C-STRAND – COVID Self-Testing through Rapid Network Distribution

This Protocol is created by the Clinical Trial investigators and the Clinical Research Computing Unit for C-STRAND. The purpose of this document is to detail procedures necessary to complete the Case Report Forms and provide an overview of the data flow. This manual is intended to convey instructions for the collection of data so that it may be entered into the data management system.

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Created by:
Cedric Bien-Gund, MD
Clinical Trial Director
Division of Infectious Diseases
Perelman School of Medicine
University of Pennsylvania, PA
Cedric.bien-gund@pennmedicine.upenn.edu

Robert Gross, MD MSCE
Principal Investigator
Division of Infectious Diseases
Perelman School of Medicine
University of Pennsylvania, PA

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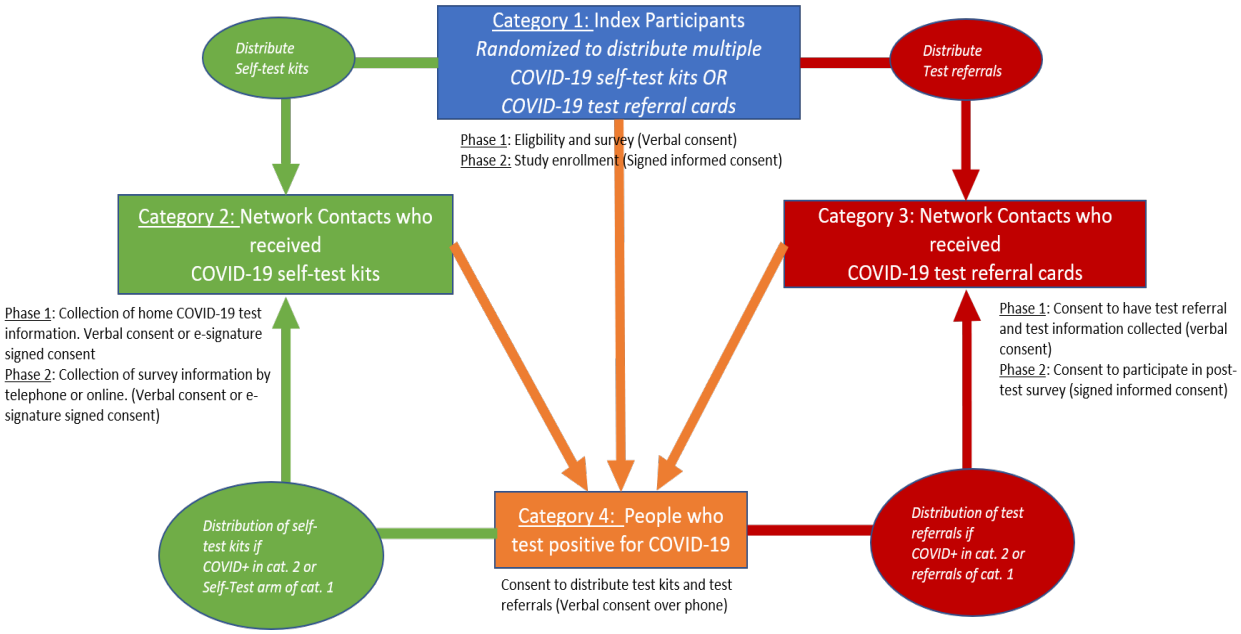
Overview of study:

Widespread testing and contact tracing are critical to controlling the COVID-19 epidemic. One promising approach to increase test uptake is the secondary distribution of self-tests, where an individual distributes test kits to contacts in their social network and encourages them to self-test. We will conduct a 1:1 randomized controlled trial randomizing individuals to receive either *multiple* self-test kits to distribute within their social circles, or referrals for standard clinic-based tests.

We will recruit individuals seeking COVID-19 testing or presenting to PHMC clinic sites for other types of appointments and randomize them to receive either *multiple* (1) home test kits or (2) clinic test referrals to encourage people in their social networks to get tested. Individuals who distribute test kits or test referrals will be designated "Index Participants," or Category 1 participants. Individuals who receive test kits or test referrals from Index Participants are called "Network Contacts." Network Contacts are divided into two categories based on what test distribution method they received: Category 2 if they received home test kits, and Category 3 if they received clinic test referrals. Our primary outcome of interest is to see which strategy (home test kits or clinic test referrals) got more Network Contacts to obtain testing within 8 weeks of the Index Participant getting tested.

Anyone in the study who tests positive for COVID-19 as part of the study (both Index Participants and Network Contacts) will be eligible for the CloseST study: a cohort study of individuals with COVID-19 infection. They will be offered additional test kits or clinic test referrals based on which study arm they were initially assigned. They will then be encouraged to get their close contacts tested as well. After the transition to Ellume test kits (planned for the start of December, 2021), we will no longer be able to monitor test results from self-testers. Self-testers who test positive must contact study staff to be enrolled in the study.

Figure 1: Overall study plan:



Study Sites:
This study will be conducted at three clinic sites across Philadelphia in the Public Health Management Corporation network.

PHMC Care Clinic – FQHC that focuses on serving people with HIV, viral hepatitis, and substance use disorders. Currently this study site provides COVID-19 testing mostly by appointment. Some walk-ins are allowed.

1200 Callowhill St
Philadelphia, PA 19123

Congreso Health Center – FQHC that provides primary care to predominately Spanish-speaking population in North Philadelphia. Currently this study site provides outdoor COVID-19 testing by appointment only. Staff are expected to be fluent in Spanish and English.
[INACTIVE STUDY SITE]
412 W Lehigh Avenue
Philadelphia, PA 19133

Health Connection – FQHC

1900 N 9th St
Philadelphia, PA 19122

Rising Sun – FQHC

5675 North Front Street
Philadelphia, PA 19120

Mary Howard Health Center For The Homeless – FQHC that focuses on providing care to people who are experiencing homelessness. There is currently no study Interviewer carrying out recruitment activities at this clinic.
[INACTIVE STUDY SITE]

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Manual of Procedures (MOP) is broken up into the following sections:

OVERVIEW OF STUDY

Trial Design
The C-STRAND study is a 1:1 randomized control trial randomizing participants to receive either multiple self-collection test kits or multiple referrals for clinic-based tests to distribute within their social networks. These individuals, called *Index Participants*, will be encouraged to distribute self-collection test kits or test referral cards to others in their social networks, called *Network Contacts*. Network Contacts can include household members, friends, family, colleagues, or others in Index Participants' social networks. We will evaluate COVID-19 test uptake among Network Contacts.

To achieve our second aim, the CloseST study is a cohort study of both index participants and network contacts diagnosed with COVID-19 from the C-STRAND trial. Participants will then receive additional self-collection test kits or referrals for clinic-based tests to distribute to close contacts, based on their treatment assignment group from the C-STRAND trial. We will compare test uptake among close contacts of individuals with COVID-19.

Allocation
In the C-STRAND trial, we will use permuted block randomization with varying block sizes stratified by study site to assign Index Participants to receive multiple self-collection test kits or multiple referral cards for standard clinic-based tests. Investigators will have access to arm assignment on a need-to-know basis only, but participants and research assistants will not be masked with respect to study arm.
For the CloseST study, Index Participants and Network Contacts who test positive will be assigned to the intervention arm (receiving multiple self-collection test kits) or control arm (test referrals) according to their original assigned arm in the C-STRAND trial.

Intervention

Secondary distribution of COVID-19 self-collection test kits

Index Participants will receive five COVID-19 self-collection test kits at study enrollment to distribute to Network Contacts. Participants will be encouraged to distribute the test kits to individuals in their social network who are symptomatic, have a known exposure to COVID-19, or are otherwise perceived to be at high risk for COVID-19 due to potential exposures. Test kits will have a link to a study website which will guide test-takers through an online informed consent page and then onto a questionnaire. The participant will be provided a tutorial, list of drop-off sites and phone number to provide further assistance. Each individual will be offered follow-up care and counseling. Index participants will be asked to complete an online follow-up survey after 8 weeks.

Self-Collection Test Kits

The intervention will use COVID-19 self- collection PCR test kits that have been authorized under FDA Emergency Use Authorization. Test kits use a mid-nasal swab that is sent to a central lab, with results returning in 24 to 48 hours. Each kit includes a test swab, test tube, a prepaid return shipping envelope, and instruction sheet in English and Spanish.

December 2021 Update:
As of December 2021, the intervention will use Ellume rapid antigen tests (Ellume COVID-19 home test, Ellume Health, Brisbane, Australia) authorized under EUA. The antigen kits will use a Bluetooth-enabled test developer device, with test results only available through a smartphone app connected to the device. Test kit packages will include a study QR code linking the test kit to the index participant. If the network contact clicked the study QR code, test results were then reported to a secure web-based study portal.

Registration of test kits

Test kits must be registered online on the study website, and participants must consent to participate in the study to activate the test kits. Participants must provide a name, date of birth, and phone number to register test kits. If participants do not have access to the Internet, they may call study hotline and study personnel will obtain informed consent and register the individual online.

Control

Secondary distribution of COVID-19 test referrals

After confirming eligibility and completing informed consent, individuals in the control arm will complete a baseline survey. Thereafter, they will receive five test referral cards at study enrollment to offer free, facility-based COVID-19 testing at clinic sites for their network contacts. Participants will be encouraged to distribute referrals to individuals in their social network who are symptomatic, have a known exposure to COVID-19, or are otherwise at high risk for COVID-19 due to potential exposures. Each referral card will be assigned a unique referral number associated with the index participant. The index participant will be provided a text message with instructions that can be disseminated to his social network along with the referral cards. Test results will be released via phone call by study staff, and a paper or electronic copy of test results will be available upon request. Consistent with public health authority guidelines, multiple efforts will be made to contact participants with positive results. Each individual will be offered follow-up care and counseling. Index participants will be asked to complete an online follow-up survey after 8 weeks.

Follow-Up

Index participants and network contacts who test positive for SARS-CoV-2 and provide verbal informed consent for the cohort study will have baseline surveys completed online or through phone. Index participants and network contacts from the treatment arm (exposed group) will be offered 3 additional self-collection test kits to distribute to close contacts. Index participants and network contacts from the control arm (unexposed group) will be offered 3 additional test referral cards to be distributed to close contacts. Test results will be released via phone call by PHMC staff. Each individual will be offered follow-up care and counseling by clinical providers of PHMC.

Measuring COVID-19 test uptake

In order to link Network Contacts who obtain COVID-19 tests to Index Participants, each Index Participant will be assigned a Referral Identification (ID) number. This number will appear on all test referral cards and text messages in the control group, and on test kits in the intervention group. When network contacts request testing, they will be asked to provide the Referral ID number linking them to the Index Participant. We will measure test uptake among self-testers through testing completed at the partner self-testing lab. Among facility-based testers, test uptake will be measured through testing at one of the clinic sites. Study personnel will communicate all test results back to study participants via telephone, with an electronic copy of test results available upon request.

Outcomes

The primary outcome in the C-STRAND trial is the proportion of Index study participants linked to at least two Network Contacts who completed testing. Secondary outcomes at the end of the follow-up (week 8) and end of the study by each arm include: number of contacts tested, number of network contacts who test positive, test positivity rate and proportion of first-time test takers. All of these outcomes will be assessed with collected testing results and not rely on self-reported measures. Baseline and follow-up surveys will provide self-reported outcomes related to socio-demographic characteristics as well as COVID-19 exposure, symptoms, testing, and vaccine acceptance.

For the CloseST study, the primary outcome is the number of close contacts who test positive in each group. Secondary outcomes at the end of the follow-up (week 8) by each group, include number of contacts tested and number of new cases identified. Similarly, baseline surveys of network contacts in the cohort study will provide similar self-reported outcomes as in aim 1.

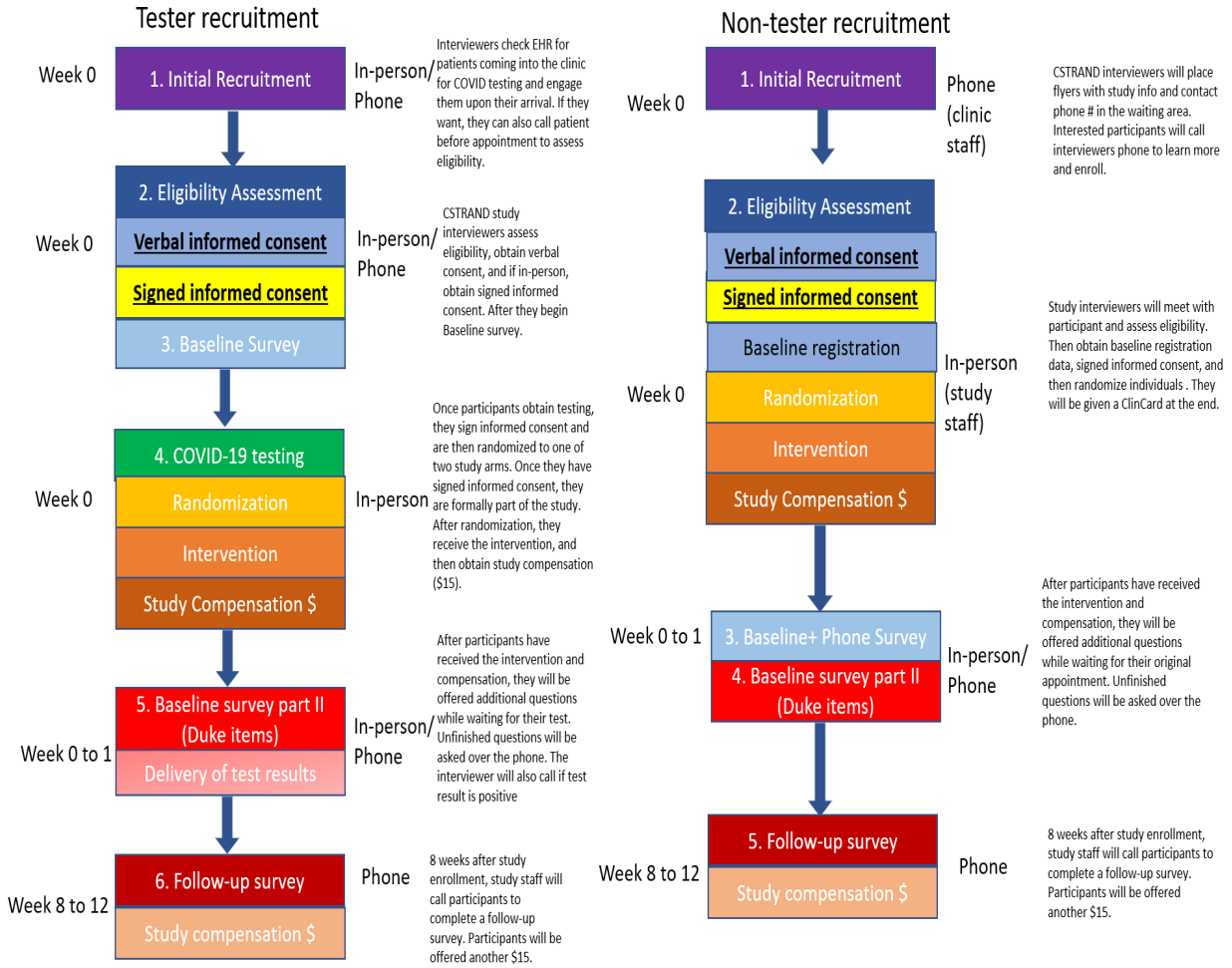
INDEX PARTICIPANTS

Index participants are the study participants that we are enrolling in our primary study. They are adults who are seeking care at one of the three PHMC sites, and we are aiming to recruit them to then distribute home test kits or clinic test referrals to their contacts.

We will recruit Index Participants both A) Over the phone, by calling patients scheduled for COVID testing prior to their appointment, and B), In-person, for individuals over 18 either receiving COVID testing at participating clinic sites ("testers") or coming in for other medical appointments ("non-testers"). See Figure 2 below.

In September 2021, we expanded eligibility to no longer require COVID-19 testing to be enrolled in the study. People who are not getting tested for COVID-19 are eligible to join the study if they are already registered patients in the PHMC clinic network who go to a PHMC clinic for any type of appointment and contact a study Interviewer to ask about the study. Flyers with basic study information and contact phone numbers on them have been printed out and placed in the clinics where patients can see them.

Figure 2: Study flow for Index Participants recruited over the phone and in-person



Index participants recruited over the phone

Steps 1-2: Recruitment, Eligibility assessment, and Enrollment of Index Participants:
As outlined in Figure 2 above, we will recruit over the phone and in-person.

In-person recruitment:
Study staff will offer recruitment in-person to testers. At that point, COVID-19 testing should be completed already.

Non-testers interested in joining the study after reading a study flyer will contact study staff.

At Rising Sun, the Interviewer will also actively recruit COVID vaccine patients and patients who are new to the clinic.

Eligibility Assessment
Who: CSTRAND research Interviewers
For participants recruited over the phone, interviewers are responsible for calling individuals scheduled to be tested for COVID-19 at their specific site (Health Connection, Rising Sun, or Care Clinic).
For participants recruited in person, Interviewers are responsible for approaching individuals being tested for COVID-19 directly to assess eligibility. Interested non-testers will contact Interviewers about the study.
What: Interviewers will call or talk with individuals who expressed interest assess eligibility.
When: During Step 1 Initial Recruitment

For Phone only:

1. Research Interviewers are responsible for monitoring their respective clinics' COVID-19 testing schedules to identify prospective participants.
2. If a prospective participant has been added to the schedule, the Interviewer will call them if they are being tested at the Interviewer's assigned clinic site (e.g., Rising Sun, Care Clinic, or Health Connection).

For both Phone and In-Person Recruitment

3. The Interviewer will describe the study to any individual who indicates interest. If they are interested, interviewers will then assess eligibility through the following questions:

    - "Are you 18 or over?"
    - "Do you have a working telephone number?"
    - "Have you ever tested positive for COVID-19 *in* ***the past 90 days?"***
    - "Have you received a test as part of a COVID study at PHMC?"
    - "Have you participated in the C-STRAND COVID testing study?"

Note: As of December 2021, we are no longer excluding individuals who have tested positive, as long as they haven't tested positive within the past 90 days.

4. If the individual answers "No" to Items 1-2, or "Yes" to Items 3-4, the Interviewer should mark "*ineligible*" and indicate the reason for ineligibility (any of the 4).
5. If the individual answers "Yes" to Item 3, the Interviewer will ask when the person received their most recent positive COVID-19 test result and note the date in the REDCap database.

In-person Recruitment only:

6. If the individual meets inclusion criteria, the Interviewer will obtain consent to participate and complete and sign the informed consent form.

Phone Recruitment only:

7. If the participant tentatively agrees to participate in the study over the phone, the Interviewer will obtain verbal consent: See Consent section for Index Participants (study script B: "Index Participant – Initial enrollment (verbal consent, phase 1)").
8. Once verbal consent is obtained, the Interviewer will then begin the baseline survey.

9. If the participant is interested but cannot complete the survey at the time, the Interviewer will call back at an agreed upon later time. Upon completion of the survey, the Interviewer will then instruct the potential participant to come to the study table after completing testing for completion of enrollment.

Baseline survey
Who: CSTRAND research Interviewers
What: Interviewers will conduct the initial baseline survey to obtain baseline information about individuals. See baseline index participant survey instrument.
Baseline survey is split into two segments on REDCap: "Baseline" and "Baseline+."
When: For participants consented over the phone: Immediately after obtaining verbal consent over the phone, prior to COVID testing. Should be conducted over the phone, although can be done in-person at the study site when the participant obtains testing. If the participant chooses to complete the baseline and baseline + surveys later over the phone, research staff will ask to call the participant's phone before they leave the clinic so the participant will recognize the research staff's number in the future.

Participants recruited In-person: In-person testers and non-testers will have the option of only completing the minimum number of baseline survey items needed for enrollment in-person, and can complete the rest of the "Baseline" and "Baseline+" survey items within the next week over the phone. This is to minimize in-person interactions and allow for people to enroll in the study who don't have time for the full survey while they are at a clinic.

Notes:
Participants recruited over the phone: While we will obtain baseline survey data prior to signed informed consent, if individuals scheduled for a COVID-19 test do not obtain testing in step 4 or signed informed consent within 30 days of completing their baseline survey, their baseline survey data will be deleted. We are collecting baseline survey data ahead of signed informed consent to minimize logistic burdens of in-person data collection.

COVID-19 testing, signed informed consent, randomization, intervention, and compensation
Who: CSTRAND research Interviewers.
What: Some prospective participants will obtain testing at one of the clinic sites, and the Interviewer will approach them about joining the study. Other prospective participants will call an Interviewer about joining the study while they are at a clinic, and the Interviewer will explain it to them.
When: Formal enrollment in the study will occur after individuals have obtained COVID-19 testing (if planning to test) and provided signed informed consent.

Testing and Informed Consent:

Once prospective study participants who are getting tested for COVID-19 arrive at study sites, Interviewers will approach them to complete consent process and obtain signed informed consent. This can be done before or after completion of COVID-19 testing. We recommend individuals obtain testing prior to signing informed consent, but the research Interviewers can approach individuals prior to testing to obtain signed informed consent if time permits.

When an Interviewer receives a call from a prospective study participant who has read a flyer in one of the clinics, the Interviewer will ask the person if their appointment at the clinic includes a COVID-19 test. If so, we recommend individuals obtain testing prior to signing informed consent, but the research Interviewers can approach individuals prior to testing to obtain signed informed consent if time permits.

Randomization:
Randomization can only occur after 1) signed informed consent, and 2) COVID-19 testing (only applies to those who registered for COVID-19 testing). If individuals Once informed consent has been completed, individuals will be formally enrolled in the trial, and randomized and assigned to one of two study arms.

The interviewer will complete the randomization and inform the Participant of their study arm allocation. They will then provide the Index Participant either 5 home test kits, or test referral cards and a text message with test information and the test referral number, as detailed below.

Index Referral ID Number

For index participants who receive test referral cards:
Upon randomization, all Index Participants who receive test referral cards will be assigned a unique 5-digit Index Referral ID Number. This number will be used to test referrals. The numbering convention will be as follows:

1st digit indicates study arm assignment:
- 2XXXX = test referral arm (control)

2nd digit indicates study site:
- 1 = Care Clinic
- 2 = Mary Howard
- 3 = Congreso Health Center
- 4 = Health Connection
- 5 = Rising Sun

3rd through 5th digits indicate consecutive numbering of study participants within that study arm and study site.

Examples:
21001 = The first participant recruited in the intervention arm at Mary Howard
12005 = The fifth participant recruited in the control arm at Care Clinic
13015 = The fifteenth participant recruited in the intervention arm at Congreso

The same Index Referral ID number will be affixed to all test referrals of the Index Participant. The Index participant will be given all test referral cards, each labeled with the same reference ID number. Please refer to the instructions for assigning Index Participant Referral IDs. All assigned IDs will be tracked in the Referral ID tracking spreadsheet associated with each clinic.

For index participants who receive self-test kits:

Self-test kit numbers will not be tracked for index participants who receive Ellume test kits (starting December 2021).

For network contacts:
If Network Contacts test positive and enroll in the CloseST study, their REDCap ID number will become their "Referral ID number." Their ID numbers will start with 1 and go up after that.

Study intervention:

Self-test kit arm procedures:
If randomized the self-test kit arm, the interviewer will go through script C "Index Participant randomized to self-test kit."

The interviewer will retrieve a package of 5 self-test kits. Self-test kits will be kept in secure locations determined by the staff of the participating clinic sites.

Assigning test kits to the index participant:
- The interviewer will affix a sticker to each of the 5 test kits instructing them to download the Ellume app. It will also include a QR code for network contacts to scan with a smartphone and a URL that network contacts can type into a web browser on a smartphone. The QR code or link will send the network contact to a page on the Ellume app for them to have their test sample analyzed. All 5 test kits will have the same

QR code and URL. For the purposes of this study, the PIs have bought the domain name *testphilly.com*. Each URL that will accompany a QR code on a test kit will include a number. The numbers will start with 1, and go up sequentially (for example, *testphilly.com/1*, *testphilly.com/2*, *testphilly.com/3*, etc.). All 5 test kits given to the same index participant will have the same QR code and URL on them.

- Each test kit will have instructions on downloading the app, taking a sample using the test kit, and having the sample analyzed, attached to it with a rubber band.

Post-randomization assessment
The Interviewer will also ask the Index Participant the "Intentions" instrument.

Self-testing kits:
The Interviewer will provide an explanation to the index participant of how to distribute test kits to contacts and how to use test kits.

In order to use the test kits, a network contact will need to have a smartphone with Bluetooth capability, and they will have to download the Ellume app. and then go to the URL on the test kit or scan the QR code.

Index participants can give the test kit to anyone aged 2 or older.

Intervention instructions:
Participants will be encouraged to distribute the self-tests to individuals in their social network, including family members, with encouragement to deliver to network contacts ages 2 and older who:
1) Has had a known exposure to COVID-19. If exposed, testing should ideally be done 5-7 days after the exposure.
2) Is symptomatic (fever, difficulty breathing, new cough, unusual fatigue, loss of taste or smell, rash on fingers or toes)
3) Is believed to be at high risk of COVID-19 due to multiple in-person interactions with others.

Update November 11, 2022:

In order to comply with changes in the FDA emergency use authorization of rapid antigen tests for SARS-CoV-2, individuals should be advised on appropriate use of test kits. This update supercedes the prior update in EUA in March 2022.

Participants who receive intervention with test kits:

- If individuals obtain an initial negative test result, they should:
    - Test again 48 to 72 hours (2-3 days) if they have symptoms on the first day of testing
    - Test 2 more times at least 48 hours apart if they do not have symptoms (A total of 3 times over 5 days)
- If individuals obtain an initial positive test result, no repeat testing is needed to confirm the result.

Note:

- If individuals test negative and need another test kit, **they can bring the study-issued test kit to a clinic to receive two additional Ellume test kits at no cost.**
- Only individuals who have proof of a **negative study-issued test can obtain two additional Ellume test kits** (to be picked up by at a study site). They must show proof of:
    - 1) a test kit from the study
    - 2) a negative result in the past 48 hours

Test referral Arm procedures:
For index participants randomized the self-referral arm, the Interviewer will go through script D "Index Participant randomized to test referrals."

The index participant will receive 5 test referral cards with guidance on distributing them. They will also receive a text message with simple instructions to send to contacts on how to get tested, which they can then copy and send to contacts (See Script N.1. "Referral for Index Participant in Test Referral arm."

Each card will be labeled with the **Index Referral ID number.** The Interviewer will then enter the 5-digit index referral number into that patient's record. Test referral cards will be kept in secure location at clinic sites.
Test referral cards:

- Test referral cards will have clinic information on where to get testing and instructions to return the card to the Interviewer in each of the clinic sites. If the Interviewer is unavailable at the time, the subject can also return the card to the front desk staff.

Instructions:
Participants will be encouraged to distribute COVID-19 testing referral cards and forward the text message referral to individuals age 18 and over in their social networks, including family members, with encouragement to deliver to network contacts who:
1) Have had a known exposure to COVID-19. If exposed, testing should ideally be done 5-7 days after the exposure.
2) Are symptomatic (fever, difficulty breathing, new cough, unusual fatigue, loss of taste or smell, rash on fingers or toes)
3) Are believed to be at high risk of COVID-19 due to in-person interactions with others.

Study Compensation:

At the end of enrollment of an index participant, Interviewers will:

- Give the index participant a $15 ClinCard and instruct them to hold onto it after use for later recharge and reuse.
- Remind the index participant they will be contacted again if their test results are positive.
- Remind the index participant they will be contacted again in 8 weeks to complete a follow-up survey, lasting approximately 5 minutes, and that if they complete it, they will get an additional $15 loaded to their gift card.

If the participant has enrolled in the study and has completed the minimum required forms on the baseline survey, the Interviewer will load $15 onto the participant's ClinCard. The following are the minimum forms required for payment are:

- *Identity* (to be completed in-person)
- *Randomization* (to be completed in-person)
- *Sociodemographics* (to be completed in-person or over the phone)
- *Symptoms* (to be completed in-person or over the phone)
- *COVID Exposure* (to be completed in-person or over the phone)

Baseline Survey+, Baseline Survey Part II (optional), delivery of test results
If the participant did not complete all of the baseline survey items at the time of enrollment, the Interviewer will call the participant within one week of randomization to complete the survey with them.

If the index participant consented to participate in the DCRI national study, they will be contacted within the week to complete the additional survey elements. This should be done within one week of study enrollment.

Delivery of test results
See the section below "Daily Review of Test results."

Follow-up survey and study compensation:

Follow up of index participants
At week 8, index participants will receive a text message, a call, or an email from study staff (See Script N.2 "Text message for Index Participants at 8-week follow-up") indicating that it is has been 8 weeks since they registered for the study. The index participant will be asked about scheduling a time to complete the follow-up survey with an Interviewer over the phone. See 8-week follow-up survey.

If the survey is completed, the Interviewer will add an additional $15 to the gift card of the Index Participant. If they have lost it, they can pick up another one at one of the study sites.

A reminder text message, call or email will be sent once a week for four weeks if the index participant has not completed the survey.

Study Compensation:

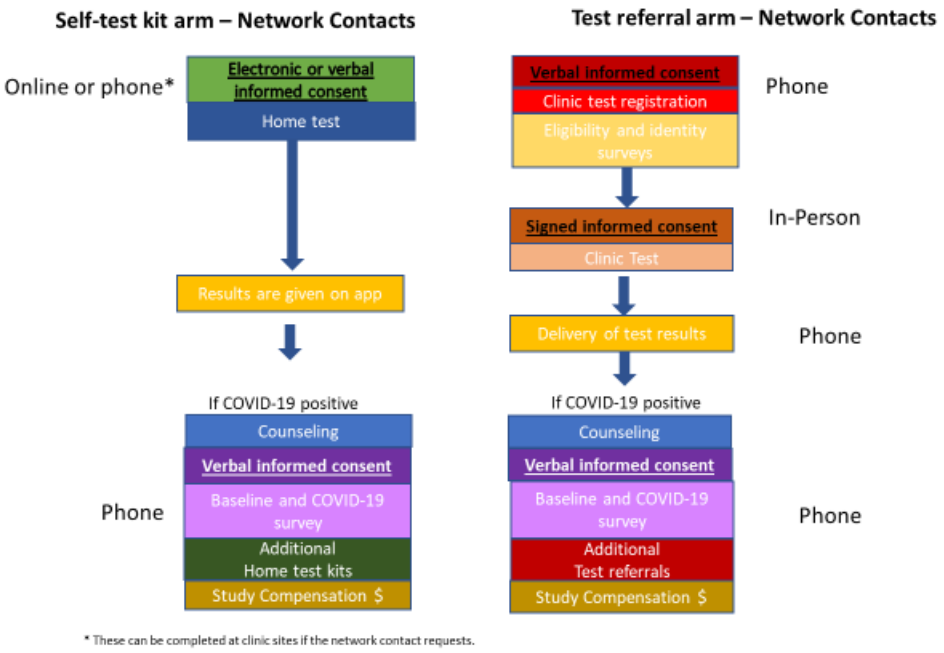
Once the follow-up survey has been completed, the research Interviewer will inform the index participant that an additional $15 will be loaded onto their ClinCard card.

If they have lost it, they will be offered the choice of an additional ClinCard, to be picked up by the index participant at one of the study sites, a virtual card to be sent by email, or an electronic Target gift card.

NETWORK CONTACTS

Network Contacts are those who received either home test kits in the self-test arm (Category 2), or test referral cards and texts in the test referral arm (Category 3).

Figure 3: Study flow for network contacts, by study arm:



Self-test arm:
Network contacts in the self-test arm will receive a home test kit that they will then be able to register. They are expected to conduct the rapid at-home

Eligibility criteria for self-test arm:
Individuals in the self-test arm must meet the following eligibility criteria:

1. At least 2 years of age
2. Have access to a smartphone with Bluetooth capabilities

Exclusion criteria

3. None

Informed Consent and test registration

- Informed consent in the self-test arm is waived (not required); participants must be at least 2 years old.
- Test registration is done through the Ellume app.

Test Referral arm:
Individuals who receive referral cards or texts will have a referral number and they will be instructed to give this number when scheduling the test. When individuals call the study number to schedule a test, research interviewers will ask for the referral number. The research interviewer will ask for verbal consent to include their test referral in the research study.

Eligibility criteria for test-referral arm:
Individuals in the test-referral arm must meet the following eligibility criteria:

1. At least 2 years of age
2. Have access to a working phone number
3. Able and willing to provide informed consent if 18+
4. Able and willing to provide assent and parental permission if ages 2-17.

Exclusion criteria

5. Severe symptoms requiring urgent medical attention
6. Not meeting any of the above inclusion criteria

Verbal informed Consent and clinic test registration:

Network contacts will be given referral cards or text messages to call in to get tested.
The phone number will be linked to the PHMC clinic site through which they are referred. The interviewer will then assist the network contact with informed consent and test registration.

See Study Script F "Verbal Consent – Network Contact TR"

1. If the individual declines consent, the interviewer will only mark that a phone call was made to schedule a test but will not retain the test referral number or any PHI.
2. If the individual provides verbal consent to participate in the study, the interviewer will record the individual's scheduled test and their name into the database to be tracked.

Electronic consent or in-person signed consent:

3. Individuals will have the option for electronically consenting for the study prior to arriving at PHMC clinic sites if desired.
4. If electronic consent forms are requested, they can be found at:
    i. Redcap.link/cstrandadult (ages 18+)
    ii. Redcap.link/cstrandteen (ages 12-17)
    iii. Redcap.lilnk/cstrandchild (ages 2-11)
5. A PDF copy of the electronic consent form will be downloadable after signing

If the Network Contact declines consent, the interviewer will only mark that a phone call was made to schedule a test but will not retain the test referral number or any PHI. If the Network Contact provides verbal consent to have the number and PHI retained, the interviewer will record the patient's scheduled test in the research database. Only the patient's medical record number and test referral number will be included in research database for test tracking purposes. The research interviewer will then track the test referral to see if the Network Contact completed testing.

Signed informed consent, clinic testing, and study compensation

Interviewers will approach Network Contacts when they arrive for their scheduled testing.

1. Interviewers will confirm that Network Contacts have signed informed consent electronically
2. If they have not signed an electronic consent form, interviewers will complete the informed consent form either electronically or the paper form.

Study Compensation

- There is no compensation for network contacts.

DELIVERY OF TEST RESULTS (for tester index participants and test-referral network contacts)

Research interviewers will be responsible for reviewing all self-test results and clinic test results on a daily basis.
Review of self-test results
Self-test results:

1. Positive test results will trigger a phone call (see Script I "Communication of test results – COVID-19 positive" for COVID-19 positive individuals.
2. Negative test results will trigger a phone call (see Script H "Communication of test results – COVID-19 negative")

Review of clinic test results:
The interviewer will be responsible for reviewing all test results daily.

1. Negative test results: No call needed (clinic staff call participants)
2. Positive test results – Follow the script as indicated below for COVID-19 positive individuals.

MANAGEMENT OF POSITIVE COVID-19 TEST RESULTS

Summary:
All individuals who test positive for COVID-19 during the trial require contact for follow-up. Here, we lay out procedures depending on *who* is testing positive.
COVID-19 participants are divided into two groups: ST participants (those in the Self-Testing arm) and TR participants (those in the Test Referral arm) (See Figure 3).

Counseling on COVID-19

COVID-19 participants Protocol (See Script I "Communication of test results – COVID-19 positive")

- If someone else picks up, ask for best way to get ahold of contact or best time to call back.
- Make at least one attempt within 24 hours of test result receipt.
- Each attempt = 2 back-to-back calls with a voicemail left.
- If no voicemail is available, try **at least 2 additional times within 48 hours** of test result receipt to reach them.
- Interviewers should make a **total of 4 attempts within 7 days** after the result of the test.
- If the individual is unable to be reached, you may mark "Unable to reach" as the final disposition.
- NEVER reveal test results to anyone else without first confirming identity.

Eligibility:

1. At least 18 years or older
2. COVID-19 positive test obtained in the study in the **past 14 days**
3. Has a working telephone number

Verbal Consent to join COVID-19 cohort

- Interviewers will try to contact any TR network contact who tests positive about joining the COVID+ cohort, and will keep track of the attempts in REDCap
- The Interviewers will make 4 attempts to reach a COVID+ TR network contact to talk to them about joining the COVID+ cohort
    - The day that the test result is received
    - 1 day following receipt of the test result
    - 2 days following receipt of the test result
    - 7 days following receipt of the test result

- Any ST network contact who tests positive can contact an Interviewer about joining the COVID+ cohort by calling a phone number printed on the bottom of their self-test kit.
- Interviewers will ask if the Network Contact would like to participate in an ongoing study of COVID-19 testing that would provide them with additional self-test kits for close contacts.
- If the COVID-19+ person entered the study through the self-testing arm Index Participant or the Network Contact Scripts J "Informed Consent for COVID-19+ network contact participant Self-Test arm" and Script K "Informed Consent for COVID-19+ network contact participant test referral arm")

If the COVID-19 participant is in the Self-testing arm (COVID-19 ST): (see Script L "Contact elicitation for COVID-19+ participants ST arm")

- The interviewer will ask individuals about close contacts and will offer up to 3 additional self-test kits to distribute to close contacts.
- The interviewer will elicit close contact information, and help the individual prioritize who to give testing to.
- The interviewer will instruct COVID-19 participant to tell close contacts to quarantine, monitor symptoms, and that if desired, they can self-test and receive a $15 card if they do so.
- The interviewer will then conduct the COVID-19 Participant survey over the phone.

Delivery of self-testing kits to close contacts:
Self-test kits can be obtained by pick-up at the PHMC clinic sites where the *Index Participant registered.* Participants should have a contact pick up the additional test kits in their place if they are unable to pick up.

The interviewer will arrange test-kit pick up and will complete the REDCap forms for COVID+ participants.

The interviewer will enter the following key elements:

- Complete COVID-19 participant questionnaire
- Will enter the test kits ID

If the COVID-19 participant is in the test referral arm: (see Script M "Contact elicitation for COVID-19+ participants TR arm")

- The interviewer will ask individuals about close contacts
- The interviewer will elicit close contact information, and help the individual prioritize who to give testing to.
- The interviewer will instruct COVID-19 participant to tell close contacts to quarantine, monitor symptoms, and that if desired, they can obtain testing at PHMC clinics
- The interviewer will then send the COVID-19 participant a "COVID-19 referral text" (See Script N.3 "Text message for COVID-19 positive contact test referral") that they can forward to contacts.

Network contacts in self-test kit arm who test positive:

- Need to be registered in RedCap

Study compensation:

Index Participants:

- At the end of the phone call, the interviewer will ask the COVID+ participant if they still have their ClinCard.
  - If they have their ClinCard, this will be reloaded with $15.
  - If they do not have their ClinCard, they can be sent a $15 compensation through an electronic gift card (Target gift card or electronic ClinCard, if available).

Network Contacts

- Study compensation for network contacts who enroll in COVID+ cohort:
  - They will be able to receive **$30** as target virtual gift cards as a single one-time payment.

Sample Size
The sample size for the C-STRAND trial was calculated based on the primary outcome of Aim 1. Power calculations were completed using STATA 15.1 (STATA Corp, College Station, TX). With an estimate that 45% in the control group achieve success, defined as at least two network contacts completing testing, we calculated a sample size of 1048 needed to detect a 10% difference (two-tailed alpha of 0.05, power of 90%). If in fact we observe a success rate as low as 25% in the control group, with a sample size of 1048, we will have 90% power to detect as small as an 8% difference.

For the CloseST study, we will aim to recruit up 210 study participants in the C-STRAND trial diagnosed with COVID-19. Data from the Philadelphia Department of Public Health shows that the median number of close contacts provided per individual with COVID-19 is approximately three.[21] Assuming the mean number of close contacts *infected* with COVID-19 is approximately one, and 50% obtain testing, we can expect the mean number of positive tests per index COVID-19 positive index participant to therefore be approximately 0.5. We assumed a conservative allocation ratio of 2:1 and estimated the standard deviation of the number of positive tests in the network of COVID-19 positive index participants to be between 0.6 and 0.8. We considered a doubling from 0.5 to 1.0 new cases identified per positive index to be clinically significant. At the low end of the standard deviation range, we would need a total N=54 for 80% power with a p=0.05. With a standard deviation as high as 1.0, we would need a total N=192 to have 90% power to detect a difference between groups. A total of 210 individuals (representing a 20% positivity rate among Index Participants), even with a standard deviation of 1.0, would give us 93% power to detect a doubling of positive cases identified.

Data Analysis
All analyses will be performed based on intention-to-treat. In the C-STRAND trial, the primary analysis will use the Cochran-Mantel-Haenszel test, adjusting for study site, to compare the proportion of individuals in each arm who succeeded in getting two contacts tested. Sex will be included with an interaction term in multivariable models using logistic regression. In secondary analyses, Wilcoxon Rank-sum tests and linear regression or negative binomial regression will be used to compare each of the count and continuous outcomes (e.g., total number of contacts tested).

In the CloseST study, we will use Poisson regression to compare the number of contacts who test positive at week 8 among contacts of SARS-COV-2 positive individuals who received the intervention or the control. Additional comparisons will follow the same approach for the secondary outcomes. Standardized mean differences (SMDs) > 0.1 will be used to determine balance between arms and identify potential confounders between participants in either study arm. If there is imbalance in the characteristics between the arms, additional analyses will consider potential confounders, including age, race/ethnicity, education, employment status, socioeconomic status, housing status, household size, relationship status, risk of COVID-19 exposure, and site of recruitment.