the screening form
- The survey queue link is a unique link per participant and can be found on the 'Project Completion Tracking' form

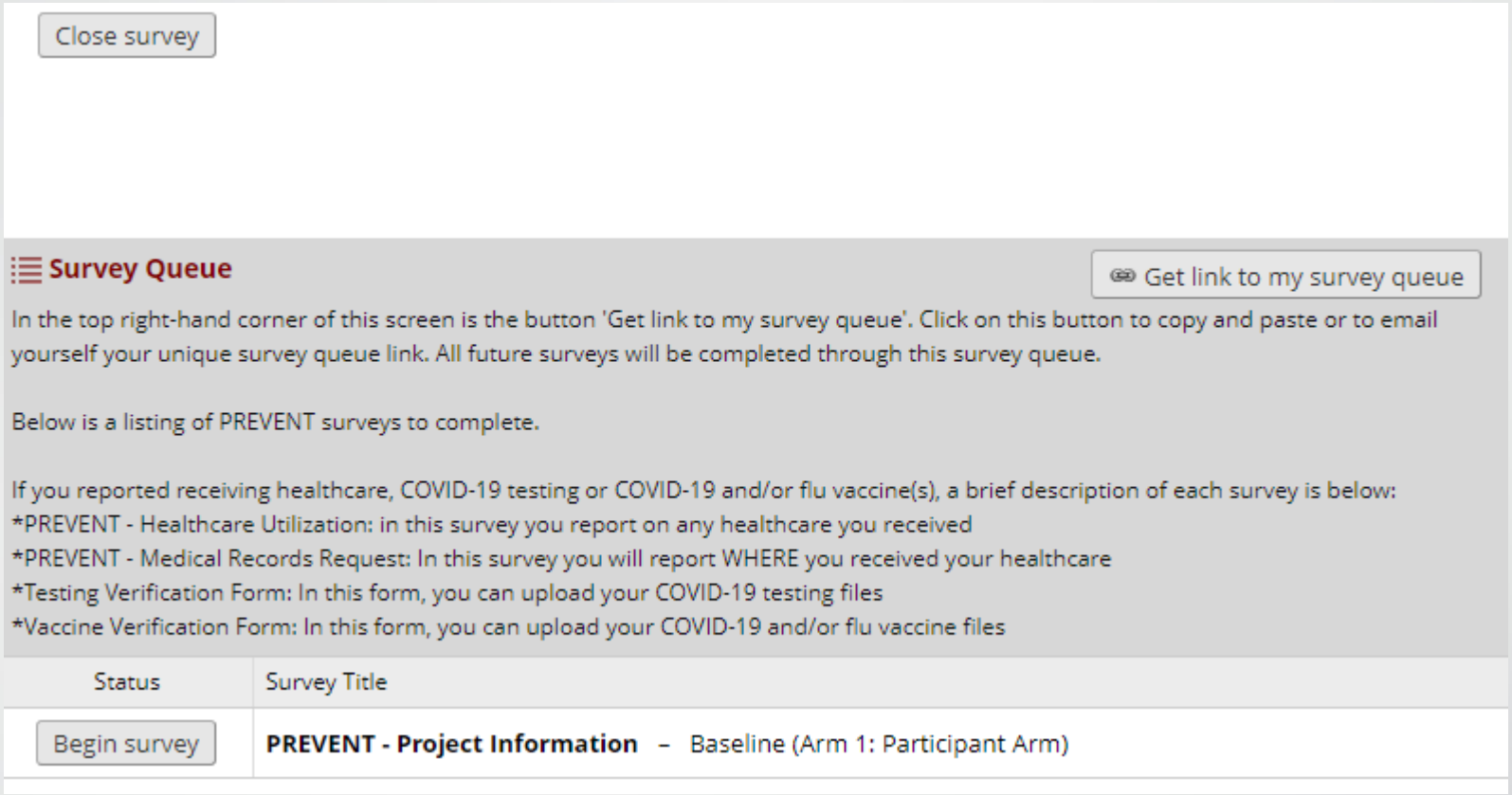
Eligible

↓

Survey Queue

↓

Consent document



Eligible

↓

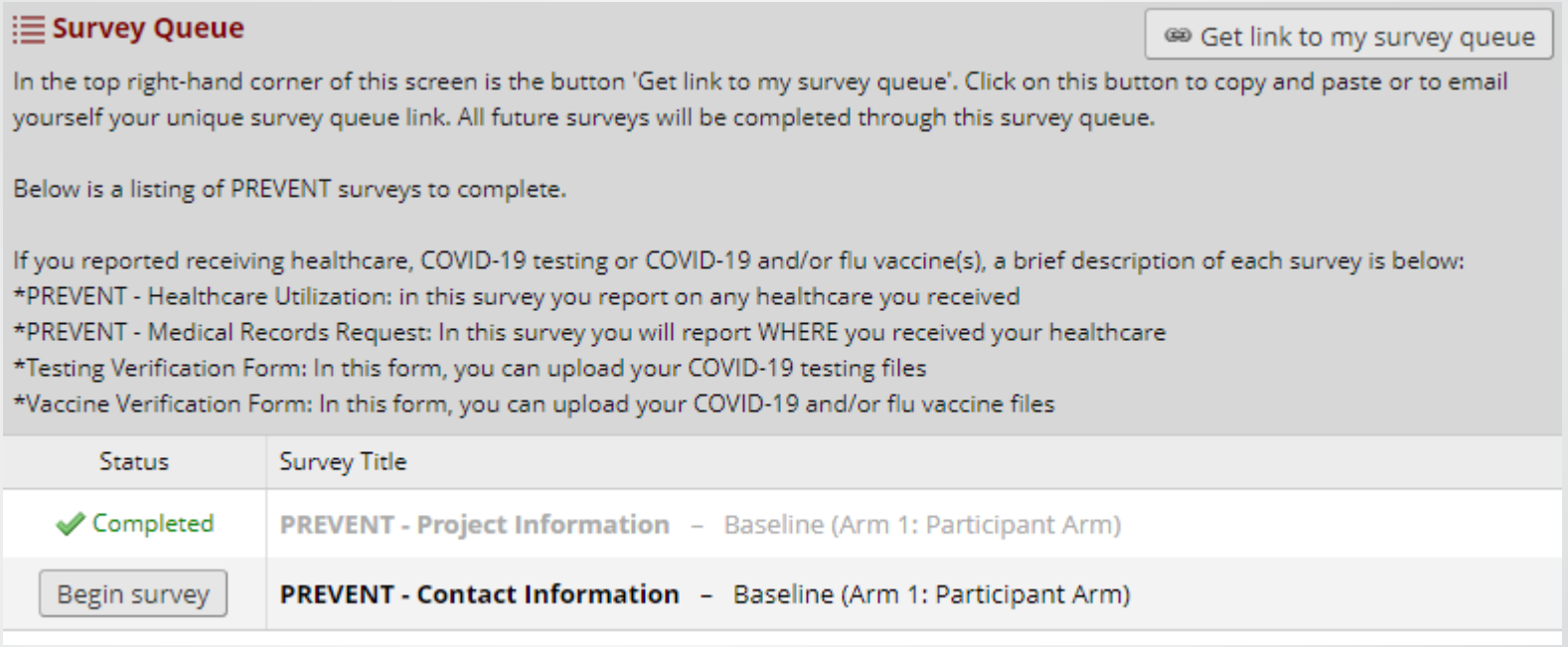
Survey Queue

↓

Consent document

↓

Contact Information



PREVENT

Eligible

↓

Survey Queue

↓

Consent document

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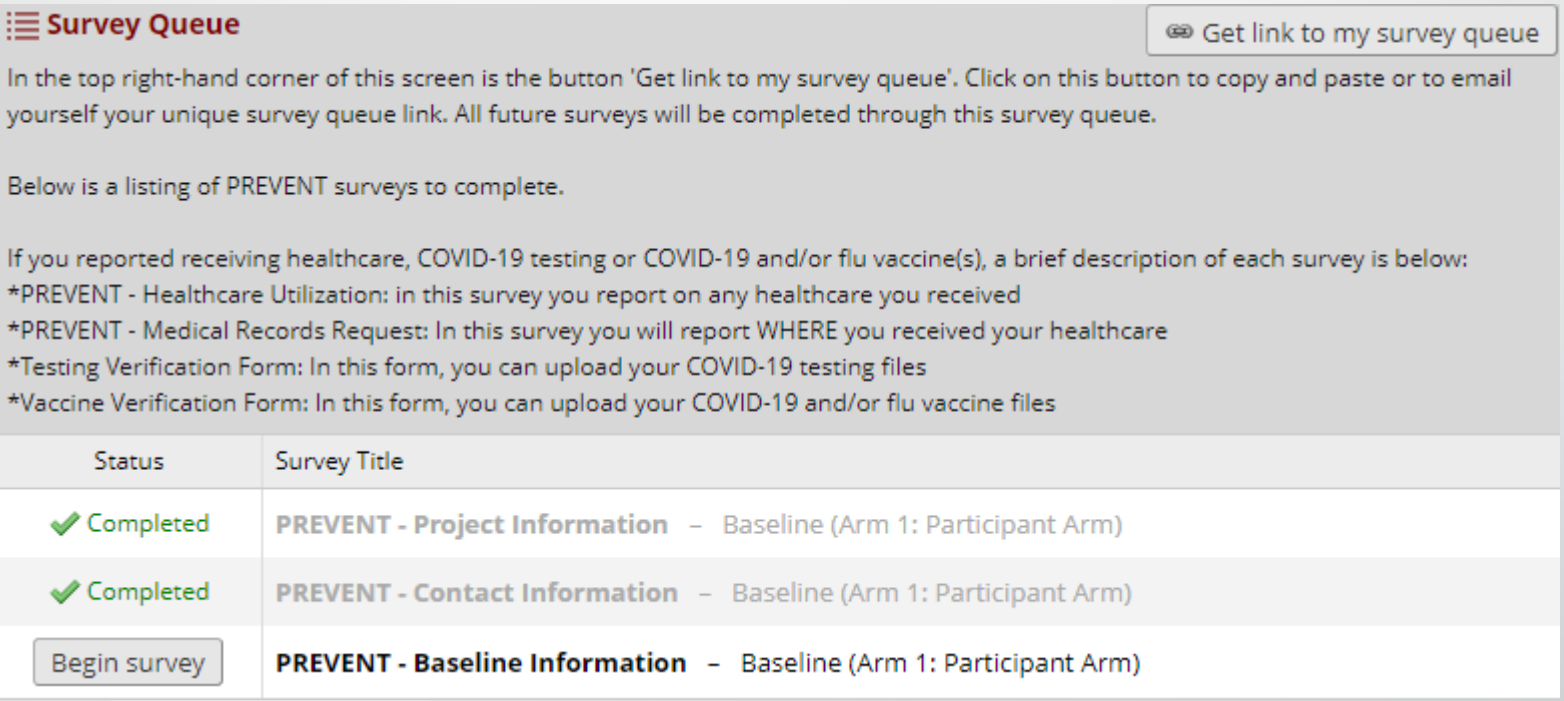
Contact Information

↓

Baseline Information



Survey Queue

Get link to my survey queue

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.

Below is a listing of PREVENT surveys to complete.

If you reported receiving healthcare, COVID-19 testing or COVID-19 and/or flu vaccine(s), a brief description of each survey is below:
*PREVENT - Healthcare Utilization: in this survey you report on any healthcare you received
*PREVENT - Medical Records Request: In this survey you will report WHERE you received your healthcare
*Testing Verification Form: In this form, you can upload your COVID-19 testing files
*Vaccine Verification Form: In this form, you can upload your COVID-19 and/or flu vaccine files

Status	Survey Title
✔ Completed	**PREVENT - Project Information** – Baseline (Arm 1: Participant Arm)
✔ Completed	**PREVENT - Contact Information** – Baseline (Arm 1: Participant Arm)
Begin survey	**PREVENT - Baseline Information** – Baseline (Arm 1: Participant Arm)

PREVENT

Eligible

Survey Queue

Consent document

Contact Information

Baseline Information

Healthcare

Vaccinations

Testing

Healthcare

Begin survey	**PREVENT - Healthcare Utilization** – Baseline (Arm 1: Participant Arm) – #1
Begin survey	**PREVENT - Medical Record Requests** – Baseline (Arm 1: Participant Arm) – #1
Begin survey	**PREVENT - Testing Verification Form** – Baseline (Arm 1: Participant Arm) – #1
Begin survey	**PREVENT - Vaccine Verification Form** – Baseline (Arm 1: Participant Arm) – #1

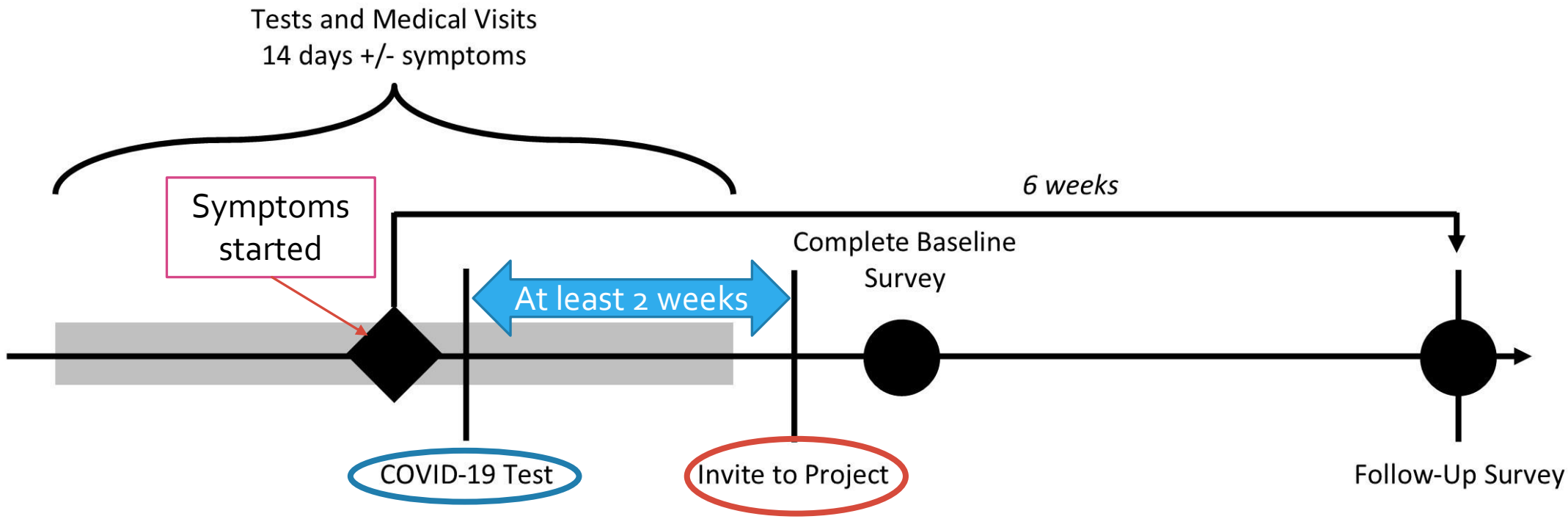
PREVENT

Medical Record Requests

- Medical Record Requests form collect data for DocuSign
  - REDCap sends necessary information to DocuSign when the REDCap request form is completed
  - DocuSign sends back to REDCap when ROI envelope is
    - Sent
    - Opened
    - Refused
    - Signed
      - Signed ROI pdf
  - NEW to PREVENT II: 10-minute delay for envelope to be sent, voiding unsigned envelopes when a new envelope is sent for the same participant

PREVENT

Data collection timeline-symptomatic



12-week and 6-surveys sent based on symptom start date

PREVENT

6-weeks follow-up survey

- Email and text message at 6-weeks post index date
  - Both include link to survey queue
    - Reminder at 2- and 4- days after first email if not started or in-progress
  - Content
    - Further testing/healthcare utilization up to 14 days post index date
    - 2nd booster vaccine acceptance, effects on work
    - Symptoms at 6-weeks

PREVENT

12-weeks follow-up survey

- Email and text message at 12-weeks post index date
  - Both include link to survey queue
    - Reminder at 2- and 4- days after first email if not started or in-progress
  - Only baseline survey is required to be completed for 12-week survey to be sent
  - Content
    - Continued symptoms at 12-weeks
      - Disruption of work
    - Healthcare between 6-weeks post index date and 12 weeks post index date (does not require verification)
    - COVID-19 vaccines received since baseline survey (does not require verification)

PREVENT

6-month follow-up survey

- Email and text message at 6-month post index date
  - Both include link to survey queue
    - Reminder at 2- and 4- days after first email if not started or in-progress
  - Only baseline survey is required to be completed for 6-month survey to be sent
  - Content
    - Current symptoms
      - Disruption of work
    - Positive COVID tests since 12-weeks post index date (does not require verification)
    - Healthcare between 12-weeks post index date and 6-month post index date (does not require verification)
    - COVID-19 vaccines received since baseline survey (does not require verification)

PREVENT

Participant Interviews

Screening form interview

- Use the unique site link provided by the DCC
- Read the questions as written
- Record participant's email
  - Used for all project communication including the release of information forms sent by DocuSign
- If eligible, will auto-continue to the survey queue for completion of the consent document.

Verbal Consent

- Read in its entirety to the participant
  - This consent document will cover both participation and data release permission for vaccine, testing, and medical records.
- The interviewer must complete the "LAR Documentation" form in REDCap. This documentation is available for both the baseline and all follow-up surveys.
- The consent will auto-continue to the survey queue for the completion of the baseline survey.

Baseline Enrollment & Follow-up Surveys

- Survey queue
  - Use URL in 'Project Tracking Completion' form
  - Enter participants first name, last name, and date of birth
  - Read questions as written

Proxy interviews

- Only if potential participant is unable to complete interview (may be for any form), still requires participant or LAR consent
- Proxy interviews will be completed by interview protocol developed for interviewing the participant.

Tracking participant progress

Reports

- Participant Follow-up
  1) Consented participant contact information
  2) Eligible but not completed consent
  3) Consented but baseline not complete
  4) Baseline survey overdue
  5) Baseline test upload overdue
  6) Baseline test upload overdue--contact info
  7) Baseline vaccine upload overdue
  8) Baseline vaccine upload overdue--contact info
  9) 6 week follow-up survey due
  10) 6 week follow-up survey overdue
  11) 6 week follow-up test upload overdue
  12) 6 week follow-up test upload overdue--contact info
  13) 12 week follow-up survey due
  14) 12-week follow-up survey overdue
  15) 6 month follow-up survey due
  16) 6 month follow-up survey overdue
  17) Medical record release not complete
  18) Medical record release not complete--contact info
  19) Medical record release overdue
  20) Medical record release overdue-contact info
  21) Clinical trial participants with unknown vaccine status
  22) COVID symptoms more than two weeks before COVID test
  23) Completed Participants
  24) Participant Project Tracking

Dashboards

- Active participants
- Activities this week
- Baseline overdue
- Completed participants
- Eligible participants
- Facility Forms
- Follow-up overdue
- Medical record release overdue
- Medical record requested but not received
- Medical records abstractions to complete
- Medical records to request
- Screened participants
- Screened participants-sorted by last name
- Testing verifications to complete
- Vaccine verifications to complete

Are the dashboards used by sites?

Site REDCap forms

Healthcare Utilization, Vaccine & Testing Verification

- Verification built within participant forms
  - Avoids probabilistic linkage
  - Verification elements are only seen in data entry mode for baseline and 6-week survey
  - Click ‘edit response’ at top of form

“To-do” Reports

- Medical Record Abstraction
  1) Medical records to request
  2) Medical records requested but not received
  3) Medical record abstractions to complete
  4) Medical record abstractions completed
  5) Healthcare utilization survey completed
  6) Vaccine verifications complete
- Verifications
  1) Vaccine verifications to complete
  2) Testing verifications to complete
  3) Healthcare utilizations to verify

PREVENT

“To-do” Reports cont.

- Medical records to request
  - Signed ROI received from DocuSign but no documentation of chart request
- Medical records requested but not received
  - Medical records requested but not received within 7 days
- Medical records abstractions to complete
  - Medical records have been received but have yet to be abstracted
- Vaccine verification
  - COVID-19 vaccine documentation uploaded by participant or provide by medical records but not yet abstracted
- Testing verification
  - COVID-19 testing documentation uploaded by participant or provided by medical records but not yet abstracted

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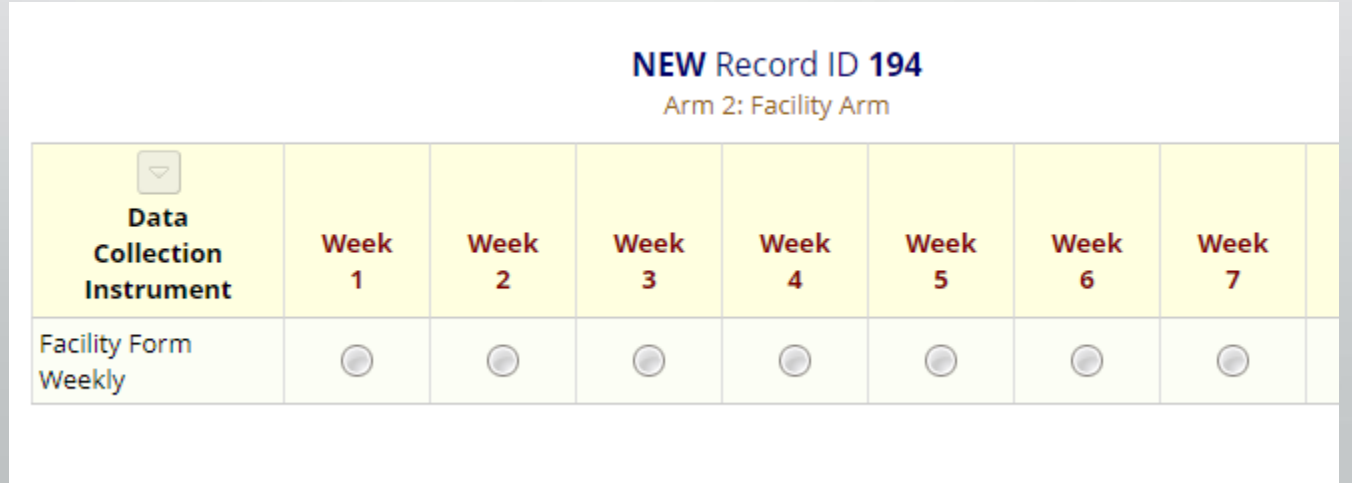
Project Progress

- Project Progress Tracking
  1) Screening report-Total
  2) COVID-19 Positive Testing status (self-reported) (sites)
  3) Screening report-Eligible
  4) Screening report-Ineligible
  5) Screening report-Refused screening
  6) Consented
  7) Screened eligible but refused consent
  8) Baseline complete
  9) Follow-up survey: eligible for survey
  10) 6 week survey complete
  11) 12 week survey complete
  12) 6 month survey complete
  13) Baseline and Follow-up Survey Complete
  14) Lost to follow-up
  15) COVID-19 Negative Testing status (self-reported) (sites)
  16) COVID-19 Vaccination received (self-reported) (sites)
  17) COVID-19 Vaccination not received (self-reported) (sites)
  18) Participant final status
  19) Completed participants

PREVENT

Weekly Facility Forms

- Go to 'Facility Forms' Dashboard
- Click on + Add new record for this arm to complete your first facility form.
- For each subsequent form, click on the week you wish to enter data
- Facility forms are due each Thursday for the previous calendar week



PREVENT

Data reports sent via e-mail

Data queries

- REDCap cannot complete all the necessary calculations needed for data cleaning or the creation of "to-do" lists, so the data is exported bi-weekly for additional data checks in SAS
- These queries are emailed from the DCC project e-mail (EmergencyIDNet-PREVENT@uiowa.edu) as excel attachments

Site Queries

- Query
  - Single row per participant that states what is missing (testing, vaccine or HCU verification) for that participant
- HCU verifications
- Testing verifications
- Vaccine verifications

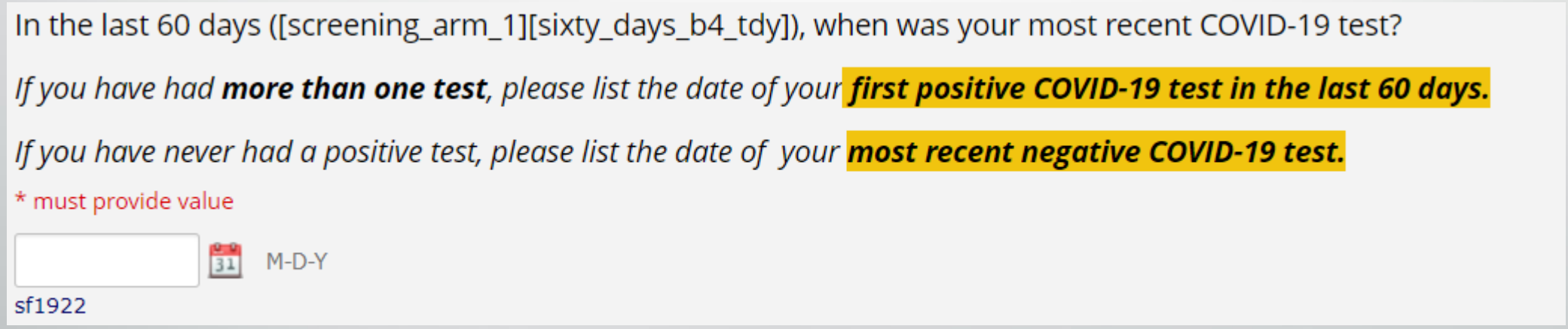
Query divided into only the participants who need this verification completed

Example Query

- training_example_query_092622.xlsx

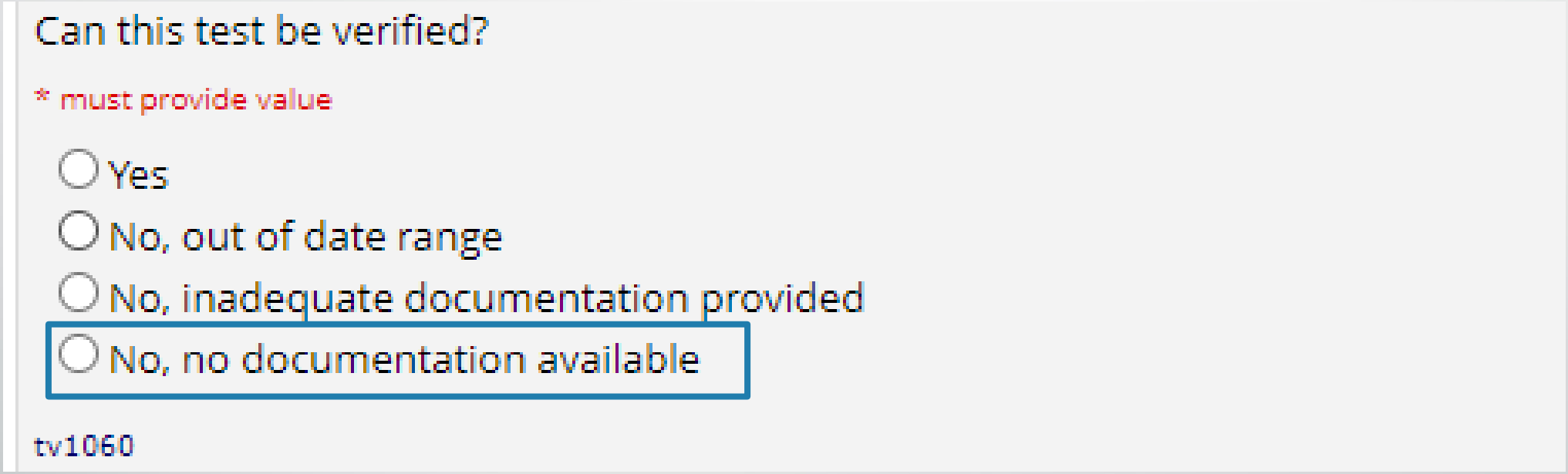
COVID Index Test Date ± 1 Day

- CDC requires attempted verification of a COVID-19 test within ± 1 day index test date (sf1922)



COVID Index Test Date ± 1 Day

- If COVID Index Test Date is unable to be verified and marked as



The participant will be removed this report

COVID Index Test Date ± 1 Day Example

- example_cov_test_gt1_061322.xlsx

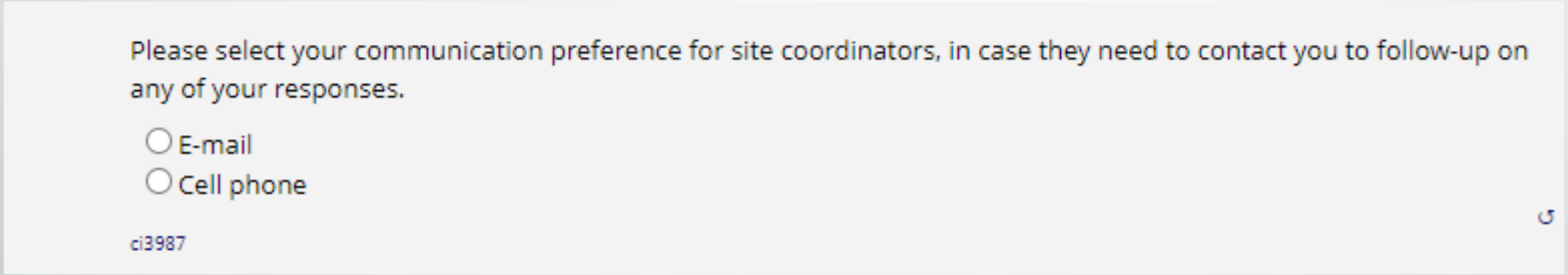
PREVENT II REDCap access

- If you were given a HawkID and password for PREVENT 1, it will be the same log in information
- For new team members, a HawkID has to be requested by the DCC.
  - After the DCC request is sent, the team member will be sent an email for ITS@uiowa.edu to create their HawkID
  - Once the participant has completed the HawkID process, go to redcap.uiowa.edu and log-in
    - You will NOT see the PREVENT II database
  - After the team member has logged into redcap, email the DCC and the team member will be added to the PREVENT II database

These instructions have been previously emailed to all team members by Kelli Wallace

Troubleshooting

How do I report an issue with a survey item?



- QUESTIONS are identified by an alphanumeric identifier.
- Report this item number to the DCC for troubleshooting. In the example above, the item # is ci3987

PREVENT

Case Report Form problems

Contact the DCC by e-mail for any PREVENT REDCap related problems

- DCC technical support hours 8a-5p CST M-F
- Do NOT contact U of Iowa ICTS unless instructed to by DCC

Participant Compensation Questions

- Contact the DCC by e-mail for all participant compensation related concerns
- Stress to participants that the payment will come by check from the University of Iowa
- Do NOT have the participant contact UIowa purchasing
- There is an approximate 1–2-week lag from when a survey is completed and when the compensation is requested and mailed.

REDCap System Improvements
Since PREVENT

- Date verification
  - Force a minimum and maximum date to allow for cleaner data at collection
    - Min or max date can be another variable date field
      - Ensure COVID index test date must be within 60 days of date of screener
- Automated "cleaning" of project dashboard for records where a screener has been started but never completed for increased database efficiency.

Questions